EA DV CONGRESS
VIENNA
30 SEP - 3 OCT 2026

Abstract N°: 3

Efficacy and Safety of MG-K10 Administered at 600 mg Every 8 Weeks Versus 300 mg Every 4 Weeks in Chinese Adults With Moderate-to-Severe Atopic Dermatitis: Results of a Randomized Phase 2 Study

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Introduction
MG-K10 is an innovative long-acting mAb that specifically binds to human IL-4Rα, and efficiently blocks the Th2 inflammatory signaling of IL-4 and IL-13. Following Fc mutation, MG-K10 allows long dosing interval owing to its prolonged half-life and demonstrated favorable efficacy and safety in adults with moderate-to-severe AD in a pivotal phase 3 trial which MG-K10 is administered at 300 mg every 4 weeks with 600 mg loading dose (MG-K10 300 mg Q4W). Herein, we report comparable efficacy and safety profiles of MG-K10 600 mg every 8 weeks (MG-K10 600 mg Q8W) and MG-K10 300 mg Q4W in Chinese adults with moderate-to-severe AD from a phase 2 trial of MG-K10 with 24 weeks' treatment.

Materials and Methods
This was a multicenter, randomized, double-blind, parallel, phase 2 study. 60 Chinese patients with moderate-to-severe AD were randomized 1:1 to subcutaneous dosing of MG-K10 300 mg Q4W or MG-K10 600 mg Q8W, both treatment regimens were administered over a 24-week treatment period. The co-primary endpoints were the proportion of patients achieving an EASI-75 response (≥75% improvement from baseline in Eczema Area and Severity Index score) and the proportion of patients achieving an IGA response (Investigator's Global Assessment score of 0 or 1 and a ≥2-point reduction from baseline) at week 24. Other efficacy endpoints included EASI-90, EASI-50, improvement from baseline in pruritus NRS, body surface area (BSA), Dermatology Life Quality Index (DLQI), and Patient Oriented Eczema Measure (POEM). Safety was assessed via adverse event (AE) and laboratory monitoring.

Results
At week 24, both MG-K10 600 mg Q8W and MG-K10 300 mg Q4W groups produced significant response rates from baseline at Week 24 on both co-primary endpoints (EASI-75 response: 88.5% % vs 83.3; IGA response: 73.1% vs 70.0%; both P>0.05). Both MG-K10 600 mg Q8W and MG-K10 300 mg Q4W groups demonstrated consistent potent efficacy over all efficacy endpoints, including EASI-90 and EASI-50 responses, as well as significant reductions in % BSA, and EASI score. Both groups achieved rapid and substantial reductions in pruritus and other

patient-reported symptoms of AD. The incidence of treatment-emergent adverse events (TEAEs) was similar between the two groups. Most TEAEs were grade 1 or 2. The incidence of conjunctivitis was low, and no injection-site reactions were reported.

Conclusion

The phase 2 trial has demonstrated that both MG-K10 600 mg Q8W and MG-K10 300 mg Q4W can rapidly and sustainably improve clinical manifestations in adults with moderate-to-severe AD. Compared to all commercially available anti-IL-4Rα therapeutics, MG-K10 features the longest dosing interval in the induction period. Further large-scale studies are warranted to confirm these findings.

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Abstract N°: 32

Positive Top-line Data from Phase 2a Proof-of-Concept Trial of EVO301, a Novel IL-18 Binding Protein, in Patients with Moderate-to-Severe Atopic Dermatitis.

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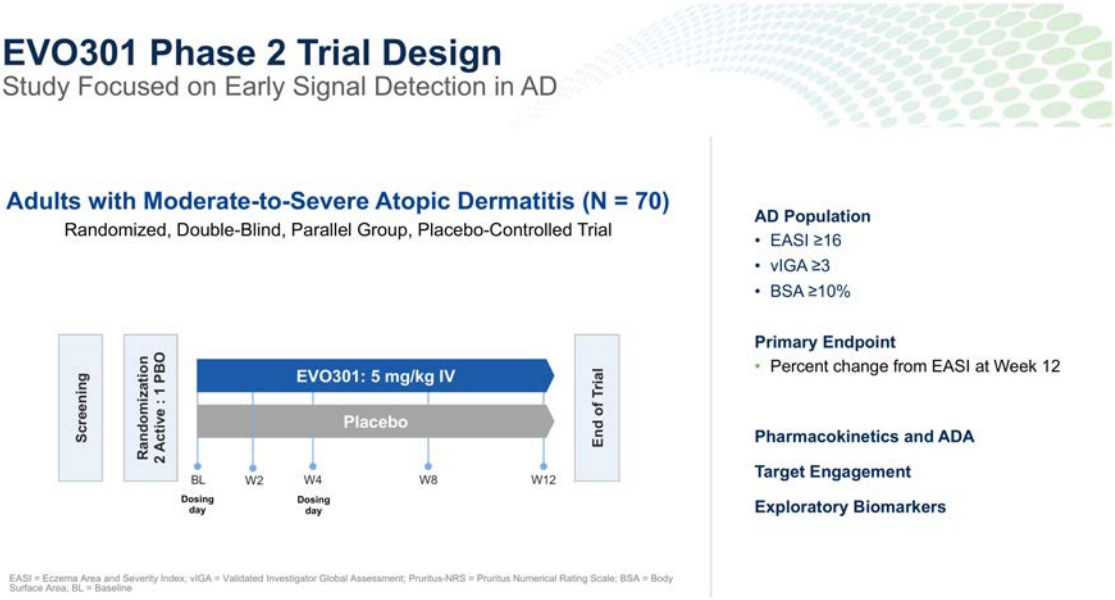
Introduction

The EVO301-AD001 Phase 2 proof-of-concept trial evaluated EVO301, an IL-18–targeting biologic, in adults with moderate-to-severe atopic dermatitis (AD).

Materials and Methods

Investigators enrolled 70 biologic-naïve subjects across 12 sites in New Zealand and Australia and randomized subjects 2:1 to receive EVO301 5 mg/kg IV or placebo, with dosing administered on Day 1 and Day 28 and follow-up through Week 12. All subjects met standard AD severity thresholds (EASI ≥16, vIGA ≥3, BSA ≥10%). The trial aimed to detect early clinical signals of efficacy, safety, pharmacokinetics (PK), and target engagement.



Results

Efficacy: The study met its primary endpoint—percent change in EASI at Week 12 using a Bayesian analysis—after only two doses (Day 1 and Day 28). EVO301 demonstrated a mITT mean response at 12 Weeks of -31.7%

(placebo adjusted) in % change in EASI. Secondary endpoints showed early onset of effect by Week 2, with statistically meaningful separation from placebo beginning at Week 4 and sustained through Week 12 in both Bayesian and frequentist analyses.At Week 12, clinically relevant categorical responses favored EVO301. EASI-50 occurred in 62.5% of EVO301-treated subjects compared with 22.7% of placebo-treated subjects (p=0.0014). Higher-threshold responses (EASI-75 and EASI-90) demonstrated numerically favorable trends. Investigators observed vIGA 0/1 with ≥2-point improvement in 22.9% of EVO301-treated subjects versus 0% on placebo. Pruritus-NRS showed improvement over time, with statistically significant differences emerging at Week 8 (p=0.0021).Non-head-to-head comparative benchmarking suggests that Week 12 EASI improvements with EVO301 align broadly with those reported for marketed AD biologics, including dupilumab, lebrikizumab, tralokinumab, and nemolizumab, when compared with published Phase 3 trials of differing designs and durations.

Safety: EVO301 was well tolerated. No treatment-related serious or severe adverse events occurred, and no subjects discontinued treatment because of adverse events. No patients developed conjuntivitis. Infusion reactions occurred infrequently; 1 subject (2.1%) receiving EVO301 and 2 subjects (9.1%) receiving placebo experienced infusion reactions, none of which were severe. Atopic dermatitis flares occurred more frequently in the placebo group than in the EVO301 group (41% vs 21%). Other adverse events occurred at similar rates between groups, with upper respiratory infections and headache reported most commonly. Investigators identified no clinically significant laboratory or ECG abnormalities, and no cases of conjunctivitis occurred.

Pharmacokinetics and Immunogenicity: PK profiles remained consistent with Phase 1 data and supported both Q2W and Q4W dosing regimens for future development. Anti-drug antibody rates were low and showed no apparent impact on efficacy or PK in preliminary analyses.

Biomarkers and Target Engagement: EVO301 demonstrated target engagement, as shown by marked increases in serum total IL-18, consistent with pharmacological binding and extended IL-18 half-life when bound to drug. Treatment also down-modulated Th2-associated cytokines, including CCL-17 and CCL-22, and non-TH-2 biomarkers, supporting mechanistic plausibility and alignment with observed clinical improvements.

Phase 2 POC Trial in AD: Baseline Characteristics

	EVO301	Placebo
n	48	22
Age (SD)	30.5 (11.1)	33.1 (11.8)
Gender (female, %)	29 (60.4%)	13 (59.1%)
Weight (kg)	78.51 (18.69)	76.35 (17.50)
BMI (kg/m^2) (SD)	27.37 (5.99)	28.13 (6.30)
EASI (SD)	30.00 (11.79)	29.83 (10.48)
IGA (SD)	3.3 (0.5)	3.5 (0.5)
Pruritus-NRS (SD)	6.34 (1.51)	6.66 (2.14)
% BSA (SD)	47.10 (21.17)	49.26 (16.12)

Source: Table 14.1.3 (demographics), 14.2.2.3.3 (EASI), 14.2.2.6.3 (IGA) ,14.2.2.4.4 (NRS), 14.2.2.5.3 (BSA),

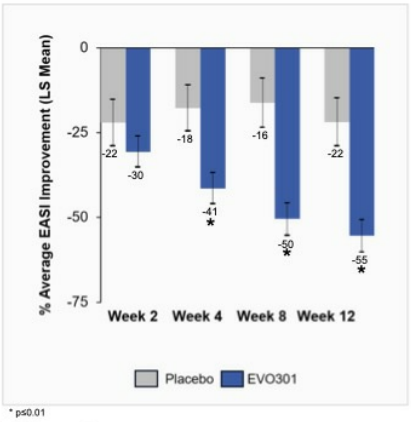
BMI: body mass index, EASI: Eczema Area and Severity Index, IGA: Investigator's global assessment, NRS: numeric rating score, BSA: body surface area, SD: standard deviation

Conclusion

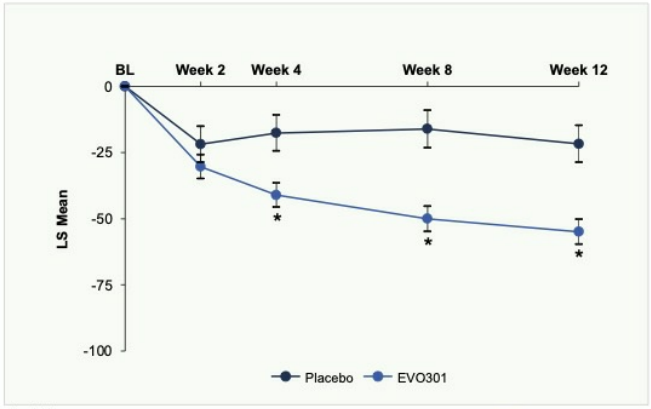
EVO301 met its primary and key secondary efficacy endpoints, produced rapid and sustained clinical improvements, demonstrated a favorable safety and tolerability profile, and showed clear biological activity. These results support further dose optimization and advancement into a Phase 2b dose-ranging study using a subcutaneous formulation.

Phase 2 POC Trial in AD: Efficacy

% Change in EASI by Study Visit: MMRM



* p≤0.01



* p≤0.01

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Abstract N°: 44

A First Insight into the Effectiveness and Safety of Dupilumab in Adolescent Patients Enrolled in the AD-BEASCUITS Study

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Introduction

Dupilumab has been approved in the European Union for adolescent patients with moderate-to-severe atopic dermatitis (AD)[1] following the randomised controlled trials (RCTs) in adolescent population that enrolled patients with Eczema Area and Severity Index (EASI) Score ≥16[2]. According to Italian Regulatory Agency (AIFA) reimbursement criteria, AD is defined as severe in adolescents (aged 12–17 years) if the following criteria are met: EASI score ≥24, or <24 with involvement of visible (face, neck, or hands) or sensitive areas (genitalia, perineal/perianal areas) or intense pruritus (Peak Pruritus Numerical Rating Scale [PP-NRS] ≥7), or significant quality-of-life impairment (Children's Dermatology Life Quality Index [CDLQI] ≥10)[3]. This interim analysis investigated the early effectiveness of dupilumab at Week 4 in adolescents with severe AD despite less extensive skin lesions (EASI Score <16) enrolled in the AD-BEASCUITS study in Italy. This is a unique study as it evaluates the effectiveness of dupilumab in a real-world setting within an adolescent patient population that has not been investigated in dupilumab RCTs for AD.

Materials and Methods

AD-BEASCUITS (Atopic Dermatitis-Beyond EAsi SCore Under the ITalian healthcare System, NCT06192563) is a

prospective, multicentre, 52-week, observational study conducted across 15 Italian centres, enrolling 150 adolescents aged 12–17 years eligible for dupilumab treatment according to Italian reimbursement criteria. This interim analysis included 147 patients who received ≥1 dose of dupilumab and had ≥1 post-baseline efficacy and safety evaluation, and 149 patients in safety analysis set. Clinical outcomes were assessed at baseline and Week 4 (Visit 2) using EASI, PP-NRS, Sleep Disturbance measured by Numerical Rating Scale (SD-NRS), CDLQI, caregiver burden measured by Dermatitis Family Impact (DFI), and Physician's Global Assessment (PGA) scores for visible/sensitive body areas. Safety was assessed through treatment-emergent adverse events (TEAEs).

Results

Patients in this interim analysis had a mean±SD age of 15.0±1.7 years, with 51.7% male and 48.3% female, and mean±SD age at AD diagnosis of 4.1±4.9 years. At baseline, mean±SD values of clinical parameters were: EASI, 9.9±4.3; PP-NRS, 7.6±2.1; SD-NRS, 5.6±3.3; CDLQI, 13.4±6.8; and DFI, 11.5±6.8. Baseline PGA scores ≥2 for visible/sensitive areas were observed in 110 (face), 44 (feet), 80 (hand) and 32 (genitalia) patients. At Week 4, patients showed significant improvements across all clinical domains. The mean EASI score decreased by 6.7 points (39.3%), with 76.2%, 51.1%, and 32.2% of patients achieving EASI-50, 75, and 90, respectively. Mean PP-NRS improved by 3.7 points (39.7%), with ≥4-point reduction achieved by 56.3% (76/135) of patients with baseline PP-NRS ≥4. The average sleep disturbance (SD-NRS) improved by 3.4 points (44.5%). CDLQI improved on average by 7.8 points (48.5%), with ≥6-point improvement achieved by 69.7% (85/122) of patients with baseline CDLQI ≥6. The DFI decreased by 6.2 points (42.6%) (Table 1). PGA scores showed marked improvement; 48.2% (n=53) of patients with baseline PGA ≥2 achieved PGA 0/1 and ≥2-point improvement in the face, 68.2% (n=30) in feet, 58.8% (n=47) in hands, and 68.8% (n=22) in genitalia. TEAEs were reported in only 1.3% of patients (n=2); no serious or fatal adverse events were observed. One patient discontinued treatment due to an adverse event (erythema).

Table 1: Change in EASI, PP-NRS, SD-NRS, CDLQI, and DFI at Week 4 from Baseline

Item	Baseline		Week 4 (Visit 2)		Mean absolute change from baseline, LS estimate (95% CI)	Mean percentage change from baseline, LS estimate (95% CI)
	Mean	n	Mean	n		
EASI	9.9	147	3.3	143	−6.7 (−7.3; −6.1)	−39.3% (−89.4; 10.8)
PP-NRS	7.6	147	3.9	145	−3.7 (−4.1; −3.4)	−39.7% (−49.9: −29.4)
SD-NRS	5.6	146	2.2	144	−3.4 (−3.8; −3.1)	−44.5% (−54.7; −34.3)
CDLQI	13.4	146	5.7	144	−7.8 (−8.4; −7.1)	−48.5% (−56.7; −40.4)
DFI	11.5	146	5.4	144	−6.2 (−6.9; −5.4)	−42.6% (−51.9; −33.2)

CDLQI, Children's Dermatology Life Quality Index; CI, confidence interval; DFI, Dermatitis Family Index; EASI, Eczema Area and Severity Index; LS, least square; n, number of patients; PP-NRS, Peak Pruritus Numerical Rating Scale; SD-NRS, Sleep Disturbance Numerical Rating Scale.

Conclusions

Dupilumab demonstrated rapid clinical benefits within 4 weeks of treatment initiation in adolescents with severe AD despite less extensive skin lesions. Improvements were observed across multiple domains, including skin clearance, pruritus, sleep, and quality of life, with a favourable safety profile consistent with previous studies.

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Abstract N°: 48

Age-related interactions between skin microbiota, epidermal barrier function and quality of life in patients with atopic dermatitis

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Introduction

Atopic dermatitis is a chronic inflammatory skin disorder characterized by epidermal barrier dysfunction, immune dysregulation and microbial imbalance. Increasing evidence suggests that alterations in the skin microbiota contribute to disease severity and may significantly influence patient quality of life. However, the relationship between microbial composition, barrier function and patient-reported outcomes across different age groups remains insufficiently characterized.The objective of this study was to evaluate associations between skin microbiota composition, biophysical parameters of the epidermal barrier and quality-of-life impairment in patients with atopic dermatitis from different age groups.

Materials and Methods

A prospective observational study included patients with clinically confirmed atopic dermatitis. Disease severity was assessed using the SCORAD index. Quality of life was evaluated using validated dermatology-specific and general health questionnaires.Non-invasive assessment of epidermal barrier function included measurements of skin hydration, transepidermal water loss, sebum levels and skin surface pH. Skin surface samples were collected for microbiological profiling to assess microbial community composition.Comparative analyses between age groups were performed. Correlation analysis was conducted to evaluate associations between microbiological findings, barrier parameters, disease severity and quality-of-life indicators.

Results

Patients with atopic dermatitis demonstrated impaired epidermal barrier function characterized by decreased skin hydration and increased transepidermal water loss. Alterations in skin surface pH and sebum levels were also observed.Microbiological profiling revealed changes in the cutaneous microbial community, including a relative predominance of opportunistic microorganisms and reduced representation of commensal taxa.Higher disease severity scores were associated with greater barrier dysfunction and more pronounced microbial imbalance. These changes were also accompanied by worse quality-of-life indicators.Age-stratified analysis suggested that older patients tended to demonstrate more persistent barrier impairment and greater cumulative quality-of-life impact, whereas younger patients showed stronger associations between inflammatory activity and microbial alterations.

Conclusions

Atopic dermatitis is associated with complex interactions between microbial dysbiosis, epidermal barrier dysfunction and quality-of-life impairment.Age-related differences in these relationships may reflect distinct disease phenotypes and highlight the importance of integrated clinical, microbiological and biophysical assessment in patients with atopic dermatitis.

Abstract N°: 50

Impact of epidermal barrier dysfunction and microbiota alterations on quality of life in patients with atopic dermatitis across different age groups

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Introduction

Atopic dermatitis is a chronic inflammatory skin disease associated with impaired epidermal barrier function and microbial dysbiosis. Beyond physical symptoms, the disease significantly affects patients' quality of life due to persistent inflammation, pruritus and visible skin lesions. Understanding the relationship between objective skin parameters and patient-reported outcomes may improve clinical assessment and treatment strategies.The objective of this study was to investigate the association between epidermal barrier parameters, microbial imbalance and quality-of-life impairment in patients with atopic dermatitis across different age groups.

Materials and Methods

A prospective observational study included patients with clinically diagnosed atopic dermatitis. Disease severity was assessed using the SCORAD index.Quality of life was evaluated using validated dermatology-specific and general health questionnaires. Biophysical assessment of skin barrier function included measurements of hydration, transepidermal water loss, sebum production and skin surface pH using non-invasive techniques.Skin surface samples were obtained for microbiological profiling to assess changes in microbial composition. Statistical analyses included intergroup comparisons and correlation analysis between clinical severity, barrier parameters, microbiological findings and quality-of-life scores.

Results

Patients with higher disease severity demonstrated more pronounced impairment of epidermal barrier function, including decreased skin hydration and increased transepidermal water loss.Microbiological analysis indicated alterations in skin microbial composition characterized by reduced diversity and increased prevalence of opportunistic microorganisms.These findings were associated with significantly worse quality-of-life indicators. Patients with greater barrier dysfunction and microbial imbalance reported higher levels of physical discomfort and psychosocial burden.Age-stratified analysis revealed a tendency toward greater cumulative quality-of-life impairment in older patients, whereas younger patients showed stronger associations between inflammatory activity and subjective symptoms.

Conclusions

Epidermal barrier dysfunction and microbial imbalance contribute significantly to quality-of-life impairment in patients with atopic dermatitis.Integrated assessment combining clinical severity, skin barrier parameters and microbiological profiling may provide a more comprehensive understanding of disease burden across different age groups.

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Abstract N°: 51

Integrated analysis of skin microbiota, epidermal barrier function and patient-reported outcomes in atopic dermatitis: an age-stratified observational study

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Introduction

Atopic dermatitis is characterized by chronic inflammation, epidermal barrier dysfunction and alterations in the skin microbiota. These factors interact to influence disease severity and patient well-being. Despite growing interest in microbiome research, the relationship between microbial dysbiosis, barrier impairment and patient-reported outcomes remains incompletely understood.The aim of this study was to perform an integrated analysis of skin microbiota composition, epidermal barrier parameters and quality-of-life indicators in patients with atopic dermatitis.

Materials and Methods

Patients with clinically diagnosed atopic dermatitis were included in a prospective observational study. Clinical severity was assessed using the SCORAD index.Quality of life was evaluated using validated dermatology-specific and general health questionnaires. Non-invasive measurements of epidermal barrier function included assessment of skin hydration, transepidermal water loss, sebum production and skin surface pH.Skin surface samples were collected for microbiological profiling to evaluate microbial community composition. Comparative analyses between age groups and correlation analyses between microbiological, clinical and instrumental parameters were performed.

Results

Patients with atopic dermatitis demonstrated significant impairment of epidermal barrier function characterized by reduced hydration and increased transepidermal water loss.Microbiological profiling revealed alterations in microbial community structure with decreased abundance of commensal microorganisms and relative predominance of opportunistic taxa.These changes were associated with higher clinical severity scores and worse patient-reported outcomes. Correlation analysis demonstrated clinically meaningful relationships between microbial imbalance, barrier disruption and quality-of-life indicators.Age-stratified analysis identified distinct interaction patterns between microbiota alterations, barrier dysfunction and disease burden across different patient groups.

Conclusions

The results highlight complex interactions between microbial dysbiosis, epidermal barrier dysfunction and quality-of-life impairment in atopic dermatitis.Integrated evaluation of these parameters may improve patient phenotyping and contribute to more individualized management strategies.

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Abstract N°: 72

Efficacy and safety of lunsekimig in moderate-to-severe atopic dermatitis: Results from the phase 2b VELVET trial

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Introduction

Lunsekimig (SAR443765) is a novel, pentavalent, bispecific NANOBODY® molecule that blocks thymic stromal lymphopoietin (TSLP) and IL-13, two drivers of inflammation in atopic dermatitis (AD). This study evaluated the clinical efficacy and safety of lunsekimig in participants (pts) with moderate-to-severe AD.

Materials and Methods

VELVET (NCT06790121) was a phase 2b, multicentre, randomised, double-blind, placebo (pbo)-controlled, parallel-group, dose-ranging study. Eligible adults (aged 18–80 years) with moderate-to-severe AD who had an inadequate response to topical therapies or for whom topical therapies were inadvisable, were randomised 3:1:3:1:3:1 to: lunsekimig 300mg every 4 weeks (Q4W; n=37) or matching pbo, lunsekimig 300mg Q2W (n=36) or matching pbo, or lunsekimig 600mg Q4W (n=38) or matching pbo. The 3 pbo arms were analysed as 1 pooled pbo arm (n=39). The primary endpoint was % change in EASI score from baseline (BL) to W24. Key secondary endpoints included % of pts achieving EASI-75, a vIGA-AD score of 0 or 1 with a reduction from BL of ≥2 points, and a reduction of ≥4 points in the weekly average of daily PP-NRS scores from BL to W24. A multiplicity-controlled testing strategy was used to evaluate multiple dose regimens vs pbo on primary and key secondary endpoints, with significance determined by a prespecified hierarchical gatekeeping sequence at 1-sided α=0.025. Pts were considered non-responders after the use of mid- to very high-potency topical corticosteroids or prohibited medications/procedures that impact efficacy before W24, or after discontinuation of study intervention due to lack of efficacy. Missing data due to reasons other than lack of efficacy were handled with multiple imputation for the primary endpoint and non-responder imputation for the secondary endpoints.

Results

Demographics and disease characteristics were balanced across treatment arms. The primary endpoint did not reach statistical significance; however, there were numerically greater differences observed in lunsekimig treatment arms in EASI reductions vs pbo (Table). Mean % change in EASI from BL to W24 was -67.7%, -61.9%, and -53.8% for the 300mg Q4W, 300mg Q2W, and 600mg Q4W arms, respectively, compared with -43.7% in the pbo group. Key secondary endpoints are reported in the table. Pbo-adjusted (adj) EASI-75 responses at W24 were 44.5%, 41.1%, and 21.9% for the 300mg Q4W, 300mg Q2W, and 600mg Q4W arms, respectively; pbo-adj vIGA-AD 0/1 responses at W24 were 25.0%, 24.0%, and 8.9% for the 300mg Q4W, 300mg Q2W, and 600mg Q4W arms,

respectively (Table). Additional secondary endpoints demonstrated greater responses vs pbo (Table). There was no clinically meaningful difference observed in PP-NRS. Lunsekimig was well tolerated. In the combined lunsekimig group, incidence of less than 5% was seen for serious adverse events, severe treatment-emergent adverse events (TEAE), and TEAEs leading to discontinuation. The most common TEAE was injection site reaction.

Conclusion

In the VELVET phase 2b dose-ranging study, while the primary endpoint was not achieved, lunsekimig showed clinically meaningful, numerical improvements across multiple measures of skin clearance and disease severity among pts with moderate-to-severe AD and was well tolerated at all doses. Further research may be warranted on the role of dual TSLP/IL-13 inhibition in AD.

Table. Efficacy of lunsekimig at Week 24

	Pooled Placebo (n=39)	300 mg Q4W (n=37)	300 mg Q2W (n=36)	600 mg Q4W (n=38)
Primary endpoint				
EASI score[a]	**37**	**36**	**35**	**38**
LS mean change from baseline, %	-43.7	-67.7	-61.9	-53.8
LS mean difference vs placebo,[b] % (95% CI)	-	23.9 (3.1, 44.7)	18.2 (-2.6, 39.0)	10.1 (-10.4, 30.5)
P value	-	.012	.044	.168
Adjusted *P*[c]	-	.036	.105	.252
Key secondary endpoints				
EASI-75[a]	**39**	**37**	**36**	**38**
Responders,[d] n (%)	7 (17.9)	23 (62.2)	21 (58.3)	15 (39.5)
Rate difference vs placebo,[e] % (95% CI)	-	44.5 (22.6, 61.2)	41.1 (19.0, 58.3)	21.9 (1.5, 40.3)
P value	-	< .001	< .001	.018
vIGA-AD 0/1[a]	**39**	**37**	**36**	**38**
Responders,[d] n (%)	4 (10.3)	13 (35.1)	12 (33.3)	7 (18.4)
Rate difference vs placebo,[e] % (95% CI)	-	25.0 (5.7, 42.3)	24.0 (4.6, 41.5)	8.9 (-7.8, 25.4)
P value	-	.005	.006	.136
PP-NRS ≥4[a]	**38**	**35**	**36**	**38**
Responder,[d] n (%)	9 (23.7)	7 (20.0)	13 (36.1)	10 (26.3)
Rate difference vs placebo,[e] % (95% CI)	-	-5.6 (-23.9, 13.9)	12.4 (-8.2, 32.1)	2.3 (-17.0, 21.6)
P value	-	.726	.123	.409
Secondary endpoints				
EASI-90 response[a]	**39**	**37**	**36**	**38**
Responders,[d] n (%)	5 (12.8)	18 (48.6)	12 (33.3)	10 (26.3)
Rate difference vs placebo,[e] % (95% CI)	-	35.6 (14.8, 52.8)	21.3 (1.6, 39.3)	14.1 (-4.3, 31.5)
P value	-	< .001	.015	.060
vIGA-AD 0/1 with BPE[a]	**39**	**37**	**36**	**38**
Responders,[d] n (%)	4 (10.3)	10 (27.0)	9 (25.0)	6 (15.8)
Rate difference vs placebo,[e] % (95% CI)	-	17.7 (-0.7, 34.9)	15.3 (-2.8, 32.7)	6.1 (-10.1, 22.3)
P value	-	.024	.042	.218

[a]N represents the number of participants included in the model. [b]LS mean difference in reduction vs placebo determined using ANCOVA model that includes treatment, randomisation strata (AD severity, prior systemic medications) as fixed effects, and baseline EASI as covariate. [c]Adjusted P value accounts for the testing hierarchy and adjusted P < .025 indicates statistical significance of the treatment effect. For endpoints after the hierarchy breaks and secondary endpoints not in the testing hierarchy, only nominal P values are presented. [d]MH. [e]MH common rate difference vs placebo, adjusting for randomisation strata (AD severity, prior systemic medications).

ANCOVA, analysis of covariance; AD, atopic dermatitis; BPE, barely perceptible erythema; CI, confidence interval; EASI, Eczema Area and Severity Index score; LS, least squares; MH, Mantel-Haenszel; PP-NRS, Peak Pruritus Numerical Rating Scale; vIGA-AD, Validated Investigator Global Assessment for Atopic Dermatitis.

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Abstract N°: 80

Drug survival in adult atopic dermatitis patients in the TREATgermany registry

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Introduction

To date, one drug survival analysis for dupilumab has been published based on data collected in the TREATgermany atopic dermatitis registry (Stölzl et al., Br J Dermatol. 2022). The registry includes now sufficiently long follow-up periods for other systemic therapies (STs) used in adult patients with moderate to severe atopic dermatitis (i.e., abrocitinib, lebrikizumab, tralokinumab, upadacitinib). We generated Kaplan-Meier (KM) curves for the various STs and report on the probability of drug survival one and two years after ST initiation. Formal comparisons between the KM curves/drug survival rates were not conducted due to the heterogeneity of the patient groups.

Materials and Methods

The analyses are based on TREATgermany registry data from 2022 to 2025. A therapeutic agent was included in the current analysis if at least 100 patients were initiated post approval on this therapy in the registry. The starting time is the initiation of ST. We consider the first treatment episode per therapy and patient, i.e., a patient may contribute to the drug survival calculation for multiple therapies. The event of interest was defined as the first discontinuation of therapy. This could include discontinuation due to adverse events, lack of effectiveness, or similar reasons, but also treatment interruptions, attempts to pause therapy, or discontinuation due to remission. Patients were censored at their last follow-up if they were still receiving therapy at that time.Gang et al. (Allergy 2026) included ST initiations from January 2021 to October 2024 to ensure that at least one alternative modern ST was available in addition to dupilumab. We follow the same approach in our primary analysis considering initiations of systemic therapy since January 1, 2022 with follow-up through data extraction (December 31, 2025). For comparison, we calculated KM drug survival estimates based on the entire available observation period (2017–2025).

Results

First, we present results of the primary analysis, where initiation of ST occurred from January 1, 2022 onwards, and follow-up through data extraction on December 31, 2025 (n=1.279). The KM-estimates for 1-year drug survival (95% CI) are as follows: abrocitinib 64% (53%, 76%), dupilumab 81% (77%, 85%), lebrikizumab 73% (65%, 81%), tralokinumab 60% (52%, 70%), and upadacitinib 75% (68%, 82%). The KM-estimates for 2-year drug survival (95% CI) were obtained as well: abrocitinib 49% (38%, 64%), dupilumab 68% (63%, 74%), lebrikizumab [not estimable], tralokinumab 43% (34%, 54%), and upadacitinib 58% (50%, 68%) (Figure 1).The entire available time period (initiation of ST 2017–2025) was considered for comparison (n=1.945). The number of patients initiated on the respective therapy are: abrocitinib (n=100), dupilumab (n=1.206), lebrikizumab (n=222), tralokinumab (n=186), and upadacitinib (n=231). The following KM-estimates for 1-year drug survival (95% CI) were obtained: abrocitinib 64% (53%, 76%), dupilumab 85% (83%, 87%), lebrikizumab 73% (65%, 81%), tralokinumab 63% (56%,

72%), and upadacitinib 73% (67%, 81%). KM-estimates for 2-year drug survival (95% CI) were calculated as well: abrocitinib 49% (38%, 64%), dupilumab 76% (73%, 79%), lebrikizumab [not estimable], tralokinumab 46% (38%, 56%), and upadacitinib 55% (47%, 65%).

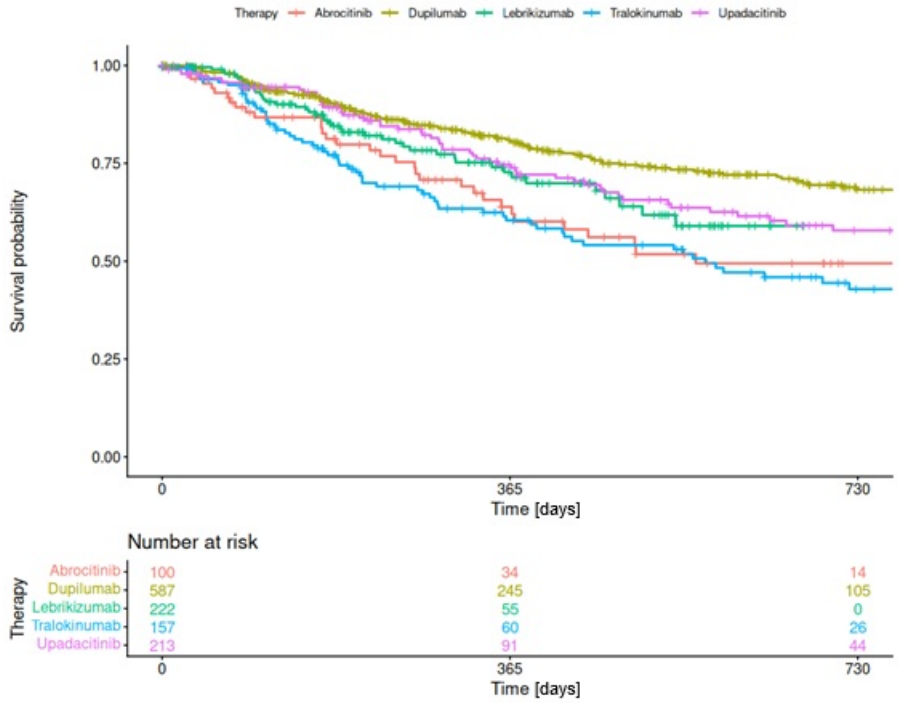

Figure 1: Drug survival estimates (for adult patients who initiated therapy on or after 01.01.2022)

Conclusions

The three therapies with the highest KM drug survival estimates at 1-year and 2-years based on TREATgermany registry data are dupilumab (81%, 68%), upadacitinib (75%, 58%) and lebrikizumab (73%, not estimable). Limiting the observation time to the time period when ST alternatives to dupilumab were available in Germany yields somewhat lower drug survival estimates for dupilumab. While multiple explanations are possible, this finding does not necessarily indicate reduced effectiveness of dupilumab. Rather, it is plausible that changes in prescribing behavior - such as a lower threshold for switching therapies in the presence of available alternatives - have contributed to the observed pattern.

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Interim Analysis of the ATTRACT Registry: Real-World Treatment Patterns and Clinical Outcomes of Abrocitinib at Week 52 in Moderate-to-Severe Atopic Dermatitis in Taiwan

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Introduction
The ATTRACT (Abrocitinib Taiwan Treatment pattern and Real-world sTudy in AtopiC dermatitis) registry was established to explore the real-world treatment patterns and clinical outcomes of abrocitinib (a selective JAK1 inhibitor) in moderate-to-severe atopic dermatitis (AD) in Taiwan. Building on earlier interim findings demonstrating early clinical improvements, this second interim analysis extends the evaluation through Week 52 to assess long term effectiveness.

Materials and Methods
This prospective, multicenter study is conducted across 8 medical centers in Taiwan. It enrolled patients aged ≥12 years with moderate-to-severe AD initiating abrocitinib for the first time. Data on demographics, clinical features, treatment history, and physician/patient-reported outcomes are collected. Recruitment began in June 2024 and ended in June 2025. Data collection continues for a minimum of 12 months and up to 24 months per participant. We sought to conduct a second interim analysis of the ATTRACT registry, with a data cut-off on 27 September 2025.

Results
A total of 154 patients were enrolled (66.9% male), with a mean age of 40.1 ± 19.8 years and a mean age at initial AD diagnosis of 29.5 ± 24.2 years. Median follow-up was 277 days (IQR: 151–344). Prior treatments comprised prescription topicals (22.1%), phototherapy (3.9%), biologic therapy (9.1%), JAK inhibitors (4.5%), and other systemic therapies (20.8%). Most patients initiated abrocitinib 200 mg once daily (79.9%). Abrocitinib therapy was

self-paid by 80.5% of the patients, while 19.5% was covered by national health insurance.

At baseline, patients exhibited heterogeneous AD phenotypes, as assessed by treating physicians. The most common phenotype was classic AD (63.0%), followed by erythroderma (39.0%), prurigo (8.4%), lichenoid (7.1%), and psoriasis-form AD (2.6%); a patient may present with more than one phenotype. Baseline disease severity among enrolled patients was distributed as 32.5% having an Eczema Area and Severity Index (EASI) score ≤7, 27.9% with 7 < EASI < 16, and 33.1% with EASI ≥16, while 6.5% of patients had missing baseline EASI score.

Table 1 provides a summary of effectiveness outcomes, including physician/patient-reported outcomes assessed across study visits from baseline up to Week 52, based on available data.

The mean EASI score decreased from 13.8 ± 9.8 at baseline to 5.1 ± 4.3 at Week 2, with further improvement to 3.2 ± 4.8 at Week 12, and remained low at 3.3 ± 4.0 through Week 52, corresponding to a mean 76.1% reduction from baseline. Furthermore, the mean EASI score showed sustained improvement across all body regions from week 2 through week 52, with consistent responses observed across regions. In the head and neck region, the mean EASI sub-score decreased by an average of 73.3% from baseline to Week 52.

The mean Peak Pruritus Numerical Rating Scale (PP-NRS) score decreased from 7.1 ± 2.7 at baseline to 3.3 ± 2.7 at week 2, 2.6 ± 2.5 at week 12, and 3.4 ± 3.6 at week 52. At weeks 2, 12, and 52, ≥4-point PP-NRS improvement was achieved by 60.7%, 61.4%, and 66.7% of patients, and PP-NRS 0/1 was achieved by 30.8%, 41.4%, and 33.3%, respectively.

By the data cutoff, 6 adverse events were reported: nausea, abdominal pain, nausea with vomiting, AD flare-up, intermittent herpes simplex, and acne, consistent with previously documented safety profiles. No new safety signals emerged during this interim analysis.

Table 1. Clinical and patient-reported outcomes with abrocitinib treatment in the full analysis set

		Baseline	Week 2	Week 4	Week 12	Week 16	Week 24	Week 52
Physician-reported outcomes								
	N	129	65	109	90	80	72	9
EASI	Mean (SD)	13.8 (9.8)	5.1 (4.3)	3.7 (4.3)	3.2 (4.8)	3.3 (5.0)	3.6 (5.4)	3.3 (4.0)
	% change from baseline, mean	-	-63.0%	-73.2%	-76.8%	-76.1%	-73.9%	-76.1%
Mean EASI by baseline EASI subgroups								
	N	88	42	74	65	60	52	8
Subjects with baseline EASI >7	Mean (SD)	18.4 (8.5)	6.2 (4.6)	4.2 (4.6)	3.8 (5.4)	3.7 (5.4)	4.3 (6.0)	2.4 (3.1)
	% change from baseline, mean	-	-66.3%	-77.2%	-79.3%	-79.9%	-76.6%	-87.0%
	N	47	17	41	37	36	30	8
Subjects with baseline EASI ≥16	Mean (SD)	24.4 (7.1)	9.5 (4.8)	5.5 (5.4)	5.3 (6.6)	5.0 (6.0)	5.8 (7.4)	2.4 (3.1)
	% change from baseline, mean	-	-61.1%	-77.5%	-78.3%	-79.5%	-76.2%	-90.2%
Mean EASI by body region								
Head & neck	Mean (SD)	1.5 (1.3)	0.6 (0.7)	0.5 (0.7)	0.4 (0.6)	0.5 (0.7)	0.5 (0.8)	0.4 (0.3)
Upper extremities	Mean (SD)	2.7 (2.3)	1.1 (1.1)	0.7 (0.9)	0.6 (0.9)	0.7 (1.2)	0.7 (1.3)	0.3 (0.4)
Trunk	Mean (SD)	4.4 (3.8)	1.4 (1.6)	1.1 (1.6)	0.9 (1.9)	1.0 (1.9)	1.2 (2.1)	1.2 (1.3)
Lower extremities	Mean (SD)	5.1 (4.4)	2.0 (2.2)	1.4 (2.0)	1.3 (2.2)	1.0 (1.9)	1.2 (2.0)	1.5 (2.2)
	N	95	50	90	76	67	65	8
IGA	Mean (SD)	3.0 (0.8)	2.0 (0.8)	1.6 (0.9)	1.2 (1.1)	1.2 (1.0)	1.3 (1.1)	1.1 (0.8)
	% change from baseline, mean	-	-33.3%	-46.7%	-60.0%	-60.0%	-56.7%	-63.3%
	N	112	64	100	84	77	64	8
BSA (%)	Mean (SD)	25.8 (21.6)	9.1 (10.2)	6.7 (8.8)	7.0 (12.7)	6.6 (13.2)	7.8 (13.7)	5.8 (6.9)
	% change from baseline, mean	-	-64.7%	-74.0%	-72.9%	-74.4%	-69.8%	-77.5%
	N	81	42	77	65	59	56	8
HECSI	Mean (SD)	25.7 (35.3)	12.0 (27.0)	4.2 (8.1)	3.6 (8.1)	7.7 (19.5)	4.3 (11.4)	3.8 (9.8)
	% change from baseline, mean	-	-53.3%	-83.7%	-86.0%	-70.0%	-83.3%	-85.2%
Patient-reported outcomes								
	N	129	65	109	87	75	65	9
PP-NRS	Mean (SD)	7.1 (2.7)	3.3 (2.7)	2.9 (2.7)	2.6 (2.5)	2.5 (2.4)	2.9 (3.0)	3.4 (3.6)
	% change from baseline, mean	-	-53.5%	-59.2%	-63.4%	-64.8%	-59.2%	-52.1%
	N	91	46	85	68	65	61	9
POEM	Mean (SD)	19.9 (7.5)	8.0 (6.6)	6.6 (6.3)	5.6 (6.6)	6.0 (6.6)	6.6 (7.7)	9.9 (9.1)
	% change from baseline, mean	-	-59.8%	-66.8%	-71.9%	-69.8%	-66.8%	-50.3%
	N	90	46	85	68	65	61	9
ADCT	Mean (SD)	16.8 (6.5)	7.1 (5.8)	5.5 (5.4)	4.8 (4.8)	5.4 (5.5)	5.9 (6.2)	8.2 (7.9)
	% change from baseline, mean	-	-57.7%	-67.3%	-71.4%	-67.9%	-64.9%	-51.2%
	N	90	46	82	69	65	61	9
DLQI	Mean (SD)	16.7 (7.7)	7.3 (5.5)	6.3 (6.3)	4.8 (5.5)	5.7 (6.9)	5.4 (6.5)	7.7 (8.0)
	% change from baseline, mean	-	-56.3%	-62.3%	-71.3%	-65.9%	-67.7%	-53.9%
	N	85	45	84	69	63	60	9
PtGA	Mean (SD)	3.5 (0.7)	2.0 (1.0)	2.0 (1.1)	1.6 (1.1)	1.6 (1.2)	1.7 (1.4)	2.1 (1.5)
	% change from baseline, mean	-	-42.9%	-42.9%	-54.3%	-54.3%	-51.4%	-40.0%

Full analysis set includes patients who received at least one dose of abrocitinib and had at least one post-baseline follow-up assessment; n varies by visit based on available data. Percentage change from baseline was calculated using mean values at each timepoint.

Data cut-off: 27 September 2025
Abbreviations: ADCT, Atopic Dermatitis Control Tool; BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; HECSI, Hand Eczema Severity Index; IGA, Investigator Global Assessment; POEM, Patient-Oriented Eczema Measure; PP NRS, Peak Pruritus Numerical Rating Scale; PtGA, patient global assessment.

Full analysis set includes patients who received at least one dose of abrocitinib and had at least one post-baseline follow-up assessment; n varies by visit based on available data. Percentage change from baseline was calculated using mean values at each timepoint. Data cut-off: 27 September 2025.

Abbreviations: ADCT, Atopic Dermatitis Control Tool; BSA, Body Surface Area; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; HECSI, Hand Eczema Severity Index; IGA, Investigator Global Assessment; POEM, Patient-Oriented Eczema Measure; PP NRS, Peak Pruritus Numerical Rating Scale; PtGA, patient global assessment.

Conclusions

ATTRACT is the first real-world registry study in Taiwan to demonstrate the rapid and sustained clinical effectiveness of abrocitinib across multiple clinical outcomes through week 52. Heterogeneous AD phenotypes were also observed, reflecting real-world patient characteristics. In addition, the study was conducted in a setting with a high proportion of self-paid treatment, and most patients initiating abrocitinib at 200 mg once daily. Future analyses of treatment patterns will be valuable in further contextualizing the role of abrocitinib in the management of AD in Taiwan.

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Abstract N°: 120

Efficacy and safety of Telikibart, a novel anti-IL-4Rα monoclonal antibody, for moderate-to-severe atopic dermatitis: 52-week outcomes and prespecified subgroup analyses from a randomized, placebo-controlled phase III trial

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Introduction
Telikibart (GR1802) is a fully human monoclonal antibody that targets the interleukin-4 receptor alpha (IL-4Rα) subunit with high affinity and potent capability of inhibiting IL-4/IL-13 signaling pathway to suppress Th2-driven inflammation. Its Fc region has been engineered with triple mutations (L234F/L235E/P331S) to eliminate antibody-dependent cell-mediated cytotoxicity, leading to a favorable safety profile. A previous phase II trial has preliminarily demonstrated promising efficacy of telikibart in moderate-to-severe atopic dermatitis. Here, we report the results of a randomized, placebo-controlled, phase Ⅲ trial (NCT06216392) to evaluate the 52-week efficacy and safety of Telikibart in a larger adult cohort, with prespecified subgroup analyses to assess consistency of therapeutic effects.

Materials and Methods
Eligible patients with moderate to severe atopic dermatitis were randomized 2:1 to receive either telikibart 300 mg (600 mg on day 1) or placebo every 2 weeks during the 16-week induction period. Subsequently, all participants received telikibart 300 mg every 2 weeks until week 52 in the maintenance period (placebo group received telikibart 600 mg at the first dose). Coprimary endpoints were the proportions of patients achieving a ≥75% improvement in Eczema Area and Severity Index (EASI-75) and an Investigator's Global Assessment (IGA) score of 0 or 1 with a ≥ 2-point reduction from baseline at week 16.

Results
Between January 2024 and August 2025, a total of 450 patients were randomized to receive either telikibart

(n=299) or placebo (n=151). At week 16, the proportion of patients achieving an EASI-75 response was significantly higher in the telikibart group than in the placebo group (69.6% vs. 22.5%; difference, 47.1% [95% CI, 38.62-55.50]; P <0.0001; Figure 1A). A higher proportion of IGA 0/1 with a ≥ 2-point reduction from baseline was also observed in the telikibart group (33.1% vs. 6.6%; difference, 26.5% [95% CI, 19.86-33.15]; P <0.0001; Figure 1B). Consistently, telikibart yielded higher rates of EASI-90, ≥4-point reduction in weekly average daily Peak Pruritus Numerical Rating Scale (PP-NRS), as well as greater least squares (LS) mean improvements in Dermatology Life Quality Index (DLQI) versus placebo (all P <0.0001; Figure 1C-E). At week 52, EASI-75 was achieved in 94.3% of patients who continued telikibart treatment and 95.9% of those switched from placebo to telikibart. Corresponding the proportion of IGA 0/1 with a ≥ 2-point reduction from baseline were 65.4% and 58.5%, respectively. 76.0% and 76.7% of patients in the two groups achieved a ≥4-point reduction in the weekly average of the daily PP-NRS score, respectively. The consistency of treatment effects was further supported by subgroup analyses, which showed higher EASI-75 response rates with telikibart versus placebo across all prespecified subgroups at Week 16 (all P <0.01), including patients with prior exposure to IL-4Rα inhibitors and immunosuppressants. During the doubleblind period, treatment-emergent adverse events (TEAEs) were reported in 64.5% of the telikibart group and 57.6% of the placebo group. Overall, 82.2% of patients who received at least one dose of Telikibart experienced TEAEs during the study, the majority of which were graded as Grade 1-2 according to the CTCAE 5.0.

Conclusion

Telikibart demonstrated promising efficacy in patients with moderate to severe atopic dermatitis at week 16 with significant improvement observed across all prespecified subgroups. Efficacy were consistent throughout 52-week treatment. The safety profile was mild and tolerable.

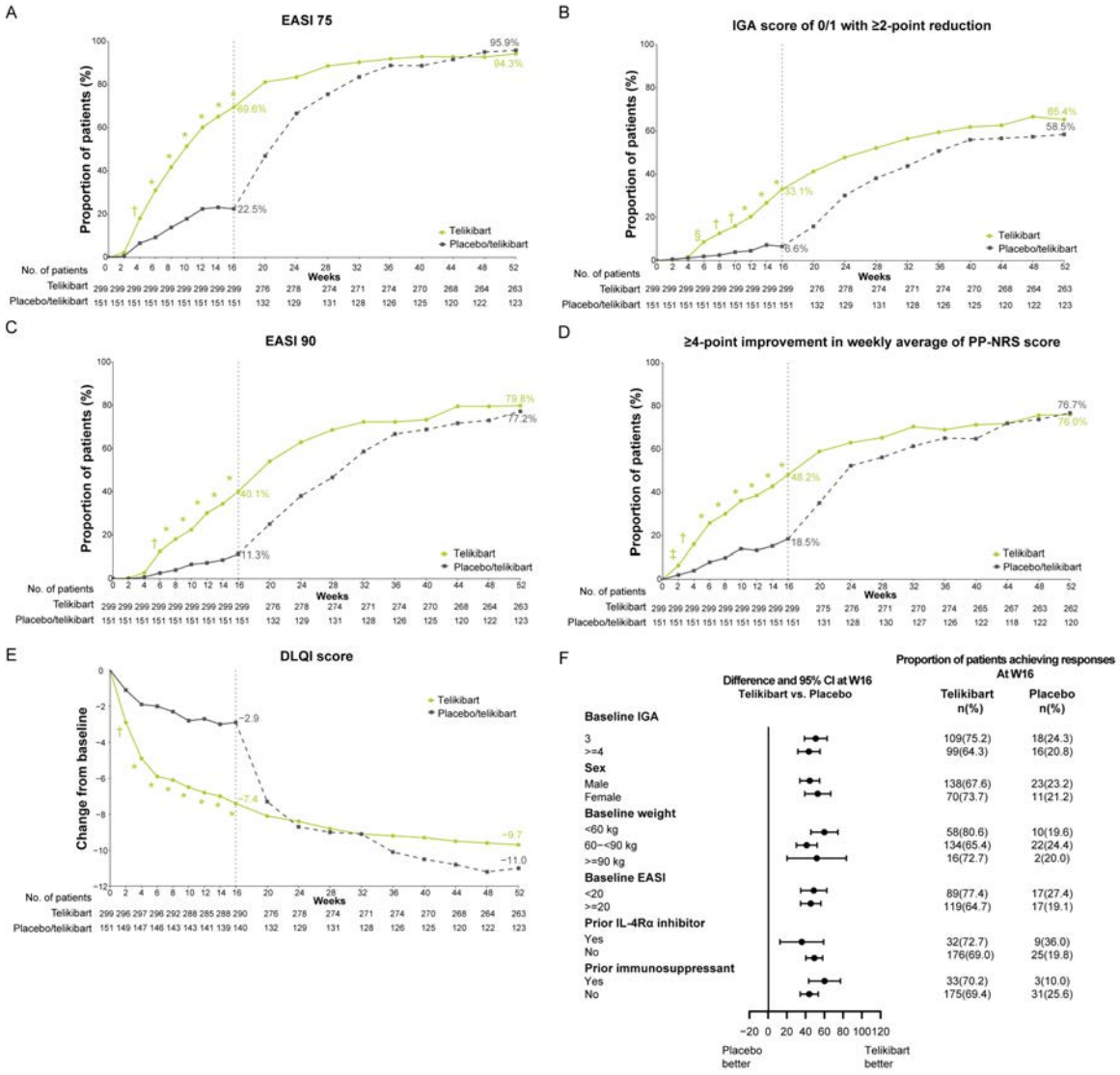

Figure 1 Efficacy of telikibart versus placebo over 52 weeks. Proportions of patients achieving (A) EASI-75 response, (B) IGA score of 0/1 with a ≥2-point reduction, (C) EASI-90 response, and (D) ≥4-

point improvement in weekly average of PP-NRS score. (E) Changes from baseline in DLQI scores, presented as LS mean for Weeks 0-16 and mean for Weeks 20-52. (F) Prespecified subgroup analyses. *p <0.0001, †p <0.001, §p <0.01, ‡p <0.05 vs. placebo.

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Abstract N°: 124

Concomitant Atopic Dermatitis and Psoriasis: From Clinicopathological Profiling to Target Treatment Observation Based on a Prospective Cohort

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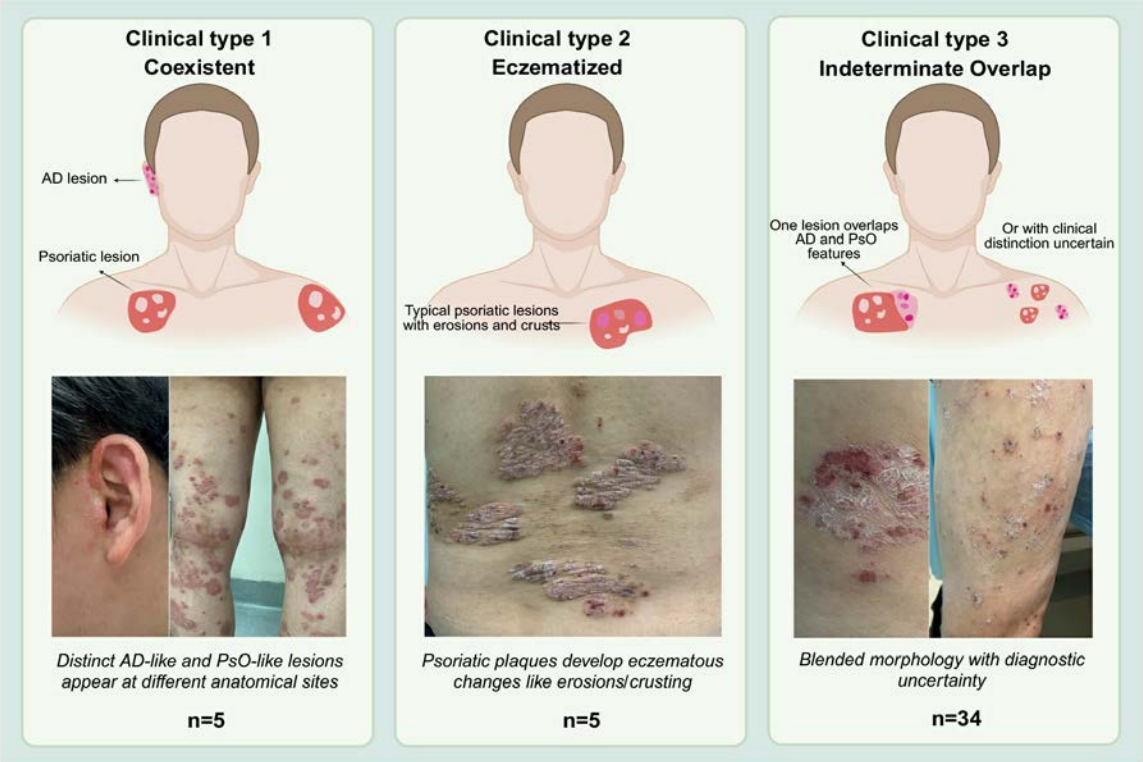
Introduction
Atopic dermatitis (AD) and psoriasis (PsO) are common chronic inflammatory skin diseases traditionally viewed as mutually exclusive due to their opposing immune profiles. However, emerging evidence suggests these conditions can coexist, posing significant diagnostic and therapeutic challenges. Studies specifically addressing this concurrent phenotype in the Chinese population are limited.

Materials and Methods
This is a prospective, single-center, observational cohort study conducted from August 2022 to August 2024, with an extended follow-up phase of one year. Patients meeting the Hanifin & Rajka criteria for AD and the clinicopathological criteria for PsO were enrolled while also adhering to the exclusion criteria. Participants underwent comprehensive clinical and histopathological evaluations. Skin biopsies were scored by dermatopathologists for psoriasiform and eczematous features. Treatment responses to targeted therapies were assessed prospectively using the Psoriasis Area Severity Index (PASI) and the Eczema Area and Severity Index (EASI).

Results
The cohort consisted of 44 patients, most of whom (40/44, 90.9%) were diagnosed with both conditions concurrently, and the majority (34/44, 77.3%) developed symptoms in adulthood. Lesional distribution analysis revealed a predominant involvement of the trunk and extensor surfaces of limbs. Also, we noticed a prominent facial involvement (16/44, 36%). Three distinct clinical phenotypes were identified: Clinical type 1 (coexistent), Clinical type 2 (eczematized), and Clinical type 3 (indeterminate overlap), further validated by histopathological correlations. During follow-up, treatment analysis showed the effectiveness of selective JAK1 inhibitors, with many patients treated with upadacitinib (5/7) achieving high-level responses in both PASI and EASI. While dupilumab was ineffective in all applied patients, and biologics targeting interleukin (IL)-17, IL-12/23, and IL-23 showed variable outcomes.



Clinical classification of atopic dermatitis and psoriasis concomitant based on lesion morphology. Created in https://BioRender.com

Conclusions

This study proposes a clinicopathological classification for concomitant AD and PsO. From a therapeutic perspective, JAK inhibitors emerged as a highly effective strategy. These findings provide a framework for diagnosing and managing concomitant AD and PsO. Large-scale, multi-center studies are required to validate these results further.

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Abstract N°: 133

Efficacy and Safety of LW402, A Novel Highly Selective JAK1 Inhibitor, in Adults with Moderate-to-Severe Atopic Dermatitis: Results from a Randomized, Double-blind, Placebo-controlled Phase II Trial

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Introduction
Objective: Despite the availability of several JAK inhibitors for atopic dermatitis (AD), unmet needs remain in patients with inadequate response to existing systemic therapies. LW402 is a novel, highly selective JAK1 inhibitor with phase I trial demonstrated 10 times safety margin. The aim of this phase II trial is to evaluate the efficacy, safety, and dose-response of LW402 in adults with moderate-to-severe AD.
Methods: A total of 144 patients were randomized to receive oral LW402 50mg, 100mg, 150mg or placebo twice daily for 12 weeks. The efficacy and safety profile were assessed.

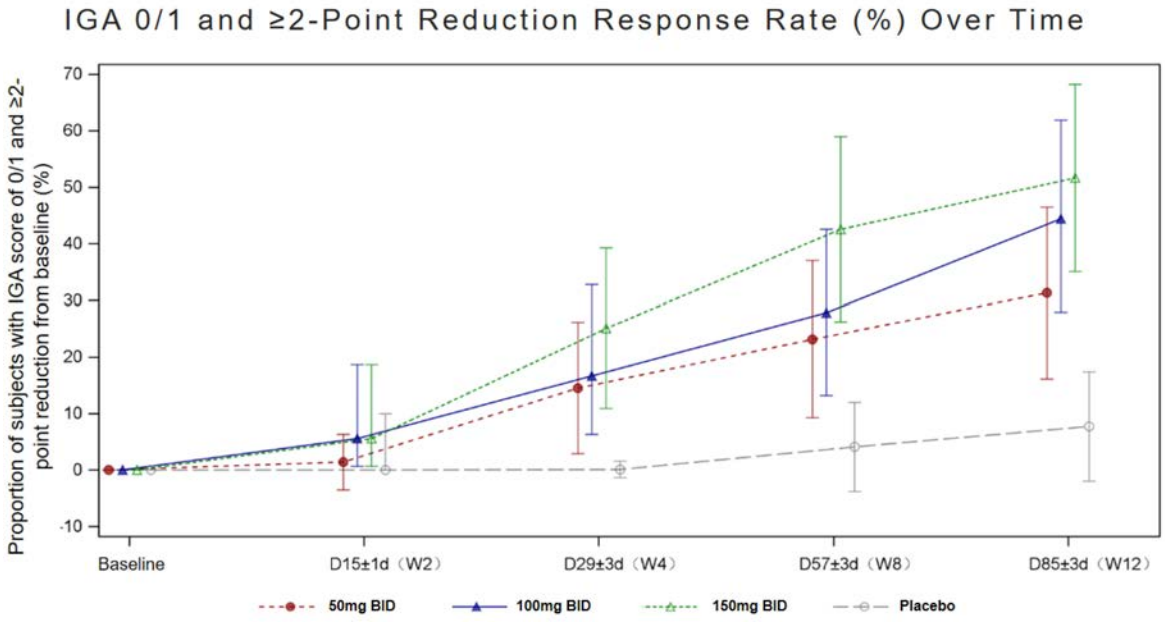
Key Efficacy Data of LW402

LW402 Week12	EASI-50 (%*)	EASI-75 (%)	EASI-90 (%)	EASI-100 (%)	vIGA-AD0/1 (%)	PP-NRS≥4 (%)	PP-NRS≥4 at Week1(%)
50 mg (n=36)	80.8%	61.4%	34.1%	9.5%	31.4%	44.1%	**5.6%**
100 mg (n=35)	77.8%	66.7%	33.3%	19.4%	44.4%	65.7%	**8.6%**
150 mg (n=34)	88.6%	74.4%	62.8%	25.9%	51.7%	74.7%	**29.4%****
Placebo (n=34)	39.6%	21.5%	3.5%	0.2%	7.7%	35.7%	**0.0%**

*The response rates of patients achieving EASI-50, EASI-75, EASI-90, EASI-100, vIGA-AD 0/1, and PP-NRS ≥4; **The 150 mg dose group significantly improved pruritus ($p < 0.01$).

Case Presentation
Results: At the end of 12 weeks treatment, significantly greater proportions of EASI-50, EASI-75, EASI-90 and EASI-100 responders were achieved in all LW402 groups comparing to placebo group. In LW402 150 mg group, EASI-90 was achieved in 62.8% of patients and EASI-100 were achieved in 25.9% of patients, both significantly higher than in placebo group (3.5% and 0.2% respectively, $P < 0.05$). The proportion of patients achieving an

Investigator’s Global Assessment (IGA) of clear(0) or almost clear(1) with >2 grades improvement from baseline were significantly higher in all LW402 groups and was in a dose-dependent manner (31%-52%). The IGA 0/1 was achieved in 51.7% patients in LW402 150 mg group comparing with only 7.7% in placebo group (P < 0.05). Treatment-emergent adverse events were similar between LW402 and placebo groups (76.1% vs. 82.9%). No treatment-related serious adverse events were reported.



Conclusion

Conclusions: LW402 demonstrated a high efficacy and good safety profile in adults with moderate-to-severe AD. The dose of 150mg twice daily showed the best results, supporting it as a recommended dose for phase III study.

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Abstract N°: 142

Kaposi Varicelliform Eruption Caused by Monkeypox Virus

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Introduction

Monkeypox (MPX), a zoonotic disease caused by monkeypox virus (MPXV), typically presents with localized skin lesions in adults. Kaposi varicelliform eruption (KVE) is classically induced by herpes simplex virus (HSV) in patients with impaired skin barriers or immunity, such as atopic dermatitis (AD). However, MPXV as an etiologic agent of KVE has rarely been reported. Upadacitinib, a Janus kinase inhibitor, is effective for AD but may compromise antiviral immunity. We report a rare case of disseminated MPX presenting as KVE in an AD patient on long-term upadacitinib.

Case Presentation

A 30-year-old male presented with an 11-day history of painful facial and genital rashes, which were subsequently followed by fever and rapid dissemination. He has a history of well-controlled AD and had been taking upadacitinib 30 mg daily for the past two years. He reported unprotected male-to-male sexual contact three weeks prior to symptom onset. Physical examination revealed tender axillary and inguinal lymphadenopathy, along with extensive vesicles, pustules, nodules, erosions, and crusts, many of which showed central umbilication. Laboratory findings were notable for elevated leukocytes, lymphocytes, monocytes, and CRP. Serological tests for HIV and syphilis were negative. Chest and head computed tomography examinations revealed no abnormalities. Skin histopathology revealed epidermal necrosis, focal pale cytoplasm in epidermal cells, and the presence of giant cells accompanied by an infiltrate of neutrophils, lymphocytes, and plasma cells. Metagenomic sequencing identified MPXV as the predominant pathogen, with a relative abundance of 80.04%. Based on these findings, the patient was diagnosed with disseminated MPX and KVE. Upadacitinib was discontinued immediately upon diagnosis. As no specific antiviral agents for monkeypox are currently available in China, the patient was treated with intravenous immunoglobulin (30 g) for fever refractory to nonsteroidal anti-inflammatory drugs. His fever resolved within four days, and significant improvement in skin lesions was observed by day six of treatment.

Conclusion

KVE is an acute vesiculopustular dermatosis classically caused by HSV; however, emerging evidence indicates that other viruses, such as varicella-zoster virus, can also induce this condition. MPX typically presents with localized papules, vesicles, and pustules in adults, whereas disseminated lesions are rarely documented. We present a unique case of disseminated MPX manifesting as KVE in AD on long-term upadacitinib, which expands the known etiology of KVE and highlights KVE is a clinical reaction pattern with the complex interplay between novel immunotherapies and emerging viral pathogens. The pathogenesis of this unusual presentation likely stems from a "dual hit" on the skin's antiviral defense. AD itself is characterized by an impaired epidermal barrier and a Th2-skewed immune environment, predisposing to microbial colonization and dissemination. And more critically, upadacitinib, a Janus kinase 1 inhibitor, potently blocks the JAK-STAT signaling pathway. While this is therapeutic for AD by inhibiting Th2 cytokines, such as IL-4, IL-13 and so on, it concurrently disrupts key antiviral mechanisms, particularly the signaling of type I and II interferons. These interferons are essential for restricting orthopoxvirus replication and coordinating an effective cytotoxic T-cell response. Therefore, upadacitinib may created an iatrogenic vulnerability that facilitated widespread MPX following high-risk exposure. In conclusion, this case carries significant clinical and public health implications. First, it mandates that clinicians include MPXV in the

differential diagnosis of KVE, especially in sexually active individuals presenting with atypical or umbilicated lesions. Second, it emphasizes the need for heightened vigilance for unusual infections in patients receiving targeted immunotherapies like JAK inhibitors, preventive vaccines may effect if available.

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Abstract N°: 169

Efficacy and Safety of Zumilokibart (APG777), a Half-Life-Extended Anti-IL-13 Antibody, in Moderate-to-Severe Atopic Dermatitis: Primary Results From the Phase 2 APEX Part B Dose-Regimen-Finding Study

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Introduction
Zumilokibart (APG777) is a novel, half-life-extended, anti-IL-13 antibody that achieves early peak and sustained drug exposures, enabling extended dosing intervals with only 4 dosing days during induction and 2 or 4 dosing days per year during maintenance. In the phase 2 APEX Part A proof-of-concept study in adults with moderate-to-severe atopic dermatitis (AD), treatment with zumilokibart led to rapid improvements in skin signs and itch, with clinical responses maintained through Week 52 with both every-12- and every-24-week dosing. Here, primary 16-week results from the ongoing phase 2 APEX Part B dose-regimen-finding study (NCT06395948) are presented.

Materials and Methods
APEX Part B is a randomized, double-blinded, placebo-controlled, phase 2 study in adults with moderate-to-severe AD (EASI ≥16, vIGA-AD ≥3, and BSA ≥10%). Participants (N=346) were randomized 1:1:1:1 and received a low-, mid-, or high-dose zumilokibart regimen or placebo during the 16-week induction period. The mid-dose regimen was identical to the induction regimen evaluated in APEX Part A. The primary endpoint was the proportion of participants achieving ≥75% reduction from baseline in EASI (EASI-75) at Week 16. Secondary endpoints included percent change from baseline in EASI, vIGA-AD 0/1 with ≥2-point improvement from baseline, EASI-90, EASI-100, and ≥4-point improvement in Itch Numeric Rating Scale (I-NRS4). Missing data were imputed using Markov Chain Monte Carlo multiple imputation, combined with non-responder imputation for rescue medication use or treatment discontinuation due to lack of efficacy.

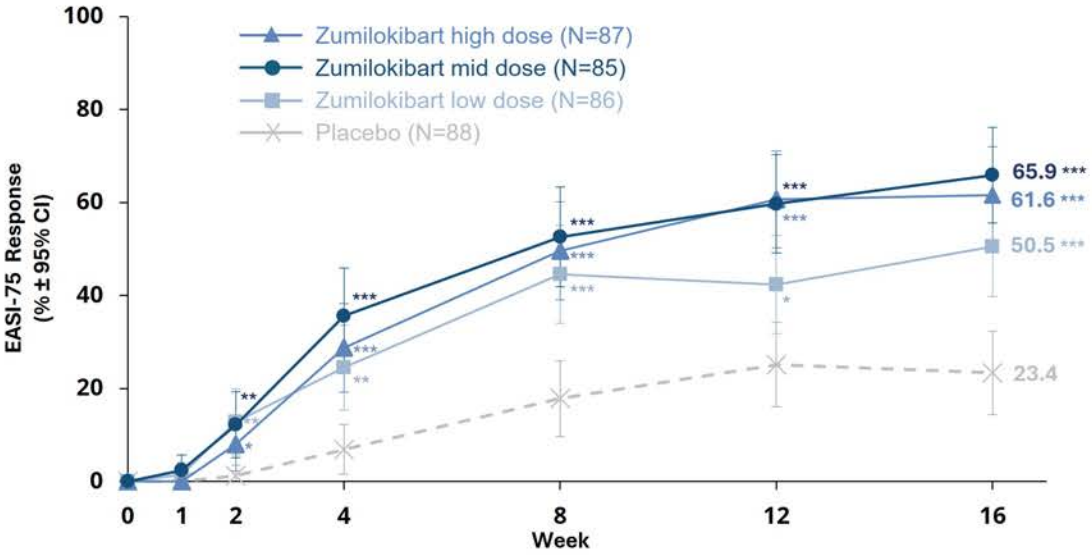
Results
All three zumilokibart dose regimens met the primary endpoint, with significantly greater EASI-75 response rates than placebo at Week 16 (Figure 1; 50.5% [low dose], 65.9% [mid dose], and 61.6% [high dose] vs 23.4% [placebo]; all $p<0.001$). Mid- and high-dose regimens demonstrated similar efficacy, whereas clinical activity was relatively lower with the low-dose regimen. Mid-dose and high-dose zumilokibart demonstrated significantly greater responses than placebo across secondary endpoints (Table 1). Improvements in skin lesions and itch were evident early, with the mid-dose zumilokibart regimen achieving significantly greater percent reductions versus placebo in EASI by Week 1 and I-NRS by Week 2. Overall adverse event rates were balanced across treatment arms through Week 16 (Table 2). Treatment-emergent adverse events (TEAEs) occurred in 67.0%, 75.6%, 60.0%, and 67.8% of patients receiving placebo and low-, mid-, and high-dose zumilokibart, respectively; corresponding rates of

serious TEAEs were 2.3%, 2.3%, 1.2%, and 3.4%. The most common TEAEs (≥5% in any treatment group) were nasopharyngitis, headache, noninfective conjunctivitis, upper respiratory tract infection, dermatitis atopic, and urinary tract infection.

Conclusion

Zumilokibart treatment led to rapid and statistically significant improvements in skin lesions and itch through Week 16, including achievement of complete skin clearance in a subset of patients, with a safety profile generally consistent with approved therapies targeting IL-13 or IL-4/IL-13. These findings support selection of the mid-dose regimen for phase 3 development and further evaluation of every 12- and 24-week maintenance dosing in adults with moderate-to-severe AD.

Figure 1. Primary Endpoint of Proportion of Participants Achieving EASI-75 at Week 16



*p<0.05, **p<0.01, ***p<0.001 (vs placebo). CI = confidence interval. EASI-75 = ≥75% reduction from baseline in Eczema Area and Severity Index. Missing data were imputed using Markov Chain Monte Carlo multiple imputation, combined with non-responder imputation (NRI) for participants who initiated any rescue medication or discontinued study treatment due to lack of efficacy (not for other reasons).

Table 1. Efficacy Outcome Measures at Week 16

Efficacy at Week 16	Placebo (N=88)	Zumilokibart Low Dose (N=86)	Zumilokibart Mid Dose (N=85)	Zumilokibart High Dose (N=87)
Primary endpoint*				
EASI-75, %	23.4	50.5 *p<0.001*	65.9 *p<0.001*	61.6 *p<0.001*
Secondary endpoints				
EASI % change from baseline, LS mean	-34.9	-61.0 *p<0.001*	-70.6 *p<0.001*	-69.3 *p<0.001*
vIGA-AD 0/1, %	10.9	27.6 *p<0.01*	46.0 *p<0.001*	33.4 *p<0.001*
EASI-90, %	9.3	28.2 *p<0.01*	47.4 *p<0.001*	35.8 *p<0.001*
EASI-100†, %	3.4	10.5 *ns*	16.5 *p<0.01*	12.6 *p<0.05*
I-NRS4‡, %	13.9	35.7 *p<0.01*	50.5 *p<0.001*	43.4 *p<0.001*

p values are compared with placebo. *Multiplicity controlled with sequential testing across dose regimens (high dose to low dose).
EASI = Eczema Area and Severity Index. I-NRS4 = ≥4-point improvement in Itch Numeric Rating Scale. ns = not significant. vIGA-AD 0/1 = Validated Investigator Global Assessment for Atopic Dermatitis with ≥2-point improvement from baseline.
For EASI % change from baseline, data collected after the initiation of rescue medication use or study treatment discontinuation were set to missing; missing data were imputed using Markov Chain Monte Carlo multiple imputation (MCMC-MI) for inferential statistics.
For categorical variables, missing data were imputed using MCMC-MI, combined with non-responder imputation (NRI) for participants who initiated any rescue medication or discontinued study treatment due to lack of efficacy (not for other reasons).
†For EASI-100, missing data and data collected after initiation of rescue medication or study treatment discontinuation (including all reasons) were imputed using NRI.
‡For I-NRS4, N's reflect the number of participants with at least 4 points on the I-NRS at baseline (N=84, placebo; N=78, low dose; N=77 mid dose; N=77, high dose).

Table 2. Adverse Events through Week 16

Safety summary through Week 16, n (%)	Placebo (N=88)	Zumilokibart Low Dose (N=86)	Zumilokibart Mid Dose (N=85)	Zumilokibart High Dose (N=87)

≥1 adverse event	59 (67.0)	65 (75.6)	51 (60.0)	59 (67.8)
≥1 serious adverse event	2 (2.3)	2 (2.3)	1 (1.2)	3 (3.4)
Adverse events leading to discontinuation	2 (2.3)	1 (1.2)	2 (2.4)	3 (3.4)
Most common adverse events through Week 16 (≥5% in any treatment group)				
Nasopharyngitis	19 (21.6)	22 (25.6)	12 (14.1)	10 (11.5)
Headache	3 (3.4)	7 (8.1)	6 (7.1)	6 (6.9)
Noninfective conjunctivitis	0 (0.0)	4 (4.7)	5 (5.9)	10 (11.5)
Upper respiratory tract infection	3 (3.4)	5 (5.8)	6 (7.1)	5 (5.7)
Dermatitis atopic	5 (5.7)	7 (8.1)	2 (2.4)	5 (5.7)
Urinary tract infection	1 (1.1)	1 (1.2)	5 (5.9)	0 (0.0)

Treatment-emergent adverse events through week 16. Most common events listed by preferred term.

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Abstract N°: 171

Risk of Cutaneous T-Cell Lymphoma and Lymphoid Malignancies With Dupilumab: A Propensity-Matched Cohort Study Across Atopic Dermatitis and other Type-2 Inflammatory Diseases

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Introduction

Concerns have been raised regarding whether dupilumab therapy may influence the development or progression of cutaneous T-cell lymphoma (CTCL), particularly in patients with atopic dermatitis (AD), in whom early CTCL may clinically mimic inflammatory dermatoses. Given the increasing use of dupilumab across type 2 inflammatory diseases (T2IDs), robust real-world data are needed to clarify its long-term oncologic safety. We aimed to evaluate the risk of CTCL and other lymphoid malignancies among patients treated with dupilumab compared with those receiving alternative systemic therapies in AD and non-dermatologic T2IDs.

Materials and Methods

We conducted a retrospective cohort study using TriNetX, a large federated electronic health record database. Patients with AD (n=7,840) or other T2IDs (n=16,926) treated with dupilumab were propensity-score matched to patients receiving alternative systemic therapies, including systemic corticosteroids, cyclosporine, methotrexate, azathioprine, and mycophenolate mofetil. Matching was based on demographics, comorbidities, and prior treatment exposure. Outcomes included CTCL, CTCL excluding Sézary syndrome (SS), SS, T/NK-cell lymphoma (NKTCL), non-Hodgkin lymphoma (NHL), myeloproliferative neoplasms (MPNs), and multiple myeloma (MM). Time-to-event analyses were performed using Cox proportional hazards models, and hazard ratios (HRs) with 95% confidence intervals (CIs) were calculated.

Results

Among patients with AD, dupilumab exposure was not associated with an increased risk of CTCL (HR 1.04, 95% CI 0.62–1.73), CTCL excluding SS (HR 1.04, 95% CI 0.62–1.73), SS (HR 0.18, 95% CI 0.04–1.18), or NKTCL (HR 0.93, 95% CI 0.57–1.51). Moreover, dupilumab was associated with reduced risks of MPN (HR 0.57, 95% CI 0.36–0.91) and MM (HR 0.51, 95% CI 0.27–0.96). In patients with other T2IDs, dupilumab was similarly not associated with increased risks of CTCL (HR 0.36, 95% CI 0.14–1.03), CTCL excluding SS (HR 0.35, 95% CI 0.15–1.04), or NKTCL (HR 0.57, 95% CI 0.26–1.26), while significantly reduced risks were observed for NHL (HR 0.24, 95% CI 0.16–0.35), MPN (HR 0.41, 95% CI 0.29–0.56), and MM (HR 0.16, 95% CI 0.08–0.31). Notably, irrespective of treatment modality, AD (HR 9.46, 95% CI 7.28–12.28) and T2IDs (HR 1.38, 95% CI 1.27–1.50) were independently associated with an increased risk of CTCL.

Conclusions

Dupilumab therapy was not associated with an increased risk of lymphoma, including CTCL, in patients with AD or other T2IDs. These findings suggest that previously reported cases of CTCL arising during dupilumab treatment are more likely attributable to underlying disease-related risk or misclassification of early CTCL rather than a causal drug effect.

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Abstract N°: 194

Efficacy and safety of lebrikizumab in the treatment of atopic dermatitis in the head-and-neck area complicated by eczema herpeticum: a case report.

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Introduction

Atopic dermatitis (AD) is one of the most common chronic inflammatory skin diseases, which may lead to an increased risk for skin and systemic infections. A subset of AD patients exhibits a disseminated severe herpes simplex virus (HSV) infection called eczema herpeticum (EH) that can cause life-threatening complications.

Case Presentation

A 40-year-old man presented to the emergency room for the recent onset of erythematous papular eroded clustered lesions on face, upper trunk, and genital area. He reported fever and pain. Conjunctivitis was also present.
He had also eczematous areas on face, neck, upper trunk and limbs; the patient reported that such lesions were itchy and had been present for a long time; however, he never sought dermatological evaluation.
The patient was otherwise healthy, except for a known sensitization to inhalant allergens.
A diagnosis of EH in AD was performed. The patient was initially treated with valaciclovir 1g, 1 tablet 3 times a day for a week. Nucleic acid amplification test confirmed the presence of HSV 1. Subsequently, treatment with valaciclovir was continued with 1 tablet a day for 1 month, and treatment with lebrikizumab was started.The herpetic lesions healed rapidly within a week, while the eczematous lesions healed within a month. Six months after starting treatment with lebrikizumab, the patient has had complete remission of the AD and has not experienced any recurrences of herpes.

Conclusion

Our case, in addition to confirm the efficacy of lebrikizumab in the treatment of AD with head-and-neck involvement, demonstrates its safety in severe herpetic infections.

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Abstract N°: 212

Long-term efficacy and safety of tralokinumab in adolescents aged 12–17 years with moderate-to-severe atopic dermatitis

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Introduction

Tralokinumab, an interleukin-13 blocker, is approved in many countries for the treatment of moderate-to-severe atopic dermatitis (AD) in patients aged ≥12 years who are candidates for systemic therapy. Here, long-term efficacy and safety of tralokinumab are reported in adolescents treated for up to 3 years with tralokinumab during the ECZTRA 6[1] and ECZTEND[2] clinical trials.

Materials and Methods

This post-hoc analysis included adolescents (aged 12–17 years) with moderate-to-severe AD treated with tralokinumab ± optional topical corticosteroids (TCS)/topical calcineurin inhibitors (TCI) for 52 weeks in the placebo-controlled phase 3 trial ECZTRA 6 (NCT03526861) plus up to 104 weeks (safety analysis) or 72 weeks (efficacy analysis) in the open-label long-term extension trial ECZTEND (NCT03587805). Trial treatment ended in May 2022 for the adolescent participants, regardless of when they enrolled in ECZTEND.

Efficacy was analyzed as observed; assessments included the Investigator's Global Assessment (IGA), Eczema Area and Severity Index (EASI), worst weekly pruritus numeric rating scale (Itch NRS), and Children's Dermatology Life Quality Index (CDLQI). The safety evaluation was based on treatment-emergent adverse events (AEs), including predefined AEs of special interest (eczema herpeticum, malignancy, skin infections requiring systemic treatment, conjunctivitis, keratoconjunctivitis, and keratitis).

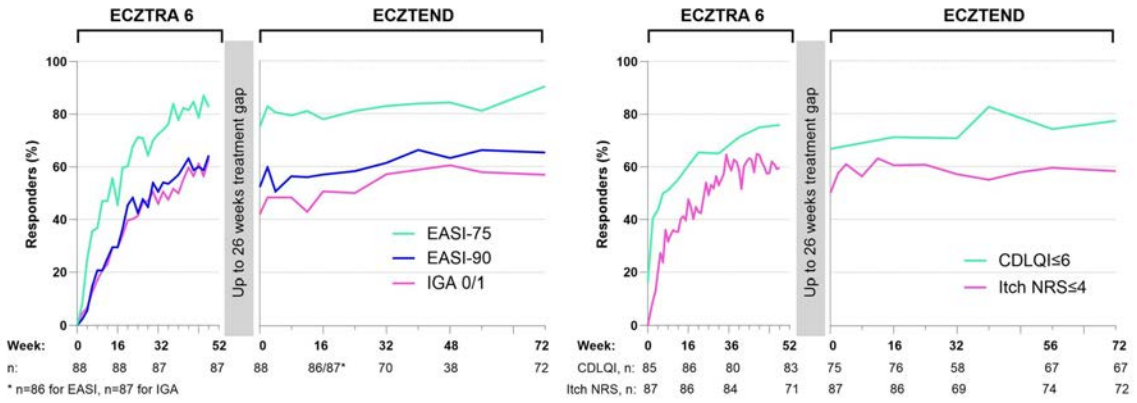
Results

88 adolescents (52.3% males) were included in the analysis set. Of these, 78.4% had a gap of <16 weeks (5 half-lives of tralokinumab) and 21.6% had a gap of 16–26 weeks (full washout) between the last tralokinumab dose in ECZTRA 6 and the first dose in ECZTEND. 80.7% completed ECZTEND on-treatment. The median and maximum exposure time in ECZTEND was 1.7 and 2.2 years.

Following tralokinumab treatment in ECZTRA 6, improvements in both clinician- and patient-reported efficacy and quality-of-life measures remained high and stable during the longer-term treatment in ECZTEND (Figure 1). Throughout most of ECZTEND, mean response rates were 80–85% for EASI-75 and EASI≤7, 65–75% for CDLQI≤6, 60–70% for EASI≤3, 60% for Itch NRS ≤4, and 50–60% for IGA 0/1 and EASI-90.

Most AEs were non-serious, of mild or moderate severity, assessed by the investigator as not related to tralokinumab, and did not lead to treatment discontinuation. Common AEs (reported in ≥5% of the adolescents) during ECZTEND were coronavirus infection, nasopharyngitis, atopic dermatitis, and anxiety. The pattern of AEs in the adolescents was overall consistent with that in the total ECZTEND population (2). AEs of special interest were only reported for 1 (1.1%) of the adolescents in the analysis set (2 events of conjunctivitis allergic). No new safety concerns were identified.

Figure 1. Long-term efficacy of tralokinumab in adolescents (12–17 years) with moderate-to-severe atopic dermatitis



Notes: Tralokinumab dosing regimens were 150 mg Q2W/Q4W or 300 mg Q2W/Q4W ± optional TCS/TCI in ECZTRA 6 and 300 mg Q2W ± optional TCS/TCI in ECZTEND. Median treatment gap (from last tralokinumab dosing in ECZTRA 6 to first dosing in ECZTEND) was 28.5 days.
Abbreviations: CDLQI, Children's Dermatology Life Quality Index; EASI-75 / EASI-90, ≥75% / 90% reduction in Eczema Area and Severity Index relative to baseline in ECZTRA 6; IGA 0/1, Investigator's Global Assessment of 0 (clear) or 1 (almost clear); n, number of participants with data; NRS, numeric rating scale; Q2W/Q4W, every 2/4 weeks; TCI, topical calcineurin inhibitors; TCS, topical corticosteroids.

Conclusions

Treatment with tralokinumab ± optional TCS/TCI provided long-term disease control in adolescents with moderate-to-severe AD. Treatment was well-tolerated in adolescents for up to 3 years, with a long-term safety profile consistent with that in adults and the known safety profile of tralokinumab.

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Abstract N°: 216

Long-term upadacitinib safety in moderate-to-severe atopic dermatitis up to 7 years: an integrated analysis with over 9600 patient-years of exposure

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by eczematous lesions, intense itch, and skin pain. The chronic nature of the disease requires safe and effective long term treatment options. Upadacitinib (UPA) is a Janus kinase inhibitor approved for the treatment of moderate-to-severe AD in adults and adolescents.

Materials and Methods

Patients in the randomized, double-blind, multicenter, placebo-controlled, phase 3 Measure Up 1 (NCT03569293), Measure Up 2 (NCT03607422), and AD Up (NCT03568318) trials were pooled for analysis. Adolescents and adults (aged 12–75 years) with moderate-to-severe AD were randomized 1:1:1 to receive once-daily oral monotherapy with UPA 15 mg, UPA 30 mg, or placebo (Measure Up 1, Measure Up 2) or in conjunction with topical corticosteroids (AD Up). The first 16 weeks of each study were placebo-controlled, double-blinded with a blinded extension period of up to 524 weeks. Patients who were initially randomized to UPA maintained their original treatment. Patients initially randomized to placebo were rerandomized (1:1) to blinded UPA 15 mg or UPA 30 mg. Treatment-emergent adverse events (TEAEs) and adverse events of special interest (AESI) were assessed by exposure-adjusted rates per 100 patient-years (PY) for the entire treatment period.

Results

A total of 2683 patients were treated with either 15 mg (N = 1337) or 30 mg (N=1346) of UPA with a total of 9623.7 PYs of exposure. Overall rates for TEAEs were higher with UPA 30 mg than UPA 15 mg. Serious AE, and AE leading to discontinuation were generally similar between UPA 15 mg and 30 mg. Rates of TEAEs leading to death remained low in both groups (both UPA 15 mg and 30 mg, 0.1 events per 100PY [E/100PY]). Rates of AESIs were: serious infections (UPA 15 mg, 2.2E/100PY; UPA 30 mg, 2.7 E/100 PY), herpes zoster (UPA 15 mg, 3.2 E/100PY; UPA 30 mg, 5.1 E/100PY), nonmelanoma skin cancer (NMSC; UPA 15 mg, 0.4 patients per 100 patient-years [n/100PY]; UPA 30 mg 0.5 n/100PY), malignancy excluding NMSC (UPA 15 mg, 0.3 n/100PY; UPA 30 mg, 0.4 n/100PY), adjudicated major adverse cardiovascular events (UPA 15 mg, 0.2 n/100PY; UPA 30 mg, < 0.1 n/100PY), and adjudicated venous thromboembolic events (UPA 15 mg, 0.1 n/100PY; UPA 30 mg, 0.2 n/100PY). Incidence rates for MACE, VTE and malignancy were similar or below background rates observed in real-world AD populations.

Conclusions

This integrated analysis of three phase 3 trials with over 9600 patient-years of exposure demonstrates consistently low rates of adverse events of special interest throughout 7 years of upadacitinib treatment. Rates were generally similar between doses and did not exceed background incidence rates in real-world atopic dermatitis populations, supporting the established benefit-risk profile of upadacitinib for moderate-to-severe atopic dermatitis.

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Multi-omic profiling identifies early molecular responses to rezpegaldesleukin, a novel regulatory T cell-inducing therapy, in atopic dermatitis

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by T-cell–mediated immune dysregulation highly impacting patients' quality of life. Although current biologics effectively target type 2 inflammation, more than 50% of adults report inadequately controlled disease despite treatment. Rezpegaldesleukin is an IL-2 receptor agonist designed to selectively expand regulatory T cells (Tregs), essential for maintaining immune homeostasis. In the REZOLVE-AD randomized, double-blind, dose-finding, placebo-controlled phase 2b trial (NCT06136741) rezpegaldesleukin 24 µg/kg q2w resulted in statistically significant improvements in the primary and secondary endpoints following the 16-week induction phase (Silverberg et al. The Lancet 2026). In this sub-study, we aim to integrate transcriptomic and proteomic biomarkers with clinical endpoints to characterize the molecular effects and clinical correlations of rezpegaldesleukin in patients with moderate-to-severe AD.

Materials and Methods

100 patients receiving rezpegaldesleukin 24 µg/kg q2w (n=59) or placebo (n=41) were analyzed in this biomarker sub-study. Blood and lesional tape strips were collected at baseline and after 2 and 4 weeks (W). Clinical assessments (EASI, vIGA-AD, Itch Numeric Rating Scale [NRS]) were performed at baseline and at two-week intervals up to W16. Differentially expressed genes/DEGs and proteins/DEPs (fold change/FCH>1.5 and $p<0.05$) were evaluated in tape strips using RNA-seq and the Olink Target 96 multiplex platform as well as in serum using Olink (fold change/FCH>1.3 and $p<0.05$). Clinical severity scores were correlated with changes in biomarker expression using Spearman correlations.

Results

Among the 59 patients in this biomarker sub-study with moderate-to-severe AD treated with rezpegaldesleukin (28 females, 31 males; mean age, 36.6 ± 13.5 years; baseline mean EASI, 26.6 ± 10.2), the mean percentage reduction in EASI from baseline reached 64.3% at W16, with 42.4% of patients achieving EASI75. Significant improvements versus baseline and versus placebo were observed as early as W2 and were significant across all clinical efficacy endpoints, including EASI-50/75/90, IGA 0/1, and≥ 4-point improvement in Itch NRS (all $p<0.05$). RNA-seq revealed that rezpegaldesleukin treatment led to a significant upregulation versus both baseline and placebo of Treg and T-cell activation markers (ICOS, CD3D/E, CTLA4, FOXP3, IL2RA, IL2RB) as early as W2. A significant reduction was conversely observed in markers of T-helper axes, including Th1 (OASL), Th2 (CCL7), Th17 (CXCL17, IL36RN, CXCL2, CXCL3, CAMP/LL-37) and Th22 (S100A12), along with fibrosis-associated markers (POSTN, COL15A1, ELN, COL16A1, COL1A1, LUM; all $p<0.05$). Gene Set Variation Analysis (GSVA) demonstrated significant reduction of Th17 ($p<0.01$) and JAK-STAT signaling ($p<0.05$) by W4. Tape-strip proteomic analyses validated transcriptomic findings, highlighting significant downregulation of markers of T-cell activation, Th17/IL-23-axes, and innate immunity. Serum proteomic analyses complemented tape-strip findings, additionally

demonstrating early, sustained upregulation of regulatory proteins (IL10, CD274, TNFRSF9) starting at W2. Blood analysis also revealed that biomarker changes as early as W2 already correlated significantly with EASI at W16, exclusively in the rezpegaldesleukin arm: IL-10 ($R=-0.621$, $p<0.0001$), CCL17 ($R=0.524$, $p<0.0001$), and TGFB1 ($R=-0.573$, $p<0.0001$). No such correlations were observed in the placebo arm (all $|R|\leq 0.30$, $p\geq 0.06$)

Conclusion

Rezpegaldesleukin induced rapid and sustained clinical improvement accompanied by early modulation of immune pathways consistent with Treg expansion and suppression of pathogenic inflammatory signaling. Early biomarker changes correlated with subsequent clinical response, providing mechanistic support for Treg-directed therapy for AD.

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Abstract N°: 283

Efficacy and safety of baricitinib versus azathioprine, both combined with topical corticosteroids, in patients with moderate-to-severe atopic dermatitis: a single-centre randomized open-label trial

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Introduction

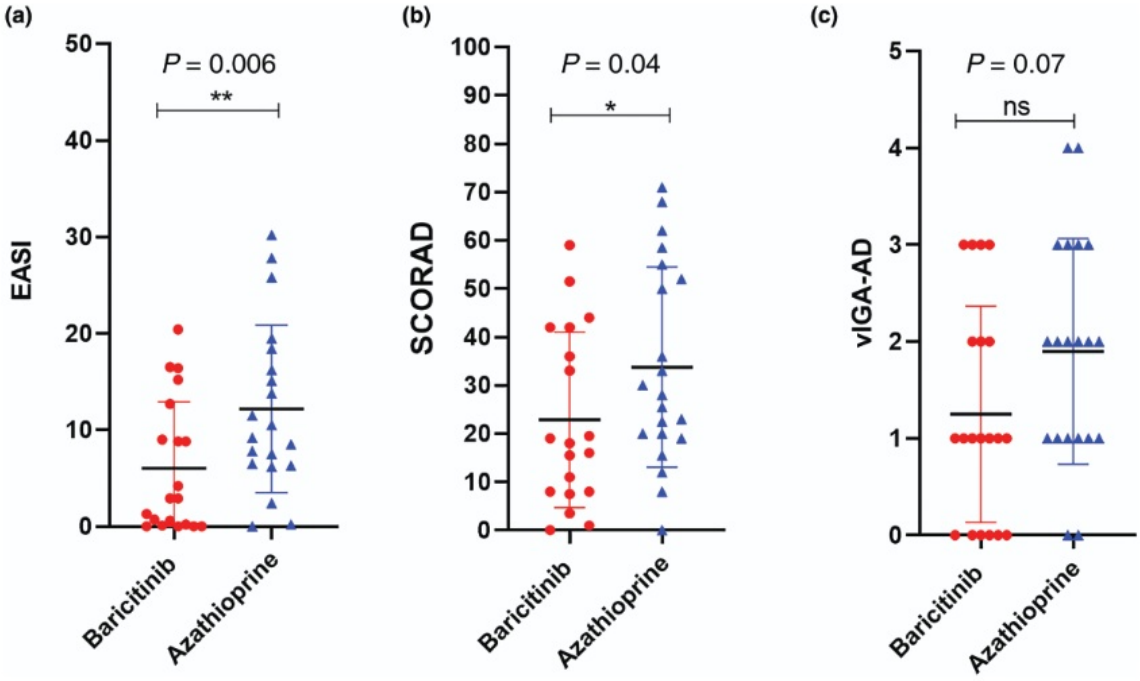
Atopic dermatitis (AD) is a chronic relapsing inflammatory skin disease that can be difficult to manage in moderate-to-severe cases. Baricitinib (a Janus kinase 1/2 inhibitor) and azathioprine (a traditional immunosuppressant) are both used in the systemic treatmentof AD. This randomized, open-label trial aims to compare the efficacy and safety of baricitinib versus azathioprine, both combined with topical corticosteroids (TCS), in patients with moderate-to-severe AD.

Materials and Methods

In this single-center, open-label, randomized head-to-head trial (NCT05969730), 40 adults with moderate-to-severe AD were randomly assigned 1:1 to receive baricitinib (4 mg/day) or azathioprine (1.5-2.5 mg/kg/day), both with TCS and urea 10% cream, for 12 weeks. The primary endpoint was the proportion achieving ≥75% reduction in eczema area and severity index (EASI-75) at week 12. Secondary endpoints included SCORing Atopic Dermatitis (SCORAD), validated Investigator's Global Assessment for AD (vIGA-AD), Itch Numeric Rating Scale (NRS), Skin Pain NRS, Patient-Oriented Eczema Measure (POEM), Dermatology Life Quality Index (DLQI) and Hospital Anxiety and Depression Scale (HADS), and safety.

Results

At week 12, 65% (n = 13/20) of patients in the baricitinib + TCS group achieved EASI 75 versus 15% (n = 3/20) in the azathioprine + TCS group [difference 50%, 95% confidence interval (CI) 23.9–76.1; P = 0.002]. The baseline-adjusted post-treatment mean (SD) EASI scores were 5.60 (7.51) for baricitinib and 12.61 (7.51) for azathioprine (difference –7.01, 95% CI –11.86 to –2.17; P = 0.006), with a large effect size (Cohen'sd = –0.93). A ≥ 75% decrease in SCORAD 75 was achieved by 55% (n = 11/20) in the baricitinib + TCS groupvs. 15% (n = 3/20) in the azathioprine group (difference 40%, 95% CI 13.2–66.8; P = 0.01). Improvements in vIGA-AD, itch NRS, skin pain NRS, POEM, DLQI, ADSS, HADS were found in both groups, with a trend favouring baricitinib, although the differences between groups were not statistically significant. Both treatments were well tolerated, with no serious adverse events or discontinuations recorded.



Comparison of adjusted mean changes in post-treatment scores for (a) Eczema Area and Severity Index (EASI), (b) SCORing Atopic Dermatitis (SCORAD) and (c) validated Investigator's Global Assessment for Atopic Dermatitis (vIGA-AD) between the baricitinib and azathioprine groups at week 12. Data are presented as individual patient values, with group means and SDs. Statistical significance was assessed using one-way anova/ancova, with P-values as indicated. ns, not statistically significant (i.e. $P > 0.05$). *$P < 0.05$, **$P < 0.01$.

Conclusions

In conclusion, our findings indicate that baricitinib + TCS was superior to azathioprine + TCS in achieving short-term improvements in disease severity in adults with moderate-to-severe AD. Clinician-reported outcomes consistently favoured baricitinib, while both agents improved PROs and were well tolerated, with no serious AEs recorded over 12 weeks. These findings support baricitinib as an effective and safe systemic option for patients requiring rapid disease control, whereas azathioprine remains a reasonable alternative when appropriate. Future studies with larger, multicentre populations and extended follow-up are warranted to confirm these results, and further explore the cost-effectiveness for patients receiving baricitinib or azathioprine in moderate-to-severe AD.

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A study comparing the efficacy of topical 2% Tofacitinib and 0.05% Fluticasone propionate in children and adolescents aged 2-18 years with mild-moderate Atopic Dermatitis.

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Introduction

Atopic dermatitis (AD) is a chronic,relapsing inflammatory dermatosis affecting up to 20–30% of children and 2–10% of adults,with the greatest burden in the paediatric population.Its pathogenesis involves a complex interplay between epidermal barrier dysfunction,immune dysregulation,and altered microbiome.Despite this,treatment remains largely uniform with topical corticosteroids (TCS) and calcineurin inhibitors.TCS are associated with adverse effects such as atrophy, telangiectasia, and systemic absorption, necessitating safer alternatives. The JAK-STAT pathway plays a central role in AD inflammation and pruritus.Tofacitinib, a selective JAK1/3 inhibitor, has shown promising efficacy (Table 1).This study aimed to compare topical 2% tofacitinib with 0.05% fluticasone propionate in paediatric AD and evaluate its role as a steroid-sparing agent.

Table 1: Synoptic view of clinical studies on topical JAK inhibitors in AD-

Drug	Number and age	Duration	Intervention Arms	Result	Limitations
1)Tofacitinib 2% OintmentBD[11] (JAK 1/3 inhibitor)	69 patients (18-60) Years	4 weeks Phase 2 trial	2% tofacitinib ointment and vehicle	Significant change in EASI from the baseline along with improvement in itching from day after starting therapy.	Short term trial with small sample size. Different age groups not assessed. Lack of an active comparator to gauge relative efficacy.
2)Ruxolitinib[21]	307 Patients 18-70 Years	8 weeks + 4 weeks Phase 2 double blinded.	-0.15% OD -0.5% OD -1.5% OD -1.5 %BD -Triamcinolone 0.1 %BD -vehicle	1.5 % BD Ruxolitinib provided the greatest improvement in EASI. Early reductions in Itch NRS scale.	Short term trial. Paediatric age group wasn't assessed.
3)Ruxolitinib[22] "JAK 1,2 inhibitor"	Study 1: 631 patients >12 years Study 2: 618 patients >12 years	8 weeks Phase 3 trials	0.75% cream BD 1.5 % cream BD Vehicle BD	At week 8, Significantly higher proportion of patients in all groups achieved IGA score of clear to almost clear. None of the serious adverse effects were treatment related.	Long term Data lacking No active arm in the study
4)Delgocitinib[23]	327 patients 16-65 years of age.	4 weeks Phase 2 Randomized Double Blinded	0.25% BD 0.5% BD 1 % BD 3 % BD Tacrolimus 0.1 % BD Vehicle	All groups of Delgocitinib showed significant reduction in EASI vs vehicle. Itch NRS score was reduced. by day 1 itself. Burning sensation and warmth was less compared to Tacrolimus ointment.	Statistical Analysis Between efficacy of tacrolimus and Delgocitinib was not performed. Paediatric patients weren't included. Study period was short.
5)Delgocitinib 0.25 % ointment [24] "JAK 1,2,3 and tyrosine kinase 2 inhibitors"	137 patients aged 2-15 years	4 week Double blinded phase 3 study	Delgocitinib 0.25 % ointment Vs Vehicle ointment	Clinically significant improvement (Achievement of EASI 75) in paediatric age group Long term treatment of the patients uptil 56 weeks showed safety and improvement.	Only Japanese cohort was included. No active arm.

Table 1: Synoptic view of clinical studies on topical JAK inhibitors in atopic dermatitis.

Materials and Methods

A prospective,randomized,observer-blinded controlled trial was conducted over 1 year including 114 patients (2–18 years) with mild–moderate AD (SCORAD ≤50).Patients fulfilling inclusion criteria (Table 2) were randomized using block randomization into two groups: fluticasone (n=57) and tofacitinib (n=57),applied twice daily for 6 weeks.All received emollients and second-generation antihistaminic.Blood samples were collected at baseline and at the end of 6 weeks to monitor the change in serum TARC levels post treatment.Follow-up was done at weeks 2,4 and 6.Primary outcome was achievement of SCORAD 75.Secondary outcomes included time to SCORAD

75,change in SCORAD and 5D itch scores,serum TARC levels and safety.Statistical analysis was performed using intention-to-treat (ITT) principles with non-inferiority margin of 10%.

TABLE 2: INCLUSION AND EXCLUSION CRITERIA

INCLUSION CRITERIA:	EXCLUSION CRITERIA:
1. Children and adolescents of both genders, aged 2-18 years with a diagnosis of atopic dermatitis diagnosed according to Hanifin and Rajka criteria. They should be having- • Mild to moderate AD as per SCORAD (less than or equal to 50) • Willing to follow up for a minimum of 6 weeks.	1. Patients not meeting the age criterion and having SCORAD more than 50. 2. Active forms of any other inflammatory dermatoses or evidence of skin infection that would interfere with evaluation and treatment. 3. Presence of major medical illnesses requiring systemic therapy including cancer. 4. History of using topical corticosteroids, topical calcineurin inhibitors, topical antibiotics and/or any other medicated topical agent 1 week before baseline. 5. History of using systemic corticosteroids, cyclosporine, methotrexate or any other systemic immunosuppressants or phototherapy a minimum of 4 weeks prior to starting the study. 6. Inability to comply with the study protocol. 7. Atopic dermatitis lesions presenting on genital areas and perianal area.

Table 2: Inclusion and Exclusion criteria for the study

Results

A total of 107 patients were analyzed for primary outcome excluding the 7 early drop-outs(Figure 1).Baseline characteristics were comparable.SCORAD 75 was achieved in 79.6% of the tofacitinib group (43/54) and 73.6% of the fluticasone group (39/53).Tofacitinib was non-inferior to fluticasone ($p=0.025$; 95% CI −7.39 to 19.48).Both groups showed significant reduction in SCORAD ($p<0.0001$) with no intergroup difference at weeks 2, 4, and

6.Median time to SCORAD 75 was 4 weeks in both groups (p=0.20).There was no statistically significant difference in the mean percentage changes in SCORAD values from baseline to 6 weeks between the fluticasone and tofacitinib groups (p=0.25).Significant reduction in 5D itch scores was observed in both groups (p<0.001),with comparable outcomes.Serum TARC levels showed significant reduction in both groups (p<0.001). Adverse effects were mild and transient. Tofacitinib group showed minor application-site irritation (n=3) while one case of atrophy was noted in the fluticasone group.None of the patients required systemic immunosuppression for flares during the treatment period.

Figure 1: CONSORT flowchart of the study:

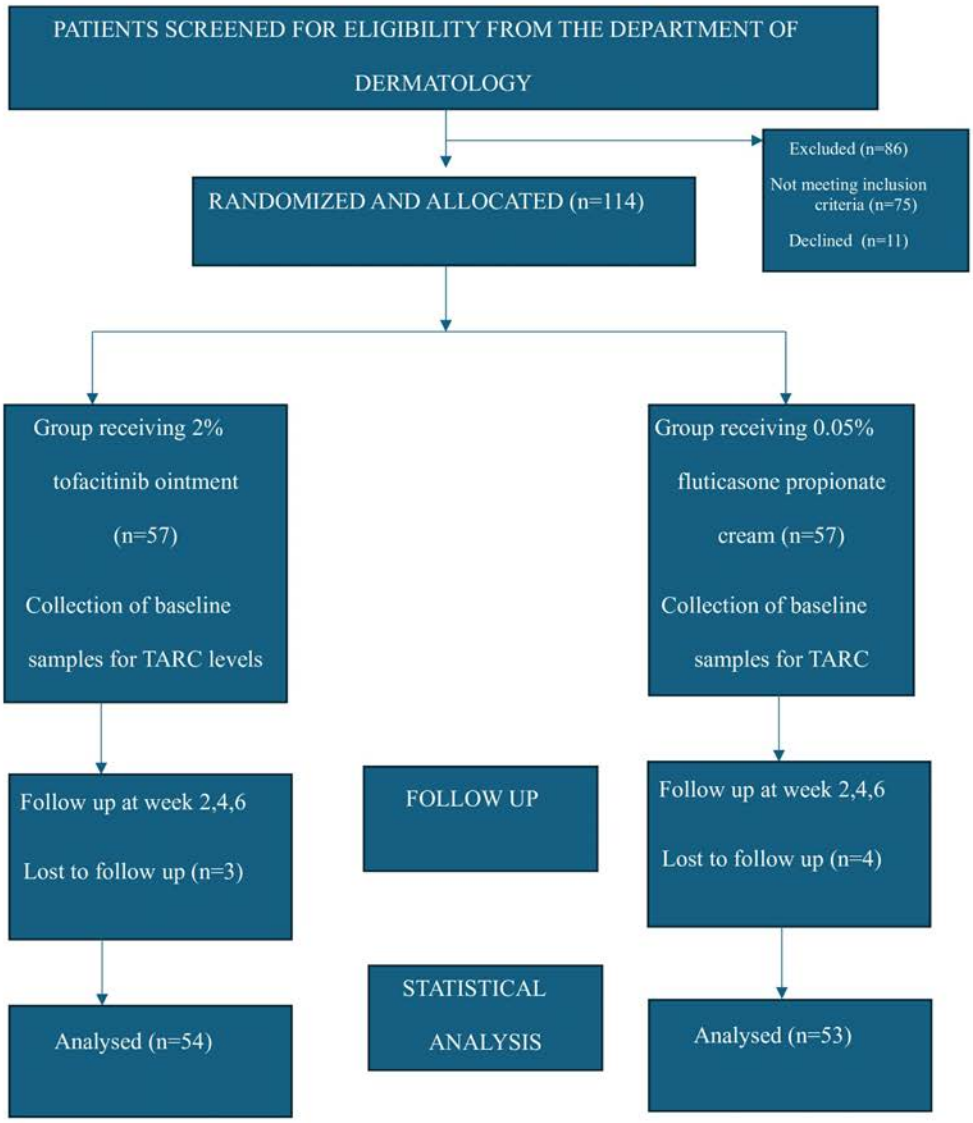

Figure 1: CONSORT flowchart of the study

Conclusions

Topical 2% tofacitinib was non-inferior to 0.05% fluticasone in paediatric mild–moderate AD (Figure 2).There was comparable improvement in disease severity, pruritus, and biomarker response.Its favorable safety profile,absence of steroid-related adverse effects and rapid clinical response support its role as an effective steroid-sparing alternative.

Strenths: This study provides important paediatric head-to-head evidence, addressing a key gap in current literature.The use of SCORAD 75 as a primary outcome incorporates patient-centred as well as investigator-reported measures.The assessment of serum TARC levels provided an objective unbiased basis for evaluating the treatment response,the results of which paralleled the SCORAD.The single-blinded design of the study reduced the observer as well as the randomization and allocation bias. Both the groups were similar at baseline avoiding any confounding variables.

Limitations:The duration of the study limited the evaluation of long-term outcomes.The serum TARC levels could not be assessed in all the patients limiting its generalizability.Further long-term studies are needed to evaluate sustained efficacy and safety.

Figure 1: Bar graph showing the intergroup comparison of SCORAD 75 responses (ITT) over a period of 6 weeks.

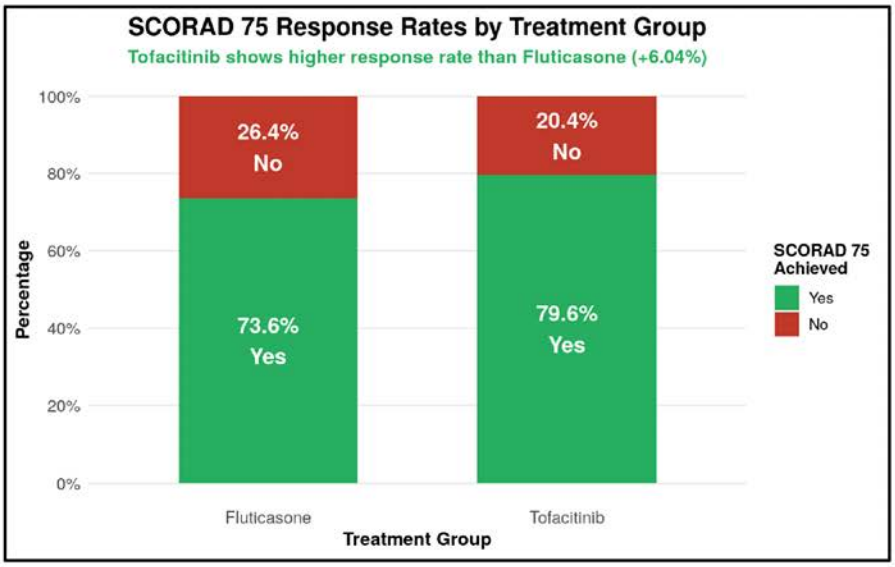

Figure 2: Bar graph showing the intergroup comparison of SCORAD 75 responses (ITT) over a period of 6 weeks

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Abstract N°: 301

Serum Adipokine Levels in Patients with Atopic Dermatitis: A Systematic Review and Meta-analysis

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease driven by complex systemic immune dysregulation. Adipokines, bioactive peptides and cytokines secreted by adipose tissue, act as critical mediators between obesity and various metabolic, inflammatory, and autoimmune conditions. However, clinical studies investigating the serum levels of various adipokines in AD patients have yielded inconsistent results. This meta-analysis aims to systematically evaluate the differences in adipokine levels between AD patients and healthy controls, while exploring their potential correlation with allergic sensitization and their overall role in AD pathogenesis.

Materials and Methods
Literature searches were conducted across PubMed, Embase, and Scopus databases to include studies comparing serum adipokine levels (adiponectin, leptin and resistin) between patients with AD and controls (from inception to April, 2026). The quality of the included studies was evaluated with Newcastle-Ottawa Scale (NOS) and the Cochrane Risk of Bias 2 (RoB2) tool. The adipokine levels were analyzed using standardized mean difference (SMD) due to heterogeneous outcomes among the included studies. Coefficients of correlation between adipokines and characteristics of AD were pooled if sufficient data were available. A random effects model was adopted because of substantial heterogeneity. Heterogeneity and publication bias were assessed with the I2 test and Egger's test respectively. The meta-analysis was conducted with Comprehensive Meta-Analysis software (version 3; Biostat, Inc, Englewood, NJ).

Results
Fourteen studies including 1339 patients with AD were included for analysis. Pooling of five studies providing adiponectin levels revealed a significantly lower level of adiponectin in AD patients than those in controls (SMD = -1.092, 95% CI = -1.928–-0.255, I2 = 94). Coefficients of correlation between serum adiponectin and IgE levels were pooled from three studies, revealing a significant correlation (r = -0.227, 95% CI = -0.359–-0.087, I2 = 0). The analyses of leptin and resistin levels do not demonstrate significant differences between AD patients and controls (leptin: SMD = -0.093, 95% CI = -0.503–0.316, I2 = 84; resistin: SMD = -0.496, 95% CI = -1.439–0.447, I2 = 95). No publication was observed in all analyses.

Table 1. Results of meta-analysis of all studies

		Study (N)	Sample size	Effect size	Effect estimate (95% CI)	p	I^2
Adiponectin	AD vs. control	5	365 vs. 257	SMD	-1.092 (-1.928 to -0.255)	0.011	94
	Adiponectin vs. IgE	3	194	COR	-0.227 (-0.359 to -0.087)	0.002	0
Leptin	AD vs. control	8	891 vs. 802	SMD	-0.093 (-0.503 to 0.316)	0.656	84
Resistin	AD vs. control	4	196 vs. 191	SMD	-0.496 (-1.439 to 0.447)	0.303	95

AD atopic dermatitis, SMD standardized mean difference, COR correlation coefficient

Results of meta-analysis of all studies

Conclusions

Our study demonstrates that adiponectin levels are significantly lower in patients with AD compared to healthy controls. Additionally, adiponectin levels are negatively correlated with IgE levels, suggesting a potential role for adiponectin in the pathogenesis of AD.

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Abstract N°: 313

Lebrikizumab Showed Sustained Efficacy and Safety Through 5 Years in Patients with Moderate-to-Severe Atopic Dermatitis: Results from the ADlong Long-Term Extension Trial

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Introduction

Lebrikizumab, an interleukin-13 inhibitor, is a systemic therapy for moderate-to-severe atopic dermatitis (AD). Longer-term data are key to guide clinical practice.

Materials and Methods

Adults and adolescents (12–17 years, ≥40 kg) from parent trials, regardless of Week (W) 16 response, could enter ADjoin 100W extension study. Upon ADjoin completion, patients in Germany and Poland enrolled in ADlong (NCT05916365; 2-year [108W] extension), receiving open-label lebrikizumab 250 mg every four weeks (Q4W), with permitted Q2W uptitration at investigator's discretion in patients not maintaining clinical benefit. Topical corticosteroids were permitted for AD flares. The primary endpoint was treatment discontinuation due to treatment-emergent adverse events (TEAEs; reported as exposure-adjusted incidence rates [EAIRs] per 100 person years [PY]). Efficacy outcomes were also reported at baseline and W108, including ≥75% improvement in Eczema Area and Severity Index (EASI-75), Investigator's Global Assessment (IGA) 0/1, EASI-90, EASI ≤7, Pruritus Numerical Rating Scale (P-NRS) ≤4 and P-NRS 0/1. Lack of efficacy discontinuations were imputed as non-responders; other discontinuations/missing data were handled using multiple imputation.

Results

174 ADjoin-completers enrolled into ADlong (parent trials: ADvocate1 [n=59]; ADvocate2 [n=36]; ADhere [n=23]; ADore [n=56]). During ADlong, the EAIRs/100PY were 2.0 (n=5) for TEAE-related discontinuations, 70.8 for any TEAE (mild/moderate/severe: 11.2/33.2/2.3) and 2.9 for serious TEAEs. No deaths were reported. At ADlong baseline/W108, 93.1%/92.9% of patients maintained or achieved EASI-75, 70.7%/66.7% IGA 0/1, 79.9%/73.8% EASI-90, 92.5%/89.8% EASI ≤7, 78.3%/78.0% P-NRS ≤4 and 31.6%/31.7% P-NRS 0/1. 39/174 (22.4%) patients underwent ≥1 uptitration to Q2W, of whom 9/39 (23.1%) returned to Q4W.

Conclusion

Long-term lebrikizumab safety profile was consistent with previous studies, with low TEAE-related discontinuations up to 5 years of exposure and no new safety signals. Most ADlong patients (up to 5 years lebrikizumab exposure) showed high rates of skin and itch responses with Q4W dosing through W108.

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Abstract N°: 315

Differential Proteomic Effects of Abrocitinib and Dupilumab in Moderate-to-Severe Atopic Dermatitis: Exploratory Analysis of JADE COMPARE

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Introduction
Atopic dermatitis (AD) is a chronic, inflammatory skin disease characterized by heterogeneous clinical and molecular phenotypes. Janus kinase (JAK) inhibitors may be effective across the AD spectrum because they modulate signalling from multiple cytokines implicated in AD pathophysiology. Abrocitinib, an oral, once-daily, JAK1-selective inhibitor, and dupilumab, an anti-interleukin-4-receptor α monoclonal antibody, are approved for the treatment of moderate-to-severe AD. The objective of this retrospective exploratory analysis was to characterize the effect of abrocitinib and dupilumab treatment on serum protein biomarkers in patients with moderate-to-severe AD.

Materials and Methods
This study evaluated serum samples stored in Pfizer's Biobank from the Phase 3 JADE COMPARE clinical study (NCT03720470), in which adult patients with moderate-to-severe AD were randomly assigned (2:2:2:1) to receive abrocitinib 200 mg or 100 mg orally once daily, dupilumab 300 mg subcutaneously every other week (after a loading dose of 600 mg), or placebo. Serum expression of 356 proteins was evaluated at baseline and at week 12 through the Olink® Target 96 Multiplex high throughput platform (Olink Proteomics AB, Uppsala, Sweden). Samples were analysed to identify differentially expressed proteins/DEPs; absolute fold changes (FCH) >1.3, *P*-value <0.05. Comparative analyses were conducted to evaluate shared and treatment-specific proteomic changes.

Results
Serum samples were collected from a total of 352 patients; of these, 90, 87, 92 and 83 received abrocitinib 200 mg, abrocitinib 100 mg, dupilumab, and placebo, respectively. Abrocitinib 200 mg produced the broadest modulation of the AD serum proteome from baseline to week 12 (8 up- and 27 down-regulated DEPs at W12 vs Baseline), exceeding both dupilumab and abrocitinib 100 mg modulation, while no changes were observed in placebo. Overall, a broad, significant and dose-dependent downregulation of key Th1- (IL12B, CXCL10, CCL3,), and Th17- (TGFB1) related markers was observed in the abrocitinib arms, as well as several T-cell/T-cell activation/migration- (CD4, CD5, CD8A, IL16, CCL19) and innate immunity- (IL1A) related markers; IL-13 was

significantly modulated only with abrocitinib 200mg (P<0.05). Similarly, selected fibrosis- (TNFRSF9, TNF), pruritus- (IL18BP, F2R, CCL3) and cardiovascular- (IGFBP2, MSR1, PGLYRP1) markers were only downregulated by abrocitinib with stronger FCHs observed in the 200mg group (P<0.05). Both abrocitinib and dupilumab also produced a parallel, significant reduction in key AD pathways such as Th2 (CCL17, CCL13), Th17/Th22 (S100A12, PI3, IL-6), fibrosis (IL18, SERPINE1, IL2RA), pruritus (CTSS, TNFRSF1B) and cardiovascular (SELE, IL1RN, PRSS27, HMOX1, PRTN3, TGFA, TNFSF14, RETN, HGF, ULBP2) (all P<0.05).

Conclusion

This study is the largest analysis of therapeutic changes in soluble protein expression levels in moderate-to-severe AD patients to date, identifying treatment-related biomarker changes following both abrocitinib doses and dupilumab therapy. The study findings highlight how JAK inhibition with abrocitinib addresses a broader anti-inflammatory effect that aligns with clinical findings. These findings are consistent with the abrocitinib JADE MOA trial (NCT03915496) and provide results at a much larger scale.[1] Results also align with previous studies describing the effect of dupilumab on protein biomarkers.[2,3] This study provides deeper insight into the mechanism of action of abrocitinib, illustrating how selective, JAK1-inhibition may provide therapeutic benefit to patients with moderate-to-severe AD across multiple domains.

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Abstract N°: 331

A Previously Undrugged Target in Immune Therapeutics: Oral ENV-294 Provides First Clinical and Molecular Proof of Concept for RAC2 Modulation in Atopic Dermatitis

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Introduction

Despite the transformative impact of IL-4/IL-13–targeted biologics, many patients with atopic dermatitis (AD) fail to achieve or sustain adequate disease control, underscoring the need for safe therapies that act more broadly beyond type 2 immunosuppression. ENV-294 is a first-in-class, allosteric, non-degrading molecular glue that selectively binds RAC2 and stabilizes the inactive RAC2:RhoGDI complex. This raises the threshold of immune activation, a novel mechanism with potential to reduce chronic inflammation while preserving protective immune function. Recently, ENV-294 demonstrated promising safety and efficacy in a Phase 1b open-label, single-arm study in moderate-to-severe AD (NCT07336940). In this translational study, weinvestigated the mechanism of action and related treatment-response biomarkers that correlate with clinical scores.

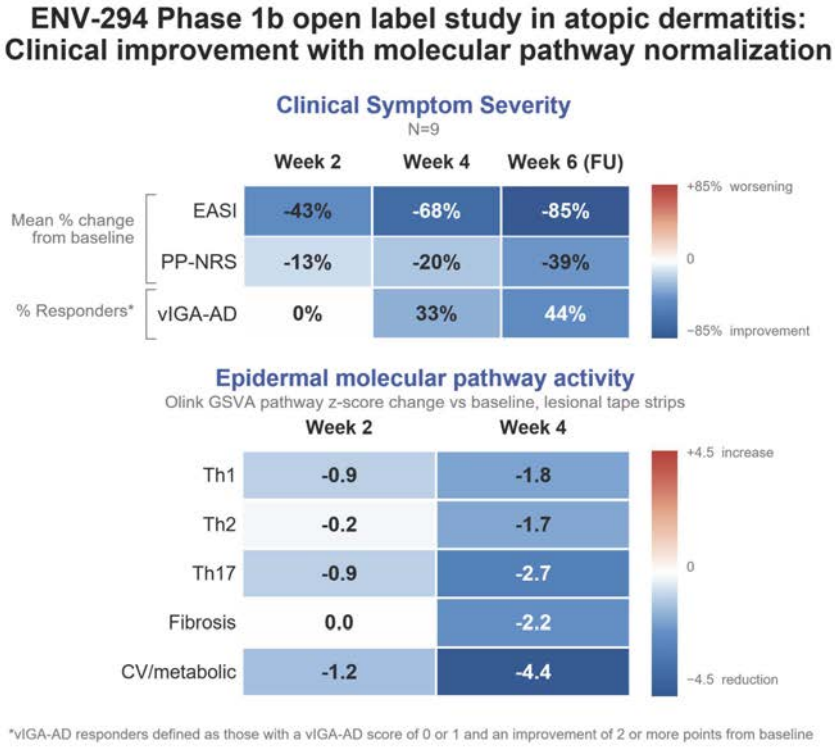
Materials and Methods

Tape-strips and biopsies were collected from lesional and non-lesional skin of adult ADpatients who receivedENV-294 800 mg QD. Tape-strips were collected at baseline, Week 2 (W2) and W4, while biopsies were collected at baseline and W4, from the same lesions at adjacent locations. Proteomic analyses of skin biopsies and tape strips were performed using the Olink Target 96 platform (354 analytes across 4 panels). Given the small, single-arm study design, we employed an exploratory analysis approach where proteins showing a mean |fold change| $\geq$1.3 from baseline or nominal $p<0.05$ were considered modulated by treatment. Coordinated pathway-level responses were assessed by Gene Set Variation Analysis (GSVA) of predefined disease-relevant protein signatures. Modulated proteins and GSVA pathway scores were correlated between compartments and with clinical scores (including EASI, vIGA-AD, BSA, SCORAD and PP-NRS).

Results

Nine patients with moderate-to-severe AD (6F, 3M; mean age 40.7; baseline EASI 21.0) enrolled and completed the study. ENV-294 was well tolerated with no serious or treatment-related adverse events, no discontinuations, and no clinically relevant laboratory changes. At W4, mean EASI score decreased by 68.2% (SD 24.8), with 44.4% of patients achieving EASI-75. Improvements deepened through W6 (2-week off-treatment follow-up); mean EASI reduction reached 84.9%, with 77.8% achieving EASI-75. Olink analysis in tape-strips showed reduction of multiple inflammatory markers at W4. Examples included Th1- (CXCL9, CXCL10, CXCL11), Th2- (CCL17, CCL11, CCL13, IL1RL1), and Th17- (IL17A, IL17RA, IL6, IL6R, CCL20, S100A12) related markers. Hyperplasia/fibrosis-related markers (SERPINE1, MMP1, MMP9, CCL2) were also suppressed. Reductions were also seen in proteins associated

with cardiovascular/metabolic inflammation(e.g., GDF15, SORT1, LDLR, PLAUR, VEGFA, SOD2, ALCAM and CTSL). Proteomic analyses on skin biopsies showed directionally concordant changes to the tape-strip data at the pathway level. Tape-strip and biopsy biomarker changes on treatment were significantly correlated across the proteome (R=0.442, p=0.0002). Reduction in several pro-inflammatory proteins (IL4, IL18, IL17C, IL12B, CCL20) was correlated with reduced EASI, BSA, vIGA-AD, PP-NRS and/or SCORAD scores at W4.



Conclusion

Treatment with ENV-294 was associated with early improvements in clinical measures, accompanied by reductions in cutaneous markers related to inflammation, hyperplasia/fibrosis and cardiovascular/metabolic pathways. Treatment-related biomarkers detected by both non-invasive tape strips and biopsies correlated with improvements in clinical severity scores. These exploratory, hypothesis-generating findings shed light onthe novel

mechanism of action of ENV-294, suggesting broad anti-inflammatory potential without negatively impacting protective immune function, and supporting its continued development as a potential therapy for rapid clinical and molecular improvement in AD and other inflammatory diseases.

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Abstract N°: 349

Lebrikizumab is effective in Patients with Atopic Hand and Foot Dermatitis: 16-Week Results from the Randomized, Double-Blind, Placebo-Controlled ADTouch Trial

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Introduction

Atopic hand and foot dermatitis (AHFD) is a common, recalcitrant, and debilitating manifestation of atopic dermatitis (AD) driven by type 2 inflammation, including overexpression of interleukin-13, with pruritus and pain as primary symptoms. Despite substantial impact on quality of life (QoL) and work productivity, systemic treatment options for AHFD remain limited.

Objective

To evaluate efficacy and safety of lebrikizumab, a selective interleukin-13-inhibitor, as monotherapy in adults and adolescents with moderate-to-severe AHFD.

Materials and Methods

ADTouch (NCT06921759) was a multi-center, randomized, double-blind, placebo-controlled, parallel-group phase 3b trial evaluating lebrikizumab versus placebo in adults (≥18 years) and adolescents (≥12 to <18 years, ≥40kg

total body weight) with moderate-to-severe AHFD.

Eligible patients had AHFD ≥1 year in at least 2 of 4 anatomical areas (left hand/right hand/left foot/right foot) at screening and baseline; a documented history of AD not limited to hands and feet; a Hand Foot Investigator's Global Assessment (HF-IGA) score of moderate (3) or severe (4) at screening and baseline; a HF-Peak Pruritus Numeric Rating Scale (NRS) score ≥4; and inadequate response to topical therapies.

Patients were randomized 1:1 to subcutaneous lebrikizumab (500mg loading doses at baseline and week 2, then 250mg every 2 weeks to week 16) or placebo. The primary endpoint was HF-IGA 0/1 with ≥2-point improvement from baseline at week 16.

Secondary endpoints evaluated safety, pruritus, pain, disease activity, QoL, and Atopic Hand Dermatitis Clearance Satisfaction (AHDCS), a novel single-item patient-reported scale. Results reflect the primary outcome database lock, which included all data through Week 16.

Results

Participants (N=221) were randomized to lebrikizumab (n=110) or placebo (n=111). Baseline disease characteristics were comparable between groups, including HF-IGA (severe: 27.3% vs 27.9%), HF-Peak Pruritus NRS (mean: 7.2 in each arm) and HF-Peak Pain NRS (mean: 6.2 in each arm).

All primary and key secondary endpoints achieved statistical significance. More participants in the lebrikizumab group achieved HF-IGA 0/1 with ≥2-point improvement vs placebo at week 16 (53.3% vs. 27.2%; $p<0.001$). A higher proportion of lebrikizumab vs placebo-treated participants achieved HF-IGA 0/1 with ≥2-point improvement at week 2 (7.8% vs 0.9%; nominal $p<0.05$) and week 4 (16.9% vs 5.6%; $p=0.008$). At weeks 2, 4, and 16, HF-Peak Pruritus NRS ≥4-point improvements were higher with lebrikizumab (15.8%; 27.3%; 57.1%) than with placebo (0.9%; 7.9%; 19.0%; all $p<0.001$). HF-Peak Pain NRS ≥4-point improvements were higher for lebrikizumab vs placebo at week 16 (59.1% vs 18.8%; $p<0.001$).

Among participants who were not satisfied at baseline on AHDCS, more lebrikizumab than placebo-treated participants were "satisfied" or "very satisfied" with hand dermatitis clearance at week 16 (76.7% vs 39.6%; $p<0.001$).

Treatment emergent adverse events (TEAEs) were reported in 41.8% of patients receiving lebrikizumab and 39.6% of patients receiving placebo; no severe TEAEs and no serious AEs were reported, and treatment discontinuations due to AEs were infrequent in lebrikizumab (0.9%) and placebo groups (2.7%).

Conclusion

Lebrikizumab monotherapy achieved clinically meaningful and statistically significant improvements over placebo in atopic hand and foot dermatitis skin clearance, pruritus, pain, and patient satisfaction. Safety findings were consistent with the established lebrikizumab profile.

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Abstract N°: 349

Achievement of Minimal Disease Activity and Moderate Treatment Targets and Patient Reported Outcomes in the Real-World AD-VISE Study

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Introduction
Limited real-world data exists demonstrating the benefits of achieving optimal and moderate treatment targets in patients report outcomes (PROs) in atopic dermatitis (AD).

Materials and Methods
Patients in the ongoing, observational, prospective, multi-country AD-VISE study assessing effectiveness of upadacitinib for treatment of AD in adults and adolescents were stratified by Eczema Area and Severity (EASI) and Worst Pruritus Numerical Rating Scale (WP-NRS) after 6 months of treatment. Patients were grouped by achievement of minimal disease activity (MDA; EASI ≤3 + WP-NRS 0/1), moderate treatment targets (EASI 3.1 to ≤7 + reduction from baseline WP-NRS ≥4), or neither (EASI 7.1 to 72 + reduction from baseline WP-NRS <4). Achievement of Dermatology and Life Quality Index (DLQI) 0/1, AD Control Tool (ADCT) 0/1, and other PROs are reported using non-responder imputation with multiple imputation. Safety was not assessed in this analysis.

Results
DLQI 0/1 was achieved by a higher proportion of patients meeting MDA (72.3%; 190/262) than those meeting moderate treatment targets (21.7%; 8/35), or neither treatment target (9.9% 7/69). ADCT 0/1 was achieved by a higher proportion of patients meeting MDA (64.5%; 176/273) than those meeting moderate treatment targets (7.3%; 3/37) and neither treatment target (1.8%; 1/73).

Conclusions
In the AD-VISE study, patients who achieved MDA were more likely to report meeting optimal treatment targets in PROs than those who met moderate or neither treatment targets. These results confirm previously reported clinical trial analyses and translate the benefits of optimal treatment targets on PROs in the real-world setting.

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Abstract N°: 383

Baseline Characteristics of Pediatric Patients With Atopic Dermatitis Receiving Dupilumab in Spain: Interim Analysis of the PROADAP Study

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory disease considerably affecting the pediatric population. Dupilumab is approved for the treatment of severe AD in children and adults. Real-world data on dupilumab use in pediatrics in Spain are limited. The PROADAP study aims to characterise the baseline profile of pediatrics with severe AD receiving dupilumab; assess disease progression, burden, atopic comorbidities, and treatment patterns in real-world clinical practice in Spain.

Materials and Methods
PROADAP (NCT06415175) is a prospective, observational, longitudinal, multicentre, study conducted in Spain across 15 hospitals, 14 actively recruiting. Patients (N=143) aged 6 months (m)–11 years (y) with severe AD at the time of dupilumab initiation were enrolled, and stratified into three groups: 6m–2y, 2–5y, and 5–11y; two main analytical groups: 6m–5y and 6–11y. Analyses are descriptive.

Results
Of 143 patients, 16.1% (n=23) were aged 6m–2y, 32.2% (n=46) were 2–5y, and 51.7% (n=74) were 5–11y; 57.3% were female. By ethnicity, 58.7% were non-Hispanic/Latino, 4.2% each were Afro-American and Asian, and 32.9% were Other. Median age at AD diagnosis (N=122) was 1y (Q1–Q3: 0–2). Median time from diagnosis to dupilumab initiation (N=123) was 51.82m (24.81–85.00). Disease burden at baseline was severe: median Eczema

Area and Severity Index (EASI) score was 22.45 (21–27) (N=142). Median Body Surface Area (BSA) affected was 30% (20–50) (N=136). Most patients (96.3%) had an Investigator's Global Assessment (IGA) score ≥3; 50% with IGA=3, 46.3% with IGA=4. Pruritus severity, measured by the Worst Scratch Itch Numerical Rating Scale (WSINRS), showed a median score of 8 (7–9), indicating intense pruritus. Median Children's Dermatology Life Quality Index/Infant's Dermatology Life Quality Index (cDLQI/iDLQI) was 15 (10–20), indicating impaired quality of life. Median Dermatitis Family Impact (DFI) score was 15 (12–21), suggesting impact on family functioning. Biomarker analysis showed immunoglobulin E (IgE) was significantly higher in 6–11y versus 6m–5y (P=0.002). Eosinophil counts and lactate dehydrogenase levels were comparable across groups. Atopic comorbidities were prevalent, with 50% of patients presenting ≥1 associated condition. The comorbidity burden increased progressively with age: 17.4% in 6m–2y, 39.1% in 2–5y, and 67.1% in 5–11y. Food allergy (49.3%), asthma (47.9%), and allergic rhinitis (29.6%) were the most common atopic comorbidities. Patients with atopic comorbidities who experienced a longer delay in dupilumab initiation (median: 55.17m [41.35–92.63]) showed a higher atopic burden compared with those without comorbidities (34.63m [13.23–74.03]). Older age was also associated with a greater atopic comorbidity burden and longer time to treatment initiation; 13.29m (9.39–21.06) in 6m–2y, 81.97m (56.43–111.26) in 5–11y. A convergent pattern of associations was observed: advanced age was linked to both higher atopic comorbidity burden and longer time to dupilumab initiation, and patients with comorbidities experienced greater treatment delays, reinforcing the need for early biologic intervention in severe pediatric AD. A substantial proportion of patients showed impaired growth: nearly two-thirds (64.1%) were below the 50th height percentile and almost half (47%) below the 25th percentile, indicating below-normal height for age. Only 35.9% of patients were at or above the 50th percentile. This pattern may reflect the systemic impact of severe, long-standing AD.

Conclusions

The study represents a severely affected pediatric AD population, with advanced age linked to both higher atopic comorbidity burden and longer time to dupilumab initiation. Growth impact findings indicate a potential systemic impact of severe AD; the biomarker profile shows high atopic burden, reflected by elevated IgE levels and eosinophilia.

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Abstract N°: 424

Optimal Treatment Targets and the Impact of Minimal Disease Activity on Quality of Life and Sleep Following Switch to Upadacitinib in Canadian Adults With Atopic Dermatitis Who Were Inadequate Responders or Intolerant to Dupilumab

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Introduction

Upadacitinib, a selective Janus kinase 1 inhibitor, has demonstrated robust efficacy across multiple clinical trials in adolescents and adults with moderate-to-severe atopic dermatitis (AD). Real-world data from the CAN UpTIMISE study further support its effectiveness in adult patients who were inadequate responders or intolerant to dupilumab. The AHEAD recommendations outline moderate and optimal treatment targets for clinician-reported outcomes (CRO) and patient-reported (PRO) outcomes, with minimal disease activity (MDA) defined as simultaneous achievement of at least one CRO and PRO treatment target.[1] This post-hoc analysis aimed to evaluate the achievement of moderate and optimal CROs and PROs, as well as MDA, following initiation of upadacitinib in patients with prior dupilumab experience, and its impact on quality of life (QoL) and sleep.

Materials and Methods

Adults with moderate-to-severe AD who had previously been treated with dupilumab for ≥16 weeks (or

discontinuation due to safety/tolerability reason) and had planned transition to upadacitinib (15 mg or 30 mg, per local labeling) were enrolled in the Canadian observational CAN UpTIMISE study (NCT05394792). Effectiveness was assessed over 4 months using CROs, such as Eczema Area and Severity Index (EASI), and PROs, such as the Worst Pruritus Numerical Scale (WP-NRS), the Dermatology Life Quality Index (DLQI), and the sleep item of the Patient Oriented Eczema Measure (POEM). Results of this analysis are presented using descriptive statistics.

Results

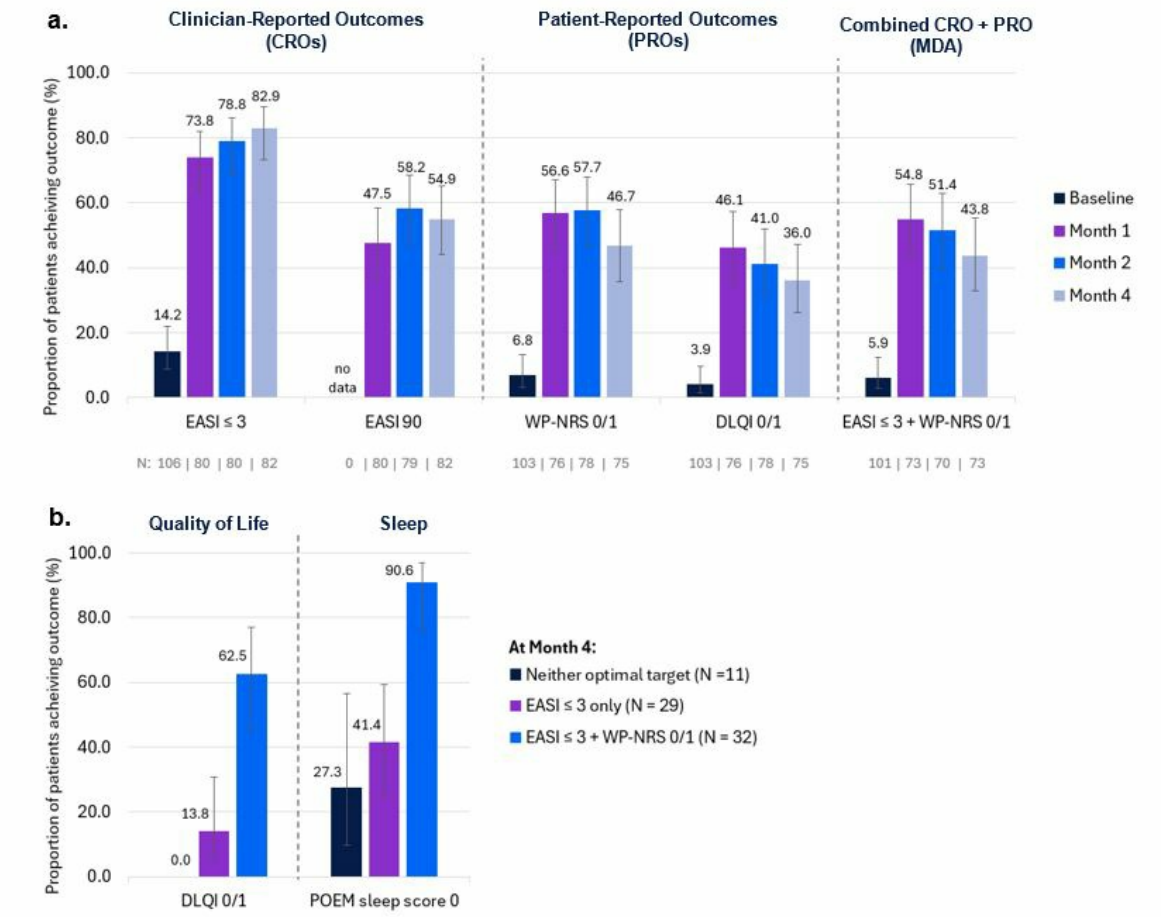
A total of 108 patients were included in the analysis (male gender: 55.6%; mainly White [61.1%] or Asian [33.3%]). Despite a prior treatment with dupilumab, at baseline: 76.9% of patients had validated Investigator Global Assessment for AD score of 3 or 4 (moderate to severe disease), mean EASI was 13.7 (moderate skin involvement), mean WP-NRS was 5.4 (moderate itch), and mean DLQI was 11.8 (very large effect on QoL); in addition, most patients had impaired sleep (70.3% POEM sleep item >0). Four months after upadacitinib initiation, most patients achieved moderate treatment targets across skin (EASI ≤7: 90.2%; EASI 75: 76.8%), itch (reduction ≥4-points in WP-NRS: 70.5%), and QoL (reduction ≥4-points in DLQI: 79.0%) outcomes. At 4 months, 61.9% of upadacitinib-treated patients simultaneously achieved moderate skin and itch treatment targets (EASI ≤7 and reduction ≥4-points in WP-NRS). Moreover, many patients achieved optimal treatment targets such as EASI ≤3 (82.9%), EASI 90 (54.9%), WP-NRS 0/1 (46.7%), and DLQI 0/1 (36.0%) at 4 months with noticeable improvements observed as early as 1 month after upadacitinib initiation (Figure 1a). At Month 4, 43.8% of upadacitinib-treated patients achieved MDA (simultaneous achievement of EASI ≤3 and WP-NRS 0/1). The achievement of combined CRO and PRO optimal treatment targets has a significantly positive impact on the patient's QoL and sleep. Indeed, 62.5% of the upadacitinib-treated patients with both EASI ≤3 and WP-NRS 0/1 at Month 4 had DLQI 0/1 compared to 13.8% who only achieved EASI ≤3 and no patients (0%) who did not achieve either EASI or WP-NRS optimal treatment targets (Figure 1b). Similarly, 90.6% of upadacitinib-treated patients who achieved both EASI ≤3 and WP-NRS 0/1 at Month 4 reported no impairment in sleep (POEM sleep score of 0) compared to 41.4% who achieved only EASI ≤3 and 27.3% who did not achieve either EASI or WP-NRS optimal treatment targets (Figure 1b).

Conclusions

Upadacitinib was effective in patients with AD who discontinued dupilumab, with rapid improvements and high rates of moderate and optimal treatment targets achievements by Month 4. Nearly half of patients switched from dupilumab to upadacitinib achieved MDA, which was linked to superior QoL and sleep outcomes, demonstrating the multidimensional benefits of achieving optimal treatment targets in the real-word.

[1]Silverberg et al.JEADV.2024.38(11):2139-48

Figure 1. Patients Achieving Optimal Treatment Targets After 4 Months of Upadacitinib and the Impact on Quality of Life and Sleep



Patients received 15 or 30 mg upadacitinib over 4 months. Error bars represent 95% confidence intervals. DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI 90, improvement of 90% in EASI; MDA, minimal disease activity; POEM, Patient Oriented Eczema Measure; WP-NRS, Worst Pruritus Numerical Rating Scale.

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Abstract N°: 429

Tralokinumab monotherapy improves atopic dermatitis severity in patients with moderate-to-severe atopic hand eczema

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease that commonly affects multiple body regions, with involvement of the head, neck, and hands often being particularly burdensome. ADHAND was the first phase 3 trial to evaluate targeted IL-13 inhibition in patients with AD and moderate-to-severe hand involvement. At Week 16, tralokinumab monotherapy significantly improved AD hand-specific signs and symptoms, and quality of life.[1] Patients in ADHAND were required to have AD affecting at least one body area beyond the hands. Here, we assess the efficacy of tralokinumab monotherapy versus placebo on overall AD severity beyond the hands in the ADHAND study population.

Materials and Methods

ADHAND (NCT05958407) was a phase 3b, randomized, controlled, double-blind trial. Participants were randomized 2:1 to receive tralokinumab monotherapy 300 mg or placebo, every two weeks, for 16 weeks. Predefined exploratory outcomes included the proportion of patients achieving ≥75% or ≥90% reduction from baseline to Week 16 in Eczema Area and Severity Index (EASI-75/90). Predefined subgroup analyses were based on baseline disease severity: EASI≤7 (mild), EASI>7 (moderate-to-severe), and EASI≥16 (inclusion criterion used in the tralokinumab pivotal trials).[2] Statistical analyses followed pre-specifications; data after rescue treatment, discontinuation due to adverse events, or discontinuation due to lack of efficacy were imputed as non-response, while other missing data were handled using multiple imputation.

Results

Baseline mean (±SD) EASI was similar in the tralokinumab monotherapy group (N=156; 9.18±9.10) and placebo group (N=78; 9.33±8.83). Of the 234 patients included in the analysis, 136 had baseline EASI≤7 (tralokinumab n=92; placebo n=44), 98 had EASI>7 (tralokinumab n=64; placebo n=34), and 36 had EASI≥16 (tralokinumab

n=24; placebo n=12). At Week 16, a higher proportion of all patients receiving tralokinumab monotherapy achieved EASI-75 (41.2% vs 15.4%) and EASI-90 (24.5% vs 7.9%) versus placebo (both *P*<0.001). Across baseline severity subgroups, results consistently favored tralokinumab. In patients with baseline EASI≤7, EASI-75 and EASI-90 were achieved by 34.5% versus 8.4% (*P*<0.001) and 25.6% versus 4.9% (*P*<0.001), respectively. In patients with baseline EASI>7, corresponding response rates were 52.3% versus 24.1% (*P*<0.01) and 22.7% versus 10.8% (*P*=0.103). In the subgroup with baseline EASI≥16, EASI-75 and EASI-90 were achieved by 39.4% versus 7.5% (*P*<0.05) and 31.7% versus 0% (*P*<0.01).

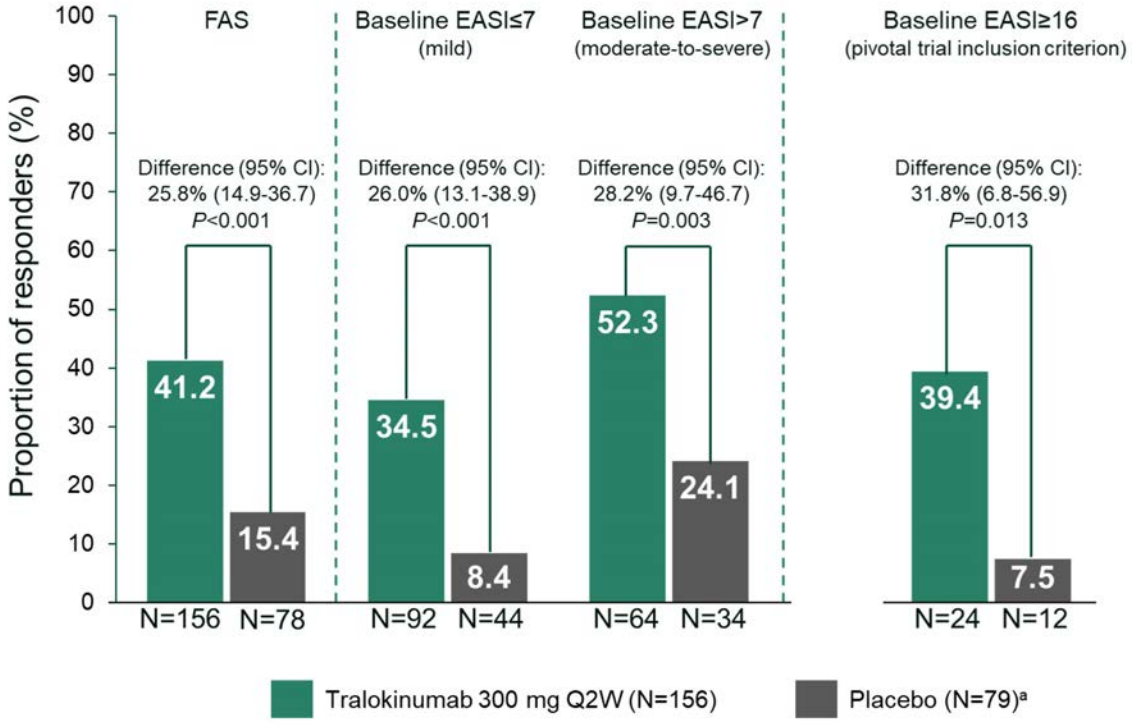
Conclusions

In patients with AD and moderate-to-severe hand involvement, tralokinumab monotherapy significantly reduced overall AD outcomes beyond the hands, with higher EASI-75 and EASI-90 response rates compared with placebo at Week 16. Treatment effects were broadly consistent across baseline disease-severity subgroups, including marked differences in patients with baseline EASI≥16. Response rates observed in ADHAND appeared higher than those reported in the pivotal tralokinumab monotherapy trials which may reflect differences in the ADHAND study design and patient population (e.g. shorter TCS wash-out period, more restricted TCS rescue use, and less severe patient population).[2] These findings further support tralokinumab as a therapeutic option for patients with AD and moderate-to-severe hand involvement.

References:

1. Ehst B, et al. Tralokinumab Treatment In Patients With Atopic Dermatitis and Moderate-to-Severe Hand Involvement: Results From the 32-week Phase 3b ADHAND Trial. J of Skin. 2026:10:s744. doi:10.25251/ppt8ep84.
2. Wollenberg A, et al. Tralokinumab for moderate-to-severe atopic dermatitis: results from two 52-week, randomized, double-blind, multicentre, placebo-controlled phase III trials (ECZTRA 1 and ECZTRA 2). Br J Dermatol. 2021:184:437-449.

Figure 1: Proportion of patients with EASI-75 at Week 16 grouped by baseline disease severity in the ADHAND trial



NRI was used for data after rescue, and missing data after discontinuation due to AE or lack of efficacy. MI was used for other missing data. The proportion of responders was analyzed using a logistic regression model, with treatment included as a factor and adjusted for baseline IGA-AHE, region, and baseline value. [a]One patient in the placebo arm did not have a baseline EASI score.

AE, adverse event; CI, confidence interval; EASI, Eczema Area and Severity Index; EASI-75, having a decrease in EASI of at least 75% from baseline; MI, multiple imputation using a regression model; N, number of patients in analysis group; NRI, non-responder imputation; Q2W, every 2 weeks.

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Abstract N°: 432

Long-Term Maintenance of Stringent Patient-Reported Outcomes With Upadacitinib in Moderate-to-Severe Atopic Dermatitis: 140-Week Results From the Measure Up 1 and 2 Phase 3 Studies

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Introduction
The Aiming High in Eczema/Atopic Dermatitis (AHEAD) recommendations stress long-term disease control in managing atopic dermatitis (AD). We examined long-term maintenance of stringent patient-reported outcomes (PROs), including quality of life (QoL), with upadacitinib 15 mg (UPA15) or 30mg (UPA30) in the Measure Up 1 and 2 studies.

Materials and Methods
Data from adults/adolescents with moderate-to-severe AD achieving a stringent PRO response at week 16 were analyzed through week 140. Assessments included the proportion of patients maintaining: little-to-no itch (Worst Pruritus Numerical Rating Scale score of 0/1), no impact of AD on QoL (Dermatology Life Quality Index [DLQI] or Children's DLQI score of 0/1), little-to-no AD-related sleep disturbance (AD Impact Scale sleep impact score of 0/1), and high treatment satisfaction (Patient Global Impression of Treatment of "extremely" or "very" satisfied). Other stringent PRO responses were also evaluated. Data are reported as observed.

Results
Among responders at week 16, over half sustained little-to-no itch at week 140 (UPA15: 62.3%; UPA30: 66.0%). Nearly 70% still reported no impact of AD on their QoL at week 140 (70.7%; 69.4%). Additionally, more than three-quarters continued to report little-to-no AD-related sleep disturbance (83.5%; 77.9%) and remained highly satisfied with their treatment (82.2%; 83.8%) at week 140. Similar patterns were observed for other stringent PRO responses.

Conclusions

Most patients treated with once-daily upadacitinib 15 mg or 30 mg who achieved a stringent PRO response at week 16 maintained their response through week 140, demonstrating the long-term sustained efficacy of upadacitinib in the treatment of moderate-to-severe AD.

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Abstract N°: 451

Impact of Optimal vs Moderate Skin and Itch Treatment Targets on Patient-Reported Outcomes in Moderate-to-Severe Atopic Dermatitis: Insights from Measure Up 1 and 2 Phase 3 Studies

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Introduction
Effective management of atopic dermatitis (AD) centers on improving clinician- and patient-reported outcomes (PROs). This analysis examined the impact of achieving optimal versus moderate skin + itch treatment targets among adults/adolescents with moderate-to-severe AD from two upadacitinib phase 3 studies (Measure Up 1 and 2).

Materials and Methods
Treatment agnostic, mutually exclusive cohorts were formed based on skin + itch target achievement at week 16: Optimal-Target cohort (≥90% Eczema Area and Severity Index improvement + Worst Pruritus Numerical Rating Scale score of 0/1 [EASI90 + WP-NRS 0/1]), Moderate-Target cohort (EASI75 + ≥4-point WP-NRS improvement [EASI75 + ΔWP-NRS≥4]) or Neither-Target cohort (achieved neither EASI75 nor ΔWP-NRS≥4). Observed proportions at week 16 were reported for stringent PRO score achievement: Dermatology Life Quality Index (DLQI) or Children's DLQI 0/1 (DLQI/CDLQI 0/1), Patient-Oriented Eczema Measure 0–2 (POEM 0–2), AD Symptom Scale Skin Pain 0/1 (Pain NRS 0/1), and AD Impact Scale Sleep Impact item 0/1 (Sleep NRS 0/1).

Results
Achievement of stringent PRO scores were 1.7–5.1x higher in the Optimal-Target (n=380) versus Moderate-Target (n=231) cohort: 3.5x for DLQI/CDLQI 0/1 (Optimal-Target=75.5%; Moderate-Target=21.5%), 5.1x for POEM 0–2 (70.5%; 13.7%), 1.9x for Pain NRS 0/1 (98.6%; 53.1%), and 1.7x for Sleep NRS 0/1 (98.3%; 59.0%). Achievement was lowest in the Neither-Target cohort (n=433) for these PROs (range: 0.5–11.0%). Results were similar for other PROs assessed.

Conclusions
These findings highlight the significance of achieving the optimal target (EASI90 + WP-NRS 0/1) versus moderate target (EASI75 + ΔWP-NRS≥4) to comprehensively minimize patient-reported burden of disease.

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Abstract N°: 455

Effect of amlitelimab, a non-depleting anti-OX40 ligand antibody, on vaccine antibody responses in adult participants with moderate-to-severe atopic dermatitis: Results from HYDRO Phase 2 trial

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Introduction

Amlitelimab (SAR445229) is a fully human, non-depleting, anti-OX40 ligand (OX40L) monoclonal antibody that blocks OX40L during the inflammatory prequel, which is upstream of T-cell expansion and inflammatory cytokine production in atopic dermatitis. Amlitelimab has demonstrated efficacy in Phase 2 and Phase 3 clinical trials in participants with moderate-to-severe atopic dermatitis and was generally well tolerated. Since amlitelimab modulates T-cell–mediated inflammation in atopic dermatitis, its effect on T-cell–dependent and T-cell–independent vaccine responses in adults with moderate-to-severe atopic dermatitis was investigated in the HYDRO study.

Materials and Methods

HYDRO (NCT06015308) was a Phase 2, multicentre, randomised, double-blind, placebo-controlled trial with a screening period of up to 4 weeks, 16-week treatment duration, and 16-week safety follow-up (for participants not entering the long-term RIVER-AD safety trial [NCT05492578]). Eligible adults (≥18 years of age) were randomly assigned 1:1 to receive a subcutaneous amlitelimab 500 mg loading dose followed by 250 mg every-4-weeks (Q4W) or matching placebo. At Week 12, participants received 2 vaccines: a tetanus toxoid-containing vaccine (tetanus, diphtheria, and acellular pertussis; T-cell–dependent response) and a 23-valent pneumococcal polysaccharide vaccine (PPSV23; T-cell–independent response). The primary endpoint was the percentage of participants with a positive tetanus vaccine response (defined as ≥2.5 IU/mL in anti-tetanus immunoglobulin G titre for participants with a pre-vaccination baseline [Week 12] tetanus antibody titre of >1 IU/mL or a ≥3-fold titre increase for participants with a pre-vaccination titre of ≤1 IU/mL) at Week 16. The key secondary endpoint was PPSV23 response (defined as ≥2-fold increase from baseline in anti-pneumococcal antibodies against >50%

of the 23 serotypes) at Week 16. Secondary endpoints included the percentage of participants achieving validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) score of 0/1 and reduction from baseline of ≥2 points at Week 16, as well as Eczema Area and Severity Index (EASI)-75 response. Safety endpoints included treatment-emergent adverse events (TEAEs), treatment-emergent serious AEs (TESAEs), and discontinuations due to TEAEs. Primary and key secondary endpoints were analysed in the per-protocol population using logistic regression with G-computation, with the model adjusted for baseline atopic dermatitis severity, age, and (for primary endpoint only) baseline antibody titre. Risk difference and 95% confidence interval (CI; amlitelimab vs placebo) were calculated (non-inferiority margin, −25%; non-inferiority was established if the 95% CI lower bound exceeded −25%).

Results

In the HYDRO trial, a total of 224 participants were enrolled and randomised (amlitelimab, n=112; placebo, n=112), and 162 were included in the per-protocol analysis population (amlitelimab, n=82; placebo, n=80). Treatment with amlitelimab was non-inferior to placebo in response to tetanus vaccine (percentage of participants with response: amlitelimab, 91.5%; placebo, 93.8%; risk difference: −1.90; 95% CI: −9.85% to 6.05%; p<0.001) and PPSV23 (amlitelimab, 90.2%; placebo, 86.3%; risk difference: 3.48; 95% CI: −5.94% to 12.91%; p<0.001). vIGA-AD 0/1 and EASI-75 responses were generally consistent with Phase 3 COAST-1 and COAST-2 results at Week 16. Amlitelimab was generally well tolerated. In amlitelimab vs placebo arms, no meaningful imbalances were observed for overall rates of TEAEs (amlitelimab: 32.1%; placebo: 31.5%), TESAEs (1.8% vs 0%), and discontinuation due to TEAEs (0.9% vs 0%).

Conclusions

Treatment with amlitelimab 250 mg Q4W did not affect T-cell–dependent or T-cell–independent vaccine responses in adults with moderate-to-severe atopic dermatitis vs placebo. Amlitelimab was generally well tolerated when administered concomitantly with the vaccines.

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Abstract N°: 491

Psoriasis after Dupilumab: Side Effect or Cure?

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Introduction

Psoriasis is a chronic, inflammatory, multisystemic disease. It is characterized by erythematous plaques covered with silvery scales on the joint surfaces, scalp, and lumbosacral region (1). It can occur primarily, or treatments used for different indications in dermatology can trigger this condition. We would like to report our patient who developed psoriasis after dupilumab treatment.

Case Presentation

A 71-year-old male patient presented to our clinic with complaints of redness and itching on his hands, feet, face, and scalp for two weeks (Figure 1, 2,3). The patient, who also had hypertension and diabetes, presented with an erythrodermia. A biopsy was taken with preliminary diagnoses of atopic dermatitis, psoriasis, and mycosis fungoides. The results indicated spongiotic dermatitis(Figure 5,6), and due to the erythrodermia,the patient was treatedwith systemic corticosteroids and then started on maintenance therapy with dupilumab. After a temporary remission was observed during clinical follow-up, the patient experienced a recurrence of erythematous, scaly plaques on his hands, feet, scalp, and face in the third month of follow-up(Figure 4). A repeat biopsy was taken (Figure 7,8), which was consistent with psoriasis. The patient's treatment was revised to methotrexate 15 mg.

Conclusion

Atopic dermatitis and psoriasis are classically considered the opposite poles of the Th1 and Th2 paradigm. The immunological mechanism by which dupilumab triggers the development of psoriasis in certain patients is still unclear. However, it is known that IL-4 is overexpressed in atopic dermatitis and negatively regulates Th-1 and Th-17 cells; both of these cells are increased in patients with psoriasis (2,3). Dupilumab can reverse this inhibition by blocking IL-4 signaling and trigger psoriasis. Recent experimental studies have shown that IL-4 can directly affect T cells, dendritic cells, and keratinocytes (4). Furthermore, these studies have shown that IL-4 is a negative regulator of Th1 and Th17 cells, capable of suppressing IL-23 production by modulating the phenotype of dendritic cells, and inhibiting IL-1β and IL-6 secreted by epidermal cells from psoriatic lesions. Blocking the Th2 response with dupilumab triggers a shift towards the Th1/Th17 phenotype and the development of psoriasis.

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Abstract N°: 541

Prospects for Using Dry Eye Syndrome as a "Minor" Diagnostic Criterion of Atopic Dermatitis

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Introduction

The diagnosis of atopic dermatitis (AD) based on sets of major and minor criteria remains clinically relevant; however, in recent years there has been a shift towards simpler diagnostic schemes and, in particular, a critical reappraisal of the role of minor signs. Modern consensus diagnostic criteria for AD are focused on maximal simplicity of use and high reproducibility. In this context, minor signs are interpreted primarily as additional diagnostic markers that increase the likelihood of diagnosis in cases of incomplete expression of major criteria, but are not considered a mandatory component of the diagnostic algorithm. The classical major criteria of Hanifin and Rajka (cutaneous pruritus, typical morphology and localization of skin lesions, chronic relapsing course of the disease and a personal or family history of atopy) continue to serve as the conceptual "gold standard". At the same time, minor criteria are characterized by heterogeneous diagnostic performance, showing variable sensitivity and specificity. Nevertheless, in situations where the formally required three major criteria are not fully met, the role of minor criteria increases substantially, and they become an optimal auxiliary tool, particularly in pediatric practice.

Materials and Methods

In the Clinic of Pediatric Skin Diseases and Ophthalmology Department, 63 children aged 4–16 years with exacerbated AD were examined for signs of keratoconjunctival xerosis during the period 2018–2026. The severity of subjective signs of dry eye syndrome (DES) was assessed using the Ocular Surface Disease Index (OSDI). Biomicroscopy examined the objective symptoms of xerosis of the ocular surface: a reducing tear film break up time according to Norn test, the severity of damage to the corneal and conjunctival epithelium using intravital stainings (sodium fluorescein, lissamine green) according to the Oxford and van Bijsterveld scales, and assessment of meibomian gland dysfunction (MGD) according to the classification of K.K.Nichols et al. (2011).

Results

Subjective discomfort scores on the OSDI consistent with dry eye syndrome (DES) of varying severity were identified in 46 of 63 children (73.0%) with AD. Reduced tear film stability on the Norn test was found in 38 children (60.3%). Symptoms of MGD were recorded in 41 children (65.1%), including obstructive MGD in 28 children (44.4%) and hypersecretory MGD in 13 children (20.6%). Characteristic changes of the conjunctival and corneal epithelium in children with AD according to the Oxford and van Bijsterveld scales were detected in 43 children (68.3%).

Conclusions

In patients with atopic dermatitis, dry eye syndrome manifests as pruritus, a subjective sensation of dryness and a foreign body in, photophobia, tearing and other symptoms. Given the high prevalence of DES symptoms in atopic dermatitis and their pathogenetic association with disorder of homeostasis of the pre-corneal tear film, this symptom complex appears justified to consider as an additional (minor) diagnostic sign of AD, not as an independent criterion, but exclusively in combination with other clinical and anamnestic features of atopic

dermatitis. The classification of meibomian gland dysfunction with concomitant dry eye syndrome as a minor diagnostic criteria / associated symptom of atopic dermatitis, in turn, requires mandatory differential diagnosis with dry eye syndrome due to other etiologies and forms of pathological changes in the ocular surface.

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Abstract N°: 542

Gut microbiota modulation during IL-4/IL-13–targeting biologic therapy in adult Atopic Dermatitis: a longitudinal pilot study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disorder driven by genetic, environmental, and immunological factors. Recent research has highlighted the role of gut microbiota in modulating immune responses, with reduced microbial diversity and altered taxa composition associated with allergic diseases. However, data in adult populations—particularly in Western countries—and on the systemic effects of biologic therapies remain limited.

Materials and Methods

This pilot study aimed to characterize the gut microbiota and fecal short-chain fatty acid (SCFA) profiles of adult AD patients, compared to healthy controls. Patients were stratified by disease severity, and a subgroup of patients with moderate-to-severe AD was longitudinally evaluated before and after IL-4/IL-13–targeting biologic therapy. Fecal samples were analyzed using 16S rRNA gene sequencing targeting the V3-V4 region to assess microbial diversity and taxonomic composition, with taxonomic assignment performed using the GTDB database. SCFA concentrations were measured by gas chromatography-mass spectrometry (GC-MS).

Results

A total of 39 adult AD patients (including 19 longitudinally evaluated before and after a 12-week course of IL-4/IL-13–targeting biologic therapy and 20 with mild untreated disease) and 17 healthy controls were included.At baseline, alpha diversity did not differ significantly between AD patients and healthy controls, nor across disease severity groups or longitudinal timepoints. Beta diversity analyses showed a significant compositional difference between mild and severe AD at baseline (weighted UniFrac; p_adj = 0.027), while other comparisons were not statistically significant. Taxonomic analysis revealed a higher relative abundance of Prevotella in patients with more severe disease, which was positively correlated with EASI score. Additional taxa, including Collinsella and Paraprevotella, also showed positive associations with disease severity. Longitudinal analysis of changes between baseline and post-treatment timepoints identified microbial shifts associated with clinical improvement. Collinsella, Gemmiger, and Blautia_A decreased in patients with greater clinical response, whereas Alistipes, Acutalibacter, and Phocaeicola showed inverse associations with clinical response. A significant reduction in fecal acetate levels was observed post-treatment (p_adj = 0.016), while other SCFAs remained unchanged.

Conclusions

Biologic therapy targeting IL-4/IL-13 is accompanied by systemic modulation of the gut–skin axis, supporting the concept that gut dysbiosis is a dynamic and potentially reversible component of AD. The subtle baseline compositional differences observed in this adult cohort may reflect stage–dependent microbiome dynamics, with alterations more evident in earlier or pediatric disease. These findings provide insight into the systemic effects of biologic therapy beyond cutaneous improvement. Larger longitudinal studies are warranted to confirm these results and further define microbiome-based therapeutic targets.

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Abstract N°: 544

Oral Pigmentation in an Atopic Dermatitis Patient Treated With Oral Upadacitinib: A Case Report

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Introduction

Upadacitinib, an oral Janus kinase (JAK) inhibitor, has demonstrated notable efficacy and safety in managing moderate-to-severe atopic dermatitis (AD). It functions by selectively inhibiting JAK1-mediated cytokine signaling, a central mechanism in the inflammatory cascade associated with AD. Several pivotal clinical trials have established its ability to significantly reduce disease severity, pruritus, and improve patient quality of life. While its safety profile is generally favorable, ongoing post-marketing surveillance and clinical experience are crucial for identifying rare or unexpected adverse events.

Case Presentation

We report a unique and previously undocumented case of dental and gingival black discoloration occurring in a 17-year-old female patient with moderate-to-severe AD following one year of continuous upadacitinib therapy at a dose of 15 mg daily. The discoloration was gradual, symmetrically distributed, and not associated with pain, ulceration, or inflammation. Laboratory tests and dental examination ruled out infectious, metabolic, and common drug-related causes of pigmentation.Given the absence of similar reported adverse effects in existing literature, this case may represent a novel mucocutaneous side effect of long-term upadacitinib use. The pigmentation prompted a temporary discontinuation of the drug, with ongoing follow-up to assess reversibility. This report underscores the need for healthcare providers to monitor for atypical mucosal changes in patients undergoing extended JAK inhibitor therapy and to consider interdisciplinary evaluation when unexplained symptoms emerge.

Conclusion

This unprecedented adverse event emphasizes the need for dermatologists and healthcare providers to closely monitor dental health in patients undergoing long-term JAK inhibitor therapy, particularly in the pediatric and adolescent populations.

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Abstract N°: 584

Clinician-Reported Perceptions of a Colloidal Oat-Based Emollient Used with Topical Corticosteroids in Eczema: Results of a Multinational SERMO Survey

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Introduction
SERMO Survey statement: SERMO RealTime is a quick-turnaround online survey platform which providesinstant access to our proprietary global network of +1.3M HCPs.

The use of emollients constitutes a fundamental component of eczema management, as consistently recommended across international clinical guidelines. Emollients may support skin-barrier function and optimise topical corticosteroid (TCS) use in eczema; however, the available evidence remains limited. A multinational clinician perception study conducted to gather insights into the use of a colloidal oat-based emollient alongside topical corticosteroids in patients with eczema.

Materials and Methods
A cross-sectional SERMO survey captured descriptive, perception-based responses from 178 clinicians in Germany (n=16), Italy (n=40), the United Kingdom (n=35), and the United States (n=87). Respondents were dermatologists (60.1%) and paediatric clinicians (39.9%). Analyses were descriptive only; there was no comparator arm and no patient-level measured outcomes. Responses were considered from participants who indicated that they recommend colloidal-oat based emollient.

Results
Overall, 87.6% of clinicians reported frequently recommending the colloidal oat-based emollient in appropriate eczema patients treated with TCS. The recommendations reported were highest for moderate eczema (77.5%) and mild eczema (72.5%), and was strong in children (83.7%), adolescents/adults (84.8%), and paediatric patients overall (78.1%), but lower in severe eczema (37.6%) and adults aged ≥60 years (48.9%). The strongest perceived benefits were in skin irritation (79.8% any improvement; 37.6% much improved) and skin-thinning concerns (72.5% any improvement) when used with TCS. In addition, 92.7% reported some steroid-sparing or steroid-optimisation effect, although estimated duration effects were heterogeneous. Barrier-related attributes were most valued, including fortifying the skin barrier (86.5%), replenishing barrier lipids (84.3%), reducing trans-epidermal water loss (80.9%), and reducing TCS side effects (79.8%).

Conclusions
In this multinational survey, clinicians positioned a colloidal oat-based emollient as a routine but selective component of layered eczema care, particularly in mild-to-moderate disease and younger populations; strongest for children and adolescents/adults. Reported benefits centred on barrier support, tolerability-related outcomes, and perceived TCS optimisation when used with TCS. These findings are descriptive, clinician perception-based and hypothesis-generating and should not be interpreted as patient-level efficacy evidence.

Disclosures: All authors were employees of or consultants to Kenvue Brands LLC at the time the study was

conducted. This study was sponsored by Kenvue Brands LLC which was responsible for study design and collection, analysis, and interpretation of the dat

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Abstract N°: 595

Sustained Health-related Quality of Life improvements with delgocitinib 20 mg/g cream in Chronic Hand Eczema – results from the phase 3 open-label extension DELTA 3 trial

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Introduction

Delgocitinib cream, a non-steroidal topical pan-Janus kinase inhibitor applied twice daily, is currently the only treatment approved by the European Medicinal Agency for moderate to severe Chronic Hand Eczema (CHE). The treatment has been shown to improve patients' Health-related Quality of Life (HRQoL) within 16 weeks.
The objective of this study was to assess changes in HRQoL, work productivity, and daily activity impairment during long-term treatment with delgocitinib cream 20 mg/g in patients with moderate to severe CHE.

Materials and Methods

In the phase 3 open-label DELTA 3 trial (NCT04949841), patients who completed the 16-week DELTA 1 and DELTA 2 trials were offered to continue the treatment with delgocitinib cream twice daily on an as-needed basis for an additional 36 weeks. Impact of the treatment on EuroQol-5 Dimensions-5 Levels (EQ-5D-5L), Dermatology Life Quality Index (DLQI), Hand Eczema Impact Scale (HEIS), and Work Productivity and Activity Impairment (WPAI) questionnaire was assessed over a total of 52 weeks.

Results

Patients (n=560) had a mean (standard deviation [SD]) age of 45.8 years (14.4), and 63.4% were female. At baseline in the parent trials, mean (SD) scores for EQ-5D-5L, DLQI, HEIS, work productivity loss, and activity impairment were 0.64 (0.23), 12.6 (6.1), 2.49 (0.76), 44.3 (28.1), and 53.4 (25.0), respectively (Table 1). By the end of the parent trials (Week 16), these scores had improved to 0.83 (0.18), 4.5 (5.0), 0.89 (0.88), 20.7 (25.8), and 23.1 (25.5), respectively (Table 1). The improvements were maintained by Week 36 of DELTA 3 trial (52 weeks from baseline in the parent trials), with scores of 0.86 (0.16), 3.9 (4.1), 0.81 (0.82), 19.0 (23.7), and 19.8 (23.2), respectively (Table 1).
For patients who completed the study, mean improvements from baseline were all statistically significant ($p<0.0001$): EQ-5D-5L score changed by 0.20 (95% confidence interval [CI]: 0.18, 0.22), DLQI score changed by -8.5 (95% CI: -9.1, -7.9), and HEIS score changed by -1.66 (95% CI: -1.75, -1.57) (Table 1). Furthermore, work productivity loss and daily activity impairment scores decreased, with mean changes from baseline of -25.4 (95% CI: -29.0, -21.9) and -33.3 (95% CI: -35.8, -30.7), respectively ($p<0.0001$ for both) (Table 1).

Table 1 Changes in EQ-5D-5L, DLQI, HEIS, and WPAI scores in patients with moderate to severe CHE enrolled in the DELTA 1 and 2 trials, treated with twice-daily delgocitinib cream for 16 weeks, followed by an additional 36 weeks (total 52 weeks from baseline) of as-needed twice-daily delgocitinib cream in the open-label DELTA 3 trial.

Outcome	Baseline	Week 16	Week 52	
	Reported value	Reported value	Reported value	Change from baseline
	mean (SD)	*mean (SD)*	*mean (SD)*	*mean (95% CI)*
EQ-5D-5L	0.64 (0.23)	0.83 (0.18)	0.86 (0.16)	0.20 (0.18, 0.22)[a]
DLQI	12.6 (6.1)	4.5 (5.0)	3.9 (4.1)	-8.5 (-9.1, -7.9)[a]
HEIS	2.49 (0.76)	0.89 (0.88)	0.81 (0.82)	-1.66 (-1.75, -1.57)[a]
WPAI				
Work productivity loss	44.3 (28.1)	20.7 (25.8)	19.0 (23.7)	-25.4 (-29.0, -21.9)[a]
Daily activity impairment	53.4 (25.0)	23.1 (25.5)	19.8 (23.2)	-33.3 (-35.8, -30.7)[a]

CI: confidence interval; DLQI: Dermatology Life Quality Index, EQ-5D-5L: EuroQol-5 Dimensions-5 Levels; HEIS: Hand Eczema Index Impact Scale; SD: standard deviation; WPAI: Work Productivity and Activity Impairment.
Note: [a] p<0.0001 compared with baseline.

Conclusions

Improvements in HRQoL, work productivity, and daily activity impairment demonstrated after 16 weeks of continuous twice-daily treatment with delgocitinib cream were maintained after an additional 36 weeks of as-needed treatment in patients with moderate to severe CHE.

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Abstract N°: 609

Optimal Itch Response in patients with moderate and severe Atopic Dermatitis on dupilumab: real-world data

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Introduction

Atopic Dermatitis (AD) constitutes one of the most burdensome factors of cutaneous morbidity, listed among the most common inflammatory dermatoses. AD affects up to 25% of paediatric population and 10% of adults, typically presenting as papules and plaques of age-dependent distribution. Chronic pruritus is an essential counterpart of exanthem in AD, as it appears in virtually all patients. The activation of IL-4 and IL-13, two main Th2 cytokines, regulates IL-31, the best-studied mediator of pruritus in AD.
Dupilumab is a monoclonal antibody that inhibits IL-4 and IL-13 signalling through binding to the α subunit of the IL-4 receptor complex. In the context of treat-to-target (T2T) approach in assessing novel therapies targeting pruritus induction in AD, combined clinical parameters as Optimal Itch Response (OIR) have been introduced. This study used OIR to quantify the efficacy of dupilumab in suppressing the self-sustaining loop that perpetuates pruritus and exanthem in AD.

Materials and Methods

A total of 75 patients with moderate and severe AD of mean 18,5-year disease duration under dupilumab treatment for 16 to 52 weeks were studied. On weeks 0, 4, 16, 24 and 52 after therapy initiation, clinical status and quality of life were assessed via measurement of EASI (Eczema Area and Severity Index), SCORAD (SCORing Atopic Dermatitis), PP-NRS (Peak Pruritus-Numerical Rating Scale), DLQI (Dermatology Life Quality Index) and PGA (Physician Global Assessment).
Additionally, rates of OIR achievement were recorded, applying OIR combined quantitative criteria of EASI≤7, DLQI≤5 and PP-NRS≤4, on all 5 points of the 52-week observation timeframe. Cohort analysis included IgE levels on week 0, along with major atopic and non-atopic comorbidities. Prior topical and systemic treatments were documented. Finally, side-effects that dupilumab treatment induced were quantified.

Results

Clinical response to dupilumab in terms of EASI and partial improvement parameters EASI 50, 75, 90 and 100, steadily rose throughout the study (week 4: EASI≥50 in 65,33% of patients, weeks 16, 24 and 52: EASI≥50 above 90%). Already on week 4, EASI≥75 reached a significant 28% and continued to increase on week 16 (66,67%), week 24 (86,44%) and week 52 (95,55%). More importantly, complete or almost complete skin clearance (EASI≥90) was achieved in 9,33% on week 4, a percentage greatly and constantly improved on week 16 (37,33%), week 24 (55,93%) and week 52 (84,44%).
Concerning the core desideratum of the analysis, over one third of participants (38,67%) had already achieved OIR on week 4, which nearly doubled on week 16 (70,67%) and rose even higher on weeks 24 (79,66%) and 52 (86,67%). Clinical outcomes in subgroups with elevated IgE levels (negative AD prognostic indicator) and/or previously treated with JAK inhibitors were not significantly inferior. Drug safety profile assessment yielded exceptional results, with 90,67% of patients experiencing no side-effects and only 6,67% presenting with dupilumab-induced conjunctivitis, while there was one report of gastritis, haematuria and xerophthalmia

respectively.

Conclusions

Dupilumab exhibited an extremely high efficacy in tackling chronic pruritus in moderate and severe AD. Clinical outcome and safety profile in a real-practice setting were both excellent and sustained. The interconnection between therapeutic agent and patient-related response has started to take an increasingly important position amidst the primary priorities of current research. This gradual shift of paradigm and the resulting individualisation of management may lead to minimizing disease burden and psychosocial impact of Atopic Dermatitis on millions of patients worldwide.

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Upadacitinib versus abrocitinib in atopic dermatitis: a propensity score-adjusted comparison from BioDay

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Introduction

Several oral treatment options for the management of moderate-to-severe atopic dermatitis (AD) have recently become available in the form of Janus kinase inhibitors (JAKi). Selecting the most appropriate JAKi can be challenging as head-to-head trials directly comparing JAKi have not been conducted and AD guidelines do not differentiate between individual JAKi. Therefore, the objective of this cohort study was to comparatively assess the effectiveness and safety of JAK1i upadacitinib and abrocitinib in adults and adolescents with moderate-to-severe AD under routine clinical conditions, using data from the BioDay registry.

Materials and Methods

This prospective multicentre cohort study enrolled JAK1i-naïve AD patients (≥12 years) initiating upadacitinib or abrocitinib between November 2021 and September 2024 from the BioDay registry. Patient visits were scheduled before the start of treatment (baseline), at weeks 4, 8 and 16, and subsequently every 3 months up to 52 weeks. Effectiveness was evaluated using Eczema Area and Severity Index (EASI), Numeric Rating Scale (NRS) for pruritus, treat-to-target thresholds (EASI≤7; NRS-pruritus≤4, with patients discontinuing treatment considered non-responders), and drug survival. Inverse probability of treatment weighting (IPTW) was used to balance treatment groups. Multiple imputation was used to mitigate bias from missing confounders. Continuous outcomes were analysed with linear mixed models with a residual covariance matrix, dichotomous outcomes using logistic regression with a random intercept, time-to-event outcomes using Cox regression, and the time-treatment interaction with likelihood ratio tests.

Results

In total, 290 patients were included (213 upadacitinib; 77 abrocitinib). Upadacitinib treatment was generally initiated at low-dose (15mg daily, 84.5%) and abrocitinib at high-dose (200mg daily, 94.8%). Most patients had previously received advanced therapy, mainly consisting of biologics (upadacitinib 78.4%; abrocitinib 75.3%). After IPTW, all characteristics were well balanced.

Mean EASI scores declined from 15.2 at baseline to 6.1 at week 4 with upadacitinib and from 15.0 to 4.4 with abrocitinib, remaining stable among patients continuing treatment. NRS-pruritus scores declined from 6.5 to 3.2 and from 6.7 to 3.6 at week 4, respectively, likewise remaining stable thereafter. Probabilities of achieving EASI≤7 were 80.6% and 91.0% at week 4 and 40.9% and 34.0% at week 52 for upadacitinib and abrocitinib, respectively; probabilities for NRS-pruritus≤4 were 84.6% and 80.2% at week 4 and 29.5% and 29.9% at week 52. Effectiveness outcomes did not differ significantly between treatments over time.

The 52-week drug survival rates were 57.8% with upadacitinib and 52.2% with abrocitinib (HR 1.1, 95% CI 0.7–1.7). Treatment was most frequently discontinued due to ineffectiveness (upadacitinib 16.9%; abrocitinib 19.5%) or adverse events (upadacitinib 11.7%; abrocitinib 18.2%), mainly due to infections (upadacitinib 6.0/100 PY; abrocitinib 8.7/100 PY). Infection and acneiform eruption rates were similar between treatments, whereas gastrointestinal complaints, namely nausea, occurred more frequently with abrocitinib (HR 3.3, 95% CI 1.9–5.6).

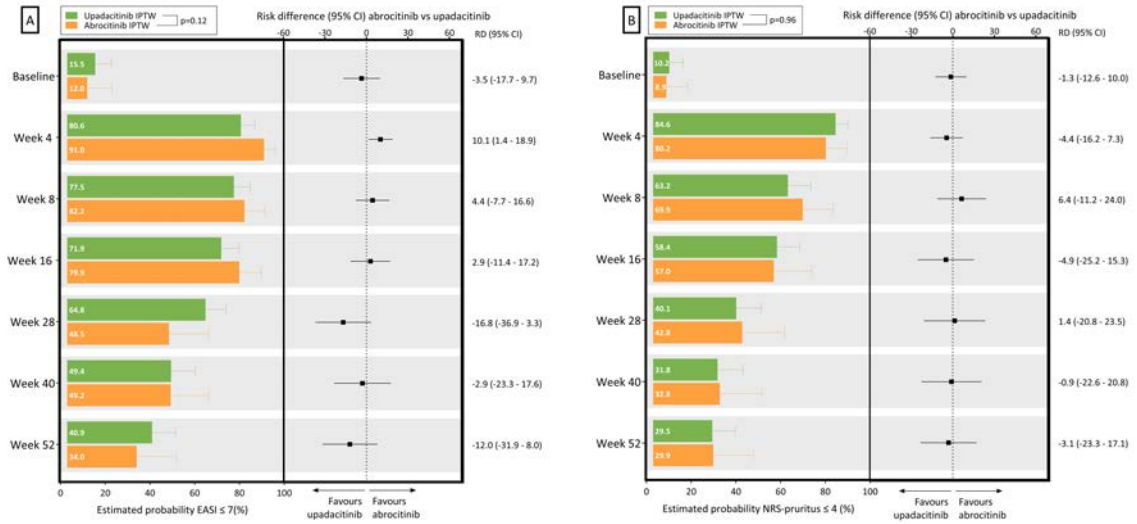

Figure 1. Treatment response based on the probability of achieving absolute cut-off scores EASI≤7 (A) and NRS-pruritus≤4 (B). IPTW-adjusted results are presented. All data were derived from the logistic regression models with a random intercept. The p-values are based on overall likelihood ratio tests for time by treatment interaction (statistical significance set at $p<0.025$). Results are presented as probability of achieving treatment response per treatment and risk differences with 95% CIs comparing abrocitinib vs upadacitinib. RDs greater than 0 indicate that abrocitinib is associated with greater improvement than upadacitinib. Abbreviations: confidence interval, CI; Eczema Area and Severity Index, EASI; inverse probability of treatment weighting, IPTW; Numeric Rating Scale, NRS; risk differences, RDs.

Conclusions

In this real-world cohort of patients with moderate-to-severe AD, upadacitinib and abrocitinib demonstrated comparable effectiveness and overall safety profiles. Although both JAK1i were associated with a high short-term probability of achieving treatment targets EASI≤7 and NRS-pruritus≤4, the probability of long-term treatment success was lower, largely reflecting treatment discontinuations due to ineffectiveness or AEs. Given the comparable effectiveness and overall safety profiles observed for JAK1i, the findings of this study suggest that treatment choice may depend on other considerations such as patient preference and/or treatment costs.

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Abstract N°: 662

Real-World Infection Risk Profile of Janus Kinase Inhibitors in Atopic Dermatitis: A Retrospective Cohot Study

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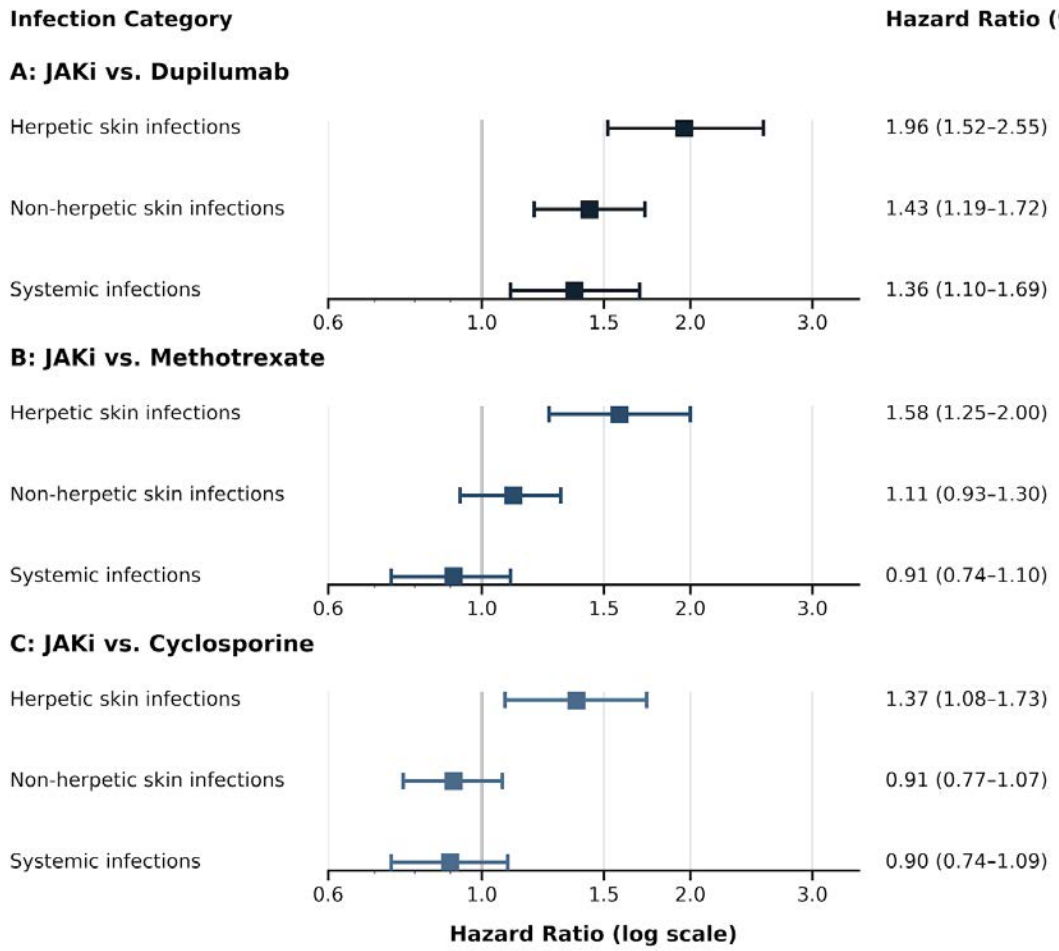
Introduction
Janus kinase inhibitors (JAKi) have expanded the therapeutic options for moderate-to-severe atopic dermatitis (AD), but concerns remain regarding their comparative safety profile, particularly the risk of infections. We aimed to evaluate the real-world risk of herpetic, non-herpetic, and systemic infections in AD patients treated with JAKi compared to those receiving dupilumab, methotrexate, or cyclosporine.

Materials and Methods
This population-based retrospective cohort study utilized the TriNetX global database. AD patients initiating JAKi (upadacitinib, abrocitinib, baricitinib) were propensity score–matched (1:1) to cohorts initiating dupilumab, methotrexate, or cyclosporine based on demographics and comorbidities. The primary outcomes were the 3-year risk of 16 distinct infections, categorized into herpetic skin, non-herpetic skin, and systemic infections. Hazard ratios (HR) and absolute risk differences were calculated.

Results
Three matched cohorts were analyzed, including 4,687, 4,676, and 4,661 patients in the JAKi versus dupilumab, methotrexate, and cyclosporine comparisons, respectively. JAKi treatment was associated with a consistently higher risk of herpetic skin infections compared with dupilumab (HR, 1.96; 95% CI, 1.52–2.55), methotrexate (HR, 1.58; 95% CI, 1.25–2.00), and cyclosporine (HR, 1.37; 95% CI, 1.08–1.73), driven largely by a high risk of herpes zoster (HZ; HR, 6.64 vs. dupilumab). Compared to dupilumab, JAKi increased risks for non-herpetic skin (HR 1.43) and systemic infections (HR 1.36); however, the absolute risk increase for systemic infections was modest (1.4 additional cases/1,000 patients). Notably, JAKi risks for non-herpetic and systemic infections were statistically comparable to methotrexate and cyclosporine.



Comparative risk of infections in patients with atopic dermatitis treated with JAKi versus conventional systemic therapies. Forest plots display the hazard ratios (HR) and 95% confidence intervals (CI) for herpetic skin infections, non-herpetic skin infections, and systemic infections over a 3-year period. (A) Propensity score–matched comparison of JAKi versus dupilumab. (B) Propensity score–matched comparison of JAKi versus methotrexate. (C) Propensity score–matched comparison of JAKi versus cyclosporine. Square markers represent the point estimates for the hazard ratio, and horizontal error bars denote the 95% CIs. The solid vertical line represents the line of no effect (HR = 1.0). The x-axis is presented on a logarithmic scale. An HR > 1 indicates an increased risk of infection associated with JAKi treatment relative to the comparator. Abbreviations: CI, confidence interval; HR, hazard ratio; JAKi, Janus kinase inhibitors.

Conclusions

JAKi carry an increased risk of herpetic infections across all comparators and a higher overall infection risk relative to dupilumab. However, their safety profile for non-herpetic and systemic infections is comparable to conventional systemic therapies. The small absolute risk increase for systemic infections suggests limited clinical impact. Findings emphasize the necessity of HZ vaccination and personalized risk assessment prior to JAKi initiation.

EADV CONGRESS
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Abstract N°: 743

Purine metabolism inhibitor mycophenolic acid inhibits DNCB-induced atopic dermatitis

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease that influences tens of thousands of people in the word. Mycophenolic acid (MPA) is a purine metabolism inhibitor, and is used off label in treatment of patients with severe refractory AD, but the potential mechanisms is still remains to be uncovered.

Materials and Methods
BABL/C mice were treated with DNCB to induce AD model in mice. At the same time, 5% MPA was applied topically to the back skin once per day on the fifteenth day after DNCB administration for a total of two weeks. The gene expression profiles were detected by RNA-sequencing (RNA-seq). Differentially expressed genes (DEGs) were analyzed by DEseq2 software. Gene ontology/Kyoto encyclopedia of Genes and Genomes (GO/KEGG) of genes and Gene Set Enrichment Analysis (GSEA) analysis were used to classify the gene functions.

Results
DNCB significantly altered purine metabolism associated genes expression in mice and purine metabolism inhibitor MPA could significantly inhibited DNBC-induced AD-like skin inflammation in mice. MPA modulates a vast of genes expression in DNCB-induced mice. GO enrichment revealed that extracellular region, immune system process and inflammatory response to be the most dramatically regulated pathways, whereas KEGG analysis indicated that cytokine-cytokine receptor interaction, TNF signaling pathway and IL-17 signaling pathway to be the most remarkably changed signaling pathways and GSEA enrichment showed dramatically suppressed signaling pathways in GO, KEGG and Reactiome database.

Conclusions
Our results for the first time unveiled the potential mechanisms of MPA to inhibit AD in the transcriptome level and MPA could be an effective medicine for AD treatment.

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Abstract N°: 754

Galvokimig, a multispecific, antibody-based IL-13, IL-17A and IL-17F inhibitor, modulates lesional transcriptome and circulating biomarkers in atopic dermatitis: findings from a 12-week Phase 2a trial

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Introduction

T helper (Th) 2 cytokines (e.g. interleukin [IL]-13) play a dominant role in the pathobiology of atopic dermatitis (AD); however, other inflammatory pathways, including Th17-derived IL-17A and IL-17F and the Th1 pathway, also contribute. The combinatorial effects of IL-13, IL-17A and IL-17F have been shown to amplify downstream inflammatory pathways and markers associated with AD pathobiology, including IL-19, a proinflammatory cytokine correlated with AD severity. Galvokimig is a fragment crystallisable–free, multispecific, antibody-based therapeutic that inhibits IL-13, IL-17A and IL-17F, with albumin binding to modulate half-life. In a Phase 2a trial (NCT04643457) in 47 participants with moderate-to-severe AD, the ≥75% improvement in Eczema Area and Severity Index (EASI75) response rate was 64.9% with galvokimig vs 12.3% with placebo, and the ≥90% improvement in EASI (EASI90) response rate was 46.6% vs 3.5%, respectively. Here, we report cutaneous lesional transcriptome profiles and circulating IL-19 serum levels from participants in this trial to evaluate the molecular effects of galvokimig.

Materials and Methods

Non-lesional (n=46) and lesional (n=47) biopsies at baseline and at week 12 post treatment (galvokimig, n=31; placebo, n=13) were collected and bulk messenger RNA (mRNA) sequencing was performed and evaluated using principal component analyses. Serum samples (galvokimig, n=30; placebo, n=14) were collected at baseline and at weeks 2 and 12 post treatment. Circulating IL-19 and thymus and activation-regulated chemokine (TARC) levels in serum were quantified using a validated ligand binding immunoassay.

Results

At baseline, there were marked differences between lesional and non-lesional skin, including upregulation of *IL13*, *IL17A* and *IL17F* gene expression. Moreover, dysregulation of Th2-, Th17- and Th1-associated gene signatures and

upregulation of additional IL-13 pathway (*IL13RA2*) and IL-17 pathway genes (*IL23A*, *IL23R*, *IL19*, *IL36G*, *S100A8* and *S100A9*) were observed. *IL31* gene expression was also upregulated in lesional vs non-lesional skin. Abnormal expression of key epidermal inflammation/hyperproliferation genes (upregulated *KRT6A* and *KRT16*) and skin barrier integrity genes (downregulated *FLG* and *LORICRIN*; upregulated *IVL*) were also observed. At week 12, compared with baseline, galvokimig treatment was associated with normalisation of *IL17A*, *IL17F* and *IL31* gene expression, reduction in *IL13* gene expression and attenuation of downstream Th2, Th17 and Th1 immune pathways and associated genes. Galvokimig treatment also resulted in downregulation of epidermal inflammation/hyperproliferation gene expression and increased expression of skin barrier integrity genes. Additionally, galvokimig treatment resulted in significant downregulation of serum IL-19 levels compared with baseline as early as week 2 (*P*=0.0008) and maintained up to week 12 (*P*=0.0010; Figure), and reduction in serum TARC levels.

Conclusions

The broad modulation of dysregulated Th2, Th17 and Th1 immune pathways and skin barrier genes in lesional skin observed with galvokimig, accompanied by the depth of clinical responses observed, supports the therapeutic potential of concurrently targeting IL-17A, IL-17F and IL-13 in patients with AD. A Phase 2b dose-ranging clinical trial to assess the efficacy, safety and pharmacokinetics of galvokimig in participants with moderate-to-severe AD is underway (PossibILity, NCT07277660).

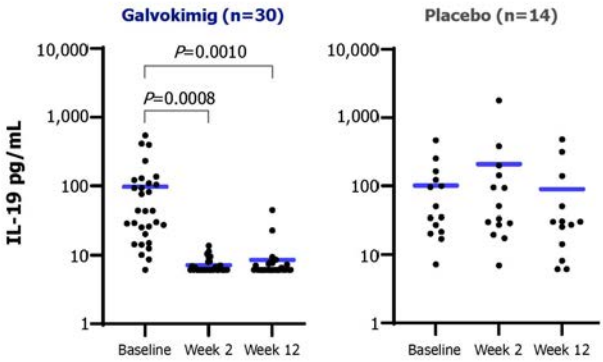

Figure. Serum IL-19 levels in participants treated with galvokimig vs placebo. Baseline was defined as the day prior to treatment initiation. Data are presented as a scatter plot with the geometric mean indicated by the horizontal line. D, day; IL, interleukin.

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Abstract N°: 779

Age at Onset Defines Distinct Clinical and Atopic Phenotypes in Adult Atopic Dermatitis: A Two-Center Study

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Introduction

Atopic dermatitis (AD) is a heterogeneous inflammatory skin disease characterized by variable clinical presentations and laboratory findings. Although age at onset may shape disease phenotype, data specifically assessing adult patients by age at onset are limited. This study examined whether age at disease onset is associated with distinct clinical and laboratory patterns in adults with AD.

Materials and Methods

In this two-center study, we included adult patients aged ≥18 years with AD, comprising both individuals with persistent disease from childhood or adolescence and those with adult-onset disease. Patients were categorized according to age at disease onset as 0–2, 2–12, 12–18, and ≥18 years. Demographic characteristics, family history of atopy, atopic comorbidities, distribution of skin involvement, hospitalization history, and laboratory parameters were compared across groups.

Results

Among 337 adults with AD, disease onset occurred at 0–2 years in 51 patients (15.1%), 2–12 years in 45 (13.4%), 12–18 years in 43 (12.8%), and ≥18 years in 198 (58.8%). Sex, body mass index, and family history of atopy were similar across groups. Compared with adult-onset disease (≥18 years), disease onset at 0–2 years was associated with higher frequencies of asthma (35.2% vs 16.6%, p=0.006), allergic rhinitis (50.9% vs 29.7%, p=0.007), head and neck involvement (84.3% vs 57.0%, p<0.001), lower extremity involvement (70.6% vs 46.4%, p=0.004), and hospitalization history (15.6% vs 2.5%, p=0.001). Head and neck involvement was also more frequent in patients with onset at 2–12 years than in those with onset at ≥18 years (82.2% vs 57.0%, p=0.003), whereas extensor involvement differed between the 0–2 years and 2–12 years groups (64.7% vs 33.3%, p=0.004). Laboratory differences were more limited: platelet counts were higher in the 0–2 years group than in the ≥18 years group (p=0.038). Total immunoglobulin (Ig) E levels were higher in the 0–2 years and 12–18 years groups than in the ≥18 years group (adjusted p=0.018 and p=0.001, respectively).

Conclusions

Very early-onset disease, particularly onset within the first 2 years of life, was associated with a more pronounced atopic phenotype, more typical head and neck and lower extremity involvement, greater hospitalization history, and higher total IgE and platelet levels.

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Abstract N°: 785

Long-term skin clearance and itch outcomes with upadacitinib in moderate-to-severe atopic dermatitis: week 260 results from the Measure Up 1 and Measure Up 2 phase 3 trials

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Introduction

Upadacitinib (UPA) is an oral selective Janus kinase 1 (JAK1) inhibitor approved to treat moderate-to-severe atopic dermatitis (AD) in adults and adolescents. In the phase 3 Measure Up 1 and Measure Up 2 trials, UPA demonstrated superior skin clearance and itch relief vs placebo at week 16.1 This integrated analysis evaluates long-term skin clearance and itch outcomes with UPA through 260 weeks of treatment.

Materials and Methods

Measure Up 1 (NCT03569293) and Measure Up 2 (NCT03607422) were replicate phase 3 trials that comprised a 16-week double-blind period and a blinded extension through week 260.1 Eligible patients were aged 12–75 years with moderate-to-severe AD (≥10% affected body surface area, Eczema Area and Severity Index [EASI] ≥16, validated Investigator's Global Assessment for AD [vIGA-AD] score ≥3, Worst Pruritus Numerical Rating Scale [WP-NRS] score ≥4) and were candidates for systemic therapy. Patients were randomized 1:1:1 to receive UPA 15 mg (UPA15), UPA 30 mg (UPA30), or placebo. At week 16, patients initially randomized to receive placebo were rerandomized 1:1 to UPA15 or UPA30; patients initially randomized to UPA continued the assigned treatment regimen. The co-primary endpoints were the proportion of patients achieving ≥75% improvement from baseline in EASI (EASI 75) and the proportion of patients achieving vIGA-AD score 0 or 1 with ≥2 grades of reduction from baseline at week 16. Outcomes assessed in this analysis included the proportion of patients achieving EASI 75, ≥90% improvement from baseline in EASI (EASI 90), meaningful itch improvement (≥4-point improvement in WP-NRS [ΔWP-NRS ≥4]) among patients with WP-NRS ≥4 at baseline, no or minimal itch (WP-NRS 0/1) among patients with WP-NRS >1 at baseline, and simultaneous achievement of EASI 90 and WP-NRS 0/1 at weeks 16 and 260. Data from Measure Up 1 and Measure Up 2 were integrated, reported as observed cases, and are presented

for patients randomized to UPA at baseline.

Results

A total of 1213 patients were randomized to UPA at baseline (UPA15, n=603; UPA30, n=610). Treatment with UPA resulted in sustained skin clearance responses and itch improvement over 5 years (Table). At week 260, 91.1% (245/269) of patients receiving UPA15 and 90.9% (271/298) receiving UPA30 achieved EASI 75, and 74.7% (201/269) and 75.5% (225/298), respectively, achieved EASI 90. A total of 63.1% (147/233) of patients receiving UPA15 and 72.3% (198/274) receiving UPA30 reported meaningful itch improvement (ΔWP-NRS ≥4) at week 260, with 42.2% (100/237) and 47.6% (131/275), respectively, reporting no or minimal itch (WP-NRS 0/1). At week 260, 39.8% (94/236) of patients receiving UPA15 and 41.8% (115/275) receiving UPA30 had simultaneous achievement of EASI 90 and WP-NRS 0/1. The safety profile of UPA was consistent with previous reports, with no new important safety risks identified through week 260.

Conclusions

UPA resulted in sustained skin clearance and itch relief through 260 weeks of treatment in adults and adolescents with moderate-to-severe AD. These findings indicate that UPA provides long-term disease control that may contribute to a more stable and predictable treatment experience for patients.

EADV CONGRESS
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Abstract N°: 796

A sebum-macrophage axis shapes site-specific immune endotypes in atopic dermatitis

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Introduction
Inflammatory skin diseases exhibit striking anatomical predilections, yet the mechanisms dictating site-specific immune programs remain poorly understood. Although atopic dermatitis (AD) is classically considered a Th2-driven disease, facial AD lesions arising in sebum-rich skin often show suboptimal responses to Th2-targeting biologics such as dupilumab, suggesting the presence of additional, site-specific immune programs shaped by the local tissue environment. We sought to define the role of sebum in shaping site-specific immune heterogeneity in AD and to elucidate the underlying cellular and metabolic mechanisms.

Materials and Methods
Single-cell RNA sequencing was performed on matched facial (sebum-rich) and popliteal (sebum-barren) AD lesions to characterize site-dependent immune landscapes. Mouse models of inflammatory skin disease were used to assess the functional impact of sebum on cutaneous inflammation, with mechanistic analyses focusing on macrophage lipid metabolism and inflammatory signaling.

Results
Single-cell transcriptomic profiling revealed a selective enrichment of type 17–associated immune programs in sebum-rich facial AD lesions compared with sebum-barren site. In mouse models, sebum exposure reprogrammed macrophage lipid metabolism via upregulation of fatty acid–binding protein 5 (FABP5), leading to enhanced IL-1β production and subsequent Th17 polarization. Pharmacological inhibition of FABP5 abrogated this sebum-induced immune shift and significantly alleviated disease severity in AD models.

Conclusions
These findings identify a previously unrecognized sebum–macrophage axis that promotes a local type 17–biased inflammatory niche, providing a mechanistic framework for anatomical immune heterogeneity in AD and suggesting therapeutic strategies for treatment-resistant facial dermatitis.

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Abstract N°: 800

Atopic dermatitis relapse after treatment discontinuation and predictive factors for relapse: JAK1 inhibitors versus dupilumab

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Introduction

In the clinical management of atopic dermatitis(AD), treatment discontinuations and subsequent disease relapse are common. Understanding relapse patterns following treatment discontinuation in AD patients is therefore essential. This study aims to investigate the time to relapse and identify predictive factors in patients with moderate-to-severe AD who responded to treatment with selective Janus kinase 1 (JAK1) inhibitors(upadacitinib or abrocitinib) or dupilumab.

Materials and Methods

This single-center, retrospective cohort analysis reviewed the data for patients aged≥12 years with moderate-to-severe AD who responded to either JAK1 inhibitors or dupilumab within 16 weeks. The primary outcome measures included the median time to skin lesion relapse after treatment discontinuation. Additionally, predictors for relapse were explored.

Results

Within 72 weeks after discontinuation, the median time to skin lesion relapse after discontinuation for JAK1 inhibitor and dupilumab responders was 60 and 457 days, respectively. Overall, 52.9% and 34.6% of patients who used JAK1 inhibitors and dupilumab reported AD skin lesion relapse (average hazard ratio =2.58, 95% confidence interval: 1.25–5.33, p = 0.01). No other factors influencing AD relapse were identified.

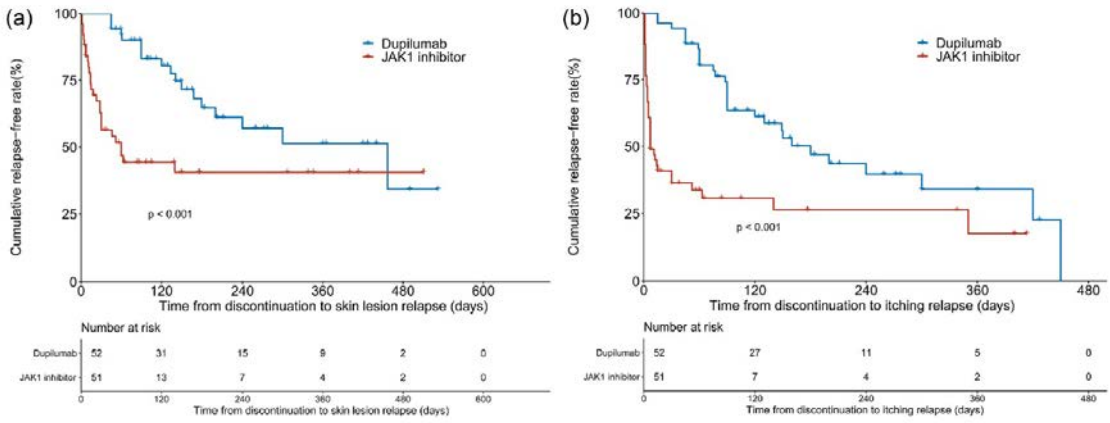

FIGURE 1 Time to events. (a) Time to skin lesion relapse (≥ 50% reduction in the initial improvement in EASI score compared to baseline at the time of discontinuation). (b) Time to itching relapse (NRS ≥ 4).

Conclusions

This study investigated real-world disease relapse after treatment discontinuation in moderate-to-severe AD patients who had responded to treatment with abrocitinib/upadacitinib/dupilumab. Treatment with injectable dupilumab was associated with a longer period of effectiveness and lower risk of relapse post-discontinuation

than treatment with oral JAK1 inhibitors. JAK1 inhibitor responders exhibited greater improvement in itching and rash within the first 4 weeks; however, these advantages were not maintained at 16 weeks. This study provides real-world data on AD patients that may help physicians develop more reasonable long-term maintenance treatment plans and discontinuation strategies in clinical practice.

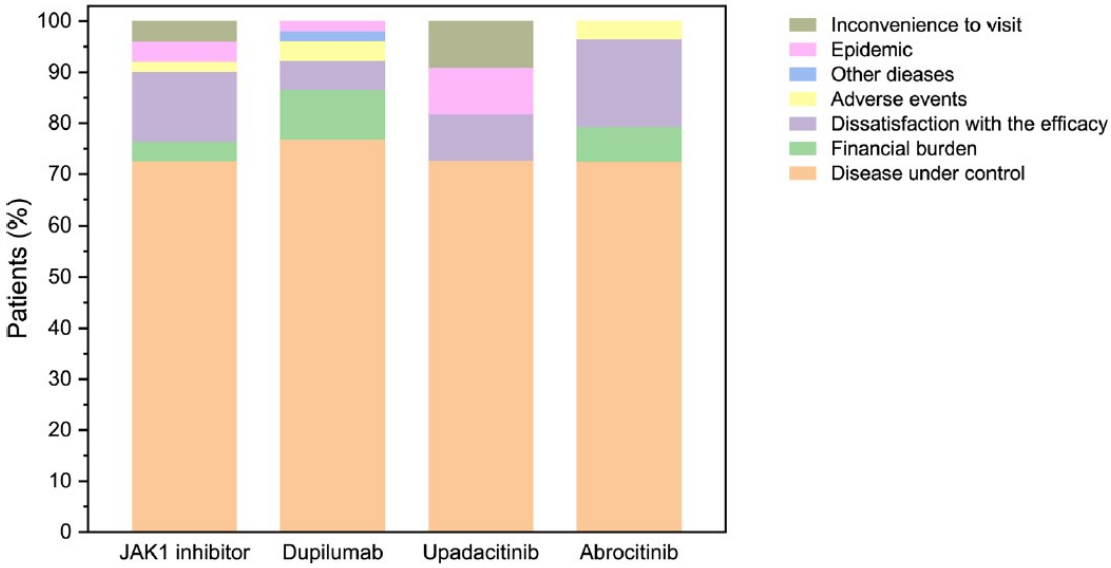

FIGURE 2 Reasons for discontinuation.

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Abstract N°: 801

Investigating Atopic dermatitis with Dynamic optical coherence tomography: A systematic review

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin condition characterised by epidermal barrier dysfunction and immune dysregulation, with significant impact on patient quality of life. Current severity assessment relies on clinical scoring systems such as SCORAD and EASI, which are subjective and have potential for interobserver variability, while histology is invasive, limiting longitudinal monitoring. Dynamic optical coherence tomography (D-OCT) is a non-invasive imaging modality enabling in vivo visualisation of cutaneous microvasculature and structural changes through detection of fluid flow. This review evaluates the evidence for D-OCT in assessing AD disease status, subclinical inflammation and monitoring treatment response.

Materials and Methods
A systematic search was conducted in March 2026 using PubMed, Scopus and Web of Science. Search terms included variations of “atopic dermatitis” and “dynamic optical coherence tomography”. Inclusion criteria encompassed studies using D-OCT in human models to investigate individuals with AD. Review articles and non-relevant studies were excluded. Following duplicate removal and screening, 13 studies were assessed for eligibility, with 6 studies included for detailed analysis. Study selection and data extraction was performed in accordance with PRISMA methodology.

Results
Across included studies, D-OCT imaging demonstrated consistent microvascular alterations in lesional AD skin. These included increased vessel density, diameter and tortuosity, alongside reduced vessel length and increased capillary loop and superficial plexus depth. Structural changes included increased epidermal thickness and vesicle formation, and reduced collagen density. Evidence also indicated the presence of subclinical microvascular changes in non-lesional skin, particularly increased superficial plexus depth, supporting the presence of subclinical inflammation in AD.

Interventional studies showed that D-OCT parameters improve following treatment, particularly with dupilumab, with reductions in epidermal thickness, vascular density and inflammation observed alongside clinical improvement. Notably, some studies reported persistence of microvascular changes despite early clinical improvement, suggesting that D-OCT may detect residual disease activity. Similar reductions in epidermal thickness and vascularisation were observed with topical treatment. However, heterogeneity between studies and overlap with vascular patterns seen in other inflammatory dermatoses limited the disease specificity.

Conclusions
D-OCT is a promising non-invasive modality for assessing microvascular and structural changes in AD skin sites. It demonstrates potential utility in objectively monitoring disease activity and treatment response, and in detecting

subclinical inflammation not captured by conventional clinical scoring systems. However, while current limited evidence supports its role as an objective adjunct to clinical assessment, further large-scale and longitudinal studies are required to establish standardised parameters and clarify its role in routine clinical practice.

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Abstract N°: 813

A MULTI-TARGET STRATEGY TO BREAK ITCH-SCRATCH CYCLE IN ATOPIC DERMATITIS

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Introduction

Chronic pruritus is often described as the most burdensome symptom of atopic dermatitis (AD). For 96% of AD patients, one of the most important treatment goals is to be free of itching [1]. This persistent itch perpetuates a vicious itch-scratch cycle, which exacerbates skin barrier dysfunction and (neuro)inflammation [2]. At a cellular level, itch signals are primarily transmitted by specialized intra-epidermal (and dermal) nerve fibers (IENF) through various receptors such as PAR-2, TRPV1, or the MRGPR family [3, 4]. Furthermore, inflammatory mediators released by keratinocytes (such as TSLP, RANTES and CCL-2) contribute to sustaining this vicious circle in addition to sustain the inflammation and barrier alteration. This study introduces a new mix of three actives, composed by Aqua posae filiformis (APF), Ophiogon japonicus root extract (Microresyl) and Antiprotease peptide, specifically designed to break the vicious itch-scratch cycle. The objective of this study is to evaluate a novel complex of active ingredients for its capacity to inhibit itch receptor activation and inflammatory mediator release in vitro.

Materials and Methods

First, the effects of APF, Microresyl and Antiprotease peptide were evaluated on various itch receptors of interest (PAR-2, TRPV1, TRPA1, PAR-4, MRGPRX1, MRGPRX2, MRGPRD) using recombinant HeLa cells. Briefly, cells were pretreated for 30 minutes with the actives and loaded with a calcium-specific fluorescent probe. Cells were then stimulated with specific agonists for each receptor. Calcim mobilization, indicating the activation of receptors, was measured through fluorescence intensity analysis. Then, to measure effects on inflammatory mediator release, human reconstructed epidermis (RHE) were pre-treated or not (Control) for 24 hours with the mix of 3 ingredients. Tissues were then triggered or not (unstimulated control) by a cytokine mix (IL-4 + IL-13 + TNF-a + Poly(I:C)) to mimick atopic skin. The release of TSLP, RANTES, and CCL2 was then measured using ELISA. All experimental conditions were performed on n=6, and an overall analysis of the data was performed using a one-way analysis of variance (ANOVA).

Results

APF inhibited the activation of itch receptors MRGPRX1, MRGPRX2 and PAR-4 (12.5%, 11.3% and 100% of inhibition respectively), Antiprotease peptide inhibited PAR-2 activation by 40% and Microresyl inhibited the activation of MRGPRD and TRPV1 (17.3% and 11.3% of inhibition respectively). In the RHE model, the combination of the 3 actives significantly inhibited the release of TSLP, RANTES, and CCL2 (59%, 66% and 75% of inhibition respectively.

Conclusions

The novel multi-ingredient complex effectively targets multiple itch pathways and reduces inflammatory mediator release, offering a promising multi-target approach to break the itch-scratch cycle and to tackle neuroinflammation in AD in the future.

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Abstract N°: 814

A NOVEL ACTIVE COMPLEX TO INHIBIT SENSORY NEURONS ACTIVATION AND TO TACKLE THE VICIOUS CYCLE OF ITCHING-SCRATCHING IN ATOPIC DERMATITIS

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Introduction

Atopic dermatitis (AD) is a chronic relapsing inflammatory skin disease affecting about 11% of children and 6% of adults worldwide, characterized by intense pruritus and a self-perpetuating itch-scratch cycle that drives disease severity [1]. At a cellular level, itch signals are primarily transmitted by specialized epidermal and dermal nerve fibers (IENF) through various receptors such as e.g. PAR-2, TRP ion channels, or the MRGPR family. Protease-activated receptor-2 (PAR2), a G protein-coupled receptor expressed on both epidermal keratinocytes and sensory C-fiber neurons, is the most studied receptor today and central in this process [2]. In AD skin, an excess of serine proteases, including mast cell tryptase and kallikrein-related peptidases (e.g. KLK5, 7, 14), activate PAR2, triggering the release of pruritogenic mediators such as Thymic Stromal Lymphopoietin (TSLP) as well as directly sensitizing TRPV1/TRPA1-positive sensory neurons thereby inducing intense itch [3,4]. This study introduces a new mix of three actives, composed by Aqua posae filiformis (APF), Ophiogon japonicus root extract (Microresyl) and Antiprotease peptide (Prot Inh), specifically designed to break the vicious itch-scratch cycle. The objective of this study was to demonstrate the efficacy of new active complexe on itch signal transmission. Given the central role of PAR2 in pruritus associated with atopic dermatitis we first focused on this pathway by measuring efficacy of this new active complex in a functional test measuring the inhibition of PAR2 activation in human sensory neurons derived from iPS cells co-cultured with keratinocytes.

Materials and Methods

Human sensory neurons were derived from hiPS cells. After 14 days of differentiation, keratinocytes were added, and the cells were cultured for an additional 4 days. The co-culture was then treated or untreated (control) for 24 hours with either the reference compound (FSLLRY-NH2 at 1 µM) or an antiprotease peptide, or the mix of all actives for 24 hours. Cells were then loaded with a calcium-specific fluorescent probe before being stimulated with trypsin at 50 ng/ml [5]. The fluorescence signal in the sensory neurons was recorded and analyzed for 2 minutes. All experimental conditions were performed on n=6, and an overall analysis of the data was performed using a one-way analysis of variance (ANOVA).

Results

A dose-dependent inhibition of trypsin-induced calcium mobilization in iPS-derived sensory neurons co-cultured with keratinocytes was observed with the active complex tested from C3 to C1 (41%, 54% and 73% of inhibition, respectively; $P<0.01$), without any cytotoxic effect on sensory neurons nor on keratinocytes.

Conclusions

These results clearly demonstrate the efficacy of the active complex by inhibiting the PAR2 pathway both on keratinocytes and neurons establishing its potential for treatment in atopic dermatitis, and demonstrating an important communication between keratinocytes and nerve fibers to break the vicious itch-scratch cycle.

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Abstract N°: 820

Atopic Dermatitis and Biologic Therapies: A Real-World Comparison Between Multifailure Patients and Long-Term Responders

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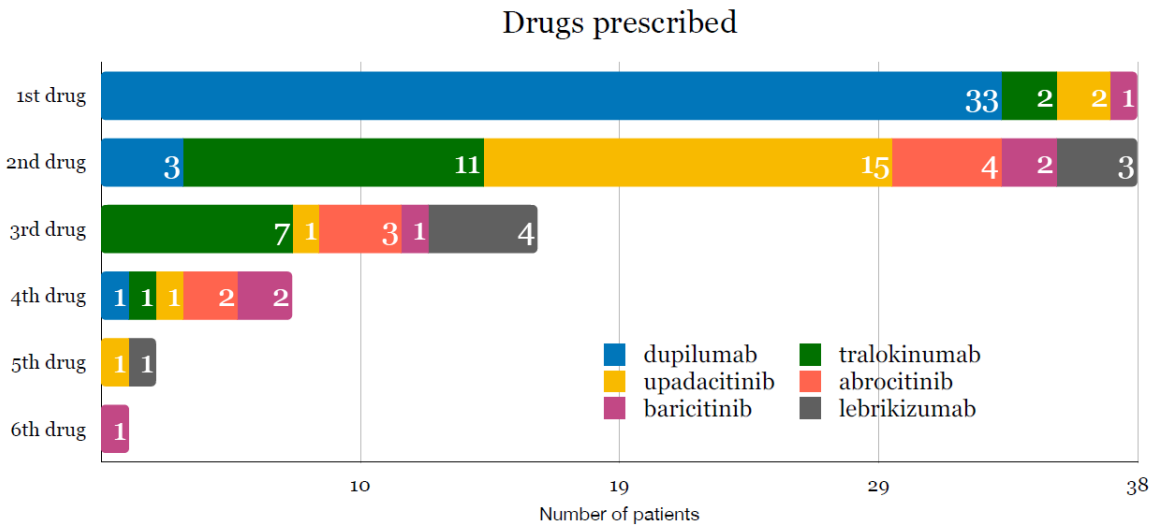
Introduction
The introduction of biologic therapies has significantly improved the management of moderate-to-severe atopic dermatitis (AD). However, in real-world clinical practice, a subset of patients exhibits inadequate response or loss of efficacy over time to multiple sequential biologic treatments, defining a difficult-to-treat disease profile. While the concept of biologic multifailure has been explored in psoriasis, albeit without a universally accepted definition, it remains largely uninvestigated in AD.
To propose an operational definition of biologic multifailure in atopic dermatitis and to compare the clinical, laboratory, and phenotypic characteristics of these patients with those achieving stable, long-term response to biologic therapy, in order to identify potential factors associated with multifailure.

Materials and Methods
We conducted a real-life, retrospective-prospective observational study including adult patients with moderate-to-severe AD treated with biologic therapies. Biologic multifailure patients were defined as those experiencing primary or secondary inefficacy to at least two consecutive biologics, excluding discontinuations due to reasons unrelated to efficacy. The comparison group included patients with stable and sustained clinical response (≥3 years) to the same biologic treatment (long-term responders).Demographic, clinical, and laboratory variables were collected. Quantitative variables were described as mean ± standard deviation or median (Q1–Q3), depending on distribution, while categorical variables were expressed as frequencies and percentages. Group comparisons were performed using Student’s t-test or Mann–Whitney U test for continuous variables, and chi-square or Fisher’s exact test for categorical variables.

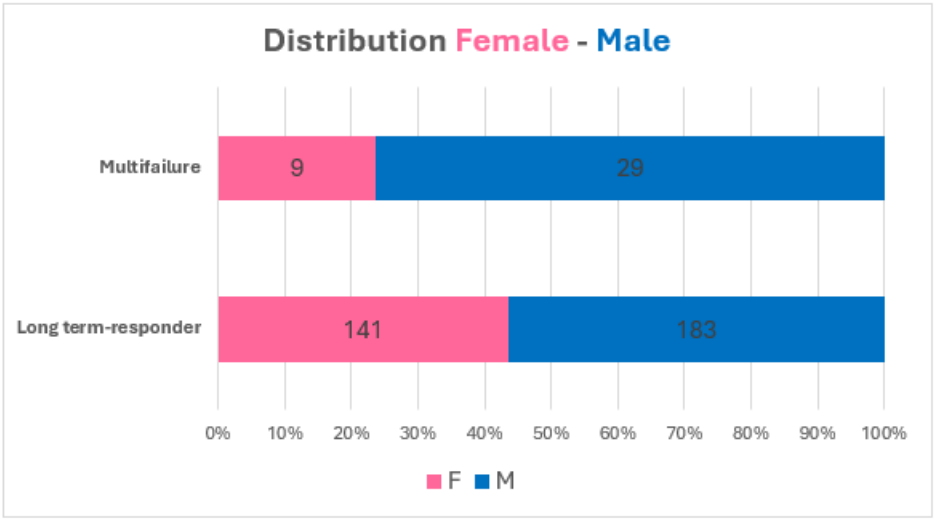
Results
Among 362 patients, 38 (10.5%) were classified as multifailure. Overall, 82% had early-onset AD. The most common phenotype was classic (59%), followed by generalized lichenoid (14.6%) and inflammatory (12.2%). Special sites included head–neck (86.6%), hands (68.4%), and genital area (18.4%). Atopic comorbidities included allergic rhinitis (73.7%), asthma (44.7%), allergic contact dermatitis (26.3%), and family history of atopy (50%).Multifailure patients were more frequently male (76.3% vs 56.5%; p=0.023) and younger at baseline (37.6±13.9 vs 44.4±17.9 years; p=0.032). No significant differences emerged in atopic comorbidities, family history, or sensitization to contact allergens.Phenotypic features were similar, with predominance of the extrinsic pattern (81.6% vs 88.5%; p=0.290) and comparable lesion distribution. Age at onset and early/late-onset distribution did not differ.Baseline severity was comparable: EASI (25.5 vs 27.4; p=0.583), P-NRS (9.5 vs 8.3; p=0.397), and DLQI (13.8 vs 15.5; p=0.296). Laboratory parameters, including total IgE (1709 vs 1491.5 IU/mL; p=0.590) and eosinophils (375 vs 400 cells/µL; p=0.248), were also similar.



In this graph, we see the failure pattern of different biological drugs in multifailure patients. In particular, we observe the distribution of therapeutic lines.

Conclusions

In our cohort, approximately one in ten patients with moderate-to-severe AD treated with biologics exhibited a biologic multifailure profile. This subgroup was characterized by a higher prevalence of male sex and younger age at baseline, factors previously suggested to be associated with reduced response to biologic therapies. No significant differences were observed in disease severity, clinical phenotype, or laboratory biomarkers.These findings suggest that biologic multifailure in AD is not easily predictable using conventional clinical and laboratory parameters, highlighting the need for novel predictive biomarkers and personalized treatment strategies for difficult-to-treat patients.



This graph shows the distribution of males and females in the two cohorts, showing how males are more represented in multifailure patients

EADV CONGRESS
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Abstract N°: 824

Safety and Efficacy of IBI356 in Moderate-to-Severe AD: A Phase 1 Randomized Clinical Trial

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Introduction

Atopic dermatitis (AD) is a chronic, inflammatory skin disease characterized by immune dysregulation and intense pruritus. OX40–OX40L signaling plays a key role in T-cell–mediated inflammation in AD. IBI356, a non-depleting monoclonal antibody targeting OX40L, is designed to inhibit this pathway and modulate the underlying immune response. This randomized, double-blind study which included placebo and active-reference groups, evaluated the safety and efficacy of IBI356 administered subcutaneously every 4 weeks (Q4W) for 16 weeks in adults with moderate-to-severe AD.

Materials and Methods

This double-blind study comprised a 16-week treatment period followed by a 20-week safety follow-up. Eligible adults aged 18–70 years with moderate-to-severe AD, defined by an Eczema Area and Severity Index (EASI) score ≥ 16, Investigator's Global Assessment (IGA) ≥ 3, and body surface area (BSA) involvement ≥ 10%. Following initial open-label administration of IBI356 15 mg to 4 patients, participants were randomized in an 8:2:2 ratio to receive subcutaneous IBI356 (60-600 mg, Q4W), dupilumab (300 mg, Q2W, with a 600 mg loading dose), or matched placebo. The primary endpoints were the incidence and severity of adverse events (AEs) and serious adverse events (SAEs). [Clinical trial number: NCT06193434]

Table 1. Baseline demographics and clinical characteristics (Safety Analysis Set)

	IBI356 (N=36)	Placebo (N=9)	Dupilumab (N=8)
Age, years [1]	31.9(12.75)	30.3(9.46)	30.4(15.86)
Male sex, n(%)	25(69.4)	4(44.4)	7(87.5)
BMI (kg/m^2)	22.94(3.179)	23.60(3.915)	24.20(4.671)
Time since first diagnosis of moderate to severe AD (Years) [1]	6.40(6.713)	4.94(7.040)	8.96(9.474)
Baseline EASI score	26.82(10.722)	36.22(25.435)	24.18(7.307)
Baseline affected BSA (%)	36.17(18.765)	45.61(36.805)	33.88(15.196)
Baseline IGA score, n (%)			
0-2	0	0	0
3	16(44.4)	5(55.6)	4(50.0)
4	17(47.2)	2(22.2)	4(50.0)
5	3(8.3)	2(22.2)	0
Baseline SCORAD score	64.30(12.012)	69.79(22.620)	61.39(10.587)
Baseline PP NRS weekly average [2]	6.62(2.170)	7.32(1.746)	6.39(1.729)

AD, atopic dermatitis; BMI, body mass index; BSA, Body Surface Area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; SCORAD, SCORing Atopic Dermatitis. Data are presented as mean+standard deviation, unless stated otherwise. [1] Age (years) = (date of informed consent - date of birth + 1)/365.25, rounded down to the nearest integer; [2] Baseline PPNRS weekly mean score is the average of the non-missing assessments performed 7 days prior to the first dose.

Results

A total of 53 patients with moderate to severe AD were enrolled, 51 completed treatment per protocol. The mean baseline age was 31.4 (range: 19-67) years. Baseline disease characteristics were balanced across treatment groups (Table 1). Mean baseline EASI scores were comparable across groups (IBI356: 26.82; dupilumab: 24.18; placebo: 36.22).

Efficacy: Most IBI356 dose groups demonstrated comparable or numerically greater improvements in efficacy outcomes compared to the placebo and dupilumab groups (Table 2). At Week16, the mean percent change from baseline in EASI score was -68.68% (IBI356), -69.20% (dupilumab) and -41.31% (placebo); the proportion of patients achieving an IGA response (≥2-point improvement from baseline) was 40.0% in the IBI356 group, 37.5% in the dupilumab and 25.0% in the placebo group. At Week36, the corresponding EASI changes were −81.82% (IBI356), −65.64% (dupilumab), and −87.65% (placebo); the IGA response rates were 65.6% (IBI356), 28.6% (dupilumab), and 80.0% (placebo). Consistent trends favoring IBI356 were also noted in EASI-75, SCORAD, PP-NRS, and BSA outcomes.

Safety: The overall AE profile was comparable across treatment groups. Treatment emergent adverse events (TEAEs) occurred in 83.3% of patients in the IBI356 group, 100% in the dupilumab group, and 77.8% in the placebo group. The majority of TEAEs were CTCAE Grade 1–2 in severity. The most common TEAE (incidence ≥10%) in IBI356 group was upper respiratory tract infection (13.9%). Incidence of treatment-related serious adverse event (TRSAE) were similar across all groups. No deaths were reported.

PK and Immunogenicity: In patients with AD, following single subcutaneous administration of IBI356 at 15–600mg, the median T_{max} ranged from 166.2-247 hours, and the geometric mean half-life was 332.4-623.4 hours.

IBI356 exhibited linear PK profiles across the 15–600 mg dose range. After multiple dosing (4 dose), the PK profile was consistent with that observed after a single dose, with the geometric mean accumulation ratio based on AUC ranging from 1.65 to 2.3. No anti-drug antibody (ADA)-mediated impact on IBI356 exposure was observed in AD patients.

Table 2. Summary of Efficacy Endpoints at Week 16 and Week 36

	IBI356							
	15 mg	**60 mg**	**150 mg**	**300 mg**	**600 mg**	**Total**	**Placebo**	**Dupilumab**
Efficacy Endpoints at Week 16								
Number	4	7	8	8	8	35	8	8
Percent change in EASI from baseline to W16	-73.83	-58.87	-76.13	-76.09	-59.82	-68.68	-41.31	-69.20
Mean (SD), %	(23.117)	(26.731)	(12.612)	(16.653)	(30.269)	(22.783)	(56.351)	(15.672)
EASI-75, n(%) [1]	2(50.0)	1(14.3)	5(62.5)	6(75.0)	4(50.0)	18(51.4)	2(25.0)	4(50.0)
IGA response rate [2], n(%)	2(50.0)	1(14.3)	3(37.5)	4(50.0)	4(50.0)	14(40.0)	2(25.0)	3(37.5)
Percent change in SCORAD from baseline to W16	-51.76	-45.32	-51.12	-53.47	-35.85	-47.08	-32.05	-50.51
Mean (SD), %	(27.652)	(15.616)	(18.771)	(24.502)	(22.130)	(21.303)	(31.532)	(15.434)
Percent change in weekly mean score for PPNRS from baseline to W16	-43.20	-35.26	-37.53	-44.63	0.79	-30.59	-44.71	-45.60
Mean (SD), %	(18.435)	(28.157)	(33.448)	(29.536)	(66.125)	(42.340)	(30.526)	(30.010)
Change in BSA baseline to W16	-19.00	-17.36	-18.56	-31.19	-23.69	-22.43	-13.19	-20.31
Mean (SD)	(14.142)	(8.826)	(12.819)	(22.121)	(20.448)	(16.753)	(31.419)	(10.106)
Efficacy Endpoints at Week 36								
Number	3	6	8	8	7	32	5[3]	7
Percent change in EASI from baseline to W36	-68.91	-83.55	-82.29	-89.28	-76.79	-81.82	-87.65	-65.64
Mean (SD), %	(30.486)	(10.698)	(18.949)	(12.808)	(25.693)	(19.004)	(12.914)	(10.334)
EASI-75, n(%) [1]	2(66.7)	4(66.7)	6(75.0)	7(87.5)	4(57.1)	23(71.9)	4(80.0)	1(14.3)
IGA response rate [2], n(%)	1(33.3)	3(50.0)	5(62.5)	8(100)	4(57.1)	21(65.6)	4(80.0)	2(28.6)

BSA, Body Surface Area; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PP-NRS, Peak Pruritus Numerical Rating Scale; SCORAD, SCORing Atopic Dermatitis. [1] n (%), number and percentage of patients; [2] IGA response, IGA score with ≥2-point improvement from baseline; [3] Two participants in the placebo group received rescue therapy and continued it throughout the study.

Conclusions

In this study of patients with moderate-to-severe AD, IBI356 demonstrated a favorable efficacy and safety profile. Efficacy outcomes, including EASI improvement and IGA response rates, were comparable to or numerically superior to dupilumab at Week 16, with a more pronounced treatment advantage emerging by Week 36. These findings support the continued clinical development of IBI356 as a promising therapeutic option for AD.

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Abstract N°: 827

Real-world drug survival of lebrikizumab the first 12 months: A nationwide register-based study

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Introduction

Biologics and small-molecule therapies have transformed the management of atopic dermatitis (AD). Lebrikizumab, an interleukin-13 inhibitor, has demonstrated high and sustained efficacy in clinical trials, yet real-world evidence remains limited. We therefore conducted a nationwide 12-month registry-based study of lebrikizumab in AD patients. The aim of this study was to investigate treatment effectiveness and drug survival in a real-world setting.

Materials and Methods

The study included data from SCRATCH; a nationwide Danish registry of AD patients treated with advanced systemic therapies. Data included patient characteristics and demographics, as well as clinical observational data such as Eczema Area and Severity Index (EASI), treatment regimen and adverse effects. Additionally, patients completed patient-reported outcomes (PROs) including Dermatology Life Quality Index (DLQI) and Patient Oriented Eczema Measure (POEM). Lebrikizumab was initiated according to national treatment guidelines.

Patients registered in SCRATCH who initiated treatment with lebrikizumab between October 1, 2024 (the date of lebrikizumab approval in Denmark) and October 1, 2025, were included in this study. Follow-up was conducted for at least 24 weeks or until lebrikizumab discontinuation. AD severity was defined by EASI; clear-to-almost clear=0-1, mild=1.1-7, moderate=7.1-21 and severe-to-very severe>21. Primary analysis estimated overall lebrikizumab drug survival using Kaplan-Meier analyses with corresponding Kaplan-Meier curves illustrating time to drug discontinuation. In secondary analyses, Cox-regression was used to calculate unadjusted hazard ratios (HR) with 95% confidence intervals (CI) to assess any possible associations between specific patient subgroups (e.g. sex and age) and lebrikizumab discontinuation. Wilcoxon signed-rank test was used to calculate P-values for changes in

EASI and PROs during treatment. P-values < 0.05 were considered statistically significant.

Results

A total of 149 AD patients from the SCRATCH registry who initiated treatment with lebrikizumab were included in this study. Of these, 57.7% were women and the median age at baseline was 34 years (interquartile range: 24, 50) (Table 1). Most patients had moderate AD with a median EASI of 11.6 (6.3, 18.3). Moreover, majority were bio-naïve (66%), and 60% presented with head and neck dermatitis at baseline. Median baseline DLQI and POEM were 12 (5, 18) and 19 (15, 23), respectively.

After six months of lebrikizumab treatment, 11.4% had discontinued therapy, whereas 88.6% remained on treatment. After 12 months of therapy 17.1% had discontinued treatment, mainly due to ineffectiveness and adverse events, while 82.9% continued treatment with lebrikizumab. The hazard of lebrikizumab discontinuation was marginally but significantly higher among patients with a history of multiple prior systemic treatments (HR: 1.29; 95% CI 1.01-1.65). In contrast, bio-naïve patients had a significantly lower hazard of drug discontinuation compared with bio-experienced patients (HR: 0.45; 95% CI 0.21-0.96). No significant hazard ratios were observed when stratifying by sex, age, BMI, educational level, disease duration or baseline EASI. After six months, EASI, DLQI, and POEM improved and decreased significantly with median changes of -9 (-15.2, -2.6; $p<0.001$), -4 (-12, -1; $p<0.001$), and -8 (-17, -2; $p<0.001$), respectively. These improvements were sustained at 12 months with median changes of -7.1 (-15.3, -2.5; $p<0.001$), -6 (-14, -2; $p<0.001$), and -8 (-12, -7; $p<0.001$), respectively.

Conclusions

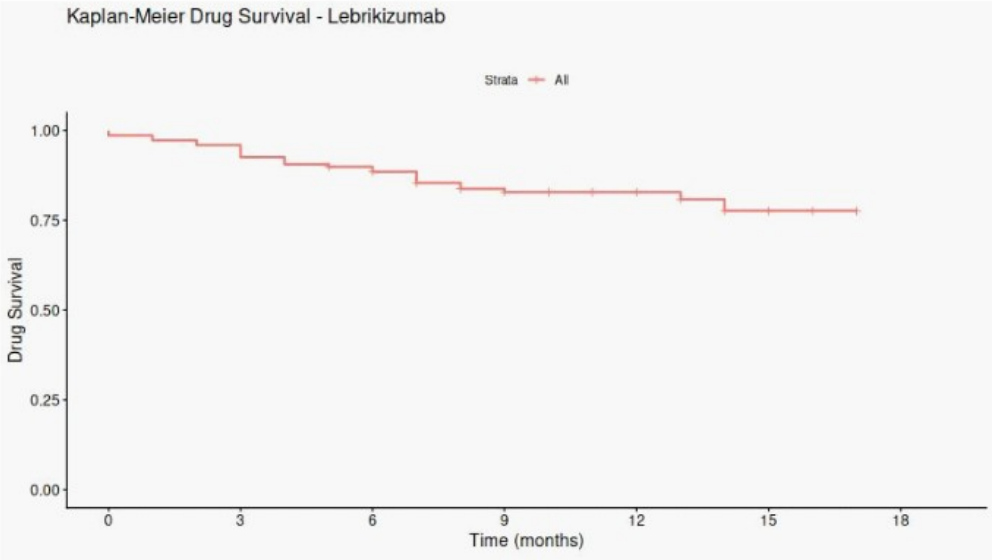
In a real world setting lebrikizumab demonstrated high drug survival after both six and 12 months of treatment. EASI, POEM and DLQI improved significantly at both timepoints, reflecting sustained treatment response. These findings support that lebrikizumab is an effective and generally well-tolerated treatment for AD patients outside a clinical trial setting.

Table 1 Patient characteristics and demographics at baseline

	AD patients treated with lebrikizumab N=149
Age (y), median (IQR)	34 (24, 50)
Women, n (%)	86 (57.7)
DLQI score, median (IQR)	12 (5, 18)
POEM score, median (IQR)	19 (15, 23)
EASI score, median (IQR)	11.6 (6.3, 18.3)
AD severity, n (%)	
Clear-to-almost clear (0-1.0)	2 (1.3)
Mild (1.1-7.0)	27 (18.1)
Moderate (7.1-21.0)	54 (36.2)
Severe-to-very severe (>21.0)	20 (13.4)
Head and neck dermatitis, n (%)	60 (40.3)
AD treatment history, n (%)	
Prednisolone	43 (28.9)
Biologics	51 (34.2)
Dupilumab	43 (28.9)
Tralokinumab	16 (10.7)
JAK inhibitors	23 (15.4)
Conventional systemic immunosuppressants (excluding prednisolone)	127 (85.2)

AD: atopic dermatitis; DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; IQR: interquartile range; JAK: Janus kinase; POEM: Patient Oriented Eczema Measure.

Figure 1 Overall drug survival of lebrikizumab



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Abstract N°: 833

The 487-gene expression profile test guides systemic therapy selection to improve outcomes for patients with atopic dermatitis: Results from a prospective, multi-center trial

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Introduction

Atopic dermatitis (AD) is a heterogenous inflammatory skin disease driven by complex biological interplay between type 1, 2, and 17 inflammatory processes. Systemic therapies, including biologics that target T helper type 2 inflammatory pathway (Th2-targeted therapies) and small molecules targeting multiple inflammatory pathways (JAK inhibitors, JAKi), have improved care for AD. However, current therapy selection is trial and error without consideration of each patient's underlying biology, resulting in inadequate disease control for approximately 45% of patients taking systemic therapies for AD. A non-invasive molecular test to characterize each patient's underlying disease biology to guide therapy selection with the goal of reducing the trial-and-error phase of therapy selection should lead to an improved proportion of patients who achieve adequate disease control and earlier response to treatment. The objective of this study was to develop and validate a non-invasive gene expression profile (GEP) test to guide systemic therapy selection for AD to improve health outcomes.

Materials and Methods

A prospective observational study enrolled patients with AD or psoriasis. Samples were acquired via non-invasive skin scraping from affected skin lesions and analyzed by RNA sequencing. Therapy use, eczema area and severity index (EASI) outcomes, itch skin clearance as measured by vIGA-AD, and flare frequency data were collected. A neural network ensemble algorithm (487-GEP test) was developed using 12 inflammatory and cutaneous biology pathways containing a total of 487 genes. A training set of n=192 patients was used to create the 487-GEP, which identified patients with a Th2 Molecular Profile or a JAK Inhibitor Responder Profile. The test was then validated in an independent validation cohort of patients aged 12 and older receiving Th2-targeted therapies or JAKi for AD (n=110 patients).

Results

The 487-GEP test scored 30.4% of AD samples as having a JAKi Responder Profile. This subset of patients achieved significantly higher rates of EASI90 (45.5% vs. 8.3%, p=0.021), achieved EASI90 3.8-times faster (p=0.049), were more likely achieve complete skin clearance (vIGA-AD, 36.4% vs. 0%, p=0.006) and “no itch” (PROMIS questionnaire, 45.5% vs. 8.3%, p=0.021), and were more likely to be flare-free (54.5% vs. 16.7%, p=0.041,) within 3 months when treated with low-dose JAKi versus a Th2-targeted therapy. In contrast, patients with a Th2 Molecular Profile had similar responses to Th2-targeted therapies and JAKi within 3 months.

Limitations: The study included patients treated with JAKi as first-line therapy as well as patients who switched to JAKi as a second-line treatment. However, this is representative of clinical practice, in which patients frequently switch medications with the goal of disease control. The 487-GEP test is predictive of response to JAKi as a class rather than predictive of response to specific therapies; however, this provides clinicians and patients with therapy guidance that also allows choice of specific therapy within the JAKi class.

Conclusions

In patients with AD, the 487-GEP test identifies a clinically meaningful group who are more likely to have high clinical benefit from JAKi than Th2-targeted therapies.

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TARGETING STAPHYLOCOCCUS AUREUS V8 PROTEASE AND VIRULENCE FACTORS WITH A NOVEL ACTIVE COMPLEX TO TACKLE MICROBE-INDUCED ITCH IN ATOPIC DERMATITIS

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Introduction

Atopic dermatitis (AD) is characterized by an altered skin barrier, Th2 inflammation, microbial dysbiosis and neuroinflammation. Chronic pruritus is often described as the most burdensome symptom of atopic dermatitis (AD). For 96% of AD patients, one of the most important treatment goals is to be free of itching. This persistent itch perpetuates a vicious itch-scratch cycle, which exacerbates skin barrier dysfunction and (neuro)inflammation. S. aureus commonly colonizes AD patients' skin and contributes to AD pathogenesis through expression of various virulence factors. Among them, a V8 protease and agonist of receptor PAR-1, has emerged as a key driver of AD pathogenesis, contributing to skin barrier alteration and immune evasion. In addition, V8 has recently been demonstrated to also directly activate itch neurons via PAR-1. Thus, targeting S. aureus virulence factors and V8 protease could be a promising strategy to tackle itch in AD. This study introduces a new mix of three actives, composed by Aqua posae filiformis (APF), Ophiogon japonicus root extract (Microresyl) and antiprotease peptide, specifically designed to break the vicious itch-scratch cycle. The objective of this study was to evaluate the capacity of this new mix to modulate S. aureus virulency.

Materials and Methods

To evaluate the efficacy of the mix of active ingredients in modulating S. aureus virulence factors to inhibit microbe-induced itch, S. aureus (CC1 strain) was treated with the mix of active ingredients and quorum-sensing inhibitors as controls (savirin and salicylic acid), and RNA was extracted at the mid-exponential phase of bacterial growth. Subsequently, cDNA was prepared, and various genes such as proteases/exoenzymes (splA, sspB, aur, V8), and genes involved in immunomodulation by regulating cytokine expression (spa), adhesion (clfa, fnbpA) and metabolic activity (isdA) were quantified using the quantitative reverse transcription polymerase chain reaction (qRT-PCR) method. Statisical analysis was performed using a one-way analysis of variance (ANOVA).

Results

The mix of active ingredients significantly reduced the mRNA gene expression levels of V8 protease ($p=0.002$), splA ($p=0.021$), fnbpA ($p=0.026$), clfa($p=0.069$), spa ($p=0.011$), and isdA ($p=0.045$) compared to controls, without inhibiting the growth of S. aureus at tested concentrations.

Conclusions

This study demonstrates the potential of this new mix of active ingredients to inhibit the expression of several S.

aureus virulence-related genes, notably V8 protease, offering a promising approach to tackle microbiota-associated itch in AD.

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Abstract N°: 911

Real-world comparative effectiveness of dupilumab versus oral JAK Inhibitors in atopic dermatitis: A propensity-matched analysis.

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disorder characterized by pruritus, sleep disturbance, and other symptoms that significantly impair patient's quality of life. The interleukin-4 receptor alpha antagonist dupilumab and oral Janus kinase inhibitors (JAKis) have demonstrated excellent efficacy in the treatment of moderate-to-severe AD. Nevertheless, comparative data regarding their real-world effectiveness remain limited.

Case Presentation

In this study, we performed a retrospective cohort analysis to compare the real-world effectiveness of dupilumab versus JAKi in patients with AD. Propensity score matching (PSM) was applied to balance baseline covariates across treatment groups. The primary outcome was defined as the proportion of patients achieving EASI-75 at week 12. After PSM, 772 AD patients were included in each group for outcome assessment.

At week 12, EASI-75 response rates were comparable between dupilumab and JAKi groups. However, dupilumab achieved superior skin clearance at early stage, as evidenced by a significantly higher EASI-75 rate at week 2 compared with JAKis. Following stratification by disease severity, dupilumab outperformed JAKi in improving skin lesions among patients with moderate-to-severe AD, with higher EASI-75 and EASI-90 response rates from week 2 to week 12. The effectiveness of dupilumab and JAKi was comparable among patients with mild AD. By contrast, JAKis yielded more rapid improvements in Dermatology Life Quality Index by week 4 and provided superior itch relief, as reflected by higher PP-NRS4 response rates from week 2 to week 8. Abrocitinib and upadacitinib demonstrated comparable efficacy in terms of skin lesion clearance and pruritus reduction.

Conclusion

Dupilumab demonstrated superior efficacy in skin lesion clearance compared to JAKis during the early treatment phase, but was associated with weaker responses in pruritus relief and quality-of-life improvement.

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Abstract N°: 922

Efficacy and Safety of Topical 1.5% Ruxolitinib Cream For Treatment of Chronic Hand Eczema, Head and Neck Dermatitis, and Prurigo Nodularis in a Cohort of Asian Patients with Atopic Dermatitis

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Introduction

Ruxolitinib (RUX) 1.5% cream is a topical Janus kinase (JAK) 1 and 2 inhibitor approved by the FDA to treat mild-to-moderate atopic dermatitis (AD) in patients 2 years and older. We aim to evaluate the efficacy and safety of prescribing topical 1.5% RUX cream, in addition to standard care, to treat chronic hand eczema (CHE), head and neck dermatitis (H&ND) and prurigo nodularis (PN) in a cohort of Asian patients with AD under follow-up at a tertiary dermatological centre in Singapore.

Materials and Methods

This prospective study assessed patients who were prescribed topical 1.5% RUX cream for three indications: CHE, H&ND and PN. Patients were instructed to treat the respective affected areas with the cream. Clinical endpoints were recorded at the point of prescription and at the follow-up visit.

The primary endpoints for the CHE arm were achievement of Investigator's Global Assessment (IGA) score 0 or 1 and reduction of Hand Eczema Severity Index (HECSI) score by 50% (HECSI-50), 75% (HECSI-75) and 90% (HECSI-90).

The primary endpoints for the H&ND arm were change in regional (head and neck) Eczema Area and Severity Index (rEASI) score and reduction of rEASI score by 50% (rEASI-50), 75% (rEASI-75) and 90% (rEASI-90).

The primary endpoints for the PN arm were achievement of IGA-PN Stage score of 0 or 1 and IGA-PN Activity score of 0 or 1.

In all 3 arms, the proportions of patients achieving a final Peak Pruritus Numerical Rating Scale (PPNRS) score of ≤ 4 and a ≥ 4 point reduction in PPNRS score were also studied.

Results

There are 106 participants at the time of writing. The median age is 37 and 68.3% were male. The median duration of disease was 22 years. 1 patient was enrolled in both H&ND and PN arms.

There were 23 patients in the CHE arm. 65.2% achieved HESCI-50, 47.8% achieved HESCI-75, 13.0% achieved HESCI-90, and 13.0% achieved IGA score 0 or 1 within a median follow-up duration of 12 weeks. 15 patients had a baseline PPNRS score of ≥ 4. Of these patients, 40.0% achieved a final PPNRS score ≤ 4, and 26.7% achieved a ≥ 4 point reduction in PPNRS score.

There were 59 patients in the H&ND arm. 60.3% achieved rEASI-50, 36.2% achieved rEASI-75 and 15.5% achieved rEASI-90 within a median follow-up duration of 12 weeks. 43 patients had a baseline PPNRS score of ≥ 4. Of these patients, 41.9% achieved a final PPNRS score ≤ 4, and 25.6% achieved a ≥ 4 point reduction in PPNRS score.

There were 25 patients in the PN arm. 33.3% achieved IGA-PN Stage score of 0 or 1, and 45.8% achieved IGA-PN Activity score of 0 or 1 within a median follow-up of 12 weeks. 19 patients had a baseline PPNRS score of ≥ 4. Of these patients, 52.6% achieved a final PPNRS score ≤ 4, and 47.4% achieved a ≥ 4 point reduction in PPNRS score.

Out of 106 patients, 23 did not receive concurrent systemic therapy, while 39, 2, 10, 25, 4 were on concurrent conventional immunosuppressants, retinoids, biologics, JAK inhibitors, and prednisolone respectively.

A total of 21 patients reported side effects ranging from acne, erythema, stinging, and upper respiratory infection. 3 cases of skin infection were deemed related (furunculosis, impetigo, and herpes), and 1 was likely unrelated (cellulitis at site distant to application) to RUX cream. 3 patients discontinued RUX cream due to furunculosis, impetigo and post-application erythema respectively.

Conclusions

Topical 1.5% RUX cream showed significant efficacy in the treatment of CHE, H&ND and PN in Asian dermatological patients, both as monotherapy and as part of combination therapy. Adverse reactions were infrequent and rarely resulted in discontinuation of RUX therapy.

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Abstract N°: 923

Exposure to sugar rationing in the first 1000 days of life and risk of atopic dermatitis

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Introduction

Atopic dermatitis (AD), also known as eczema, is an inflammatory skin disease that often begins in early life and is linked to immune dysregulation and skin barrier dysfunction. Sugar intake during early life is recognised as an important determinant of later disease risk. High sugar intake has been associated with systemic inflammation, alterations in the gut microbiome, and immune dysregulation that may contribute to AD. The period of sugar rationing in the United Kingdom (UK), which began in January 1940 during World War II and ended in September 1953 provides a unique natural experiment to examine these relationships. This study evaluates whether early-life exposure to sugar rationing is associated with the risk of developing AD later in life.

Materials and Methods

We employed population-based, quasi-experimental regression discontinuity study design using the UK Biobank (UKB) cohort. The study included 29,075 UKB participants with linked primary care electronic health records who were born between October 1951 and March 1956. Participants born outside the UK, adopted, or multiple births were excluded. Follow-up was defined using age, starting at birth and ending at the earliest of first AD diagnosis or age 66 years (censoring). Negative control outcomes (NCOs) included rheumatoid arthritis, fracture, trauma and appendicitis. Exposure was defined using date of birth relative to the end of UK sugar rationing. Individuals conceived between October 1951 and June 1954 were classified as exposed and categorised by duration of exposure (in-utero only; in utero + ≤12 months postnatally; in utero + ≤24 months postnatally). Individuals born between July 1954 and March 1956 were classified as never exposed and served as the reference group. Time-to-event analysis was conducted using parametric survival model with a Gompertz distribution, while sensitivity analyses included Cox and flexible parametric models. Treatment effect was estimated to assess differences in age at disease onset.

Results

Among exposed individuals, 43.6% were males and the mean age was 55.1 years, compared with never exposed (43.3% and 53.7 years respectively). Incident AD was 12.48 per 10,000 patients-years at risk. Exposure to sugar rationing extending from in-utero through 24 months postnatally was associated with lower risk of AD (adjusted hazard ratio [aHR], 0.82; 95%CI, 0.73-0.92). Findings were consistent across Cox (0.81; 0.72-0.91) and flexible parametric (0.81; 0.72-0.91) models. Absolute risk differences at the end of follow-up demonstrated 24 fewer cases of AD per 1,000 individuals exposed 24 months postnatally. Early-life exposure to sugar until 24 months postnatally was associated with a delay in AD presentation for up 9 years (7.14-11.07). No associations were observed for NCOs.

Conclusions

Early-life exposure to sugar rationing especially through the first 24 months postnatally was associated with a reduced long-term risk of AD. These findings suggest that reducing sugar intake during pregnancy and early

childhood may help prevent and delay AD, highlighting the lasting influence of early-life sugar intake on lifelong skin health. This study underscore early-life sugar reduction as a potential population-level prevention strategy.

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Abstract N°: 926

Impact of Head and Neck Involvement on Clinical Response to Lebrikizumab in Atopic Dermatitis: A Real-World Cohort Study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease with increasing availability of targeted therapies, including biologics such as lebrikizumab, an anti–IL-13 monoclonal antibody approved for moderate-to-severe AD. While clinical trials have demonstrated its efficacy, real-world evidence remains essential to better understand its performance in heterogeneous populations. Head and neck involvement represents a distinct and clinically challenging phenotype of AD, although its impact on response to IL-13 inhibition is not well established. This study aims to evaluate the real-world effectiveness of lebrikizumab and to assess whether head and neck involvement influences treatment outcomes.

Materials and Methods

This was a multicenter, observational, ambispective study including adolescent and adult patients with moderate-to-severe AD treated with lebrikizumab in routine clinical practice across multiple tertiary hospitals. Baseline data included demographics, disease duration, atopic comorbidities, and prior systemic treatments. Patients were stratified according to the presence of head and neck involvement. Disease severity was assessed using EASI, IGA, and pruritus NRS at baseline and week 16. Effectiveness outcomes included absolute and relative changes in these scores and the proportion of patients achieving EASI75, EASI90, IGA 0/1, and pruritus response thresholds.

Statistical analyses included non-parametric tests and multivariate logistic regression adjusted for potential confounders.

Results

A total of 147 patients were included, with 80.3% presenting head and neck involvement. Baseline characteristics were generally comparable between groups, although patients with head and neck involvement had longer disease duration and a trend toward higher aeroallergen sensitization. At week 16, both groups showed clinically meaningful improvements across all effectiveness outcomes, including reductions in EASI, IGA, and pruritus scores. Response rates (EASI75, EASI90, IGA 0/1, and NRS thresholds) were similar between groups, with no statistically significant differences observed. Multivariate analyses did not identify head and neck involvement as an independent predictor of treatment response.

Conclusions

Lebrikizumab demonstrated consistent effectiveness in patients with moderate-to-severe AD in real-world clinical practice, regardless of head and neck involvement. These findings support its use across different clinical phenotypes, including patients with traditionally more challenging disease presentations, aligning with evidence from clinical trials and prior studies.

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Abstract N°: 941

Efficacy and Safety of Moisturizing Cream containing EOP(1), NP(3), & AP(6-II) Combined with Crisaborole as Adjunctive Therapy in Adult Patients with Mild Atopic Dermatitis: A Multicenter, Randomized, Parallel-Controlled Trial

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Introduction

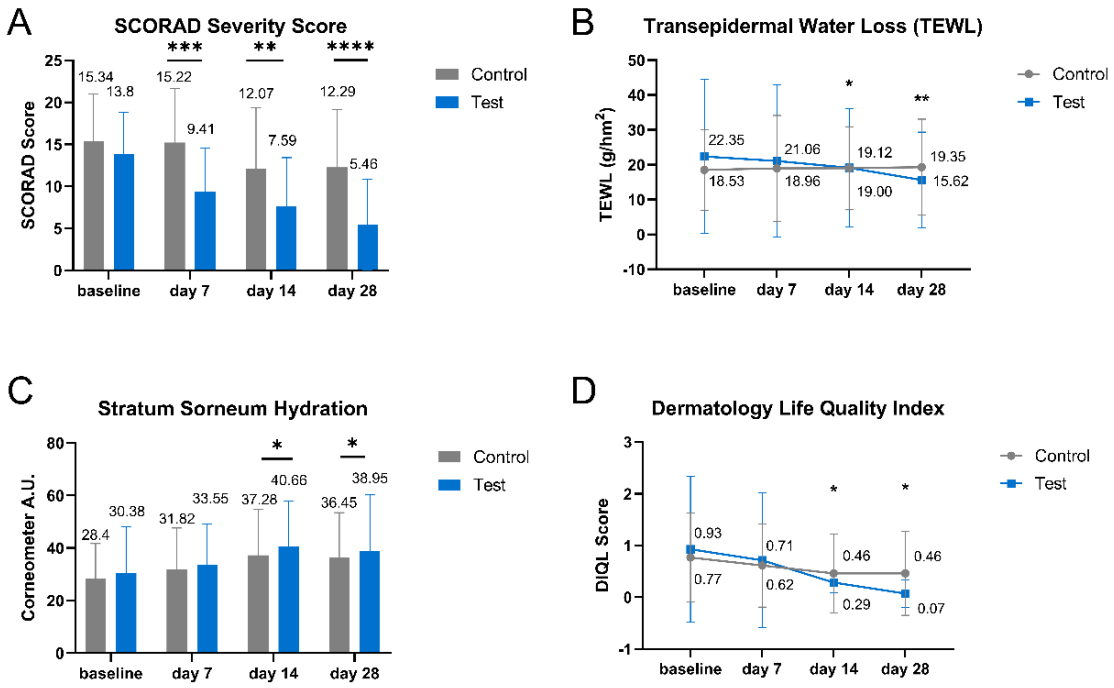
Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by skin barrier dysfunction. Topical crisaborole, a PDE-4 inhibitor, is widely used for mild-to-moderate AD due to its anti-inflammatory and antipruritic effects, but it does not directly restore the impaired skin barrier. Therefore, combining crisaborole with a barrier-repair moisturizer may offer added benefit. This study evaluated the efficacy and safety of a ceramide-containing moisturizer (CCM) containing ceramdes EOP(1), NP(3), & AP(6-II) as adjunctive therapy in adult patients with mild AD.

Materials and Methods

This study presents data from two center sub-cohorts of a larger multicenter, randomized, parallel-controlled trial. A total of 54 adult patients (aged 18-45 years) with mild atopic dermatitis (SCORAD <24) were enrolled Patients were randomly assigned to receive either Crisaborole ointment plus CCM (test group, n=28) or Crisaborole ointment alone (control group, n=26) for 4 weeks. Assessments were conducted at baseline (Day 0), Day 7, Day 14, and Day 28. Primary endpoint was SCORAD score change. Secondary endpoints included transepidermal water loss (TEWL), stratum corneum hydration (Corneometer), and Dermatology Life Quality Index (DLQI).

Results

Baseline characteristics were comparable between groups. At Day 28, SCORAD scores decreased by 60.4% in the test group (13.80 to 5.46) versus 19.9% in the control group (15.34 to 12.29, $p < 0.05$). Total effectiveness rate (the percentage of patients achieving a ≥20% reduction in SCORAD from baseline) as significantly higher in the test group (82.1% vs 42.3%, $p < 0.05$). Cure rate, which was defined as the percentage of patients who achieved a ≥95% reduction in SCORAD from baseline, was 28.6% in the test group versus 3.8% in the control group(Figure A). The reduction in TEWL level at Day 28 was significantly greater in the test group (22.35±22.1 to 15.62±13.74 g/hm^2, 30.1% reduction) than in the control group (18.53±11.55 to 19.35±13.72 g/hm^2, $p < 0.001$) (Figure B). Stratum corneum hydration significantly improved in the test group (30.38±17.71 to 38.95±21.3 units, $p < 0.05$ vs Baseline) with peak improvement at Day 14 (40.66±17.17 units, +33.8% vs Baseline, $p < 0.001$ vs Control)(Figure C). Moreover, DLQI scores improved by 92.5% in the test group (0.93 to 0.07) versus 40.3% in the control group (0.77 to 0.46, $p < 0.05$)(Figure D). Both treatments were well-tolerated with no serious adverse events.



Efficacy of Moisturizing Cream containing EOP(1), NP(3), & AP(6-II) as Adjuvant Therapy in Patients with Mild Atopic Dermatitis. Data are presented as mean SD. *p<0.05, **p<0.01, ***p<0.001, ****p<0.0001 vs Control group. TEWL: Transepidermal Water Loss; SCORAD: SCORing Atopic Dermatitis.

Conclusions

Moisturizing Cream containing EOP(1), NP(3), & AP(6-II) as potential adjunctive therapy to topical crisaborole (a PDE4 inhibitor) significantly improved skin barrier function, reduced AD severity, and enhanced quality of life in adult patients with mild atopic dermatitis.

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Abstract N°: 945

Safety, Pharmacokinetics, and Pharmacodynamics of SHR-1819 in Children and Adolescents with Uncontrolled Moderate-to-Severe Atopic Dermatitis：Results from a Multicenter, Open-label, Single-arm Phase Ib/II Study

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Introduction

Interleukin-4 receptor alpha (IL-4Rα), a shared receptor subunit for IL-4 and IL-13, represents a promising therapeutic target for type 2 inflammatory diseases, such as atopic dermatitis (AD). SHR-1819 is a novel monoclonal antibody targeting IL-4Rα, blocking the signaling of IL-4 and IL-13. In the previous phase II study in adults with AD, SHR-1819 effectively ameliorated the signs and symptoms, demonstrating a favorable safety profile with good tolerability, as well as favorable pharmacokinetic (PK) and pharmacodynamic (PD) characteristics. Given the promising results above, this Phase Ib/II study (Clinicaltrials.gov, NCT06713499) aims to investigate the safety, PK and PD of SHR-1819 in the pediatric population of children and adolescents with moderate-to-severe AD.

Materials and Methods

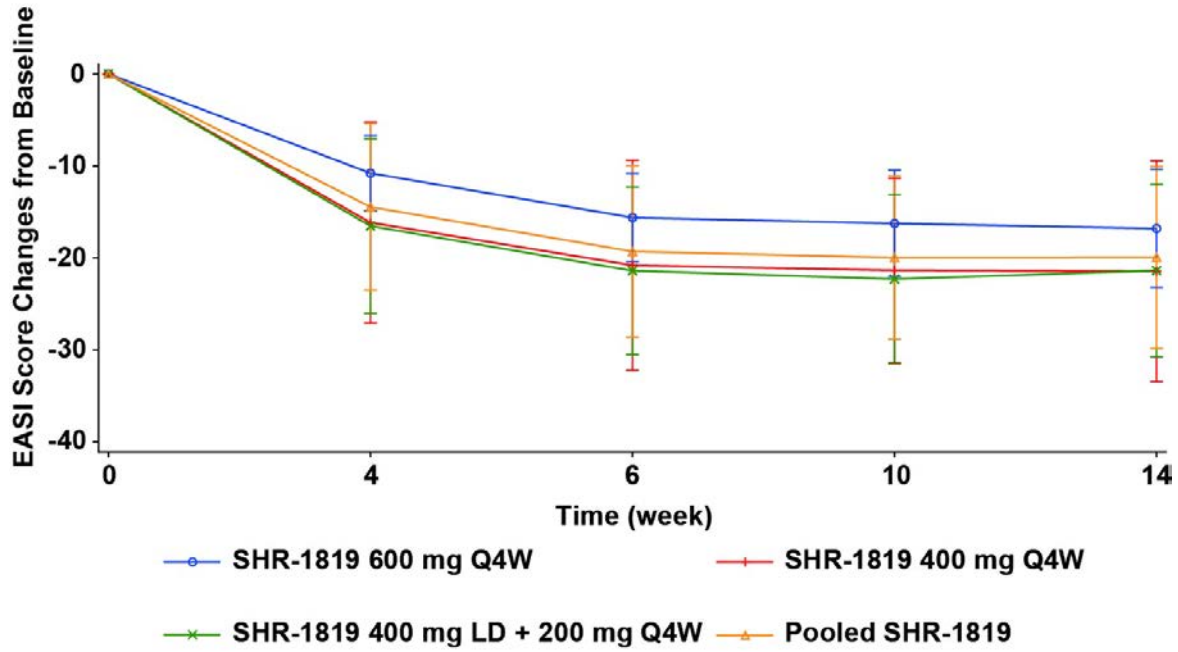
Eligible patients with uncontrolled moderate-to-severe AD (meeting an Eczema Area and Severity Index [EASI] score ≥16, an Investigator’s Global Assessment [IGA] score ≥3, and ≥10% of body surface area [BSA]) were enrolled from 13 centers in China into two cohorts: adolescents (12–17 years) and children (6–11 years). Each cohort included 15–25 patients (with a minimum of 6 patients in each weight stratum: 30–<60 kg and 15–<30 kg). This study consisted of a 4-week screening/run-in period (≥7 days of stable emollient use prior to the first dose), a 6-week treatment period, and an 8-week safety follow-up. Patients were assigned to receive subcutaneous injections of SHR-1819 at Week 0 and 4, dosed according to baseline weight ranges (patients weighing ≥60 kg

received 600 mg once every 4 weeks [Q4W], SHR-1819 400 mg Q4W for 30–<60 kg, and 400 mg as the loading dose (LD) at Week 0 then 200 mg Q4W for 15–<30 kg, respectively). The primary endpoints were safety and tolerability assessed up to Week 14. Secondary endpoints included PK and PD parameters, such as changes in serum thymus and activation-regulated chemokine (TARC/CCL17). Additionally, various exploratory efficacy endpoints were assessed.

Results

A total of 26 adolescents and 25 children received the assigned treatment and all were recruited in the safety set, PK concentration set and PD set. The mean AD duration across all groups was 5.4 years; mean EASI score was 25.2; mean BSA affected by AD was 41.8%; and 64.7% of patients had an IGA score of 3 (moderate) and 35.3% had a score of 4 (severe). The incidence of treatment-emergent adverse events (TEAEs) was 57.7% (15/26) in the adolescent cohort and 56.0% (14/25) in the children cohort. Most TEAEs were mild to moderate in severity. The most common TEAEs were alanine aminotransferase increased (7.8%, 4/51) and eosinophil count increased (7.8%, 4/51). One TEAE (heart rate decrease and blood pressure decrease in the adolescent group) resulted in treatment discontinuation and no TEAE leading to death were reported. The PK exposure in different dose groups of the pediatric population is similar to that in adults. PD data showed that SHR-1819 led to reductions in the median concentrations of TARC/CCL17 in most groups in both cohorts. In the efficacy outcome of overall population, the EASI scores and the weekly average of the Peak Pruritus Numerical Rating Scale (PP-NRS) showed marked mean percentage reductions of 57.2% and 37.6% from baseline at Week 4, and these reductions remained generally stable through Week 14. Notably, the rapid reduction of PP-NRS was observed as early as the first week after one dose, with a 13.59% decrease from baseline.

Figure. EASI score changes from baseline in all population over 14 weeks



Data are mean ± SD. EASI, Eczema Area and Severity Index.

Conclusions

SHR-1819 was well tolerated and demonstrated favorable safety, PK, and PD profile and showed clinically meaningful reductions in EASI score in children and adolescents with moderate-to-severe AD. These findings support further development in Phase III trials.

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Abstract N°: 958

Association of atopic multimorbidity with childhood pet exposure and caesarean section delivery: a retrospective study from the Lifelines Cohort Study

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Introduction

The hygiene hypothesis suggests that reduced microbial exposure may contribute to the development of atopic diseases, whereas higher exposure may exacerbate symptoms and promote disease progression.

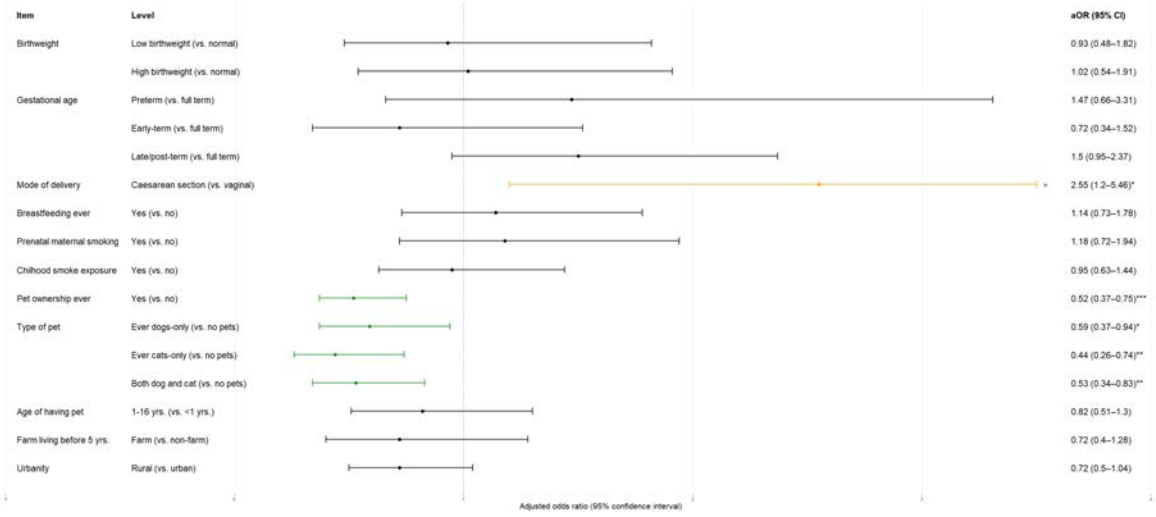
The current study aims to investigate the association between multiple childhood environmental exposures and atopic multimorbidity, defined as atopic dermatitis (AD) accompanied by at least two other atopic comorbidities, including asthma, food allergy (FA), or allergic rhinitis (AR).

Materials and Methods

Data on self-reported physician-diagnosed AD in lifetime was collected between February and May 2020 via a digital questionnaire from the Lifelines Cohort Study (N=167,729). Adults retrospectively reported their childhood environmental exposures during the Lifelines baseline assessment between 2006 and 2013, including birthweight, gestational age, delivery mode, breastfeeding, tobacco smoke, living conditions (self-reported farm-living before the age of 5; rural or urban residence according to living addresses density), and pet exposure before the age of 16. Pet exposure was assessed through three variables: pet ownership ever (no/yes), the type of pets (no pets/dog only/cat only/both dog and cat), and the age at which they had pets (≤1 year old/1–15 years old). Additionally, data on lifetime asthma, AR, and FA were also collected between 2006 and 2013. The study population was categorized into those without atopic disease and those with atopic multimorbidity. Associations between environmental exposures and atopic multimorbidity were examined using binary logistic regression, with each individual environmental exposure adjusted for age, sex, socioeconomic status, parental history of asthma, and sibling status.

Results

Among the 28,791 included participants, 27,939 (97.0%) had no atopic disease, and 852 (3.0%) had atopic multimorbidity. Compared with participants without atopic diseases, delivery by caesarean section was associated with a higher odds of atopic multimorbidity (adjusted odds ratio [aOR]: 2.55, 95% confidence interval [CI]: 1.20–5.46), while having pets before age 16 (aOR: 0.52, 95% CI: 0.37–0.75), regardless of owning dogs only (aOR: 0.59, 95% CI: 0.37–0.94), cats only (aOR: 0.44, 95% CI: 0.26–0.74), or both dogs and cats (aOR: 0.53, 95% CI: 0.34–0.83), were all negatively associated with atopic multimorbidity (Figure 1).



Conclusions

Childhood pet ownership may protect against atopic multimorbidity, whereas caesarean section was associated with an increased likelihood of atopic multimorbidity. These findings support preventive strategies that promote controlled microbial exposure, such as interaction with pets.

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Abstract N°: 960

Serum IL-31 in Adult Atopic Dermatitis: Association with Disease Severity and Response to Systemic Therapy

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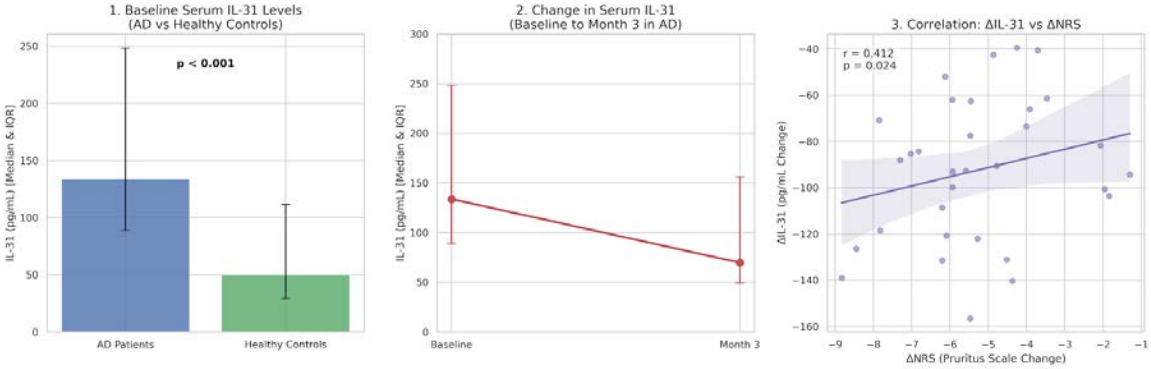
Introduction
Atopic dermatitis (AD) is a chronic inflammatory dermatosis characterized by intense pruritus, epidermal barrier dysfunction, and heterogeneous immune activation. Interleukin-31 (IL-31), a Th2-associated cytokine with recognized pruritogenic effects, has emerged as a potential link between cutaneous inflammation and neuroimmune itch pathways. Although experimental data support a pathogenic role for IL-31 in AD, clinical data on its value as a biomarker of disease burden and treatment response in adult patients remain limited and partly inconsistent. We aimed to compare baseline serum IL-31 levels in adults with AD and healthy controls, to evaluate changes in IL-31 after systemic treatment, and to examine associations between IL-31, clinical severity, pruritus intensity, and laboratory markers of systemic inflammation.

Materials and Methods
This prospective case-control study included 32 adults with AD initiating systemic treatment and 27 age- and sex-matched healthy controls. Patients received cyclosporine, dupilumab, upadacitinib, or abrocitinib according to clinical indication. In the AD group, serum IL-31 levels were measured by ELISA before treatment and at month 3. Clinical assessment included the Eczema Area and Severity Index (EASI) and itch Numerical Rating Scale (NRS). Laboratory parameters included eosinophil count, neutrophil-to-lymphocyte ratio (NLR), eosinophil-to-lymphocyte ratio (ELR), total IgE, and mean platelet volume. Associations with baseline disease severity, age at disease onset, and body mass index were also evaluated. Statistical analysis was performed using non-parametric tests, correlation analysis, and receiver operating characteristic analysis.

Results
Baseline serum IL-31 levels were significantly elevated in the AD group compared to healthy controls ($p<0.001$). ROC analysis identified a cut-off value of 69.33 pg/mL for IL-31, providing a sensitivity of 87.5% and a specificity of 66.7%(AUC = 0.851), which supports its role as a reliable peripheral biomarker. Categorical analysis revealed that patients with mild AD had significantly lower IL-31 levels than those with moderate-to-severe disease ($p=0.015$). IL-31 levels showed significant positive correlations with markers of systemic inflammation, specifically NLR ($r=0.386, p=0.029$) and ELR ($r=0.438, p=0.012$), while remaining independent of total IgE levels.Following 12 weeks of systemic therapy, serum IL-31 levels decreased significantly across all treatment groups ($p=0.001$), with no statistical difference observed between specific systemic agents ($p=0.830$). Crucially, while baseline static IL-31 measurements did not correlate with instantaneous clinical scores, the magnitude of its reduction (ΔIL-31) was significantly associated with the clinical improvement in pruritus intensity (ΔNRS) ($r=0.412, p=0.024$). This biochemical response was more pronounced in the adult-onset phenotype compared to the early-onset group ($p=0.029$). Additionally, higher BMI was found to be a limiting factor, showing a significant negative correlation with both biochemical clearance (ΔIL-31: $r=-0.456, p=0.009$) and objective clinical healing (ΔEASI: $r=-0.377, p=0.033$).



Serum IL-31 dynamics in adult atopic dermatitis. (A) Baseline serum IL-31 levels in AD patients versus healthy controls. (B) Change in serum IL-31 levels from baseline to month 3 of systemic treatment. (C) Correlation between the change in serum IL-31 (ΔIL-31) and the change in pruritus severity (ΔNRS).

Conclusions

Serum IL-31 may represent a potential biomarker in AD, reflecting not only baseline disease burden but also dynamic treatment-associated changes related to neuroimmune pruritus response. Its elevated baseline levels and discriminatory performance versus healthy controls support its potential clinical relevance. The correlation between IL-31 reduction and pruritus improvement suggests that IL-31 may serve as a complementary biological marker for disease monitoring. In addition, the association of higher BMI and early-onset phenotype with a more limited biochemical response highlights the importance of personalized approaches that also consider metabolic and phenotypic characteristics in AD management.

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Abstract N°: 961

Preliminary real-world patient-reported outcomes and mHealth engagement with lebrikizumab in moderate-to-severe atopic dermatitis: a multicenter ePROM study using the NAVETA platform

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Introduction

Introduction
Lebrikizumab is a selective IL-13 inhibitor with demonstrated efficacy in randomized trials for moderate-to-severe atopic dermatitis (AD). Real-world evidence on patient-reported outcomes (PROs) collected through digital health platforms remains limited. NAVETA is a multicenter mHealth platform enabling systematic ePROM collection and bidirectional patient-clinician communication in routine clinical practice.

Objective
To evaluate preliminary real-world effectiveness, safety, treatment satisfaction, patient experience, and digital engagement with lebrikizumab in AD patients monitored through the NAVETA ePROM platform.

Materials and Methods

Ambispective observational study of consecutive AD patients initiating lebrikizumab across 5 Spanish hospitals (February 2025–February 2026) monitored via NAVETA. ePROMs included POEM, DLQI, QoLIAD, NRS Pruritus, 5D-Pruritus, PROMIS-29 (7 T-score domains), TSQM, and P3CEQ. Patient-reported AEs, treatment persistence (Kaplan-Meier), and ePROM response rates were also analyzed. Descriptive statistics were used; no inferential analyses were performed due to sample size.

Results

Twenty-seven patients were included (63.0% male; mean age 42.2±20.6 years; disease duration 10.1±10.6 years), with a mean baseline EASI of 38.3±14.3, confirming moderate-to-severe disease. Treatment was first-line in 44.4%, second-line in 40.7%, and third-line in 14.8%, (prior dupilumab n=12, tralokinumab n=6). Mean follow-up was 7.7±3.5 months, and 33.3% used concomitant corticosteroids.
Sixteen of 27 patients (59%) completed at least one ePROM during follow-up. Despite limited sample sizes, consistent improvement was observed across all ePROMs from baseline to 12 months. Mean POEM decreased from 13.3 to 4.0, DLQI from 8.2 to 1.3, NRS Pruritus from 5.7 to 2.0, QoLIAD from 8.0 to 4.0, and 5D-Pruritus from 12.8 to 9.7. PROMIS-29 T-scores improved across all seven domains, notably depression (56.8 to 41.0), anxiety (53.3 to 42.9), fatigue (50.2 to 38.7), sleep disturbance (49.5 to 42.0), and social participation (51.6 to 64.2). Treatment satisfaction assessed by TSQM (n=10) showed high satisfaction scores for side effects (95.0±15.8), convenience (75.0±13.4), and global satisfaction (69.4±17.6), with 90% reporting no treatment-related AEs. Self-

reported AEs collected via a dedicated ePROM questionnaire (n=14) were predominantly mild (55%) or moderate (34%), with severe events in only 2 patients (14%). The most frequent were mild ocular disorders and dermatologic reactions (50% each), injection site reactions (43%, mostly mild), fatigue, musculoskeletal pain, headache, and mood changes (36% each). Patient experience (P3CEQ, n=10) yielded a score of 22.2±6.6, with all patients reporting a reference healthcare professional.
Kaplan-Meier treatment persistence was 100% at 6 months (n=16) with no discontinuations Digital engagement: 59.3% completed at least one ePROM, with response rates improving from 35.3% at baseline to 75.0% at 12 months. The bidirectional chat feature (25.9% of patients) was used primarily for appointment scheduling, adverse event reporting, and medication-related queries.

Conclusions

In this preliminary real-world multicenter analysis, lebrikizumab showed consistent improvement across disease activity, quality of life, pruritus, and general health PROs collected via the NAVETA mHealth platform, with 100% persistence at 12 months and a favorable safety profile. The platform enabled comprehensive multidimensional monitoring including patient-reported AEs, treatment experience, and bidirectional communication. Baseline ePROM completion (35.3%) highlights the need for strategies to enhance early digital engagement.

Data source: NAVETA mHealth platform – All numbers verified against raw CSV data.Hospitals: H.U. Son Espases (n=8), H.C. d'Inca (n=9), H. de Manacor (n=6), H. Mateu Orfila (n=3), H.G. de Tomelloso (n=1).

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Abstract N°: 967

Upadacitinib Targets Multiple Disease-Relevant Inflammatory Pathways and Restores Skin Barrier in Atopic Dermatitis Lesions: Extending Beyond Type 2 Responses

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Introduction

Advances in systemic therapies enable targeted modulation of inflammatory pathways driving atopic dermatitis (AD) pathophysiology. While Type 2 inflammation is characteristic of AD, the disease is heterogeneous and, especially in the chronic stage, is often marked by elevated Type 1 and Type 17/Type 22 responses. Dupilumab (DUPI) is a biologic agent that diminishes Type 2 inflammation by antagonizing interleukin (IL)-4Rα. Upadacitinib (UPA), a selective Janus kinase 1 (JAK1) inhibitor, modulates multiple inflammatory pathways signaling via JAK-STAT. We previously reported modulation of inflammatory mechanisms beyond Type 2 inflammation by UPA in peripheral blood. The current study aims to further investigate these effects in lesional skin of patients with AD.

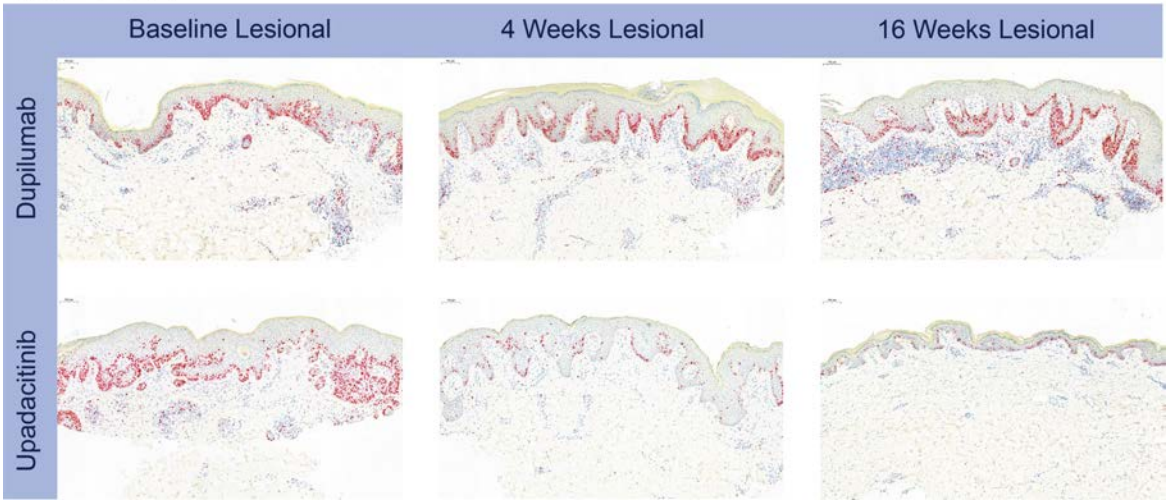
Materials and Methods

Skin biopsies were optionally collected from adults with moderate-to-severe AD in the open-label, assessor-blinded Level Up biomarker cohort (NCT05601882). Lesional biopsies were taken at baseline (BL), week 4 (W4), and week 16 (W16); non-lesional biopsies were taken at BL and W16. Thirty-three healthy control samples were obtained from multiple external vendors. At BL, 33 lesional (UPA n = 14; DUPI n = 19) and 28 non-lesional (UPA n = 12; DUPI n = 16) biopsies were collected. Bulk transcriptomics profiled differentially expressed genes (DEGs) using Benjamini-Hochberg False Discovery Rate <0.05 with log2 fold change >1. Pathway and upstream regulator analyses were conducted using Ingenuity Pathway Analysis (Qiagen). Histological assessment evaluated epidermal proliferation (Ki67) and barrier integrity (filaggrin immunostaining and measurement of epidermal thickness).

Results

Baseline lesions exhibited hallmarks of AD pathophysiology—including pathways associated with dysregulated skin barrier and increased Type 2, Type 1, Type 17/Type 22, and innate immune responses—as compared to non-lesional or healthy skin. UPA drove large changes in gene expression in lesional skin at W4, which continued through W16, with gene expression convergence between lesional and non-lesional profiles, whereas DUPI demonstrated more modest gene expression changes to lesional skin in this dataset, likely indicating DUPI's restricted targeting of Type 2 responses. UPA treatment downregulated pathways associated with Type 2, Type 1, and Type 17/Type 22 responses and normalized keratinization and tissue-remodeling responses in lesional skin as early as W4 post treatment. UPA decreased inflammatory mediators beyond Type 2 inflammation—including IL-22, S100A12, S100A9, STAT1, IRF1, IRF9 and interferon-related chemokines (CXCL10/CXCL11)—while enhancing skin barrier genes (FLG, FLG2, LCE family, LOR). Histological analysis confirmed that UPA reduced epidermal hyperproliferation (decreased Ki67 and epidermal thickness) and restored expression of barrier integrity proteins including filaggrin as early as W4, indicating rapid restoration of skin barrier integrity (Figure).

Figure. Ki67 Expression by Immunostaining in Lesional Biopsies at Baseline, Week 4, and Week 16 in Patients with Moderate-to-Severe Atopic Dermatitis Treated with Upadacitinib or Dupilumab



Abbreviations: AD, atopic dermatitis. Images at magnification of 10x.

Conclusions

UPA rapidly normalized the integrity of the epidermal barrier and attenuated multiple pathogenic inflammatory pathways in AD lesions, beyond Type 2 inflammation. While DUPI also showed evidence of some convergence in molecular normalization between lesional and non-lesional profiles, it elicited more subtle changes in pathway activity, gene expression, and histological features in this cohort. These findings are consistent with the effects previously observed in peripheral blood analyses and suggest that JAK1 inhibition may provide more rapid and comprehensive tissue-level effects than IL-4Rα antagonism, although confirmatory studies are needed. Given the exploratory nature of this cohort, between-arm comparisons are descriptive, and bulk RNA-seq thresholds may underestimate differences.

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Abstract N°: 986

Clinical Spectrum of Atopic Dermatitis with Elevated IL-6: A Cross-Sectional Study.

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Introduction
Atopic dermatitis (AD) is chronic inflammatory skin disorder characterized by pruritus, barrier dysfunction, and immune dysregulation. Cytokine Interleukin-6 (IL-6) has a critical role in inflammatory modulation and immune responses. This study aimed to evaluate clinical manifestations associated with elevated IL-6 levels in AD across diverse population.

Case Presentation

Method and Material

A total of 170 patients with clinical diagnosis of atopic dermatitis were included. Age distribution: 5–12 years (10), 12–18 years (23), 18–50 years (96), 50–75 years (41). Positive family history of atopy was seen in 120 cases. Individuals from higher socioeconomic backgrounds reported excessive hygiene practices, including over-washing and frequent use of alcohol-based sanitizers and wet wipes.

Around 10 patients had occupational exposure to industrial chemicals.

Result

Severe disease was noted in cases with reduced Ferritin,Vitamin D3 and Vitamin B12 levels. Vitamin D3 deficiency was associated with impaired barrier function, reduced antimicrobial peptide production, and increased susceptibility to recurrent *Staphylococcus aureus* infections. Low Vitamin B12 levels were associated with neuropathic pruritus. It was often intense. Elevated IL-6 levels correlated strongly with persistent, intractable pruritus, often worsening at night and disturbing sleep. Increased IL-6 was also associated with elevated serum IgE. Prevalence of food allergies, including peanuts, dust mites, egg, chicken, fish, and prawns was more with increased IL-6 levels. In several patients, pruritus was exacerbated by sweating, suggesting possible interaction between IL-6 and thermosensitive TRPV1 receptors.Higher IL-6 levels were further associated with increased incidence of pityriasis alba and recurrent *Staphylococcus aureus* infections. 18% cases showed atypical presentation including shiny erythematous papules over soles and shoulders, excoriated plaques over shoulder girdle, and one case of oozing periareolar lesion. Dennie–Morgan folds were not seen. Differential diagnosis of scabies and papular urticaria was excluded.

Management focused on symptomatic relief and barrier restoration. Sedative antihistamines, including levocetirizine and hydroxyzine, were effective in controlling pruritus. Patients were advised to use cotton clothing, avoid synthetic fabrics, and adopt gentle skincare practices, including lukewarm bathing and immediate application of fragrance-free, ceramide-rich moisturizers. “Soak and seal” method and topical corticosteroids under occlusion were beneficial for lichenified lesions. Systemic agents such as azathioprine, mycophenolate mofetil, and methotrexate showed promising results. Recurrence was observed in approximately 2% patients.

Discussion

In classical pathway, IL-6 attaches to receptor (IL-6R) on cell membrane, forming complex with gp130 and affecting cell signalling, promoting healing and regulation. Only few cells have this receptor, and pathway has controlled anti-inflammatory effect.

In trans-signalling pathway, part of IL-6 receptor is cleaved and released into bloodstream as soluble IL-6 receptor (sIL6R). IL-6 binds to sIL6R and forms complex with gp130, affecting signalling in most cells as gp130 is widely expressed, bypassing need for membrane receptor. This pathway has widespread pro-inflammatory effects and is linked with chronic inflammatory disease.

Balance between classical and trans-signalling determines overall effect. Disturbance leads to chronic inflammation and autoimmune diseases such as atopic dermatitis. Severe pruritus after sweating suggests IL-6 may modulate TRPV1 channels, increasing sensitivity to temperature changes.

Conclusion

Conclusion

IL-6 is significant mediator in atopic dermatitis, influencing clinical severity, allergic associations, and infection risk. Targeting IL-6 pathways may offer therapeutic benefit and warrants further investigation.

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Abstract N°: 990

Efficacy and Safety of Moisturizing Cream containing EOP(1), NP(3), & AP(6-II) as Adjuvant Therapy in Pediatric Patients with Mild Atopic Dermatitis: A Multicenter, Randomized, Parallel-Controlled Trial

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Introduction

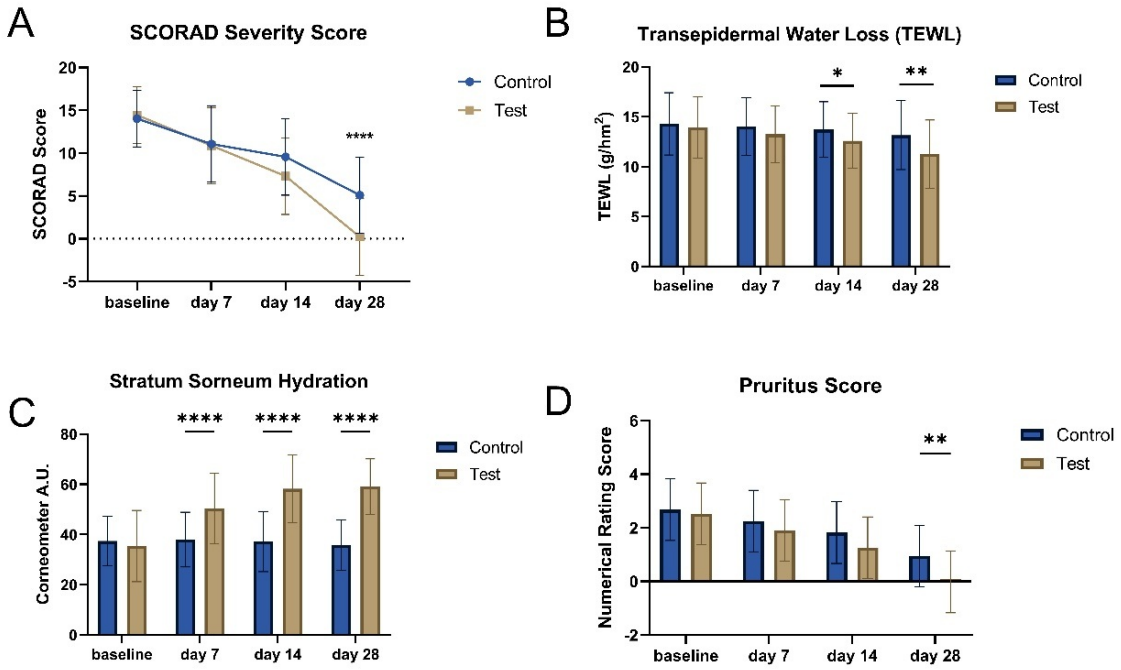
Atopic dermatitis (AD) is one of the most common chronic inflammatory skin diseases in children, characterized by skin barrier dysfunction and significant impact on quality of life. This study evaluated the efficacy and safety of a ceramide-containing moisturizer (CCM) containing ceramdes EOP(1), NP(3), & AP(6-II) as adjunctive therapy to topical crisaborole in pediatric patients with mild AD.

Materials and Methods

This study presents data from a single-center sub-cohort of a larger multicenter, randomized, parallel-controlled trial. A total of 76 pediatric patients (aged 3-14 years) with mild atopic dermatitis (AD, SCORAD 0-24) were enrolled. Patients were randomly assigned to receive either Crisaborole ointment plus Moisturizing Cream containing EOP(1), NP(3), & AP(6-II) (Test Group, n=38) or Crisaborole ointment alone (Control Group, n=38) for 4 weeks. Assessments were conducted at baseline (Day 0), Day 7, Day 14, and Day 28. Primary endpoint was SCORAD score change. Secondary endpoints included transepidermal water loss (TEWL), stratum corneum hydration (Corneometer), Children's Dermatology Life Quality Index (CDLQI) and numerical rating score for pruritus.

Results

Baseline demographics and disease severity were comparable between groups (SCORAD: 14.44±3.31 vs 14.04±3.31, P=0.719). The Test Group demonstrated significantly greater SCORAD reduction compared to Controls (group×time interaction P<0.001), achieving significantly lower scores at Day 28 (0.21±4.47 vs 5.09±4.47, P=0.006)(Figure A). TEWL showed significantly greater reduction in the Test Group at D14 and D28 (interaction P=0.012, Day 28 P=0.004)(Figure B). Stratum corneum hydration significantly improved (interaction P<0.001, Day 28 P<0.001)(Figure C). CDLQI showed numerical improvement in the Test Group compared to the Control Group at Day 28 (-0.02±2.84 vs 1.43±2.84, mean difference: -1.45; 95% CI: -2.77, -0.13). Meanwhile, numerical rating score for pruritus was significantly reduced in the Test Group at Day 28 (0.95±1.15 vs -0.02±1.15, P=0.039)(Figure D). Patient-reported experience and satisfaction scores were excellent (59.29±2.14/65 and 29.25±2.05/35, respectively), with over 90% of participants expressing willingness to continue use or purchase the product.



Legend: Efficacy of Moisturizing Cream containing EOP(1), NP(3), & AP(6-II) as Adjuvant Therapy in Pediatric Patients with Mild Atopic Dermatitis. Data are presented as mean SD. *p<0.05, **p<0.01, ****p<0.0001 vs Control group. TEWL: Transepidermal Water Loss; SCORAD: SCORing Atopic Dermatitis.

Conclusions

Moisturizing Cream containing EOP(1), NP(3), & AP(6-II) as adjunctive therapy significantly improved skin barrier function, achieved higher cure rates, and significantly reduced pruritus, while showing numerical improvements in quality of life, with excellent tolerability and patient satisfaction in pediatric patients with mild atopic dermatitis.

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Abstract N°: 991

Efficacy and safety of manfidokimab (AK120) in adults with moderate-to-severe atopic dermatitis: A randomized, double-blinded, placebo-controlled phase 3 trial

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Introduction

Interleukin-4 (IL-4) and interleukin-13 (IL-13) are pivotal cytokines that drive the Th2-mediated inflammation in diseases like atopic dermatitis (AD). Manfidokimab (AK120) is a humanized immunoglobulin G subclass 4 (IgG4) monoclonal antibody that targets the IL-4 receptor alpha (IL-4Rα) subunit, which is shared by the IL-4 and IL-13 receptor complexes. By binding to IL-4Rα, it inhibits signaling from both cytokines. This is a confirmative phase 3 trial aiming to evaluate the efficacy and safety of manfidokimab in patients with moderate-to-severe AD.

Materials and Methods

A total of 420 moderate-to-severe AD patients, aged 18–75 years, were enrolled and randomized in a 2:1 ratio to receive either manfidokimab or matching placebo. The manfidokimab group received 300 mg Q2W (with a 600 mg loading dose) through week 50. The placebo group received placebo Q2W until week 14, then crossed over to manfidokimab from week 16 (600 mg loading dose, then 300 mg Q2W until week 50).The primary endpoint was the proportion of patients achieving ≥75% improvement from baseline in Eczema Area and Severity Index (EASI-75) at week 16. The key secondary endpoint was the proportion achieving an Investigator's Global Assessment score of 0 or 1 (IGA 0/1) with a ≥2-point reduction from baseline at week 16. Other secondary endpoints included, among others, the proportion of patients achieving EASI-50 and EASI-90 responses (≥50% and ≥90% improvement from baseline, respectively) at each visit, as well as the weekly mean change and percent change from baseline in the Peak Pruritus Numerical Rating Scale (PP-NRS) score. See Figure 1 for study design.

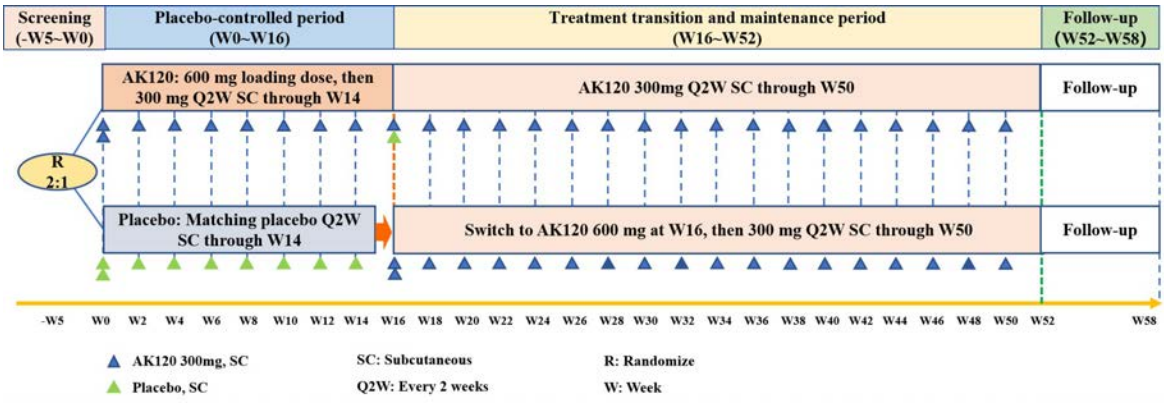

Figure 1. Overall study design

Results

Efficacy: At week 16, the proportion of patients achieving the primary endpoint was significantly higher in the manfidokimab group than in the placebo group (EASI-75: 66.5% vs 19.0%; P < 0.0001; Figure 2). The key secondary endpoint also demonstrated a significant treatment benefit (IGA 0/1 with ≥2-point improvement: 42.1% vs 7.0%; P < 0.0001; Figure 2). Manfidokimab also demonstrated superiority across all other secondary endpoints at week 16, including higher response rates for EASI-50 and EASI-90, as well as significantly greater reductions in EASI score and body surface area (BSA) affected by AD. Furthermore, manfidokimab provided rapid and substantial alleviation of pruritus and patient-reported symptoms, along with corresponding improvements in quality of life, as assessed by PP-NRS, patient-oriented eczema measure (POEM), and the dermatology life quality index (DLQI). Efficacy was sustained and continued to improve beyond week 16 through one year of treatment (The 52-week efficacy data is pending release).

Safety: During the placebo-controlled period, the incidence of treatment-emergent adverse event (TEAEs) was comparable between the manfidokimab (66.5%) and placebo (63.4%) groups. Most TEAEs were mild to moderate in severity. Serious adverse events (SAEs) were reported in 2.5% (manfidokimab) and 2.8% (placebo) of patients, respectively, with the majority considered unrelated to the treatment. No deaths occurred in this period. The most common TEAE was upper respiratory tract infection. Notably, the incidence of conjunctivitis was lower compared with approved drugs targeting the same pathway.

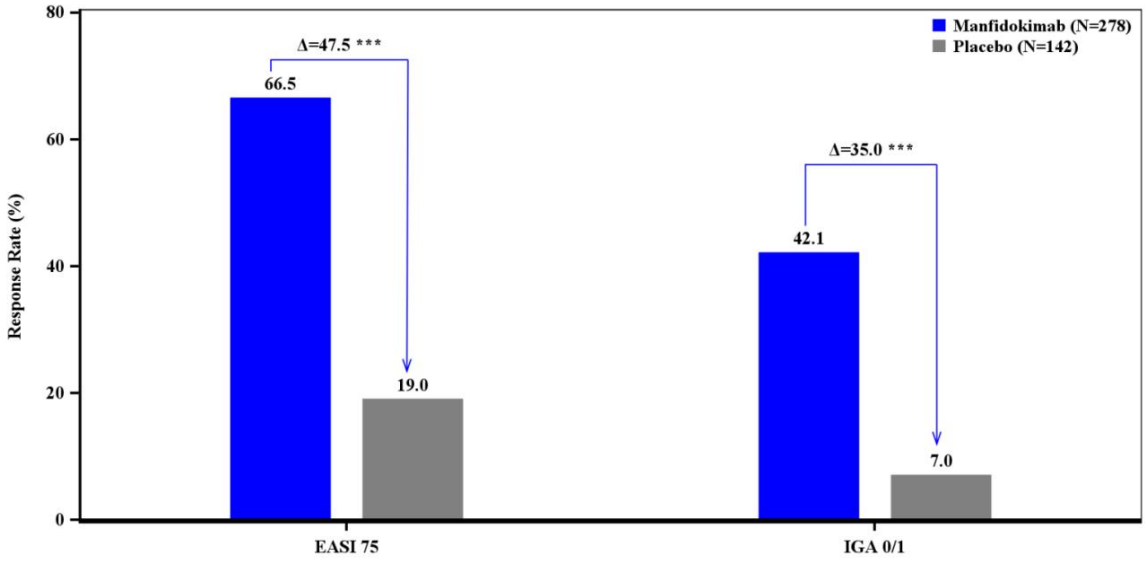

Figure 2. Primary endpoint and key secondary endpoint

Conclusions

Manfidokimab (300 mg Q2W after a 600 mg loading dose) demonstrated robust efficacy and was well tolerated in adults with moderate-to-severe AD. It also significantly improved skin lesions, pruritus, and quality of life. Notably, the treatment effect over placebo was numerically greater than that reported for the approved drugs targeting the same pathway, suggesting a potentially superior treatment option for patients with AD.

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Abstract N°: 994

Cardiovascular Risk Assessment Using SCORE2 in Patients Aged 40 - 69 Years with Atopic Dermatitis: A Case - Control Study

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Introduction

Atopic dermatitis (AD) is the most common chronic inflammatory skin disease, resulting from a complex interplay between genetic and environmental factors. It typically presents with scaly, eczematous, pruritic lesions and may persist throughout life. Topical corticosteroids, emollients, and systemic agents—such as dupilumab, tralokinumab, JAK inhibitors, and conventional immunosuppressants—are commonly used to control disease symptoms.

Inflammatory signaling pathways involving Interleukin-6, Interleukin-33, and TSLP are upregulated in AD patients, and underlie the systemic inflammation. Consequently, AD is a systemic disease associated with an increased risk of both atopic comorbidities (asthma, rhinitis, and food allergy) and nonatopic comorbidities, including ocular, psychiatric, infectious, endocrine, autoimmune, and cardiovascular diseases, as well as certain cancers.

Globally, cardiovascular diseases (CVD) are the leading cause of death. The association between AD and CVD is highlighted in the findings of a systematic meta-analysis by *Untaaveesup et al.* that moderate-to-severe AD is associated with a modest but significantly higher risk of cardiometabolic conditions such as myocardial infarction, stroke, heart failure, and hypertension.

This study aims to highlight the increased 10-year risk of fatal and nonfatal cardiovascular events by evaluating SCORE2 values in AD patients aged 40–69 years and comparing them with a healthy control group.

Materials and Methods

In this study, 42 patients diagnosed with atopic dermatitis aged 40–69 years were included. They were matched based on baseline demographics with a control group of 48 patients without any inflammatory skin diseases. Demographic data, clinical features, and laboratory test results were retrieved from the Nucleus Database at Gazi University Hospital. The primary outcome was to calculate SCORE2 values to evaluate 10-year cardiovascular risk and compare differences between the patient and healthy cohorts. Continuous variables (age, blood pressure, cholesterol, HDL, and mean SCORE2) were analyzed using the Mann-Whitney U test. Categorical variables (gender, smoking) were analyzed using the Chi-square test.

Results

As the details are shown in **Table 1**, two groups were statistically similar regarding age, gender, smoking habits, total cholesterol, HDL levels, and categorical SCORE2 risk groups. However, the patient group exhibited significantly higher systolic blood pressure values (121.74 ± 17.12 mmHg) compared to the healthy group (114.06 ± 9.77 mmHg) ($p=0.011$). Furthermore, the mean SCORE2 value was significantly elevated in the patient group (7.03 ± 6.05) compared to the control group (3.70 ± 4.11) ($p=0.001$). Upon categorizing the risk groups, a higher proportion of AD patients fell into the "high risk" category (19.0%) versus the healthy group (6.3%), though the

overall distribution across low, moderate, and high-risk groups did not reach statistical significance.

Parameter	Patient Group (n=42)	Healthy Group (n=48)	p-value
Age, mean (years)	58.40 ± 11.61	55.25 ± 8.21	0.202*
Gender, n(%)			0.181**
Female	27 (64.3%)	37 (77.1%)	
Male	15 (35.7%)	11 (22.9%)	
Smoking, n(%)			0.365**
Yes	17 (40.5%)	24 (50.0%)	
No	25 (59.5%)	24 (50.0%)	
Blood Pressure (mmHg)	121.74 ± 17.12	114.06 ± 9.77	**0.011***
Total Cholesterol (mg/dL)	196.24 ± 36.46	202.35 ± 43.29	0.811*
HDL (mg/dL)	57.20 ± 39.14	53.65 ± 15.25	0.616*
SCORE2, mean	7.03 ± 6.05	3.70 ± 4.11	**0.001***
SCORE2 Groups, n(%)			0.119**
Low Risk	20 (47.6%)	31 (64.6%)	
Moderate Risk	14 (33.3%)	14 (29.2%)	
High Risk	8 (19.0%)	3 (6.3%)	

*:Mann-Whitney U test, **: Chi-square test

Table 1 – Baseline demographic and clinical characteristics of patient and healthy groups

Conclusions

Our study substantiates current literature demonstrating a heightened risk of cardiovascular disease in atopic dermatitis patients, uniquely quantified in this study by using the standardized SCORE2 tool. These findings underscore the need for clinicians to implement early preventive measures and consider proactive cardiology consultations for patients older than 40 years, presenting with cardiac risk factors or symptoms.

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Abstract N°: 1000

Sustained improvement of paediatric atopic dermatitis with a novel emollient plus: a 6-month double blind comparative study

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease characterized by xerosis, pruritus, and alternating phases of flares and remission. Clinical guidelines recommend the use of dermocosmetic care in combination with topical corticosteroids as first-line management to alleviate clinical symptoms and improve patients' quality of life.

The present study aimed to evaluate the efficacy and tolerability of a balm emollient containing active ingredients (AD balm) compared with a glycerin-based cream (GC) over a 6-month period in infants and children with AD, with particular focus on the evolution of clinical signs and disease burden.

Materials and Methods

This controlled, comparative clinical study was conducted in Poland during winter and included 88 infants and children aged 3 months to 12 years with mild to moderate AD (SCORAD 16–40; mean score: 26). All participants presented with active flares at inclusion and had experienced at least 3 flares during the preceding 6 months (range: 3–12 flares; mean: 6).

At baseline, all subjects received an 8-day course of topical corticosteroids (D-8 to D0), combined with twice-daily whole-body and facial application of either the AD balm or GC, assigned at random. After cessation of corticosteroid therapy, participants continued applying the assigned skincare product alone for 6 months (D0 to M6).

Clinical evaluations using SCORAD and PO-SCORAD (Patient-Oriented SCORAD) were performed at D0, M2, M4, and M6, with changes assessed relative to D0 (skincare use only). SCORAD sub-scores—including pruritus, insomnia, erythema, and xerosis—were specifically analyzed. Quality of life was also assessed throughout the study.

Subjective assessments included self-reported AD flares and global product satisfaction. Tolerability and standardized skin photographs were also collected.

Results

During the 6-month period of exclusive use of the GC (D0–M6), mean SCORAD showed a reduction of 22% at Month 2 and 57% at Month 6 (compared to D0, $p>0.001$), while the AD balm demonstrated significant superior efficacy with -52% at M2 and -86% at M6 (compared to D0, $p>0.001$ versus D0 and GC). Improvements observed with PO-SCORAD closely paralleled those obtained with SCORAD.

Across all SCORAD sub-scores—including disease extent, lesion intensity, and subjective symptoms—the AD balm demonstrated greater improvements than GC. Notably, pruritus decreased significantly more with the AD balm ($p>0.001$ versus GC), with -48% at M2 and -87% at M6, compared with -17% and -56%, respectively, with GC. Similarly, insomnia decreased significantly more with the AD balm, with -92% versus -65% with GC at M6 ($p>0.01$ between products)

Consistent with clinical improvement, children's quality of life improved over time. The CDLQI score showed a significantly greater reduction with the AD balm at M6 (-53%) compared with GC (-35%) ($p>0.01$ between products). This difference was particularly evident for items related to social life (question 3 at M6) and daily activities (question 5 at M4), with scores threefold lower in the AD balm group ($p>0.01$ between products).

Subjective efficacy of the AD balm was rated positively by 79–100% of participants, and overall tolerability was excellent. Importantly, all subjects using the AD balm experienced a reduction in flare frequency during the 6-month study period compared with the previous 6 months, and 88% reported no flares at all during treatment.

Conclusions

Over a 6-month period, the novel emollient developed for AD patients demonstrated significantly superior efficacy compared with a glycerin-based cream in improving disease severity and quality of life in infants and children with atopic dermatitis. The AD balm reduced SCORAD, improved key clinical and functional signs—including disease extent, erythema, xerosis, pruritus, and insomnia —substantially decreased flare frequency, and enhanced life comfort, supporting its role as an effective adjunctive skincare in pediatric AD.

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Abstract N°: 1004

Rapid and effective skin barrier repair in atopic dermatitis with a novel emollient plus combining biomimetic lipids and actives to restore the hydrolipidic film, the stratum corneum and tight junctions

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Introduction

Atopic dermatitis (AD) affects millions worldwide and markedly impairs quality of life. AD is characterized by genetically determined and inflammation-driven skin barrier dysfunction. Barrier impairment increases transepidermal water loss (TEWL), xerosis, pruritus and scratching, and facilitates the penetration of allergens, pathogens and irritants, thereby promoting type 2 inflammation.

Beyond the long-described ceramide deficiency in AD, recent lipidomic profiling of atopic skin has shown reduced levels of additional lipids originating from both sebum and the *stratum corneum*. In addition, tight junctions in the *stratum granulosum* are impaired in AD, facilitating allergen and irritant penetration; with reduced claudin-1 expression being inversely correlated with type 2 inflammation.

We therefore assessed two combinations of ingredients designed to reinforce barrier function, as well as a novel emollient balm for AD (AD balm) incorporating these actives

Materials and Methods

Active ingredients were assessed in atopic-like models. First, a lipid blend reflecting lipids reduced in AD (fatty acids C12:0, C14:0, C16:0, C18:0, C18:1, C18:2, C20:1, C22:1; fatty alcohol FOHC22:0; wax esters C40:2, C42:2; squalane; ceramides N18P18 and A18P18; and phytosphingosine) was evaluated for *stratum corneum* strengthening via: i) filaggrin and loricrin synthesis in IL-4/IL-5/IL-13/IL-22/IL-31-treated normal human skin explants (immunostaining); and ii) long-chain ceramide synthesis in stripped human skin explants (LC-MS). Second, a duo of biomimetic ingredients (an amino acid and glycosphingolipids) was evaluated for tight junction reinforcement via claudin-1 synthesis in IL-1β/IL-33/histamine-treated human primary keratinocytes.

Clinical performance of the AD balm was evaluated in adults with moderate AD (SCORAD 25–50) in a comparative, double-blind study. Participants applied either AD balm (AD balm group, n=20) or a glycerin-containing cream (GC group; n=23) to face and body 1–2 times daily for 37 days; hygiene was standardized using a shower oil. Barrier function was assessed at day 8 (D8) and day 37 (D37) by measuring TEWL on non-lesional areas (forearm or leg). Tolerance was assessed by both patients and dermatologists.

Results

On skin explants, the biomimetic lipid blend significantly increased filaggrin (+22%), loricrin (+180%), and NP and NS long-chain ceramides (both +51%). On 2D-keratinocytes, the duo of biomimetic actives synergistically

increased claudin-1 (+250%) versus atopic-like controls.

Clinically, TEWL decreased significantly in the AD balm group from D8 (−29%, $p<0.001$) and further to D37 (−38%, $p<0.001$). In the GC group, TEWL only decreased significantly on D37 (−9%, $p<0.05$). At both time points, barrier improvement was significantly greater with AD balm than with GC ($p<0.05$). AD balm was very well tolerated, including on lesional areas when used alongside topical corticosteroids.

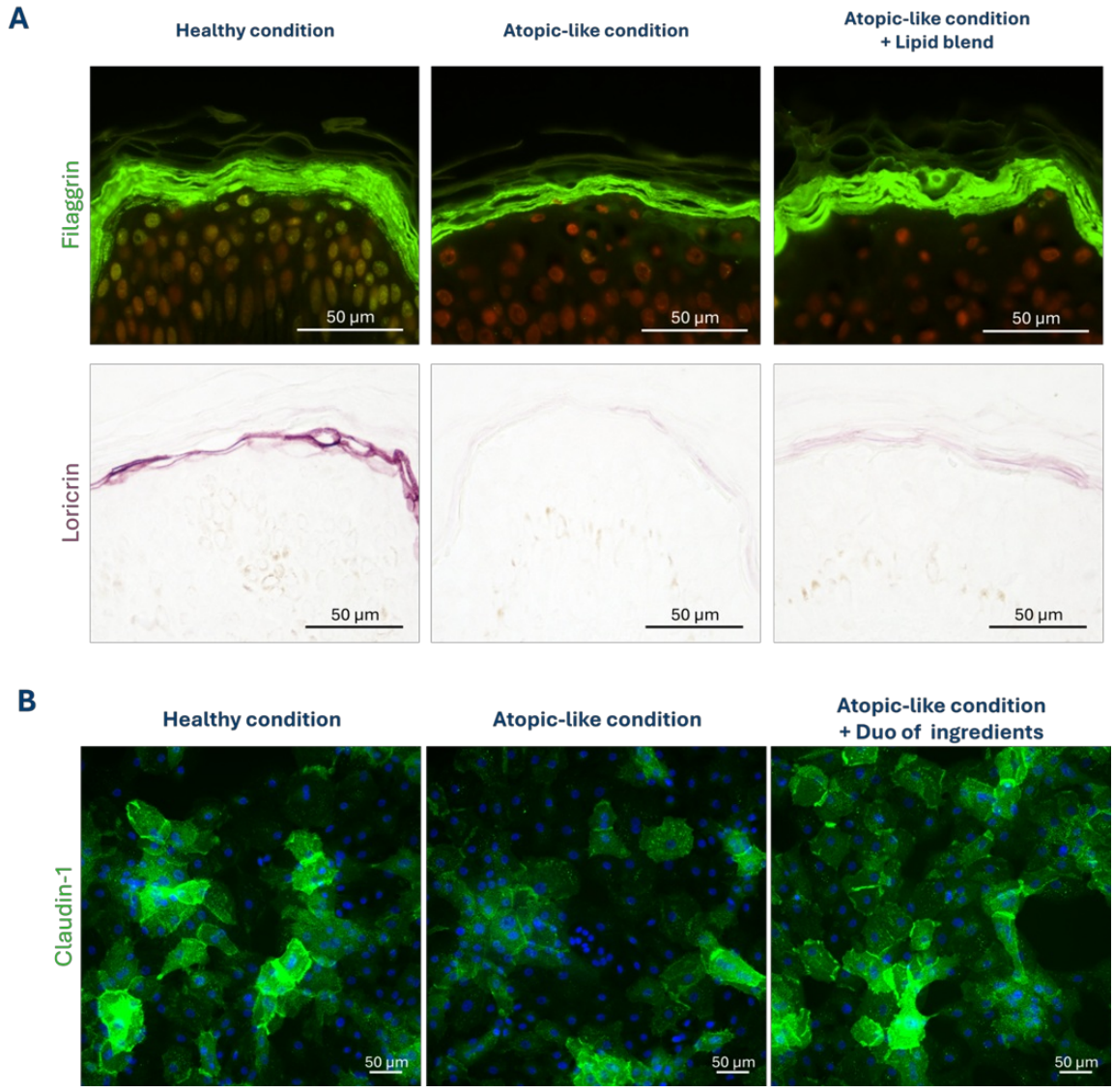

Figure 1. Immunostaining of skin barrier components on normal (left), cytokines-stressed condition (middle) and cytokines-stressed condition with addition of ingredients associations (right). A/ Filaggrin and loricrin immunostaining on human skin explants (sections). B/ Claudin-1 immunostaining on normal human primary keratinocytes.

Conclusions

Replenishing with lipids reduced in AD and biologically supporting both the *stratum corneum* and tight junctions in the *stratum granulosum*, this novel emollient balm robustly improved skin barrier function in adults with moderate AD from 8 days of use. These effects may help improve hydration and provide sustained protection against penetration of flare triggers such as allergens and irritants.

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Abstract N°: 1028

Treatment Outcomes and Failure Patterns in Multi-Refractory Atopic Dermatitis: A Single-Centre Descriptive Study

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Introduction
Atopic dermatitis is a chronic inflammatory skin disease characterized by complex pathophysiological mechanisms. The advent of targeted therapies, including monoclonal antibodies and Janus kinase inhibitors, has enabled a more precise modulation of the underlying immune pathways. In clinical practice, a particularly challenging-to-treat patient profile is increasingly recognized, defined by refractoriness to multiple lines of targeted therapies, rendering treatment switching an increasingly common strategy in dermatology settings. Although some studies suggest that factors such as the presence of atopic comorbidities may be associated with this condition, evidence regarding the clinical and demographic characteristics of this subpopulation remains limited. This study aims to describe treatment outcomes, patterns of therapeutic failure, and reasons for discontinuation across multiple advanced therapies in multi-refractory atopic dermatitis patients.

Materials and Methods
A descriptive, single-center study was conducted, collecting data from 20 patients diagnosed with severe atopic dermatitis who had received three or more advanced therapies. The analysis was conducted at two levels: per patient and per treatment line. In the treatment-line analysis, each therapeutic course was considered an independent descriptive unit, allowing a single patient to contribute multiple lines. Data are presented descriptively, and no formal statistical comparisons between treatments were performed. Baseline characteristics were described, including previous treatments and clinical scores (EASI, IGA, BSA, and pruritus NRS) prior to the initiation of advanced therapy. Data regarding the various treatment lines and the reasons for discontinuation were systematically recorded. Primary failure was defined as the inability to achieve a 50% reduction in EASI, a 2-point or greater reduction in IGA, or a 4-point or greater reduction in pruritus NRS. Secondary failure was defined as the loss of these clinical targets after they had been previously achieved during treatment. Other reasons for discontinuation included adverse events or patient preference.

Results
The study population comprised 55% males with a mean age of 33.5 years (range 25–65). Childhood-onset atopic dermatitis was observed in 70% of patients, and 60% presented with atopic comorbidities. A generalized phenotype was present in 70%, with 25% exhibiting associated prurigo nodularis. Patients presented with high baseline disease severity, with median EASI 26.5 (range 14–52), pruritus NRS 8 (range 2–10), IGA 4 (range 3–4), and BSA 40% (range 10–85). A total of 73 treatment lines were analyzed. Therapeutic failure occurred in 45 cases: 25 primary failures (predominantly with dupilumab and tralokinumab) and 20 secondary failures (mainly with upadacitinib and baricitinib). Additionally, 7 discontinuations were attributed to adverse events, primarily viral infections and acneiform eruptions. Median treatment duration was longest for upadacitinib, 13 months (range 4–42), followed by dupilumab, 10 months (range 3–36).

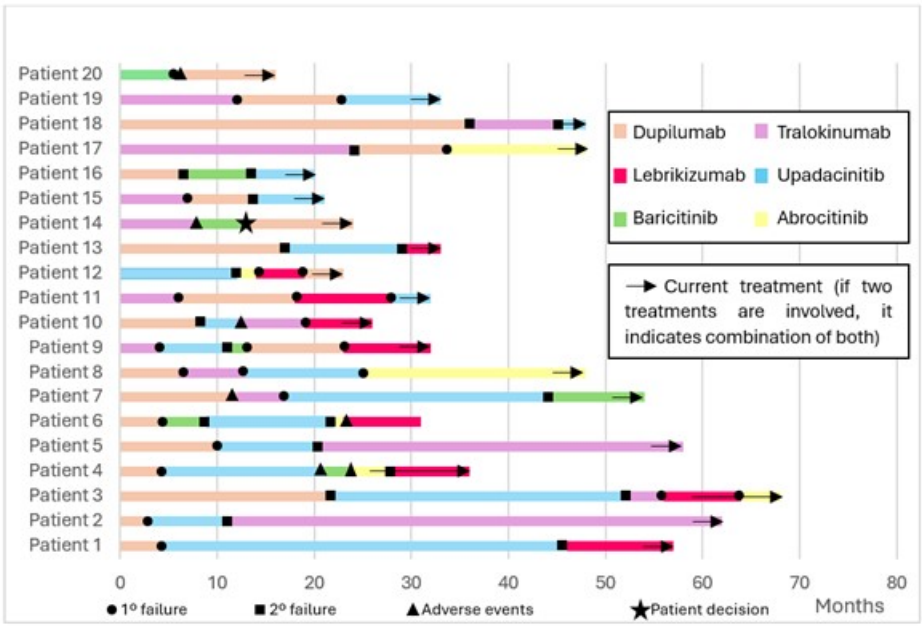

Figure 1. Swimmer plot of treatment lines per patient, showing the different therapies used and the reasons for discontinuation for each treatment.

Conclusions

Our findings highlight the therapeutic complexity of managing highly pre-treated AD patients. Prurigo nodularis and high baseline disease severity may be associated with a more refractory disease course. To our knowledge, few studies have specifically focused on patients receiving three or more advanced therapies. This descriptive analysis of multi-refractory cases underscores the need for predictive biomarkers and long-term efficacy data to optimize therapeutic sequencing in this challenging population.

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Abstract N°: 1039

Patient Reported Effectiveness of Upadacitinib for Atopic Dermatitis Using ADCT: A 6-month Interim Analysis of the Real-World AD-VISE Study by Prior Biologic Exposure

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Introduction

Upadacitinib (UPA), an oral selective Janus kinase (JAK) inhibitor administered once daily, is approved for the treatment of moderate-to-severe atopic dermatitis (AD) or eczema in adolescents and adults. Efficacy and safety of UPA have been previously reported in clinical trials and analyses of its real-world effectiveness are ongoing. Here we assess patient-perceived disease control of AD with UPA treatment using the Atopic Dermatitis Control Tool (ADCT).

Materials and Methods

AD-VISE is an ongoing observational, prospective, multicountry study evaluating the clinical effectiveness of UPA in adults and adolescents with AD over 2 years. In this interim analysis (data cutoff: Jan 16 2025), we report effectiveness for patients who enrolled ≥6 months before data cutoff date or had discontinued the study. Patient-perceived disease control was reported up to month 6 using individual questions of the ADCT. The 6 questions evaluate overall severity of symptoms (Q1), days with intense episodes of itching (Q2), bothersome intensity (Q3), problems with sleep (Q4), impact on daily activities (Q5), and impact on mood or emotions during the preceding week (Q6). Question-level results are reported for the proportion of patients achieving ADCT 0 score (no impact) or 0/1 score (little to no impact) on each question stratified by prior biologic experience (bio-naïve/bio-experienced), using non-responder imputation with multiple imputation. Safety was not assessed in this analysis.

Results

A total of 826 patients (658 bio-naïve; 168 bio-experienced) with AD were included in this analysis. After 6 months of treatment with UPA, most patients (70.9% to 86.8%) reported ADCT 0/1 (little to no impact of eczema) for all ADCT questions (Table 1). Importantly, after 6 months of treatment, patients (22.1% to 67.5%) reported no impact of their eczema on their lives (ADCT 0) for all questions (Table 1). Most patients reported intense itching ≤2 days (ADCT Q2 0/1; 80.1%) or on 0 days (ADCT Q2 0; 54.3%) in the past week. Furthermore, most patients reported having trouble falling asleep or staying asleep ≤2 nights (ADCT Q4 0/1; 86.8%) or 0 nights (ADCT Q4 0; 67.5%).

Additionally, most patients reported no effect of eczema on patients' daily activities (ADCT Q5 0; 60.8%) and no effect of eczema on mood or emotions (ADCT Q6 0; 53.8%). Results were generally similar, across all questions, regardless of prior biologic treatment (Table 1), and remained consistent between 2 and 6 months of UPA treatment.

Table 1. Responses to Individual Questions of the ADCT After 6 Months of Treatment with Upadacitinib

n (%) [95% CI]	Overall (N=826)		Bio-Naïve (N=658)		Bio-Experienced (N=168)	
	ADCT 0	ADCT 0/1	ADCT 0	ADCT 0/1	ADCT 0	ADCT 0/1
Eczema symptoms (Q1)	183 **(22.1)** [19.1, 25.2]	586 **(70.9)** [67.6, 74.3]	157 **(23.9)** [20.3, 27.4]	470 **(71.5)** [67.6, 75.3]	26 **(15.3)** [9.2, 21.4]	116 **(68.8)** [61.0, 76.6]
Intense itching (Q2)	449 **(54.3)** [50.6, 58.0]	662 **(80.1)** [77.2, 83.0]	358 **(54.3)** [50.1, 58.5]	528 **(80.3)** [76.9, 83.6]	91 **(54.3)** [46.0, 62.5]	133 **(79.4)** [72.6, 86.2]
Bothered by eczema (Q3)	305 **(37.0)** [33.4, 40.6]	662 **(75.3)** [72.1, 78.5]	247 **(37.6)** [33.5, 41.6]	495 **(75.3)** [71.7, 78.8]	58 **(34.7)** [26.8, 42.5]	127 **(75.3)** [68.1, 82.5]
Trouble sleeping (Q4)	558 **(67.5)** [64.0, 71.0]	717 **(86.8)** [84.3, 89.3]	444 **(67.5)** [63.6, 71.4]	574 **(87.2)** [84.4, 90.0]	114 **(67.7)** [59.9, 75.5]	143 **(85.0)** [79.3, 90.8]
Daily activities (Q5)	503 **(60.8)** [57.2, 64.4]	707 **(85.6)** [83.1, 88.1]	393 **(59.8)** [55.7, 63.8]	564 **(85.6)** [82.8, 88.5]	109 **(65.1)** [57.1, 73.0]	144 **(85.4)** [79.8, 91.1]
Mood or emotion (Q6)	445 **(53.8)** [50.2, 57.5]	668 **(80.8)** [77.9, 83.7]	350 **(53.2)** [49.0, 57.3]	535 **(81.3)** [78.1, 84.5]	95 **(56.5)** [48.2, 64.7]	133 **(79.0)** [72.2, 85.8]

ADCT, Atopic Dermatitis Control Tool

Conclusions

After up to 6 months of treatment with UPA, most patients reported little or no impact (question-level score 0/1), and many reported no impact of AD (question-level score 0) on most dimensions of the ADCT. These results demonstrate the stringent benefits reported by patients with AD treated with UPA in the real world. Effectiveness results were consistent over the treatment period, and regardless of prior biologic treatment experience.

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Lebrikizumab achieves rapid facial clearance in severe atopic dermatitis refractory to Dupilumab and JAK inhibitors

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Introduction

Atopic dermatitis (AD) with predominant facial involvement represents a particularly challenging clinical scenario due to its chronic course, high symptomatic burden, and significant impact on quality of life. Management is especially complex in patients refractory to multiple systemic therapies, including biologics and Janus kinase (JAK) inhibitors. Lebrikizumab, a monoclonal antibody targeting interleukin-13 (IL-13), has demonstrated efficacy in clinical trials; however, real-world evidence in multi-refractory cases remains limited.

Case Presentation

We report the case of a 45-year-old male with a 25-year history of AD, with persistent moderate-to-severe disease predominantly affecting the face. The patient had previously received multiple treatments, including topical corticosteroids, topical calcineurin inhibitors, systemic corticosteroids, cyclosporine, JAK inhibitors, and dupilumab, without achieving sustained disease control.

At baseline, the patient presented with marked facial erythema, infiltration, and scaling, associated with intense pruritus and sleep disturbance, significantly impairing quality of life. Disease severity scores were: EASI 18, BSA 12%, IGA 4, NRS pruritus 8, and NRS sleep 7.

Given the refractory nature of the disease, treatment with lebrikizumab was initiated at a loading dose of 500 mg (two 250 mg injections at weeks 0 and 2), followed by 250 mg administered subcutaneously every 2 weeks.

After 8 weeks of treatment, a rapid and marked clinical improvement was observed, particularly in facial involvement, with substantial reduction of erythema, infiltration, and scaling. Disease severity scores improved to: EASI 5, BSA 2%, IGA 2, NRS pruritus 3, and NRS sleep 2.

The patient reported significant symptomatic relief, including a notable reduction in pruritus and clear improvement in sleep quality. No relevant adverse events were observed during follow-up.

Conclusion

Lebrikizumab may represent an effective therapeutic option in patients with severe AD refractory to multiple systemic therapies, including biologics and JAK inhibitors. This case highlights a rapid and clinically meaningful response, particularly in facial involvement, a location often associated with therapeutic resistance and high impact on quality of life. These findings support its potential role as a valuable alternative in difficult-to-treat patients in real-world clinical practice. Further real-world studies are needed to better define its role in this challenging population.

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Abstract N°: 1046

Tralokinumab provides early and sustained improvements in head and neck atopic dermatitis among adolescents with moderate-to-severe disease

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Introduction

Atopic dermatitis (AD) is a fluctuating chronic disease characterized by recurrent eczematous skin lesions affecting multiple body regions. Over 70% of patients with moderate-to-severe AD have disease involving the head and neck (H&N) (1), which is particularly burdensome for adolescents. H&N involvement is difficult to treat, with a high unmet need for long-term efficacious treatments. Tralokinumab provides long-term control of H&N AD in adults treated for up to 6 years (2). Here, we evaluate the long-term efficacy of tralokinumab in adolescents with moderate-to-severe AD and H&N involvement.

Materials and Methods

This post hoc analysis includes observed efficacy data from adolescents (aged 12–17 years) with moderate-to-severe AD who had an EASI H&N score ≥1 at baseline in the Phase 3 ECZTRA 6 (E6) study. Adolescents received tralokinumab for 52 weeks in E6 (3), followed by up to 88 weeks in the long-term extension study ECZTEND (4), totaling up to 140 weeks of treatment.

H&N AD was assessed using the Eczema Area and Severity Index (EASI) H&N score, a sub-score of whole-body EASI with a maximum score of 7.2. Adolescents achieving EASI H&N <1 with tralokinumab therapy were defined as H&N responders.

Outcomes assessed include the proportion of H&N responders and proportions with: 90% improvement from baseline in whole-body EASI score (EASI-90); a Children's Dermatology Life Quality Index (CDLQI) score of 0/1; a CDLQI score of 0 for items 2 (feelings), 5 (leisure) & 8 (personal relationships); and a Worst Weekly Pruritus Numeric Rating Scale (Itch-NRS) score ≤4.

Results

172 adolescents with EASI H&N score ≥1 were randomized in E6 and 73 continued in ECZTEND. Mean age was 14.7 (SD±1.74) years and mean duration of AD was 12.4 (SD±3.67) years.

Median EASI H&N score (25th;75th percentile) decreased from 2.8 (1.8;3.6) at baseline to 1.0 (0.8;2.6) at Week 8 in E6. From Week 34 in E6 through Week 88 in ECZTEND, median EASI H&N score was ≤0.4 and the 75th percentile was ≤1.0.

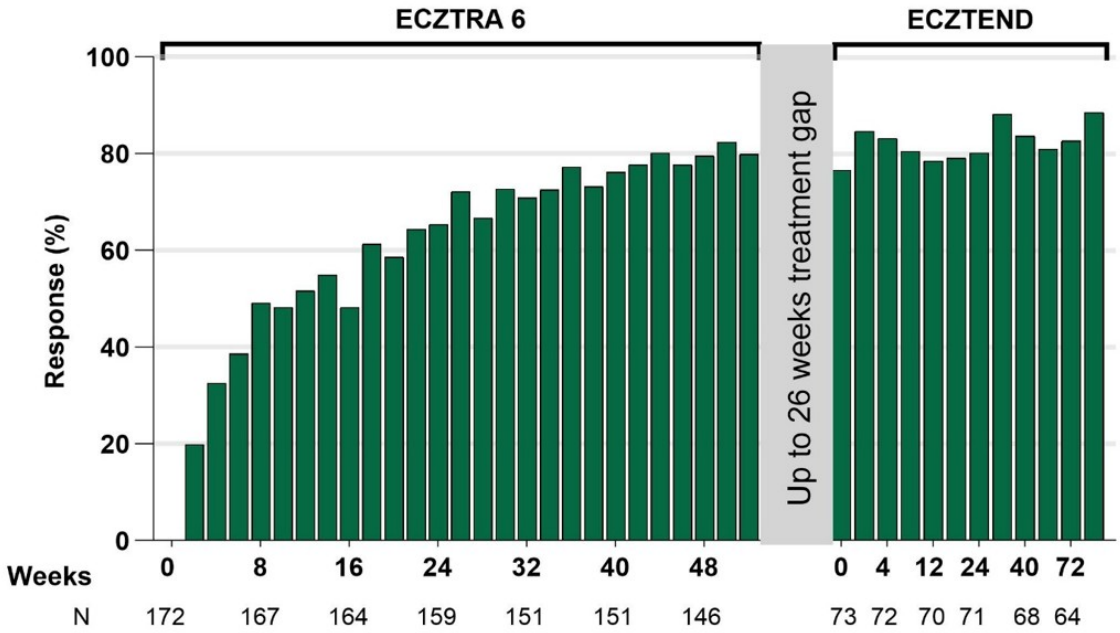
The proportion of H&N responders increased from 19.9% at Week 2, to 51.6% at Week 12 and 79.9% at Week 52 in E6, thereafter remaining stable between 76.7% and 88.6% through Week 88 in ECZTEND (Figure 1). Among H&N responders, the proportion with whole-body EASI-90 increased from 8.8% at Week 2 to 56.8% at Week 20 in E6, and reached 71.8% at Week 88 in ECZTEND.

The proportion of H&N responders with a CDLQI score of 0/1 increased from 11.8% at Week 4 to 23.7% at Week 16 in E6, remaining stable between 18.5% and 29.7% through Week 88 in ECZTEND.

For CDLQI items 2, 5, and 8, the proportions of H&N responders with a score of 0 increased from Week 2 to Week 6 in E6 for item 2 (48.5% to 63.3%) and item 5 (57.6 to 76.7%); thereafter the proportions remained stable between 53.7% and 70.9% (item 2) and 67.4% and 80.4% (item 5) until Week 88 in ECZTEND. For item 8, the proportion was stable between 84.8% and9 5.7% from Week 2 in E6 until Week 88 in ECZTEND.

The proportion of H&N responders with itch-NRS score ≤4 increased from 15.2% at Week 2 to 64.4% at Week 16 in E6, thereafter remaining stable between 48.9% and 68.3% through Week 88 in ECZTEND.

Figure 1: Proportion of H&N responders by visit in ECZTRA 6 and ECZTEND



Notes: Adolescents who achieved EASI H&N <1 with tralokinumab were defined as H&N responders.
Abbreviations: EASI = Eczema Area and Severity Index; H&N = head and neck.

Conclusions

Tralokinumab demonstrated early efficacy and long-term disease control of H&N AD in adolescents with moderate-to-severe AD. Most adolescents achieved EASI-90, and had substantial benefits in quality of life related to feelings, leisure, and personal relationships, reflecting no impact of AD on these three aspects of life.

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Abstract N°: 1056

Are emollient body wash products effective at preventing atopic symptom relapses? Biocompatibility assessment formulas of body wash, bath additive and a micellar shampoo in dry and atopic skin

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Introduction

Emollients are a baseline therapy of atopic dermatitis regardless of symptom severity. Gentle cleansing agents play a significant role in maintaining skin barrier integrity, particularly in sensitive populations such as infants and individuals with compromised skin. The use of botanical oils, rich in phytosterols and lipid-soluble vitamins, not only provides the optimum occlusive film, but also soothing effect on persistent itch. Their biocompatibility and safety of cleansing emollient formulas are critical for ensuring both efficacy and tolerability.

The aim of this study was to evaluate the biocompatibility, irritation potential, and barrier-maintaining properties of three emollient cleansing formulations: an emollient creamy cleansing gel (16911A), a bath additive (16931), and a micellar shampoo (16930). All tested products were fragrance-free and contained canola oil and hemp seed oil as key lipid components.

Materials and Methods

Biocompatibility assessment was conducted using *in vitro* models to determine cytotoxicity (L929 murine fibroblasts; agarose overlay assay), irritation potential (RHE – reconstructed human epidermis model, in accordance with ISO 10993-23:2021/Amd 1:2025) and sensitizing potential (quantification of Interleukin-18 in RHE medium after exposure to tested chemicals, in accordance with ISO 10993-10:2021). Additionally, the ability of the products to maintain skin hydration after washing was evaluated in groups of volunteers with dry, very dry and atopic skin (n=25 for 16911A, n=20 for 16930; n=23 for 16931). Clinical safety was further assessed in a study involving a group of newborns, including application from the first days of life under neonatologist and neonatal nurse supervision.

Results

All tested formulations demonstrated high biocompatibility. Agarose overlay assay showed low cytotoxic effect (grade 1 – *slight growth inhibition, cells partially degenerated under the filter disc*). Tissue viability values indicated no irritating potential (RHE viability was 106.6% for 16911A, 126.9% for 16930, and 91.0% for 16931). They were reported non-sensitizing (IL-18 concentration was lower than in negative control – untreated cells). *In vivo* analyses confirmed that the products effectively preserved skin hydration levels even after cleansing, supporting their protective action on the skin barrier. The formulas were very well perceived by the volunteers, with isolated cases of adverse events, none of which were considered serious adverse events (one for 16911A, one for 16930, one for 16931). In case of 16930, pH level after single application of the product remained unchanged, which is particularly important considering relatively high level of surfactant. In the clinical study involving newborns, all three products were very well tolerated, with no adverse reactions reported. Their safety profile was confirmed for use from the first days of life.

Conclusions

The evaluated emollient cleansing gel, bath additive, and micellar shampoo exhibited high biocompatibility, low irritation potential, and the ability to maintain skin hydration after use. The presence of canola oil and hemp seed oil likely contributes to their beneficial effect on the skin barrier. The favorable safety outcomes, including confirmation in newborns, support their suitability for sensitive skin care from birth.

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Abstract N°: 1067

Two year real-world effectiveness, safety, and drug-survival of JAK inhibitors in moderate-to-severe atopic dermatitis: results from the BioDay registry.

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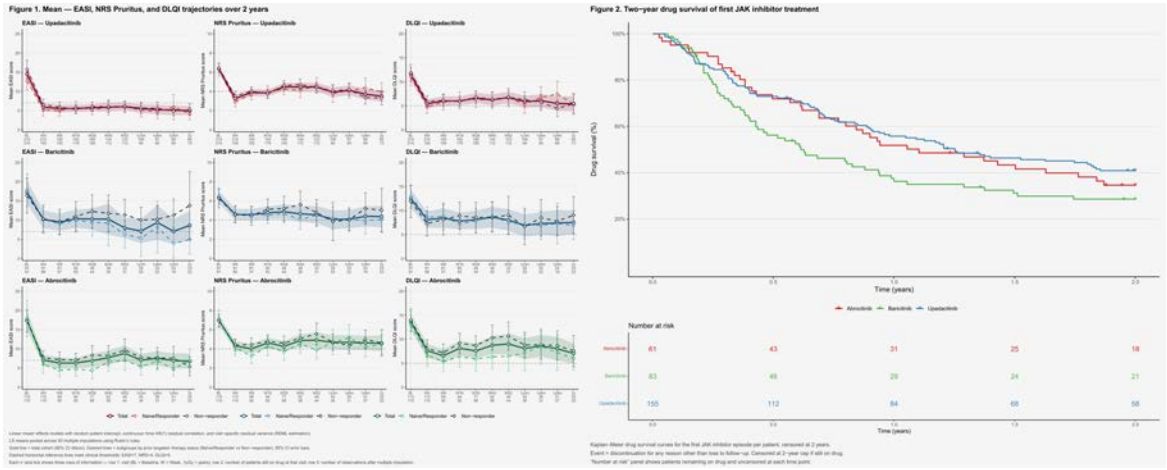
Introduction
JAK inhibitors (JAKi) are increasingly used for moderate-to-severe atopic dermatitis (AD). Given the chronic course of AD and recent European Medicines Agency safety warnings associated with JAKi use, long-term real-world data on effectiveness and safety are essential to inform clinical practice. This study evaluated the effectiveness, safety, and drug survival of upadacitinib, abrocitinib, and baricitinib over 2 years.

Materials and Methods
This prospective cohort study included patients aged ≥12 years with moderate-to-severe AD initiating upadacitinib, abrocitinib, or baricitinib from the multicenter BioDay registry. The first treatment episode (TE) per JAKi type was included. Visits were scheduled at baseline, weeks 4, 8, 16, and every 3 months up to 2 years. Effectiveness was assessed using the Eczema Area and Severity Index (EASI), weekly average Numeric Rating Scale (WA-NRS) for pruritus, Dermatology Life Quality Index (DLQI), and the Recap of Atopic Eczema (RECAP; measured at baseline, week 16, week 52, 18 months, and 2 years). Patients were stratified into two subgroups based on prior advanced systemic therapy: (I) biologic- and JAKi-naïve or previous responders (discontinued for reasons other than ineffectiveness), and (II) those who discontinued prior biologic or JAKi therapy due to ineffectiveness. Safety was assessed by adverse events (AEs). In addition, drug survival limited to the first JAKi treatment episode (first-JAKi subcohort), and a composite endpoint of drug survival and achievement of treatment targets EASI ≤7 and WA-NRS pruritus ≤4 were evaluated. Missing outcome values at observed visits were imputed by multiple imputation (50 imputations). Mean trajectories were estimated using linear mixed models. Drug survival was analyzed using Kaplan-Meier and adjusted Cox regression.

Results

A total of 311 patients with 411 treatment episodes were included (upadacitinib n=210, abrocitinib n=110, baricitinib n=91). EASI, WA-NRS pruritus, DLQI, and RECAP improved significantly over time within each JAKi (P<0.001), with no significant trajectory differences between prior-treatment subgroups within any JAKi. At 2 years, mean (95% CI) values for upadacitinib, abrocitinib, and baricitinib were: EASI 5.0 (3.9-6.2), 6.8 (4.9-8.8), and 8.6 (4.8-12.5); WA-NRS 3.5 (2.9-4.1), 4.6 (3.7-5.4), and 4.4 (3.3-5.5); DLQI 5.4 (3.9-7.0), 7.1 (4.9-9.2), and 7.5 (5.1-9.9); and RECAP 7.6 (6.1-9.2), 8.9 (6.5-11.2), and 8.3 (5.7-11.0). Two-year discontinuation rates were 59.5%, 70.9%, and 74.7% for upadacitinib, abrocitinib, and baricitinib, respectively, driven mainly by ineffectiveness (40.0%, 46.2%, 67.6%), AEs (30.4%, 29.5%, 13.2%), or a combination of both (11.2%, 11.5%, 7.4%). The most frequent AEs were acneiform eruptions with upadacitinib (15.5%) and abrocitinib (21.7%), and airway infections with baricitinib (12.5%).

In the first-JAKi subcohort (upadacitinib n=155, abrocitinib n=61, baricitinib n=83), 2-year discontinuation rates were 61.3%, 67.2%, and 73.5%, respectively. Baricitinib drug survival was significantly lower compared to both upadacitinib (HR 0.58, 95% CI 0.40-0.82) and abrocitinib (HR 0.60, 95% CI 0.39-0.92), whereas abrocitinib and upadacitinib drug survival did not differ significantly (HR 1.05, 95% CI 0.72-1.54). Among patients still on treatment at 2 years, 74% on upadacitinib, 69% on abrocitinib, and 61% on baricitinib met the treatment targets of EASI ≤7 and WA-NRS pruritus ≤4.



Conclusions

In this real-world cohort, abrocitinib, baricitinib, and upadacitinib provided significant improvement in both clinical and patient-reported outcomes over 2 years, regardless of prior advanced systemic treatment. However, 60-75% of patients discontinued JAKi therapy within 2 years, predominantly due to ineffectiveness or AEs. These findings highlight the need for strategies to identify patients most likely to achieve sustained response, in order to optimize JAKi selection and support more personalized treatment decisions in AD.

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Baseline Demographics, Clinical Characteristics and Disease Burden Among Patients with Atopic Dermatitis (AD) Treated with Lebrikizumab in Real-World Clinical Practice: Interim Results from a European Prospective Observational Study (ADtrust)

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Introduction

In phase 3 trials, lebrikizumab (LEB) has demonstrated significant clinical benefit in patients (pts) with atopic dermatitis (AD).[1] Since clinical trial populations may not represent the full diversity of pts, real-world evidence on patient characteristics and treatment patterns is highly relevant to clinical decision-making. The objective of this analysis was to report the baseline (BL) demographics, clinical characteristics and humanistic burden among pts with AD treated with LEB in real-world clinical settings across Europe.

Materials and Methods

We report an interim analysis of the ongoing, single-arm, prospective cohort study, ADtrust (NCT06815380), conducted in adults with moderate-to-severe AD who were newly initiated on LEB as part of routine clinical care across Europe. Both pts and clinicians completed surveys and clinical assessments over a period of two years. Patient self-assessments included psychological well-being using the World Health Organisation-Five Well-Being Index (WHO-5; range 0–100; higher scores indicate better well-being; change of ≥10 considered clinically relevant; primary endpoint of study),[2] AD burden associated with itch, sleep, fatigue and pain on a Numeric Rating Scale (NRS; range 0–10; 0=no symptoms, 10=worst symptoms imaginable),[3] impact of AD on patient life using the Dermatology Life Quality Index (DLQI; range 0–30; higher scores represent a greater impairment in health-related quality of life; 0–1.99: no effect on patient life),[4] AD control using the Atopic Dermatitis Control Tool (ADCT; range 0–24; higher scores indicate worse disease control),[5] proportion of pts experiencing ≥1 AD flare in the past 12 months (defined as a sudden and severe worsening of AD signs and symptoms requiring treatment change),[6] and the Patient-Oriented Eczema Measure (POEM; range 0–28; higher scores indicate worse symptoms).[7] Clinician-

reported assessments of AD severity included the Eczema Area and Severity Index (EASI; range 0–72; higher scores indicate greater severity) and Investigator Global Assessment (IGA; range 0–4; higher scores indicate greater AD severity).[8] This interim analysis was performed when at least 300 pts were enrolled.

Results

A total of 319 pts completed the BL surveys and were included in the analyses; mean (standard deviation [SD]) age: 39.1 (15.6) years; female: 50.8%. At BL, 25.1% smoked daily/occasionally, 78.7% drank alcohol daily/occasionally and 67.4% were employed full/part-time. Of those included, 295 pts had evaluable clinician-reported assessments. At BL, the majority of pts had moderate (74.6%) or severe (22.7%) AD based on overall IGA score; 84.4% had an EASI score >7 and mean (SD) EASI score was 18.7 (12.0). Mean (SD) WHO-5 score was 49.4 (21.6). Mean (SD) NRS scores of AD burden were: itch 6.3 (2.4), sleep 4.9 (3.0), fatigue 5.2 (2.9) and pain 4.9 (2.9). Mean (SD) impact of AD scores were: DLQI 15.4 (7.2) and POEM 18.4 (6.6). Mean (SD) ADCT score was 15.9 (5.3); 95.9% of pts had $\geq$1 AD flare in the past 12 months. To manage these flares, 61.0% and 27.4% of pts used topical and systemic treatments, respectively. The top three reasons for stopping previous treatments prior to initiating LEB were: “topical therapy alone was not sufficient” (57.3%), “previous systemic therapy was not sufficient” (42.7%) and “previous systemic therapy was not tolerated” (17.0%).

Conclusions

In real-world clinical practice settings in Europe, pts with AD who were newly initiated on LEB showed considerable multidimensional disease burden at BL across AD signs, symptoms and quality of life despite previous treatments.

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An Inflammatory-Driven Ex Vivo Human Skin Model to Mimic Atopic Dermatitis–Like Barrier Dysfunction

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease with a complex and multifactorial pathophysiology involving epidermal barrier dysfunction, immune dysregulation, and altered host–microbiome interactions. Central to its pathogenesis is a Th2-skewed immune response, characterized by elevated levels of interleukin-4 (IL-4) and interleukin-13 (IL-13), which directly impair keratinocyte differentiation and downregulate epidermal key structural proteins such as filaggrin. The resulting barrier disruption promotes increased transepidermal water loss, enhanced penetration of allergens and irritants, and heightened susceptibility to microbial colonization, perpetuating a vicious cycle of inflammation and barrier impairment.Beyond its cutaneous manifestations, AD represents a systemic inflammatory condition with significant clinical burden, impacting quality of life and predisposing patients to other atopic comorbidities. Therefore, the development of translational and physiologically relevant models capable of reproducing key disease mechanisms is essential to support both mechanistic studies and the evaluation of therapeutic strategies.Human ex vivo skin models have emerged as a highly relevant experimental approach in dermatological research, as they preserve native tissue architecture, including epidermal stratification and intercellular communication, while enabling controlled induction of disease-like conditions. These models provide a unique opportunity to investigate inflammatory processes in a clinically meaningful context, bridging the gap between reductionist in vitro systems and in vivo human studies

Materials and Methods

In the present study, a human ex vivo skin model was established to reproduce key molecular and functional features of AD-like inflammation, with a particular focus on epidermal barrier disruption. To mimic the Th2-driven inflammatory milieu characteristic of AD, skin explants were exposed to IL-4 and IL-13. An initial pro-inflammatory stimulus was applied on Day 1 using elevated cytokine concentrations (100 ng/mL each), followed by sustained exposure at 30 ng/mL from Days 2 to 4, aiming to replicate both the acute activation and chronic persistence of the inflammatory response observed in patients.On Day 5, skin samples were collected for analysis. Explants were cryopreserved, cryosectioned, and subjected to immunohistochemical staining to assess filaggrin expression as a key biomarker of epidermal barrier integrity. This approach enabled the evaluation of cytokine-induced alterations within a preserved tissue context, closely reflecting in vivo conditions.

Results

Cytokine exposure resulted in a marked and statistically significant reduction in filaggrin expression (−51.56% vs. basal control, $P < 0.001$), confirming the effective induction of a barrier-disrupted phenotype consistent with AD pathophysiology. The magnitude of this reduction highlights the critical role of IL-4 and IL-13 in driving structural impairment of the epidermis and supports the translational relevance of the model.

Conclusions

Taken together, these findings demonstrate that this human ex vivo skin model reliably reproduces key immunopathological features of atopic dermatitis, particularly those associated with Th2-mediated barrier dysfunction. This platform represents a robust, reproducible, and ethically relevant tool for dermatological

research, with strong potential for investigating disease mechanisms and supporting the preclinical evaluation of therapeutic and dermocosmetic interventions targeting barrier restoration in patients with AD and sensitive skin conditions.

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Abstract N°: 1085

Dissecting IL-4, IL-13, and TSLP Signaling Reveals Complementary Roles in Cutaneous Type 2 Inflammation

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Introduction

The cytokines IL-4 and IL-13 are critical drivers of atopic disease, inducing downstream effectors associated with inflammation, edema, pruritus, airway hyper-responsiveness, and mucus secretion. Engagement of their common receptor, IL4RA, activates STAT6, inducing expression of genes mediating a range of inflammatory responses. TSLP is also elevated in AD, asthma, and COPD and has been implicated in promoting type 2 immune responses at epithelial barrier surfaces. Upon barrier damage, TSLP regulates production of type 2 cytokines and downstream effector responses. Although TSLP is an upstream regulator of IL-4 and IL-13, it also triggers distinct signaling pathways linked to STAT5, the blockade of which may provide additional therapeutic benefit. Antibodies neutralizing IL4RA and IL13 are approved for several atopic indications, and antibodies neutralizing TSLP are approved for use in both allergic and non-allergic asthma. PF-07275315 is trispecific antibody being developed for the treatment of AD, asthma, and COPD, which simultaneously neutralizes IL-4, IL-13, and TSLP. It is hypothesized that simultaneous blockade of these cytokines will more fully inhibit the effector functions of type 2 immune responses while generating additional efficacy from non-type 2 STAT5-induced pathways.

Materials and Methods

In this study, we stimulated human skin explants with recombinant IL-4, IL-13 and/or TSLP and conducted RNA-sequencing to characterize the unique and overlapping transcriptional signatures.

Results

3749 genes were significantly perturbed by IL-4 and IL-13 and 2066 genes by TSLP. Of these, 838 genes were shared. Shared genes were enriched for markers of type 2 immune activation. Genes unique to IL-4 and IL-13 were enriched in maintenance of keratinocyte barrier function, whereas those unique to TSLP were enriched in lymphocyte survival, stromal and vascular remodeling.

Conclusions

These data demonstrate that TSLP orchestrates both shared and unique inflammatory processes compared to IL-4/13 and suggest that combined blockade with PF-07275315 may provide patients with additional efficacy compared to standards of care.

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Abstract N°: 1090

Duration-Dependent Adverse Events of Systemic Glucocorticosteroids in Atopic Dermatitis: A Nationwide Claims Cohort Study

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Introduction
Systemic glucocorticosteroids (SGCs) are recommended only for short-term treatment of atopic dermatitis (AD) because of their side effect profile. Nevertheless, prolonged and repeated use remains common in routine care. Evidence on whether treatment duration or cumulative dose is the main driver of adverse events is limited. To investigate the longitudinal association between SGC treatment duration and side effect in persons with AD and to compare its impact with cumulative dose.

Materials and Methods
A retrospective cohort study based on German statutory health insurance data including persons with AD initiating SGC therapy. Associations between SGC exposure and side effect were analysed using logistic regression and adjusted time-dependent Cox models.

Results
Longer treatment duration was associated with higher odds of multiple side effect including osteoporosis (ORs 1.21–1.27). In time-dependent Cox models, each additional quarter of SGC therapy increased the hazard of mental disorders (HR 1.21; 95% CI 1.10–1.32), gastritis/duodenitis (HR 1.07; 1.00–1.15), osteoporosis (HR 1.37; 1.23–1.52), hypertension (HR 1.26; 1.08–1.48), and diabetes mellitus (HR 1.35; 1.09–1.69).

Conclusions
Prolonged SGC therapy is associated with increasing risks of multiple SE, supporting guideline recommendations for short-term use only. Treatment duration is a more relevant risk driver than cumulative dose.

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Abstract N°: 1092

Prevalence, Treatment Patterns and Comorbidities of Severe Chronic Hand Eczema

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Introduction
Chronic hand eczema (CHE) is a prevalent work-related skin condition, significantly contributing to symptom burden and economic costs. Timely diagnosis and treatment according to guidelines are crucial. This retrospective cross-sectional study aimed to evaluate the prevalence, real-world care, and comorbidities of individuals with severe CHE in Germany.

Materials and Methods
We analyzed anonymized routine data from DAK-Gesundheit covering the years 2016 to 2022. Alitretinoin prescriptions (ATC D11AH04) alongside an eczema diagnosis (ICD-10-GM L20–L30) served as a proxy for prevalence of severe CHE. Healthcare pathways were examined before and after alitretinoin initiation. Comorbidities were assessed by comparing persons without eczema diagnosis and alitretinoin prescription.

Results
From 2016 to 2022, the annual number of alitretinoin recipients with severe CHE remained stable, ranging from 9.35 to 9.97 per 100,000 persons. In 2022, the average age was 57 years, with 59% being female; the highest prevalence was noted among adults aged 35–65 years and older. Prior to starting alitretinoin, topical glucocorticosteroids (GCs) were most commonly prescribed treatment (67%), followed by systemic GCs (24%), both of which decreased after treatment commencement (52% and 10%, respectively). The duration of alitretinoin treatment decreased over consecutive quarters (38% in the first quarter; 13% in the five quarter). In the index quarter, 85% of prescriptions were issued by dermatologist, who accounted for the majority of defined daily doses. Significant comorbidity associations were identified with chronic skin diseases, including psoriasis (OR = 17.98, 95% CI = 13.18–24.54), urticaria (OR = 7.28, 95% CI = 3.72–14.22), and rosacea (OR = 3.47, 95% CI = 1.84–6.56).

Conclusions
The treatment observed landscape for severe CHE largely corresponds with national guidelines, reflecting effective real-world application.

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Abstract N°: 1096

Pathways and Predictors of Systemic Glucocorticosteroid Prescription in Atopic Dermatitis: A Longitudinal Claims Data–Based Analysis

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Introduction
Although the guidelines recommend the short-term use of systemic glucocorticosteroids (SGCs) for atopic dermatitis (AD) due to potential side effects, studies show that these medications are often prescribed inappropriately. However, there is only limited information available on the care situation of these individuals. This longitudinal analysis aimed to characterize the care patterns of individuals with AD and SGCs prescriptions, and to identify predictors to derive a safer, guideline-oriented care.

Materials and Methods
Using routine data from the statutory health insurance system (SHI data), individuals (aged ≥18 years) with AD and at least one SGCs index prescription in 2019 were identified (n=4,292; mean age=55.96 years; 72.6% female). Daily cumulative SGCs doses (DDDs) over the entire three-year SGCs prescription period were grouped using k-medoids clustering (partitioning around medoids) with dynamic time warping (DTW) distance. Predictors were identified using adjusted bivariate logistic regression.

Results
We identified three clusters - Persons in cluster 1 had a high SGCs intensity (mean = 407.1 days, mean DDD = 777.5) and received off-label prescriptions more frequently (OR range: 1.06–1.21), while guideline-compliant prescriptions were more common in cluster 2 with medium SGCs intensity (mean = 391.1 days, mean DDD = 206.83, OR: 1.07; 95% CI: 1.02–1.13). Dermatologists were significantly involved in initial SGCs prescriptions and AD follow-up treatments in cluster 3 with low SGCs intensity (mean = 182.2 days, mean DDD = 40.8), while general practitioners primarily took on this role in clusters with higher SGCs intensity.

Conclusions
For the first time, extensive time-dependent cluster analyses of SGCs treatment pathways were carried out. By identifying different care pathways we observed patterns indicate discrepancies between recommended systemic therapy options and actual care. Additionally, ongoing quality deficits among various specialist groups were highlighted. This emphasizes the need for a more guideline-oriented, interdisciplinary approach.

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Abstract N°: 1100

A Real-World Short-Term Study on the Efficacy and Safety of Stapokibart in Middle-Aged and Elderly Patients with Moderate-to-Severe Atopic Dermatitis

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Introduction

Stapokibart, a monoclonal antibody targeting interleukin-4 receptor alpha (IL-4Rα), has demonstrated promising efficacy in moderate-to-severe atopic dermatitis (AD). However, real-world evidence in middle-aged and elderly patients remains limited. This study evaluated the real-world efficacy and safety of stapokibart in middle-aged and elderly patients with moderate-to-severe AD.

Materials and Methods

This real-world observational study included 66 middle-aged and elderly patients with moderate-to-severe AD treated with stapokibart at a tertiary dermatology center in China. Patients received a 600 mg loading dose followed by 300 mg subcutaneously every two weeks for up to 16 weeks. Clinical outcomes, including Eczema Area and Severity Index (EASI), validated Investigator Global Assessment for AD (vIGA-AD), body surface area (BSA), Itch Numerical Rating Scale (NRS), Sleep NRS, and Dermatology Life Quality Index (DLQI), were assessed longitudinally. The primary endpoint was percentage change in EASI from baseline to Week 12.

Results

Among 66 enrolled patients (mean age 64.6 ± 9.1 years), rapid and clinically meaningful improvement was observed from Week 2 onward across all efficacy outcomes. Mean EASI decreased from 20.9 ± 3.4 at baseline to 4.7 ± 3.6 at Week 12, representing a mean reduction of 78.0% ($P < 0.001$) (A). Sustained reductions were also observed in vIGA-AD, BSA, DLQI, Itch NRS, and Sleep NRS throughout follow-up, indicating substantial improvement in disease severity, pruritus burden, sleep disturbance, and quality of life (B). At Week 16, observed-case response rates for EASI50, EASI75, and EASI90 reached 96.2%, 88.5%, and 57.7%, respectively, demonstrating deep and sustained clinical responses with continued treatment (C). Stapokibart was generally well tolerated, with injection-site reactions being the most common adverse event. No serious adverse events were reported during the observation period.

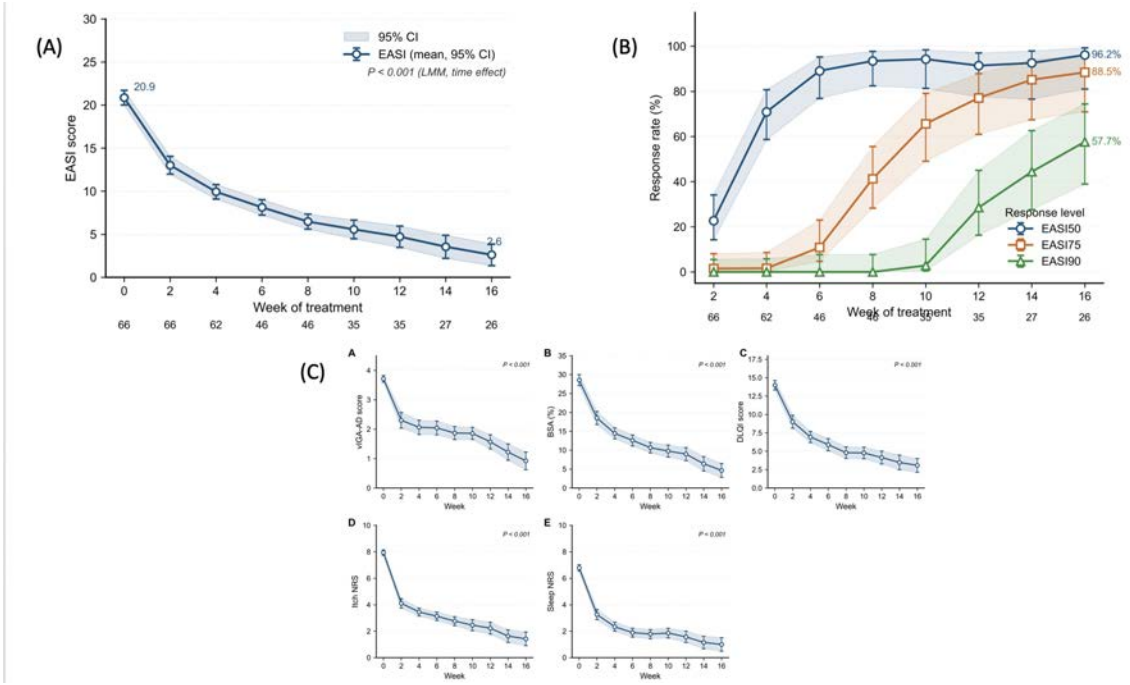

Figure. Longitudinal changes in clinical efficacy outcomes during 16 weeks of stapokibart treatment. (A) Mean EASI scores demonstrated rapid and sustained improvement throughout follow-up. (B) Significant reductions were observed in vIGA-AD, BSA, DLQI, Itch NRS, and Sleep NRS, reflecting improvements in disease severity, pruritus burden, sleep disturbance, and quality of life. (C) Progressive increases in EASI50, EASI75, and EASI90 response rates were observed over time, demonstrating deep and sustained clinical responses with continued treatment. Symbols and shaded bands represent mean or point estimates and 95% confidence intervals, respectively. Numbers below the x-axis indicate the number of patients evaluated at each visit (observed-case analysis).

Conclusions

Stapokibart demonstrated rapid, effective, and generally well-tolerated clinical outcomes in middle-aged and elderly patients with moderate-to-severe atopic dermatitis in a real-world setting. Significant improvements were observed across disease severity, pruritus, sleep disturbance, and quality-of-life measures from early treatment stages onward. These findings support stapokibart as a promising therapeutic option for middle-aged and elderly patients with moderate-to-severe AD in routine clinical practice.

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Abstract N°: 1104

Lebrikizumab Impact on Alleviating Disease Severity, Itch Burden and Quality of Life, in Patients with Moderate-to-Severe Atopic Dermatitis (AD): 16-Week Interim Results from a European Prospective Observational Study (ADtrust)

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Introduction

In phase 3 trials, lebrikizumab (LEB) has demonstrated significant effectiveness in treating patients (pts) with atopic dermatitis (AD).[1] Real-world evidence highlighting the benefit associated with LEB use in clinical practice is emerging. The objective of this analysis was to assess disease severity, itch burden and impact on health-related quality of life (HRQoL) at Week (W) 16 among pts with moderate-to-severe AD treated with LEB in real-world clinical settings across Europe.

Materials and Methods

We report an interim analysis of the ongoing, single-arm, prospective cohort study, ADtrust (NCT06815380), conducted in adults with moderate-to-severe AD who were newly initiated on LEB as part of routine clinical care across Europe. Both pts and clinicians completed surveys and clinical assessments over a period of two years. Clinician-reported assessments included the evaluation of treatment response using the Eczema Area and Severity Index (EASI; score 0–72; higher scores indicate greater severity; meaningful change: 6.6).[2] Patient self-assessments included evaluation of itch burden using the itch Numerical Rating Scale (NRS; score 0–10; higher scores indicate more severe itching; meaningful change: 3.0),[3] and impact of AD on patient life using the Dermatology Life Quality Index (DLQI; score 0–30; higher scores indicate greater impairment in HRQoL; 0–1.99: no effect on patient life; meaningful change: 4.0).[4] This interim analysis was performed when at least 100 pts completed the study assessments at W16. Changes from baseline (CfB) at W16 for mean EASI and itch NRS scores, as well as the proportion of pts achieving ≥50% improvement from baseline (BL) in EASI (EASI 50), ≥75% improvement from BL in EASI (EASI 75) and ≥90% improvement from BL in EASI (EASI 90) at W16 are reported as observed cases.

Results

A total of 107 pts completed W16 surveys and were included in the analyses; mean (standard deviation [SD]) age: 40.1 (15.7) years; female: 48.6%. Of those included, 103 pts had evaluable clinician-reported assessments. Almost half of pts (45.8%) initiated LEB treatment because previous systemic therapy was not sufficient. At W16, a meaningful decrease in EASI score from BL was observed: mean CfB: −12.5 (BL: 17.8; W16: 5.3). At W16, 75.7% of pts achieved EASI 50, while 53.4% and 27.2% achieved EASI 75 and EASI 90, respectively. Among pts with an EASI score >7 at BL, 67.1% achieved EASI ≤7 at W16. At W16, meaningful decreases from BL were observed in itch NRS (mean CfB: −3.2 [BL: 6.1; W16: 2.9]) and DLQI scores (mean CfB: −8.4 [BL: 14.6; W16: 6.2]).

Conclusions

In real-world clinical practice settings in Europe, the majority of pts with moderate-to-severe AD receiving LEB at W16 experienced meaningful reductions in EASI, itch NRS and DLQI scores, highlighting treatment effectiveness in this population.

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Abstract N°: 1105

Lebrikizumab Real-World Effectiveness and Patient Satisfaction in Patients with Moderate-to-Severe Atopic Dermatitis (AD) and Face or Hand Involvement: 16-Week Interim Results from a European Prospective Observational Study (ADtrust)

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Introduction

Atopic dermatitis (AD) poses considerable psychosocial and functional burdens on patients (pts), especially when visible areas, such as the face and hands, are involved.[1] Real-world evidence highlighting the benefit associated with lebrikizumab (LEB) use in alleviating these burdens in clinical practice is limited. The objective of this analysis was to assess the Investigator Global Assessment (IGA) of overall AD severity, as well as AD severity on the face and hands, using specific IGA scores designed to examine improvements in these body regions (Face IGA and Hands IGA). In addition, Week (W) 16 satisfaction of pts with moderate-to-severe AD treated with LEB in real-world clinical practice settings across Europe was evaluated.

Materials and Methods

We report an interim analysis of the ongoing, single-arm, prospective cohort study, ADtrust (NCT06815380), conducted in adults with moderate-to-severe AD who were newly initiated on LEB as part of routine clinical care across Europe. Both pts and clinicians completed surveys and clinical assessments over a period of two years. Clinician-reported assessments included the evaluation of treatment response using IGA of overall AD severity (Overall IGA), and AD severity on the face (Face IGA) and hands (Hands IGA); each of the IGAs were scored as 0 (clear), 1 (almost clear), 2 (mild), 3 (moderate) or 4 (severe).[2] Patient self-assessments included satisfaction with LEB treatment measured using the Treatment Satisfaction Questionnaire for Medication score (TSQM-9: three domains [treatment effectiveness, convenience of use, overall satisfaction] range 0–100; higher scores represent higher satisfaction).[3] This interim analysis was performed when at least 100 pts completed the study assessments at W16. In each respective IGA group, among pts with baseline (BL) IGA ≥3, the percentages of pts at W16 with ≥1-point improvement in IGA score from BL, and those with IGA 0/1 and ≥2-point reduction in IGA score from BL were assessed. Overall patient satisfaction scores were also assessed. Data are reported as observed cases.

Results

A total of 107 pts completed W16 surveys and were included in the analyses; mean (standard deviation [SD]) age: 40.1 (15.7) years; female: 48.6%. Of those included, 103 pts had evaluable clinician-reported assessments. Among pts with BL IGA ≥3 (in each respective IGA group), the percentages of pts at W16 with ≥1-point improvement in IGA score from BL were: Overall IGA (n=102): 84.3%; Face IGA (n=56): 82.1%; Hands IGA (n=46): 91.3%. The percentages of pts at W16 with IGA 0/1 and ≥2-point reduction in IGA score from BL were: Overall IGA (n=102): 50.0%; Face IGA (n=56): 46.4%; Hands IGA (n=46): 65.2%. At W16, mean (SD) TSQM-9 scores for the individual domains were: effectiveness: 71.8 (25.2); convenience of use: 80.3 (17.2); global satisfaction: 76.7 (22.7).

Conclusions

In real-world clinical practice settings in Europe, the majority of pts with moderate-to-severe AD using LEB at W16 experienced consistent improvement in Overall, as well as Face and Hands, IGA scores, highlighting similar treatment effectiveness across different body regions, including impactful areas. Pts also reported high levels of satisfaction with LEB treatment.

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Abstract N°: 1108

Lebrikizumab Impact on Patient-Reported Outcomes (PROs) Among Patients with Atopic Dermatitis (AD) in Real-World Clinical Practice: 16-Week Interim Results from a European Prospective Observational Study (ADtrust)

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Introduction

Atopic dermatitis (AD) has considerable psychosocial effects on patients (pts), negatively impacting quality of life and causing substantial disease burden.[1] The objective of this analysis was to assess the impact of lebrikizumab (LEB) on patient-reported outcomes (PROs). We report impact on quality of life and psychological well-being, disease control, AD signs and symptoms and itch/skin pain/fatigue/sleep burden at Week (W) 16 among pts with moderate-to-severe AD treated with LEB in real-world clinical practice settings across Europe.

Materials and Methods

We report an interim analysis of the ongoing, single-arm, prospective cohort study, ADtrust (NCT06815380), conducted in adults with moderate-to-severe AD who were newly initiated on LEB as part of routine clinical care across Europe. Both pts and clinicians completed surveys and clinical assessments over a period of two years. Patient self-assessments included psychological well-being using the World Health Organisation-Five Well-Being Index (WHO-5; range 0–100; higher scores indicate better well-being; change of ≥10 considered clinically relevant; primary endpoint of study),[2] impact of AD on patient life using the Dermatology Life Quality Index (DLQI; range 0–30; higher scores indicate greater impairment in health-related quality of life; 0–1.99: no effect on patient life; meaningful change: 4.0),[3] AD control using the Atopic Dermatitis Control Tool (ADCT; range 0–24; higher scores indicate worse disease control; meaningful change: 5.0),[4] Patient-Oriented Eczema Measure (POEM; range

0–28; higher scores indicate worse symptoms; meaningful change: 3.4),[5] and AD burden associated with itch, fatigue, skin pain and sleep disturbance on a Numeric Rating Scale (NRS; range 0–10; 0=no symptoms, 10=worst symptoms imaginable; meaningful change: 4.0 [itch], 2.2–2.9 [skin pain], 2.0–4.0 [sleep], no validated meaningful change established for fatigue NRS scores in AD).[6] This interim analysis was performed when at least 100 pts completed the study assessments at W16. Data are reported as observed cases.

Results

A total of 107 pts were included in the analyses; mean (standard deviation [SD]) age: 40.1 years (15.7); female: 48.6%. An improvement in WHO-5 scores from baseline (BL) was observed at W16 (mean change from BL [CfB]: 10.7 [BL: 51.3; W16: 62.1]). Among pts with a BL DLQI score ≥4, 75.2% had a ≥4-point improvement in DLQI score at W16. Two-thirds (67.3%) had a ≥5-point reduction in ADCT score from BL at W16. A meaningful reduction in POEM scores from BL was observed at W16 (mean CfB: −10.2 [BL: 17.7; W16: 7.5]). Among pts with a BL itch NRS score ≥4, 47.7% had a ≥4-point improvement in itch NRS scores at W16. At W16, a numerical decrease in score from BL was observed in fatigue NRS (mean CfB: −2.1 [BL: 5.0; W16: 2.9]) and a meaningful decrease in scores from BL was observed in skin pain NRS (mean CfB: −2.9 [BL: 4.9; W16: 2.0]) and sleep NRS (mean CfB: −2.4 [BL: 4.3; W16: 1.9]).

Conclusions

In real-world clinical practice settings in Europe, most pts with moderate-to-severe AD treated with LEB experienced meaningful improvements in AD signs and symptoms, as well as overall well-being by W16. This was accompanied by meaningful reductions in itch/skin pain/fatigue/sleep burden and AD impact on quality of life. These outcomes suggest that treatment effectiveness with LEB translated into improvements in PROs.

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EADV CONGRESS
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Abstract N°: 1126

Adjunctive Polyvalent Bacteriophage Therapy in Pediatric Atopic Dermatitis: Clinical Improvement and Reduction of Staphylococcus aureus Colonization

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with epidermal barrier impairment and microbial dysbiosis, particularly Staphylococcus aureus overcolonization. Microbiome-targeted approaches may provide a useful adjunctive strategy in pediatric AD. This study aimed to evaluate the clinical and microbiological effects of adjunctive polyvalent bacteriophage therapy in children with AD.

Materials and Methods
A total of 40 pediatric patients aged 1–18 years with AD were included in this non-randomized comparative study. Patients were allocated into two groups: a bacteriophage group (n=21) receiving standard therapy for 10 days plus adjunctive polyvalent bacteriophage therapy for 5 days, and a control group (n=19) receiving standard therapy alone for 10 days. Standard therapy included antihistamines, emollients, and topical mometasone cream. Clinical severity was assessed before and after treatment using the SCORAD and EASI indices. Skin microbiota samples were collected from standardized body sites using sterile swabs. Microbiological analysis included culture-based methods, MALDI-TOF mass spectrometry, and antimicrobial susceptibility testing according to EUCAST recommendations. Quantitative bacterial load was expressed as CFU/cm^2. Outcome changes were analyzed descriptively as absolute and percentage differences.

Results
Greater improvement was observed in the bacteriophage group than in the control group. SCORAD decreased from 45.3 to 23.5 in the bacteriophage group versus 45.8 to 36.8 in the control group. EASI decreased from 12.1 to 5.8 versus 12.3 to 10.2, respectively. In the bacteriophage group, S. aureus colonization decreased from 4.8×10^4 to 8.5×10^2 CFU/cm^2, corresponding to an approximate 2-log reduction, whereas only a modest decrease was observed in the control group.

Conclusions
In this non-randomized comparative study, adjunctive polyvalent bacteriophage therapy was associated with greater clinical improvement and a more pronounced reduction in S. aureus colonization than standard therapy alone in pediatric AD. These findings support further evaluation of microbiome-targeted adjunctive strategies in controlled studies.

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Abstract N°: 1128

Impact of Disease Duration on Clinical Responses and Short-Term Safety With Abrocitinib Combination Therapy in Patients With Moderate-to-Severe Atopic Dermatitis

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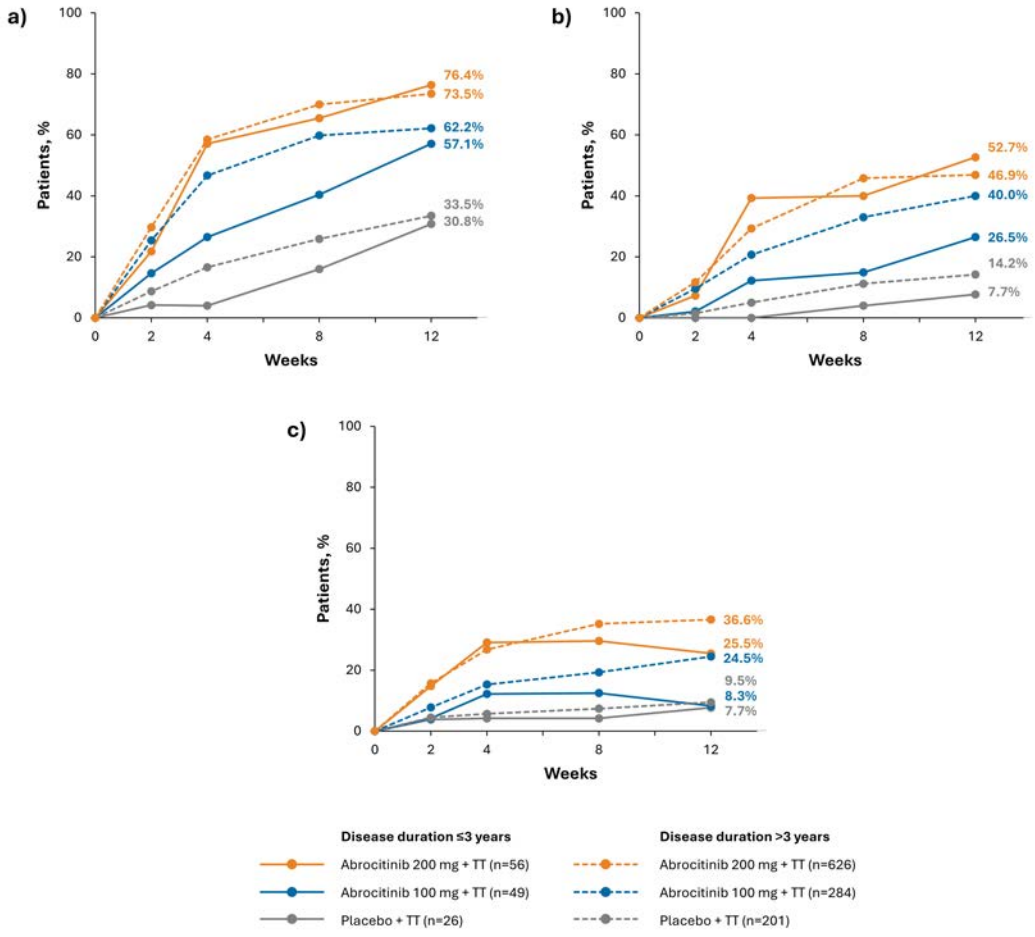
Introduction
Atopic dermatitis (AD) is a common, chronic, inflammatory skin disorder. Longer AD duration is associated with chronic itch driven by established, adaptive immune pathways, whereas shorter duration may reflect earlier, more acute symptoms mediated by innate immune responses. Abrocitinib is an oral, once-daily, Janus kinase 1-selective inhibitor approved for the treatment of adults and adolescents with moderate-to-severe AD. The effect of shorter versus longer AD disease duration on treatment outcomes is unclear. Here, we explore the impact of time since initial AD diagnosis on patient response to abrocitinib.

Materials and Methods
This post hoc analysis included adult and adolescent (≥12 years) patients with moderate-to-severe AD from JADE COMPARE (NCT03720470), TEEN (NCT03796676), and DARE (NCT04345367) who received abrocitinib (200 mg or 100 mg) or placebo with concomitant topical therapy (TT). Patients were categorized by AD disease duration at baseline, defined as time since initial diagnosis (≤3 vs >3 years). Assessments included ≥75%/90% improvement from baseline in Eczema Area and Severity Index score (EASI-75/90) and Peak Pruritus Numerical Rating Scale score of 0 or 1 (PP-NRS 0/1) through Week 12. Safety was assessed via treatment-emergent adverse event (TEAE) monitoring throughout. Data are reported with nonresponder imputation.

Results
Among patients with baseline AD disease duration ≤3 vs >3 years, 56 vs 626, 49 vs 284, and 26 vs 201 received abrocitinib 200 mg + TT, abrocitinib 100 mg + TT, and placebo + TT, respectively. Mean age was 34.8 years and 31.9 years in the ≤3 and >3 years groups, respectively. Median EASI at baseline was 21.4 and 26.6 for patients with disease duration ≤3 and >3 years, respectively, and mean EASI was 25.6 and 30.5, respectively. Median PP-NRS score at baseline for patients with disease duration ≤3 and >3 years was 8.0 and 7.0, respectively; mean PP-NRS score was 7.4 and 7.3, respectively. At Week 12, the proportion of patients with ≤3 vs >3 years disease duration who achieved EASI-75/90 response was 76.4%/52.7% vs 73.5%/46.9% with abrocitinib 200 mg + TT, 57.1%/26.5% vs 62.2%/40.0% with abrocitinib 100 mg + TT, and 30.8%/7.7% vs 33.5%/14.2% with placebo + TT (**Figure 1a/b**). The proportion of patients in the ≤3 vs >3 years groups achieving PP-NRS 0/1 response at Week 12 was 25.5% vs 36.6%, 8.3% vs 24.5%, and 7.7% vs 9.5% with abrocitinib 200 mg + TT, abrocitinib 100 mg + TT,

and placebo + TT, respectively (**Figure 1c**). Safety findings were consistent with those observed in the wider JADE clinical development program. Patients with >3 years disease duration had numerically higher rates of TEAEs and infections; however, no differences between disease duration groups were observed in serious TEAEs or clinically significant safety risks. No differences were observed between groups in serious infections, malignancy, cardiovascular safety, or venous thromboembolism events, and no qualitative differences in the types of TEAEs were reported.

Figure 1. Proportion of Patients Achieving (a) EASI-75, (b) EASI-90, and (c) PP-NRS 0/1 Response by Baseline AD Disease Duration



AD, atopic dermatitis; EASI-75/90, ≥75%/90% improvement from baseline in Eczema Area and Severity Index score; PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 or 1; TT, topical therapy.

Conclusions

In this post hoc analysis, shorter disease duration was associated with higher skin clearance responses with abrocitinib 200 mg plus concomitant TT through Week 12, while patients with longer disease duration were more likely to achieve an itch-free state at Week 12, potentially consistent with differences in AD pathophysiology over time. Prolonged duration of AD may shift central itch processing and subjective itch valuation, potentially explaining the higher rates of 4-point itch reduction in participants with >3 years disease duration. Further research is warranted to better understand how disease duration may influence treatment response, including potential differences in the microbiome, skin barrier, and immune pathways of itch and skin clearance.

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Abstract N°: 1140

Usage, Barriers, and Clinical Impact of Patient-Reported Outcome in Atopic Dermatitis Care: Findings from a Japanese Physician Survey

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease that markedly impairs quality of life (QOL). Although recent advances in biologics and molecular-targeted therapies have improved objective clinical outcomes, patient-perceived symptoms such as pruritus and their impact on daily activities often persist, underscoring the need for comprehensive assessment beyond clinician-reported outcome (ClinRO).

Japanese AD treatment guidelines recommend the use of patient-reported outcome (PRO) to complement ClinRO in routine clinical practice, aiming to achieve and maintain symptom control without disruption of daily life. PRO assessment is also expected to facilitate physician–patient communication and support shared decision-making. However, PRO was originally developed for clinical trials, and its real-world feasibility and sustainability remain insufficiently characterized.

Despite the availability of validated PRO instruments recommended in Japan, real-world uptake appears limited. A global survey reported that fewer than 20% of physicians routinely use PRO in AD management, suggesting that daily clinical decision-making largely relies on ClinRO. Country-specific evidence addressing implementation barriers and practical impact on clinical workflow is scarce. This study aimed to clarify the current status of PRO use in routine AD care in Japan and to identify key barriers, facilitators, and perceived clinical impact.

Materials and Methods

A nationwide, cross-sectional, web-based survey was conducted among 385 Japanese physicians who independently managed outpatient AD care, assessing PRO usage status, purposes of assessment, barriers and facilitators to implementation, impact on consultation time and staff workload, patient behavioral changes, and unmet informational needs using descriptive analyses.

Results

Among 385 physicians, 31.7% reported routine use of PRO, 33.0% were past users, and 35.3% had never used PRO. Among current users, the most frequently applied instruments were the Patient-Oriented Eczema Measure (POEM; 55.7%) and dermatology-specific quality-of-life measures (DLQI/CDLQI/IDQoL; 40.2%).

PRO assessments were primarily implemented to monitor disease control (56.6%), facilitate physician–patient communication (46.7%), and improve consultation efficiency (44.3%). Key barriers to PRO implementation included increased patient burden (35.0%), insufficient physician knowledge regarding interpretation and application of PRO data (34.6%), and concerns about disruption of clinical workflow (30.8%). The most commonly cited facilitators were reimbursement eligibility for PRO assessment (60.3%) and stronger evidence demonstrating clinical usefulness (44.2%).

Regarding consultation time, most current users reported either no change (43.4%) or reduced consultation time (34.4%), whereas nearly half of past users perceived longer consultations (49.6%). Increased staff workload was reported in both groups but was more frequent among past users than current users (53.5% vs 41.0%).

PRO use was perceived to promote positive patient behaviors, including earlier reporting of symptom changes (current users: 66.4%; past users: 56.7%) and greater engagement in treatment decision-making (current users: 63.2%; past users: 53.5%). Unmet information needs regarding appropriate PRO use were particularly pronounced among past users (38.6%) and never users (35.3%), as were needs related to practical implementation (38.6% and 33.8%, respectively).

Conclusions

Despite guideline recommendations, routine PRO assessment in Japanese AD practice remains limited. While PRO may enhance patient engagement and support efficient clinical evaluation, increased staff workload and insufficient physician knowledge regarding PRO represents a key barrier to implementation. Practical operational guidance, and educational initiatives are essential to facilitate effective and durable integration of PRO into routine AD care.

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Abstract N°: 1148

Itch-dominant Phenotype in Atopic Dermatitis: Prevalence, Biomarker Dissociation, and Therapeutic Implications

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Introduction
Atopic dermatitis (AD) is characterized by eczematous skin lesions and intense pruritus, both contributing independently to disease burden. Current eligibility criteria for advanced therapies rely predominantly on objective lesion-based measures — most notably the Eczema Area and Severity Index (EASI) — potentially excluding patients whose symptom burden is driven by disproportionate pruritus rather than lesion severity alone. Therefore, we aimed to characterize the prevalence, clinical profile, inflammatory biomarker features, and treatment response of the itch-dominant phenotype in AD.

Materials and Methods
In this retrospective study, 289 AD patients were stratified into four phenotypic groups based on baseline EASI (cutoff: 16) and Itch Numeric Rating Scale (NRS; cutoff: 7): moderate lesion–moderate itch (ML-MI; n=69), moderate lesion–severe itch (ML-SI; n=103), severe lesion–moderate itch (SL-MI; n=36), and severe lesion–severe itch (SL-SI; n=81). The ML-SI group was designated the itch-dominant phenotype. Clinical variables, inflammatory biomarkers (total IgE, peripheral eosinophil count), EASI subscores, and regional scores were compared across groups. Multivariate logistic regression adjusted for age and sex was performed to identify independent predictors of itch-dominant phenotype within each lesion-severity stratum. Treatment response at follow-up was assessed by change in Itch NRS and percentage EASI improvement.

Results
The ML-SI itch-dominant group was the single largest subgroup, comprising 35.6% of the entire cohort. Despite reporting pruritus severity comparable to the most severe group (SL-SI; both NRS ≥7), ML-SI patients showed no significant differences from ML-MI in total IgE (p=0.33) or peripheral eosinophil counts (p=0.80), demonstrating a clear dissociation between severe pruritus and type 2 inflammatory biomarkers. ML-SI patients had significantly higher erythema subscores (median 3.0 vs. 2.6; p=0.013) and trunk regional EASI subscores (median 3.8 vs. 2.9; p=0.004) compared to ML-MI, despite equivalent total EASI. On multivariate analysis in the moderate-lesion stratum, baseline erythema subscore (OR 1.57; 95% CI 1.12–2.22; p=0.009) and trunk EASI subscore (OR 1.28; 95% CI 1.07–1.54; p=0.008) were independent predictors of itch-dominant phenotype. In the severe-lesion stratum, excoriation subscore was the sole independent predictor of severe itch (OR 1.71; 95% CI 1.19–2.61; p=0.007), despite equivalent total EASI, IgE, and eosinophil levels between SL-SI and SL-MI. At follow-up, ML-SI patients demonstrated the greatest improvement in Itch NRS of all groups (median reduction 3.0 points; Kruskal-Wallis p<0.001), while EASI improvement did not differ significantly across groups (p=0.251).

Conclusions
The itch-dominant phenotype (ML-SI) was the most prevalent subgroup in this AD cohort. Severe pruritus in these patients was not explained by type 2 inflammatory biomarkers alone, implicating neurogenic sensitization as a key driver. The selective elevation of erythema subscore and trunk distribution suggests a distinct neuro-inflammatory state sustaining itch beyond classical immune activation. ML-SI patients represent a high-yield therapeutic target,

demonstrating the greatest pruritus improvement at follow-up. Incorporating Itch NRS alongside EASI in treatment eligibility frameworks may better reflect the full burden of AD and ensure equitable access to advanced therapies for patients with itch-dominant disease.

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Abstract N°: 1158

Lebrikizumab Provides Clinically Meaningful Response in Face and Hands in Adults and Adolescents with Moderate-to-Severe Atopic Dermatitis: ADhope 1 Study

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Introduction

Most patients (pts) with atopic dermatitis (AD) have face or hands involvement, posing a major psychological burden, including stigmatisation and impact on quality of life.[1] There is a need to generate data with new endpoints specifically measuring efficacy in these impactful and clinically meaningful areas. Lebrikizumab (LEB) is a monoclonal antibody that selectively targets the cytokine interleukin-13 with high affinity, blocking its downstream signalling; LEB is approved for moderate-to-severe (mod-sev) AD and has previously demonstrated efficacy and a favourable safety profile.[2–4] Here, we report LEB efficacy in face and hands using data from the ADhope 1 study (NCT05990725).

Materials and Methods

ADhope 1 was a 24-Week (W), interventional, single-arm, open-label study in adults and adolescents (≥12 to <18 years, ≥40 kg) with an Eczema Area and Severity Index (EASI) ≥12, Investigator's Global Assessment (IGA) ≥3, ≥10% body surface area of uncontrolled AD and who were not adequately controlled with topical therapies. Prior dupilumab use was allowed. Pts received 500 mg dose at baseline (BL) and W2, then 250 mg every 2 weeks (Q2W) until W16, followed by 250 mg Q4W until W24, regardless of response. Topical corticosteroid use was allowed. Response in the face was defined as Face IGA 0/1 with ≥2-point improvement from BL, in pts with Face IGA ≥2 at BL; Face IGA ≥1-point improvement from BL in the same population is also reported. Percent change from BL in modified Total Lesion Symptom Score (mTLSS) assessed response in hands. 13 pts from one site had to be excluded due to quality issues and data are reported in the modified Full Analysis Set (mFAS). Treatment discontinuation due to lack of efficacy was considered as non-response, while treatment discontinuations due to any other reason, as well as any other missing data, were handled through multiple imputation. Data collected after use of prohibited medication were included in the analysis.

Results

A total of 260 pts were enrolled. Efficacy was assessed in 247 pts from the mFAS. At BL, the mean age (standard deviation [SD]) of pts was 32.8 (14.1) years, 61.1% were male and 8.5% had previous dupilumab exposure. Mean (SD) EASI score was 23.1 (9.0), mean (SD) Pruritus Numerical Rating Scale was 6.7 (1.6) and IGA scores of 3

(moderate) and 4 (severe) were reported in 74.1% and 25.9% of pts, respectively. 69.6% of pts had Face IGA ≥2 at BL (15.8% Face IGA=2, mild; 42.5% Face IGA=3, moderate; 11.3% Face IGA=4, severe) and 64.0% had AD in their hands (mean [SD] BL mTLSS was 9.7 [4.1]).

79.1% of the pts with Face IGA ≥2 at BL achieved Face IGA ≥1-point improvement at W24; 61.7% achieved this endpoint by W4 and 76.3% achieved it at W16 (**Figure**). 44.8% of the pts with Face IGA ≥2 at BL, achieved Face IGA 0/1 with ≥2-point improvement at W24; 18.8% achieved this endpoint by W4 and 30.6% achieved it at W16. The response in the face correlated well with the overall response in the body, with 11.0%, 32.3% and 41.3% of pts reporting IGA 0/1 at W4, W16 and W24, respectively. For the pts with AD in the hands at BL (n=158; 64.0%), the mean percent change from BL in mTLSS progressively increased over time, from −37.9% at W4, to −62.1% at W16 and −66.3% at W24.

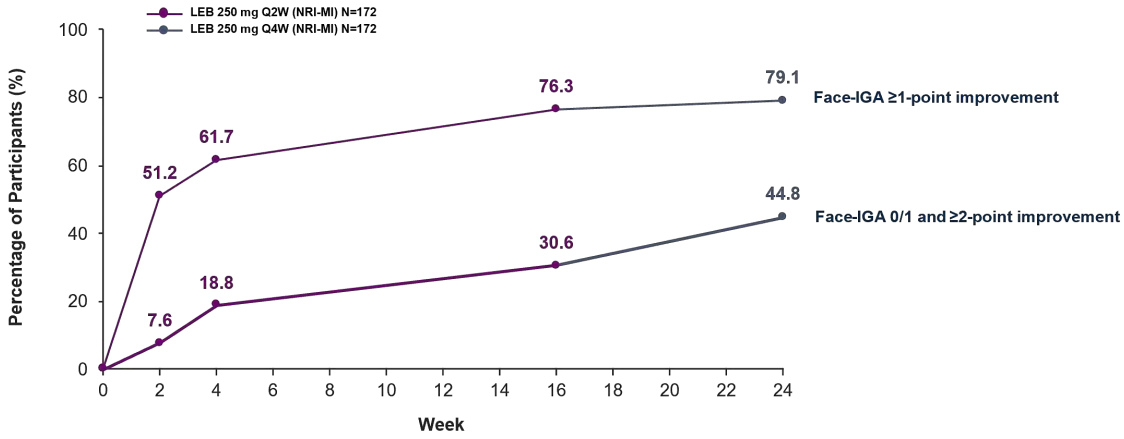
Conclusions

LEB provided improvements in facial AD in the majority of pts with a rapid onset of action. Almost half of the population achieved clear or almost clear skin on the face within 24 weeks of treatment. The response in the face correlated with the response seen in the rest of the body. Pts with hand AD achieved meaningful overall improvement. These findings indicate that lebrikizumab is an effective treatment option for pts with mod-sev AD, including those with facial and hand involvement. **References**

1. Blicharz L. Ital J Dermatol Venereol 2025;160:123–44; 2. Silverberg JI. N Engl J Med 2023;388:1080–91; 3. Blauvelt A. Br J Dermatol 2023;188:740–8; 4. Simpson EL. JAMA Dermatol 2023;159:182–91.

Previously presented at EADV Symposium 2026

Figure. Face IGA 0/1 with ≥2-point improvement and Face IGA ≥1-point improvement through W24 in patients with Face IGA ≥2 at baseline (mFAS, NRI-MI)



Restricted to patients with Face IGA ≥2 at baseline. Treatment discontinuation due to lack of efficacy was considered as non-response, while treatment discontinuations due to any other reason, as well as any other missing data, were handled through multiple imputation. Data collected after use of prohibited medication was included in the analysis. LEB: lebrikizumab; mFAS: modified full analysis set; MI: multiple imputation; NRI: non-responder imputation; QXW: every X weeks; W: Week.

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Abstract N°: 1160

Lebrikizumab Provided High Levels of Effectiveness in Patients with Moderate-to-Severe Atopic Dermatitis: Results from ADlife, A Real-World Study

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Introduction

Lebrikizumab (LEB) has shown efficacy and a favourable safety profile in moderate-to-severe atopic dermatitis (mod-sev AD). ADlife is a 52-week (W) prospective, multi-centre, non-interventional study. In the interim W16 analysis, LEB was shown to be highly effective. Given the chronic nature of AD, longer treatment exposures in larger cohorts are needed. Here, we report interim W28 effectiveness and safety data from ADlife.

Materials and Methods

Eligible patients (pts) were ≥18 years with mod-sev AD requiring systemic therapy, who received LEB per label at physician's discretion and provided informed consent. Baseline (BL)/W4/W16/W28 effectiveness outcomes included mean score and percent change from BL (%CfB) of Eczema Area and Severity Index (EASI), the percentage of pts with ≥75%/≥90% improvement from baseline in EASI (EASI 75, EASI 90), the percentage of pts achieving scores of EASI ≤7, EASI ≤5, EASI ≤3 and EASI ≤1 and the percentage of pts achieving 24h-Peak Pruritus Numerical Rating Scale (PP-NRS) ≥4-point improvement from baseline, in patients with PP-NRS scores ≥4 at baseline. Concomitant topical corticosteroid (TCS) use was also evaluated. W28 safety outcomes included adverse drug reactions (ADRs) and serious ADRs. Data are reported as observed cases (OC) from the full analysis set (FAS) and include patients who enrolled in the study for ≥28W and had either a documented visit at W28 or a confirmed early termination within the first 28Ws. A sensitivity analysis was performed using last observation carried forward (LOCF). Analyses are presented descriptively.

Results

For effectiveness analyses, 263 pts were included from the FAS; safety was assessed in all treated pts (safety analysis set; N=264). Mean (standard deviation [SD]) age was 43.5 (16.4) years, 50.2% were female and average AD duration was 27.6 (18.8) years. At BL, mean (SD) EASI was 20.7 (11.3), PP-NRS was 7.3 (2.2) and Dermatology Life Quality Index was 16.3 (7.2). The most common atopic comorbidities included rhinitis (60.8%), asthma (36.9%) and food allergy (31.6%). At BL, 85.9% of pts had prior TCS use, 31.6% had prior biologic or Janus kinase inhibitor use and 23.6% had prior dupilumab use.

Over 28Ws, mean EASI scores reduced from 20.7 at BL to 9.4 at W4, 5.0 at W16 and 4.4 at W28. Early reductions in EASI were observed at W4 (%CfB: −51.7%) and further reductions were observed at W16 and W28, with a mean %CfB of −71.1% and −74.6%, respectively. At W4, EASI 75 was achieved by 26.7% of pts which increased to 59.6% at W16 and 66.8% at W28. EASI 90 was achieved by 10.3% of pts at W4 and approximately a third of pts at W16 (34.1%) and W28 (37.7%). At W28, most pts achieved EASI ≤7 (79.1%) and EASI ≤5 (70.4%). Notably, over half of pts achieved EASI ≤3 (54.4%) and approximately one third achieved EASI ≤1 (29.6%) (**Figure**). Of patients with PP-NRS scores ≥4 at BL (n=232), almost half achieved a ≥4-point improvement from BL at W4; this increased to

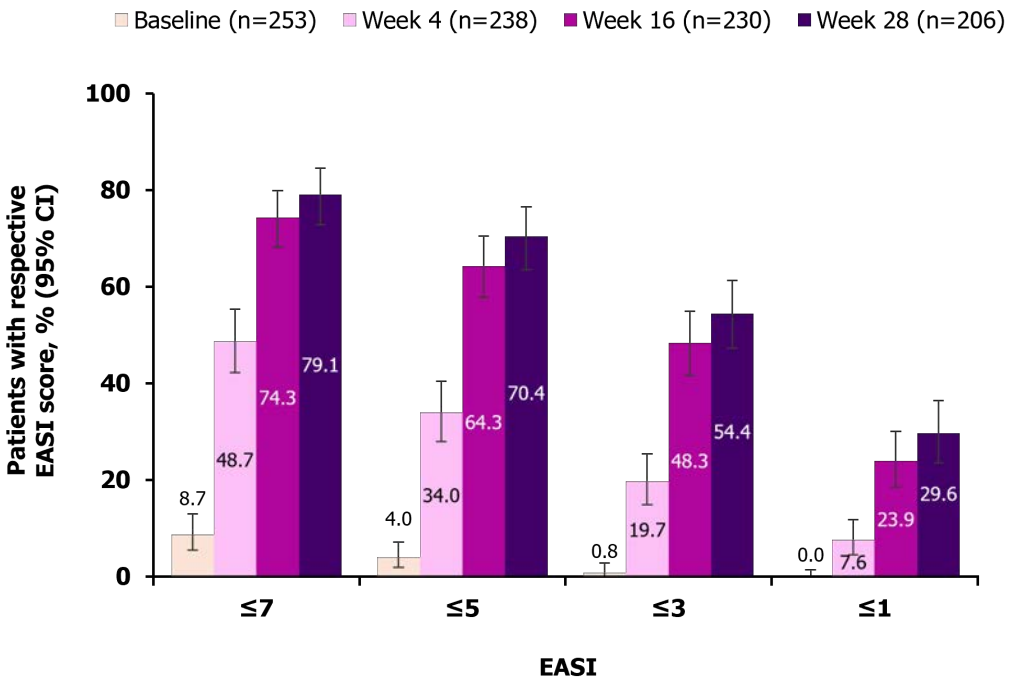
65.3% at W28. Across all outcomes, OC and LOCF data were comparable. At BL, 49.0% of pts were using concomitant TCS and this reduced at W28 with 33.3% use.

In this W28 interim analysis, LEB showed a favourable safety profile and ADRs were consistent with those observed in clinical trials. No new safety signals were observed.

Conclusions

In this W28 interim analysis, LEB showed early and high levels of effectiveness in pts with mod-sev AD, as indicated by absolute and relative EASI measures, in a real-world setting. Following 28Ws of treatment, fewer patients required TCS. LEB showed a favourable safety profile and no new safety signals were observed.

Figure. Proportion of patients achieving EASI ≤1, ≤3, ≤5, and ≤7 over time (OC)



Data reported for the FAS (N=263). CI: confidence interval; EASI: Eczema Area and Severity Index; FAS: full analysis set; OC: observed case.

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Abstract N°: 1163

Skin Microbiome Insights: Mechanistic Validation of A Cream Containing 5% Panthenol and Prebiotic Complex in the Treatment of Mild Facial Atopic Dermatitis

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Introduction

Skin microbiome dysbiosis is widely recognized as a pivotal contributor to the pathogenesis and recurrence of atopic dermatitis (AD). In lesional skin, significantly reduced microbial diversity and excessive colonization by Staphylococcus aureus are frequently observed, both of which exacerbate skin barrier impairment and inflammatory cascades. Considering the unique characteristics and physiological sensitivity of facial skin, this study aimed to systematically investigate the modulatory effects of a cream containing 5% panthenol and a prebiotic complex. By assessing longitudinal alterations in microbial abundance, diversity, and key pathogenic taxa, we sought to elucidate the microecological mechanisms underlying barrier repair and anti-inflammatory clinical efficacy. These findings provide robust evidence supporting the use of specialized dermocosmetics as a valuable adjunctive approach in the management of atopic dermatitis.

Materials and Methods

A total of 62 patients with mild facial AD (40 males, 22 females) were enrolled in this randomized, parallel-controlled study. Subjects applied either the test cream or a standard control cream to the entire face twice daily (morning and evening). Samples were collected and assessments were performed at baseline (T0, pre-application), immediately post-application (Timm), and at Weeks 2 (T2w), 4 (T4w), and 8 (T8w). Longitudinal genus-level microbial shifts and inter-group differences were comparatively analyzed.

Results

1. Compared with baseline, the test cream exhibited significant increases in both the PD_whole_tree and goods_coverage indices at T4w (Figure 1).

2. At T8w, a cream containing 5% panthenol and prebiotic complex significantly increased the PD_whole_tree, Chao1, observed_species, goods_coverage, and ACE indices (Figure 2).

3. Compared with the baseline, the principal coordinates analysis (PCoA) distances between the baseline and T4w (Figure 3A, B), as well as between the baseline and T8w (Figure 3C, D), were significantly reduced.

4. After 8 weeks of application of the test cream, the marked enrichment of Streptococcus, accompanied by a parallel reduction in non-skin-associated genera, directly recalibrated the cutaneous microenvironment (Figure 4).

5. Microbial diversity improved significantly at T4w and persisted through T8w, with a high degree of temporal alignment with improvements in efficacy outcomes: IGA scores, F-EASI scores, itching intensity, and quality of life. The shift toward a more balanced microbiome aligned with the trends in parameter improvement, such as TEWL and pH (Table 1).

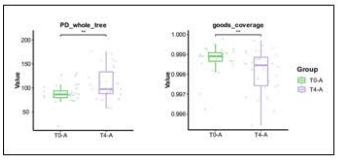

Figure 1. Alpha diversity at baseline and T4w.

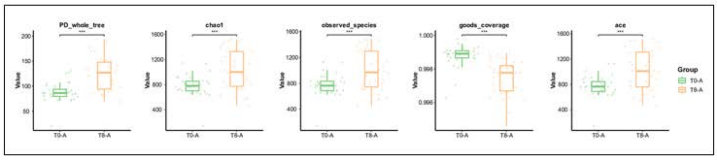

Figure 2. Alpha diversity at baseline and T8w.

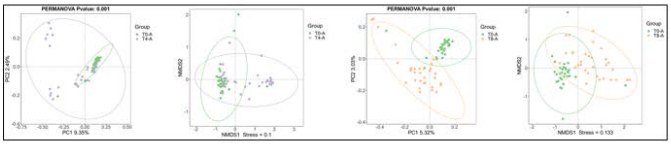

Figure 3. Beta diversity at baseline, T4w, and T8w.

Category	Action standard	T2w	T4w	T8w
INSTRUMENT MEASUREMENT	Transepidermal Water Loss (TEWL)	√(C)	√(C)	√(C)
	pH value	√	√	√
CLINICAL ASSESSMENT	Investigator's Global Assessment (IGA) Score	√(C)	√(C)	√(C)
	Eczema Area and Severity Index (F-EASI) Score	√	√(C)	√(C)
SELF-ASSESSMENT	Visual Analog Scale (VAS)_Itching	√(C)	√(C)	√(C)
	Dermatology Life Quality Index (DLQI)	√(C)	√(C)	√(C)

Table 1. Instrumental measurement, clinical assessment, and self-assessment efficacy outcomes of the test cream

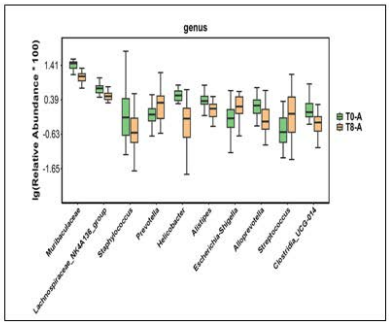

Figure 4. Abundance Difference

Figure 1. Alpha diversity at baseline and T4w. Figure 2. Alpha diversity at baseline and T8w. Figure 3. Beta diversity at baseline, T4w, and T8w. Figure 4. Abundance Difference. Table 1. Instrumental measurement, clinical assessment, and self-assessment efficacy outcomes of the test cream

Conclusions

In conclusion, the cream containing 5% panthenol and a prebiotic complex facilitates a taxonomic shift in the facial skin microbiome, transitioning from a low-diversity, dysbiotic state toward a rich and resilient homeostasis. This microbial modulation stabilizes the resident microbiota and fortifies the skin barrier, paralleling the observed clinical recovery. These findings establish microbiome regulation as a central and fundamental mechanism underlying the reparative efficacy of this formulation.

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Abstract N°: 1166

Lebrikizumab Shows Efficacy in Patients with Moderate-to-Severe Atopic Dermatitis, Including Patients with Predominantly Moderate Disease (ADhope 1)

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Introduction
Lebrikizumab (LEB) is a monoclonal antibody that selectively targets interleukin-13. LEB demonstrated efficacy and safety in patients with moderate-to-severe atopic dermatitis (AD) defined by an Eczema Area Severity Index (EASI) ≥16. ADhope 1 (NCT05990725) is the first Phase 3b LEB trial to include patients with lower AD severity (EASI ≥12). Here, LEB efficacy by baseline AD severity is reported.

Materials and Methods
Eligible patients (adults or adolescents ≥12 years and ≥40 kg, AD ≥1 year, EASI ≥12, Investigator's Global Assessment [IGA] ≥3 and ≥10% body surface area involvement) received 500 mg LEB at baseline/Week (W) 2, 250 mg every 2 weeks (Q2W) for W4–16, and moved to Q4W at W16, regardless of response. Patients stratified by baseline EASI: moderate (group 1: ≥12−≤16, group 2: >16−≤21), severe/very severe (>21). % patients achieving EASI ≤7 (primary endpoint), ≥75% improvement from baseline in EASI (EASI 75), IGA 0/1 with ≥2-point reduction (IGA 0/1) and Pruritus Numerical Rating Scale (P-NRS) ≤4 (in patients with P-NRS >4 at baseline), are reported at W16/W24 by baseline AD severity. 13 patients (one site) were excluded due to quality issues; results reported for the modified full analysis set. Discontinuation due to lack of efficacy was considered as non-response; discontinuations due to any other reason, and any other missing data, were handled through multiple imputation. Data collected after use of prohibited medication were included.

Results
At baseline, 57 patients were in group 1-moderate, 74 in group 2-moderate and 116 in severe/very severe AD. Demographics, AD duration and pruritus were similar across groups. More patients with severe/very severe AD had baseline IGA=4 compared with moderate AD. At W16, EASI ≤7 was achieved by 81.3% of patients in group 1, 75.7% group 2 and 62.0% severe/very severe AD, and by 78.2%, 82.5%, 68.1% of patients at W24. EASI 75 was achieved by 50.9%, 54.8%, 64.9% at W16, and 64.2%, 58.6%, 66.3% at W24, respectively. IGA 0/1 was achieved by 47.4%, 28.6% and 27.2% of patients at W16, and 49.5%, 37.2% and 40.0% of patients at W24. Among patients with P-NRS >4 at baseline, P-NRS ≤4 was achieved regardless of baseline severity at W16 (group 1: 70.3%, group 2: 71.1%, severe/very severe: 70.7%) and W24 (70.6%, 76.0%, 75.2%).

Conclusions

ADhope 1 included patients with EASI ≥12, a more moderately affected population compared to trials. LEB showed efficacy across the spectrum of moderate-to-severe AD including more moderate patients.

Previously presented at AEDV 2026

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Abstract N°: 1170

Lebrikizumab Delivers Improvements Across Patient-Reported Itch, Sleep, Overall Assessment of Disease Severity and Treatment Satisfaction in ADhope 1

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterised by persistent itch and eczema. Clinical trial outcomes, such as Eczema Area and Severity Index (EASI) scores, do not capture the full disease burden since they do not assess symptoms like itch severity and sleep loss, or treatment experience. Additionally, patients with similar EASI scores may experience AD differently, highlighting the need for patient-reported outcome (PRO) measures. We report PROs from ADhope 1 (NCT05990725), assessing the impact of lebrikizumab (LEB) for patient burden, disease severity and treatment satisfaction in patients with moderate-to-severe (mod-sev) AD through 24 weeks (W).

Materials and Methods

ADhope 1 was an open-label study in adolescents (≥12 to <18 years, ≥40 kg) and adults with mod-sev AD (EASI ≥12, IGA ≥3, ≥10% body surface area of AD involved) who had inadequate responses to topical or systemic treatment. Prior dupilumab use was allowed. Patients received a 500 mg loading dose of LEB at baseline and W2, then 250 mg every 2 weeks (Q2W) to W16 when all patients transitioned to 250 mg every 4 weeks (Q4W) through W24, regardless of response. Topical corticosteroids (TCS) were permitted under investigator's discretion. The PRO endpoints were: Patient-Oriented Eczema Measure (POEM) score, worst Pruritus Numerical Rating Scale (P-NRS) score, Sleep-Loss Scale, Patient Global Assessment of Disease Severity (PGADS) and Patient Reported Satisfaction Questionnaire (PRSQ). 13 patients from one site had to be excluded due to quality issues and data are reported in the modified Full Analysis Set (mFAS). Treatment discontinuation due to lack of efficacy was considered as non-response, while treatment discontinuations due to any other reason, as well as any other missing data, were handled through multiple imputation. Data collected after use of prohibited medication were included in the analysis. Observed results exclude data collected after treatment discontinuation and missing data were not imputed.

Results

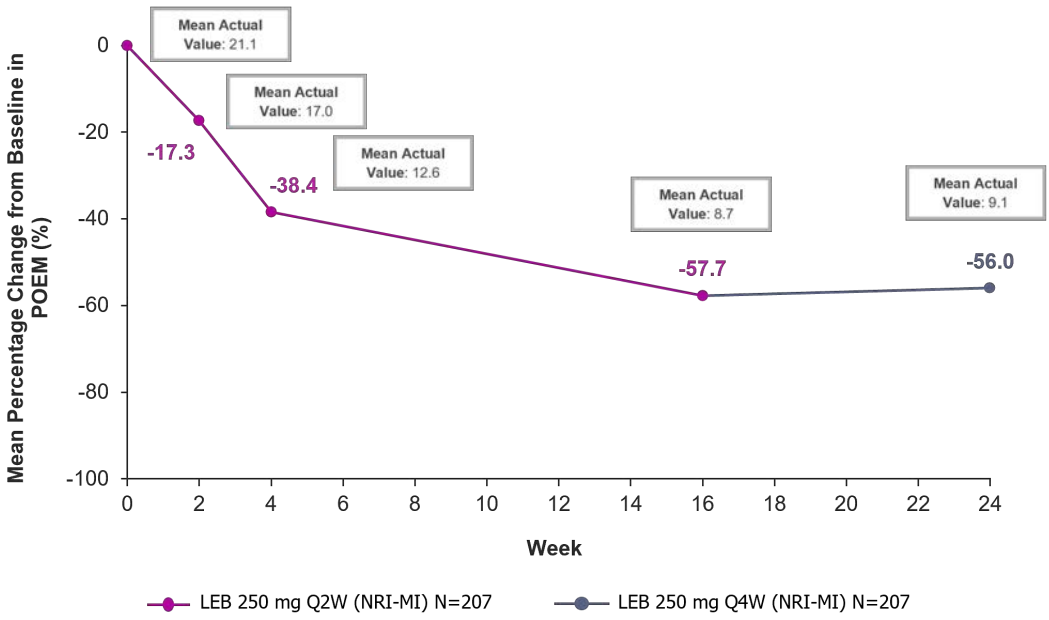
In total, 247 patients from the mFAS were assessed. Baseline (BL) characteristics included mean (standard deviation [SD]) age 32.8 (14.1) years, 61.1% male EASI 23.1 (9.0), P-NRS 6.7 (1.6) and POEM 21.1 (5.4). At BL,

75.4% of patients had poor or fair disease status (PGADS) and 72.8% of patients were either ‘not satisfied’, ‘slightly satisfied’ or ‘somewhat satisfied’ with their treatment” (PRSQ). During the study, 44.5% of patients (n=110) used any TCS, and 32.8% (n=81) were using TCS at BL before initiating LEB. LEB led to improvements across all PROs at W16, which were sustained or enhanced after increasing the dose interval from Q2W to Q4W. Overall POEM scores improved as early as W2, with a mean change from baseline (CfB) of -57.7% (standard error of the mean [SEM] 2.12) at W16, which was maintained to W24 (**Figure**). In the POEM Itch Individual Score, 41.8% of patients reported being itch free or almost itch free (0–2 days of reported itch over the last week) at W16, increasing to 45.1% at W24. Similarly, P-NRS scores showed sustained improvements, with a mean CfB of -52.2% at W16 and -54.8% at W24. Sleep-Loss Scale scores improved, with a mean CfB of -55.1% at W16 and -62.7% at W24. The POEM Sleep Item Score showed sustained improvement, with 50.8% of patients reporting no sleep disturbances at W16 and 45.1% at W24. According to the PGADS, the proportions of patients considering their disease status to be ‘good’ to ‘excellent’ continually improved from BL, reaching 79.1% at W16 and 80.5% at W24. PRSQ scores improved continuously over time with 70.6% of patients reporting they were ‘very’ or ‘completely’ satisfied with treatment at W16, which was maintained to W24 (69.9%).

Conclusions

LEB showed early, continuous PRO improvements from W2 in eczema characteristics, itch and sleep. These were maintained over 24 weeks and reflected in improved overall disease assessment and treatment satisfaction.

Figure. Mean percentage change from baseline in POEM score (mFAS, NRI-MI)



Data collected after treatment discontinuation due to lack of efficacy were set as non-response and discontinuation due to any other reason, as well as missing data, were handled through multiple imputation. Data collected after use of prohibited medication was included in this analysis. LEB, lebrikizumab; mFAS, modified Full Analysis Set; n, number of patients in the specified category; N, number of patients in the analysis population; POEM, Patient-Oriented Eczema Measure; Q2W, every 2 weeks; Q4W, every 4 weeks.

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Abstract N°: 1172

Objective assessment of nocturnal scratching and sleep impairment using accelerometry in patients with moderate-to-severe atopic dermatitis treated with abrocitinib: results from ADAIR (Treating Atopic Dermatitis with Abrocitinib and its Impact in Real Life) study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory disease associated with intense pruritus, scratching and sleep disturbances. These symptoms substantially impair patients quality of life. Moreover, scratching leads to further skin inflammation and further damage perpetuating the disease. However, objective assessments of nocturnal scratching and sleep remain limited. The French real-world observational ADAIR study evaluated the effectiveness and safety of abrocitinib in patients with moderate-to-severe AD. As part of interim analysis planned, a dedicated accelerometry analysis (AA) was performed to objectively assess scratching behavior and sleep outcomes. The objective is to evaluate changes in scratching and sleep outcomes using accelerometry monitoring during the early phase of abrocitinib treatment in patients with moderate-to-severe AD.

Materials and Methods

At the AA cutoff date (12/31/2025), among 133 enrolled patients across 29 French centers, 35 participated in the AA. Wrist-worn accelerometers, single-arm–worn device, was worn continuously for up to 3 weeks, up to 1 week before starting treatment and 2 weeks after abrocitinib treatment. AA endpoints included the total number and duration of scratch episodes, total sleep opportunity (TSO), sleep efficiency (percent time asleep during TSO), total time asleep (TST), wake after sleep onset (WASO), sleep onset latency (SOL), and number of wake bouts. Clinical outcomes such as PP-NRS score were also assessed. Baseline is defined as the average of available measures collected 3 days before treatment. The descriptive analysis were performed. The weighted repeated measures correlation coefficient by Kondo et.al was used to assess the correction of PP-NRS and digital measures.

Results

At baseline (n=35), patients in the AA had a mean (SD) age of 34.5 (14.8) years, and 54.3% were female. Most patients had infant- or childhood -onset AD (34.3% and 60.0% respectively), with a high atopic history (80.0%). Mean (SD) PP-NRS and Epworth Sleepiness Scale scores were 5.8 (2.7) and 9.1 (5.2), respectively (n=32).

Substantial baseline nocturnal scratching and sleep disruption was observed (n=30), prior abrocitinib initiation: mean number (SD)) was 92.2 (61.3) scratching episodes per night and with the total scratching duration of 7.5 (5.4) minutes (min). With regard to sleep (Mean (SD)), the sleep efficiency was 85.7 % (10.7), TST of 397.2 (150.6) min, TSO of 462.5 (162.3) min, WASO was 58.7 (50.4) min, SOL was 5.1 (3.2) min and the number of wake bouts was 14.7 (8.0). Over the first 2 weeks of treatment, reductions in nocturnal scratching were observed, with a mean (SD) change of −17.1 (69.6) nocturnal scratch episodes and −1.2 (6.3) min in total scratch duration by day 14 (D14). Improvements in sleep parameters were also noted at D14 compared to baseline (mean (SD)): sleep efficiency increase was 3.9% (8.4) , reduction in TSO change of -13.0 min (181.6) and TST increase of 6.7 (147.8) min. Improvements were also observed with change in mean (SD) WASO, SOL and a reduction in the number of wake bouts, respectively of -16.5 (55.3) min, -3.6 (3.5) min and -2.1 (8.7). These quantitative objective findings were consistent with clinical improvements observed: absolute change from baseline at week 2 of mean PP-NRS was -2.7 (2.5), 60.9% of patients had PP-NRS improvement ≥ 2 [39.25%;79.3%] and 43.5% of patients had PP-NRS improvement ≥ 4 [24.1%;64.8%]. PP-NRS was consistently correlated with objective measures of scratching behavior and sleep fragmentation parameters (total scratch episodes, WASO and number of wake bouts (total scratch episodes, WASO and number of wake bouts: r=0.671, r=0.673, r=0.672 respectively).

Conclusions

Abrocitinib led to rapid, objective improvements in nocturnal scratching and sleep metrics, specifically reduced nocturnal scratching and wakefulness, increased overall TST and sleep efficiency within 14 days. AA provided complementary, objective insights into treatment response.

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Abstract N°: 1172

Emollient SCORAD study in atopic eczema: Open label, multi-centre clinical study reflecting real-life settings

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Introduction

Atopic eczema is a chronic inflammatory skin condition associated with impaired barrier function, pruritus, and reduced quality of life. Emollients are a cornerstone of management; however, real-world evidence on simplified once-daily regimens remains limited. This study evaluates the clinical performance of DGPF, a leave-on emollient, under routine clinical practice conditions.

Case Presentation

This was a 4-week, open-label, multi-centre study conducted across five general practice (GP) centres in the UK. Patients of any age and disease severity with atopic eczema and a baseline SCORAD ≥15 were eligible. Patients used DGPF, ideally only once daily instead of their usual emollient, and either as their standalone emollient or as part of a combination of treatments. A total of 61 patients were recruited, with 58 completing the study. The primary endpoint was change in SCORAD from baseline to week 4. Secondary outcomes included subjective symptom scores (itch and sleeplessness) and quality of life (QoL) assessed via patient questionnaire. Treatment with DGPF resulted in clinically meaningful improvements in disease severity and patient-reported outcomes in Per Protocol analysis. Mean SCORAD reduced from 35.96 to 17.91, a reduction of 18.05 ($p \leq 0.0001$. Subjective symptom scores also showed statistically significant improvements, with mean itch score reductions of 2.0 at week 1 and 3.1 at week 4 ($p < 0.0001$), and sleeplessness score reductions of 1.3 and 2.4 at weeks 1 and 4, respectively ($p < 0.0001$). Quality of life improved substantially, with mean total QoL scores decreasing from 20.2 at baseline (N=61 patients) to 13.0 at week 4 (N=57 patients).

Conclusion

The findings support the effectiveness of DGPF a once daily emollient in improving the clinical signs and symptoms of atopic eczema, as part of an overall treatment approach, as well as enhancing patient quality of life in routine clinical practice.

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Treatment persistence and switching patterns of targeted therapies in moderate-to-severe atopic dermatitis: an episode-level real-world cohort study

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Introduction
Targeted systemic therapies have broadened treatment options for moderate-to-severe atopic dermatitis, but comparative long-term data from routine care remain limited. We aimed to describe episode-level treatment persistence and switching across targeted therapies used in real-world practice.

Materials and Methods
We conducted a retrospective single-centre pharmacy-dispensing cohort study. Treatment episodes were reconstructed from dispensing coverage. Persistence was defined from episode start to discontinuation or switch using medication coverage plus a dynamic grace rule with a minimum of 60 days. A switch was recorded when another targeted therapy started on or before the discontinuation date. Administrative censoring was applied on 30 December 2025. Kaplan-Meier estimates were summarised overall, by therapeutic class and by individual drug. Sensitivity analyses explored fixed grace periods of 30, 60, 90 and 120 days. These dispensing-based endpoints were treated as pragmatic proxies and do not directly measure adherence or fully adjudicate the reasons for treatment change.

Results
The cohort included 265 patients and 496 targeted-therapy episodes. Overall 12-month persistence was 62.2% (95% CI 57.4-66.5) and was higher for biologics than for JAK inhibitors at the same time point: 69.8% (95% CI 64.1-74.8) versus 47.7% (95% CI 39.7-55.3). Drug-specific 12-month estimates were 76.1% (95% CI 69.9-81.2) for dupilumab, 59.3% (95% CI 48.0-69.0) for upadacitinib 30 mg, 40.6% (95% CI 26.6-54.1) for tralokinumab, and 21.3% (95% CI 10.6-34.6) for upadacitinib 15 mg. Of 265 events, 139 were switches and 126 were discontinuations, while 46.6% of episodes were administratively censored. A total of 116/265 patients (43.8%) received at least two targeted lines. The most frequent transitions were upadacitinib 15 mg to upadacitinib 30 mg (n=26), upadacitinib 30 mg to upadacitinib 15 mg (n=19), and dupilumab to upadacitinib 30 mg (n=18).

Conclusions
Episode-level, dispensing-based analyses captured clinically relevant sequencing patterns that patient-level summaries can obscure. In this real-world cohort, biologics showed higher 12-month persistence than JAK inhibitors, and switching clustered around dose adjustment and post-dupilumab treatment changes. These findings may help contextualise longer-term treatment pathways in routine care.

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Burden of Disease in Atopic Dermatitis Patients in Belgium (APOLO Study)

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Introduction

Atopic dermatitis (AD) is a common, chronic, highly pruritic inflammatory skin disease with a substantial impact on the quality of life. However few data are available on the burden experienced by patients suffering from moderate to severe AD (M2S-AD) in Belgium.

Materials and Methods

The 9-month (Aug 2022 – May 2023) cross-sectional study included patients with clinical diagnosis of M2S-AD who presented for the first time (index date) at one of 7 dermatological centers across Belgium. Data on demographics, clinical characteristics, healthcare utilization, treatment patterns and burden of disease via patient reported outcomes (PROs), including Dermatology Life Quality Index(DLQI), EuroQol-5D (EQ-5D), Work Productivity and Activity Index (WAPI), Patient Oriented Eczema Measure (POEM), Peak Pruritus Numerical Rating Scale (PP-NRS©) were recorded at index date. We herein report the burden of disease experienced by M2S-AD (as per Eczema Area Severity Index) patients in Belgium.

Results

The study included 42 patients (38 adults and 4 below the age of 18 years of age) with 59.5% males and 40.5% female and a median (min-max) age of 25 (14-70) years and a median EASI 14.9 (3.2-34.3). Current treatment (past 2 weeks), prior to expert consultation, included topical corticosteroids (63.4% of patients), topical calcineurin inhibitors (12.2%), phototherapy (2.4%), antihistamines (39%), systemic steroids [9.8%, median course 7 days (7-10)], cyclosporin (2.4%), baricitinib (2.4%) and dupilumab (2.4%).

The median DLQI score of the patients was 13.5 (2-29) with 67.9% of them presenting with severe impact on their QoL. Highest impact [mean (SD)] involved the domains of symptoms and feelings [4.23 (1.52)], followed by leisure [2.87 (2.11)] and daily activity [2.68 (1.83)]. Median (min-max) EQ-5D-3L total score was 3 (1-7) and the health state score 70 (5-100). Among 24 employed patients, WAPI scores for absenteeism, presenteeism, work productivity loss and activity impairment were, mean (SD), 9.5% (28.1), 34.5% (25.6), 35.1% (25.9), and 45.7% (29.8) respectively. The median POEM score was 19 (2-28), while 63.9% of patients reported severe/very severe eczema (POEM >16). The median PP-NRS score was 8 (3-10). Interestingly, apart from pruritus, 88.9% of patients reported pain with a median intensity of 5.5 out of 10 (0-10), while about 46.2% experience pain > 4 days a week.

Moreover, 88.9% of patients reported sleep disturbances in the last 3 days. Controlling for baseline factors, the impact on quality of life as measured by the DLQI score was significantly associated, with itching intensity and pain intensity ($p<0.0001$). PROs by severity subgroups are presented in Table 1.

In terms of healthcare resource utilization, the data show that dermatologists played a crucial role in the initial diagnosis and patient referral. This finding supports the existing literature, which recognizes the importance of specialized dermatological care in managing AD. The higher frequency of referral of patients above 16 years of age by general practitioners in this study is consistent with the healthcare setup in Belgium for M2S AD patients. Since there was a single patient below 16 years of age it is difficult to reach any meaningful conclusion about the pediatric patients.

		Severity Group *	
Patient Reported Outcome	**Total (n=42)**	**Moderate AD (n= 26)**	**Severe AD (n=15)**
DLQI score, median (min-max)	13.5 (2-29)(n=28)	10.0(2.0-19.0)(n=17)	18.0 (9.0-29.0 (n=11)
-DLQI >10 (severe impact), # (%)	19 (67.9%)(n=28)	9 (52.9%)(n=17)	10 (90.9%)(n=11)
Total EQ-5D-3L score, median (min-max)	3 (1-7)(n=13)	2 (1-4)(n=8)	5 (1-7)(n=5)
Health State score, median (min-max)	70 (5-100)(n=36)	75 (34-100)(n=22)	62,5 (5-77) (=14)
WPAI - Work Productivity and Activity Impairment			
Absenteeism, mean (SD),%	9.5 (28.1)(n=24)	7.3 (25.0)(n=16)	14.1 (35.0)(n=8)
Absenteeism, median (min-max),%	0 (0-100)(n=24)	0.0 (0.0-100.0)(n=16)	0.0 (0.0-100.0)(n=8)
Presenteeism, mean (SD),%	34.5 (25.6)(n=22)	32.0 (28.1)(n=15)	40.0 (20.0)(n=7)
Presenteeism, median (min-max),%	30.0 (0.0-80.0)(n=22)	20.0 (0.0-80.0)(n=15)	30.0 (20.0-70.0)(n=7)
Work productivity loss, mean (SD), %	35.1 (25.9)(n=22)	32.2 (28.5)(n=15)	41.2 (19.5)(n=7)
Work productivity loss, median (min-max), %	30.0 (1.0-82.9)(n=22)	20.0 (0.0-82.9)(n=15)	38.8 (20.0-70.0)(n=7)
Activity impairment, mean (SD), %	45.7 (29.8)(n=35)	38.1 (30.6) (n=21)	57.1 (25.6)(n=14)
Activity impairment, median (min-max), %	50.0 (0.0-100.0)(n=35)	40.0 (0.0-100.0)(n=21)	55.0 (20.0-100.0)(n=14)
POEM, median (min-max)	19.0 (2.0-28.0)(=36)	17.3 (2.-28.0)(n=22)	20.6 (13.0-28.0)(n=14)
POEM>16 (severe eczema), # (%)	23 (63.9%)(n=36)	12 (54,5%)(n=22)	11 (78.6%)(n=14)
PP-NRS, median (min-max)	8.0 (3.0-10.0)(n=35)	8.0 (3.0-10.0)(n=21)	7.0 (5.0-10.0)(n=14)
Pain, presence, # (%)	32(88.9%)(n=36)	18 (81.8%)(n=22)	14 (100%)(n=14)
Pain intensity (0-10 scale), median (min-max)	5.5 (0-10)(n=36)	4.0 (0-10)(n=22)	6.0 (4-10)(n=14)
Frequency of pain > 4 days a week	17(46.2%)(n=36)	8 (36.4%)(n=22)	9 (64.3%) (n=14)
3-day Sleep VAS, presence of disturbances, # (%)	32(88.9%)(n=36)	18 (81.8%)(n=22)	14 (100%)(n=14)
3-day Sleep VAS, median (min-max)	3.5 (0-10)(n=36)	2,9 (0,0-7.0)(n=22)	5.7 (0.7-10.0)(n=14)

** for severity only n=41 patients were scored*

Table 1. Patient reported outcomes in M2S AD patients and by severity subgroups.

Conclusions

This is the first detailed report on the burden experienced by physician diagnosed M2S-AD patients in Belgium. Both patients with moderate and severe AD present with substantial itch, pain and sleep disturbances that have a significant impact on their quality of life, highlighting M2S-AD extends beyond visible skin symptoms.

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Abstract N°: 1203

Patient treatment needs and individualized benefit assessment in moderate-to-severe atopic dermatitis: Insights from a nationwide registry

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Introduction

The Patient Benefit Index (PBI) provides a validated tool to assess individual treatment goals and their

achievement, yet comprehensive data on treatment need heterogeneity across subgroups and the concordance between clinical response and patient-perceived benefit remain limited in atopic dermatitis (AD). To systematically assess treatment needs in adults with moderate-to-severe AD, identify subgroup-specific need profiles, and examine the concordance between clinical response and individualized patient benefit under systemic therapy in a real-world setting.

Materials and Methods

Two complementary prospective cohort analyses were conducted using data from a nationwide AD registry. In the first analysis (n=697), treatment needs were assessed at baseline using the Patient Needs Questionnaire (PNQ), with subgroup comparisons by age, sex, educational status, and age at AD onset. Patient benefit was evaluated after two years using the PBI. In the second analysis (n=242), patients initiating dupilumab were followed over one year. Concordance between EASI-75 and great patient benefit (PBI≥3) was examined, and factors associated with PBI≥3 were analyzed using logistic regression adjusted for age, sex, and EASI.

Results

"Being free of itching" was the most frequently prioritized treatment goal (97.8% high agreement), followed by "regaining disease control" (95.3%). Treatment needs varied significantly across subgroups: older patients prioritized treatment safety and independence from medical visits, women emphasized psychosocial and appearance-related goals, patients with lower educational status highlighted financial concerns, and those with adult-onset AD prioritized diagnostic certainty. The importance of itch reduction was not correlated with baseline pruritus intensity. After two years, 96.6% reported meaningful benefit (PBI≥1) and 62.0% great benefit (PBI≥3). Patient-reported outcomes were more strongly associated with perceived benefit than physician-assessed measures. In the dupilumab cohort, 72.7% achieved PBI≥3 at one year, with perceived benefit continuing to increase between 3 and 12 months while symptom measures plateaued. EASI-75 and PBI≥3 were statistically independent: 17.2% achieved EASI-75 without great patient benefit and 19.2% achieved great benefit without EASI-75. Discordance was not explained by objective disease severity but was associated with residual pruritus, depressive symptoms, and head-neck dermatitis.

Conclusions

Treatment needs in moderate-to-severe AD are heterogeneous and vary across demographic and clinical subgroups. Clinical response and patient-perceived benefit represent related but distinct outcomes, with psychosocial dimensions central to their divergence. Systematic needs assessment and individualized benefit evaluation should complement clinical response criteria to guide personalized treatment decisions and shared decision-making.

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60-Week Efficacy Maintenance and Relapse Control with MG-K10 in Adults with Moderate-to-Severe Atopic Dermatitis: MG-K10 Phase 3 Long-Term Extension Results

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Introduction
MG-K10 is an innovative long-acting mAb that specifically binds to human IL-4Rα, and efficiently blocks the Th2 inflammatory signaling of IL-4 and IL-13. Following Fc mutation, MG-K10 allows long dosing interval owing to its prolonged half-life. We report the long-term efficacy results from a pivotal phase 3 trial (NCT06026891).

Materials and Methods
The study enrolled 499 adults with moderate-to-severe AD and randomized 2:1 to receive subcutaneous MG-K10 300 mg (600 mg loading dose, n=333) or placebo (n=166) every 4 weeks (Q4W). After 16-week double-blind treatment completed, all patients entered a 36-week maintenance treatment period and received MG-K10 300 mg Q4W. After the completion of the maintenance treatment phase, all patients will be followed up for an additional 8 weeks.

Results
Regarding efficacy maintenance, among patients in the MG-K10 treatment group who achieved EASI-75 or IGA 0/1 with a ≥2-point reduction from baseline at Week 16, 98.9% maintained EASI-75 response and 92.6% maintained IGA response at Week 52. More importantly, 8 weeks after the end of treatment, these response rates remained as high as 97.7% and 89.5%, respectively. Regarding relapse control, among patients who simultaneously achieved both EASI-75 and IGA 0/1 with a ≥2-point reduction from baseline at Week 16, the relapse rate during the subsequent 52-week treatment period was 0% (relapse defined as: a less than 50% reduction in EASI score from baseline and an IGA score of ≥ 2). Moreover, no relapse occurred following an 8-week follow-up after treatment completion.

Conclusions
In adult patients with moderate-to-severe atopic dermatitis, MG-K10 Q4W provides stable long-term therapeutic efficacy, sustain high-level responses following treatment completion, and effectively prevent disease relapse.

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Abstract N°: 1208

Tape Stripping–Derived Biomarkers in Atopic Dermatitis: A Scoping Review

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Introduction
Stratum corneum sampling via tape stripping represents a minimally invasive approach to epidermal biomarker collection, offering a practical and patient-acceptable alternative to punch biopsy in atopic dermatitis (AD) research. Its advantages are particularly relevant in pediatric populations, where repeated skin biopsies are practically constrained, and in longitudinal study designs requiring serial sampling. Despite growing adoption across academic and industry settings, the application of tape stripping in AD research remains methodologically inconsistent, with substantial variation in strip number, anatomical site, sample processing, and analytical platforms. Formal standardization is lacking.

Materials and Methods
Objectives: To characterize the breadth of AD-relevant biomarkers accessible through tape stripping and to synthesize available evidence across three clinical and research domains: prediction and differential diagnosis, disease phenotyping, and treatment response monitoring.

Methods: A scoping review was performed in accordance with PRISMA-ScR guidelines. Systematic searches were conducted in PubMed/MEDLINE, Embase, Web of Science Core Collection, and CENTRAL from database inception to 9 April 2025, supplemented by backward citation searching and expert-informed record identification. Eligible studies were primary human research enrolling patients with AD in whom tape stripping served as the biomarker sampling method, with no restrictions on age, disease severity, or treatment status.

Results
From 857 identified records, 87 studies met inclusion criteria. Biomarker classes detected spanned proteins (57.5%), small molecules and metabolites (23.0%), RNA and gene expression markers (19.5%), lipids (17.2%), structural and biophysical parameters (11.5%), and enzymes (8.0%). Nine studies examined prediction or differential diagnosis, with dysregulated ceramide profiles, elevated TSLP, and increased TARC/CCL17 emerging as candidate early markers. Fifty-seven studies applied tape stripping to disease phenotyping, capturing molecular signatures associated with Th2 skewing, barrier dysfunction, and disease severity. Twenty-one studies assessed treatment monitoring across topical and systemic therapies, demonstrating biomarker shifts consistent with attenuated cutaneous inflammation and progressive barrier restoration. Considerable methodological heterogeneity was observed across the body of evidence, limiting cross-study comparability.

Conclusions

Tape stripping provides a viable, minimally invasive platform for profiling diverse epidermal biomarkers in AD, with demonstrated utility across prediction, phenotyping, and monitoring applications. Its potential as a digital biomarker sampling tool in decentralized and real-world trial settings warrants further attention. Broader clinical and research implementation will require coordinated standardization of sampling protocols, strip number conventions, and analytical approaches.

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Abstract N°: 1213

Lebrikizumab Treatment Led to Low Disease Activity in the Majority of Patients with Moderate-to-Severe Atopic Dermatitis: Findings from the ADhope 1 Trial

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Introduction

Atopic dermatitis (AD) is a common, chronic, relapsing, inflammatory skin condition that is frequently accompanied with bothersome itch. Low disease activity (LDA) was recently defined by the International Eczema Council (IEC) as Investigator's Global Assessment (IGA) score ≤2 or Eczema Area and Severity Index (EASI) ≤7, as assessed by a clinician + Pruritus Numerical Rating Score (P-NRS) ≤4, as reported by the patient.[1] Lebrikizumab (LEB) has previously demonstrated efficacy in adults and adolescents with AD in Phase 3 trials. We report data from ADhope 1 (NCT05990725), assessing the efficacy of LEB in achieving LDA and improving symptoms such as skin and itch responses in adults and adolescents with moderate-to-severe (mod-sev) AD through Week (W) 24.

Materials and Methods

ADhope 1 was an open-label prospective cohort study that enrolled adults and adolescents (≥12 to <18 years, ≥40 kg) with mod-sev AD (EASI ≥12, IGA ≥3, ≥10% body surface area [BSA] of uncontrolled AD) who had inadequate responses to topical treatment. Previous exposure to dupilumab was permitted. Patients received a 500 mg loading dose of LEB at baseline (BL) and W2, then 250 mg every 2 weeks (Q2W) to W16, when all patients were transitioned to 250 mg Q4W through W24, regardless of response. Topical corticosteroid (TCS) use was permitted under Investigator's discretion. The primary efficacy endpoint was the percentage of patients achieving EASI ≤7 at W24. To assess LDA, the combined endpoints of EASI ≤7 or IGA ≤2 + P-NRS ≤4, EASI ≤7 + P-NRS ≤4 and IGA ≤2 + P-NRS ≤4 were calculated. A modified full analysis set (mFAS) was reported as due to quality issues in one centre, 13 patients had to be excluded from the analysis. Treatment discontinuation due to lack of efficacy was considered as non-response, while treatment discontinuations due to any other reason, as well as any other missing data, were handled through multiple imputation (MI). Data collected after use of prohibited medication were included in the analysis.

Results

Efficacy was assessed in 247 patients (mFAS). BL demographics included mean (standard deviation [SD]) age 32.8 (14.1) and 61.1% male. Clinical characteristics included mean (SD) EASI 23.1 (9.0), P-NRS 6.7 (1.6) and Dermatology Life Quality Index 14.8 (6.2). IGA scores were moderate (3) in 74.1% (n=183) of patients and severe (4) in 25.9% (n=64) of patients. At W24, most patients demonstrated substantial improvements in the individual endpoints, with 74.7% (n=185) achieving EASI ≤7, 80.1% (n=198) achieving IGA ≤2 and 74.8% (n=170) achieving P-NRS ≤4. Most patients achieved LDA at W24: 66.0% (n=150) of patients achieved EASI ≤7 or IGA ≤2 + P-NRS ≤4 (**Figure**), 59.2% (n=135) of patients achieved EASI ≤7 + P-NRS ≤4 and 63.4% (n=144) of patients achieved IGA ≤2 + P-NRS ≤4. During the study, 44.5% (n=110) of patients used TCS, and 32.8% (n=81) were using TCS at BL before initiating LEB.

Conclusions

Two thirds of patients receiving LEB achieved LDA, as defined by the IEC, within 24 weeks. High rates of response were also seen when looking at the individual endpoints of the LDA definition, in both skin (EASI ≤7, IGA ≤2) and itch endpoints (P-NRS ≤4). These findings can inform treatment decisions, considering treat-to-target recommendations for AD.

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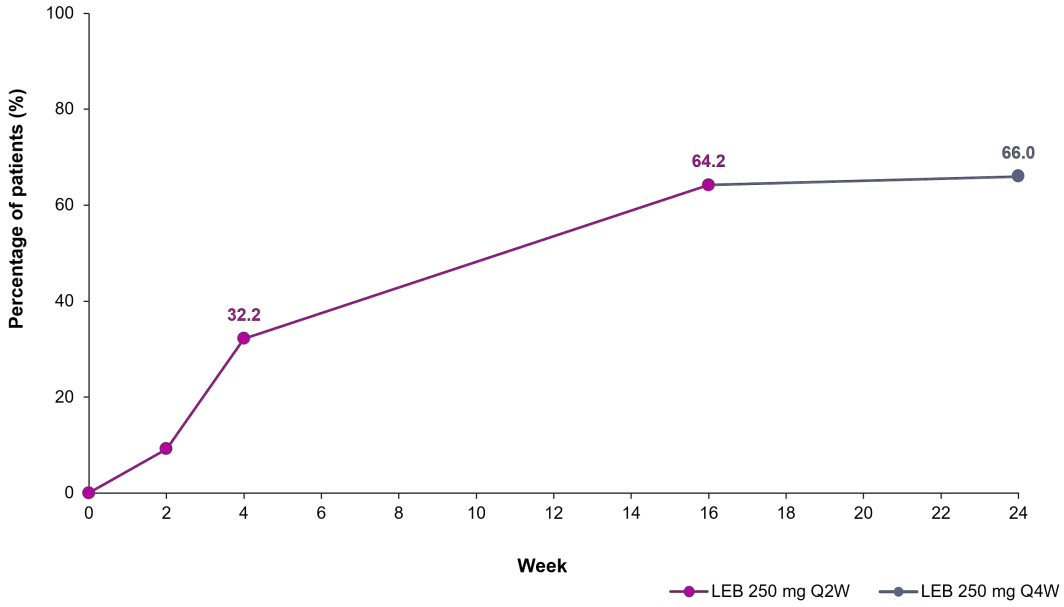
Figure. Percentage of patients with EASI ≤7 or IGA ≤2 + P-NRS ≤4 through W24 (mFAS, NRI-MI)



Data collected after treatment discontinuation due to lack of efficacy were set as non-response and discontinuation due to any other reason, as well as missing data, were handled through multiple imputation. Data collected after use of prohibited medication were included in this analysis. AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; LEB, lebrikizumab; mFAS, modified full analysis set; NRI-MI, non-responder imputation-multiple imputation; P-NRS, Pruritus Numerical Rating Score; Q2W, every 2 weeks; Q4W, every 4 weeks; W, week.

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Abstract N°: 1215

Lebrikizumab Provided Meaningful Improvements in Patient-Reported Disease Control and Reduced the Number of Flares in Patients with Moderate-to-Severe Atopic Dermatitis: ADlife Real-World Study

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Introduction

Atopic dermatitis (AD) is a common, chronic, recurrent, inflammatory skin disease often characterised by frequent flares. Lebrikizumab (LEB) has shown meaningful improvements in the signs and symptoms of AD in patients (pts) with moderate-to-severe (mod-sev) AD and improved pts' health-related quality of life (HRQoL). Here, we report Week (W) 28 interim patient-reported outcomes from ADlife, a 52-W prospective, multi-centre, non-interventional study, with a focus on eczema control and flare frequency.

Materials and Methods

Eligible pts were aged ≥18 years with mod-sev AD requiring systemic therapy, who received LEB per label at the physician's discretion and provided informed consent. Treatment response was evaluated at baseline (BL), W16 and W28 and included the percentage of pts achieving Patient-Oriented Eczema Measure (POEM) total scores ≤7 and the percentage of pts per Recap of Atopic Eczema (RECAP) eczema control category (scored 0–28 and categorised by the degree of eczema control, with lower scores indicating greater control over eczema). The mean number of flares within the last 12 weeks was also recorded. Data are reported as observed cases (OC) from the full analysis set (FAS) and include patients who were enrolled in the study for ≥28Ws and had either a documented visit at W28 or a confirmed early termination within the first 28Ws. A sensitivity analysis was performed using last observation carried forward (LOCF). Analyses are presented descriptively.

Results

263 pts were included from the FAS. Mean (standard deviation [SD]) age was 43.5 (16.4) years, 50.2% were female and average AD duration was 27.6 (18.8) years. Mean (SD) disease characteristics at BL were Eczema Area and Severity Index 20.7 (11.3), 24-hour Peak Pruritus Numerical Rating Scale 7.3 (2.2), Dermatology Life Quality Index 16.3 (7.2), POEM 20.5 (5.9), RECAP 19.1 (5.7) and the overall mean number of flares over the 12 weeks prior to baseline was 2.5 (5.9). The most common atopic comorbidities included rhinitis (60.8%), asthma (36.9%) and food allergy (31.6%). At BL, 85.9% of pts had prior TCS use, 31.6% had prior biologic or Janus kinase inhibitor use and 23.6% had prior dupilumab use.

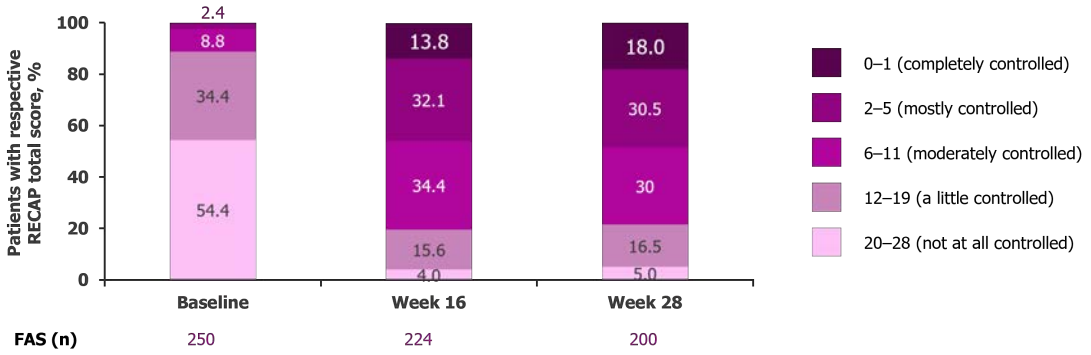
At BL, 2.8% of pts had POEM scores ≤7; this notably increased to 50.9% at W16 and 54.2% at W28. The majority of pts reported that their eczema was not controlled at all (54.4%) or a little controlled (34.4%) at BL, as assessed by RECAP total scores (**Figure**). At W16, these proportions notably reduced to 4.0% and 15.6%, respectively, with over 80% of patients reporting meaningful control over eczema: 34.4% reported moderate control, 32.1% reported mostly controlled and 13.8% reported complete control. Responses were maintained at W28; low

proportions of pts (5.0%) reported there was no control over eczema, 16.5% reported little control, 30.0% reported moderate control, 30.5% reported mostly controlled and 18.0% reported that their eczema was completely controlled. The overall mean number of flares over the past 12 weeks decreased from 2.5 at baseline to 0.6 at W16 and decreased further to 0.4 at W28. Across all outcomes, OC and LOCF data were comparable.

Conclusions

During 28Ws of treatment, LEB provided improved control over eczema, with approximately half of the patients reporting that their eczema was completely to mostly controlled. By W16, flare frequency reduced to a mean of ≤1 over the past 12 weeks, which was sustained until W28. These results are consistent with the improvements in signs, symptoms and HRQoL previously reported in this patient cohort.

Figure. RECAP total score by individual categories over time (OC)



Data reported for the FAS (N=263). RECAP is scored 0–28 with lower scores indicating greater control over eczema and is categorised by the degree of eczema control. FAS: full analysis set; OC: observed case; RECAP: Recap of Atopic Eczema.

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Abstract N°: 1216

Lebrikizumab Achieved High Levels of Absolute EASI Optimal Response in Patients with Moderate-to-Severe Atopic Dermatitis for Up to 3 Years (ADvocate 1 & 2 to ADjoin)

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Introduction

Lebrikizumab (LEB), a monoclonal antibody binding with high-affinity to interleukin-13, is approved for the treatment of moderate-to-severe atopic dermatitis (AD). While most trials report relative improvements in clinical scores, absolute Eczema Area and Severity Index (EASI) values at specific time points provide a clear measure of residual disease and are relevant to clinical decision-making in daily practice. In Phase 3 trials, high proportions of LEB-treated patients achieving ≥75% improvement from baseline (BL) in EASI (EASI 75) by Week (W)16 also achieved absolute EASI scores of ≤7 (mild disease), ≤5, ≤3 (optimal target) and ≤1 (clear/almost clear skin), with percentages of responders maintained through 2 years of continuous treatment.[1,2] Here, we report the proportion of W16 per-protocol responders from ADvocate 1 & 2 (NCT04146363 & NCT04178967) who achieved these outcomes through 3 years of continuous LEB treatment in the ADjoin long-term extension study (NCT04392154).

Materials and Methods

ADvocate 1 & 2 were two identically designed, randomised, placebo-controlled Phase 3 monotherapy trials in adults (≥18 years) and adolescents (12 to <18 years, ≥40 kg) with moderate-to-severe atopic dermatitis. Patients were randomised 2:1 to LEB 250mg every 2 weeks (Q2W; loading dose 500mg at BL and W2), or placebo Q2W until W16. Responders (EASI 75 or Investigator's Global Assessment [IGA] 0/1 with ≥2-point improvement, without rescue therapy) were re-randomised 2:2:1 at W16 to LEB 250mg Q2W, LEB 250mg every 4 weeks (Q4W), or placebo (LEB withdrawal) through W52. Patients completing W52 were eligible to enrol in ADjoin (W52–W152) and these patients continued the same dose regimen; patients in the LEB withdrawal group were offered LEB Q2W but were excluded from this analysis. Intermittent use of topical corticosteroids (TCS) was permitted in ADjoin to treat AD flares. This post-hoc analysis assessed the proportion of LEB-treated W16 per-protocol responders achieving absolute EASI ≤7, ≤5, ≤3 and ≤1 through W152. Data are reported as observed, using all collected data regardless of rescue medication use; however, data collected after patients switched to the escape arm

during ADvocate 1 & 2 maintenance (i.e. those not achieving ≥50% improvement from BL in EASI) were excluded.

Results

The 291 W16 per-protocol responders were re-randomised and continued to W52; of these, 81 (LEB Q2W) and 96 (LEB Q4W) entered ADjoin. BL characteristics were generally comparable between treatment groups (Q2W and Q4W): 50.6% and 60.4% female; mean age (standard deviation [SD]) 35.3 (16.2) and 35.8 (17.2) years; mean EASI (SD) 29.3 (11.1) and 29.1 (12.2). At W152 (3 years), 88.9% (n=56) of patients receiving LEB Q2W and 97.1% (n=66) receiving LEB Q4W achieved EASI ≤7 (indicating mild disease); 88.9% (n=56) and 89.7% (n=61) achieved EASI ≤5, respectively. The optimal target of EASI ≤3 was achieved by 76.2% (n=48) and 86.8% (n=59), and clear/almost clear skin (EASI ≤1) was achieved by 57.1% (n=36) and 72.1% (n=49) (Q2W and Q4W, respectively). During ADjoin (W52–152), low-to-moderate potency TCS were used by 4.9% (n=4) of patients receiving LEB Q2W and 9.1% (n=9) receiving LEB Q4W; high-potency TCS were used by 6.1% (n=5) and 9.1% (n=9), respectively. LEB was generally well tolerated, and no new safety signals were observed.

Conclusions

In W16 responders who entered ADjoin and continued LEB 250mg Q2W or Q4W, most patients achieved the optimal target (absolute EASI ≤3) and over half achieved clear/almost clear skin (EASI ≤1) through 3 years of continuous treatment. Across both dosing regimens, percentages of responders were maintained at W152 across all absolute EASI thresholds assessed, with most patients not using concomitant TCS. Overall, these findings support long-term disease control with LEB.

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Table. Proportion (%) of W16 per-protocol responders achieving absolute EASI thresholds at W16, with LEB Q2W induction dose, and at W152, after re-randomization at W16, by LEB dosing regimen (Q2W and Q4W)

%	W16		W152	
	LEB Q2W n=112	LEB Q4W n=115	LEB Q2W n=63	LEB Q4W n=68
EASI ≤7	92.9	94.8	88.9	97.1
EASI ≤5	86.6	88.7	88.9	89.7
EASI ≤3	63.4	69.6	76.2	86.8
EASI ≤1	38.4	35.7	57.1	72.1

Data are shown as observed cases among W16 per-protocol responders to LEB Q2W induction dose who entered the ADjoin long-term extension and received continuous LEB through W152 per re-randomised dose at W16.

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Abstract N°: 1224

Dose Escalation of Upadacitinib Achieves Marked Clinical Improvement in a CD25-Deficient Patient with Treatment-Refractory Atopic Dermatitis

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Introduction

CD25 deficiency is a rare autosomal recessive disorder characterized by early-onset autoimmune enteropathy, recurrent viral and opportunistic infections, and frequent autoimmune manifestations such as cytopenias and diabetes. Severe eczema is a prominent feature, often accompanied by variable autoimmune symptoms. Atopic dermatitis (AD) is a common inflammatory skin disorder characterized by chronic pruritic erythematous papules and plaques, significantly affecting quality of life. Pruritus is the primary and most distressing symptom of AD. Janus kinase (JAK) inhibitors offer a promising alternative to injectable biologics, providing rapid symptom relief and effective disease control. Here, we present a CD25-deficient patient with atopic dermatitis unresponsive to conventional therapies, where cyclosporine use was contraindicated.

Case Presentation

A 15-year-old female with CD25 deficiency and long-standing atopic dermatitis, also diagnosed with Hashimoto's thyroiditis, presented with treatment-resistant skin lesions and recurrent infections. Conventional therapies including topical agents and systemic corticosteroids were ineffective, and cyclosporine was contraindicated. Following immunology consultation, upadacitinib was initiated at **15 mg/day**. By the second week, pruritus had completely resolved. At month 3, the dose was escalated to **30 mg/day**. Clinical improvement became apparent at **month 1** and was markedly evident by **month 6**, with near-complete clearance of skin lesions. No infections or adverse events were recorded throughout the treatment course.

Conclusion

CD25 deficiency complicates AD management due to immune dysregulation and impaired skin barrier function. Upadacitinib, an oral JAK inhibitor approved for moderate-to-severe AD in patients aged ≥12, demonstrated significant efficacy in our patient. Initial improvement was observed at month 1, with marked clinical response achieved at month 6 following dose escalation to 30 mg/day. No infectious complications occurred, highlighting its tolerability even in the context of complex immune dysregulation.

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Abstract N°: 1227

Efficacy and Safety of A Cream Containing 5% Panthenol and Prebiotic Complex in Patients with Mild-to-Moderate Facial Atopic Dermatitis: a Randomized Controlled Trial

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Introduction

Atopic dermatitis (AD) is a challenging chronic, relapsing inflammatory skin disease characterized by a complex pathogenesis involving the interplay between epidermal barrier dysfunction, immune dysregulation, and skin microbiome dysbiosis. The compromised skin barrier leads to increased transepidermal water loss (TEWL), which, alongside microbial imbalance driven by Staphylococcus aureus overgrowth, perpetuates the inflammatory cycle of AD. Consequently, repairing the physical barrier and restoring microbial equilibrium are critical clinical strategies for alleviating symptoms and preventing recurrences. Panthenol (Pro-vitamin B5) is widely utilized for its superior epithelial repair and anti-inflammatory properties, while prebiotic complex, a novel active complex, aims to strengthen skin defense by modulating the microbiome. This randomized controlled trial aims to evaluate the clinical efficacy of a cream containing 5% panthenol and prebiotic complex on barrier restoration and lesion improvement in patients with mild-to-moderate AD, compared to a standard moisturizer lacking specific barrier-repairing and microbiome-modulating active ingredients.

Materials and Methods

This study enrolled 62 patients (male: n=40, female: n=22, age: 18-65 years) with mild facial atopic dermatitis, who applied the test or standard cream to the entire face twice daily (morning and evening). Clinical assessments were conducted across four patient visits: a baseline visit (T0, Timm) and three follow-up visits (T2w, T4w, T8w), to compare the efficacy of the test cream with that of the standard cream.

Results

1. The test cream significantly decreased TEWL in AD-lesioned skin, achieving superior improvement versus the standard cream at T2w, T4w, and T8w (Figure 1A). The improvement in hydration and sebum secretion was also greater with the test cream at T2w and T8w (Figure 1B, C). Concurrently, pH value shifted toward a healthy weak acidity and remained consistently more stable than the standard cream from T2w through T8w, although the differences were not statistically significant (Figure 1D).

2. The test cream showed better efficacy in attenuating atopic dermatitis symptoms: IGA scores dropped significantly at T2w, T4w, and T8w, while EAIS-assessed symptoms also showed marked improvement at T4w and T8w (Figure 2).

3. Subjects reported significantly reduced itching with the test cream, outperforming the standard cream at T2w, T4w, and T8w (Figure 3A). Additionally, quality of life improved substantially, with DLQI scores decreasing significantly more than those of the standard cream at T2w, T4w, and T8w (Figure 3B).

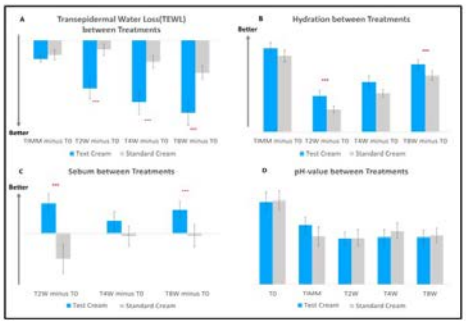

Figure 1. Instrument measurements of efficacy (compared to the standard cream, ***p < 0.001)

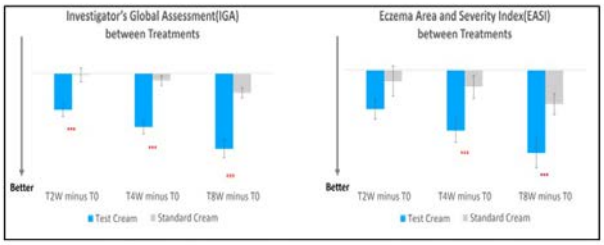

Figure 2. Clinical assessment of efficacy (compared to the standard cream, ***p < 0.001)

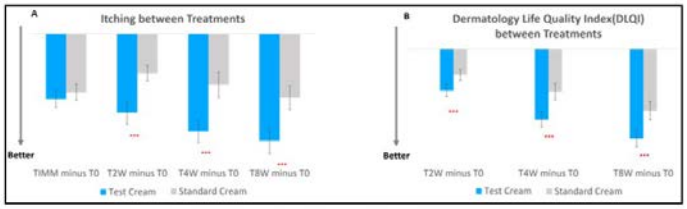

Figure 3. Self assessment of efficacy (compared to the standard cream, ***p < 0.001)

Figure 1. Instrument measurements of efficacy (compared to the standard cream, ***p < 0.001) Figure 2. Clinical assessment of efficacy (compared to the standard cream, ***p < 0.001) Figure 3. Self assessment of efficacy (compared to the standard cream, ***p < 0.001)

Conclusions

This study demonstrates that the repair cream, formulated with active ingredients (5% panthenol and prebiotic complex) designed for barrier restoration and microbiome modulation, yields superior clinical outcomes compared to a standard moisturizer in the management of mild facial atopic dermatitis. The formulation exhibited significant superiority in accelerating barrier recovery, enhancing skin hydration, and alleviating pruritus, resulting in rapid improvements in patient quality of life. Furthermore, sustained application led to a continuous reduction in disease severity and demonstrated high efficacy in preventing long-term clinical relapses.

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Abstract N°: 1228

Acute Generalized Exanthematous Pustulosis Induced by Upadacitinib Dose Escalation in a CD25-Deficient Patient: A Novel Adverse Event

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Introduction

Upadacitinib is a selective Janus kinase (JAK) inhibitor approved for the treatment of moderate-to-severe atopic dermatitis in patients aged ≥12 years, demonstrating significant efficacy and a generally favorable safety profile in clinical trials. CD25 deficiency is a rare primary immunodeficiency characterized by immune dysregulation, severe eczema, and increased susceptibility to infections. Acute Generalized Exanthematous Pustulosis (AGEP) is a rare, severe cutaneous adverse reaction typically triggered by medications, presenting with widespread sterile pustules on an erythematous background. To our knowledge, upadacitinib-induced AGEP has not been previously reported in the literature, particularly in the setting of an underlying primary immunodeficiency.

Case Presentation

A 15-year-old female with CD25 deficiency and treatment-refractory atopic dermatitis, also diagnosed with Hashimoto's thyroiditis, was initiated on upadacitinib 15 mg/day. At month 1, clinical improvement was observed, and the dose was escalated to 30 mg/day at month 3, achieving marked skin clearance by month 6. Subsequently, the dose was further escalated to 45 mg/day. Three days following dose escalation, the patient developed widespread erythematous pustular lesions covering the entire body. Given the clinical presentation, differential diagnoses included AGEP and Kaposi Varicelliform Eruption. Skin biopsy was performed and histopathological examination confirmed AGEP. Herpes Simplex Virus (HSV) testing returned negative. Upadacitinib was dose-reduced to 30 mg/day and systemic corticosteroid therapy was administered for 15 days. Lesions regressed significantly within this period.

Conclusion

This case represents the first reported instance of upadacitinib-induced AGEP following dose escalation in a patient with CD25 deficiency. The rapid onset of widespread pustular eruption within 3 days of dose escalation, histopathological confirmation of AGEP, and clinical resolution upon dose reduction strongly suggest a dose-dependent adverse reaction. Clinicians should remain vigilant for severe cutaneous adverse events when escalating upadacitinib doses, particularly in patients with underlying immune dysregulation. Skin biopsy is essential to establish a definitive diagnosis and to differentiate AGEP from other pustular eruptions, including Kaposi Varicelliform Eruption, in immunocompromised patients.

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Delgocitinib cream reduces patient-reported disease severity in adults with moderate to severe Chronic Hand Eczema: pooled analysis of the Phase 3 DELTA 1 and DELTA 2 trials

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Introduction

Chronic Hand Eczema (CHE) is a multifactorial, heterogeneous, inflammatory skin disease presenting with a range of symptoms, including itch and pain, which impose a substantial burden on patients' quality of life. Delgocitinib cream 20 mg/g – a topical pan-Janus kinase inhibitor applied twice daily – has demonstrated efficacy and a favourable safety profile in the Phase 3 DELTA 1 and DELTA 2 trials, and is currently the only nonsteroidal topical treatment approved for adults with moderate to severe CHE. However, few studies have reported the efficacy of delgocitinib cream based on changes in patient-reported disease severity.

The objective of this study was to evaluate the effect of delgocitinib cream on patient-reported disease severity in adults with moderate to severe CHE.

Materials and Methods

Data from patients who received delgocitinib cream (N=638) or cream vehicle (N=321) twice daily were pooled from the DELTA 1 (NCT04871711) and DELTA 2 (NCT04872101) trials. Patient-reported severity of CHE was evaluated with the Patient Global Assessment (PaGA), the Patient Global Impression of Change (PGI-C), and the Patient Global Impression of Severity (PGI-S). The PaGA is a 5-point scale (0='clear', 1='almost clear', 2='mild', 3='moderate', 4='severe') based on the patient's own assessment of severity of their CHE. The PGI-C is a 1-item questionnaire designed to assess the subject's impression of changes in their itch, pain, or disease severity (based on Hand Eczema Symptom Diary [HESD]) using 5 response options ('much better', 'a little better', 'no change', 'a little worse', 'much worse'). The PGI-S is a 1-item questionnaire assessing the subject's global perception of their itch, pain, or CHE signs and symptoms over the past week on a 4-point categorical response scale ('none', 'mild', 'moderate', 'severe'). Changes from baseline were measured over 16 weeks and compared between the delgocitinib cream and cream vehicle groups.

Results

At Week 2, the percentage of patients reporting PaGA scores of 0/1 ('clear' or 'almost clear') was significantly higher in the treatment group (delgocitinib cream) than in the control group (cream vehicle) (11.6% [n=73] vs. 5.4% [n=17]; p=0.002), and the difference was maintained through Week 16 (33.8% [n=213] vs. 13.6% [n=43]; p<0.001) (Table 1). Similarly, at Week 2, the percentage of patients reporting the change in their disease to be 'much better' (PGI-C 0) was significantly higher in the treatment group than in the control group for itch (35.4% [n=216] vs. 15.4% [n=47]), pain (37.4% [n=228] vs. 15.4% [n=47]), and HESD (34.9% [n=213] vs. 12.7% [n=39]) (p<0.001 for all comparisons), with differences maintained through Week 16 (54.6% [n=333] vs. 24.2% [n=74], 56.7% [n=346] vs. 24.5% [n=75], 55.4% [n=338] vs. 24.2% [n=74] for itch, pain, and HESD, respectively; p<0.001 for

all comparisons) (Table 1). The percentage of patients reporting PGI-S 0 at Week 2 was also significantly higher in the treatment group compared with the control group for itch (7.1% [n=45] vs. 3.8% [n=12]; p=0.041) and pain (19.0% [n=120] vs. 9.2% [n=29]; p<0.001), with differences maintained through Week 16 (23.9% [n=151] vs. 11.1% [n=35] and 37.6% [n=237] vs. 15.5% [n=49] for itch and pain, respectively; p<0.001 for both) (Table 1). For HESD, a significant difference between the groups was first observed at Week 8 (12.9% [n=81] vs. 5.4% [n=17]; p<0.001) and maintained through Week 16 (16.3% [n=103] vs. 4.7% [n=15]; p<0.001). When PGI-S HESD (see Table 1) was extended to include scores 0/1, a significant difference was observed from Week 2 (43.7% [n=275] vs. 31.0% [n=98]; p<0.001) and continued through Week 16 (60.6% [n=382] vs. 32.3% [n=102]; p<0.001).

Table 1 Changes in patient-reported CHE severity, expressed as the percentage of patients by PaGA, PGI-C, and PGI-S, over 16 weeks of twice-daily delgocitinib cream treatment in the DELTA 1 and DELTA 2 trials.

Outcome, n*(%)*		**Baseline**	**Week 2**	**Week 4**	**Week 8**	**Week 16**
PaGA 0/1						
	Delgocitinib cream (N=631)	6 (1.0%)	73 (11.6%)[a]	130 (20.6%)[b]	187 (29.6%)[b]	213 (33.8%)[b]
	Cream vehicle (N=317)	1 (0.3%)	17 (5.4%)	24 (7.6%)	37 (11.7%)	43 (13.6%)
PGI-C 0						
Itch	Delgocitinib cream (N=610)	–	216 (35.4%)[b]	283 (46.4%)[b]	305 (50.0%)[b]	333 (54.6%)[b]
	Cream vehicle (N=306)	–	47 (15.4%)	46 (15.0%)	72 (23.5%)	74 (24.2%)
Pain	Delgocitinib cream (N=610)	–	228 (37.4%)[b]	288 (47.2%)[b]	307 (50.3%)[b]	346 (56.7%)[b]
	Cream vehicle (N=306)	–	47 (15.4%)	51 (16.7%)	73 (23.9%)	75 (24.5%)
HESD	Delgocitinib cream (N=610)	–	213 (34.9%)[b]	286 (46.9%)[b]	323 (53.0%)[b]	338 (55.4%)[b]
	Cream vehicle (N=306)	–	39 (12.7%)	47 (15.4%)	81 (26.5%)	74 (24.2%)
PGI-S 0						
Itch	Delgocitinib cream (N=631)	3 (0.5%)	45 (7.1%)[c]	90 (14.3%)[b]	157 (24.9%)[b]	151 (23.9%)[b]
	Cream vehicle (N=316)	1 (0.3%)	12 (3.8%)	17 (5.4%)	25 (7.9%)	35 (11.1%)
Pain	Delgocitinib cream (N=630)	11 (1.7%)	120 (19.0%)[b]	174 (27.6%)[b]	229 (36.3%)[b]	237 (37.6%)[b]
	Cream vehicle (N=316)	4 (1.3%)	29 (9.2%)	41 (13.0%)	47 (14.9%)	49 (15.5%)
HESD	Delgocitinib cream (N= 630)	2 (0.3%)	24 (3.8%)	38 (6.0%)[d]	81 (12.9%)[b]	103 (16.3%)[b]
	Cream vehicle (N=316)	1 (0.3%)	12 (3.8%)	10 (3.2%)	17 (5.4%)	15 (4.7%)
PGI-S 0/1						
HESD	Delgocitinib cream (N= 630)	29 (4.6%)	275 (43.7%)[b]	338 (53.7%)[b]	377 (59.8%)[b]	382 (60.6%)[b]
	Cream vehicle (N=316)	16 (5.1%)	98 (31.0%)	100 (31.6%)	113 (35.8%)	102 (32.3%)

PaGA 0/1; Patient Global Assessment score of 0/1 (clear/almost clear); PGI-C 0: Patient Global Impression of Change reported as 'much better'; PGI-S 0: Patient Global Impression of Severity score reported as 'none'; PGI-S 0/1: Patient Global Impression of Severity score reported as 'none' or 'mild'; HESD; Hand Eczema Symptom Diary; n; number of subjects with an outcome; N; number of subjects with data available at baseline; %: percentage of subjects with an outcome.

Notes: Statistical difference between the delgocitinib cream and cream vehicle groups: [a]p=0.002; [b]p<0.001; [c]p=0.041; [d]p=0.059.

Conclusions

Treatment with delgocitinib cream 20 mg/g twice daily resulted in rapid and sustained reductions in patient-reported severity of CHE during the DELTA 1 and 2 pivotal trials, as indicated by improvements in PaGA, PGI-C, and PGI-S.

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Efficacy and safety of Telikibart for moderate to severe atopic dermatitis: a randomized placebo-controlled, phase III trial

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Introduction

Telikibart (GR1802) is a fully human monoclonal antibody that specifically targets the interleukin-4 receptor alpha (IL-4Rα) subunit, featuring a unique epitope and structural characteristics distinct from dupilumab. Preliminary results from a phase Ⅱ trial have demonstrated its potential therapeutic effects in treating atopic dermatitis by inhibiting IL-4 and IL-13 signaling pathways. This randomized, placebo-controlled, phase Ⅲ trial (NCT06216392) aimed to evaluate the efficacy and safety of Telikibart in adult patients with moderate to severe atopic dermatitis over 52 weeks.

Materials and Methods

In this trial, participants diagnosed with moderate to severe atopic dermatitis were randomized 2:1 to receive either Telikibart 300 mg (600 mg on day 1) or placebo every 2 weeks during the 16-week induction period. Subsequently, all participants received Telikibart 300 mg every 2 weeks until week 52 in the maintenance period (placebo group received Telikibart 600 mg at the first dose). Primary endpoints were the proportion of patients achieving ≥75% improvement in Eczema Area and Severity Index (EASI-75) and ≥2-point improvement in Investigator's Global Assessment of clear/almost clear skin (IGA 0/1) at week 16.

Results

Between January 2024 and August 2025, a total of 450 patients were randomized to receive either Telikibart 300

mg (n=299) or placebo (n=151). Among these, 419 patients completed the double-blind period, and 388 completed the 52-week treatment. At week 16, the proportion of patients achieving an EASI-75 response was significantly higher in the Telikibart group than in the placebo group (69.6% vs. 22.5%; difference, 47.1% [95% CI, 38.62-55.50]; P <0.0001). A higher IGA 0/1 response was also observed in the Telikibart group (33.1% vs. 6.6%; difference, 26.5% [95% CI, 19.86-33.15]; P <0.0001). These therapeutic benefits were consistently observed across all secondary endpoints. At week 52, EASI-75 was achieved in 94.3% of patients who continued Telikibart treatment and 95.9% of those switched from placebo to Telikibart. Corresponding IGA 0/1 response rates were 65.4% and 58.5%, respectively. 76.0% and 76.7% of patients in the two groups achieved a ≥4-point reduction in the weekly average of the daily Peak Pruritus Numerical Rating Scale, respectively (Table 1). During the doubleblind period, treatment-emergent adverse events (TEAEs) were reported in 64.5% of the Telikibart group and 57.6% of the placebo group. Overall, 82.2% of patients who received at least one dose of Telikibart experienced TEAEs, the majority of which were graded as Grade 1-2 according to the CTCAE 5.0.

Conclusions

Telikibart demonstrated promising efficacy in patients with moderate to severe atopic dermatitis at 16 weeks, with consistent efficacy observed throughout 52-week treatment. The safety profile was mild and tolerable.

Table 1 Efficacy endpoints at week 16 and week 52

		Telikibart (n=299)	Placebo (n=151)	Difference (95%CI)	P value
Co-primary endpoints					
Week 16	Patient with EASI-75, n (%)	208 (69.6)	34 (22.5)	47.1 (38.6, 55.5)	P <0.0001
	Patients with IGA 0/1 and ≥2-point improvement from baseline, n (%)	99 (33.1)	10 (6.6)	26.5 (19.9, 33.2)	P <0.0001
Secondary endpoints					
Week 16	Patients with EASI-90, n (%)	120 (40.1)	17 (11.3)	28.9 (21.4, 36.4)	P <0.0001
	LS mean change in AD-affected %BSA from baseline, mean (SE)	-24.68 (0.9)	-20.86 (2.3)	-12.51 (-15.7, -9.3)	P <0.0001
	LS mean percent change in EASI score from baseline, mean (SE)	-76.5 (28.3)	-39.1 (41.7)	-37.6 (-44.2, -30.9)	P <0.0001
	Patients with ≥3-point reduction in weekly average of daily PP-NRS score from baseline, n (%)	184 (61.5)	38 (25.2)	36.4 (27.5, 45.2)	P <0.0001
	Patients with ≥4-point reduction in weekly average of daily PP-NRS score from baseline, n (%)	144 (48.2)	28 (18.5)	29.6 (21.3, 38.0)	P <0.0001
	LS mean change in DLQI score from baseline, mean (SE)	-7.4 (0.4)	-2.9 (0.5)	-4.5 (-5.7, -3.3)	P <0.0001
	LS mean change in POEM score from baseline, mean (SE)	-10.8 (0.4)	-3.1 (0.6)	-7.7 (-9.1, -6.3)	P <0.0001
	LS mean change in SCORAD score from baseline, mean (SE)	-39.1 (1.1)	-17.5 (1.5)	-21.6 (-25.3, -17.8)	P <0.0001
Week 52	Patient with EASI-75, n (%)	248 (94.3)	118 (95.9)	-	-
	Patients with IGA 0/1 and ≥2-point improvement from baseline, n (%)	172 (65.4)	72 (58.5)	-	-
	Patients with EASI-90, n (%)	210 (79.8)	95 (77.2)	-	-
	Mean change in AD-affected %BSA from baseline, mean (SD)	-33.9(17.7)	-33.0 (18.5)	-	-
	Mean percent change in EASI score from baseline, mean (SD)	-93.4(10.0)	-93.1(10.4)	-	-
	Patients with ≥3-point reduction in weekly average of daily PP-NRS score from baseline, n (%)	228 (87.0)	103 (85.8)	-	-
	Patients with ≥4-point reduction in weekly average of daily PP-NRS score from baseline, n (%)	199 (76.0)	92 (76.7)	-	-
	Mean change in DLQI score from baseline, mean (SD)	-9.7 (6.9)	-11.0 (7.3)	-	-
	Mean change in POEM score from baseline, mean (SD)	-13.9 (7.3)	-13.3 (7.6)	-	-
	Mean change in SCORAD score from baseline, mean (SD)	-52.6 (14.6)	-51.2 (13.8)	-	-

EASI-75, ≥75% improvement in Eczema Area and Severity Index; IGA 0/1, Investigator's Global Assessment of clear/almost clear skin; LS, Least squares; EASI-90, ≥90% improvement in Eczema Area and Severity Index; AD, atopic dermatitis; SE, standard error; SD, standard deviation; %BSA, percent of total body surface area; PP-NRS, Peak Pruritus Numerical Rating Scale; DLQI, Dermatology Life Quality Index; POEM, Patient-Oriented Eczema Measure; SCORAD, Scoring Atopic Dermatitis Index; CI, confidence interval.

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Real-World Effectiveness and Safety of 200 mg Abrocitinib Initiation in Chinese Adults with Moderate-to-Severe Atopic Dermatitis: A Retrospective Study

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Introduction

The pathogenesis of atopic dermatitis (AD) involves complex interactions between skin barrier dysfunction and immune dysregulation, with cytokine signaling mediated by the Janus kinase (JAK)/Signal Transducer and Activator of Transcription (STAT) pathway playing a pivotal role. Abrocitinib, a highly selective JAK1 inhibitor approved in 2022, has demonstrated significant efficacy in multiple clinical trials.

Current guidelines recommend initiating abrocitinib at 100 mg, escalating to 200 mg if efficacy is inadequate. However, real-world data on 200 mg initiation in Chinese patients remain scarce, and clinicians often face a dilemma: whether to start with a higher dose for rapid relief or a standard dose to minimize potential adverse effects. Early identification of patients likely to have a suboptimal response to standard dosing, and the evaluation of a 200 mg induction strategy in a real-world setting, are critical for clinical decision-making. This retrospective study analyzes data from the patients with moderate-to-severe AD treated with abrocitinib in our department to compare the effectiveness and safety of 100 mg versus 200 mg initiation strategies, aiming to provide a reference for individualized management.

Case Presentation

Methods: This retrospective study included 20 patients with moderate-to-severe AD treated with abrocitinib from our department. Patients were stratified into Group A (n=7, initiated at 200 mg, tapered to 100 mg if EASI-75 or ≥4-point PP-NRS reduction was achieved by week 12) and Group B (n=13, initiated at 100 mg, escalated to 200 mg if targets were not met). Primary outcomes included Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA), Peak Pruritus Numeric Rating Scale (PP-NRS), and Dermatology Life Quality Index (DLQI). Adverse events (AEs) were recorded.

Results: Both groups showed significant reductions in all outcome measures at weeks 4, 12, and 24. Baseline DLQI was significantly higher in Group A (22.0 vs. 18.0, $P < 0.001$). At week 4, Group A showed superior PP-NRS improvement ($P = 0.019$). By week 12, Group A achieved significantly higher rates of EASI < 5 (57.14% vs. 0%, $P < 0.01$) and IGA 0/1 (85.71% vs. 7.69%, $P < 0.01$). Notably, 50% of patients had failed prior systemic therapies, including 85.7% in Group A, reflecting the refractory nature of the cohort. At week 24, Group A maintained superiority in EASI and PP-NRS ($P < 0.05$), while EASI-75 response exceeded 90% in both groups. AEs were comparable between groups (71.43% vs. 61.54%), with no serious events.

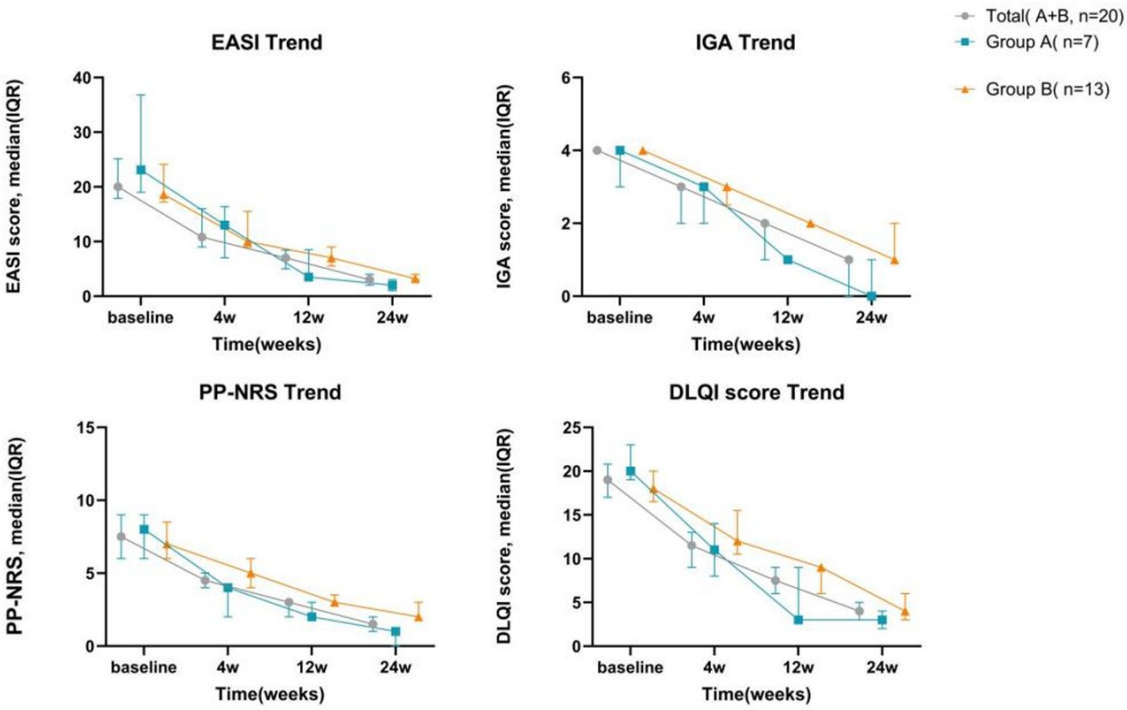

Figure 1. Changes of follow-up indicators with the course of treatment
IQR = the interquartile range.

Conclusion

Comparing to 100 mg abrocitinib, 200 mg abrocitinib initiation strategy offers rapid and sustained disease control, particularly for patients with high baseline disease activity and severe quality of life impairment. The 100 mg strategy achieves favorable outcomes by Week 24 for those with milder burden. These findings support personalized dosing that we can start higher dose, 200 mg abrocitinib, at the initial treatment or maintenance treatment phase, though larger prospective studies are warranted to confirm results.

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Dose modulation of Upadacitinib in the treatment of moderate-to-severe atopic dermatitis: insights from an Italian real-world experience

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Introduction

Upadacitinib, a selective Janus kinase 1 inhibitor, represents an effective therapeutic option for moderate-to-severe atopic dermatitis (AD). However, evidence regarding real-world dose adaptability and its impact on long-term disease control remains limited.

To assess the real-world effectiveness and dose modulation patterns of upadacitinib 15 mg and 30 mg in adults with moderate-to-severe AD, focusing on the achievement and maintenance of Minimal Disease Activity (MDA).

Materials and Methods

This multicenter retrospective study included 202 adults with AD treated with upadacitinib between July 2019 and February 2024. Patients received 15 mg or 30 mg daily according to physician judgment. Clinical outcomes—including EASI, pruritus and sleep disturbance NRS (NRS-p and NRS-sd), and DLQI—were collected at baseline (T0), week 16 (T1), and week 32 (T2). MDA was defined as simultaneous achievement of EASI90 and NRS-p 0/1

Results

Out of 202 patients, 123 (60.9%) initiated treatment at 15 mg and 79 (39.1%) at 30 mg. MDA was achieved by 52.5% at T1 and 56.4% at T2. At T1, significantly more patients on 30 mg achieved MDA compared to those on 15 mg (62.0% vs. 46.3%, $p<0.05$). However, by T2, this difference was not statistically significant (57.7% vs. 55.7%, $p=0.78$). During follow-up, dose adjustments occurred in 12.9% of patients: 7.3% escalated from 15 to 30 mg, while 21.5% reduced from 30 to 15 mg. Maintenance of MDA between weeks 16 and 32 was similar across dose groups (82.1% for 15 mg vs. 76.9% for 30 mg; $p=0.52$). Dose escalation from 15 mg or reduction from 30 mg did not significantly influence subsequent MDA outcomes.

Conclusions

Both upadacitinib 15 mg and 30 mg are highly effective in real-world settings for achieving and maintaining MDA in moderate-to-severe AD. Dose modifications were infrequent and not associated with different medium-term MDA outcomes, supporting a flexible, response-driven approach to treatment personalization.

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Abstract N°: 1339

Atopic Dermatitis in Adolescents: Exploring Maternal Caregiving and Its Impact on Mother–Adolescent Relationships

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Introduction

Atopic dermatitis is one of the most prevalent chronic inflammatory skin conditions in childhood and adolescence and it is associated with a considerable psychosocial burden. Persistent pruritus and visible skin lesions may impair daily functioning, social interactions, and emotional well-being. Its impact extends to families, with mothers frequently assuming primary caregiving roles and experiencing substantial psychological and practical demands. This study aimed to explore how atopic dermatitis and its management affect the mother–adolescent relationship.

Materials and Methods

A qualitative descriptive study was conducted. Fifteen mothers of adolescents aged 12–17 years with atopic dermatitis were recruited through purposive sampling from the dermatology departments of two public hospitals in north-western Spain. Data were collected through semi-structured interviews conducted between November 2024 and August 2025. Interviews were audio-recorded, transcribed verbatim, and complemented with field notes. Data were analysed using thematic analysis following Braun and Clarke's framework. Methodological rigour was ensured through strategies such as investigator triangulation. Ethical approval was obtained from the Research Ethics Committee, and all participants provided written informed consent.

Results

Responsibility for managing atopic dermatitis gradually shifted to adolescents; however, mothers continued to

bear the cognitive and organisational burden of disease management, including coordinating treatments, medical appointments, and adherence to clinical recommendations. Atopic dermatitis influenced the mother–adolescent relationship, giving rise to conflicts around treatment adherence, communication difficulties, and tensions between autonomy and supervision. Mothers reported feelings of frustration and helplessness, while some described strengthened relationships characterised by increased closeness and mutual support. Overall, caregiving demands shaped family dynamics and reinforced maternal responsibility.

Conclusions

This study provides insight into the complex experiences of mothers caring for adolescents with atopic dermatitis and its impact on the mother–adolescent relationship. Maternal care encompasses not only daily care and emotional support but also active involvement in dermatological management. These findings highlight the persistence of a gendered distribution of care, in which maternal responsibility remains central despite adolescents' increasing autonomy. These results underscore the need for holistic, family-centred interventions in dermatological care that address psychosocial and gender dimensions, support maternal well-being, and promote effective collaboration between families and healthcare professionals to improve outcomes and well-being for adolescents and their families.

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Abstract N°: 1346

Defining long-term management strategies in chronic hand eczema: Consensus from an international expert panel

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Introduction

Chronic hand eczema (CHE) is a high-burden inflammatory condition with substantial impact on patients' daily functioning and quality of life (QoL). Current clinical management of CHE frequently relies on repeated cycles of topical corticosteroids (TCS) despite limited evidence to support their long-term use and known risks of cumulative exposure. Clear guidance is needed to define when TCS are no longer appropriate and when escalation to non-steroidal options would be suitable. Standardised definitions of disease severity, treatment response and patient-centric success criteria are required to inform these treatment decisions. The Global CHE Consensus was initiated to develop practical, expert-informed guidance for long-term management of patients with CHE.

Materials and Methods

A seven-member international Steering Committee (SC) undertook a modified Delphi process. Following a scoping literature review to identify areas where consensus could add value, SC members completed two surveys comprising information-gathering and iterative Delphi voting statements. The consensus threshold was predefined as ≥80% voting 'agree' or 'strongly agree' on a five-point Likert scale for both surveys. As part of the ongoing Delphi process, these findings are being validated in a wider Delphi panel (N=13 additional panellists).

Results

The seven members of the SC completed both surveys. Consensus was achieved across multiple domains, including acknowledging chronicity of hand eczema; assessing the patient condition; reviewing current treatment; triggers for changing treatment approach; continuing the current treatment approach; changing treatment approach; selecting and initiating maintenance treatment; and reassessing patient condition and treatment response over time (**Figure**).

As of the second SC survey, consensus was reached on 106 statements. Key recommendations include (number voting 'agree' or 'strongly agree'/total respondents): CHE should be recognised as a long-term condition

requiring a proactive management plan rather than being managed solely as a series of recurrent flares (7/7); clear guidance is needed on what constitutes an adequate and safe trial of different treatments in CHE (7/7); relapse in CHE is defined as worsening of signs, symptoms or function after a period of disease control, with the need to modify or escalate treatment (6/7); the functional and QoL impact of CHE (e.g. itch and pain, impaired hand function, work limitations) should be considered to have equal importance to the visible disease signs when assessing disease burden (7/7); timely reassessment is essential to avoid prolonged ineffective treatment in moderate-to-severe CHE (7/7); and repeated cycling of TCS without sustained disease control should prompt reassessment of the overall treatment strategy in CHE (7/7).

The consensus emphasises that while TCS remain an important component of management, they should not be relied upon indefinitely in chronic disease. Consideration of cumulative exposure, adverse events and patient tolerability is critical in guiding treatment decisions. The need for structured reassessment and earlier escalation to non-steroidal therapies to achieve sustained disease control is consistently supported.

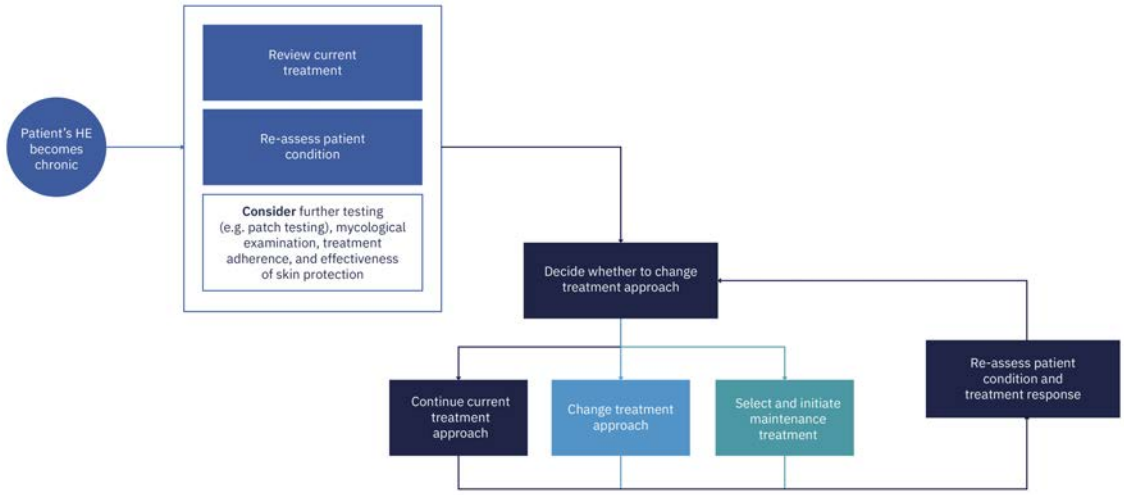

Figure: Consensus-based decision tree for the long-term management of moderate to severe chronic hand eczema. HE, hand eczema.

Conclusions

These findings demonstrate strong international agreement on key principles underpinning the long-term management of CHE, including recognition of chronicity, the need for multidimensional assessment beyond the visible signs of CHE, and the limitations of prolonged TCS use. Ongoing validation with a broader Delphi panel aims to ensure the consensus is fit to guide timely, consistent and patient-centred care for patients with CHE.

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Abstract N°: 1355

Sustained effectiveness of upadacitinib and abrocitinib in moderate-to-severe atopic dermatitis: a 104-week, real-world, retrospective study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by severe pruritus and eczematous skin lesions resulting from skin barrier dysfunction. Upadacitinib and abrocitinib are selective Janus kinase (JAK)-1 inhibitors approved for the treatment of moderate-to-severe AD in adults and pediatric patients 12 years and older. Although their high efficacy and good safety profile have been demonstrated in randomized controlled trials, few real-world studies reporting long-term data are available. The aim of this study was to summarize our experience with upadacitinib and abrocitinib over a 104-week period.

Materials and Methods

We conducted a retrospective, single-center cohort study including all AD patients that received at least one dose of either upadacitinib or abrocitinib. Clinical and patient-reported outcomes were recorded and assessed at each follow-up visit and included the eczema area severity index (EASI), investigator global assessment (IGA), dermatology life quality index (DLQI) and the worst pruritus numerical scale score (WP-NRS). In addition, the proportion of patients achieving EASI75/90/100 (reduction in baseline EASI score by 75/90/100%), absolute DLQI≤2, WP-NRS 0/1 and IGA0/1 were calculated at each follow-up visit. Discontinuations and drug-related adverse events (AEs) were assessed and documented.

Results

In total, 59 upadacitinib (females 47.4%) and 28 abrocitinib (females 35.7%) patients were included with a mean age of 32.6 and 29.1 years respectively. Regarding upadacitinb, the mean baseline EASI was 27.7, the mean DLQI 20.3 and the mean WP-NRS 8.5. Forty patients (67.8%) received the 30mg dose and the rest (32.2%) the 15mg. The EASI75/90/100 were achieved by 78.1/65.4/49.1% after 12 weeks and by 84/78/72% of patients after 52 weeks of treatment. After 12 and 52, the WP-NRS 0/1 was achieved by 76.3% and 80% of patients respectively. At 104 weeks, EASI100 was achieved by 84.1% of those evaluated. Twenty-two patients (37.2%) suffered from AEs (4 acne, 4 hepatic enzyme elevation, 3 elevated CPK, 2 urinary tract infections, 2 upper respiratory infections, 2 folliculitis, 2 herpes zoster infections, 2 neutropenia, 1 anemia) leading to 8 (13.5%) discontinuations. Regarding abrocitinib, the mean baseline EASI was 25.3, the mean DLQI 19.4 and the mean WP-NRS 8.8. The EASI75/90/100 were achieved by 70.3/51.8/44.4% after 12 weeks and by 84/72/60% of patients after 52 weeks of treatment. After 12 and 52, the WP-NRS 0/1 was achieved by 70.3% and 76% of patients respectively. At 104 weeks, EASI100 and DLQI≤2 was achieved by 72.7% and 77.2% of patients. Eleven (39.2%) experienced AEs (4 elevated CPK, 3 acne, 2 upper respiratory infections, 2 hepatic enzyme elevation, 1 persistent diarrhea, 1 herpes zoster infection, 1 folliculitis) leading to 4 discontinuations. Another three patients discontinued due to incomplete disease management and one self-discontinued due to complete and sustained disease remission.

Conclusions

Our study demonstrated the high efficacy of both upadacitinib and abrocitinib, in both the short- and long-term, comparable to phase-3 clinical trials' data, without detecting new safety concerns. Our data supports the real-world, long-term effectiveness of upadacitinib and upadacitinib in patients suffering from moderate-to-severe AD. Nevertheless, large prospective studies are warranted to validate these findings.

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Exploring Oral Microbiome and Metabolic Characteristics of Atopic Dermatitis in Children and Adolescents Using Salivary Metagenomics and Metabolomics

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Introduction

Objective: This study aimed to compare the oral microbiome and metabolic profiles of pediatric and adolescent atopic dermatitis (AD) patients with healthy controls using metagenomics and metabolomics, and to analyze differences among mild, moderate, and severe AD. We also investigated the relationship between clinical characteristics, early colonization factors, and disease severity in pediatric/adolescent AD patients.

Methods: Thirty pediatric/adolescent AD patients (aged 4–18 years) treated at Chengdu Second People's Hospital from January to December 2025 were enrolled as the AD group, classified as mild (n=14), moderate (n=9), and severe (n=7) based on SCORAD scores. Ten age-matched healthy individuals served as controls. Unstimulated saliva samples were collected under natural conditions. Baseline data included age, sex, mode of delivery, feeding method, antibiotic exposure before age 2, history of food allergies, history of atopic diseases, and family history of atopic diseases. In the AD group, SCORAD scores, serum 25-hydroxyvitamin D, and total IgE levels were measured. Saliva samples underwent high-throughput metagenomic sequencing and LC-MS for analysis of oral microbial communities and metabolites. Microbial and metabolite functions were annotated using KEGG pathways.

Results:

1. Children with AD had a higher prevalence of food allergy history and family history of atopic diseases than controls ($P<0.05$). Serum total IgE levels were positively correlated with SCORAD scores ($\beta=0.01$; 95% CI, 0.00–0.01; $P=0.016$).
2. AD patients with a family history of atopic diseases had lower SCORAD scores than those without ($\beta=-25.01$; 95% CI, −39.12 to −10.89; $P=0.002$).
3. Oral microbiome analysis showed reduced abundance of Actinomycetes, Diatomella, Lipomyces, and TM7 saccharomycetes in AD patients compared to controls (all $P<0.05$). Staphylococcus aureus was enriched in patients with severe AD ($P=0.03$).
4. KEGG functional annotation revealed increased metabolic activity in AD-associated oral microbiota, including enrichment in antimicrobial resistance-related pathways ($P=0.04$). Metabolic profiles clustered according to AD severity.
5. Compared to controls, the AD group showed downregulation of metabolites such as hydroxy-β-piperine, LysoPE(12:0/0:0), LysoPE(0:0/20:3), and gingerol. Metabolites including LysoPC(O-18:2/0:0), valyl-aspartyl-tryptophan, 7-hydroxyheptanoic acid, and arginyl-glycyl-phenylalanine were elevated in mild-to-moderate AD but decreased in severe AD (all $P<0.05$).
6. KEGG analysis indicated downregulation of PI3K-Akt, mTOR, and AMPK signaling pathways, as well as cortisol synthesis/secretion pathways, in AD patients versus controls. The propionate metabolism pathway differed across mild, moderate, and severe AD groups (all $P<0.05$).

Conclusion

1. Children and adolescents with AD exhibit a clear history of allergic susceptibility in their clinical characteristics, and early identification and timely intervention by families for high-risk children may help slow disease progression to some extent.
2. The oral microbiome of children and adolescents with AD may shift from a relatively stable symbiotic state to a state of inflammatory imbalance; oral Staphylococcus aureus shows promise as a potential microbial biomarker for assessing the severity of AD.
3. In the oral cavity of pediatric and adolescent AD patients, local immune regulation occurs alongside abnormalities in lipid metabolism, inflammation, energy metabolism, and endocrine-related pathways; furthermore, these oral metabolic abnormalities in AD may undergo stage-specific changes as the disease progresses.

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Abstract N°: 1377

Biologics and Small Molecule Inhibitors in Nummular Dermatitis: A Systematic Review

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Introduction
Biologics and small molecule inhibitors are well-established treatments for atopic dermatitis (AD). However, data on their use in nummular dermatitis (ND), whether as a phenotype of AD or a distinct condition, remains limited. This systematic review evaluates therapeutic and adverse effects of biologics and small molecule inhibitors, including Janus kinase inhibitors (JAKi) and phosphodiesterase 4 inhibitors (PDE4i), in ND.

Materials and Methods
This PROSPERO-registered systematic review (CRD420251060607) followed PRISMA guidelines. MEDLINE, Embase, Web of Science, and CENTRAL were searched through April 2025. Of 122 screened articles, 12 studies published between 2020 and 2025 were included, encompassing 66 patients.

Results
Among studies reporting demographics, mean patient age was 34.2 years (range 4–90), and 43.9% were female. Most patients had the nummular phenotype of AD (81.1%), while 13.7% had primary ND and 4.6% had secondary ND, following infection or biologics. Nearly all reported cases were refractory to prior topical therapies.

Dupilumab was the most frequently used biologic, followed by tralokinumab and guselkumab. Roflumilast and delgocitinib were the only PDE4i and JAKi identified respectively. Dupilumab demonstrated significant improvement in disease severity and quality-of-life measures (85.6% in Eczema Area and Severity Index, 78.1% in Dermatology Life Quality Index and 89.1% in Patient Oriented Eczema Measure) in nummular AD and partial improvement in primary and secondary ND. Other biologics and small molecule inhibitors identified were reported in limited cases of nummular AD and primary/secondary ND with variable responses. Adverse events were infrequent but included paradoxical psoriasiform reactions and conjunctivitis (1 case reported for each) leading to treatment discontinuation of dupilumab.

Conclusions
Dupilumab demonstrates consistent clinical benefit and acceptable safety in patients with ND, particularly those with a nummular AD phenotype. Dupilumab works likely through Th2 modulation via interleukin (IL)-4 and IL-13 inhibition. However, evidence supporting other biologics and small molecule inhibitors remains limited to isolated cases with inconsistent outcomes. Larger prospective studies are needed to better define the role of targeted immunomodulatory therapies in nummular dermatitis.

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Abstract N°: 1382

Head and Neck Clearance with Lebrikizumab in Atopic Dermatitis: A Real-World Cohort Study

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease with an increasing number of targeted therapies, including lebrikizumab, a monoclonal antibody against interleukin-13 (IL-13). Although its efficacy has been demonstrated in clinical trials, real-world data are needed to better characterize its performance in specific clinical scenarios. Head and neck involvement represents a particularly challenging phenotype due to its high visibility, impact on quality of life, and limitations in the use of topical therapies. Achieving complete clearance in this anatomical region remains a relevant therapeutic goal. This study aims to evaluate the effectiveness of lebrikizumab in achieving head and neck clearance in patients with AD in routine clinical practice.

Materials and Methods
This multicenter, observational, ambispective study included adolescent and adult patients with moderate-to-severe AD treated with lebrikizumab across multiple tertiary hospitals. Baseline data collected from medical records included demographic characteristics, disease duration, atopic comorbidities, and prior systemic treatments. Disease severity in the head and neck region was

assessed using the Head and Neck Physician Global Assessment (H&N PGA) at baseline, week 8, and week 16. Effectiveness outcomes included changes in H&N PGA over time and the proportion of patients achieving complete clearance (H&N PGA = 0) at weeks 8 and 16. Analyses were performed on available cases, and results were expressed descriptively. Given that H&N PGA = 0 represents absence of visible lesions, this endpoint was considered a stringent measure of response.

Results

A total of 147 patients were included. At baseline, 17% of patients already presented complete clearance in the head and neck region (H&N PGA = 0). The proportion of patients achieving complete clearance increased substantially by week 8, reaching approximately 60%, and remained stable at week 16, as illustrated in the graph on page 1. Overall, around 50–60% of patients achieved complete clearance with lebrikizumab during follow-up. Clinical images included in the poster show both early responders (week 8) and later responders (week 16), supporting a rapid and sustained treatment effect. Importantly, cases with marked clinical improvement but minimal residual erythema did not meet criteria for H&N PGA = 0, highlighting the strictness of this endpoint.

Conclusions

Lebrikizumab demonstrates rapid and sustained effectiveness in achieving head and neck clearance in patients with moderate-to-severe AD in real-world practice. Approximately half of patients achieve complete clearance, often as early as week 8, with maintenance over time. Given the stringent definition of H&N PGA = 0, these results likely underestimate the overall clinical benefit. These findings support the role of lebrikizumab as an effective option for managing this challenging anatomical phenotype.

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Abstract N°: 1382

Management of non-atopic hyperkeratotic palmoplantar eczema by Dupilumab therapy: A new case report

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Introduction

Hyperkeratotic hand eczema (HHE) is a clinical subtype of hand eczema, defined by hyperkeratotic plaques on an erythematous background, mainly impacting the palmar aspects of the fingers and the palm. These hyperkeratotic plaques may be associated with painful and bleeding fissures without pustules or vesicles. The clinical and histopathological similarities between eczema and psoriasis make HHE probably indistinguishable from psoriasis. Additionally, hand eczema management has challenges because of the potential side effects and limited effectiveness associated with many available systemic and topical treatments. Dupilumab, a monoclonal human antibody inhibiting interleukin (IL)-4 and IL-13 signaling, is a Food and Drug Administration (FDA) approved agent indicated for several conditions, such as atopic dermatitis, prurigo nodularis, and eosinophilic esophagitis. However, data on the effectiveness of Dupilumab for treating non-atopic hyperkeratotic palmoplantar eczema is limited. The current study aimed to report a new case of non-atopic hyperkeratotic palmoplantar eczema that was initially misdiagnosed and treated as psoriasis, as well as to assess the effectiveness of dupilumab in managing this condition.

Case Presentation

A 15-year-old male adolescent presented to the dermatology clinic with sharply demarcated hyperkeratotic plaques and thick scaling on the palms and plantar areas, along with painful fissures, dry scales, no or mild redness, and moderate pruritus with no evidence of nail or joint involvement. The patient had no medical or family history of atopy or psoriasis. He was previously diagnosed with psoriasis and was treated with topical and systemic corticosteroids, acitretin, methotrexate, narrowband ultraviolet B (NB-UVB), and secukinumab, all with no significant improvement. His Investigator's Global Assessment Scale (IGA) was 4, indicating severe disease. Additionally, his Dermatology Life Quality Index (DLQI) score of 22 reflected a markedly impaired quality of life. A patch test was performed and was negative, effectively excluding allergic contact dermatitis (ACD). Additionally, histopathology from a skin biopsy confirmed chronic eczema. The patient started on dupilumab 600 mg as a loading dose, followed by 300 mg subcutaneously every 2 weeks. Additionally, a topical moisturizer containing dexpanthenol was prescribed. After 12 weeks on dupilumab, there was a complete response, with IGA and DLQI scores reaching 0. Over 1 year, the patient remained well with no relapses or reductions in the treatment efficacy, maintaining a consistent safety profile.

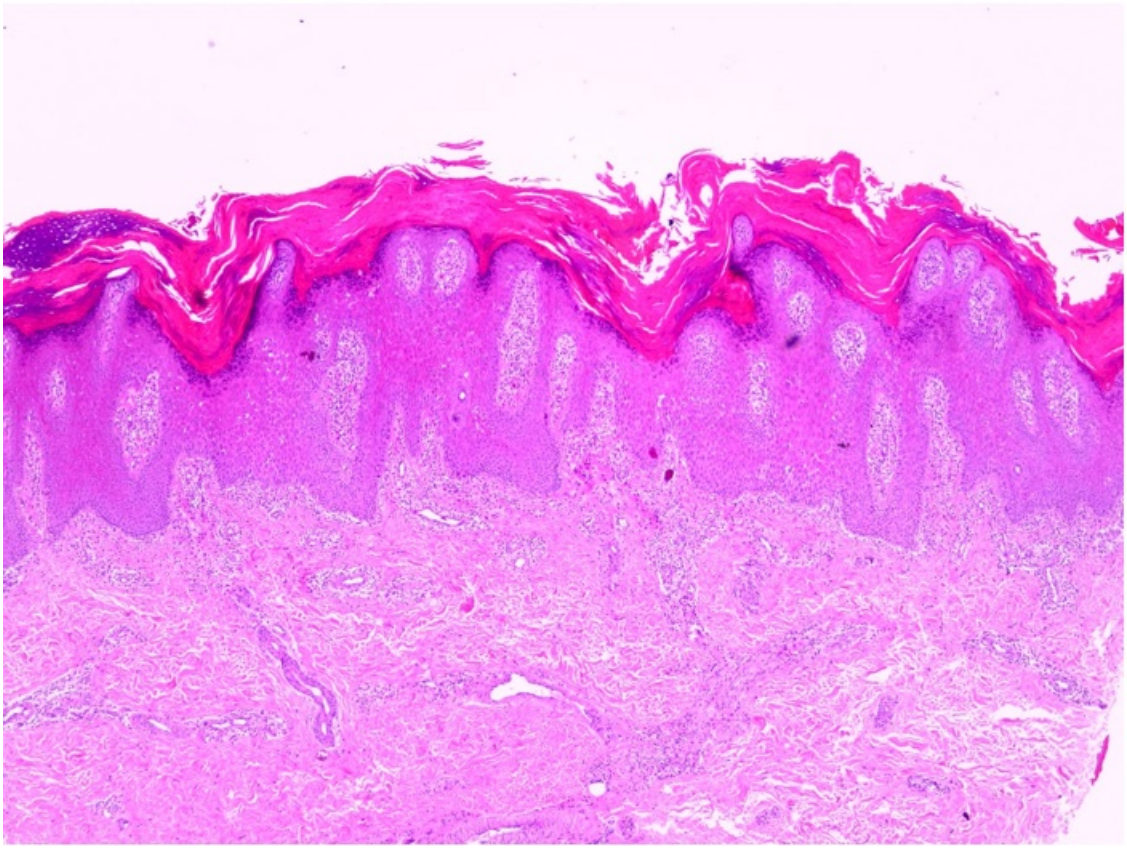

Figure: Hematoxylin and eosin (H&E) staining showed compact orthokeratosis and parakeratosis. The epidermis was hyperplastic with spongiosis with vesicles formation. Within the dermis, there was a mild lymphocytic infiltrate with no definite eosinophils.

Conclusion

Non-atopic hyperkeratotic palmoplantar eczema is a distinct variation of chronic hand eczema and should be included in the differential diagnosis of other palmoplantar keratodermas. Furthermore, dupilumab is a promising treatment option for non-atopic hyperkeratotic palmoplantar eczema, offering a substantial improvement and a favorable safety profile with long-term use. Further research and clinical trials are recommended to assess its long-term effectiveness, potential adverse events, and optimal dosage strategies.

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Abstract N°: 1404

Short- and long-term efficacy of abrocitinib in atopic dermatitis in a real-world longitudinal study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory disease driven by type 2 immune pathways and JAK-mediated cytokine signaling, characterized by pruritus and significant quality-of-life impairment. Abrocitinib, an oral selective JAK1 inhibitor, has demonstrated rapid and effective disease control in clinical trials. However, real-world evidence is needed to better define its effectiveness and safety, particularly in patients with prior treatment failure. This study aimed to assess the real-world effectiveness, safety, and tolerability of abrocitinib in patients with moderate-to-severe AD who were refractory to cyclosporine or required rapid disease control.

Materials and Methods

A longitudinal observational study was conducted in 17 patients with atopic dermatitis treated with abrocitinib. Baseline data included demographic and clinical variables such as age, sex, lifestyle factors, disease onset, time to treatment initiation, comorbidities, and prior biologic exposure. Abrocitinib dose and adverse events were recorded throughout follow-up. Efficacy was assessed using EASI, IGA, and PP-NRS at baseline and weeks 12, 16, 24, and 52.

Categorical variables were expressed as frequencies and percentages, while quantitative variables were reported as medians and interquartile ranges due to small sample size and non-normal distribution. Normality was assessed using the Shapiro–Wilk test. Changes from baseline were analyzed using the Wilcoxon signed-rank test for paired samples. A p-value < 0.05 was considered statistically significant. Statistical analyses were performed using IBM SPSS Statistics version 31.0.

Results

A total of 17 patients were included. The median age was 26 years (IQR: 19–36), with a slight predominance of females (9 patients, 52.9%). Three patients (17.6%) were active smokers and four (23.5%) reported current alcohol consumption. The median age at onset of atopic dermatitis was 13 years (IQR: 8–22), and the median time from disease onset to initiation of abrocitinib was 12 years (IQR: 7–21). Eight patients (47.1%) had atopic comorbidities, nine (52.9%) had non-atopic comorbidities, and six (35.3%) had previously received biologic therapy with dupilumab.

Regarding treatment, 9 patients initiated abrocitinib at a dose of 100 mg,of whom 4 were subsequently increased to a 200 mg dose; and 8 patients initiated abrocitinib at 200 mg, with dose selection based on disease severity and/or patient weight.

At baseline, the median EASI score was 21.0 (IQR: 15.0–27.0), the median IGA was 3.0 (IQR: 3.0–3.0), and the median PP-NRS was 8.0 (IQR: 8.0–9.0). Follow-up data were available for 16 patients at week 12, 11 at week 16, 9 at week 24, and 6 at week 52. Missing data were primarily due to patients not yet reaching the corresponding

follow-up timepoints; however, treatment discontinuation occurred in 2 patients due to lack of efficacy and in 1 patient due to pregnancy. No patient discontinued treatment due to adverse effects.

A statistically significant improvement in all efficacy outcomes (EASI, IGA, and PP-NRS) was observed as early as week 12, with median EASI decreasing from 21.0 to 5.5, IGA from 3.0 to 1.0, and PP-NRS from 8.0 to 4.5 (all $p \leq 0.003$). This clinical response was maintained at week 16 (EASI 6.0, IGA 1.0, PP-NRS 3.0; all $p \leq 0.016$) and further improved at week 24 (EASI 1.0, IGA 1.0, PP-NRS 1.0; all $p \leq 0.008$). Despite the smaller number of evaluable patients at later timepoints, the therapeutic effect remained sustained through week 52 (EASI 0.0, IGA 0.0, PP-NRS 0.0; $p=0.031$), indicating a durable response over time.

Conclusions

Overall, these findings support a rapid onset of action of abrocitinib, followed by progressive improvement and long-term maintenance of clinical response across multiple validated efficacy endpoints. However, the decreasing number of evaluable patients at later visits should be considered when interpreting long-term outcomes.

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Abstract N°: 1433

Lebrikizumab Treatment Leads to Relevant Improvements in Patient-Reported Outcomes for Moderate-to-Severe Atopic Dermatitis in a Real-Life Setting: Findings from ADlife

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Introduction

ADlife is a prospective, observational study in adults with moderate-to-severe atopic dermatitis (mod-sev AD), assessing long-term effectiveness, safety and patient-reported outcomes (PROs) with lebrikizumab (LEB) treatment through Week (W) 52. Previously, LEB treatment has demonstrated meaningful improvements in clinical symptoms and health-related quality of life (HRQoL). An earlier interim analysis of real-world evidence at W16 with a smaller patient cohort indicated PRO improvements in HRQoL, sleep loss and itch in real-world practice. Here, we report an interim PRO analysis from W28 of the ADlife study.

Materials and Methods

Eligible patients were ≥18 years old with mod-sev AD requiring systemic therapy, received LEB according to physician's discretion and provided informed consent. This analysis included patients who were enrolled in the study for at least 28 weeks and had either a documented visit at W28 or a confirmed early termination within the first 28 weeks. Treatment response was assessed using the percentage of patients achieving: Dermatology Life Quality Index (DLQI) ≤5 and 0/1 (W16, W28), peak Pruritus Numerical Rating Score (PP-NRS) improvement of ≥4 points (W4, W16, W28), PP-NRS ≤4 and 0/1 (W4, W16, W28) and Sleep Loss Scale (SLS) improvement of ≥1 point (W16, W28). Concomitant topical corticosteroid (TCS) use was evaluated. Safety outcomes included adverse drug reactions (ADRs) and serious ADRs. Data are reported as observed case (OC). A sensitivity analysis using last observation carried forward (LOCF) imputation was performed. Analyses are presented descriptively.

Results

This analysis included 263 patients with a mean (standard deviation [SD]) age of 43.5 (16.4) years and 50.2% were female. Mean (SD) baseline (BL) clinical scores were Eczema Area and Severity Index 20.7 (11.3), PP-NRS 7.3 (2.2), DLQI 16.3 (7.2) and SLS 2.2 (1.1). At BL, 85.9% of patients had a history of receiving TCS, 31.6% had received other biologics or Janus kinase inhibitors and 23.6% had previously received dupilumab. Overall, 18.6% (n=49) of patients discontinued the study and 16.3% (n=43) discontinued treatment based on: lack of efficacy (6.5%, n=17), tolerability (3.8%, n=10), achieving the treatment goal (0.4%, n=1) and other reasons (5.7%, n=15). After 28 weeks of LEB treatment, 69.7% of patients reported only a small impact of AD on HRQoL (DLQI ≤5) and 31.3% reported no impact on HRQoL (DLQI 0/1; **Figure A**). Most patients experienced considerable improvements in itch, with 65.3% of patients achieving an improvement of ≥4 points PP-NRS by W28. By W28, 72.5% of patients achieved PP-NRS ≤4, and 33.0% achieved PP-NRS 0/1 (**Figure B**). Additionally, a substantial proportion of patients experienced improvements in sleep loss with the majority (83.2%) achieving SLS improvement of ≥1 point at W28. Similar outcomes were demonstrated after sensitivity analyses with LOCF. At W28, concomitant TCS use fell to 33.3% from 49.0% at BL. In this preliminary analysis, ADRs under LEB were consistent with those observed in

clinical trials.[1] No new safety signals were observed.

Conclusions

LEB showed clinically meaningful improvements in PROs during the first 28 weeks of treatment. Substantial improvements in HRQoL, itch and sleep loss were observed over the course of the study. Concomitant TCS use decreased and the safety profile of LEB was consistent with previous trials. These data suggest that improvements in symptoms and HRQoL observed in clinical trials translated well in a real-world setting.

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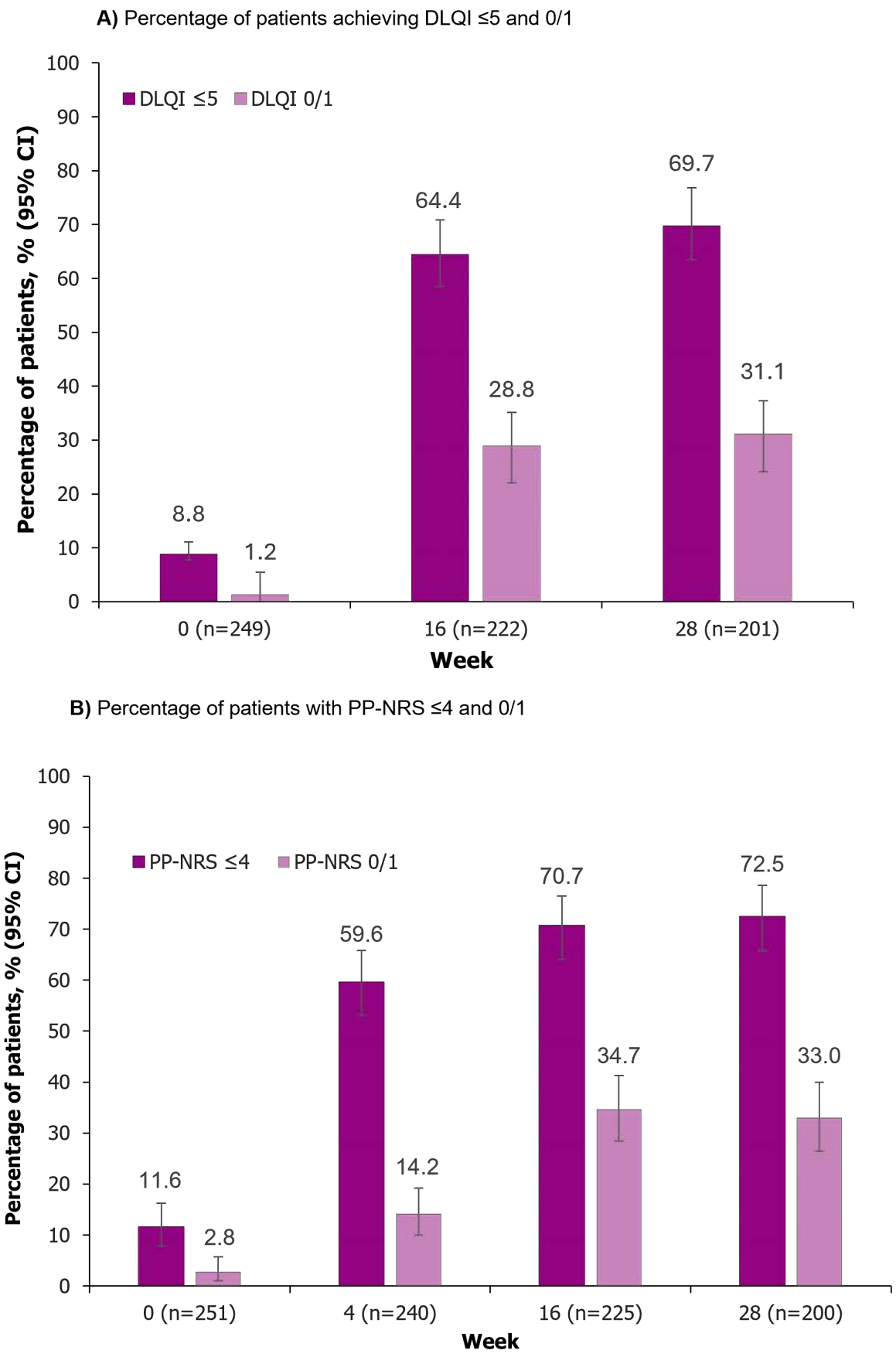
Figure. (A) Percentage of patients achieving DLQI ≤5 and 0/1 and **(B)** PP-NRS 0/1 and PP-NRS ≤4 (OC)



CI, confidence interval; DLQI, Dermatology Life Quality Index; n, number of patients; OC, observed case; PP-NRS, peak Pruritus Numerical Rating Score.

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Abstract N°: 1433

Long-term Efficacy and Safety of Dupilumab in an 88-year-old Atopic Dermatitis Patient with Stage 4 Chronic Kidney Disease: An 18-month Case Report

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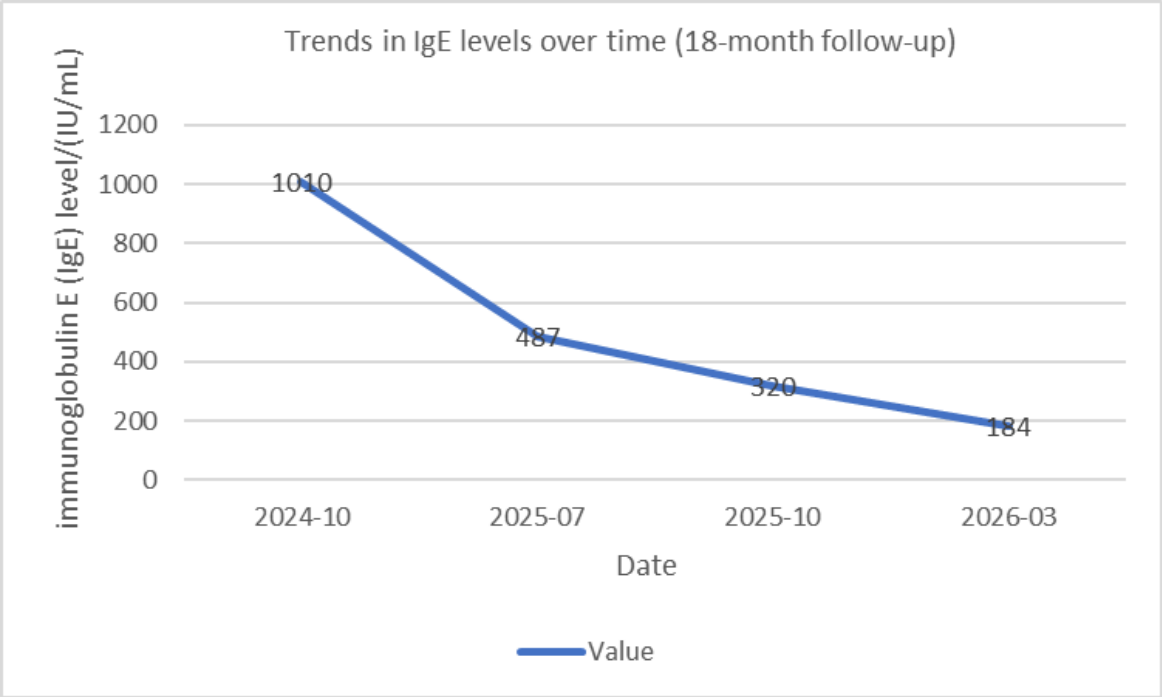
Introduction
With the accelerating aging population, treating elderly patients with atopic dermatitis (AD) is highly challenging. This vulnerable group often presents with complex comorbidities and polypharmacy, making traditional immunosuppressants contraindicated due to hepatorenal toxicity or severe drug-drug interactions (DDIs). Dupilumab, which bypasses hepatic CYP450 metabolism and renal clearance, offers a highly safe alternative.This article reports an 88-year-old patient with moderate AD, complicated by stage 4 chronic kidney disease (CKD) and polypharmacy challenges, who achieved deep remission of skin lesions and successfully implemented a step-down strategy during an 18-month real-world treatment with dupilumab. To the best of our knowledge, this represents the longest followed-up real-world case reported to date for this specific patient profile.

Case Presentation
An 88-year-old male patient presented in October 2024 with a history of erythematous papules and pruritus on the head, neck, and shoulders for over one year. Physical examination revealed widespread scattered erythema, scales, and lichenification with localized fissuring in the affected areas. The patient had highly complex underlying diseases, with a medical history of allergic rhinitis, radical mastoidectomy (>60 years ago), lacunar cerebral infarction, hyperuricemia, and benign prostatic hyperplasia. He had long-standing chronic kidney disease (CKD stage 3, estimated glomerular filtration rate [eGFR]: 31.1 mL/min), accompanied by renal anemia and renal hypertension. His daily routine medication regimen included over 10 internal medicine drugs, such as clopidogrel, felodipine, terazosin, and febuxostat. Baseline laboratory tests showed an eosinophil count of 0.55 × 10^9/L, an eosinophil ratio of 14.2%, and an IgE level of 1010 IU/mL. Baseline renal function indicators were urea 12.09 mmol/L, serum creatinine 168.5 umol/L, and eGFR 31.1 mL/min. The SCORAD score was 32.4, classifying the condition as moderate AD. Given the extremely complex medical comorbidities, subcutaneous dupilumab treatment (300 mg, q2w) was initiated on October 22, 2024, supplemented by oral antihistamines and topical emollients. After 2 months of treatment, the SCORAD score rapidly decreased to 20.9; after 1 year, the total IgE dropped to 320 IU/mL, and the SCORAD score further declined to 5.9. At this point, the patient's rash and pruritus symptoms were significantly relieved. In December 2025, a step-down strategy was successfully implemented, extending the dosing interval to once every 4 weeks (q4w). During the 18-month follow-up period (currently still under q4w maintenance), renal function monitoring indicated a minimum eGFR of 25 mL/min (progression to CKD stage 4). Considering the patient's advanced age of 88 years and long-term history of hypertension and hyperuricemia, this slight decline in renal function is consistent with the natural progression of his underlying nephropathy, essentially ruling out the possibility of drug-induced renal injury. No adverse events were detected during the medication period, nor were any interactions with the complex internal medicine drugs observed.



During the 18-month follow-up period following continuous treatment with dupilumab, IgE levels showed a gradual decline

Conclusion

Dupilumab provides a safe and highly effective therapeutic regimen for elderly AD patients with severe renal impairment. It not only rapidly and sustainably clears intractable skin lesions and significantly reduces total IgE levels, but crucially, its unique non-renal clearance pathway ensures exceptional pharmacokinetic safety. It neither increases the renal excretory burden nor interferes with complex baseline medical regimens. Furthermore, after achieving deep clinical remission, the q4w step-down maintenance strategy proved to be safely feasible and pharmacoeconomically advantageous, establishing a vital reference paradigm for the clinical management of vulnerable elderly AD patients with multi-system comorbidities.

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Abstract N°: 1437

Real-world effectiveness of abrocitinib in the treatment of patients with moderate-to-severe atopic dermatitis: systematic review and meta-analysis

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Introduction
Abrocitinib has demonstrated efficacy in randomized controlled trials for the treatment of moderate-to-severe atopic dermatitis (AD); however, real-world (RW) evidence regarding its effectiveness remains limited. This study aimed to evaluate the RW effectiveness of abrocitinib in clinical practice, assessing outcomes for both approved doses (100mg and 200mg) through a meta-analysis (MA) of RW data.

Materials and Methods
A systematic review (PROSPERO CRD420251208244) was conducted between 01/09/2021 and 04/30/2025 in the databases PubMed, Scopus, and Web of Science. Eligible references were those relating RW effectiveness outcomes, with EASI75 as the minimum required outcome, of patients aged ≥12 years with a confirmed diagnosis of moderate-to-severe AD treated with standard dose abrocitinib (100mg or 200mg) administered orally once daily with or without topical agents. Two independent researchers performed the selection with a third acting as a referee to resolve discrepancies. The quality of evidence was assessed using the Newcastle–Ottawa Scale. Random-effects MAs were performed for EASI75, EASI90, IGA0/1, and PP-NRS4 at the 4-, 12–16-, and 24–28-week time horizons. Subgroup MAs by geographic region were also conducted, as Asian studies used only the 100-mg dose, whereas European and North American studies both doses (mainly 200mg). Analyses were performed in R using the "meta" package.

Results
Of the 382 references initially identified, after removing duplicates (n=103), title/abstract screening, and full-text review, 14 studies were selected. Two references published after the search cutoff date were added subsequently to gather all available evidence. However, 2 studies were not included in the MAs: the only study having a time-horizon at 48 weeks and the only pediatric study. Overall, the included studies comprised a total of 684 patients, most of whom presented with severe AD and had previously been treated, with other advanced therapies, including conventional immunosuppressants, biologics, and Janus kinase inhibitors.

Based on the MAs, at 4, 12-16, and 24-28 weeks, 49% (95% CI 45−54%), 68% (95% CI 55−79%) and 60% (95% CI 43−75%) of patients treated with abrocitinib achieved EASI75 (Figure 1), while 31% (95% CI 20−44%), 46% (95% CI 35−57%), and 35% (95% CI 22−51%) achieved EASI90, respectively. IGA0/1 was attained by 35% (95% CI 31−40%), 54% (95% CI 42−66%), and 39% (95% CI 23−58%) of patients along the three timepoints. Finally, PP-NRS4 was reached by 59% (95% CI 53−65%), 67% (95% CI 58−75%), and 63% (95% CI 56−69%) of participants, respectively. Heterogeneity between studies was low or zero at 4 weeks but increased to high levels in the longer term, making estimations less conclusive. In general, effectiveness increased with longer exposure and was

maintained up to 28 weeks. European/North American studies generally showed higher effectiveness compared to Asian studies, probably due to the use of a higher mean dose. Heterogeneity could be reduced in some cases through geographical subanalysis, however, it remained high in most cases, limiting result interpretability. This is not surprising when dealing with RW studies, half of which had small sample sizes (<50 patients), maybe due to the relatively short time that abrocitinib has been in the clinical practice. Thus, limitations include risk of detection bias and selection bias.

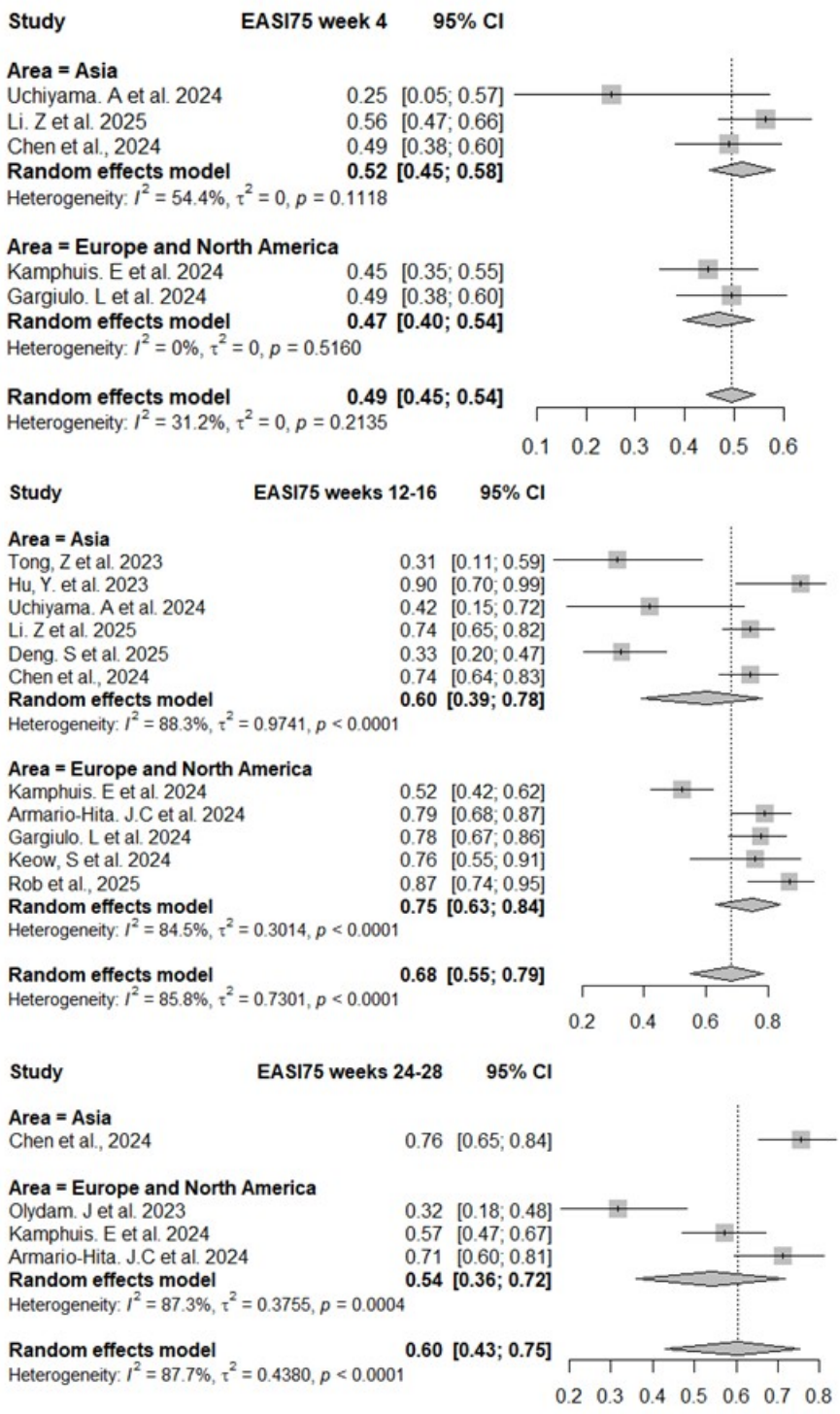

Figure 1. EASI75 at 4, 8-12, and 24-28 weeks. Notes: Deng et al, 2025 data correspond to the "maintenance" cohort, which was chose among available cohorts ("discontinuation", "tapering", "resumption") under the assumption that this would be the stable-treatment cohort, with data more comparable to other studies. Rob et al. 2025 data are the weighted mean between response rate in the naïve cohort and the dupilumab-non-responders cohort. Search strategy for PubMed: ("atopic

dermatitis"[tiab] OR "atopic eczema"[tiab]) AND ("abrocitinib"[tiab] OR "Cibinqo"[tiab] OR "PF-04965842"[tiab]) AND ("Observational Studies as Topic"[Mesh] OR Observational OR Descriptive OR Cohort* OR longitudinal OR retrospective* OR prospective* OR Case-Control OR "case reports" OR “case serie*” OR follow-up OR followed OR effectiveness OR real-life OR "real practice" OR experience OR RWE OR "Real-world" OR RWD OR "long-term") NOT (Trial*[ti] OR random[ti] OR randomi?ed[ti] OR blind[ti] OR blinded[ti] OR placebo[ti] OR phase[ti]) from 2021/09/1 - 2025/12/31. This strategy was then adapted to Scopus and Web of Science. References: Armario-Hita JC et al. J Investig Allergol Clin Immunol. Chen Y et al. Front Med. 2024;752–6. Deng S et al. Dermatitis. 2025. Gargiulo L et al. Dermatol Ther (Heidelb). 2024;14(4):919–32. Hu Y et al. Chin Med J (Engl). 2024;137(6):740–2. Keow S et al. J Am Acad Dermatol. 2024;91(4):734–5. Kamphuis E et al. Acta Derm Venereol. 2024;104. Li Z et al. Allergy. 2025;80(5):1417–27. Olydam JI et al. J Eur Acad Dermatol Venereol. 2023;37(12):2537–42. Rob et al. Derm Ther. 2025;2025(1). Tong Z et al. J Am Acad Dermatol. 2023;89(4):826–8. Uchiyama A et al. J Dermatol. 2024;51(6):849–53.

Conclusions

Abrocitinib demonstrates early RW effectiveness in the treatment of moderate-to-severe AD in patients highly refractory to conventional immunosuppressants and advanced systemic therapies. Effectiveness increases in the mid-term (12–16 weeks) and it is maintained through 24–28 weeks. Particularly favorable results were observed in itch reduction. Although between-study heterogeneity currently limits the interpretability of the findings, the availability of new and more robust RW studies is expected to allow more precise estimates of treatment effectiveness. This meta-analysis was sponsored by Pfizer S.L.U.

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Abstract N°: 1469

Simultaneous control of atopic dermatitis and inflammatory bowel disease with upadacitinib: a multicenter real-world observational study.

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Introduction

The coexistence of atopic dermatitis (AD) and inflammatory bowel disease (IBD) poses a therapeutic challenge due to divergent immune pathways (Th2 in AD; Th1/Th17 in IBD) and the risk of worsening one condition while treating the other. Upadacitinib, a Janus kinase inhibitor, has demonstrated high efficacy and rapid onset of action in AD, as well as efficacy in IBD, making it an attractive option when both diseases coexist. However, evidence in patients with concomitant AD and IBD treated with upadacitinib remains limited. The primary objective of this study was to describe the effectiveness and safety of upadacitinib in patients with concomitant AD and IBD after 16 weeks of treatment.

Materials and Methods

Multicenter retrospective observational study. Patients with AD and IBD treated with upadacitinib between 2020 and October 2025 from 17 Spanish hospitals were included. Sociodemographic data, disease severity scores, and clinical and laboratory parameters related to AD and IBD were collected at baseline and at weeks 16, 24, and 52.

Results

A total of 23 patients were included (13 Crohn's disease, 10 ulcerative colitis), with a mean age of 36.2 years (SD 14.2); 61% (14/23) were male. Patients presented with severe baseline AD, with a mean EASI of 21 (17-30), pruritus NRS of 8.5 (7-9), and DLQI of 12 (6-19). At baseline, 16 patients had inadequately controlled IBD. Among Crohn's disease cases, 66.7% had an inflammatory phenotype; in ulcerative colitis, 50% extended to the splenic flexure and 30% had extensive disease. Most patients had previously received conventional systemic therapy (86.7%) and advanced systemic therapy (78.3%). After 16 weeks of treatment, patients showed marked improvement in EASI (0.3), pruritus NRS (1), DLQI (0), and bowel movement frequency (2), with sustained improvement at weeks 24 and 52 ($p<0.05$). Additionally, at week 16, 12 patients (52.2%) achieved optimal simultaneous control of both diseases. Four patients discontinued treatment (2 due to non-serious adverse events, 1 due to lack of efficacy, and 1 due to pregnancy planning).

Conclusions

In this multicenter cohort of patients with concomitant AD and IBD, upadacitinib demonstrated high cutaneous efficacy and intestinal improvement, with more than half of patients achieving simultaneous optimal control at week 16 and a low discontinuation rate.

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Abstract N°: 1472

Atopic Dermatitis Skin Microbiota Changes in Diverse Ethnically Patients Following Prebiotic Skincare Regimen

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Introduction

Variations in AD epidemiology, clinical presentation, and disease course between racial/ethnic populations have been reported. Microbial dysbiosis is associated with flare-ups and skin barrier disfunction in atopic dermatitis (AD). Although skincare regimens are recommended to manage symptoms, little is known about the effect of those treatments on the skin microbiota of AD patients, particularly from different racial/ethnic backgrounds.

Objective:

Given the nuances of AD persistence across racial/ethnic groups,here we investigated skin microbiome changes in diverse patients presenting with AD, following prebiotic skincare regimen.

Materials and Methods

A total of 20 subjects from diverse racial/ethnic backgrounds, aged 3-80 years old with skin phototypes I-VI and presenting with mild-AD completed study. After dermatological evaluations, all subjects started using a prebiotic skincare regimen, consisting of a cleanser and moisturizer for 10 weeks. Evaluations on patients' legs included microbiome sampling for whole genome sequencing analysis, clinical and instrumental assessments, plus imaging at baseline and week 10.

Results

Following 10 weeks of prebiotic regimen (cleanser and moisturizer), all patients showed significant reduction in global eczema severity, increased skin hydration and decreased pH levels on both normal and lesional skin. Microbiome analyses revealed changes in bacterial profile on both lesional and normal skin, with bacteria species relative abundance alterations, such as *Lysobacter enzymogens* and *Staphylococcus*, being more reduced following treatment on lesional skin. Interestingly, sub-analyses revealed unique changes in bacteria profile between racial/ethnic groups following prebiotic regimen.

Conclusions

In summary, our findings suggest that a prebiotic cleanser and moisturizer can effectively decrease AD severity and improve symptoms by restoring skin barrier integrity while modulating skin bacterial profile in diverse ethnically patients. Additionally, we demonstrate the importance of including diverse racial/ethnic patients into clinical studies, as nuances in skin microbiota composition may be observed following treatment. We hope that our new research help support clinicians on disease diagnosis and management strategies to consider for all patients, particularly for patients of color.

EADV CONGRESS
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Abstract N°: 1475

Occupational determinants in dyshidrotic eczema: a multicentre study based on the Spanish Registry of Research in Contact Dermatitis and Cutaneous Allergy (REIDAC).

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Introduction

Dyshidrotic eczema (DE) is currently regarded as a clinical phenotype within the spectrum of hand eczema (HE). From an occupational standpoint, DE may be associated with different work-related aetiologies, including allergic contact dermatitis (ACD), irritant contact dermatitis (ICD), and protein contact dermatitis (PCD). However, heterogeneity in terminology, together with evolving classifications of chronic hand eczema (CHE)—in which DE is defined as a morphological rather than an aetiological subtype—has limited the comparability of existing studies. The aim of this study was to assess the relationship between occupational exposure and sensitisation profile in patients diagnosed with DE, compared with those presenting HE with non-dyshidrosiform morphology (non-DE HE).

Materials and Methods

We performed a retrospective, observational, multicentre study using data from the REIDAC registry. Occupational variables and patch test sensitisation profiles were analysed in patients diagnosed with DE, and comparisons were made with patients presenting non-dyshidrosiform HE (non-DE HE).

Results

A total of 4,378 patients with CHE were included, of whom 559 (12.8%) were classified as DE and 3,819 (87.2%) as non-DE HE. DE was more prevalent among young adults (21–50 years). Occupationally related factors were identified in 9% of DE patients, compared with 29% in the non-DE HE group. DE showed a higher representation among administrative workers and students, and a lower representation among hairdressing and cosmetology professions, which were more strongly associated with ACD.

At least one positive patch test reaction was observed in 43% of DE patients, compared with 52% in non-DE HE. Although the overall sensitisation profile was broadly comparable between groups, DE was characterised by a lower frequency of sensitisation to 2-hydroxyethyl methacrylate (2-HEMA), carba mix, and thiuram mix. No definitive aetiological factor was identified in 57.3% of DE cases.

Conclusions

Data specifically addressing occupational determinants in DE remain scarce. In this cohort, DE was more frequently observed in women, with a chronic disease course, and was preferentially associated with non-manual occupations such as administrative work and student status, while showing a lower association with high-risk occupations such as hairdressing and cosmetology—typically linked to ACD. These findings are broadly consistent with previous reports. However, prior studies have described a stronger association with occupational factors, which may be attributable to methodological differences, including study design and case definitions.

DE shows a weaker association with occupational exposure compared with other HE subtypes, supporting its interpretation as a clinical morphological pattern. However, clinically relevant sensitisation remains frequent, highlighting the need for patch testing particularly when occupational exposure is suspected.

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Abstract N°: 1487

Characterizing the Burden of Hand Dermatitis in Canada: A Cross-Sectional Survey of Disease Impact

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Introduction

Hand eczema, or hand dermatitis, is a common and often chronic cutaneous condition that affects up to 10% of the general population and 6.2% of adults in Canada. Marked by xerosis, scaling, vesiculation, or fissuring of the hands and wrists, this condition can adversely impact patients' quality of life (QoL). A survey was conducted to explore the demographics, symptoms, treatment, and therapeutic outcome patterns of adults with hand eczema in Canada. Our aim was to characterize Canadians impacted by hand eczema to better understand disease burden and unmet therapeutic needs.

Materials and Methods

Participants were recruited to complete an online survey, administered via Survey Monkey between June 1st and September 30th 2025, promoted via email newsletter and social media by the community and advocacy group of Eczema Society of Canada (IRB no. Pro00085364). Inclusion criteria included residence in Canada, age ≥18 years, and a diagnosis of hand eczema by a healthcare provider. A total of 230 respondents (74.7%) met eligibility criteria. The sample was predominantly women (85.2%), with the largest age group being 45–64 years (38.7%). Participants were geographically distributed across Canada, most commonly in Ontario (38.70%), Quebec (20.0%), and Alberta (10.87%).

Results

Hand eczema severity was reported by patients to be mild (7.4%), moderate (46.5%) or severe (41.3%). During flares, most participants reported interference with daily activities often or always (60.4%), with 71.7% describing moderate to extreme impact on hand-based tasks. Symptoms during flares included itching (93.9%), pain (80.9%), and stress/anxiety (79.6%). 28.3% believed their hand eczema was related to their job, 13.5% had missed work or school due to symptoms, and 29.6% reported impaired work or school performance. These figures reflect not only the substantial impact on QoL, but also the possibility for monetary loss because of this condition.

Most participants used multiple strategies for managing flares, including moisturizers (83.5%), prescribed medications (77.8%), protective gloves (69.1%), and trigger avoidance (53.9%). Past treatments commonly included topical corticosteroids (86.1%) and moisturizers (83.0%). Treatment discontinuation was often due to lack of improvement (46.5%), concerns about side effects (24.8%), or discomfort (21.7%). Current use of systemic agents, such as biologics (8.3%), oral JAK inhibitors (3.0%), or alitretinoin (1.3%) was low despite the degree of patient reported severity. This may reflect limited access to dermatologists, cost owing to the few approved therapies for hand dermatitis, or patient preference for topicals. Overall, disease control varied with 53.9% reporting somewhat to poorly controlled hand eczema, while 17.8% reported poor control. Key treatment goals

included reducing itch (83.9%), minimizing rash (83.9%), achieving clear skin (77.4%), and improving daily functioning (47.4%) and sleep (44.3%). Full survey reported outcomes can be found in Tables S1 and S2. Hand eczema also impacts employment, as respondents reported having to change jobs due to their hand eczema (13.9%).

Conclusions

These findings highlight the significant QoL impact on Canadians afflicted with hand eczema, and the importance of clinicians utilizing advanced therapies when appropriate. Additionally, these findings highlight the need for potential updates to the Canadian hand dermatitis management guidelines which have not been updated since 2010. Study limitations include selection bias and reliance on self-reported outcomes inherent to a survey study.

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Abstract N°: 1489

Preclinical development of IFX-101, an anti-IL-22 antibody, for the treatment of moderate-to-severe atopic dermatitis

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Introduction

The pathologic role of interleukin-22 (IL-22) in atopic dermatitis (AD) has been shown in a number of clinical settings, including improved AD symptoms in moderate-to-severe AD patients after anti-IL-22 and anti-IL-22RA1 inhibition and induction of AD in patients receiving exogenous IL-22 for treatment of non-dermatological disease. Where commercially successful anti-IL-4/13 receptor and anti-IL-13 antibody drugs inhibit the Th2 inflammatory processes inherent to AD, inhibition of IL-22 acts directly on the epithelium to address the dysregulated antimicrobial and barrier function of AD skin. Anti-IL-22 antibody treatment represents both a compelling standalone therapy and a clear complement to existing drugs.

Materials and Methods

Infinimmune has developed a novel approach to therapeutic antibody discovery and optimization by combining direct human B cell screening with GLIMPSE, an antibody language model built to replicate the human immune repertoire. Trained exclusively on a proprietary dataset of human antibodies, GLIMPSE achieves state-of-the-art performance comparable to models trained on 20-fold larger datasets. Using our proprietary Anthrobody® discovery platform and GLIMPSE antibody language model, we developed IFX-101, a fully human anti-IL-22 antibody. Beginning with antibodies discovered directly from human patients, we engineered initial candidates optimizing stability, developability, and potency. We then evaluated IFX-101 in relevant in vivo models, including quantifying a dose-dependent reduction of ear thickening in an mIL-23 driven AD model and pharmacokinetic (PK) evaluation in non-human primates (NHPs).

Results

The result was the identification of IFX-101, a monoclonal antibody with extremely high affinity (~7pM) and manufacturability (>7g/L titer). IFX-101 also demonstrates potent in vivo efficacy, with significant reduction in mIL-23 injected ear thickening observed with doses as low as 0.1mg/kg and maximal reduction (~30%) observed at 1mg/kg. The PK profile of IFX-101 was also evaluated following a single-dose administration in cynomolgus monkeys. IFX-101 demonstrated an extended half-life that projects via allometric scaling to a human half-life of ~87 days, with robust systemic exposure characterized by a low clearance rate. Together these data suggest that IFX-101 supports a potential human dosing interval of every 3 to 6 months.

Conclusions

We believe that the combination of a distinct mechanism of action relative to existing therapeutics and superior drug exposure and dosing schedule enabled by the long half life of IFX-101 will have a positive impact on AD patients, particularly those for whom existing therapies have failed.

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Abstract N°: 1498

Head and Neck dermatitis in Adults: a distinct clinical entity and a diagnostic challenge

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Introduction

Head and neck dermatitis is increasingly recognized as a distinct clinical phenotype of adult atopic dermatitis, characterized by predominant involvement of the face and neck. This particular distribution pattern may pose diagnostic challenges, as several inflammatory dermatoses can present with similar localization. Therefore, recognizing this phenotype is essential to evoke the diagnosis of atopic dermatitis and to guide appropriate diagnostic evaluation and management.
We report a case of a 53 year old male with and adult atopic dermatits onset.

Case Presentation

A 53-year-old man, former smoker, with a history of allergic rhinitis, allergic conjunctivitis, and food allergies, and no history of skin issues in childhood,presented with a 7-year history of highly pruritic vesicular and eczematous lesions, initially affecting the face and scalp and gradually extending to the neck, upper back, and trunk. The disease followed a chronic-relapsing course with repeated flares and periods of partial remission, often exacerbated by stress and exposure to cold or hot climates. Similar lesions were reported in two adult female relatives. On examination,generalized xerosis and multiple millimetric vesicular and eczematous lesions were observed across the face, scalp, neck, upper back, and trunk, as well as on the extensor surfaces of the limbs, and the patient displayed intense pruritus, scratching continuously throughout the assessment. Screening for Demodex and Malassezia was negative. A complete bloodtest revealed no abnormalities, the patient refused a skin biopsy and ELISA testing to exclude other differential diagnoses was negative. The distribution pattern, chronic course, xerosis, familial occurrence, identifiable triggers, and exclusion of other conditions are consistent with head and neck dermatitis as a phenotype of adult atopic dermatitis.Our patient was initially treated with topical steroids along with therapeutic education and showed a satisfiying clinical improvement few weeks after.

Conclusion

Head and neck dermatitis is a distinct form of atopic dermatitis affecting the seborrheic regions of the face, neck, and upper trunk. Clinically, it presents with sharply demarcated erythema, vesiculation,scaling, lichenification, and xerosis, which can impact deeply the quality of life. Its pathophysiology involves epidermal barrier dysfunction, Th2-driven inflammation, and Malassezia colonization, which amplifies local cytokine release and pruritus. These mechanisms explain the frequent suboptimal response to topical therapies and, in some cases, systemic biologics like dupilumab. Emerging treatments, including Janus kinase inhibitors, provide targeted control in refractory cases. Recognizing HND as a distinct phenotype is essential for accurate diagnosis and personalized management, combining barrier repair, anti-inflammatory, and antifungal strategies.

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Abstract N°: 1505

Spatial neuro-immune axis underlies regional refractoriness in atopic dermatitis: a cross-sectional study with mechanistic exploration

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Introduction

Treatment response in atopic dermatitis (AD) varies significantly across body regions. However, both the characteristic patterns and the mechanisms underlying of refractory lesions during biologic therapy remain poorly understood. Immune dysregulation alone does not fully explain this site-specific resistance or the clinical heterogeneity seen in practice. We aimed to characterize regional refractory patterns and explore their neuro–immune basis.

Materials and Methods

This single-centre cross-sectional study included 238 patients with moderate-to-severe AD (SCORAD≥25) treated with dupilumab for ≥12 weeks. A subgroup treated for≥52 weeks was analysed to assess the stability of refractory patterns. Refractory lesions were classified as persistent or recurrent and mapped by anatomical site. To explore the biological basis of these clinical differences, we compared paired flexural and extensor biopsies from a treatment-naïve cohort, alongside normal skin controls. Quantitative proteomics and immunofluorescence were used to evaluate regional immune burden and autonomic nerve distribution. The functional relevance of cholinergic signalling was tested in an MC903-induced mouse dermatitis model using pharmacological blockade.

Results

The cohort comprised 133 males (55.9%) and 105 females (44.1%), aged 6–64 years. Refractory lesions demonstrated non-uniform anatomical clustering, predominantly affecting intertriginous areas (35.3%), limb flexures (34.0%), and the head/face/neck region (32.2%). Heat exposure or sweating was the most frequently reported recurrence trigger (44.5%). In patients treated for ≥52 weeks (n=87), extensor refractoriness declined whereas head/neck involvement increased to 44.8%. Proteomic analysis (n=7 paired biopsies) identified enrichment of type 1/17 immune pathways and adrenergic signalling in extensor lesions; type 2-associated proteins showed comparable regional expression. Immunofluorescence revealed relative cholinergic

predominance in flexural and facial skin, with stronger adrenergic signalling in extensor sites. Cholinergic markers co-localised with type 2 immune features, mirroring the clinical distribution of refractory disease. In vivo, cholinergic blockade significantly reduced dermatitis severity, epidermal hyperplasia, and serum IgE concentrations ($P<0.05$).

Conclusions

Regional variations in autonomic signalling correlate with the spatial organisation of type 2 immunity and may underlie site-specific refractoriness in AD. These exploratory findings suggest that local neuro-immune pathways represent potential adjunctive targets for managing persistent disease in biologic-treated patients.

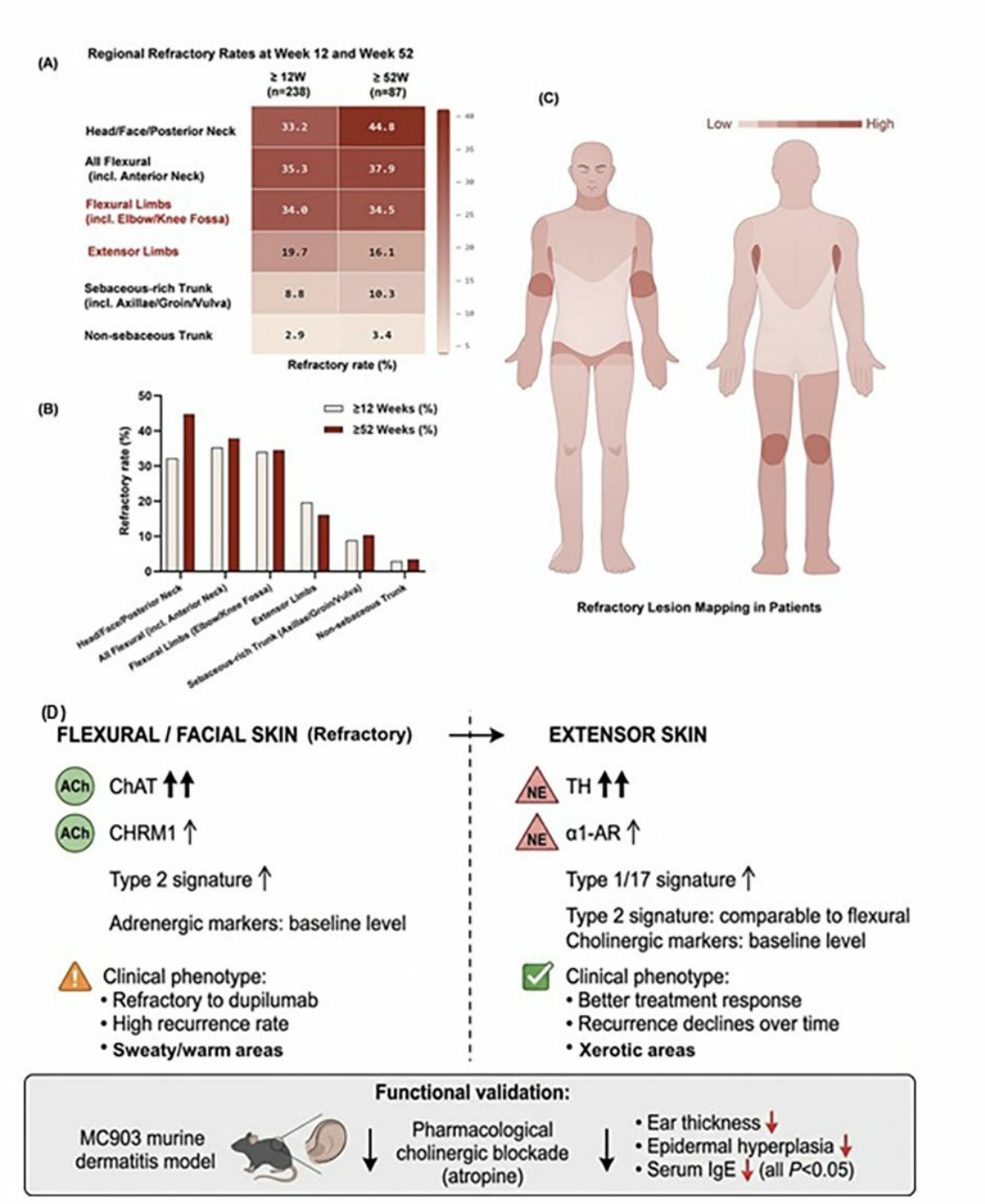

Figure 1. Spatial neuro-immune axis underlies regional refractoriness in atopic dermatitis. (A, B) Heatmaps and bar plots showing the anatomical distribution of refractory lesions in patients treated with dupilumab for ≥12 weeks (N = 238) and ≥52 weeks (N = 87). The ≥52-week group represents a subset of the ≥12-week cohort. (C) Anatomical heatmap illustrating the spatial distribution of refractory lesions after ≥12 weeks of treatment. Color intensity indicates relative lesion frequency

across regions. (D) Proposed neuro-immune signature by anatomical site: flexural/facial skin shows cholinergic predominance co-localising with type 2 immune markers; extensor skin exhibits adrenergic enrichment with type 1/17 signatures, while type 2 markers are comparable across regions. These patterns align with clinical refractoriness and were functionally supported by cholinergic blockade in a murine model. Abbreviations: ChAT, choline acetyltransferase; TH, tyrosine hydroxylase; ACh, acetylcholine; NE, norepinephrine; AR, adrenergic receptor.

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Abstract N°: 1516

Fire-Retardancy Properties of DPF19, a Novel Emollient Formulation, on Different Types of Fabrics

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Introduction

Emollients used to treat dry skin conditions such as eczema and psoriasis have been implicated in over 50 fire-related fatalities in the UK due to their fire-accelerant properties when residues accumulate on fabrics. Whilst emollients are not flammable on their own, once the emollient dries on fabrics, they pose a fire risk when exposed to sources of ignition. There is an urgent need to develop emollients that do not increase flammability when built up on textiles. The objective of the study is to investigate the fire-retardancy capabilities of DPF19, a novel developmental emollient formulation, when applied to eight different fabric types, compared to a standard emollient cream (positive control) and untreated fabrics (negative control).

Materials and Methods

Fabric samples (5 cm × 5 cm) representing diverse household textiles - including 100% cotton bedsheets, 100% cotton pyjamas, 95% cotton/5% elastane, 94% polyester/6% spandex, 100% polyester, 100% rayon, 100% acetate, and 55% cotton/45% linen - were treated with 12.5 mg/cm^2 of DPF19 or a standard emollient cream twice daily for two days, followed by a two-day drying period. Flammability testing employed a low-energy ignition source (gas utility lighter) with 1-second flame exposure followed by 5-second intervals, repeated up to five cycles. Three replicates per fabric type were analysed, with burning times recorded via video analysis.

Results

All untreated control fabrics ignited readily (except 100% polyester which melted and shrank away), with average burning times ranging from 12.7 ± 0.6 s (cotton bedsheets) to 18.5 ± 2.1 s (95% cotton/5% elastane). A standard emollient cream treated fabrics exhibited significantly enhanced flammability across all fabric types, with vigorous, ferocious flames, rapid spread, and increased burning times (16.0 – 25.0 s), accompanied by black smoke and melting of the fabric. In stark contrast, all DPF19 treated fabrics (n=24 replicates across 8 fabric types) failed to ignite after five ignition cycles, demonstrating fire-retardancy properties. Minor glowing or charring was occasionally observed but rapidly dissipated without flame propagation.

Conclusions

In this study, DPF19 demonstrated fire retardancy properties across a diverse range of natural and synthetic fabrics, effectively preventing ignition from low-energy household fire source and reduced the fire risk associated with emollient contaminated textiles. These findings support DPF19 as a safer alternative for patients requiring chronic emollient therapy, with potential to significantly reduce fire-related injuries and fatalities in vulnerable populations.

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Abstract N°: 1517

Longitudinal blood proteomics in childhood atopic dermatitis

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Introduction

Atopic dermatitis (AD) affects approximately 1 in 5 children and presents with substantial variation in disease burden, with some children experiencing remission and others developing persistent symptoms. The mechanisms underlying these different disease trajectories remain poorly understood and are not adequately captured by current biomarkers. There is a need for identification of novel biomarkers that may improve disease understanding and enable prediction, prevention, and more effective treatment. While proteomic biomarker studies have primarily focused on adults, there is limited research on children, especially in relation to the early stages of AD.

Materials and Methods

We included children from the COPenhagen Prospective Studies on Childhood in Asthma (COPSAC2010) cohort, which consists of 700 population-based mother-child pairs born between 2008 and 2011. The children were seen at scheduled clinical visits regularly until the age of 13 years (and ongoing). At each visit, the medical history was reviewed and supported by day-to-day diary cards filled from birth, capturing skin symptoms related to AD and use of topical steroids between visits.

To understand the processes involved in early AD development, we explored a novel, large-scale blood proteomics panel measured before and after disease development; at birth, 6 months, 18 months, and 6 years of age. The proteomic profiling was performed using the antibody-based immunoassay platform Olink, and covered more than 5,000 fully annotated proteins.

Results

Proteomic profiling revealed multiple protein alterations associated with the development of AD. Associations were explored using both parent-reported diary data and AD diagnosis within the first year of life assessed by medical doctors. AD diagnosis by 12 months of age was associated with the 6-month proteome, including SERPINB4, PGLYRP3, and CEACAM19 as well as additional proteins implicated in AD-relevant pathways, such as IL19, IVL, and CDSN (**Figure 1**).

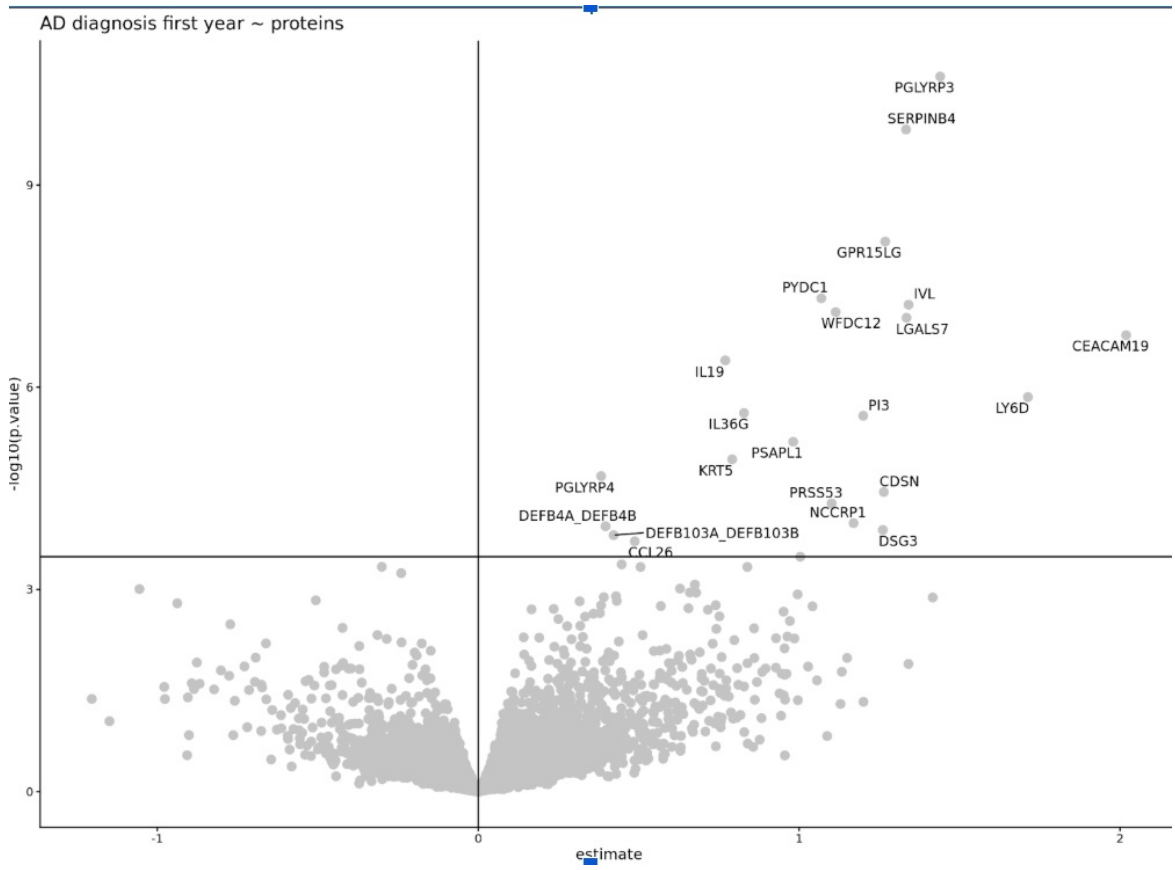

Figure 1. Volcano plot illustrating the association between AD diagnosis within the first year of life (exposure) and blood proteome levels at 6 months of age (outcomes). Each dot represents one protein. The x-axis shows the estimated effect size, and the y-axis shows -log10 (p-value). The horizontal line indicates the significance threshold ($p < 0.05$), and the vertical line marks no effect (estimate = 0). Selected significant proteins are labeled.

Conclusions

Early-life blood-based identification of children at risk of AD and characterization of phenotype-specific molecular profiles may enable patient stratification and support the development of targeted therapies, with potential improvement of prevention and treatment strategies.

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Abstract N°: 1523

Flammability Assessment of Five Commercial Urea Products on 100% Cotton Bedsheets: Evaluating Fire Hazards and Safety Risk

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Introduction

Emollients are essential treatments for dry skin conditions, but over 50 fire-related deaths have been linked to fabric contamination with these products. Whilst emollients are not flammable on their own, once the emollient dries on fabrics, they pose a fire risk when exposed to sources of ignition. The objective of the study is to investigate flammability of five commercial emollients containing varying urea concentrations (5%, 10%, and 25% (w/w)) when applied to 100% cotton bedsheets, and compare to a standard emollient cream (positive control) and untreated fabric (negative control).

Materials and Methods

Cotton fabric replicates (5 cm × 5 cm, n=3 per product) were treated with 12.5 mg/cm^2 of each product twice daily for two days, followed by a two-day drying period. Flammability testing was conducted in a controlled fume hood environment using a low-energy gas lighter with 1-second flame exposure. Burning times, flame characteristics, and ignition behaviour were recorded and analysed.

Results

All commercial urea products demonstrated fire-accelerant properties with significantly longer burning times compared to untreated controls (10.3 ± 0.6 s). The first emollient cream (5% urea) showed the longest burning time among 5% urea products (19.0 ± 2.0 s), while the second cream (10% urea) exhibited the most vigorous combustion (34.3 ± 4.2 s). The third one, with 25% urea, burned for 23.3 ± 2.3 s. All treated replicates ignited easily, produced larger and more vigorous flames than controls, burned completely, and generated black smoke with formulation melting.

Conclusions

Despite literature suggesting fire-retardant properties of urea, all tested commercial urea-containing emollients (5-25% (w/w)) increased fire risk when built up on cotton fabric, demonstrating fire-accelerant behaviour comparable to or exceeding a standard emollient cream. The overall formulation composition, rather than urea content alone, determines flammability characteristics, highlighting the need for a comprehensive safety assessment of emollient products.

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Abstract N°: 1534

Agreement Between Clinician- and Patient-Reported Outcomes and Development of an Operational Definition of Minimal Disease Activity in Atopic Dermatitis

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with a significant impact on quality of life. Disease severity is commonly assessed using clinician-reported outcomes (CROs) and patient-reported outcomes (PROs), which are not interchangeable as they reflect different dimensions of the disease. Discrepancies between CROs and PROs are frequent, highlighting the need for multidimensional evaluation strategies such as minimal disease activity (MDA). This study aimed to evaluate the agreement between CROs and PROs and to develop a pragmatic, operational definition of MDA in patients with AD receiving advanced therapies.

Materials and Methods

A prospective observational study was conducted in a tertiary hospital. Patients aged ≥12 years with moderate-to-severe AD initiating advanced therapies (biologics or JAK inhibitors) were included. Disease severity was assessed using clinician-reported outcomes (CROs): Eczema Area and Severity Index (EASI), SCORing Atopic Dermatitis (SCORAD), Investigator's Global Assessment (IGA), and Body Surface Area (BSA). Patient perspective was evaluated using patient-reported outcomes (PROs): Peak Pruritus Numerical Rating Scale (PP-NRS), Sleep Disturbance Numerical Rating Scale (SD-NRS), Patient-Oriented Eczema Measure (POEM), and Dermatology Life Quality Index (DLQI). Assessments were performed at baseline and week 16. Agreement was evaluated between CRO–CRO, PRO–PRO, and CRO–PRO measures at week 16 through pairwise comparisons. Summary variables were defined as achieving ≥1 optimal criterion within each domain. Candidate definitions of MDA (≥1 CRO + ≥1 PRO) were constructed and externally validated using the Atopic Dermatitis Control Tool (ADCT), Skindex Mini, and the World Health Organization Quality of Life questionnaire (WHOQOL), through effect size (r).

Results

A total of 96 patients were included (mean age 40.98 years [SD 20.37]; 55.2% male). At baseline, mean disease severity was EASI 22.49 (SD 9.03), PP-NRS 7.32 (SD 2.60), and DLQI 10.21 (SD 6.65). Agreement between CROs was consistently high (78.6%–96.2%), whereas agreement among PROs was more heterogeneous (50.8%–89.6%). Overall concordance between CROs and PROs was lower (49.4%–83.6%). Among CROs, EASI ≤3 demonstrated the strongest agreement (97.7%) and showed moderate-to-good concordance with all PROs. Among PROs, PP-NRS, POEM, and DLQI showed the highest agreement with CROs, whereas SD-NRS showed the lowest and most variable agreement. The combination of EASI ≤3 and DLQI 0/1 showed the strongest and most consistent performance across external validation measures, achieving the highest effect sizes in ADCT and Skindex Mini and the highest values in WHOQOL.

Conclusions

There is limited concordance between clinician- and patient-reported perspectives, indicating that they capture complementary dimensions of disease activity. This underscores the importance of integrating both perspectives when defining disease control and reinforces the value of MDA as a multidimensional therapeutic target. In this context, the combination of EASI ≤3 and DLQI 0/1 emerges as a simple, pragmatic, and clinically meaningful operational definition of MDA for use in routine clinical practice.

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Abstract N°: 1550

Mortality in Adults with Atopic Dermatitis: A Swedish Nationwide Matched Cohort Study

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease and is increasingly recognised as part of a broader systemic disease burden. Although AD is known to be associated with cardiometabolic and respiratory comorbidity, population-based evidence on all-cause and cause-specific mortality in adults, particularly accounting for disease severity over time, remains limited.

The objectives of this is to investigate all-cause and cause-specific mortality among adults with atopic dermatitis compared with matched population-based reference individuals, and to assess associations according to AD severity.

Materials and Methods
A nationwide matched cohort study was conducted using linked Swedish health and population registers from 2007 to 2024. Adults aged ≥18 years with specialist-diagnosed atopic dermatitis were identified and matched by birth year and sex with up to five population-based reference individuals without AD. Reference individuals were censored at the time of AD diagnosis and did not contribute further person-time as reference individuals. The index date was defined as the date of first recorded AD diagnosis for cases and the corresponding matched date for reference individuals. Follow-up accrued from the index date until death, emigration, or end of study (31 December 2024).

AD severity was modelled as a hierarchical time-varying exposure, allowing transitions from non-severe to severe disease, after which individuals remained in the severe category. Severe AD was defined by initiation of systemic therapy or AD-related inpatient hospitalisation. The primary outcome was all-cause mortality; secondary outcomes included cause-specific mortality by major ICD-10 categories. Incidence rates and hazard ratios (HRs) with 95% confidence intervals were estimated using Cox proportional hazards models, preserving the matching and adjusting for country of birth and baseline comorbidity.

Results
Among individuals with AD, 3,256 had severe disease and 216,593 had non-severe disease at baseline, and 7,193 developed severe disease during follow-up.

During follow-up, 8,488 deaths occurred among individuals with AD and 39,978 among reference individuals. All-cause mortality rates per 1,000 person-years were 3.59 (95% CI 3.56–3.63) in reference individuals, 3.64 (3.57–3.74) in non-severe AD, and 6.47 (6.09–6.94) in severe AD. Corresponding IRR versus reference individuals were 1.01 (95% CI 0.99–1.02) for non-severe AD and 1.80 (1.69–1.88) for severe AD.

In adjusted Cox models, adults with AD overall had a modestly elevated all-cause mortality risk compared with

reference individuals, HR 1.09 (95% CI 1.06–1.12). When analysed by severity, the adjusted HRs versus reference individuals were 1.06, 95% CI 1.03–1.09 for non-severe AD and 1.43 (1.31–1.53) for severe AD.

For cause-specific mortality, adjusted HRs were elevated for cardiovascular mortality, non-severe: 1.08 (1.03–1.12); severe: 1.17 (1.01–1.36) and respiratory mortality, non-severe: 1.13 (1.09–1.19); severe: 1.30 (1.12–1.51).

Conclusions

In this large, nationwide cohort of adults, atopic dermatitis was associated with a modestly elevated all-cause mortality compared with reference individuals. This association was largely confined to severe disease and driven primarily by cardiovascular and respiratory mortality, underscoring severe atopic dermatitis as a marker of systemic disease burden.

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30 SEP - 3 OCT 2026

Abstract N°: 1559

Selective expansion of functional Tregs and induction of clinically relevant regulatory biomarkers in Healthy Volunteers by TRB-061, a novel TNFR2 agonist in development for immune mediated diseases

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Introduction

Regulatory T cells (Tregs) reside in barrier tissues and play a major role in maintaining immune homeostasis and epithelial repair. TNFR2 is a cell surface receptor enriched on tissue-localized Tregs, including in the skin. Signaling through TNFR2 activates multiple immunoregulatory pathways to control inflammation. In contrast, defects in TNFR2 impair Treg function and exacerbate inflammatory responses. TRB-061 is a novel, selective, TNFR2-agonist Fc-fusion protein designed to expand and activate TNFR2-expressing Tregs, restoring their functional capacity in chronically inflamed tissues. A Ph1a/1b clinical trial of TRB-061 in healthy participants and patients with AD is ongoing. This abstract reports results of the Ph1a SAD portion of the trial.

Materials and Methods

This First-in-Human (FIH) study is a randomized, double-blind, placebo-controlled SAD and multi-ascending dose (MAD) study being conducted in healthy adult participants (HAs) and in patients with moderate-to-severe AD (clinialtrials.gov ID: NCT06934252). The study consists of three parts: Part 1: SAD in HAs, Part 2: MAD in HAs, and Part 3: MAD in patients with moderate-to-severe AD. In Part 1, a total of 32 healthy participants received one subcutaneous dose of TRB-061 or placebo (3:1) in four ascending-dose Cohorts. Safety, pharmacokinetics (PK), and pharmacodynamics (PD) were assessed over 85 days. PK parameters were calculated from concentration-time data using a noncompartmental analysis method. TNFR2-linked functional biomarkers, including cell surface CD39, a critical marker of Treg identity and stability, and other immune lineage cells, were measured with flow cytometry. Cytokine levels were measured with electrochemiluminescence immunoassay.

Results

TRB-061 was well-tolerated across all dose levels of 2.4, 8, 24, and 80 mg. There were no serious adverse events (SAEs), severe AEs, laboratory-related AEs, or dose-limiting AEs. Near-dose–proportional PK was observed. Dose-dependent selective expansion of CD39+ Tregs was observed. TRB-061 increased expression of tissue-licensed markers, including CCR8, consistent with a tissue-adaptive Treg phenotype. Treg augmentation was accompanied by dose-dependent increases in serum IL-10, consistent with enhanced immunoregulatory activity. Robust PD effects were observed at doses that enable convenient low-volume subcutaneous injection. TRB-061 showed selective effects on Tregs, with no detectable expansion of other immune cell subsets, including conventional T cells or natural killer cells.

Conclusions

TRB-061 was well tolerated and promoted preferential Treg expansion and increased markers of immunoregulatory function following single doses in healthy adults, indicating the first evidence of proof of

mechanism in a clinical trial for a TNFR2 agonist. The PK and PD profiles support a convenient dose regimen for patients. The study is ongoing, including in patients with moderate to severe AD.

EADV CONGRESS
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30 SEP - 3 OCT 2026

Abstract N°: 1560

Air Pollution and Its Implications for Atopic Dermatitis and Psoriasis: A Systematic Review

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Introduction

Air pollution is increasingly recognised as an environmental determinant of inflammatory skin disease. Air pollutants, such as particulate matter (PM), nitrogen dioxide (NO_2) and ozone (O3) can trigger oxidative stress in the skin, weakening the skin barrier and activating pro-inflammatory pathways. Although atopic dermatitis (AD) and psoriasis are multifactorial, environmental pollutants can affect risk and disease activity. This systematic review synthesises current evidence linking air pollution exposure with AD and psoriasis outcomes.

Materials and Methods

A systematic literature search was conducted in PubMed, Embase and MEDLINE, for studies published between 2021 and 2026. Search terms included "air pollution", "particulate matter", "PM2.5", "nitrogen dioxide", "ozone", "atopic dermatitis", "eczema" and "psoriasis". Two reviewers independently screened records for observational studies investigating associations between air pollution and disease outcomes.

Results

Of 1,128 records, 103 articles underwent full-text screening (77 AD, 23 psoriasis, 3 both). Increased exposure to PM2.5, NO_2 and ozone was consistently associated with higher disease incidence and exacerbations of AD and psoriasis. Epidemiological data shows a 10 $\mu g/m^3$ increase in PM2.5 is correlated with a 7-14% rise in AD-related outpatient visits. In a large cohort study (n = 474,055), greater exposure to PM2.5, PM10 and NO_2 increased psoriasis risk (HR 1.41, 1.47 and 1.28, respectively). Notably, individuals in the highest exposure groups suggest nearly double the risk of developing psoriasis (HR 2.01).

Conclusions

Air pollution is a significant factor in inflammatory dermatoses. Recognising these environmental triggers is essential for patient education and developing public health interventions. Further research is needed to guide future clinical recommendations.

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Abstract N°: 1564

Synchronous Meyerson Phenomenon Affecting Three Melanocytic Nevi: A Rare Clinical Presentation

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Introduction

Meyerson phenomenon, also known as halo dermatitis, is a rare inflammatory dermatosis characterized by the appearance of a pruritic eczematous plaque surrounding a central skin lesion. It most commonly develops around a melanocytic nevus, in which case the term *Meyerson nevus* is often used. Similar reactions have also been reported in association with other benign lesions, including seborrheic keratoses, as well as dysplastic nevi and, rarely, melanoma. For this reason, the broader term Meyerson phenomenon is generally preferred.

Case Presentation

We present the case of a 40-year-old male with a two-month history of pruritic skin changes on the abdomen. His past medical history was significant for celiac disease, hypertension, venous thrombosis, pulmonary embolism, and intracranial hemorrhage. Clinical examination revealed three spatially separated, intensely inflamed erythematous plaques on the anterior trunk, each arising precisely around a pre-existing melanocytic lesion. The lesions were characterized by oozing, crusting, and marked pruritus, producing a striking synchronous pattern of selective inflammation affecting only three nevi, while numerous surrounding nevi remained clinically unaffected. Dermoscopic examination revealed mild asymmetry and variegated pigmentation of the central melanocytic lesions, but assessment was significantly limited by the intense surrounding inflammation. Biopsies of all three central lesions were performed, including a portion of the surrounding peripheral erythematous skin. Histopathological examination demonstrated intradermal melanocytic nevi without cytological atypia, accompanied by overlying eczematous inflammatory changes with superficial crusting and a mild lymphocytic infiltrate containing rare eosinophils, findings consistent with Meyerson phenomenon. Treatment with potent topical corticosteroids, topical antibiotic therapy, and antihistamines resulted in clinical improvement; however, the lesions showed recurrence during follow-up.

Conclusion

Meyerson phenomenon is a rare dermatosis of uncertain etiology that typically presents as a solitary, and less commonly multiple, eczematous plaque surrounding a central pre-existing skin lesion. Importantly, it may also occur in the setting of malignant lesions such as melanoma. Our case is unusual because of the simultaneous involvement of three separate melanocytic nevi, all histopathologically confirmed as benign lesions, while numerous other nevi remained unaffected. The reason for this selective involvement remains unclear. Marked inflammation may obscure dermoscopic structures and complicate clinical assessment, sometimes requiring histopathological examination to exclude dysplastic or malignant transformation. Careful dermoscopic evaluation is recommended in all such cases. Non-melanocytic central lesions should prompt exclusion of melanoma, while dermoscopically atypical lesions or lesions unresponsive to standard therapy warrant histopathological examination. The prognosis is excellent, with topical corticosteroids representing the most commonly used therapy, although spontaneous resolution may also occur. This case emphasizes the need for careful evaluation of inflamed melanocytic lesions and awareness of this uncommon clinical presentation.

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Abstract N°: 1569

Efficacy of a Moisturizing Cream for Mild Atopic Dermatitis in Adults: A Multi-center, Open-Label, Prospective Single-arm Clinical Trial: Part I

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Introduction
Atopic dermatitis (AD) is a common chronic inflammatory skin disorder characterized by skin dryness, intense pruritus, and recurrent eczematous lesions. Impaired skin barrier function is one of the key pathophysiological mechanisms of AD. Impaired barrier function drives increased transepidermal water loss (TEWL) and enhanced penetration of external allergens, perpetuating inflammatory responses and pruritus. Moisturizers represent a cornerstone of non-pharmacological AD management, targeting skin hydration restoration and barrier repair.

Materials and Methods
This multi-center, open-label, single-arm trial evaluated the efficacy and safety of a Restoring Moisturizing Cream on mild AD in children and adults. A total of 70 patients with mild atopic dermatitis (Scoring Atopic Dermatitis, SCORAD < 25) were enrolled in a 1:1 ratio across two age groups: 0–12 years and >12 years. Patients applied the Restoring Moisturizing Cream to affected lesions twice daily (morning and evening) for 28 days, with follow-up visits on days 7, 14, and 28. Primary endpoint was change in SCORAD score from baseline; secondary endpoints included Peak Pruritus Numeric Rating Scale (PP-NRS), stratum corneum hydration, TEWL, and Dermatology Life Quality Index (DLQI), and patient and physician satisfaction scores. Adverse events during the treatment period were also evaluated. This report presents results in patients aged >12 years.

Results
All 35 patients aged >12 years completed the study. Mean (standard deviation, SD) SCORAD score decreased significantly from 18.93 (4.30) at baseline to 14.02 (4.97) on day 7, 10.40 (4.62) on day 14, and 6.82 (5.35) at day 28, representing a 64% reduction at end of treatment (all $P < 0.01$). PP-NRS pruritus score showed a continuous downward trend at all visits [median (IQR): 4.0 (3.0, 6.0), 3.0 (1.0, 3.0), 1.0 (0.0, 2.0), 1.0 (0.0, 1.0); $P < 0.01$]. Stratum corneum water content was significantly increased at days 7 and maintained at day 14, and day 28. DLQI improved markedly at day 28 compared to baseline [8.0 (4.0, 10.0) vs. 1.0 (0.0, 3.0); $P < 0.01$]. Patient and physician satisfaction rate at day 28 were 91.4% and 85.7%. No adverse events were recorded throughout the study.

Conclusions
In adolescents (>12 years) and adults with mild atopic dermatitis, a Restoring Moisturizing Cream provides rapid, sustained in disease severity, pruritus, skin hydration, and quality of life over 28 days, with high patient and physician satisfaction and excellent safety profile.

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Abstract N°: 1583

One year efficacy and safety findings for patients with moderate-to-severe atopic dermatitis receiving dupilumab in the Canadian phase IV prospective, observational study (CANDID).

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Introduction
Currently, limited data are available on long-term use of dupilumab to treat patients with moderate-to-severe atopic dermatitis (AD) in a Canadian real-world setting. The aim of this analysis was to report 1 year (12-month) effectiveness and safety data for patients with moderate-to-severe AD receiving dupilumab as part of the CANDID study (phase 4 AD dupilumab Canada study).

Materials and Methods
CANDID (NCT06099704) is an ongoing, 18-month, long term, prospective, observational study of adults/adolescents/children (aged ≥ 6 years at baseline) with moderate-to-severe AD who initiated dupilumab in real-world settings according to Canadian-specific prescribing guidelines. Effectiveness outcomes evaluated at baseline and months 3, 6, 12, and 18 included scores for 75% improvement in Eczema Area and Severity Index (EASI-75), body surface area (BSA) involvement, Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI), Hospital Anxiety and Depression Scale (HADS), Sleep Disturbance Numerical Rating Scale (SD NRS), and Peak Pruritus Numeric Rating Scale (PP NRS). Safety events were collected from the time of signed informed consent.

Results
One year (12-month) data were obtained from 245 patients enrolled into the CANDID study (adults: 195; adolescents [aged 12-17 years] and children [aged 6-11 years]: 50). After dupilumab treatment initiation, mean improvements in effectiveness outcome measures from baseline to month 12 were 87% for EASI-75 (from 21.0 to 2.7), 84% for BSA (from 30.3% to 4.8%), 73% for DLQI (from 15.7 to 4.3), 65% for CDLQI (from 14.4 to 5.1), 31% for HADS (from 15.9 to 11.0), 66% for SD NRS (from 6.4 to 2.2), and 59% for PP NRS (from 7.8 to 3.2). No new safety concerns were identified at 12 months.

Conclusions

In a Canadian real-world setting, dupilumab demonstrated robust and sustained long-term effectiveness in patients aged ≥ 6 years, with moderate-to-severe AD across multiple disease domains, including AD signs, symptoms, and quality of life. Safety was consistent with the known dupilumab safety profile.

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Psychiatric Outcomes in Pediatric Patients with Atopic Dermatitis: A Systematic Review and Meta-Analysis

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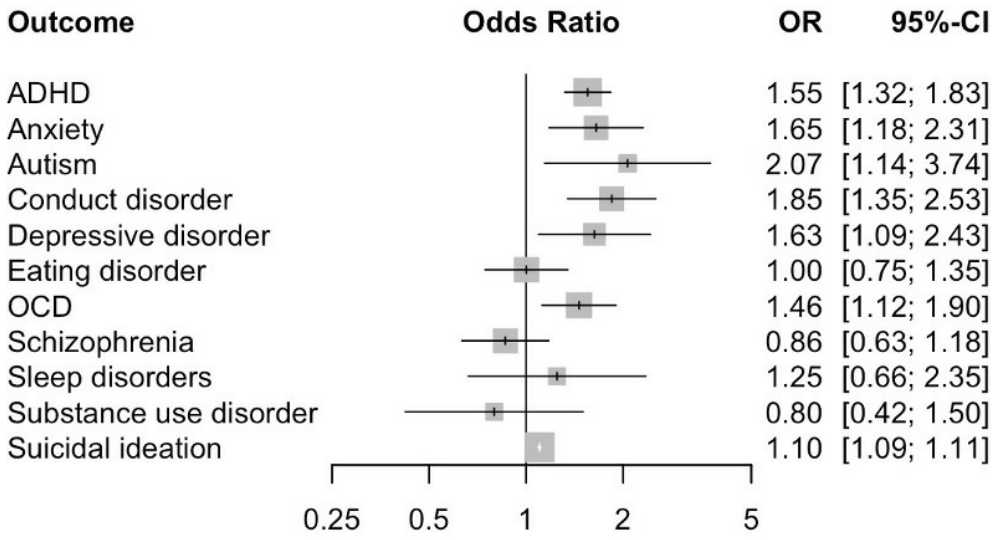
Introduction
Atopic dermatitis (AD), a chronic inflammatory skin disease, affects approximately 25% of children worldwide with potential neuropsychiatric sequelae. However, prior literature syntheses have largely focused on select outcomes, non-standardized symptom-based scales or mixed-age populations, limiting applicability to pediatric care. Accordingly, this review aimed to comprehensively evaluate the association between pediatric AD and psychiatric outcomes.

Materials and Methods
MEDLINE, Embase, PsycINFO, CINAHL, and Scopus were searched in October 2025 using keywords related to "atopic dermatitis" and "mental health." Eligible studies: (1) were observational (cohort, case-control, cross-sectional), (2) enrolled pediatric patients (≤18 years) with AD, as defined by clinical diagnoses or ICD codes, alongside a healthy comparator group and (4) investigated any clinical mental disorder (number of events, odds ratios [OR]) based on physician diagnosis, DSM-5 criteria or ICD codes. Suicidal outcomes, including ideation and attempts, were also analyzed due to high overlap with psychiatric comorbidities. Random-effects meta-analyses were used to calculate pooled ORs and 95% confidence intervals (CIs). When outcomes were available from longitudinal studies, separate meta-analyses limited to these data were performed to assess stability of associations across the follow-up period. Study quality was assessed using the Newcastle-Ottawa Scale and evidence certainty with Grading of Recommendations, Assessment, Development, and Evaluation (GRADE). For outcomes with sufficient data (≥10 studies), post-hoc mixed-effects meta-regressions were used to explore sources of heterogeneity, including study location, NOS scores, publication year, and AD ascertainment method as moderator variables.

Results
Of 4829 studies identified, 23 (52.2% retrospective cohort, 26.1% cross-sectional, 13.0% case-control, 8.7% prospective cohort) were eligible, spanning an average of 8.3 years from inclusion to end of follow-up. Overall,

28,718,357 participants (mean age: 7.82 years; 9.4% female) were described. Of these, 1,294,322 (4.5%) participants had a baseline diagnosis of AD. Children with baseline AD demonstrated increased odds of attention-deficit hyperactivity disorder (ADHD; OR 1.55, 95% CI 1.30-1.85, low certainty), anxiety (OR 1.65, 95% CI 1.13-2.41, low certainty), autism (OR 2.07, 95% CI 1.01-4.22, low certainty), conduct disorder (OR 1.85, 95% CI 1.11-3.08, low certainty), depressive disorders (OR 1.63, 95% CI 1.04-2.55, low certainty), and suicidal ideation (OR 1.10, 95% CI 1.08-1.13, low certainty) compared to healthy controls. Associations for incident ADHD and anxiety persisted in analyses of longitudinal studies. Associations for eating disorders, obsessive-compulsive disorder, sleep disorders, schizophrenia, or substance-use disorders were not significant. As per exploratory meta-regressions, clinician diagnosis was identified as a significant moderator in ADHD versus diagnostic codes, and recent publication years in anxiety and depressive disorders.



Summary of meta-analyses by psychiatric outcome, as odds ratios (ORs) and 95% confidence intervals. Abbreviations: ADHD: attention-deficit/hyperactivity disorder; CI: confidence interval; OCD: obsessive-compulsive disorder; OR: odds ratio

Conclusions

This meta-analysis suggests increased odds of psychiatric outcomes among pediatric AD patients, particularly ADHD, anxiety, autism, conduct disorder, depressive disorders, and suicidal ideation. Notably, pediatric AD patients demonstrated the highest risk for autism. These findings may be attributed to multiple factors including cytokine-mediated effects on neurodevelopmental circuits, sleep disruption due to persistent pruritus, and psychosocial stressors like stigmatization. Although strengthened by the inclusion of large cohort studies and use of maximally adjusted effect estimates where available, limitations of this analysis include geographic bias towards European and East Asian populations and potential misclassification associated with administrative diagnostic codes. Prospective studies stratified by AD severity and sex are warranted to clarify the magnitude and clinical implications of these associations.

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Abstract N°: 1602

Effectiveness of Upadacitinib Stratified by Baseline Itch in Patients With Atopic Dermatitis who Were Inadequate Responders or Intolerant to Dupilumab: Results From the CAN UpTIMISE Study

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Introduction

Upadacitinib, a selective Janus kinase 1 inhibitor, has shown superior efficacy to dupilumab in randomized controlled trials involving patients with moderate-to-severe atopic dermatitis (AD).[1,2] Recently, real-world findings from the CAN UpTIMISE observational study further demonstrated that upadacitinib is effective and well tolerated in adults with AD who discontinued dupilumab due to inadequate response or safety/tolerability reasons.[3-5] However, limited evidence is available on the effectiveness of upadacitinib based on the severity of baseline itch. This post hoc analysis evaluates treatment outcomes following a switch from dupilumab to upadacitinib stratified by patients baseline itch severity.

Materials and Methods

CAN UpTIMISE (NCT05394792) was a Canadian observational study involving adults with moderate-to-severe AD who had received dupilumab as the most recent prior systemic therapy for at least 16 weeks (unless discontinued for safety/tolerability reasons), with decision to change treatment to upadacitinib (per local label) made prior to, and independently of, enrolment into the study. Effectiveness was assessed over 4 months using scores for

validated Investigator Global Assessment for AD (vIGA-AD), Eczema Area and Severity Index (EASI), Worst Pruritus Numerical Scale (WP-NRS), and Dermatology Life Quality Index (DLQI). Results are presented stratified by baseline WP-NRS score (mild to no itch [≤mild; 0-3], moderate itch [4-6], and severe itch [7-10]) using descriptive statistics.

Results

A total of 103 patients were included in the analysis (male gender: 54.4%; mainly White [61.2%] or Asian [33.0%]). Patients with severe baseline itch had a higher mean EASI score (20.2) than patients with ≤mild (7.6) or moderate (10.9) itch. Interestingly, despite having ≤mild itch at baseline, 57.1% of these patients still presented with moderate or severe skin disease per baseline vIGA-AD score. Discontinuation of dupilumab was primarily due to inadequate response rather than intolerance, particularly among patients with severe baseline itch (95.5% vs 4.5%), compared with those with ≤mild itch (71.4% vs 28.6%). Of note, there was a higher proportion of Asian patients in the subgroup with severe itch (43.2%) than with moderate (29.0%) or ≤mild (21.4%) itch. After 4 months of upadacitinib, patients experienced meaningful and consistent improvements in skin disease (vIGA-AD score 0/1: 61.8-78.3%; EASI ≤ 3: 73.9-91.3%), itch (WP-NRS score 0/1: 38.7-54.5%), and quality of life (DLQI score 0/1: 29.0-45.5%) outcomes regardless of there initial itch severity (Figure 1a). Moreover, 36.7-52.4% of the patients reached minimal disease activity (EASI ≤ 3 and WP-NR score 0/1). Across all subgroups, patients showed a notable reduction in mean EASI scores as early as Month 1 after switching from dupilumab to upadacitinib (Figure 1b), and these improvements were generally maintained through Month 4. Similar trends were also observed in mean WP-NRS score (Figure 1c).

Conclusions

This post hoc analysis of the CAN UpTIMISE study demonstrate that upadacitinib helps many patients achieve high rates of skin clearance, itch relief, and quality of life improvements across subgroups of patients regardless of baseline itch severity prior to switch from dupilumab. These results support upadacitinib as a suitable treatment option in a variety of patients, who may be experiencing an inadequate response or intolerance to dupilumab.

[1]Blauvelt A et al. JAMA Dermatol. 2021;157(9):1047-55

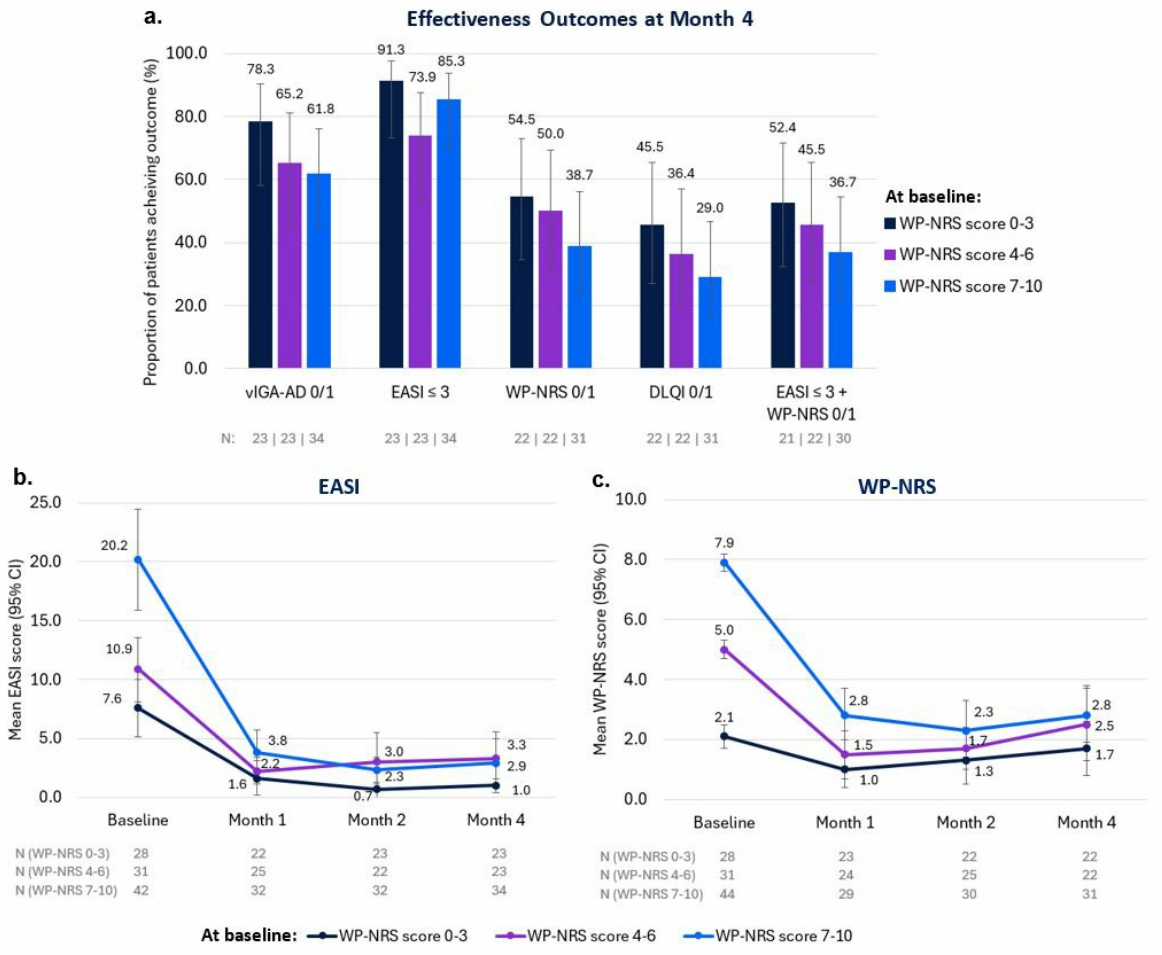
[2]Silverberg JI et al. Br J Dermatol. 2024;192(1):36-45

[3]Hong HC-H et al. RAD Conference. 2025, Nashville, TN, United States

[4]Prajapati et al. (P2802) EADV. 2025, Paris, France

[5]Hong HC-H et al. (P3294) EADV. 2025, Paris, France

Figure 1. Effectiveness Outcomes Stratified by Baseline WP-NRS Score After 4 Months of Upadacitnib



Patients received 15 or 30 mg upadacitinib over 4 months. Error bars represent 95% confidence intervals. DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numerical Rating Scale.

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Abstract N°: 1609

Comparative Efficacy of Dupilumab, Tralokinumab, and Lebrikizumab on Patient-Reported Outcomes in Moderate-to-Severe Atopic Dermatitis: A Frequentist Network Meta-Analysis

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Introduction
Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease whose burden extends well beyond its cutaneous manifestations. Persistent pruritus, sleep disruption, and visible skin involvement profoundly impair health-related quality of life, self-esteem, and psychosocial functioning, with rates of anxiety and depression significantly elevated compared to the general population. Patient-reported outcomes (PROs), including the Dermatology Life Quality Index (DLQI) and the pruritus Numerical Rating Scale (NRS), are central to holistic treatment assessment in moderate-to-severe AD. Three IL-4/IL-13 pathways biologics - dupilumab, tralokinumab and lebrikizumab - are approved for this indication, yet no head-to-head randomised controlled trials exist. Indirect comparisons are necessary to support decision-making.

Materials and Methods
A frequentist NMA (R, netmeta v3.3-1) was conducted using six phase 3 RCTs: SOLO 1 and SOLO 2(dupilumab 300 mg Q2W), ECZTRA 1 and ECZTRA 2 (tralokinumab 300 mg Q2W), ADvocate 1 and ADvocate 2 (lebrikizumab 250 mg Q2W), forming a star-shaped network with placebo as the common reference. DLQI was the primary continuous outcome and proportion achieving a ≥4-point pruritus NRS reduction the binary secondary one, both at Week 16. Treatment ranking used P-scores and an exploratory meta-regression investigating sources of DLQI heterogeneity was performed. Sensitivity analyses included a common-effects model and exclusion of individual drug pairs.

Results
For the primary outcome (DLQI), all three biologics demonstrated significant improvements versus placebo. Lebrikizumab achieved the highest P-score (0.858), followed by dupilumab (0.772) and tralokinumab (0.371). For the secondary outcome (pruritus NRS ≥4-point reduction), lebrikizumab again ranked first (P-score 0.863), followed by dupilumab (0.801) and tralokinumab (0.336). Lebrikizumab consistently demonstrated the greatest probability of superiority across both outcomes. Lebrikizumab and dupilumab were not significantly different from each other, whereas both were significantly superior to tralokinumab in pruritus NRS response. All sensitivity analyses confirmed stability of estimates.

Several methodological considerations warrant acknowledgement. The network comprises only six trials - two per drug - substantially limiting statistical power; all comparisons should be regarded as hypothesis-generating. The precision of the lebrikizumab DLQI estimate is somewhat wider than for comparators, reflecting differences in statistical modelling across trials, which may attenuate the observed effect. Rescue medication use in the ECZTRA placebo arms was relatively high compared to other trials, which may have led to an underestimation of tralokinumab's true treatment effect. All drug-versus-drug comparisons are indirect, via placebo as a common node.

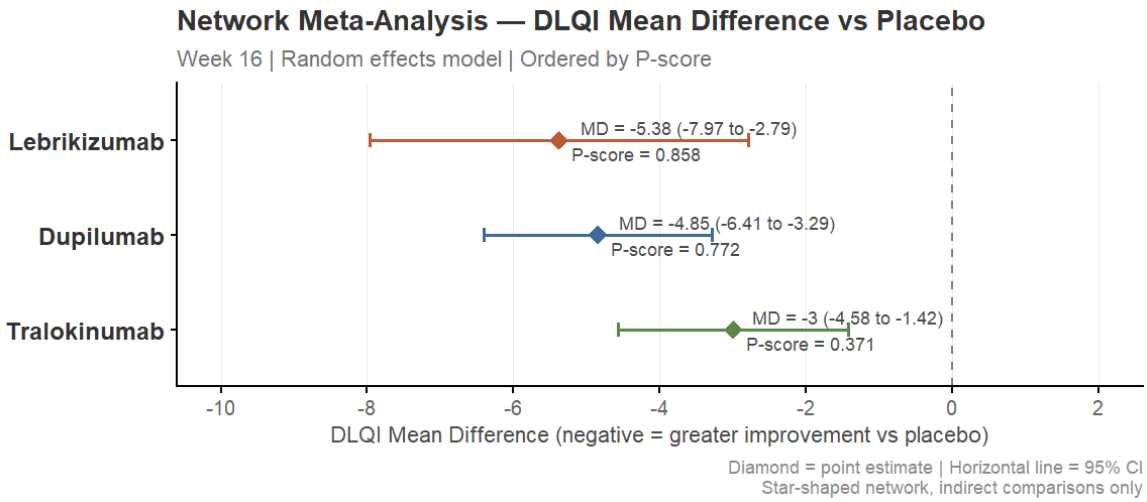

Figure 1. Network Meta-Analysis Results - DLQI Mean Difference vs Placebo at Week 16 (Random-Effects Model, Ordered by P-score).

Conclusions

In this indirect NMA of six phase 3 RCTs, lebrikizumab consistently ranked first across both PRO outcomes at Week 16, with P-scores exceeding 0.8, suggesting the highest probability of being the most effective IL-4/IL-13 biologic for patient-reported quality of life and pruritus relief. Dupilumab performed comparably, and together with lebrikizumab were significantly superior to tralokinumab in itch response. These findings should be interpreted as exploratory and directional given the inherent limitations of indirect comparisons and the modest evidence base. Nevertheless, they provide a meaningful framework to guide individualised treatment decisions in moderate-to-severe AD, pending direct head-to-head trial data.

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Abstract N°: 1611

Type 2 and epithelial-derived cytokines exhibit distinct effects on human dermal endothelial cells

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Introduction

Recruitment of immune cells to sites of inflammation is a key step in initiating and maintaining chronic inflammatory skin diseases, such as atopic dermatitis (AD). Though numerous cytokines, such as IL-4, IL-13, IL-33 and thymic stromal lymphopoietin (TSLP), have been implicated in driving disease pathology in AD, only blockade of the canonical type 2 cytokines, IL-4 and IL-13, is clinically validated, while that of IL-33 or TSLP monotherapies have not met with benefit.

Materials and Methods

To evaluate their effects on regulating inflammation, we stimulated primary human dermal endothelial cells with each cytokine, followed by bulk RNA sequencing for gene signatures and Luminex assay for cytokine/chemokine production.

Results

Endothelial cells treated with IL-4 and IL-13 shared similar gene expression patterns, which was consistent with expression of their shared receptor (*IL4RA/IL13RA1*) on endothelial cells. Interestingly, endothelial cells only expressed the receptor for IL-33 (*IL1RL1/IL1RAP*), but not that of TSLP (*CRLF2/IL7R*), and as a result only IL-33 promoted gene expression changes. Comparison of gene signatures between IL-4/IL-13 and IL-33 highlighted important differences: with IL-4/IL-13 inducing expression of genes involved in eosinophil recruitment (*CCL26*) and endothelial cell adhesion molecules (*VCAM1*, *SELP*), while IL-33 had a distinct chemokine (*CXCL1, CXCL2, CXCL8*) and adhesion molecule (*ICAM1, SELE*) profile consistent with type 1/type 3 neutrophilic inflammation. This differential cytokine profile was further validated by protein in Luminex assays.

Conclusions

Together our data outline one putative mechanism by which IL-4/IL-13 condition endothelial cells to facilitate leukocyte recruitment, and thus orchestrate the predominant type 2 inflammatory bias observed in AD.

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Abstract N°: 1640

Efficacy and Safety of SSGJ-611 in Chinese Patients with Moderate to Severe Atopic Dermatitis: A Phase 3 Randomized Clinical Trial

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Introduction

SSGJ-611 is an antibody against interleukin-4 receptor α, which has demonstrated efficacy with acceptable safety in clinical trials in patients with moderate to severe atopic dermatitis (AD). This study aimed to evaluate the efficacy and safety of SSGJ-611 in adult Chinese patients with moderate to severe AD.

Materials and Methods

In this randomized, double-blind, placebo-controlled, phase 3 study (NCT06173284), patients with moderate to severe AD were randomly assigned in a ratio of 2:1 to receive SSGJ-611 (300mg Q2W after a loading dose of 600mg) or placebo during a 16-week treatment period. During the maintenance period (week 16 to week 52), patients who had a clinical response at Week 16 (defined as a ≥75% reduction in EASI score from baseline, or an IGA score of 0 or 1 with a ≥2-point reduction from baseline) were randomly reassigned in a 2:1 ratio to either Maintenance Group A (SSGJ-611 300 mg Q2W) or Maintenance Group B (SSGJ-611 300 mg Q4W); patients without a clinical response received SSGJ-611 300mg Q2W. Patients originally on placebo received a single 600mg dose of SSGJ-611 at Week 16. The treatment period was followed by an 8-week safety follow-up. Primary efficacy endpoints were the proportion of patients achieving EASI-75 at Week 16 and the proportion achieving IGA 0/1 with a ≥2-point reduction from baseline at week 16. The main secondary efficacy endpoints included the proportion achieving a ≥4-point reduction in itch-NRS; and the proportion of patients maintaining EASI-75 or IGA

0/1 (with ≥2-point reduction) from Week 16 through Week 52. Safety, pharmacokinetics, immunogenicity, and pharmacodynamics were also evaluated.

Results

A total of 519 patients were randomized and assigned to SSGJ-611 group (n=345) or placebo group (n=174). At Week 16, the EASI-75 response rate was significantly higher with SSGJ-611 (68.4%) than with placebo (26.5%), with a difference of 41.9% (95% CI: 33.80–50.06%, P < 0.0001); similarly, the IGA 0/1 (with ≥2-point reduction) response rate was significantly higher with SSGJ-611 than with placebo (36.6% vs. 14.6%), with a difference of 22.1% (95% CI: 14.83–29.38%; P < 0.0001). At Week 16, a ≥4-point reduction in weekly average itch-NRS was achieved by 45.4% of patients in the 611 group vs. 15.6% in the placebo group (difference: 29.8%; P<0.0001). Notably, at week 2, the SSGJ-611 group showed greater improvements than the placebo group in both EASI percentage change from baseline (-25.94% vs. -13.00%; difference: -12.94%; 95% CI: -17.33%, -8.54%; nominal P < 0.0001) and least squares mean of weekly average Itch NRS change rate from baseline (-13.38% vs. -7.24%; difference: -6.14; 95% CI: -9.89%, -2.40%; nominal P = 0.0013). For week-16 EASI-75 responders in the SSGJ-611 group continuing maintenance therapy, week-52 response maintenance rates were 96.9% with Q2W vs. 95.8% with Q4W (difference: 1.2% [95% CI: -4.37 to 6.73%]); for week-16 IGA 0/1 responders, maintenance rates were 89.6% vs. 89.1% (difference: 2.5% [95% CI: -9.93 to14.85%]) at week 52. During the 16-week treatment period, treatment-emergent adverse event (TEAE) occurred in 66.1% (228/345) of patients in the SSGJ-611 group and 65.5% (114/174) in the placebo group. The incidence of TEAEs during the treatment period was similar in the two groups. Most TEAEs were Grade 1 to 2. SSGJ-611 demonstrated a favorable safety profile, with no increase in risk observed with longer drug exposure.

Conclusions

SSGJ-611 demonstrated rapid, substantial, and durable levels of skin clearance in Chinese patients with moderate to severe AD. It showed a rapid onset of action, and significant improvements in skin lesions and relief of itching, with high maintenance rate even at a longer dosing interval of Q4W. The safety profile of SSGJ-611 in this patient population was favorable, and no new risk signals were identified. Our findings support SSGJ-611 as a promising new treatment option for moderate to severe AD.

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Treating successfully and keeping long-term remission in a patient with chronic hand eczema using delgocitinib

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Introduction

Chronic hand eczema (CHE) is a common, relapsing, inflammatory skin disease that impairs hand function and quality of life. Despite its prevalence and impact on patients' lives, treatment options are limited, with many patients showing inadequate response or intolerance to topical corticosteroids and systemic immunosuppressants. As a result, there is a significant unmet need for effective, well-tolerated, safe treatments that provide long-term disease control with minimal systemic risk. Using delgocitinib, a topical pan JAK inhibitor as monotherapy in a patient resistant to all available on and off-label topical and systemic treatments, we achieved a rapid, excellent and safe long-term response in CHE.

Case Presentation

A 47- year- old Caucasian female patient presented with redness, scaling, fissures, intense itching, and pain on both palms for the last 5 years, resistant to topical corticosteroids, calcineurin inhibitors, cyclosporine and alitretinoin. Patient's symptoms were calculated with Investigator's Global Assessment for CHE IGA-CHE 4 (0-5) and Hand Eczema Severity Index score HECSI 85 (0-360). She was described treatment with delgocitinib 2% cream twice daily for 4 weeks, followed by maintenance dose 3 times a week for almost 1 year. Patient's symptoms disappeared in the first month of the intensive application of the cream and were in complete remission after the maintenance dose for almost 1 year. The IGA-CHE was 0 in the first month of treatment and remained similar in the one year follow-up. Respectively HESCI score was 32 in the first month and decreased to 5 in one year treatment.

Conclusion

Delgocitinib is the first treatment specifically indicated for moderate to severe CHE, providing a favorable therapeutic option for this challenging skin condition. In disease pathogenesis all cytokines involved in pathophysiologic mechanism signal through Janus kinase pathway and this is the reason that it addresses all the various subtypes of CHE. Based on our clinical experience with 2% delgocitinib cream, we have concluded that it is an effective, safe and well-tolerated treatment for CHE, even in patients who have previously shown inadequate response to alitretinoin, cyclosporine, and corticosteroids. Our patient maintained the remission of disease for over a year by using the cream as a maintenance dose three times a week. Case reports like these suggest that studies with larger number of patients could in the future, help confirm the above benefits in daily clinical practice.

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Baseline Burden and Clinical Profile of Paediatric Patients with Atopic Dermatitis Before Initiating Dupilumab: Interim Results from the French DUPILAB Real-World Cohort

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory disease associated with substantial burden in children and their family.[1] Real-world data on disease severity and its impact on quality of life (QoL) in the paediatric population remain limited. This interim analysis aims to describe baseline clinical severity, comorbidities, and disease burden in paediatric patients included in the DUPILAB study.

Materials and Methods

DUPILAB (NCT06169527) is a large, French, multicentre, prospective, observational cohort study including 303 patients aged ≥6 years with AD, initiating dupilumab treatment according to French prescribing guidelines. This interim analysis reported baseline data of paediatric subgroups (children of age 6–<12 years with severe AD; adolescents of age 12–<18 years with moderate-to-severe AD). Baseline variables collected were exposure to prior treatments, family history of atopy and AD, Eczema Area and Severity Index (EASI), Atopic Dermatitis Control Tool (ADCT; patients aged ≥12 years), itch and sleep scores, and Patient/Caregiver Global Assessment of Disease Severity (P/CGADS). QoL measures included Children's Dermatology Life Quality Index (CDLQI; patients aged <16 years), Dermatology Life Quality Index (DLQI; patients aged 16–<18 years), Dermatitis Family Impact questionnaire (DFI; patients aged <16 years), and European Quality of Life 5-Dimensions 3-Level (EQ-5D-3L). Additional assessments were work productivity, activity, and classroom impairment. Descriptive statistics were used for the data analysis.

Results

This interim analysis investigated 102 paediatric patients (33.7% of 303 participants), including 50 children and 52 adolescents before initiating dupilumab. All patients had prior exposure to topical treatments, while systemic treatments were used in 2% of children and 3.8% of adolescents. Family history of atopy was reported in children more frequently than in adolescents, with a similar pattern observed for familial AD. Both age groups reported moderate-to-severe AD, with adolescents demonstrating numerically higher mean EASI scores (18.98±12.16) than children (14.01±8.43). Mean itch scores were comparable between age groups, while poor overall wellbeing was

reported in 48.9% of children (CGADS) and 39.2% of adolescents (PGADS). Disease control was poor among adolescents with frequently reported sleep disturbances. QoL was impaired across both age groups. Moderate impact on daily life was consistently reported across both age groups, as measured by CDLQI in children and adolescents aged 12–<16 years, and DLQI in adolescents aged 16–<18 years. Mean EQ-5D-3L health scores were similar among both age groups. Within the EQ-5D-3L anxiety/depression dimension, moderate-to-extreme impairment was reported in both age groups, with higher rates of extreme anxiety/depression in adolescents. Families of children and adolescents (aged 12–<16 years) experienced significantly altered burden (DFI), characterized by emotional distress, exhaustion, and financial burden. Adolescents experienced notable school/activity impairment due to AD. Detailed baseline and clinical characteristics data are presented in Table 1.

Table 1: Demographic and clinical data at baseline

Parameter	Children aged 6–<12 years with severe AD (N=50)	Adolescents aged 12–<18 years with moderate-to-severe AD (N=52)
Demographic data		
Age, mean±SD, years	9.02±1.79	15.14±1.67
Gender, n (%)		
Female	22 (44.0%)	27 (51.9%)
Male	28 (56.0%)	25 (48.1%)
Family history of 1st degree atopy, n (%)	40 (80.0%)	28 (53.8%)
Family history of AD, n (%)	37 (74.0%)	26 (50.0%)
Prior treatments, n (%)		
Topical	50 (100.0%)	52 (100.0%)
Systemic	1 (2.0%)	2 (3.8%)
Disease severity		
n_1	47	50
EASI score,[a] mean±SD	14.01±8.43	18.98±12.16
Moderate-to-severe AD, n (%)	34 (72.3%)	42 (84%)
Moderate, n (%)	27 (57.4%)	24 (48.0%)
Severe, n (%)	7 (14.9%)	18 (36.0%)
Symptoms and control		
n_1	49	51
Itch score, mean±SD	6.61±2.16	6.39±2.62
n_1	45	51
Poor overall wellbeing, n (%)		
CGADS score	22 (48.9%)	NA
PGADS score	NA	20 (39.2%)
n_1	NA	51
ADCT: Uncontrolled disease (ADCT ≥7), n (%)	NA	41 (80.4%)
n_1	NA	52
ADCT: Difficulty falling or staying asleep at least once during the previous week, n (%)	NA	41 (78.9%)
Quality of life		
n_1	46	22
CDLQI score, mean±SD	8.74±5.47	9.32±6.09[b]
n_1	NA	18
DLQI score, mean±SD	NA	9.50±5.60[c]
n_1	30	47
EQ-5D-3L health scores, mean±SD	67.10±20.89	65.40±19.40
n_1	30	47
EQ-5D-3L: Moderate-to-extreme anxiety/depression, n (%)	13 (43.3%)	24 (51.0%)
Extreme	1 (3.3%)	9 (19.1%)
Moderate	12 (40.0%)	15 (31.9%)
n_1	32	18
Family burden (DFI score), mean±SD	8.16±6.28	11.00±6.82[b]
n_1	34	18
DFI: Parental emotional distress,[b,d] n (%)	14 (41.2%)	11 (61.1%)
n_1	33	18
DFI: Parental exhaustion,[b,d] n (%)	11 (33.3%)	9 (50.0%)
n_1	34	18
DFI: Financial burden,[b,d] n (%)	11 (32.4%)	9 (50.0%)
Work productivity and activity impairment		
n_1	NA	34
School time missed, mean (%)	NA	9.27%
n_1	NA	35
Hours of class missed in the past week due to AD, mean±SD, h	NA	4.11±16.31
n_1	NA	25
Studying impairment, mean (%)	NA	32.0%
n_1	NA	25
School impairment, mean (%)	NA	35.45%
n_1	NA	45
Activity impairment, mean (%)	NA	28.89%

[a]The EASI scores were reported for head/neck, trunk, upper extremities, and lower extremities. [b]The scores are reported for adolescents aged 12–<16 years. [c]The scores are reported for adolescents aged 16–<18 years. [d]The reported values are a combining response of 'a lot' and 'very much'.

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool; CDLQI, Children's Dermatology Life

Quality Index; CGADS, Caregiver Global Assessment of Disease Severity; DFI, Dermatitis Family Impact; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EQ-5D-3L, European Quality of Life 5 Dimensions 3 Level; N, number of patients; n, number of patients evaluated for parameter; n1, number of patients filled “Yes” in the questionnaire; NA, not applicable; PGADS, Patient Global Assessment of Disease Severity; SD, standard deviation.

Conclusions

Paediatric patients initiating dupilumab showed high baseline clinical and symptom burden, with disease severity associated with marked QoL impairment and significant family impact. Adolescents represented a subgroup with notable clinical and psychosocial burden. This large, national, real-world cohort highlights the unmet medical need in paediatric moderate-to-severe AD.

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Lebrikizumab in Real-world North American Practice: Preliminary Week 24 Outcomes from the ADjoy Prospective Observational Study in Moderate to Severe Atopic Dermatitis

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Introduction

Lebrikizumab demonstrated efficacy and safety across an extensive Phase 3 global clinical development program in adolescents and adults with moderate-to-severe atopic dermatitis (AD). However, there is a need for real-world data to further inform routine practice. ADjoy is the first North American prospective observational real-world study following a single cohort treated with lebrikizumab in routine clinical practice. This abstract reports the preliminary clinical results at Week 24.

Materials and Methods

ADjoy is an ongoing, 104-week, observational, prospective, multicenter, Phase 4 study evaluating lebrikizumab initiated as part of routine care in adolescents and adults with moderate-to-severe AD in the United States and Canada. This analysis represents an interim evaluation of 249 subjects, with a March 2026 data cut-off. The primary endpoint was the proportion of participants achieving an Investigator's Global Assessment (IGA) score of 0 or 1 with a ≥2-point improvement from baseline at Week 24. Secondary outcomes included Eczema Area and Severity Index (EASI), pruritus Numeric Rating Scale (NRS), sleep-loss scale (SLS), and Patient Global Impression of Severity–AD (PGI-S-AD). All data were summarised descriptively without imputation of the missing.

Results

Among the participants in the baseline dataset, median age was 37.0 years and 53.4% were female-at-birth. A total of 157 (63.1%), 39 (15.7%) and 28 (11.2%) of participants were White, Black and Asian, respectively. In all, 224 participants (90%; 55 sites) were from the United States, and 25 (10%; 5 sites) were from Canada. At baseline, most participants had moderate (65.7%) or severe (17.7%) IGA severity. Participants had a median EASI sign severity of 10.58 and a median pruritus NRS of 7.0. A total of 51.6% of participants had a sleep-loss score (SLS) of

at least moderate (SLS ≥2) at baseline. Most participants (65%) had at least moderate PGI-S-AD at baseline (score ≥4). The majority of participants with prior AD treatment had been treated with biologics (62.3%), or other AD medications (37.7%) including systemic treatments.

For this interim analysis, 79 participants had completed their week 24 visit. At week 2, 22.0% (95% CI 16.0%-28.9%) of participants achieved IGA 0/1 with ≥2-point improvement (clear/almost clear skin). By week 24, IGA 0/1 with ≥2-point improvement increased among participants to 49.3% (95% CI 37.2%–61.4%) at Week 24.

Mean (SD) change from baseline in EASI total absolute score at Week 24 was -10.40 (11.17) (95% CI -12.95 to -7.85; n=76) from a mean baseline EASI of 12.8. At Week 24, 68.4% achieved EASI 75, 46.1% achieved EASI 90, and 18.4% achieved EASI 100.

At Week 24, mean (SD) pruritus NRS was 3.8 (2.81), with a mean (SD) change from baseline of -2.5 (3.16). A ≥4-point improvement in pruritus NRS was achieved by 52.5% at Week 24. Improvements in sleep interference were also observed, with 52.9% (18/34) achieving a ≥2-point improvement. At Week 24, the majority of participants rated their disease as no symptoms to mild on PGI-S-AD, with a mean (SD) score of 2.7 (1.13) (n=78).

Conclusions

In this 24-week preliminary analysis of the prospective real-world North American ADjoy study, half of patients treated with lebrikizumab experienced clear-almost clear skin, pruritus relief, sleep improvement, and reduced patient-reported disease severity at Week 24. These real-world findings are consistent with lebrikizumab evidence from randomised trials. Continued follow-up will further characterise long-term outcomes through 104 weeks.

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Real-world effectiveness, treatment patterns and persistence of UPaDAcitinib in patients with moderate-to-severe atopic dermatitis: 12-month results of the UPDATE study

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Introduction
Upadacitinib has proven effective and well-tolerated in clinical trials in patients with moderate-to-severe atopic dermatitis (AD). However, real-world data on achievement of optimal treatment targets in the French population remain limited. The UPDATE study aims to describe real-world efficacy, safety of upadacitinib and optimal disease management, as assessed by clinicians and patients through minimal disease activity (MDA), up to 2 years. Here we present the interim results for 12 months.

Materials and Methods
UPDATE is an ongoing, multicenter, prospective, non-interventional study assessing upadacitinib in routine practice among 306 patients across 51 French centers. This interim analysis (data cutoff: Dec 9, 2025) reports efficacy and safety in adults and adolescents (> 12 years) with moderate-to-severe AD of ≥1 year's duration, initiating 15 or 30 mg/day upadacitinib. Clinical reported outcome (CRO) included validated Scoring Atopic Dermatitis (SCORAD); patient reported outcomes (PRO) included Worst Pruritus NRS (WP-NRS), Sleep disturbance NRS, Dermatology Life Quality Index (DLQI), and Atopic Dermatitis Control Tool (ADCT).

Results
Among 296 patients analyzed, the mean age at baseline was 33.1 years, 53.7% were male, and predominant head/neck phenotype occurred in 46.3%. Most patients (98.3%) presented with at least one comorbidity, 60.5% had atopic comorbidities, and 80% reported to have at least one AD flares in the previous 6 months (mean per-patient: 5.41). Prior conventional systemic therapy was used by 43.9% and 33% of the patients were biologic naïve. Most patients received 30 mg/day upadacitinib at study initiation (77.6%), and at least one dose change was made for 56.4% of these patients. Overall, the median persistence for patients treated with upadacitinib was 12.1 months, and the persistence rate after 6 months was 84.9%. A total of 71.3% of patients used topical

treatments concomitantly with upadacitinib, mainly topical corticosteroids (94.5%) and topical tacrolimus (30.5%) **(Table 1)**.

Regarding effectiveness, among patients with baseline SCORAD >25 (N=296), 79.8% achieved ≥50% reduction in SCORAD (SCORAD-50) at 4 months, and the response was sustained at 12 months (76.8%). Efficacy was consistent across age groups, BMI class, severity level, and upadacitinib dose. The proportion of patients achieving 47% optimal SCORAD response (SCORAD ≤10) at 4 months, maintained this optimal target in 48.1% patients at one year. Individual AD symptoms were well controlled according to clinical assessments. A substantial proportion of patients (57.6%) achieved an absolute itch score of 0/1 at one year and 79.5% achieved absolute sleep disturbance 0/1 score at one year of treatment with upadacitinib. Regarding the patient reported outcomes, ADCT scores decreased from a mean of 12.9 at baseline to 4.8 at 12 months and 75.8% of the patients had clinically relevant improvement of ADCT (decrease of ≥5 points of ADCT) at one year. Similarly, patients reporting a DLQI score of 0/1 increased from 2.8% at baseline to 47 % at one year. MDA as defined by WP-NRS 0/1 and an absolute SCORAD of ≤10, was achieved by 41.5% (103/248) of patients at 4 month and similarly by 42.2% at one year. At 1 year, 87% of patients who achieved MDA were flare-free, compared to 44.9% of patients who did not achieve MDA. In terms of safety, 175 patients (59.1%) experienced at least one adverse event at 12 month follow-up and 11 patients (3.9%) experienced a serious adverse event. Most frequently reported adverse events were acne (18,6 %), herpes simplex (7,8 %), herpes zoster (6,1%), folliculitis (3,7%), bronchitis (2,7%) and influenza (2,4 %).

Table 1. Baseline Demographic and Disease Characteristics in the UPDATE study

Characteristic	Value
Age, years	
Median (IQR)	29.0 (21.0–42.0)
12–17 years, n (%)	28 (9.5)
≥18 years, n (%)	268 (90.5)
Male, n (%)	159 (53.7)
BMI, kg/m²	
Median (IQR)	24.1 (20.9–27.0)
Duration of AD since diagnosis, years	
Median (IQR)	23.0 (14.0–34.0)
Disease severity at baseline (vIGA-AD), n (%)	
Moderate (3)	143 (50.0)
Severe (4)	104 (36.4)
SCORAD	
Mean (SD)	50.1 (17.9)
Pruritus (SCORAD sub-score C)	
Mean (SD)	5.9 (2.6)
Sleep loss-NRS (SCORAD sub-score C)	
Mean (SD)	4.5 (3.1)
Clinical phenotype of AD, n (%*)	
Head and neck predominant	137 (46.3)
Erythroderma	55 (18.6)
Nummular eczema	41 (13.9)
Prurigo	11 (3.7)
No specific clinical form reported	66 (22.3)
AD localization at initiation, n (%*)	
Face/head/neck involvement (any)	178 (61.6)
Hand and/or foot involvement	118 (40.8)
Genital involvement	29 (10.0)

Characteristic	Value
Comorbidities, n (%)	
≥1 comorbidity	291 (98.3)
Atopic comorbidities, n (%*)	
Any atopic comorbidity	176 (60.5)
Asthma	130 (73.9)
Allergic rhinitis	112 (63.6)
Allergic conjunctivitis	82 (46.6)
Food allergy	36 (20.5)
Previous AD treatments, n (%*)	
Topical treatments	279 (94.3)
Conventional systemic therapies	130 (43.9)
Biologic therapies	192 (64.9)
Other JAK inhibitors	33 (11.1)
Concomitant AD treatment at initiation, n (%)	
Upadacitinib + topical corticosteroids	211 (77.6)
Upadacitinib monotherapy	61 (22.4)

AD, atopic dermatitis; BMI, body mass index; IQR, interquartile range; SD, standard deviation; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; SCORAD, SCORing Atopic Dermatitis; NRS, numeric rating scale; JAK, Janus kinase.

Conclusions

In this real-world French cohort, upadacitinib's efficacy in achieving optimal treatment targets at 4 months was maintained up to one year. Safety profile was consistent with established data; no new safety signals were identified.

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Abstract N°: 1700

Current Atopic Dermatitis Treatment Perceptions for Pediatric Patients: Data from Adelphi Real World

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Introduction
Atopic dermatitis (AD) is a common disease among children, and early treatment may benefit disease course. As AD treatments have advanced, additional options have been approved for children as young as 6 months of age. However, understanding of current clinical assessments and treatment decision-making in pediatric patients is limited. This study describes how AD is managed by physicians treating pediatric patients with moderate-to-severe AD in real-world settings.

Materials and Methods
We analyzed data from the Adelphi Real World Pediatric AD Wave II Disease Specific Programme™, a cross-sectional survey with elements of retrospective data collection conducted in the United States from May to December, 2025. Patients included in this analysis were <12 years of age with current moderate-to-severe AD. Physicians completed a survey regarding their perceptions/attitudes of disease management/treatments and then completed record forms for each patient. Caregivers completed survey questions regarding the child's worst itch in the past 24 hours (scale=0 [no itch] to 10 [worst imaginable]). Analyses were descriptive and sample size varied for each response.

Results
Of 169 pediatric patients with moderate-to-severe AD at the time of data collection, the mean (SD) age was 5.9 (3.56) years, 49% were aged <6 years, and 53% were female. Most patients (73%) had a current Investigator Global Assessment score of 3 (moderate) or 4 (severe). The mean (SD) body surface area affected by AD was 23.2% (16.76%), n=136. The caregiver-reported mean (SD) worst itch in the previous 24 hours was 5.2 (2.92), n=51. Among 125 patients with moderate-to-severe AD who were prescribed their current treatment by the study physician, the top three reasons influencing treatment choice were to relieve itching (65%), reduce or control flares (59%), and improve skin lesions (55%). Among 165 patients with moderate-to-severe AD who ever received treatment, 69 (42%) were currently receiving a biologic, and 5 (3%) were receiving an oral JAK inhibitor. Physicians indicated that 31 of 100 (31%) patients with moderate-to-severe AD who were not currently receiving a biologic

were suitable candidates. The most common barriers to prescribing a biologic to these patients were the caregiver/family being uncomfortable with either the mode of administration (26%) or the benefit–risk (26%), the physician preferring to exhaust all treatment classes used to date (topical PDE4 inhibitors, corticosteroids, and calcineurin inhibitors; systemic corticosteroids; phototherapy; systemic immunosuppressants) (26%), and insurance coverage/restrictions (23%). Only 23 of 164 (14%) patients who were not currently receiving an oral JAK inhibitor were suitable candidates, with the most common prescribing barriers being insurance coverage/restrictions (30%), the physician preferring either to first try a biologic (22%) or exhaust all biologic options (22%), and the caregiver/family being uncomfortable with the benefit–risk (22%).

Conclusions

Physicians who manage AD indicated that among eligible pediatric patients not currently prescribed a biologic, at most one-third were suitable candidates, despite all having moderate-to-severe disease. This highlights the undertreatment of patients and a gap in clinical practice in identifying the patients who should be offered advanced systemic therapies by physicians. Caregiver concerns with the mode of administration and benefit–risk profile were important barriers to prescribing a biologic.

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Responders to Zumilokibart (APG777) Show Durable Maintenance and Deepening of Response Beyond Week 16: Results from the Phase 2 APEX Part A Study in Atopic Dermatitis

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Introduction
Zumilokibart (APG777) is the first half-life-extended anti-IL-13 antibody to be evaluated in atopic dermatitis (AD), with the goal of reducing injection burden for patients. The pharmacokinetics (PK) of zumilokibart allow for only 4 dosing days during induction and 2 or 4 dosing days per year in maintenance. The phase 2 APEX AD Part A study (NCT06395948) met the primary endpoint at Week 16, with significant improvements in AD lesions by Week 2 and itch by 48 hours after the first dose of zumilokibart. Here, maintenance and deepening of responses achieved at Week 16 with zumilokibart are presented at completion of the maintenance period at Week 52 of APEX Part A.

Materials and Methods
Adults (N=123) with moderate-to-severe AD were randomized 2:1 to an induction regimen of zumilokibart (720mg: Day 1, Week 2; 360mg: Weeks 4, 12) or placebo. Upon completing Week 16, participants initially randomized to zumilokibart (N=72) were re-randomized 1:1 to receive 360mg zumilokibart every 12 weeks (Q12W; Weeks 24, 36, 48) or every 24 weeks (Q24W; Weeks 24, 48) in maintenance. Maintenance of response was defined as the proportion of participants that maintained Week 16 response thresholds of EASI-75 and EASI-90 at Week 52. Maintenance analyses were conducted with multiple imputation combined with non-responder imputation. Deepening of response was defined as the proportion of EASI-75 responders at Week 16 that achieved deeper, more stringent thresholds of EASI-90 and EASI-100 at Week 52; this analysis was conducted as-observed.

Results
At Week 16, EASI-75 was achieved by 66.9% of participants receiving zumilokibart (vs. 24.6% with placebo; $p<0.001$), and EASI-90 was achieved by 33.9% of participants receiving zumilokibart (vs. 14.7% with placebo; $p<0.05$). Among Week 16 responders, maintenance of EASI-75 at Week 52 was achieved by 75.2% and 85.3% in the Q12W and Q24W arms, respectively, and maintenance of EASI-90 at Week 52 was achieved by 87.6% and 72.2%, respectively. Deepening of response was observed among participants who achieved EASI-75 at Week 16. Among Week 16 EASI-75 responders, EASI-90 response rates increased from 61.5% (Q12W) and 41.7% (Q24W) at Week 16 to 84.0% (Q12W) and 54.5% (Q24W) at Week 52. Similarly, EASI-100 response rates of 7.7% and 12.5% at Week 16 increased to 52.0% and 18.2% at Week 52 in the Q12W and Q24W arms, respectively. Treatment was well-tolerated over 52 weeks; AEs in ≥5% zumilokibart-treated participants included noninfective conjunctivitis, upper respiratory tract infection, nasopharyngitis, and atopic dermatitis.

Conclusions

Both every 12- and 24-week maintenance dosing with zumilokibart led to durable maintenance and deepening of response across all lesional endpoints through Week 52. These results, together with the improved PK of zumilokibart enabling less frequent dosing, support further clinical investigation with zumilokibart.

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Abstract N°: 1714

Zumilokibart (APG777) Provides Robust, Progressive Improvement in the Signs and Symptoms of Atopic Dermatitis: 52-Week Results from the Phase 2 APEX Part A Study

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Introduction
Optimal management of atopic dermatitis (AD) aims to achieve treatment targets in both clinician-reported outcomes, such as skin clearance, and patient-reported outcomes, such as itch. Zumilokibart (APG777) is an optimized, half-life-extended anti-IL-13 antibody that achieves early and sustained therapeutic drug levels, which allows for only 4 dosing days during induction and 2 or 4 dosing days per year in maintenance. The phase 2 APEX Part A study (NCT06395948) met the primary endpoint at Week 16, with significant improvements in AD lesions by Week 2 and itch by 48 hours after the first dose of zumilokibart. Here, we report achievement of clinician- and patient-reported treatment thresholds with zumilokibart over the full 52-week period of APEX Part A.

Materials and Methods
Adults (N=123) with moderate-to-severe AD were randomized 2:1 to an induction regimen of zumilokibart (720mg: Day 1, Week 2; 360mg: Weeks 4, 12) or placebo. Upon completing Week 16, participants initially randomized to zumilokibart (N=72) were re-randomized 1:1 to receive 360mg zumilokibart every 12 weeks (Q12W; Weeks 24, 36, 48) or every 24 weeks (Q24W; Weeks 24, 48) in maintenance. Participants initially randomized to placebo and completing Week 16 (N=37) crossed over to receive a modified induction regimen of zumilokibart (720mg: Week 16; 360mg: Weeks 20, 24, 36, 48). Clinician assessments through Week 52 included LS mean percent change from Baseline in EASI and proportions achieving thresholds of EASI-75, EASI-90, EASI-100 and vIGA-AD 0/1 with ≥2-point improvement from Baseline. Patient-reported outcomes included LS mean percent change from Baseline in Itch (I)-NRS through Week 48 and ≥4-point improvement in DLQI through Week 52. All analyses were conducted as-observed.

Results
Treatment with zumilokibart led to continued reduction in EASI over time, with participants in the Q12W and Q24W arms achieving a -90.8% and -86.0% LS mean change from Baseline in EASI, respectively, at Week 52. Participants crossing over from placebo to zumilokibart achieved a similar -85.2% LS mean change from Baseline in EASI at Week 52. Among participants re-randomized to continue zumilokibart in maintenance, 87.5% and 80.6% of those in the Q12W and Q24W arms, respectively, achieved EASI-75 at Week 52. The higher threshold of EASI-90 was met by 75.0% and 48.4% of participants in the Q12W and Q24W zumilokibart arms, respectively, at Week 52, showing further improvement of response from Week 16 during the maintenance period. Similarly, 71.9% and 51.6% of participants in the Q12W and Q24W arms, respectively, achieved clear/almost clear skin with a vIGA-AD

0/1 response at Week 52. Complete skin clearance (EASI-100) at Week 52 was achieved in 40.6% and 19.4% of participants in the Q12W and Q24W zumilokibart arms, respectively. Treatment with zumilokibart led to progressive improvement in patient-reported itch over time, with participants in the Q12W and Q24W arms reaching a -72.5% and -64.1% LS mean change from Baseline in I-NRS, respectively, at Week 48. By the end of the 52-week treatment period, ≥4-point improvement in DLQI was achieved by 92.9% and 88.5% of participants in the Q12W and Q24W arms, respectively. Treatment was well-tolerated over 52 weeks; AEs in ≥5% zumilokibart-treated participants included noninfective conjunctivitis, upper respiratory tract infection, nasopharyngitis, and atopic dermatitis.

Conclusions

Participants receiving zumilokibart demonstrated progressive improvement in AD signs, symptoms, and quality of life over the 52-week treatment period of APEX Part A. These results, together with the improved PK of zumilokibart enabling less frequent dosing, support further clinical investigation with zumilokibart.

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Abstract N°: 1715

Efficacy of Zumilokibart (APG777) in Patients with Atopic Dermatitis and Evidence of Type 2 Inflammatory Comorbidities: Results from the Phase 2 APEX Part A Study

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Introduction
Zumilokibart (APG777) is the first half-life-extended anti-IL-13 antibody to be evaluated in atopic dermatitis (AD). As AD is often associated with comorbid type 2 inflammatory diseases, we evaluated zumilokibart in patients with AD with and without evidence of asthma and sinonasal conditions in the phase 2 APEX Part A study (NCT06395948).

Materials and Methods
Adults (N=123) with moderate-to-severe AD were randomized 2:1 to zumilokibart (720mg Day 1, Week 2; 360mg Weeks 4, 12) or placebo. For this post-hoc, as-observed analysis, treatment comparisons in participants with and without evidence of type 2 comorbidities at baseline were assessed by the percentage achieving 75% improvement in the Eczema Area and Severity Index (EASI-75) at Week 16.

Results
Treatment with zumilokibart led to an overall EASI-75 response rate of 74.7% (n=56/75) at Week 16 (vs. 26.3% [n=10/38] placebo; p<0.001). Among participants with a history of asthma and/or sinonasal conditions, 71.1% (n=27/38) of zumilokibart-treated participants achieved EASI-75 at Week 16 (vs. 36.8% [n=7/19] placebo). Similarly, among participants without a history of asthma and sinonasal conditions, more zumilokibart- vs. placebo-treated participants achieved EASI-75 (78.4% [n=29/37] vs. 15.8% [3/19]). EASI-75 response rates were also greater with zumilokibart vs. placebo for subgroups with baseline BEC≥300 cells/μL (71.1% vs. 19.0%), BEC<300 cells/μL (78.4% vs. 35.3%), IgE≥100 IU/mL (76.4% vs. 32.0%), and IgE<100 IU/mL (70.0% vs. 15.4%). No new safety signals were detected in patients with or without asthma and sinonasal conditions.

Conclusions

Treatment with zumilokibart was well tolerated and provided clinically meaningful improvements in AD signs and symptoms, regardless of coexisting type 2 inflammatory conditions. In support of these findings, an ongoing phase 1b study (NCT06920901) is evaluating zumilokibart in patients with mild-to-moderate asthma and elevated levels of fractional exhaled nitric oxide (FeNO), a key biomarker of type 2 inflammation that is correlated with asthma exacerbations. A single dose of zumilokibart led to rapid suppression of FeNO (-60% change from baseline by Week 2) that was maintained through 32 weeks of available follow-up. These results, together with the improved pharmacokinetics of zumilokibart enabling less frequent dosing, support further clinical investigation with zumilokibart for the treatment of patients with diseases of type 2 inflammation, including AD and asthma.

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Abstract N°: 1716

Real-world abrocitinib dose adjustments and treatment patterns vary by prior treatment history and line of therapy in adults with moderate-to-severe atopic dermatitis

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Introduction
Since approval, real-world abrocitinib dose regimens and subsequent treatment patterns in patients with atopic dermatitis (AD) are not well characterized. This study aimed to describe treatment patterns, including dose adjustments and post-abrocitinib treatment choices, by line of therapy (LoT), defined as the sequential order of advanced treatment exposure, and prior AD treatment history.

Materials and Methods
This retrospective cohort study used the Komodo Healthcare MapTM, containing US medical and pharmacy closed claims data, from January 1, 2021, through April 30, 2025. Adults with AD who newly initiated abrocitinib on or after January 14, 2022, with ≥12 months continuous enrollment pre-index and ≥6 months post-index were included. Outcomes included rates of abrocitinib dose adjustment and switching to alternative therapies following treatment initiation. Outcomes were assessed at both 6 months and 12 months post-initiation and summarized by LoT (1L vs ≥2L) and by prior AD treatment history (prior systemic biologic or oral JAK inhibitor [JAKi] use vs prior systemic immunosuppressant use).

Results
Among adult abrocitinib initiators assessed at 6 months post-index (N=2,295; median age 40.0 years; 54.1% female), 34.4% of patients initiated abrocitinib as a 1L advanced treatment. At baseline, 45.0% had prior exposure to any systemic biologic, 7.1% had exposure to any conventional systemic immunosuppressant, and 15.5% had exposure to an oral JAKi. Dose adjustments within 6 months were more common among ≥2L vs 1L initiators (12.8% vs 8.7%) and were more frequent among patients with prior systemic immunosuppressant use compared with those with prior systemic biologic or oral JAKi use (17.3% vs 13.5%). Most patients that received abrocitinib maintained treatment (84.6% 1L and 80.5% ≥ 2L) within 6 months post-index.

Among patients who switched therapy within 6 months, subsequent treatment choices differed depending on LoT at index date: 1L abrocitinib initiators more frequently transitioned to oral systemic corticosteroids (60.0% vs 35.9%), whereas ≥2L initiators more frequently transitioned to oral JAKi (23.1% vs 10.0%) and systemic biologics (30.5% vs 20.8%). Similarly, among switchers, patients with prior systemic biologic or oral JAKi use at baseline more frequently transitioned to oral JAKi (24.4% vs 10.0%) and systemic biologics (31.8% vs 10.0%) after abrocitinib use, whereas those with prior systemic immunosuppressant use at

baseline more frequently transitioned to oral systemic corticosteroids after abrocitinib use (37.5% vs 34.3%). Findings were consistent over time, with outcomes at 12-months demonstrating similar directional trends (N= 2,009; Table 1).

Conclusions

In this US real-world cohort of adults with AD, abrocitinib dosing and treatment patterns differed meaningfully by LoT and prior AD treatment exposure. Patients initiating abrocitinib in later LoT and those with prior systemic immunosuppressant use were more likely to experience dose adjustments, suggesting greater treatment complexity and/or optimization needs in these populations. Post-abrocitinib treatment choices also varied by prior treatment context, with earlier-line patients more commonly transitioning to oral corticosteroids, while later-line and biologic/ oral JAK-experienced patients more often moving to advanced systemic therapies. Together, these findings underscore how treatment history shapes real-world abrocitinib management and subsequent treatment sequencing decisions, offering practical insight for healthcare providers when setting expectations around dose optimization and considering downstream care in routine practice.

Table 1. Abrocitinib Treatment Patterns by LoT and Prior AD Treatment History measured 6 and 12 months post-index

Characteristic	LoT of Index Abrocitinib (n, %)		Prior AD treatment history (n, %)	
	1L	≥ 2 L	Prior systemic biologic or oral JAKi	Prior systemic immunosuppressant
Total Patient Count – 6 months	781	1,514	1,245	162
Dose adjustment within 6 months of index				
Yes	68 (8.7)	194 (12.8)	168 (13.3)	28 (17.3)
No	713 (91.3)	1,320 (87.2)	1,077 (86.5)	134 (82.7)
Treatment switch from abrocitinib within 6 months of index				
Yes	120 (15.4)	295 (19.5)	242 (19.4)	40 (24.7)
No	661 (84.6)	1,219 (80.5)	1,003 (80.6)	122 (75.3)
New AD therapy among switched pts within 6 months of index				
Oral JAKi	12 (10.0)	68 (23.1)	59 (24.4)	4 (10.0)
Oral systemic corticosteroids	72 (60.0)	106 (35.9)	83 (34.3)	15 (37.5)
Systemic biologics	25 (20.8)	90 (30.5)	77 (31.8)	4 (10.0)
Total Patient Count – 12 months	695	1,314	1,066	146
Dose adjustment within 12 months of index				
Yes	102 (14.7)	246 (18.7)	205 (19.2)	36 (24.7)
No	593 (85.3)	1,068 (81.3)	861 (80.8)	110 (75.3)
Treatment switch from abrocitinib within 12 months of index				
Yes	206 (29.6)	493 (37.5)	402 (37.7)	60 (41.1)
No	489 (70.4)	821 (62.5)	664 (62.3)	86 (58.9)
New AD therapy among switched pts within 12 months of index				
Oral JAKi	22 (10.7)	100 (20.3)	88 (21.9)	7 (11.7)
Oral systemic corticosteroids	123 (59.7)	197 (40.0)	150 (37.3)	25 (41.7)
Systemic biologics	45 (21.8)	153 (31.0)	131 (32.6)	6 (10.0)

Abbreviations: AD = atopic dermatitis; JAKi = Janus kinase inhibitor; LoT = line of therapy

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Abrocitinib Intermittent Dosing and Response Recapture

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Introduction

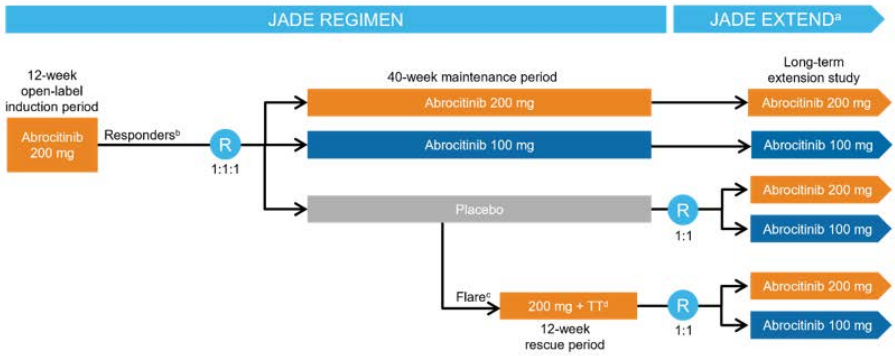
Long-term management of moderate-to-severe atopic dermatitis (AD) may include treatment interruption for patients who achieve disease control and treatment escalation in the event of flare during treatment pause. In the phase 3 JADE REGIMEN trial (NCT03627767), patients who responded to 12 weeks of open-label once-daily abrocitinib 200-mg induction therapy were randomised to double-blinded maintenance therapy with once-daily abrocitinib 200 or 100 mg or placebo for 40 weeks. Patients who experienced a protocol-defined flare during the maintenance period received abrocitinib rescue therapy, providing an opportunity to evaluate recapture of response. Here, data from JADE REGIMEN and the long-term extension study, JADE EXTEND (NCT03422822; data cutoff: 5 September 2022) were examined to assess the potential for response recapture after pausing abrocitinib treatment in patients who experienced a protocol-defined flare while receiving placebo.

Materials and Methods

This post hoc analysis included adult patients with moderate-to-severe AD randomised to placebo during the maintenance phase of JADE REGIMEN. Patients received 12 weeks of open-label, once-daily induction therapy with abrocitinib 200 mg and achieved response (defined as Investigator's Global Assessment [IGA] score of 0/1 with ≥2-point reduction from baseline and ≥75% improvement from baseline in the Eczema Area and Severity Index [EASI]) and were then randomised to placebo for 40 weeks. Patients who experienced a flare (defined as ≥50% loss of initial EASI response at Week 12 and IGA score ≥2) during the 40-week maintenance period received rescue therapy (abrocitinib 200 mg plus topical therapy) for 12 weeks (**Figure 1**). Patients could then

enrol in JADE EXTEND, where they were randomised to abrocitinib 200 or 100 mg. Assessments included mean total EASI, EASI mean change from baseline and the proportion of patients achieving ≥75% improvement in EASI (EASI-75) through Week 96 after start of rescue therapy. Missing data were handled with nonresponder imputation.

Figure 1. Study design



EASI, Eczema Area and Severity Index; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; PDE4, phosphodiesterase 4; R, randomised; TT, topical therapy.

[a] JADE EXTEND was an ongoing trial at the time of this analysis. Data cutoff: 5 September 2022.

[b] Patients who achieved an IGA score of 0 (clear) or 1 (almost clear) with a ≥2-grade improvement from baseline and EASI-75 after 12 weeks of treatment with abrocitinib 200 mg.

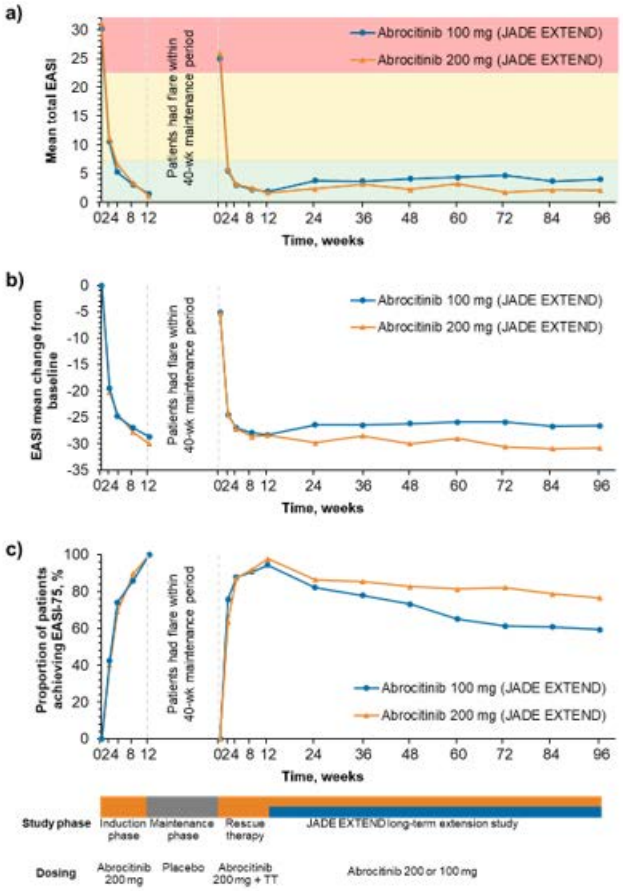
[c] Patients who experienced a protocol-defined flare (≥50% loss of Week 12 EASI response and new IGA score ≥2) during the maintenance period of JADE REGIMEN entered a 12-week open-label rescue period (abrocitinib 200 mg + topical medicated treatment).

[d] Topical therapy included topical corticosteroids of any potency, calcineurin inhibitors and topical PDE4 inhibitors.

Results

Of 234 patients included in this analysis, 39 received placebo without experiencing a protocol-defined flare during the maintenance period of JADE REGIMEN, and 192 experienced a protocol-defined flare. Of those patients who experienced a protocol-defined flare while receiving placebo, 49 and 143 received abrocitinib 100 and 200 mg, respectively, after randomisation to JADE EXTEND. After reinitiating abrocitinib treatment, patients who experienced a protocol-defined flare rapidly recaptured clinical response on reintroduction of abrocitinib, as determined by mean total EASI and EASI change from baseline (**Figure 2a,b**). Most patients recaptured EASI-75 response by Week 2 of rescue therapy in JADE REGIMEN. Patients further maintained a mean EASI <7 (clear/mild) with both doses of abrocitinib throughout the JADE EXTEND long-term extension study (**Figure 2a**). Of patients receiving abrocitinib 200 mg in JADE EXTEND, 97.8% achieved EASI-75 following 12 weeks of rescue therapy, and 76.6% achieved EASI-75 at Week 96 after restarting abrocitinib (**Figure 2c**). In the abrocitinib 100-mg arm of JADE EXTEND, 94.3% of patients achieved EASI-75 after the rescue therapy period, and 59.3% achieved EASI-75 at Week 96 (**Figure 2c**).

Figure 2. Recapture of efficacy responses with abrocitinib 200 or 100 mg after experiencing a protocol-defined flare[a] on placebo as measured by (**a**) mean total EASI, (**b**) EASI mean change from baseline and (**c**) proportion of patients achieving EASI-75 through Week 96 of return to abrocitinib treatment



EASI, Eczema Area and Severity Index; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; IGA, Investigator's Global Assessment; TT, topical therapy.

[a] Defined as ≥50% loss of Week 12 EASI response and new IGA score ≥2.

EASI colour banding: 0.1 to 6.9 = clear/mild, 7.0 to 21.0 = moderate, 21.1 to 72.0 = severe.

JADE EXTEND was an ongoing trial at the time of this analysis. Data cutoff: 5 September 2022.

Conclusions

Patients who experienced a protocol-defined flare after abrocitinib interruption while on placebo treatment in the 40-week double-blind maintenance therapy period of JADE REGIMEN were able to rapidly recapture clinical response through rescue therapy and maintain response with either dose of abrocitinib. A numerical dose-response relationship was observed, in which patients who received abrocitinib 200 mg showed numerically higher recapture and maintenance rates. These data suggest that treatment interruption or pausing may be an option for patients with good clinical response to abrocitinib; in the case of disease recurrence, restarting abrocitinib is an effective, fast rescue therapy.

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Abstract N°: 1730

Phase 2 study of novel trispecific tilrekimig (PF-07275315) in patients with moderate-severe atopic dermititis: Interim efficacy and safety results at 16 weeks

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Introduction
Tilrekimig (PF-07275315) is an investigational trispecific antibody targeting 3 clinically validated targets in atopic dermatitis (AD), interleukin (IL)-4, IL-13, and thymic stromal lymphopoietin (TSLP). Targeting multiple cytokines is intended to provide synergistic inhibition of type 2 inflammatory pathways implicated in AD, with the aim of improving disease control in individuals with moderate-to-severe AD.

Materials and Methods
This ongoing randomised, double-blind, placebo-controlled Phase 2 study (NCT05995964) includes biologic-naïve patients aged ≥18 years with moderate-to-severe AD (baseline Eczema Area and Severity Index [EASI] score ≥16). Patients received subcutaneous tilrekimig 450 mg or placebo every 2 weeks (Q2W) in Stage 1, and tilrekimig 400, 200, or 50 mg or placebo every 4 weeks (Q4W) in Stage 2, through Week 16. The primary endpoint was the proportion of patients achieving EASI-75 at Week 16. Key secondary endpoints included the proportion of patients achieving a validated Investigator's Global Assessment (vIGA) score of 0/1 with ≥2-point improvement from baseline and safety. Exploratory endpoints included a ≥4-point reduction in weekly average Peak Pruritus Numerical Rating Scale (PP-NRS4). Stage 1 data cut: May 2025. Stage 2 data cut: December 2025.

Results
A total of 61 patients were included in the Week 16 analysis in Stage 1 (tilrekimig 450 mg, n=41; placebo, n=20) and 127 in Stage 2 (400 mg, n=41; 200 mg, n=41; 50 mg, n=23; placebo, n=22). At Week 16, EASI-75 was achieved by a significantly greater proportion of patients receiving tilrekimig versus placebo, with 63% versus 20% for the 450 mg Q2W group (p=0.0008) and 59%, 61%, and 48% for the 400, 200, and 50 mg Q4W groups, respectively, versus 9% for placebo (all p<0.003; **Table**). vIGA 0/1 was achieved by more patients receiving tilrekimig than placebo, with 30% versus 12% for the 450 mg Q2W group and 26%–27% across Q4W dose groups versus 0% for placebo (p=0.0251 for Q2W; p<0.006 for Q4W; **Table**). Greater proportions of patients achieved PP-NRS4 with tilrekimig versus placebo, with 35% and 44% treatment differences in the 400 mg and 200 mg Q4W groups (43% and 51% vs 7%, respectively). Tilrekimig was well tolerated, with no dose-dependent safety signals and a similar frequency of adverse events compared with placebo.

Table. Proportion of patients achieving EASI 75 and vIGA 0/1 at Week 16

	Tilrekimig dose	Tilrekimig (%)	Placebo (%)	Δ vs placebo (%)	p value
EASI 75	450 mg Q2W	63	20	+43	0.0008
	400 mg Q4W	59	9	+50	0.0001
	200 mg Q4W	61	9	+52	<0.0001
	50 mg Q4W	48	9	+39	0.0024
vIGA 0/1	450 mg Q2W	30	12	+18	0.0251
	400 mg Q4W	27	0	+27	0.0048
	200 mg Q4W	27	0	+27	0.0048
	50 mg Q4W	26	0	+26	0.0054

EASI, Eczema Area and Severity Index; vIGA, validated Investigator's Global Assessment; Q2W, every 2 weeks; Q4W, every 4 weeks; Δ, treatment difference

Conclusions

Blockade of IL-4/IL-13/TSLP with tilrekimig improved clinical and patient-reported outcomes in moderate-to-severe AD compared with placebo, with a favourable safety profile.

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Abstract N°: 1732

Rezpegaldesleukin Provides Durable and Deepening Improvements in the Signs and Symptoms of Atopic Dermatitis with Monthly and Quarterly Dosing: Results from the Phase 2b REZOLVE-AD Maintenance Part of Study

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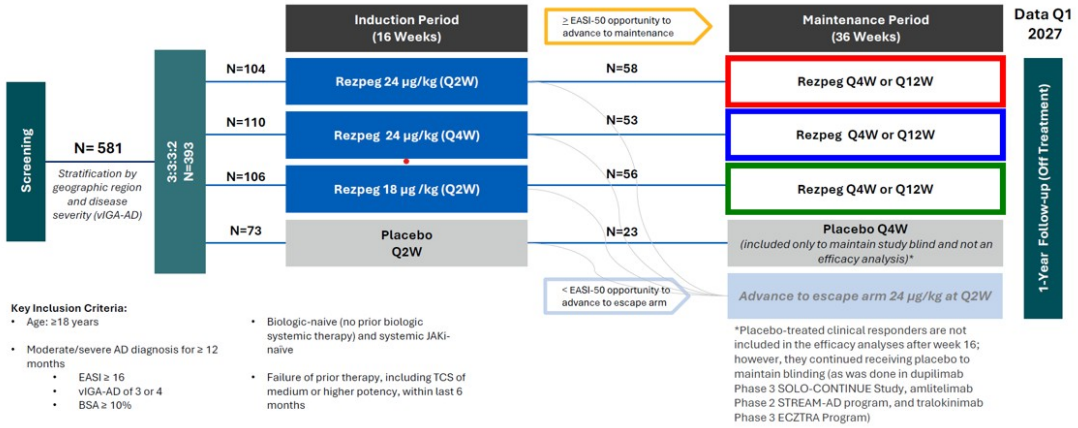
Introduction

Atopic dermatitis (AD) is a chronic, inflammatory skin disease characterized by dysregulation of effector and regulatory T-cells (Treg). Current treatments offer similar mechanistic approaches and require frequent maintenance administration to provide long-term disease control. Thus, new mechanistic approaches beyond those approved could provide greater benefit over time, and with favourable dosing intervals, would be a therapeutic advancement for patients. Rezpegaldesleukin is an investigational IL-2 receptor pathway agonist biologic therapy that increases the number and function of Tregs, a novel therapeutic strategy for multiple autoimmune and inflammatory diseases. Positive induction therapy results in patients with moderate-to-severe AD were previously reported from the ongoing Phase 2b study. Here, we report results from the 36-week maintenance period.

Materials and Methods

The global REZOLVE-AD Phase 2b study (NCT06136741) enrolled 393 patients with moderate-to-severe AD. Following a 16-week induction period (rezpegaldesleukin 24 µg/kg Q2W, 18 µg/kg Q2W, 24 µg/kg Q4W, or placebo), 190 patients who achieved a ≥50% reduction in eczema area and severity index (EASI) were re-randomized (1:1) to a 36-week maintenance period to continue the same induction dose either monthly (Q4W) or quarterly (Q12W) during the blinded 36-week maintenance period (Figure 1). Patients with acute AD exacerbations (<25% EASI reduction from baseline) were eligible for Open-Label Escape (OLE) therapy of 24 µg/kg Q2W. Key endpoints assessed included maintenance and/or achievement of EASI-75, EASI-90, EASI-100, vIGA-AD 0/1 (clear/almost clear), and Itch Numerical Rating Scale (NRS) improvement (≥ 4 points) responses. Treatment-emergent adverse events (TEAEs) were assessed for the blinded maintenance period.

Figure 1. Study Design



Results

The clinical responses for EASI-75, EASI-90, vIGA-AD 0/1, NRS Itch (≥ 4 points) were highly durable with maintenance dosing among re-randomized clinical responders, and a substantial portion of Week 16 non-responders achieved clinical response by Week 52 responders (data is summarized in Table 1). At Week 52, for the pooled 24 µg/kg arms, the responses were maintained by dose frequency as follows: 71% (Q4W) and 83% (Q12W) for EASI-75, 80% (Q4W) and 78% (Q12W) for EASI-90, 85% (Q4W) and 63% (Q12W) for vIGA-AD 0/1, and in 75% (Q4W) and 77% (Q12W) for patient-reported Itch NRS response. For the pooled 24µg/kg arms with an

EASI ≥75 and/or VIGA-AD 0/1 at re-randomization, EASI-100 increased from Week 16 to Week 52, improving 6% to 30% (Q4W) and from 14% to 27% (Q12W). For the pooled 24µg/kg arms, new responses developed in patients who had not reached these thresholds by Week 16: 51% (Q4W) and 39% (Q12W) achieved new EASI-75 and 33% (Q4W) and 26% (Q12W) achieved new EASI-90 responses at Week 52.

The 52-week safety profile during the maintenance period was favorable and consistent with prior studies. TEAEs occurred in 72% of rezpegaldesleukin-treated compared to 65% in the placebo re-randomized patients. The overall discontinuation rate due to AEs was low at 0.6%. The most frequent TEAE was injection site reactions (53%), with 69% events reported as mild and none leading to discontinuation. The median time to resolution of ISRs was 6 days. No increased risk of conjunctivitis, oral herpes, or malignancy was observed in a combined database of over 1,000 treated patients.

Table 1. Week 52 Efficacy Measurements in Maintenance for Re-Randomized EASI-50 Responders

	24 µg/kg Q4W (N=55)	24 µg/kg Q12W (N=56)
Absolute Responses Among Pooled Re-Randomized Patients		
EASI-100	22%	18%
vIGA-AD 0/1	52%	48%
Maintenance of Response Among Pooled Re-Randomized Patients[a]		
EASI-75	71% (n=36)	83% (n=35)
EASI-90	80% (n=18)	78% (n=20)
vIGA-AD 0/1	85% (n=14)	63% (n=21)
*Itch NRS**	75% (n=25)	77% (n=17)
New Responses Among Pooled Re-Randomized Patients[b]		
EASI-75	51% (n=19)	39% (n=21)
EASI-90	33% (n=37)	26% (n=36)
vIGA-AD 0/1	41% (n=41)	40% (n=35)
*Itch NRS**	33% (n=26)	18% (n=32)

'N' is the entire maintenance population; "n" is the denominator which equals the number of responders/nonresponders at Week 16; % represents proportion of patients who either maintained or developed (based on Week 16 status) that response at Week 52; missing data are multiply imputed.
[a] Patients achieving that response at Week 16 and maintained response at Week 52 (maintenance); [b] Patients not achieving that response at Week 16 who attained response at Week 52 (maintenance).
*Only patients with baseline Itch NRS ≥ 4 used as denominator for assessing Itch NRS response

Conclusions

Rezpegaldesleukin monthly and quarterly maintenance dosing demonstrated robust, durable effects and displayed a unique increased improvement in signs and symptoms of AD out to Week 52 with opportunities for complete disease clearance. The long-term efficacy suggests the potential for a differentiated mechanistic approach with monthly and quarterly maintenance dosing for moderate-to-severe atopic dermatitis treatment. These new data support the advancement of rezpegaldesleukin into Phase 3 clinical trials with an induction dose of 24µg/kg Q2W and maintenance doses of 24µg/kg Q4W and Q12W.

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Abstract N°: 1735

Tilrekimig, a trispecific IL-4/IL-13/TSLP antibody, reduces type 2 inflammatory biomarkers in moderate-to-severe atopic dermatitis: Interim biomarker analyses from a randomised, double-blind, placebo-controlled phase 2 trial

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Introduction

Tilrekimig (PF-07275315) is a trispecific antibody targeting interleukin (IL)-4, IL-13, and thymic stromal lymphopoietin (TSLP) in atopic dermatitis (AD), a type 2 inflammatory disease. The pharmacological and clinical effects of tilrekimig are being evaluated in an ongoing, randomised, double-blind, placebo-controlled, dose-ranging phase 2 study in patients with moderate-to-severe AD (NCT05995964). Changes in IL-4, IL-13 and TSLP-driven biomarkers of type 2 inflammation are being assessed to demonstrate mechanistic activity of tilrekimig in AD.

Materials and Methods

The ongoing phase 2 study included biologic-naïve patients (aged ≥18 years) with moderate-to-severe AD (baseline Eczema Area and Severity Index [EASI] score ≥16). Patients received subcutaneous tilrekimig 450 mg or placebo every 2 weeks (Q2W) in Stage 1, and tilrekimig 400, 200 or 50 mg or placebo every 4 weeks (Q4W) in Stage 2, through Week 16. Exploratory biomarker analyses included thymus and activation-regulated chemokine (TARC), total serum immunoglobulin E (IgE) and absolute blood eosinophil counts (EOS) in participants with baseline and ≥1 post-baseline assessment at data cut-off. Change from baseline (CFB) was analysed using a linear mixed effects model adjusting for baseline biomarker levels, treatment and number of visits; baseline comparisons across treatment groups were assessed using analysis of variance (ANOVA). Pearson correlation coefficients between baseline EASI score and baseline TARC, IgE and EOS were calculated by combining Stages 1 and 2.

Results

At baseline, sample sizes ranged from N=13 to N=41 across biomarker, treatment and placebo groups in Stage 1 and Stage 2. Baseline biomarker levels were similar across treatment groups and stages without any significant differences but correlated significantly with baseline EASI scores (all $p<0.001$). At Week 16, tilrekimig significantly reduced TARC, IgE and EOS from baseline at 450 mg Q2W, 400 mg Q4W and 200 mg Q4W doses, with respective reductions of 64.2%, 62.5% and 58.6% for TARC (all $p<0.001$), 35.8%, 31.7% and 34.1% for IgE (all $p<0.001$), and 29.6%, 33.7% and 26.4% for EOS (all $p<0.01$) (**Table**). Significant reductions from baseline in TARC and IgE were observed as early as Week 8, the earliest timepoint assessed in this study, across the 450 mg Q2W, 400 mg Q4W,

and 200 mg Q4W dose groups (TARC: all p<0.001; IgE: all p<0.05). No significant changes were observed in the placebo Q2W, placebo Q4W or tilrekimig 50 mg Q4W groups (**Table**).

Table. Least squares mean percent change from baseline for TARC, IgE and absolute eosinophil counts at Week 16

	LS mean percent change from baseline at Week 16 (95% CI; p value)		
	TARC	Total IgE	Absolute eosinophil counts
Tilrekimig, 450 mg Q2W	n=36 **-64.2** (-71.2, -55.4; p<0.001)	n=35 **-35.8** (-44.8, -25.2; p<0.001)	n=35 **-29.6** (-44.0, -11.6; p=0.003)
Placebo, Q2W	n=12 **-6.4** (-35.5, 36.0; p=0.728)	n=12 **21.5** (-6.4, 57.7; p=0.143)	n=9 **-20.9** (-48.2, 20.7; p=0.275)
Tilrekimig, 400 mg Q4W	n=28 **-62.5** (-70.2, -52.7; p<0.001)	n=33 **-31.7** (-41.3, -20.5; p<0.001)	n=31 **-33.7** (-47.4, -16.5; p<0.001)
Tilrekimig, 200 mg Q4W	n=34 **-58.6** (-66.7, -48.5; p<0.001)	n=38 **-34.1** (-43.1, -23.6; p<0.001)	n=32 **-26.4** (-41.7, -7.0; p=0.01)
Tilrekimig, 50 mg Q4W	n=20 **-17.5** (-38.3, 10.3; p=0.194)	n=20 **-4.0** (-21.7, 17.8; p=0.697)	n=18 **-0.2** (-27.4, 37.2; p=0.990)
Placebo, Q4W	n=12 **-24.9** (-46.5, 5.5; p=0.099)	n=14 **2.9** (-17.5, 28.4; p=0.799)	n=12 **-14.1** (-39.4, 21.8; p=0.392)

CI, confidence interval; IgE, immunoglobulin E; LS, least squares; Q2W, every 2 weeks; Q4W, every 4 weeks; TARC, thymus and activation-regulated chemokine.

Conclusions

Tilrekimig demonstrated significant dose-dependent reductions in multiple key type 2 inflammatory biomarkers (TARC, IgE and EOS), consistent with its mechanism of action in patients with moderate-to-severe AD.

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Abstract N°: 1736

The Efficacy and Safety of Upadacitinib in Patients with Atopic Dermatitis Defined as Moderate vs. Severe: Post-hoc Analyses from Phase 3 Measure Up 1 and 2 Clinical Trials

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Introduction

Atopic dermatitis (AD), a leading cause of global burden from skin disease, is characterized by chronic itch, typical eczematous morphology, and a significant impact on the quality of life (QoL) of patients. Upadacitinib (UPA), a Janus kinase inhibitor, has been approved for treatment of moderate-to-severe AD. While the efficacy and safety profile of UPA has been demonstrated across several clinical trials, the efficacy of UPA on clinician- and patient-reported outcomes has not yet been thoroughly described in patients living with moderate or severe AD.

Materials and Methods

This post-hoc analysis evaluated the efficacy and safety of UPA monotherapy in adolescent and adult patients with moderate or severe AD using integrated data from two UPA Phase 3 studies—Measure Up 1 (NCT03569293) and Measure Up 2 (NCT03607422). Patients received UPA 15 mg (UPA15), UPA 30 mg (UPA30), or placebo for 16 weeks. Patients were stratified by baseline Eczema Area and Severity Index (EASI) score as either moderate (EASI ≥ 16 and ≤ 21) or severe (EASI > 21). The number/proportion of patients achieving ≥ 75/90/100% EASI improvement from baseline (EASI75/90/100), Worst Pruritus Numerical Rating Scale (WP-NRS) reduction of ≥ 4 from baseline and absolute score of 0/1, Dermatology Life Quality Index (DLQI) reduction of ≥ 4 from baseline and absolute score of 0/1, and Minimal Disease Activity[1] (MDA; defined as EASI90 + WP-NRS 0/1) was recorded at Weeks 1, 2, 4, 8, 12, and 16. Response rates are based on non-responder imputation. Safety was evaluated through Week 16.

Results

Of the 1682 patients with baseline EASI score, 530 patients (31.5%) and 1152 patients (68.5%) were classified as moderate and severe, respectively, based on baseline EASI score. Patients with moderate disease had a numerically lower, although still substantial, burden of disease compared to patients with severe disease, as shown by mean body surface area (moderate: 28.0%; severe: 55.5%), WP-NRS (moderate: 7.0; severe: 7.4), and DLQI (moderate: 15.3; severe: 17.4). At Week 16, more patients randomized to UPA15 and UPA30, regardless of baseline

severity, achieved EASI 75/90, WP-NRS reduction of ≥ 4 from baseline, and DLQI reduction of ≥ 4 from baseline compared with placebo (Table 1). These improvements were observed as early as Week 1. Response rates were largely consistent across both moderate and severe patients. Similarly, moderate and severe AD patients treated with UPA15 or UPA30 rapidly achieved stringent endpoints (EASI100, WP-NRS 0/1, DLQI 0/1, and MDA) at higher rates compared with placebo (Table 1) through Week 16; response rates for stringent outcome measures were generally similar between moderate and severe patients but numerically higher in moderate patients (Table 1). Regardless of baseline EASI score severity and across all efficacy endpoints at Week 16, more UPA30 patients achieved clinical responses compared with UPA15 patients. The safety profile of UPA in patients with moderate and severe AD was largely consistent regardless of baseline disease severity and aligned with the known safety profile across trials. Limitations include the post-hoc, exploratory nature of these analyses and the smaller sample size in the moderate AD subgroup.

Table 1. Outcome measures at Week 16 in patients with moderate AD and severe AD defined by EASI

	Moderate AD			Severe AD		
Outcome, n/N (%)	Placebo (N = 187)	UPA 15 mg (N = 171)	UPA 30 mg (N = 172)	Placebo (N = 371)	UPA 15 mg (N = 386)	UPA 30 mg (N = 395)
EASI75	35/187 (18.7)	110/171 (64.3)*	133/172 (77.3)*	46/371 (12.4)	251/386 (65.0)*	296/395 (74.9)*
EASI90	15/187 (8.0)	79/171 (46.2)*	111/172 (64.5)*	22/371 (5.9)	187/386 (48.4)*	240/395 (60.8)*
EASI100	2/187 (1.1)	30/171 (17.5)*	52/172 (30.2)*	5/371 (1.3)	56/386 (14.5)*	78/395 (19.7)*
Reduction in WP-NRS ≥ 4[a]	21/179 (11.7)	76/166 (45.8)*	94/168 (56.0)*	35/366 (9.6)	180/378 (47.6)*	241/392 (61.5)*
WP-NRS 0/1[b]	12/182 (6.6)	60/171 (35.1)*	85/170 (50.0)*	15/369 (4.1)	116/383 (30.3)*	173/393 (44.0)*
Reduction in DLQI ≥ 4[c]	60/166 (36.1)	177/156 (75.0)*	115/151 (76.2)*	82/334 (24.6)	254/349 (72.8)*	287/356 (80.6)*
DLQI 0/1[d]	6/171 (3.5)	46/159 (28.9)*	62/154 (40.3)*	17/338 (5.0)	92/351 (26.2)*	143/363 (39.4)*
MDA (EASI90 + WP-NRS 0/1)[b]	2/182 (1.1)	45/171 (26.3)*	78/170 (45.9)*	8/369 (2.2)	95/383 (24.8)*	144/393 (36.6)*

Abbreviations: AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; EASI75/90/100, ≥ 75/90/100% EASI improvement from baseline; MDA, Minimal Disease Activity; UPA, upadacitinib; WP-NRS, Worst Pruritus Numerical Rating Scale. [a]Among subjects with baseline WP-NRS ≥ 4. [b]Among subjects with baseline WP-NRS > 1. [c]Among subjects with baseline DLQI ≥ 4. [d]Among subjects with baseline DLQI > 1. Response rates based on non-responder imputation. *, Nominal p-value < 0.0001. Nominal p-values for the comparisons of UPA15 and UPA30 with placebo are based on Mantel-Haenszel tests adjusted for study and age.

Conclusions

Results from UPA monotherapy Phase 3 clinical trials showed that the baseline disease burden was substantial in both moderate and severe patients, defined by EASI score. Regardless of patient disease severity at baseline, treatment of moderate or severe AD with UPA15 and UPA30 for 16 weeks demonstrated consistently rapid and sustained rates of clear/almost clear skin, little to no itch, MDA, and no impact of AD on QoL compared with placebo. These findings support the use of UPA as an effective therapeutic strategy for patients with moderate and severe AD, respectively.

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Abstract N°: 1738

The Relationship Between IgE Reduction and Clinical Response in Abrocitinib-Treated Atopic Dermatitis: Results From the JADE COMPARE Study

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Introduction

Immunoglobulin E (IgE) is commonly elevated in moderate-to-severe atopic dermatitis (AD), although its relationship with disease activity is variable. Abrocitinib, an oral Janus kinase 1 inhibitor, and dupilumab, an interleukin-4 receptor α inhibitor, are approved treatments for moderate-to-severe AD. Prior studies have suggested that both therapies are associated with changes in IgE levels, with no significant differences observed between treatments.[1] Abrocitinib has also been shown to reduce expression of proposed AD biomarkers, along with disease severity and serum IgE.[2] It is unknown whether IgE reduction during the course of systemic therapy is required for improved AD skin outcomes. This post hoc analysis evaluated the relationship between treatment-related changes in IgE and clinical response, as assessed by the Eczema Area and Severity Index (EASI) and Investigator's Global Assessment (IGA).

Materials and Methods

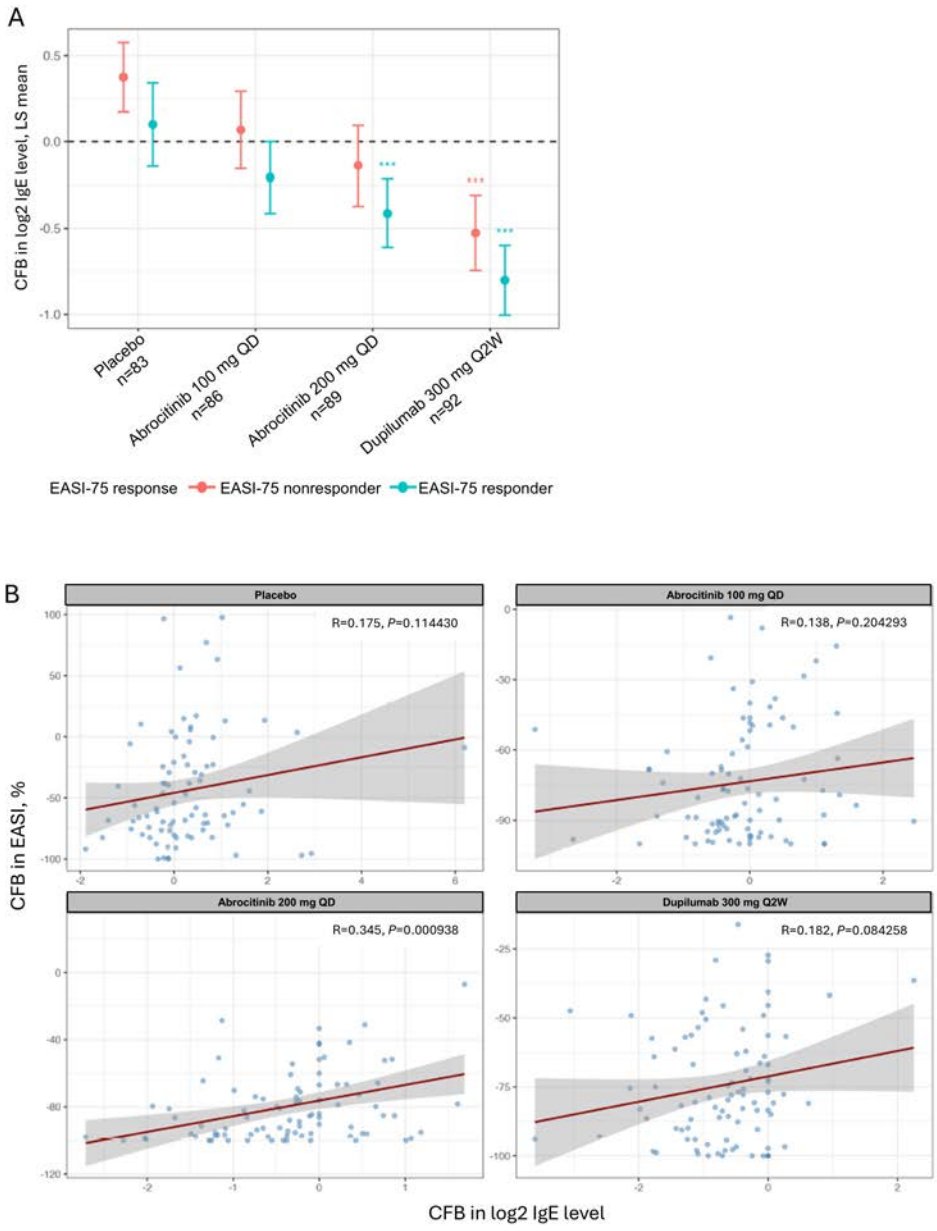
This post hoc analysis of JADE COMPARE (NCT03720470) included data from patients aged ≥18 years who were randomly assigned 2:2:2:1 to receive abrocitinib (200 mg or 100 mg) once daily, dupilumab 300 mg every 2 weeks, or placebo with concomitant topical therapy for 16 weeks. Serum samples collected from 349 patients were analysed for soluble IgE levels at baseline and Week 12. Analyses included the correlation between baseline IgE levels and EASI scores, change from baseline (CFB) in IgE levels both overall and stratified by achievement of a ≥75% reduction from baseline in EASI score (EASI-75) or an IGA response (0/1 with ≥2-point improvement from baseline), percentage CFB in EASI scores by baseline IgE level, and the correlation between CFB in IgE levels and CFB in EASI scores.

Results

Pearson correlation at baseline showed that higher IgE levels were moderately but significantly associated with higher baseline EASI scores (r=0.454; *P*<0.001); however, change in EASI score at Week 12 was not correlated with baseline IgE levels. No statistically significant difference in baseline IgE level was found between responders and

nonresponders as defined by EASI-75 (P=0.23) or IGA 0/1 (P=0.101) at Week 12. By Week 12, least squares mean log2-transformed IgE levels had significantly decreased from baseline in patients receiving abrocitinib 200 mg and dupilumab 300 mg (−0.330 and −0.696, respectively; $P \leq 0.001$ for both). EASI-75 and IGA 0/1 responders showed a greater reduction in IgE levels compared with nonresponders in the abrocitinib and dupilumab groups. When defining responder status by EASI-75, dupilumab treatment resulted in a significant reduction in IgE levels in both responders and nonresponders, whereas abrocitinib 200 mg showed significant IgE reduction in EASI-75 responders only (**Figure 1A**). A similar trend was found when responder status was defined by IGA 0/1. Pearson correlation analysis showed a statistically significant positive association between CFB in log2 IgE levels and percentage CFB in EASI scores in patients treated with abrocitinib 200 mg (r=0.345; P<0.001), indicating that greater IgE reductions were associated with greater relative improvements in disease severity; however, no such correlation was found for abrocitinib 100 mg, dupilumab 300 mg, or placebo (**Figure 1B**).

Figure 1. (**A**) CFB in IgE by Treatment and EASI-75 Response and (**B**) Scatter Plot of CFB in Log2 IgE Level vs Percentage CFB in EASI by Treatment



CFB, change from baseline; EASI, Eczema Area and Severity Index; EASI-75, ≥75% reduction from baseline in Eczema Area and Severity Index score; IgE, immunoglobulin E; Q2W, every 2 weeks; QD,

once daily. References: 1. Song D, et al. Clin Cosmet Investig Dermatol. 2025;18:817-825. 2. Del Duca D, et al. J Invest Dermatol. 2024;144(8):S1-S228. 3. Calabrese L, et al. J Pers Med. 2024;14(7):775.

Conclusions

In the current post hoc analysis, greater serum IgE reductions occurred with both abrocitinib 200 mg and dupilumab treatment vs placebo. Dupilumab showed significant reductions in IgE levels in both EASI-75 and IGA 0/1 responders and nonresponders. This difference in soluble IgE levels by clinical response status may reflect differences in mechanism of action between these therapies, as abrocitinib modulates IgE signalling further downstream than dupilumab.[3] More research is needed to understand whether early IgE kinetics through a 12-week treatment period can predict or precede objective skin improvement in patients receiving abrocitinib 200 mg.

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Efficacy Outcomes of Abrocitinib in Adult Patients With Moderate-to-Severe Atopic Dermatitis Using Canadian Treat-to-Target Criteria

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Introduction

Recent consensus efforts have emphasised the importance of structured, measurable treatment goals through treat-to-target (T2T) strategies, which incorporate both physician-rated disease severity and patient-reported outcomes to guide therapeutic decision-making. As advanced systemic therapies such as biologics and Janus kinase (JAK) inhibitors become increasingly available, T2T frameworks have emerged as a practical way to ensure timely treatment escalation, treatment optimisation, or treatment transition based on achievement of predefined clinical benchmarks.[1-3] T2T criteria proposed in Canada make the T2T process more flexible for physicians and

patients.[2] Abrocitinib, an oral, once-daily, JAK1-selective inhibitor approved for moderate-to-severe atopic dermatitis (AD), offers rapid and clinically meaningful improvements in physician-rated disease severity and patient-reported outcomes.[4-7] It is unknown how it performs in the context of the Canadian T2T criteria beyond 16 weeks. This study assessed the efficacy of abrocitinib in clinical trials when evaluated within the Canadian T2T criteria for up to 2 years.

Materials and Methods

This pooled post hoc analysis included adult patients with moderate-to-severe AD receiving abrocitinib 200 mg or 100 mg daily in JADE DARE (NCT04345367), COMPARE (NCT03720470), and EXTEND (NCT03422822; data cutoff: 31 December 2024).[4,5,8] In line with the Canadian T2T criteria, concomitant topical therapy was permitted during treatment. The Canadian T2T strategy leverages physician-rated disease severity and patient-reported outcomes.[2] The Week 12-16 target is achievement of either a 50% improvement in Eczema Area and Severity Index score (EASI-50) or a Physician Global Assessment (PGA) score ≤2, and a decrease from baseline in 1 of the following: Peak Pruritus Numerical Rating Scale (PP-NRS) score ≥3, Dermatology Life Quality Index (DLQI) score ≥4, or Patient Oriented Eczema Measure (POEM) score ≥3. The Month 6-8 target is achievement of EASI-75 or PGA score ≤2, and a decrease from baseline in 1 of the following: PP-NRS score ≥4, DLQI score ≥5, or POEM score ≥4. The Year 1 target is achievement of either an absolute EASI score ≤7, EASI-90, or PGA score of 0 or 1, and 1 of the following: absolute PP-NRS score ≤4, DLQI score ≤5, or POEM score ≤7. The proportion of patients achieving Canadian T2T was assessed using nonresponder imputation across all time points. Kaplan-Meier methodology was used to estimate the time to first achieving T2T criteria.

Results

By Week 12 of treatment, 86.0% and 72.9% of patients receiving abrocitinib 200 mg or 100 mg, respectively, achieved the first set of Canadian T2T criteria (**Table**). By Months 6-8 of treatment, 73.3% and 59.3% of patients receiving abrocitinib 200 mg or 100 mg, respectively, achieved the second set of Canadian T2T criteria. Following Year 1 of treatment, 69.3% and 57.1% of patients receiving abrocitinib 200 mg or 100 mg, respectively, achieved the third set of Canadian T2T criteria. Finally, by Year 2 of treatment, 54.0% and 41.9% of patients receiving abrocitinib 200 mg or 100 mg, respectively, maintained the Year 1 Canadian T2T criteria. Median times to first achievement of the T2T criteria were months shorter with both abrocitinib 200 mg and 100 mg than the timeframe the T2T criteria allowed for, and patients receiving abrocitinib 200 mg achieved all T2T criteria more quickly than those receiving abrocitinib 100 mg.

Table. Proportion of Patients Who Achieved the Canadian T2T Criteria and Kaplan-Meier Estimates of Time to First Achievement of the Canadian T2T Criteria at Week 12, Months 6-8, Year 1, and Year 2

	Abrocitinib 100 mg QD	Abrocitinib 200 mg QD
Week 12		
Number of patients	236	586
Proportion of patients who achieved Week 12-16 Canadian T2T criteria, n (%)	172 (72.9)	504 (86.0)
Median time to achieving Week 12-16 Canadian T2T criteria (95% CI), days	29.0 (23.0-31.0)	15.0 (NE-NE)
Months 6-8		
Number of patients	189	547
Proportion of patients who achieved Month 6-8 Canadian T2T criteria, n (%)	112 (59.3)	401 (73.3)
Median time to achieving Month 6-8 Canadian T2T criteria (95% CI), days	85.0 (66.0-144.0)	29.0 (29.0-55.0)
Year 1		
Number of patients	191	488
Proportion of patients who achieved Year 1 Canadian T2T criteria, n (%)	109 (57.1)	338 (69.3)
Median time to achieving Year 1 Canadian T2T criteria (95% CI), days	144.0 (113.0-394.0)	82.5 (57.0-85.0)
Year 2		
Number of patients	191	483
Proportion of patients who maintained Year 1 Canadian T2T criteria, n (%)	80 (41.9)	261 (54.0)

NE, not evaluable; QD, once daily; T2T, treat-to-target. References 1. De Bruin-Weller M et al. Acta Derm Venereol. 2021;101(2):adv00402. 2. Yeung J et al. J Am Acad Dermatol. 2023;89(2):372-375. 3. Vestergaard C et al. Am J Clin Dermatol. 2024;25(1):91-98. 4. Reich K et al. Lancet. 2022;400(10348):273-282. 5. Bieber T et al. N Engl J Med. 2021;384(12):1101-1112. 6. Cibinqo (abrocitinib). Prescribing information. Pfizer Labs; December 2023. 7. Cibinqo 100 mg film-coated tablets. Summary of product characteristics. Pfizer Europe MA EEIG; 2025 8. Simpson EL et al. Am J Clin Dermatol. 2024;25(4):639-654.

Conclusions

At all time points, high proportions of patients in both abrocitinib 200-mg and 100-mg groups achieved the Canadian T2T criteria, and treatment responses were maintained for up to 2 years. Better T2T response rates were observed in patients receiving abrocitinib 200 mg vs patients receiving abrocitinib 100 mg. Patients receiving either dose of abrocitinib achieved the Canadian T2T criteria in a fraction of the allotted time, with 200 mg acting faster than 100 mg.

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On-Treatment Complete Disease Control Attainment With Abrocitinib

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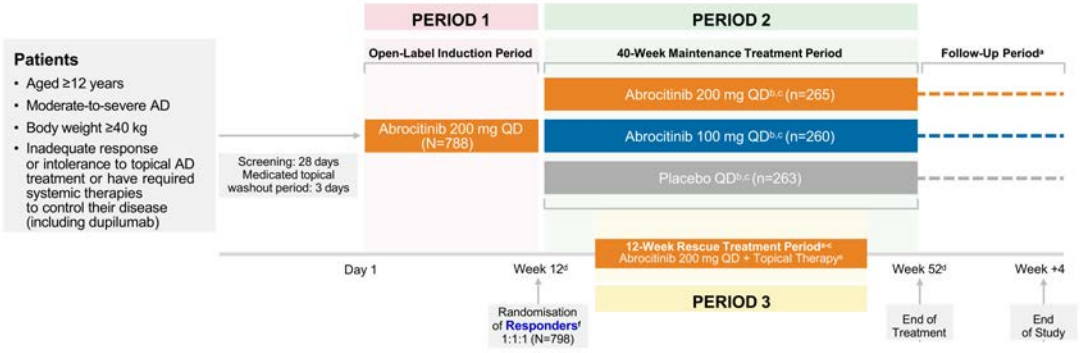
Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disorder with substantial burden, and its relapsing nature complicates long-term disease control. The International Eczema Council (IEC) recently developed consensus definitions of very low disease activity (vLDA) and on-drug complete control (ODCC). These composite endpoints include components of both skin clearance and itch improvement to better standardise and evaluate treatment response to advanced therapies. IEC guidance defines vLDA as achievement of either Investigator's Global Assessment (IGA) 0/1 or Eczema Area and Severity Index (EASI) ≤3, together with a Peak Pruritus Numerical Rating Scale (PP-NRS) score of 0/1. ODCC is defined as achievement of either IGA 0 or EASI-100, together with a PP-NRS score of 0/1. The phase 3 JADE REGIMEN (NCT03627767) trial enables evaluation of the attainment and maintenance of vLDA and ODCC in patients who received the oral Janus kinase 1–selective inhibitor abrocitinib in consistent or variable dosing regimens. This post hoc analysis assessed the achievement of vLDA and ODCC in patients with AD enrolled in JADE REGIMEN.

Materials and Methods

In JADE REGIMEN, patients aged ≥12 years with moderate-to-severe AD received 12 weeks of open-label (OL) daily abrocitinib 200-mg induction therapy (**Figure**). After OL induction, patients who achieved an IGA score of 0/1 (with ≥2 grades of improvement) and ≥75% improvement in EASI were considered responders and were randomised 1:1:1 to 40 weeks of double-blind maintenance therapy with daily placebo, abrocitinib 100 mg, or abrocitinib 200 mg. Patients were evaluated during the OL induction and 40-week maintenance periods to determine the proportions who achieved vLDA and ODCC; time to achievement of each outcome; and changes in EASI, IGA, and PP-NRS scores in those who lost response.

Figure. Study Design



Participants were assessed at the end of Period 1 and Period 2. AD, atopic dermatitis; EASI, Eczema Area and Severity Index; IGA, Investigator's Global Assessment; QD, once daily. (a)Patients who discontinued treatment early or were otherwise ineligible for the long-term extension study entered the 4-week untreated follow-up period. (b)Patients who experienced a flare received 12-week rescue treatment with open-label abrocitinib 200 mg QD plus topical therapy. Patients who completed the rescue period also had the option to enter the long-term extension study (JADE EXTEND; NCT03422822). (c)Flares (loss of response) were defined as ≥50% loss of initial EASI response at Week 12 with a new IGA score ≥2. (d)Patients who did not meet the responder criteria at the end of the open-label induction period and eligible patients at the end of Week 52 had the option to enter the long-term extension study (JADE EXTEND; NCT03422822). (e)Topical therapy options were topical corticosteroids, calcineurin inhibitors, and PDE4 inhibitors, used per investigator's usual practice. (f)Response defined as IGA 0/1 response (with ≥2-grade improvement) and EASI-75 response.

Results

In total, 788 patients responded during the OL induction and were randomised in the 40-week maintenance period (placebo, n=263; abrocitinib 100 mg, n=260; abrocitinib 200 mg, n=265). Among these responders, 52% achieved vLDA in a median of approximately 85 days from OL baseline. Additionally, 22% and 26% of responders achieved ODCC according to the EASI-100–based and IGA 0–based definitions, respectively, in a median of approximately 3 months from OL baseline (**Table**). Following randomisation in the maintenance period, most patients who continued receiving abrocitinib 200 mg did not lose vLDA (64.4%) or ODCC (64.2% and 63.1% using EASI-100– or IGA 0–based definitions, respectively) during the 40-week maintenance period. Many patients who switched to abrocitinib 100 mg did not lose vLDA (37.6%) or ODCC (22.6% and 25.8% by EASI-100 or IGA 0 definitions, respectively). Few patients who switched to placebo did not lose vLDA (11.1%) and ODCC (6.3% and 5.3% using the EASI-100– or IGA 0–based definitions, respectively). On average, patients receiving abrocitinib 100 or 200 mg who achieved then lost EASI-100 after randomization stayed within the very low disease activity range of EASI ≤3. Additionally, most patients receiving active treatment who lost IGA 0 stayed within the very low disease activity of IGA 0/1. Patients randomised to receive abrocitinib 100 or 200 mg who lost PP-NRS 0/1 stayed, on average, within the mild pruritus range (≤3).

Table. Achievement and Maintenance of IEC Outcomes From OL Baseline in Randomised Responders by Treatment Received During the 40-Week Maintenance Period

	Maintenance: Placebo n=263	Maintenance: Abrocitinib 100 mg n=260	Maintenance: Abrocitinib 200 mg n=265
vLDA (IGA 0/1 or EASI ≤3 + PP-NRS 0/1), n (%)			
Patients who achieved vLDA	135 (51.3)	141 (54.2)	132 (49.8)
Total response rate	408 (51.8)		
Patients who did not lose vLDA during maintenance	15 (11.1)	53 (37.6)	85 (64.4)
ODCC (EASI-100 + PP-NRS 0/1), n (%)			
Patients who achieved ODCC	64 (24.3)	53 (20.4)	53 (20.0)
Total response rate	170 (21.6)		
Patients who did not lose ODCC during maintenance	4 (6.3)	12 (22.6)	34 (64.2)
ODCC (IGA 0 + PP-NRS 0/1), n (%)			
Patients who achieved ODCC	75 (28.5)	66 (25.4)	65 (24.5)
Total response rate	206 (26.1)		
Patients who did not lose ODCC during maintenance	4 (5.3)	17 (25.8)	41 (63.1)

EASI, Eczema Area and Severity Index; EASI-100, 100% improvement from baseline in Eczema Area and Severity Index score; IEC, International Eczema Council; IGA, Investigator's Global Assessment; ODCC, on-drug complete control; OL, open label; PP-NRS, Peak Pruritus Numerical Rating Scale; vLDA, very low disease activity.

Conclusions

Abrocitinib 200-mg OL treatment enabled a substantial proportion of patients to achieve vLDA and, in some cases, ODCC, with many maintaining these responses during 200-mg or 100-mg maintenance therapy. Although some patients lost these stringent thresholds during maintenance therapy, our findings highlight that these patients remained close to total skin clearance and itch control with abrocitinib. Overall, application of the IEC consensus definitions provides a clinically meaningful framework to evaluate the depth and durability of response and supports the role of abrocitinib in achieving and maintaining high levels of disease control in AD.

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Abrocitinib Recapture to On-Drug Complete Disease Control and Very Low Disease Activity Thresholds

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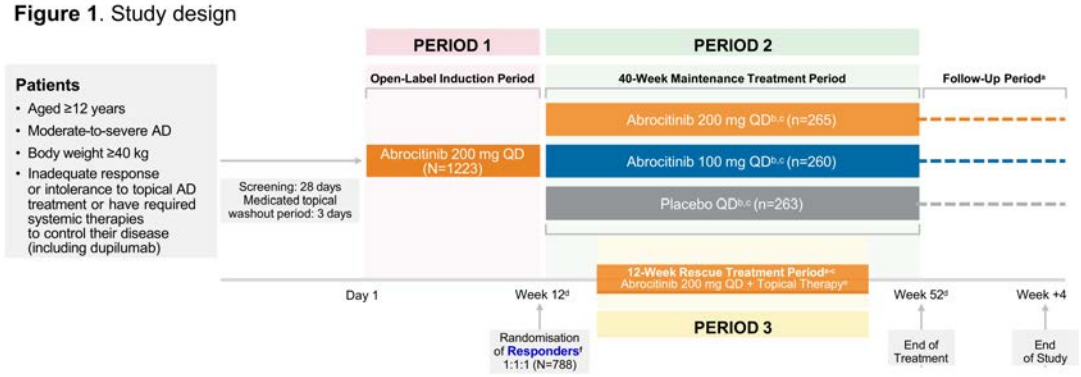
Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with substantial burden. Its relapsing nature complicates assessment of disease control following flare. The International Eczema Council (IEC) recently introduced consensus definitions of very low disease activity (vLDA: Investigator's Global Assessment [IGA] score of 0/1 or Eczema Area and Severity Index [EASI] ≤3, with a Peak Pruritus Numerical Rating Scale [PP-NRS] score of 0/1) and on-drug complete control (ODCC: either IGA 0 or 100% improvement from baseline in EASI score [EASI-100], together with PP-NRS 0/1) to better evaluate treatment outcomes. Abrocitinib, an oral Janus kinase 1 (JAK1)-selective inhibitor, is approved for moderate to severe AD. This study evaluated recapture of disease control with abrocitinib 200 mg plus prescription topical therapy following a protocol-defined disease flare occurrence.

Materials and Methods

In this post hoc analysis of the JADE REGIMEN trial (NCT03627767), patients aged ≥12 years with moderate-to-severe AD received 12 weeks of open-label (OL) daily abrocitinib 200 mg. Responders (IGA 0/1 with ≥2-grade improvement and EASI-75) were randomised to 40 weeks of double-blind maintenance therapy with placebo (n=263), abrocitinib 100 mg (n=260), or abrocitinib 200 mg (n=265). Patients who experienced a flare (defined as ≥50% loss of initial EASI response vs Week 12 and a new IGA score ≥2) during maintenance therapy went on to receive 12 weeks of rescue therapy (abrocitinib 200 mg plus prescription topical) in the rescue period of the study (**Figure 1**). Outcomes included proportions of patients regaining vLDA and ODCC after rescue therapy.

Figure 1. Study design

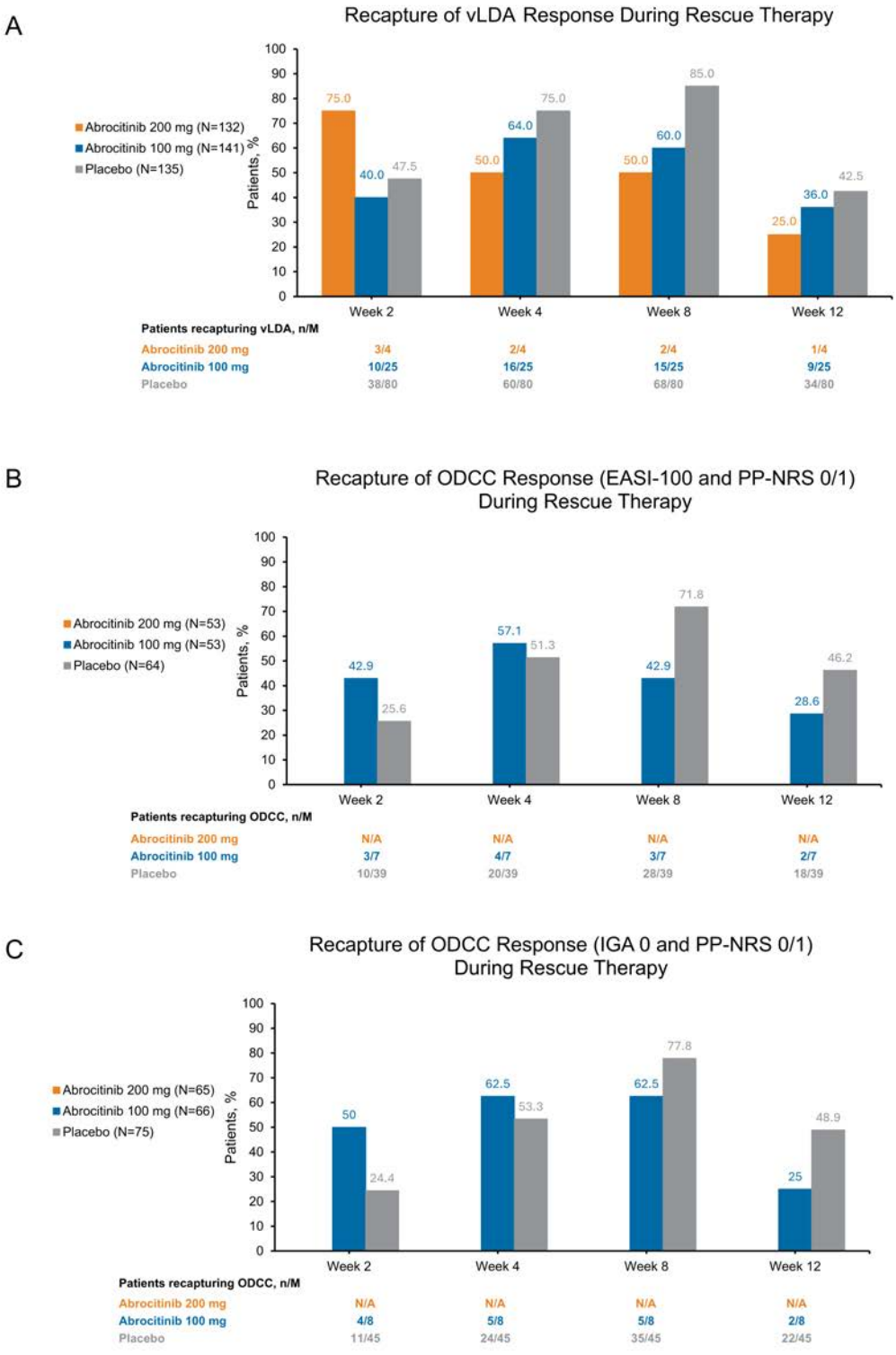


Patients who experienced a protocol-defined flare during the randomisation period received rescue therapy consisting of 200 mg abrocitinib plus topical therapy and were assessed for IEC outcome recapture during Period 3. AD, atopic dermatitis; IEC, International Eczema Council; QD, once daily. (a)Patients discontinuing treatment early or who are otherwise ineligible for the long-term extension study enter the 4-week untreated follow-up period. (b)Patients who experienced a flare received 12-week rescue treatment with open-label abrocitinib 200 mg QD plus topical therapy. Patients who completed the rescue period also had the option to enter the long-term extension study (JADE EXTEND, NCT03422822). (c)Flares (loss of response) defined as ≥50% loss of initial EASI response at Week 12 with a new IGA score ≥2. (d)Patients who did not meet the responder criteria at the end of the open-label induction period and eligible patients at the end of Week 52 had the option to enter a long-term extension study (JADE EXTEND, NCT03422822). (e)Topical therapy options were topical corticosteroids, calcineurin inhibitors, and PDE4 inhibitors, used per investigator's usual practice. (f)Response defined as patients who achieved IGA 0/1 response (with ≥2-grade improvement) and EASI-75 response.

Results

During the 40-week maintenance therapy period, protocol-defined flares occurred among 207 patients (78.7%) receiving placebo, 105 (40.4%) receiving abrocitinib 100 mg, and 44 (16.6%) receiving abrocitinib 200 mg. Among patients who achieved vLDA in the OL period and subsequently experienced a protocol-defined flare, response was rapidly recaptured with rescue therapy in all treatment groups. By Week 2 of rescue therapy, 38 of 80 (47.5%) patients originally randomised to placebo, 10 of 25 (40.0%) originally randomised to abrocitinib 100 mg, and 3 of 4 (75%) originally randomised to abrocitinib 200 mg who had initially achieved vLDA recaptured this outcome (**Figure 2A**). Similarly, many patients who initially achieved ODCC and experienced a flare during double-blind treatment were able to recapture ODCC by Week 2 of rescue therapy. Notably, no patients who achieved ODCC response in the OL period and who were randomised to abrocitinib 200 mg experienced a flare during the maintenance period (**Figure 2B and C**). Recapture rates were higher for vLDA and similar for ODCC compared with previously reported, less-stringent EASI thresholds or with EASI-100. For EASI-100 alone, recapture rates were 30.0% (15 of 50 patients) and 42.9% (3 of 7 patients) in the placebo and abrocitinib 100 mg groups, respectively, as early as Week 2. Only 3 of 74 (4.1%) patients randomised to 200 mg with disease control after induction experienced flares during maintenance, and all 3 patients recaptured response by Week 12 of rescue.

Figure 2. Proportion of OL responders who experienced a protocol-defined flare and who were recaptured to IEC thresholds while receiving rescue therapy



Patients who experienced a protocol-defined flare during the randomisation period were quickly recaptured after receiving rescue therapy consisting of 200 mg abrocitinib plus topical therapy. EASI-100, 100% improvement from baseline in the Eczema Area and Severity Index; IEC, International Eczema Council; IGA, Investigator's Global Assessment; N, number of patients who achieved IEC response during the open label period and were randomised; M, number of open-label responder patients who experienced a flare during the maintenance period and received rescue therapy; n, number of patients who achieved recapture of response; n/M, percentages are calculated as n/M; N/A, not applicable, as no patients experienced a flare; PP-NRS, Peak Pruritus Numerical Rating Scale;

ODCC, on-drug complete control; vLDA, very low disease activity.

Conclusions

Abrocitinib 200 mg (plus prescription topical treatment) as rescue therapy enabled a substantial proportion of patients to recapture vLDA and, in some cases, ODCC following disease flares. Fewer flares occurred among stringent responders who continued receiving abrocitinib, especially abrocitinib 200 mg, compared with placebo. When flares occurred, rapid recapture was observed across all groups. The application of IEC consensus definitions, including vLDA and ODCC, provides a clinically meaningful, standardised framework to evaluate depth and durability of abrocitinib response beyond traditional EASI-based endpoints. Lastly, these findings support the role of flexible dosing with abrocitinib in achieving and maintaining high levels of disease control in AD.

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Abstract N°: 1745

From Psoriasis to Eczema: A Case of Changing Th1/Th2 Predominance

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Introduction

Atopic dermatitis (AD) and psoriasis are both T-cell mediated inflammatory diseases with distinct clinical presentations and comorbidities. Many experts recognize AD as a spectrum, including nummular and follicular eczema as subtypes. Immunologically, AD has a predominantly Th2-mediated pathway, whereas psoriasis has a Th1/Th17-mediated pathway. New evidence suggests immunological shifts between these Th1 and Th2 pathways can occur, changing the clinical presentation. Some studies suggest a bidirectional association between eczematous and psoriatic conditions, with biologics fueling immune dysregulation, however, no clear pathway has been elucidated. We describe a case of a 65-year-old female with treatment-refractory pruritic dermatitis, initially diagnosed as nummular eczema, whose disease course shifted between sequential psoriasiform and eczematous eruptions with multiple biologic therapies.

Case Presentation

The patient is a 65-year-old female with past medical history of polyarthralgias, HTN, GERD, and lumbar radiculopathy who presented to the clinic with a six-year history of progressively worsening pruritic skin eruptions. Her initial presentation in 2016 involved enlarging itchy red spots in her arms and legs that did not resolve with oral diphenhydramine. The patient denied a history of eczema or any family history of dermatologic conditions. Physical examination revealed a few small erythematous papules in the bilateral upper and lower extremities. She was diagnosed with nummular eczema and was prescribed triamcinolone 0.025% cream.

Between 2019 and 2023, she returned multiple times with persistent scaly plaques, most prominent on the lower back. Physical examination revealed bright red-pink papules and plaques with overlying scale and occasional collarettes of scale with central erosion involving the trunk, extremities, neck, and face. She did not respond to triamcinolone 0.1% ointment, hydrocortisone 2.5% cream, clobetasol, or daily oral cetirizine. Laboratory studies were non-specific. A punch biopsy demonstrated subcorneal pustules with mild spongiosis, parakeratosis, and superficial perivascular mixed inflammation with scattered eosinophils. Direct immunofluorescence was nonspecific. The differential diagnosis included guttate psoriasis and subcorneal pustular dermatosis. Over the following year, her disease remained refractory despite treatment with adalimumab 40mg, apremilast 30mg, methotrexate 10mg, clobetasol 0.05% cream, tacrolimus 0.1% ointment, mupirocin 2% ointment, fexofenadine and cetirizine.

In early 2025, the patient was started on secukinumab. After two doses, she experienced acute worsening of her eruption. A punch biopsy of the lower back (0.4×0.4cm, 0.6cm depth) showed psoriasiform hyperplasia with minimal epidermal involvement, mild parakeratosis, and superficial perivascular dermatitis with numerous eosinophils. PAS and GMS stains were negative. The findings favored a psoriasiform drug eruption secondary to secukinumab. Secukinumab was discontinued, resulting in partial improvement.

In late 2025, ustekinumab was initiated. After one injection, she developed a new rash with erythematous scaly papules and patches on the neck, trunk, and extremities. A punch biopsy of lower back revealed subacute

spongiotic dermatitis with parakeratosis, focal excoriation, and superficial perivascular lymphocytic inflammation with numerous eosinophils. The findings were most consistent with an eczematous dermatitis. The patient was initiated on hydrocortisone 2.5% ointment, hydroxyzine 25 mg, and pimecrolimus 1% cream and her symptoms improved.

Conclusion

This case demonstrates sequential shifting between psoriatic presentations following initiation of multiple biologic therapies. Clinically, this emphasizes the need for routine diagnostic reassessment in patients to best tailor biologic treatment, as well as further research to fully characterize the role of biologics in immunologic pathway shifting.

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Abstract N°: 1762

Patient-Reported Outcomes in Paediatric Atopic Dermatitis Treated with Mometasone Furoate 0.1% Cream

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease commonly affecting children, characterized by pruritus, xerosis, and recurrent eczematous lesions. Topical corticosteroids remain the cornerstone of AD management, aiming for rapid symptom control with minimal adverse effects. Real-world data on patient-reported outcomes with commonly used therapies in paediatric practice remain limited. Here, we report real-world evidence of short-term effectiveness and safety of mometasone furoate 0.1% cream in paediatric patients.

Materials and Methods

Objective of this study was to evaluate real-world effectiveness, onset of symptom relief, and tolerability of mometasone furoate 0.1% cream in paediatric patients with mild to moderate atopic dermatitis.This multicentre, retrospective, cross-sectional observational study was conducted across 408 centres in India following independent ethics committee approval. Medical records of paediatric patients aged 2–12 years with mild to moderate AD treated with mometasone furoate 0.1% cream were analysed. Data were collected using a pre-designed structured proforma.

Effectiveness was assessed using patient-reported outcomes on a 10-point scale evaluating reduction in itching, reduction in rash, improvement in skin dryness, and overall AD symptom improvement. Scores of 8–10 were defined as clear or almost clear. Time to symptom improvement and safety outcomes were analysed using descriptive statistics.

Results

A total of 1,084 children were included; 61.0% were boys and 39.0% girls. Most patients were aged 6–12 years (68.4%), while 31.6% were aged 2–6 years. Disease severity was mild in 61.1% and moderate in 38.9% of patients. The duration of AD was ≤5 years in more than 90% of cases. Commonly affected sites included the face (27.3%), trunk (24.4%), and back (11.3%). Concomitant medication in the form of moisturizers was reported in 62.6% of patients.

After 7 days of treatment, mean patient-reported scores on the 10-point scale were 7.7 ± 2.01 for reduction in itching, 7.7 ± 1.98 for reduction in rash, 7.7 ± 1.97 for improvement in skin dryness, and 7.8 ± 1.94 for overall symptom improvement. Clear or almost clear responses (score 8–10) were achieved by 66% for itching, 68% for rash, 65% for dryness, and 70% for overall symptoms.

The mean time to symptom improvement was short, with reduction in itch observed at 4.5 ± 1.68 days, reduction in rash at 4.7 ± 1.60 days, improvement in dryness at 4.5 ± 1.44 days, and overall symptom improvement at 4.7 ± 1.60 days. In many patients, symptom relief started as early as day 3. Details of effectiveness scores are

mentioned in Table 1.

A total of 39 participants (3.6%) reported experiencing irritation or burning during the 7-day period, itching during the treatment period was reported by 36 participants (3.3%) and Skin redness was reported by 32 participants (3.0%).

Parameter	Mean score (SD)	Percentage of patients with clear or almost clear (score of 8-10)	Mean duration for improvement (SD)	Percentage of patients showing improvement				
				Day 3	Day 4	Day 5	Day 6	Day 7
Reduction in Itch	7.7 (2.01)	66	4.5 (1.68)	23	15.8	17.4	13.9	16.7
Reduction in Rash	7.7 (1.98)	68	4.7 (1.60)	23.2	14.7	20.8	15.7	18.4
Improvement in Dryness	7.7 (1.97)	65	4.5 (1.44)	22.8	17.3	25.4	10.2	15.1
Improvement in overall AD symptoms	7.8 (1.94)	70	4.7 (1.60)	21.4	12.5	19.9	16.1	19.6

Table 1: Patient Reported Outcome measures for different parameters in AD (N= 1084)

Conclusions

In this large real-world paediatric cohort, treatment with mometasone furoate 0.1% cream resulted in rapid and clinically meaningful improvement in patient-reported symptoms of mild to moderate atopic dermatitis, with symptom improvement typically observed within 3–5 days. The therapy was well tolerated, with a low incidence of predominantly mild local adverse events. These findings are consistent with previously published clinical evidence on the efficacy and safety of mometasone furoate 0.1% in atopic dermatitis.[1] Collectively, the results support the short-term use of mometasone furoate 0.1% cream as an effective and well-tolerated option for the routine management of paediatric atopic dermatitis in clinical practice.

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Abstract N°: 1764

Lebrikizumab for Paediatric Patients Aged ≥6 Months with Moderate-to-Severe AD: Phase 3 ADorable-1 Week-16 Results

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Introduction

Atopic dermatitis (AD) is the most prevalent chronic inflammatory skin condition impacting 15-20% of children globally, with significant unmet need due to limited treatment options. Lebrikizumab (LEB) inhibits interleukin (IL)-13, a key driver of AD, and is approved for patients ≥12 years (y), ≥40 kg with moderate-to-severe (mod/sev) AD inadequately treated with topicals.

We assessed the 16-week efficacy and safety of LEB and topical corticosteroids (TCS) vs placebo (PBO) and TCS in patients 6 months (m) to <18 y with mod/sev AD in the randomised, double-blind, PBO-controlled, phase 3 ADorable-1 study (NCT05559359).

Materials and Methods

363 patients were randomised 2:1 to LEB (N=245) or PBO (N=118), stratified by age, region, and baseline (BL) Investigator's Global Assessment (IGA; 3 vs 4). Low-to-mid potency TCS were initiated 2 weeks (W) pre-randomisation. Dosing was weight-based (≥40 kg: 500 mg W0 and W2, then 250 mg every 2W from W4; 15–<40 kg: 250 mg W0, then 250 mg every 4W [Q4W] from W2; 6–<15 kg: 125 mg W0, then 125 mg Q4W from W2). Co-primary endpoints were IGA (0,1) with ≥2-point improvement and ≥75% improvement from BL in Eczema Area

and Severity Index (EASI) at W16. Efficacy analyses used the Intent-to-Treat population; safety analyses used the Safety population. This study is ongoing.

Results

Data are reported as LEB vs PBO, respectively. At BL, mean age: 7.7 y vs 7.6 y; female: 47.3% vs 54.2%; mean weight: 29.9 kg vs 30.7 kg. BL disease characteristics: IGA 3, 74.6% vs 76.3%; prior systemic therapy use, 53.9% vs 59.3%, with prior dupilumab use 12.2% vs 11.0%. Co-primary endpoints at W16: IGA (0,1) and EASI 75 were achieved by 43.5% vs 15.2% ($p<0.001$) and 62.6% vs 21.6% ($p<0.001$). Key secondary endpoints at W16: EASI 90, 38.6% vs 11.0% ($p<0.001$); EASI 100, 13.7% vs 4.6% ($p=0.007$); ≥6-point improvement in Children's Dermatology Life Quality Index (4 to <17 y, BL≥6), 61.6% vs 36.2% (n=238, $p=0.001$); ≥4-point improvement in Pruritus Numeric Rating Scale (NRS) (≥6 y, BL≥4), 34.5% vs 5.5% (n=196, $p<0.001$). 41.6% vs 0.0% (n=66, $p<0.001$) had ≥4-point improvement in Worst Scratching/Itching NRS (<6 y, BL≥4). 57.1% vs 59.3% reported adverse events (AEs), mostly mild/moderate in severity, with no trial discontinuations. Injection site reactions were reported similarly in the LEB and PBO arms, with no injection site pain reported.

Conclusions

LEB was superior to PBO for the co-primary endpoints at W16 in paediatric patients 6 m to <18 y with mod/sev AD. No new safety findings were identified at W16 from the available data. These results support LEB as a potential first selective IL-13 inhibitor treatment option for this paediatric population.

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Abstract N°: 1768

A biomarker of type VII collagen degradation is correlated with EASI and decreases after 12 weeks of abrocitinib and baricitinib treatment in patients with atopic dermatitis

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Introduction

Atopic dermatitis (AD) is an inflammatory skin disease characterized by chronic itch, impaired skin barrier, and inflammation. The basement membrane (BM) of the skin separates the dermis from the epidermis and type VII collagen plays an important role in anchoring the two skin layers. The AD related impairment of the skin barrier is reflected by excessive turnover of type VII collagen. The aim of this study was to investigate if a biomarker quantifying matrix metalloproteinase (MMP)-degraded type VII collagen fragments (C7M) is correlated with EASI, can show a pharmacodynamic effect or identify AD patients responding to systemic immunomodulatory treatments.

Materials and Methods

The immunoassay C7M was measured in serum from 40 AD patients receiving Dupilumab (300 mg bi-weekly, n = 16), Tralokinumab (300 mg bi-weekly, n = 5), Abrocitinib (200 mg/day, n =14) or Baricitinib (4 mg/day, n = 5). Blood samples were available at baseline, 2 and 12 weeks of treatment. Clinical characteristics were assessed at the same time points (Eczema Area and Severity Index (EASI), BMI, Age, and intensity of itch measured by the Peak Pruritus Numeric Rating Scale (PPNRS). Patients were considered responders if they achieved a reduction in EASI of 75% or more (EASI75) within the 12-week study period. Correlations between C7M concentration and clinical characteristics were assessed using Spearman's Regression. Longitudinal data was analyzed using a linear mixed effects regression model using treatment modality as a covariate. Associations with treatment response were evaluated by comparing responders and non-responders within each treatment pathway using a Wilcoxon test for percentage change from baseline to week 12. All p-values were adjusted using Benjamini-Hochberg's False Discovery Rate.

Results

Patients had a mean age of 37.9 (SD 14.5) years, 47.5% were female, and the baseline mean EASI score was 20.5 (SD ±13.6). At baseline, C7M had a positive, non-significant correlation with EASI (R = 0.414, p = 0.11) and no correlation with other clinical features. Regarding the potential of C7M to show a pharmacodynamic effect, only patients receiving JAK inhibitors showed a significant decrease in C7M levels at week 4 compared to baseline (median 8.45 ng/ml vs 10.12 ng/ml, p=0.03, Figure 1A). Among patients treated with IL-4/IL-13 inhibitors, responders presented a reduction in C7M at week 12, with a median percentage change of −9.48%, whereas non-responders showed an increase (17.21%; Figure 1B.1). Although most responders exhibited decreased levels, one patient showed a considerable increase (~130%), contributing to substantial within-group variability. Similarly, among patients receiving JAK inhibitors, responders showed a median decrease in C7M from baseline to week 12

(−17.45%), while non-responders presented an increase (5.2%; Figure 1B.2). However, percentage change did not differ significantly between responders and non-responders in either treatment group (p = 0.20 and p = 0.14, respectively).

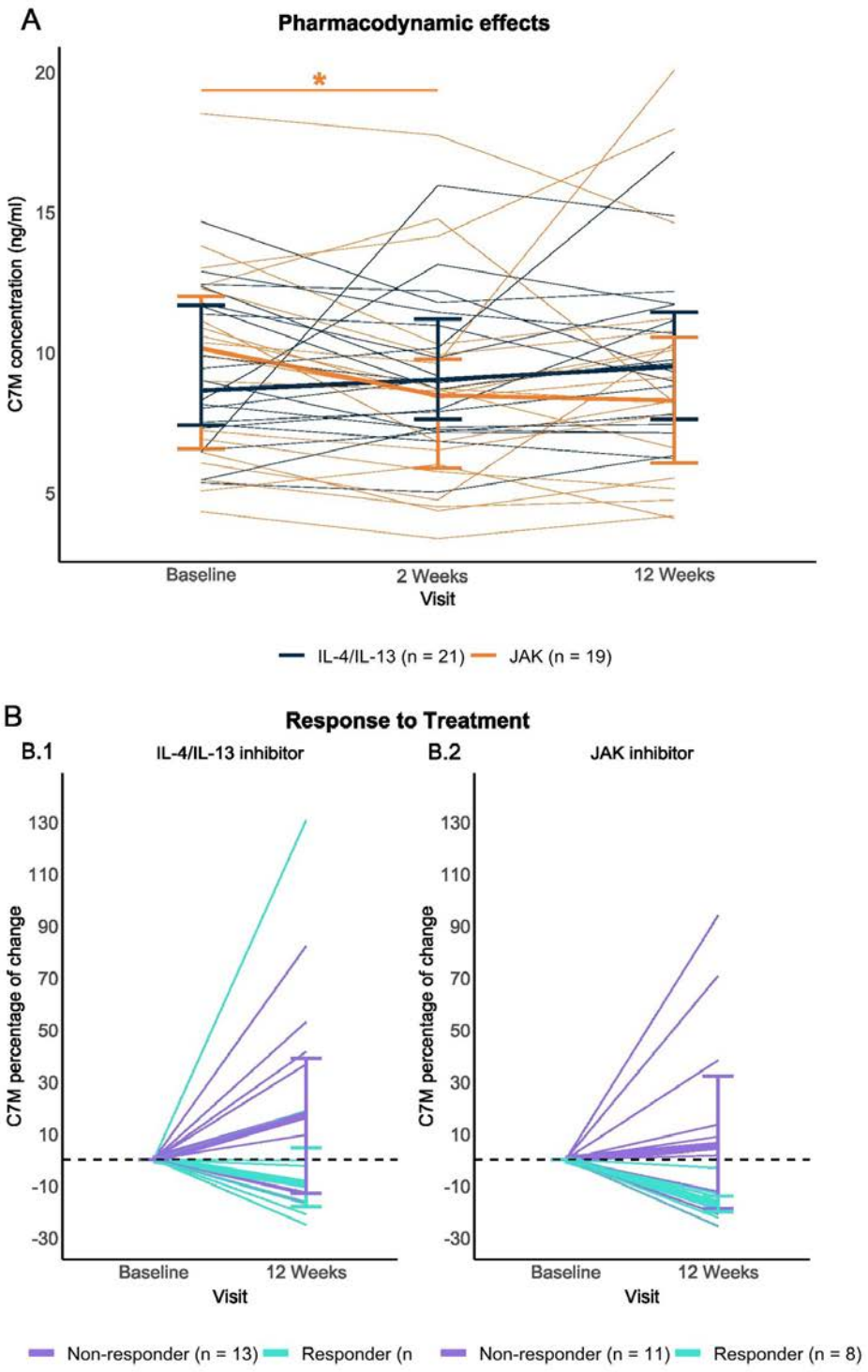

Figure 1

Conclusions

These exploratory findings suggest that C7M may be associated with disease severity and could have potential as a biomarker of treatment response to JAK inhibitory therapy in AD, although this requires confirmation in larger studies.

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Abstract N°: 1778

Efficacy and Safety of Gecacitinib Tablets in Chinese Adults with Moderate-to-Severe Atopic Dermatitis: A Multicenter Phase III Trial

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Introduction
Atopic dermatitis (AD) is a chronic, recurrent, inflammatory skin disease. Gecacitinib is an oral Janus kinase (JAK) inhibitor. Here we report preliminary results from a phase 3 clinical trial on the efficacy and safety of gecacitinib hydrochloride tablets 75 mg and 100 mg twice daily (BID) versus placebo in adult patients with moderate-to-severe AD.

Materials and Methods
The trial consisted of a main study and an extension study. The main study adopted a 16-week randomized, double-blind, placebo-controlled, multicenter design. Chinese adult participants with moderate-to-severe AD (Investigator's Global Assessment [IGA] ≥3, Eczema Area and Severity Index [EASI] ≥16, body surface area [BSA] involvement ≥10%, and peak pruritus Numerical Rating Scale [NRS] ≥4 at baseline) were randomized in a 1:1:1 ratio to receive gecacitinib 75 mg, 100 mg, or placebo BID. The co-primary endpoints were the proportion of participants achieving EASI-75 (≥75% improvement from baseline in EASI) and the proportion of participants achieving IGA 0/1 (an IGA score of 0 or 1 with a ≥2-point improvement from baseline) at week 16. Secondary endpoints included the proportion of participants achieving a ≥4-point improvement from baseline in the pruritus NRS (NRS4), EASI-90 at various time points etc., as well as safety measures. Eligible participants who completed the 16-week main study could continue treatment in the extension study for an additional 36 weeks.

Results
A total of 146, 147, and 148 participants received gecacitinib 75 mg BID, 100 mg BID, and placebo in the main study, respectively. Baseline demographics and disease characteristics were generally balanced across groups. Mean baseline EASI scores were 22.50, 23.42, and 22.89, and mean AD duration was 9.04, 9.48, and 9.83 years,

respectively.

Both the 75 mg and 100 mg regimens of gecacitinib met the co-primary efficacy endpoints. At week 16, EASI-75 response rates were 58.9% in the 75 mg group, 67.3% in the 100 mg group, and 17.6% in the placebo group; the corresponding IGA 0/1 rates were 41.1%, 44.9%, and 7.4% Both doses showed statistically significant improvements over placebo ($p < 0.0001$ for each). Gecacitinib also rapidly relieved pruritus. The Kaplan-Meier curves for NRS4 separated from placebo as early as at the end of the first week. By week 16, the proportion of patients achieving NRS4 was 45.8% in the 75 mg group and 41.2% in the 100 mg group, compared with 19.9% in the placebo group ($p < 0.001$ for both comparisons), the corresponding EASI-90 rates were 36.3%, 43.5% and 9.5% ($p < 0.0001$ for both comparisons *vs.* placebo). For the 55 and 61 participants continuing the 75 mg and 100 mg regimens after week 16 and completed 52-week treatment, EASI-75 rates were 76.4% and 75.4%, and IGA 0/1 rates 52.7% and 49.2% at week 16; corresponding values at week 52 were 80.0% and 82.0% for EASI-75, and 56.4% and 57.4% for IGA 0/1.

During the main study, adverse events (AEs) were reported in 95.2%, 93.2%, and 76.4% of participants in the gecacitinib 75 mg, gecacitinib 100 mg, and placebo groups, respectively. Most AEs were of CTCAE grade 1 or 2. The most common AEs (with an incidence of ≥10% in either gecacitinib group and greater than that observed with placebo) included decreased neutrophil or white blood cell counts, elevated creatine kinase, elevated alanine aminotransferase, upper respiratory tract infection, and hyperlipidemia. Serious adverse events (SAEs) occurred in 4.8% of participants in both gecacitinib groups and in 6.1% of the placebo group. The long-term safety profile over 52 weeks was consistent with that observed in the double-blind main study.

Conclusions

Gecacitinib showed superior efficacy in comparison to placebo and acceptable safety profile during the main study phase in patients with moderate-to-severe atopic dermatitis. The clinical response peaked at Week 16 and then plateaued through the 52-week treatment period, with no new safety signals identified during long-term treatment.

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Abstract N°: 1786

Eczema–Psoriasis Overlap: An Italian eDelphi Consensus on Clinical Presentation and Therapeutic Management

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Introduction
Atopic dermatitis (AD) and psoriasis (PSO) are common chronic inflammatory skin diseases traditionally considered distinct entities, driven by Th2 and Th1/Th17 immune pathways, respectively. However, increasing evidence suggests that these conditions may share overlapping genetic, molecular, and immunologic mechanisms. The coexistence of eczematous and psoriatic features in the same patient may create diagnostic and therapeutic challenges in clinical practice. The aim of this study was to establish an Italian consensus on the clinical definition and management of eczema–psoriasis overlap.

Materials and Methods
A consensus was developed using an electronic Delphi (eDelphi) methodology. A steering committee composed of eight dermatologists with expertise in inflammatory skin diseases conducted a literature review and identified key areas of uncertainty regarding the coexistence of eczema and PSO in clinical practice. Based on these findings, 43 statements were developed covering three key areas: problem definition, clinical presentation, and therapeutic management. The statements were distributed to 131 dermatologists from referral centers across Northern, Central, and Southern Italy. Participants rated their level of agreement using a numeric rating scale ranging from 1 (strongly disagree) to 9 (strongly agree). Consensus was defined as a mean score ≥7.

Results
Of the 131 invited dermatologists, 104 responded, yielding a response rate of 79.4%. Overall, consensus was achieved for 42 of the 43 proposed statements. The only statement that failed to reach the predefined consensus threshold concerned the influence of respiratory atopic comorbidities on the choice of biologic therapy in patients with PSO. Given the dichotomous nature of the statement, it was not revised or resubmitted for a second round of voting.

Conclusions

This consensus highlights that eczema and PSO may represent different clinical expressions within a broader spectrum of immune dysregulation. Some patients may present with both eczematous and psoriatic lesions, either concurrently or sequentially, or may experience phenotypic switches between the two conditions during the course of the disease. Careful assessment of patient history, clinical phenotype, and potential risk factors for drug-induced forms is essential when selecting treatment strategies. Mild cases can often be managed with topical therapies, whereas moderate-to-severe disease may require broader T-cell immunomodulatory approaches, including systemic agents or targeted small molecules. This consensus provides practical guidance for clinicians managing patients with eczema–PSO overlap and highlights the need for further studies to better clarify the underlying pathogenic mechanisms and optimize treatment strategies.

EA DV CONGRESS
VIENNA
30 SEP - 3 OCT 2026

Abstract N°: 1788

When context matters: successful management of severe atopic dermatitis during lactation with lebrikizumab

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory disease that, in its moderate-to-severe forms, may significantly impair function and quality of life. Management of AD in special situations such as pregnancy and lactation represents an additional clinical challenge due to therapeutic limitations and the need to ensure safety for both mother and infant. We report a case of severe, disabling AD with challenging management in the context of pregnancy and subsequent lactation.

Case Presentation

A 36-year-old woman with severe AD since childhood presented with chronic relapsing disease, progressively worsening in adulthood. She reported intense pruritus, sleep disturbance, and marked impairment in quality of life, particularly due to persistent involvement of the hands and anogenital and gluteal areas. Her medical history included bronchial asthma, with no relevant comorbidities or drug allergies.

Previous treatments included medium-to-high potency topical corticosteroids and short courses of systemic corticosteroids, achieving only transient improvement. Conventional systemic therapies included methotrexate (discontinued due to gastrointestinal intolerance) and ciclosporin (up to 200 mg/day for several months), with insufficient clinical response and persistent active disease requiring frequent topical rescue therapy.

Due to pregnancy planning and subsequent gestation, systemic therapy was discontinued, and only intermittent topical treatment was maintained, with poor disease control. The patient presented to our clinic 4 months postpartum, during mixed breastfeeding

Clinical examination revealed active eczematous involvement of the face and hands, with erythema, scaling, lichenification, and painful fissures. Notably, there was extensive and severe involvement of the anogenital and gluteal regions, with chronic, highly inflamed eczematous plaques, marked lichenification, and intense pruritus. Multiple excoriated nodular lesions consistent with prurigo were observed, leading to significant discomfort, pain, and functional impairment.

Disease severity was consistent with moderate-to-severe AD (EASI 24, DLQI 18, pruritus NRS 8/10). Based on clinical history, examination, and validated scoring systems, a diagnosis of severe, chronically active AD with predominant involvement of special areas and associated prurigo component was established, refractory to topical and conventional systemic therapies.

Given the persistence of severe, disabling AD and considering the lactation setting, targeted biologic therapy was initiated after individualized benefit–risk assessment, selecting lebrikizumab, a monoclonal antibody targeting interleukin-13 (IL-13). Treatment was administered according to approved dosing guidelines. Concomitant therapy included daily emollients and intermittent medium-potency topical corticosteroids as needed during early phases.

A rapid clinical response was observed within the first weeks, with marked reduction in pruritus and skin inflammation. Follow-up demonstrated a fast and sustained improvement, with near-complete resolution of lesions on the face and hands, and especially in the anogenital and gluteal regions, along with disappearance of prurigo lesions.

At week 16, significant improvement was documented (EASI ≤2, DLQI 1, pruritus NRS 1/10), allowing substantial reduction in topical corticosteroid use. No relevant adverse events were reported, with good tolerability and sustained improvement in quality of life.

Conclusion

Severe AD represents a therapeutic challenge in complex clinical settings such as pregnancy and lactation.
IL-13 inhibition was effective in a severe, refractory case, including difficult-to-treat areas such as the anogenital and gluteal regions.
Treatment during lactation showed a favorable efficacy and safety profile, with rapid and sustained clinical response.

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30 SEP - 3 OCT 2026

Abstract N°: 1792

Injection site-related pain and treatment adherence to dupilumab in children with atopic dermatitis: a real-life cohort study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease often presenting in early childhood with significant impact on quality of life. Children with moderate-to-severe AD unresponsive to topical therapy may require systemic treatment, including dupilumab (IL-4/IL-13 receptor antagonist), approved from 6 months of age.

Despite its efficacy, injection-related pain remains clinically underreported. Repeated injections may affect adherence, family burden, and treatment acceptability, yet real-world paediatric studies rarely assess pain severity, preventive strategies, or need for specialized support. This gap is especially relevant in younger children and those with neuropsychiatric comorbidities. Structured pain management, including topical anaesthesia, distraction, and behavioural support may be required in a subset of patients, but data on how pain influences adherence, dosing changes, and discontinuation remain scarce.

Optimal treatment duration is similarly unclear. Evidence on long-term persistence, remission, tapering, and potential disease-modifying effects in children is still emerging. Given dupilumab's cost and uncertainties around treatment burden and discontinuation patterns, real-world data from the national registry are needed to characterize clinical outcomes and benchmark against published cohorts.

Objectives

To describe the use of systemic therapies with a focus on dupilumab, in children with severe AD, and to determine optimal treatment duration, identify predictors of injection-related pain, and map treatment sequences across age groups.

Materials and Methods

Our National Quality Registry provides prospective data on 476 children with severe AD receiving systemic treatment across 65 dermatology clinics, including Eczema Severity Score Index (EASI), Patient-Oriented Eczema Measure (POEM), visual analogue scale 10cm (VAS) or Numeric Rating Scale (NRS) for pruritus, and Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) for children aged 4-16 years at each visit. Systemic drugs and treatment sequences will be analysed using the National Prescribed Drug Register and the National Patient Register (NPR). Drug survival will be estimated with Kaplan–Meier curves, logistic regression will be used to identify predictors of remission and injection-site pain, and Cox regression to identify predictors of discontinuation. An in-depth study of 78 children treated with dupilumab 2021-2025 (maximum follow-up time 5 years) will be performed by reviewing electronic medical records (EMR). Reports on injection-site pain and pain management interventions, extracted from EMR, will be categorised as either simple measures (topical anaesthesia, cooling, distraction), or advanced measures (play therapy, psychologist, pain clinic).

Results

Preliminary data from the registry include 476 children (age 0–5 years (n=76), age 6–11 (n=156), age 12–17 (n=244)). Drug survival analyses, reasons for discontinuation, and post-discontinuation disease trajectories are currently being finalised. From the EMR, documented injection pain and intervention data are available for all 78 dupilumab-treated patients, categorisation and regression analyses are ongoing. Results on pain predictors, including age, sex, neuropsychiatric comorbidity, and baseline severity, and on remission rates with associated clinical predictors will be presented.

Conclusions

This study will provide the largest real-world dataset on systemic treatment in paediatric AD patients. Findings on dupilumab drug survival, remission, and injection-site pain management will offer actionable guidance for individual treatment in clinical practice.

EA DV CONGRESS
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Abstract N°: 1795

Dupilumab-associated hypereosinophilia in pediatric patients with atopic dermatitis: results from the BioDay registry.

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Introduction
Dupilumab, a fully human IgG4 monoclonal antibody directed against interleukin (IL)-4 and IL-13, is an effective systemic treatment for moderate-to-severe pediatric atopic dermatitis (AD). However, (transient) hypereosinophilia (HE) has been reported. This study aims to investigate eosinophil levels in pediatric patients during dupilumab treatment and to identify the occurrence and potential predictors of HE.

Materials and Methods
Pediatric patients (aged ≤16 years) treated with dupilumab for moderate-to-severe AD were included from the BioDay registry. Data were collected at the start of dupilumab (baseline) and at weeks 4, 16, 28, 40, and 52; then every three months thereafter for up to two years. Patients were divided, based on their highest measured eosinophil count after baseline, into three groups: no HE (<1.5 x 10^9/L), mild HE (≥1.5-<3.0 x 10^9/L), or moderate-severe HE (≥3.0 x 10^9/L). Additionally, predictors of moderate-severe HE were assessed.

Results
A total of 320 patients were included, with a mean age of 10.3 years (SD 4.2), and slightly more than half were male (52.5%). Overall, 64 patients (20.0%) developed HE; 43 (67.2%) had mild HE and 21 (32.8%) had moderate-severe HE. In the total cohort, the median eosinophil count was 0.53 x 10^9/L (95% CI 0.48-0.59) at baseline, increasing to a peak of 0.63 x 10^9/L (95% CI 0.55-0.72) at week 28 and subsequently declining throughout follow-up (Figure 1). In both the mild and moderate-severe HE groups, eosinophil levels remained above the HE-defining thresholds throughout follow-up; however, of the six patients evaluated by a pediatric hematologist, none showed any clinically relevant findings. Notably, higher baseline EASI score was associated with increased risk of developing moderate-severe HE (HR 1.15 [95% CI 1.09-1.22]). EASI scores improved over time, regardless of HE status.

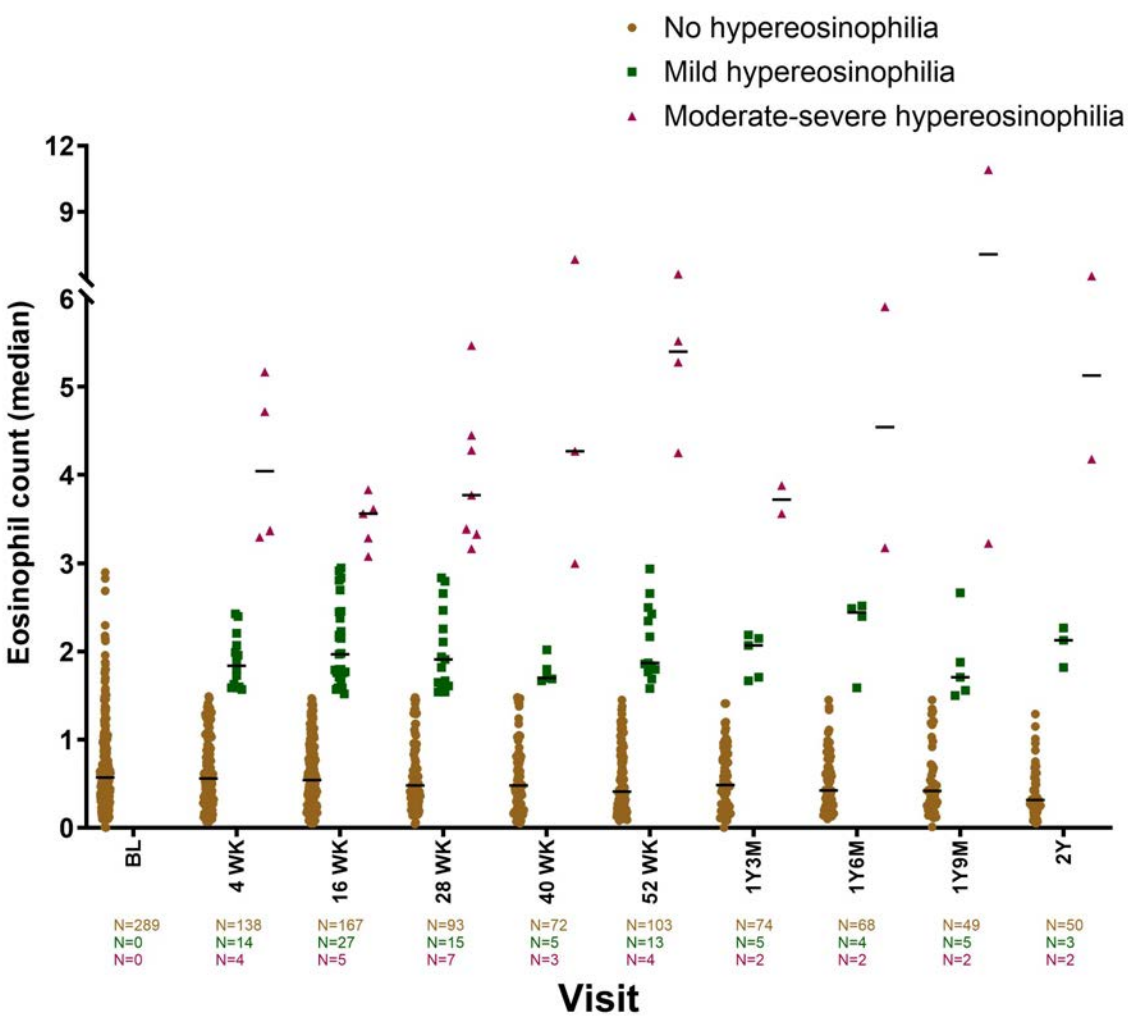

Figure 1. Scatterplot of eosinophil counts over time per hypereosinophilia group. Data as observed. M, months; N, number; WK, weeks; Y, years.

Conclusions

Dupilumab-associated and transient hypereosinophilia was seen in 20.0% of our pediatric AD patients. Higher baseline EASI scores were associated with an increased risk of developing moderate-severe HE. Importantly, no evidence was found that HE requires clinical action.

EADV CONGRESS
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30 SEP - 3 OCT 2026

Abstract N°: 1801

Long-term effectiveness, safety, and survival of dupilumab in pediatric atopic dermatitis across age groups: results from the BioDay registry.

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Introduction
Limited data are available on the long-term effectiveness and safety of dupilumab in pediatric patients with atopic dermatitis (AD) in daily practice. We aimed to investigate the real-world effectiveness, safety, drug survival, and reasons for discontinuation of dupilumab across pediatric age groups with up to three years of follow-up.

Materials and Methods
Pediatric patients (aged ≤16 years) treated with dupilumab for moderate-to-severe AD were included from the prospective BioDay registry. Data were collected at the start of dupilumab (baseline) and at weeks 4, 16, 28, 40, and 52, followed by every 3-6 months thereafter. Clinical effectiveness was evaluated by the Eczema Area and Severity Index (EASI) and Investigator Global Assessment (IGA). Additional outcomes included the Numeric Rating Scale (NRS) for pruritus, NRS pain, and quality of life (QoL) scores. Safety was assessed by evaluation of adverse events (AEs). Drug survival and reasons for discontinuation were evaluated.

Results
Overall, 309 pediatric AD patients (mean [SD] age: 10.2 [4.2] years; 51.5% male) were treated with dupilumab; 51 patients aged 6 months–5 years (median follow up [IQR] 45.0 [26.0-101.0] weeks), 120 patients aged 6–11 years (80.0 [32.0-135.0] weeks), and 138 patients aged 12–16 years (89.5 [48.0-143.0] weeks) at baseline. Most patients maintained controlled AD across age groups, with mean EASI and NRS pruritus remaining low after 3 years (3.4 [95% CI 2.4-4.5] and 3.6 [95% CI 3.1-4.1], respectively) (Figure 1). A statistically significant difference, which was consistent at all time points, was observed between age groups for NRS pruritus and QoL scores, with higher scores in the 6 months–5 years age group compared with older children ($p<0.01$) (Figure 1). The most frequently reported AE was dupilumab-associated ocular surface disease (DAOSD; 35.6%). Fifty (16.2%) patients discontinued dupilumab, mainly due to ineffectiveness (38.0%) and/or AEs (30.0%), or administration problems (22.0%); most discontinuations occurred within 1.5 years. Overall drug survival at three years was 80.1%.

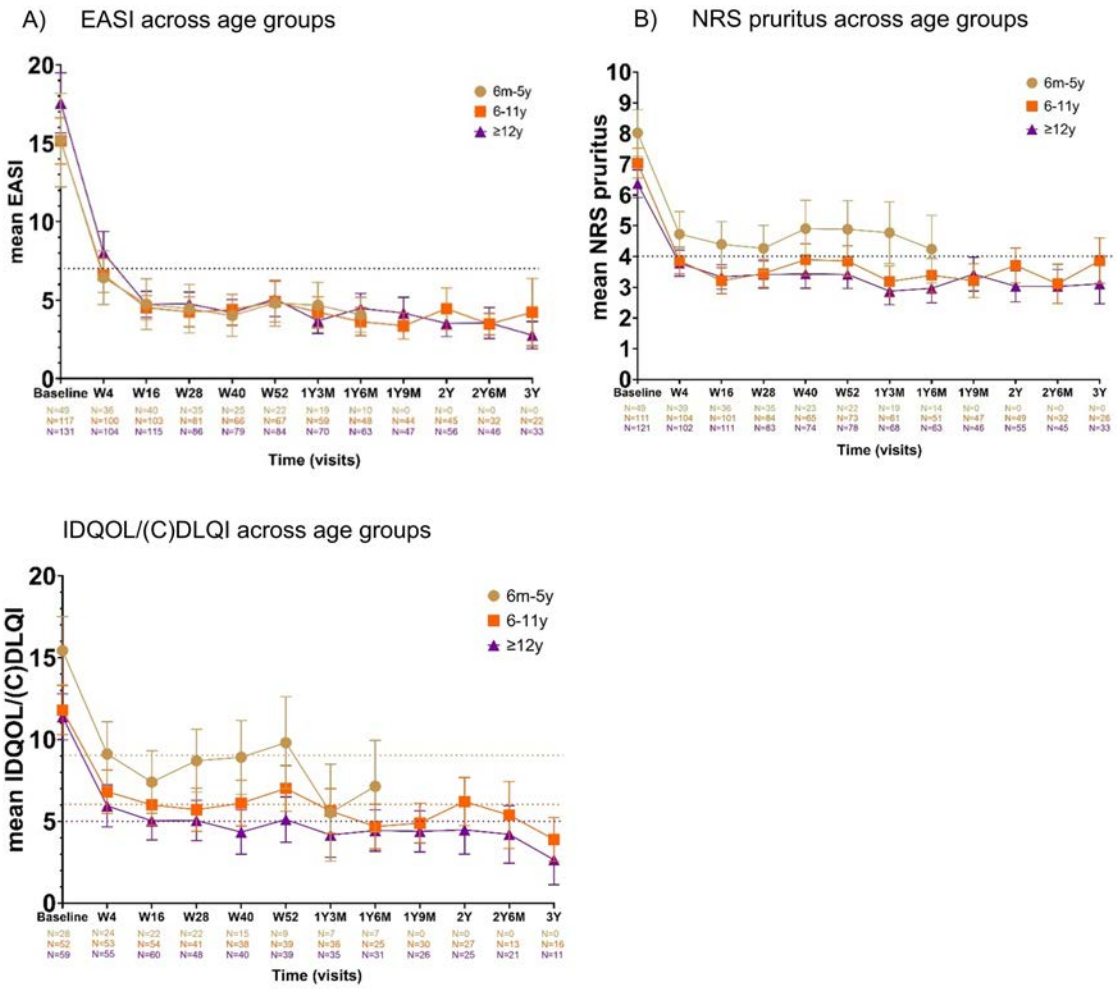

Figure 1. Continuous outcomes in pediatric patients with atopic dermatitis across age groups during 3 years of dupilumab treatment. A; LR test for age group, p=0.85, dotted line refers to cut-off score of EASI≤7. B; LR test for age group, p<0.01, dotted line refers to cut-off score of NRS pruritus≤4. C; LR test for age group, p<0.01, dotted line refer to respectively cut-off scores of IDQOL≤9, CDLQI≤6, and DLQI ≤5. (C)DLQI, (Children's) Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IDQOL, Infant's Dermatitis Quality of Life Index; LR test, likelihood ratio test; M, months; N, number; NRS, Numeric Rating Scale; W, weeks; Y, years. Error bars represent 95% confidence intervals (CIs).

Conclusions

Dupilumab demonstrates long-term effectiveness and safety in pediatric AD in daily practice. Younger children show higher NRS pruritus and QoL scores and discontinue treatment more often due to administration problems, highlighting age-specific challenges.

EA DV CONGRESS
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30 SEP - 3 OCT 2026

Abstract N°: 1803

Clinical Phenotyping of Atopic Dermatitis Using Combined Global Severity (POEM) and Facial Burden (BoFA): A French Population-Based Observational Study

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Introduction
Atopic dermatitis (AD) is characterized by substantial clinical heterogeneity. Global severity is typically assessed using scores such as the POEM. However, lesion localization—particularly on the face—may generate psychosocial consequences that are partly independent of overall disease severity. **Objective:** To define clinical phenotypes of AD through the combination of global severity (POEM) and facial involvement intensity (BoFA), and to characterize their respective psychosocial burden.

Materials and Methods
This cross-sectional observational study (VISEABLE) included 1,400 French adults with physician-confirmed AD. Severity was measured using the POEM (Clear/Almost Clear: 0–7 vs. Moderate–severe: ≥8) and facial involvement using the BoFA (0–109; threshold = 36). Six phenotypes were defined (2 × 3 combination). Psychosocial burden was assessed using the PUSH-d (stigmatization), DLLIM/SOL (life trajectory impact), and DMLQ (mental load).

Results
The POEM and BoFA correlation was moderate ($r = 0.365$; $\rho = 0.389$; $p < 0.001$). Phenotype Ph3 (Clear/Almost Clear POEM / Severe facial involvement, n = 58) exhibited stigmatization scores (PUSH-d = 21.93) and life trajectory impact (DLLIM = 14.76) that were not significantly different from Ph4 (Moderate–severe POEM / No facial involvement, n = 527; $p > 0.25$ for all comparisons). In multiple regression analysis, BoFA emerged as the dominant independent predictor of stigmatization ($\beta = 11.44$, $p < 0.001$; $R^2 = 0.532$), superseding POEM ($p = 0.076$, ns).

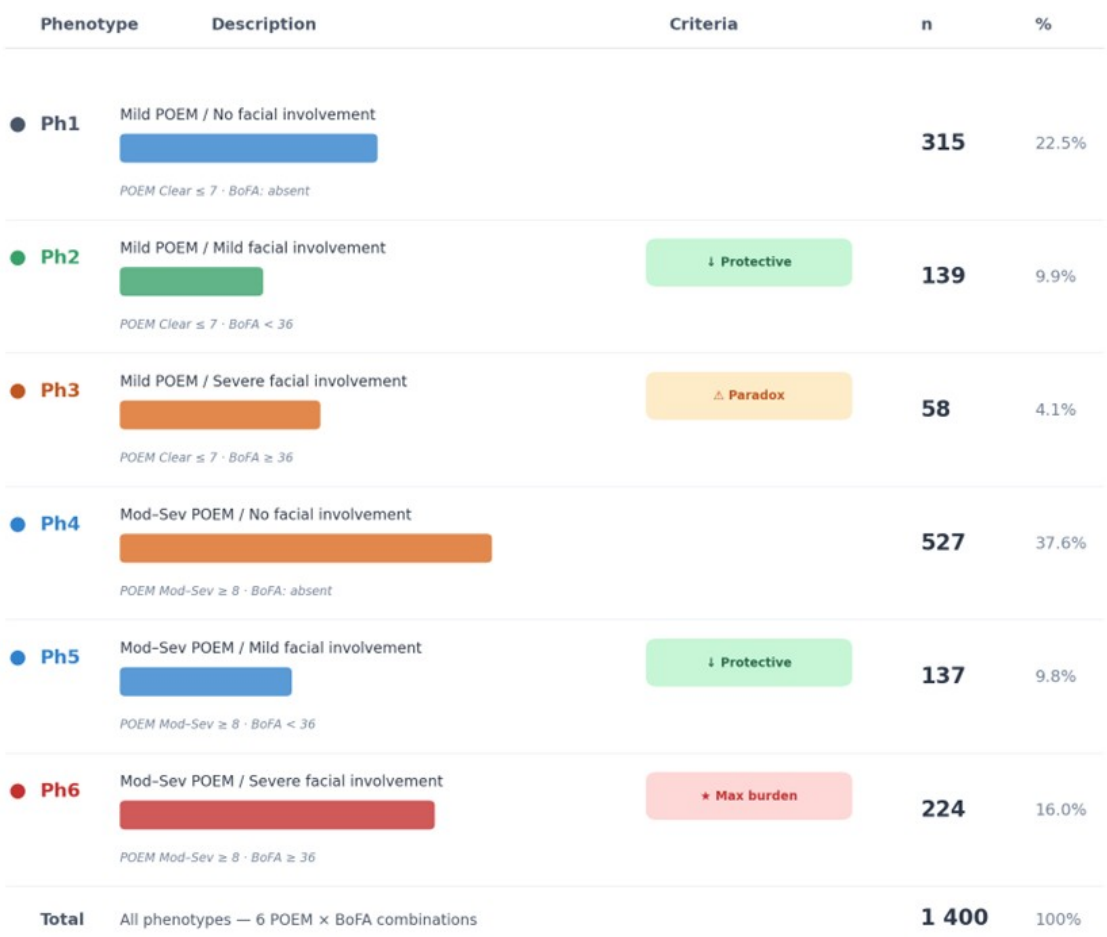

Figure 1. Distribution of the six POEM × BoFA phenotypes (N = 1,400)

Conclusions

Mild eczema with severe facial involvement generates a psychosocial burden comparable to that of moderate-to-severe eczema without facial involvement. Systematic BoFA assessment is essential in all patients with AD.

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Abstract N°: 1827

Adjunctive Barrier Support with a Vernix-Inspired Branched-Chain Ceramide NP in AD-Like Compromised 3D Epidermal Models

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Introduction

Epidermal barrier repair is a central part of atopic dermatitis (AD) management, particularly in pediatric patients and other populations with vulnerable skin. Vernix caseosa, the natural protective covering of fetal skin, provides a biologically relevant reference for barrier-oriented lipid design. In this study, a vernix-inspired branched-chain ceramide NP was evaluated as a potential adjunctive approach for AD-related compromised skin. To assess the effects of a vernix-inspired ceramide NP on barrier differentiation, stress-associated responses and lipid metabolism in in vitro and 3D AD-like epidermal models.

Materials and Methods

The test material was evaluated in SLS-challenged HaCaT cells and in two reconstructed 3D human epidermal models: a saliva-associated challenge model reflecting pediatric perioral barrier stress, and a UVB-damaged model. Key markers related to inflammation, differentiation and lipid metabolism were assessed by RT-qPCR, ELISA and immunofluorescence.

Results

In SLS-challenged keratinocytes, the ceramide NP reduced IL-1α, IL-8 and TSLP to 82%, 77% and 78% of control levels, respectively, while increasing Keratin 1 and Keratin 10. In the saliva-associated 3D model, it reduced S100A8, S100A9 and TSLP by up to 72.13%, and increased HBD1, LL37 and epidermal lipid staining. In the UVB-damaged model, IL-1α and TSLP were reduced by 42.69% and 39.15%, respectively, while FLG, Claudin-1 and lipid metabolism-related markers, including ACACA, GBA, SPT1 and PPAR-α, were increased, with changes up to 187.50%.

Conclusions

The vernix-inspired ceramide NP improved multiple barrier-related responses in AD-like compromised epidermal models, including reduced stress-associated signalling, enhanced barrier differentiation and improved lipid metabolism-related markers. These findings support its potential relevance as an adjunctive barrier-support approach for AD-related epidermal dysfunction.

EADV CONGRESS
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Abstract N°: 1838

Similarities and Differences in Expectations of Future Atopic Dermatitis Treatment in the USA, France, and Germany

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Introduction

Ensuring that treatment options align with the preferences and expectations of those using them is critical to improving outcomes. To better understand this, we conducted an international multilingual survey examining the experiences of adult patients and caregivers of children with atopic dermatitis (AD), including treatment use across the care journey and perspectives on future therapies (Willard, Kristen et al. "Patient and Caregiver Perceptions on Education and Treatment Needs in Atopic Dermatitis from an International Survey." *Dermatology and therapy* vol. 16,1 (2026): 391-403).

Materials and Methods

In this report, we aimed to understand potential regional differences by comparing the responses obtained from 893 respondents living in the USA (n=620; 70% patients, 30% caregivers), France (n=141; 81% patients, 19% caregivers), and Germany (n=132; 69% patients, 31% caregivers).

Results

Reducing flare-ups was consistently identified as a top priority across countries, with the highest proportion of "very important" responses reported in the United States (56%), followed by Germany (42%) and France (38%). Achieving sustained, symptom-free control was also a key expectation, particularly in the United States (83%: 51% "very important," 32% "important"), while over 60% of respondents in France (75%) and Germany (63%) rated this outcome as at least important. Safety and tolerability were similarly prioritized, with 63% of respondents in Germany, 76% in the United States, and 77% in France considering an acceptable safety profile and minimal side effects to be important or very important.

Across all countries, additional factors – including reducing healthcare utilization, minimizing impact on quality of life, and the ability to pause treatment without symptom recurrence – were valued by at least 60% of respondents. Convenience also played a significant role, with 75% or more in all countries expressing a preference for at-home treatment. Cost remained a critical consideration, particularly in the United States and France, where at least 80% rated it as important or very important, compared with 67% in Germany.

Conclusions

Overall, this sample consistently prioritized treatments that reduce flare-ups and provide sustained, symptom-free control with a favorable safety profile. Beyond clinical outcomes, respondents value treatments that minimize impact on daily life, reduce healthcare use, and offer flexibility, including the potential to pause treatment without relapse. The strong preference for at-home administration further underscores the importance of convenience.

While these core expectations are shared globally, regional differences highlight the particularly strong emphasis on symptom control and cost considerations in the United States (Figure). Overall, these findings reinforce the need for patient-centered treatment strategies that balance efficacy, safety, convenience, and affordability to better meet patient needs across diverse healthcare settings.

Funding:

The survey was funded by GAAPP, supported by an educational grant from Sanofi.

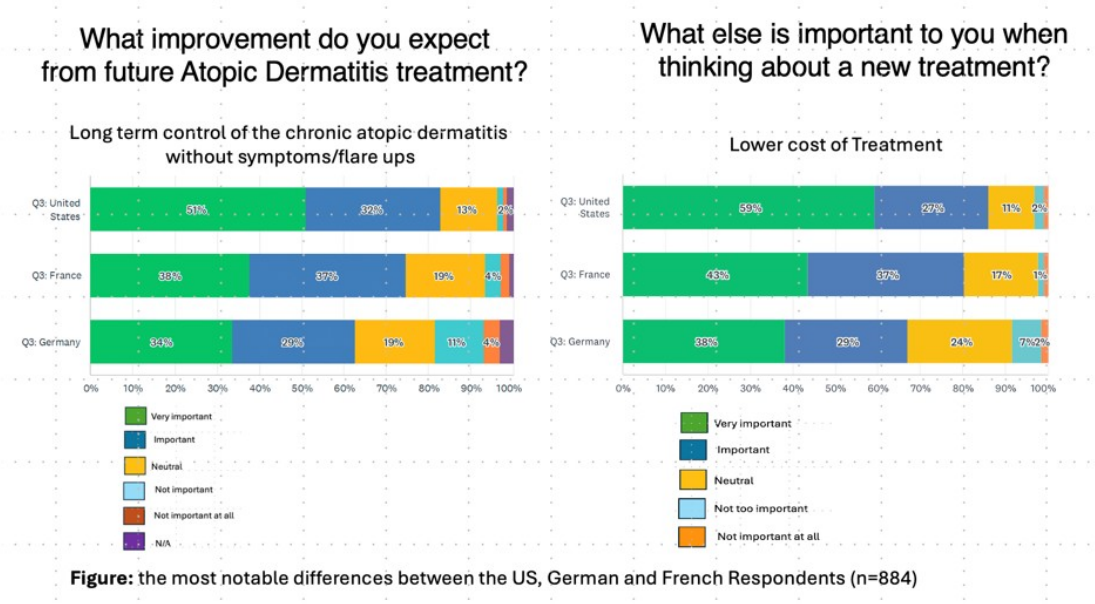

Figure: the most notable differences between the US, German and French Respondents (n=884)

EA DV CONGRESS
VIENNA
30 SEP - 3 OCT 2026

Abstract N°: 1844

Tralokinumab monotherapy rapidly improves sleep, daily functions, and health-related quality of life in patients with atopic dermatitis and moderate-to-severe hand involvement

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[8] Department of Dermatology-Allergology, Amsterdam UMC, Amsterdam, Netherlands
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[10] LEO Pharma GBS, Gdańsk, Poland
[11] Oregon Medical Research Center, Portland, OR, United States

Introduction

Atopic dermatitis (AD) is a chronic, inflammatory skin disease that typically affects multiple body areas and can negatively impact patients' emotional well-being and daily function. AD involving the hands is particularly burdensome, as hands are highly visible and essential for everyday function. Health-related quality of life (HRQoL) measures may be more informative than standard clinical endpoints in understanding patient-perceived severity involving high-burden areas.

The ADHAND trial (NCT05958407) was the first phase 3 trial to evaluate targeted IL-13 inhibition with tralokinumab in adults with AD and moderate-to-severe hand involvement. At Week 16, tralokinumab monotherapy demonstrated significant improvements in the signs and symptoms of atopic hand eczema and its impact on HRQoL measures compared with placebo, with sustained or further improvements with continued tralokinumab treatment through Week 32.[1]

Here, we further assess the impact of tralokinumab monotherapy versus placebo on patient HRQoL outcomes in ADHAND, as measured by the general Dermatology Life Quality Index (DLQI) and the hand eczema-specific Hand Eczema Impact Scale (HEIS).

Materials and Methods

Adults in ADHAND were randomized 2:1 to receive tralokinumab monotherapy 300 mg once every two weeks (Q2W) or placebo for 16 weeks. From Weeks 16-32, all patients received open-label tralokinumab Q2W. Analyses included the pre-specified endpoint, proportion of patients achieving a clinically meaningful improvement in DLQI (≥4-point reduction), with post hoc evaluation of the proportion of patients achieving a clinically meaningful improvement in HEIS (≥1.3-point reduction) and the mean change from baseline in individual HEIS domain

scores. Statistical analyses followed pre-specifications, with data after rescue or discontinuation due to adverse events or lack of efficacy handled using nonresponder imputation (for binary endpoints) or last observation carried forward (for continuous endpoints); multiple imputation was applied to all other missing data.

Results

A total of 235 patients were randomized to tralokinumab (N=156) and placebo (N=79). At Week 16, a significantly greater proportion of patients who received tralokinumab achieved a ≥4-point improvement in DLQI compared with placebo (74.3% vs 41.0%; difference: 33.3%, 95% CI: 19.7-46.8; *P*<.001) and achieved a ≥1.3-point improvement in HEIS (60.8% vs 25.3%; difference: 35.5, 95% CI: 23.2-47.8; *P*<.001). Early separation between treatment groups was observed within 2 weeks for both outcomes. Response rates continued to improve with continuous tralokinumab treatment up to Week 32 in the open-label period, with clinically meaningful improvements in DLQI and HEIS observed in 89.6% (n/N: 112/125) and 83.2% (99/119) of patients, respectively.

At Week 16, greater improvements were observed across all individual HEIS domains in the tralokinumab group versus placebo (**Figure 1**), with differences evident by Week 2. Mean percentage change from baseline to Week 16 with tralokinumab versus placebo were observed for proximal daily activity limitations (–63.3% vs –24.5%), embarrassment related to hand eczema (–59.4% vs –22.4%), frustration due to hand eczema (–58.1% vs –25.3%), impact on quality of sleep (–68.5% vs –24.3%), difficulty working (–72.5% vs –32.7%), and difficulties with physical functions (–74.6% vs –29.8%) (all *P*<.001).

Conclusions

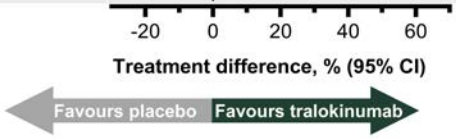
Tralokinumab monotherapy provided clinically meaningful improvements in HRQoL, as measured by both dermatology-specific (DLQI) and hand eczema-specific (HEIS) measures, in patients with AD and moderate-to-severe hand involvement. Further improvements were observed with continued treatment up to Week 32. In addition, statistically significant improvements across all HEIS domains were observed at Week 16.

References

1. Ehst B, et al. Tralokinumab Treatment In Patients With Atopic Dermatitis and Moderate-to-Severe Hand Involvement: Results From the 32-week Phase 3b ADHAND Trial. *J of Skin*. 2026;10(2):s744. doi:10.25251/ppt8ep84.

Figure 1: Treatment difference (tralokinumab vs placebo) in mean change from baseline to Week 16 in overall HEIS and individual HEIS domains

	Treatment Difference (95% CI)	*P* value
Overall HEIS	36.3% (25.5 to 47.1)	<.001
Individual HEIS domains		
Proximal daily activity limitations (PDAL)	38.8% (27.0 to 50.5)	<.001
Embarrassment related to hand eczema	37.0% (23.4 to 50.5)	<.001
Frustration related to hand eczema	32.8% (17.9 to 47.7)	<.001
Impact of hand eczema on **quality of sleep**	44.3% (28.5 to 60.0)	<.001
Difficulty working due to hand eczema	39.7% (23.1 to 56.4)	<.001
Difficulties with physical functions (ie, gripping or holding objects)	44.9% (29.5 to 60.2)	<.001



Last observation carried forward was used for data after rescue, and data after discontinuation due to adverse event or lack of efficacy. Multiple imputation was used following other reasons for discontinuation and for other missing data.
CI, confidence interval; HEIS, Hand Eczema Impact Scale.

EADV CONGRESS
VIENNA
30 SEP - 3 OCT 2026

Abstract N°: 1845

Real-world use of tralokinumab in patients with atopic dermatitis involving high-burden areas: Effectiveness and impact on quality of life in the prospective, non-interventional 12-month TRACE study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by recurrent erythema, itching, and painful skin, and is associated with a negative impact on patients' quality of life (QoL). Managing AD involving high-burden areas, such as the head, neck, hands, feet, or genitals, can be challenging, with a need for long-term, effective treatment. Tralokinumab, a high-affinity monoclonal antibody that specifically neutralizes IL-13, a key driver of skin inflammation in AD, was effective and well tolerated in phase 3 trials. To date, TRACE is the largest real-world study of adults with AD treated with tralokinumab. Here, we evaluate the effectiveness of tralokinumab in patients with moderate-to-severe AD involving high-burden areas, and the corresponding improvements in QoL measures.

Materials and Methods

TRACE was a prospective, non-interventional study of adults with AD who were prescribed tralokinumab and observed for up to 12 months of treatment. Patients included in this analysis reported AD involvement at baseline of at least one high-burden area, which included the head and neck (H&N; comprising face and/or neck and/or scalp), hands and/or feet (H&F), or genitals. Patients were assigned to one of three subgroups based on whether they presented with AD involvement of one, two, or three high-burden areas at baseline.

Results

Of 824 patients enrolled in TRACE, 742 had AD involving one (n=302), two (n=349), or three (n=91) high-burden areas at baseline; the most common was H&N (n=654), followed by H&F (n=495), and genitals (n=124). One in four patients (24.5%) had previous experience with biologic treatment.

Patients with involvement of multiple high-burden areas tended to be slightly younger and had a longer AD disease duration (mean durations; 16.9, 21.7, and 21.1 years for patients with one, two, or three high-burden areas involved, respectively).

Patients with multiple high-burden areas affected at baseline were more likely to have severe AD (mean baseline Investigator Global Assessment [IGA] score=4 in 27.2%, 37.2%, and 57.1% of patients with one, two, or three high-burden areas involved, respectively) and experience a greater negative impact on QoL and sleep (mean baseline Dermatology Life Quality Index [DLQI]; 11.8, 13.6, and 15.8 for patients with one, two, or three high-burden areas involved, respectively; mean Sleep Numeric Rating Scale [Sleep-NRS]; 4.7, 5.5, and 5.6 for patients with one, two, or three high-burden areas involved, respectively).

At Month 12 of tralokinumab treatment, 71.0% (n=193) of patients with two high-burden areas involved at baseline showed improvement. Of these, 28.0% no longer reported any involvement of the high-burden areas identified at baseline, while 43.0% had reduced involvement to just one of the areas. Similarly, among patients with three high-burden areas involved at baseline, 79.2% (n=48) improved with treatment: 25.0% reported no involvement in any of the baseline high-burden areas, while 37.5% and 16.7% reduced involvement to one or two of these areas, respectively. Additionally, 43.3% (n=178) of patients with one high-burden area involved at baseline no longer reported involvement of that area after 12 months of treatment. Among patients with baseline involvement of at least one high-burden area, tralokinumab was effective overall, with mean Eczema Area and Severity Index (EASI) scores decreasing from 20.4 at baseline to 2.8 at Month 12, and a ≥4-point reduction in DLQI for 76.9% (n=130) of patients with a baseline DLQI score of at least 4.

Conclusions

Among patients with multiple high-burden areas affected at baseline, over 70% demonstrated a reduction in high-burden involvement after 12 months of treatment. These sustained improvements were closely aligned with clinically meaningful gains in QoL, underscoring the substantial and long-term patient benefit of tralokinumab in the management of difficult-to-treat AD.

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Abstract N°: 1852

Real-world characterization of early and delayed responses to tralokinumab among patients with atopic dermatitis: Results from the prospective, international, non-interventional 12-month TRACE study

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Introduction
Atopic dermatitis (AD) is a chronic, inflammatory skin condition associated with negative impacts on several aspects of patients' lives. Interleukin (IL)-13 is a key driver of skin inflammation in AD. Phase 3 trials demonstrated that tralokinumab, a monoclonal antibody specifically targeting IL-13, was effective and well tolerated, leading to its approval for patients ≥12 years of age with moderate-to-severe AD. To date, TRACE is the largest non-interventional, real-world study of tralokinumab in adults with AD. This analysis aimed to describe early and non-early responses to tralokinumab among patients with AD in a real-world setting.

Materials and Methods
TRACE was an international, non-interventional study of adults with AD who were prescribed tralokinumab and followed for up to 12 months. Assessments were conducted per local practice and reported at baseline and every 3 months. Investigator-assessed outcomes included Investigator Global Assessment (IGA) score, Eczema Area and Severity Index (EASI), and SCORing Atopic Dermatitis (SCORAD). Patient-reported outcomes (PROs) included Dermatology Life Quality Index (DLQI), peak pruritus numerical rating scale (PP-NRS), and Sleep-NRS. Improvements in DLQI and PP-NRS were measured among patients with a baseline score of ≥4 and improvements in Sleep-NRS among patients with a baseline score of ≥2. As measures of disease severity can vary between practices, a composite response was utilized, whereby patients achieving any of the following were considered composite responders: EASI ≤7, IGA 0/1, or SCORAD <10. Subpopulations examined in this analysis included early responders (achieving composite response at 3 months) and non-early responders (not achieving composite response at 3 months). Area under the response curve (AUC) was calculated for each patient with available data for Month 3 and at least one other visit. The mean proportion of time with response was the AUC divided by the total observed time interval. Data are presented as observed.

Results
A total of 824 patients were enrolled in TRACE. At Month 3, 60.7% (430/708) were composite responders, and 32.3% (229/708) had not yet achieved composite response. Baseline demographics were comparable between the

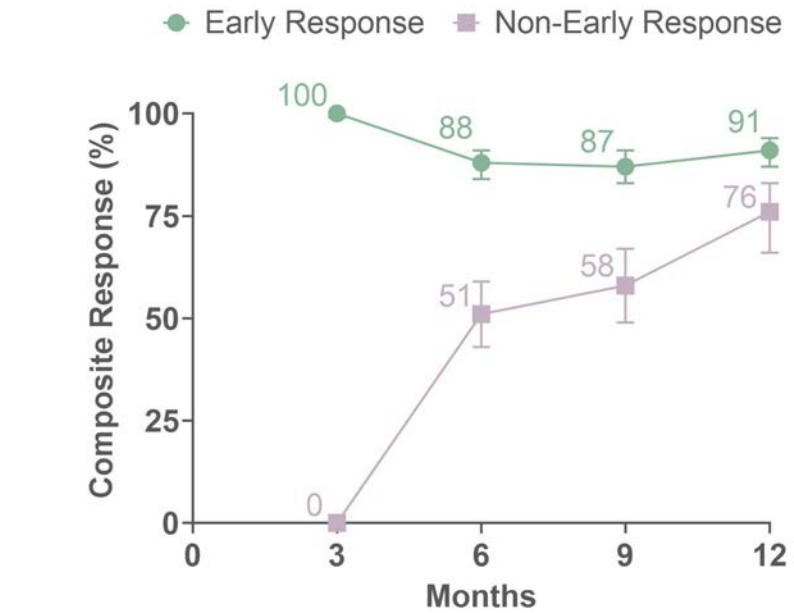
two groups. Overall, non-early responders had more severe disease at baseline (mean [SD] EASI 24.0 [10.9] vs. 18.8 [10.6]) and were more likely to be biologic-experienced (27.9%, n=229 vs. 20%, n=430) compared with early responders.

Of the 430 patients achieving early (Month 3) composite response, 91% (n=288, 95% confidence interval [CI]: 87-94) also had a composite response at Month 12 (**Figure 1**), and the observed mean (SD) time with response after Month 3 was 87.8% (22.9). Among patients who did not achieve a composite response at Month 3, composite response was met by 51% (n=162, 95% CI: 43-59) at Month 6, and 76% (n=107, 95% CI: 66-83) at Month 12. Both early and non-early responder subpopulations achieved improvements in PROs by Month 12. DLQI ≥4-point improvement was met by 76% (n=99, 95% CI: 66-84) of early responders and 81% (n=36, 95% CI: 64-92) of non-early responders, PP-NRS ≥4-point improvement by 53% (n=87, 95% CI: 42-64) of early responders and 51% (n=39, 95% CI: 35-68) of non-early responders, and Sleep-NRS ≥2-point improvement by 72% (n=68, 95% CI: 60-82) of early responders and 68% (n=25, 95% CI: 46-85) of non-early responders.

Conclusions

Overall, these results support the early and long-term effectiveness of tralokinumab for up to 12 months in a real-world setting. Of patients who demonstrated a clinical response at 3 months of treatment, over 90% also had a response at 12 months, and 76% of patients who did not meet early response criteria were able to achieve the composite response by 12 months of treatment. These findings offer valuable insights into tralokinumab responsiveness for clinicians managing patients with moderate-to-severe atopic dermatitis.

Figure 1. Proportion of patients achieving composite response who either did or did not meet response criteria at Month 3 of treatment with tralokinumab in the TRACE study



Composite response defined as meeting any of the following criteria: EASI ≤7, IGA 0/1, or SCORAD <10. Error bars represent 95% confidence intervals for each data point. Numbers adjacent to data points represent the percentage of patients meeting composite response criteria at each time point. All data as observed.

CI, confidence interval; EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; n, number of patients meeting criteria; N, number of patients with available data; SCORAD, SCORing Atopic Dermatitis.

EADV CONGRESS
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Abstract N°: 1862

Pre- and Post-Abrocitinib Treatment Journey in Patients with Atopic Dermatitis: Real-World Evidence from the DREAM TO TREAT AD (D2T AD) Consortium

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Introduction

There is limited real-world evidence on the systemic treatment journey of patients with atopic dermatitis (AD). DREAM TO TREAT AD is a European register-based study evaluating the use of abrocitinib in routine clinical practice in Denmark, Germany, the Netherlands, Belgium, and the United Kingdom.

Aim

To characterise the systemic treatment journey of AD patients before initiation of abrocitinib and subsequent treatment patterns after the first course of treatment with abrocitinib.

Materials and Methods

Prospectively collected data from A-STAR UK (UK), SCRATCH Denmark (DK), TREATgermany (GER), and the TREAT-NL/BE (NL/BE) registers from patients initiating abrocitinib were harmonised. Patient characteristics and the treatment journeys were summarised using descriptive statistics.

Results

261 abrocitinib treated patients were included (GER:89, UK: 50, NL/BE:72, DK:50). The mean (standard deviation (SD)) age varied from 31.0 (15.7) in the UK to 40.3 (13.7) in GER.

In GER, 33 % of patients were systemic-naïve. Among those previously exposed to systemic therapy, the mean number of prior systemic treatments was 1.4 (SD 1.4). In contrast, patients in the UK, DK, and NL/BE patients received a mean of 3.1, 3.2, and 3.2 systemic treatments before initiating abrocitinib (SD 1.6, 1.7, 1.8), respectively.

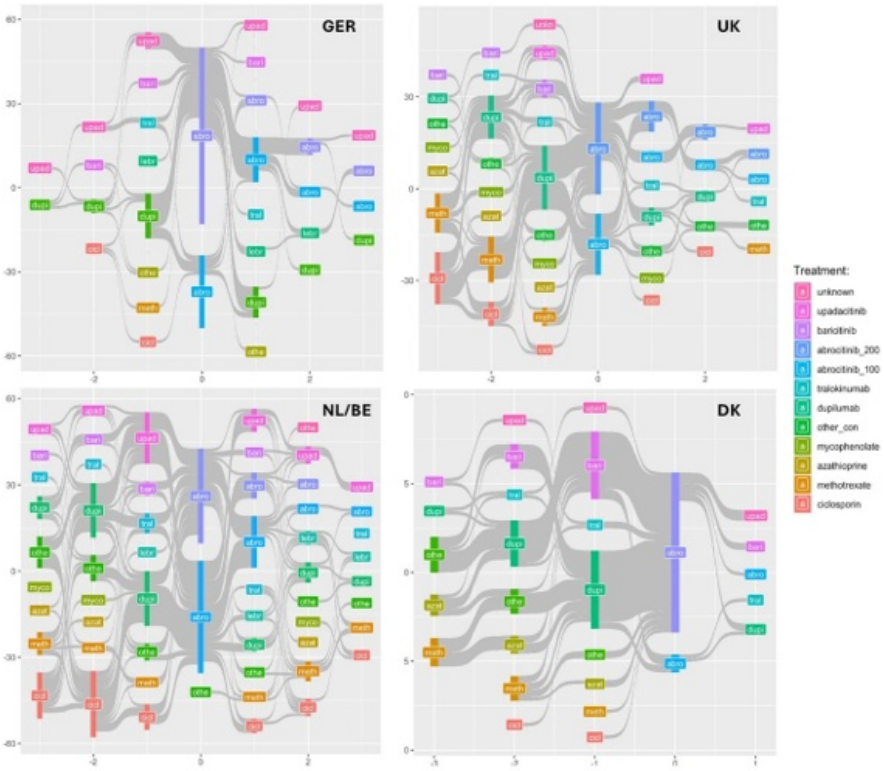
Across registers, the most commonly used 1st and 2nd line systemic medications prior to abrocitinib were dupilumab (48% and 38% respectively) and upadacitinib (18.8%; 23%) in GER, dupilumab (40%; 30%), methotrexate (12%; 33%) and baricitinib (12%; 2%) in the UK, dupilumab (28%; 28%), upadacitinib (26%; 6%), and ciclosporin (13%; 34%) in the NL/BE, and dupilumab (44%; 30%), baricitinib (38%; 16%), and methotrexate (2%; 16%) in DK (Figure 1).

Following the first course of abrocitinib, 46% of patients in GER, 60% in the UK, 80% in NL/BE and 20% in DK had treatment modifications. The most frequent subsequent treatments were another abrocitinib dose, followed by a switch of treatment to dupilumab (GER: 27%, UK: 22%, NL/BE: 9%, DK: 6%) or to upadacitinib (GER: 7%, UK: 9%, NL/BE: 14%, DK: 6%) (Figure 1). Abrocitinib dose adjustments after the first course were common in most registers (GER: 49%, UK: 52%, NL/BE: 37.5%, DK: 2%). Dose reduction from 200 mg to 100 mg occurred in 16.8% of patients in GER, 8% in the UK, 11% in NL/BE, and 2% in DK. Dose increases from 100 mg to 200 mg were recorded in 3.4% of patients in GER, 12% in the UK, 11% in NL/BE, and none in DK (Figure 1).

Conclusions

Substantial variability exists in treatment journeys prior and following abrocitinib initiation across European registers, likely reflecting the national differences in approval regulations, prescribing practices, and therapy availability.

Figure 1. Sankey diagrams illustrating treatment journeys of patients with atopic dermatitis on abrocitinib in 4 European registers (GER: TREATgermany, UK: A-STAR UK, NL/BE: TREAT-NL/BE, DK: SCRATCH Denmark).



EADV CONGRESS
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Abstract N°: 1867

Dual targeted therapy using Janus kinase inhibitors and biologics for atopic dermatitis: A systematic review

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Introduction

Atopic dermatitis is a chronic, relapsing inflammatory dermatosis characterized by epidermal barrier dysfunction and immune dysregulation, leading to pruritic lesions and significant impairment in quality of life. Dual targeted therapy combining Janus kinase inhibitors (JAKi) and biologics has emerged as a potential strategy for patients with treatment-refractory atopic dermatitis. This systematic review summarizes the evidence on the efficacy and safety of dual targeted therapy using JAKi and biologics in atopic dermatitis.

Materials and Methods

A systematic review was conducted following PRISMA guidelines (PROSPERO: CRD420261359143). MEDLINE, Embase, and CENTRAL were searched from inception to April 1, 2026. Studies reporting dual therapy with JAKi and biologics in atopic dermatitis were included. Screening and data extraction were performed independently by two reviewers. Evidence quality was assessed using the Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence.

Results

Twelve studies comprising 75 patients were included. Mean age was 31.9 years (range: 13-54), with 61.0% male. All patients had treatment-refractory atopic dermatitis, with 84.2% classified as severe among those reporting severity. The most common dual targeted therapy regimens were upadacitinib with dupilumab (37.3%), baricitinib with dupilumab (33.3%), and abrocitinib with dupilumab (16.0%). Mean follow-up was 6.5 months (range: 1.0-32.0). Clinical improvement was observed in 94.7% of patients. The greatest reductions in Peak Pruritus Numeric Rating Scale (PP-NRS) were achieved by abrocitinib with dupilumab (-87.5%; n=5; 16.0 weeks) and upadacitinib with dupilumab (-78.3%; n=10; 20.8 weeks). The greatest reductions in Patient-Oriented Eczema Measure (POEM) were achieved by upadacitinib with dupilumab (-87.5%; n=4; 16.0-weeks) and abrocitinib with dupilumab (-73.3%; n=5; 16.0-weeks). The greatest reductions in Eczema Area and Severity Index (EASI) were achieved by upadacitinib with dupilumab (-75.9%; n=7; 22.3-weeks) and abrocitinib with dupilumab (-67.5%; n=3; 30.0-weeks). The greatest proportion of patients achieving EASI75 were upadacitinib with dupilumab (100%; n=4; 16.0-weeks) and baricitinib with dupilumab (85.0%; n=7; 16.0-weeks). The greatest proportion of patients achieving ≥4 points reduction in PP-NRS were achieved by upadacitinib with dupilumab (100%; n=4; 16.0-weeks) and upadacitinib with tralokinumab (100%; n=4; 12.0-weeks). Adverse events occurred in 6.7% of patients and were predominantly mild, including nausea, acne, allergic reactions, and neutropenia. No ocular adverse events were reported. Disease recurrence following treatment cessation occurred in 5.3% of patients but resolved with re-treatment.

Conclusions

Dual targeted therapy with JAKi and biologics appears to be an effective and well-tolerated option for patients with refractory atopic dermatitis, providing substantial improvements in pruritus and disease severity. These findings support a complementary mechanistic approach targeting both intracellular JAK-STAT signaling and extracellular cytokine pathways. However, evidence is limited by small sample sizes and heterogeneity. Larger prospective studies are warranted to establish long-term safety and optimal patient selection.

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Abstract N°: 1868

A study on the blood mRNA expression of specific inflammatory cytokines in Atopic Dermatitis

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Introduction
Atopic Dermatitis (AD) is a complex and multifactorial disorder, with strong genetic susceptibility, leading to immune dysregulation due to excessive T-helper (Th) 2 activity with skin barrier dysfunction. Prolonged duration of AD results in significant skin damage and a negative impact on quality of life. Recently, AD has been found to be associated with an excessive Th17 response, characterized by the production of IL-17. This study aims to investigate the role of Th 2 and Th 17 cytokines with AD to better understand their roles in disease pathogenesis.

Materials and Methods
A total of 23 patients diagnosed to have AD based on Hanifin-Rajka criteria were included. Detailed clinical history was taken and severity determination was done using SCORing Atopic Dermatitis (SCORAD) and Eczema Area and Severity Index (EASI). Blood samples were collected for determination of mRNA expression of IL-4, IL-10, IL-17, IL-23 from both cases and controls. mRNA isolation was done by Trizol method and subjected to RTPCR. Cytokine expression was assessed and relative expression of mRNA levels of cytokine genes was determined.

Results
IL-4, IL-17, and IL-23 mRNA expression was elevated in AD patients compared to healthy controls, whereas IL-10 mRNA expression was reduced in AD patients.

Conclusions
The complex pathogenesis of AD is not just limited to TH 1/TH 2 axis, but also involves TH 17 axis (IL-17 & IL-23). IL-10 levels are generally elevated in AD; but highly symptomatic patients could have reduced IL-10 expression by allergen- specific CD4+ T cells. Hence topical and systemic drugs targeting IL-17 in addition to IL4 may be beneficial in AD.

EA DV CONGRESS
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Abstract N°: 1876

Integrated Safety Analysis of Abrocitinib in 3850 Patients With Moderate-to-Severe Atopic Dermatitis: Final Data From More Than >9600 Patient-Years With Up to 6.5 Years of Exposure

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease that may require long-term treatment to maintain disease control. Treatment with the oral, once-daily, Janus kinase 1–selective inhibitor abrocitinib demonstrated efficacy through 112 weeks in patients (pts) with moderate-to-severe AD. Previous integrated safety analyses evaluated select adverse events of special interest (AESIs) by age (18 to <65 years [y] and ≥65 y) and smoking status in 3848 pts, including data from >7000 pt-y (PYs) with up to 4.5 y of abrocitinib exposure. The current final readout of the updated integrated safety analysis extends follow-up to 6.5 y of abrocitinib exposure using refined baseline age categories and cardiovascular risk factors in 3850 pts, including data from >9600 PYs.

Materials and Methods

Analysis included pts from eight phase 2 and 3 parent trials (phase 2b [NCT02780167], JADE MONO-1 [NCT03349060], MONO-2 [NCT03575871], REGIMEN [NCT03627767], COMPARE [NCT03720470], TEEN [NCT03796676], MOA [NCT03915496], and DARE [NCT04345367]) and 1 long-term extension trial (JADE EXTEND [NCT03422822]; completed: January 2026) in the JADE clinical program. Incidence rates (IRs; number of pts with events/100 PYs) of AESIs were assessed in pts by age category (including <18 y, 18 to <40 y, 40 to <50 y, 50 to <65 y, and ≥65 y).

Results

Of 3850 pts in the pooled safety population, 3052 received the same abrocitinib dose throughout (consistent-dose cohort, described herein [**Table**]) and 798 pts comprised the variable-dose cohort; both cohorts represent a

total of 9634.1 PYs of abrocitinib exposure. Mean age of the consistent-dose cohort was 33.5 y; 5% of pts were aged ≥65 y and 1% were ≥75 y. IRs per 100 PYs (95% CI) in the consistent-dose cohort were numerically higher in older versus younger pts for major adverse cardiovascular events (MACEs; <18 y: 0.07 [0.00-0.42]; 18 to <40 y: 0.14 [0.04-0.32]; 40 to <50 y: 0.09 [0.00-0.51]; 50 to <65 y: 0.80 [0.32-1.64]; and ≥65 y: 2.03 [0.74-4.41]) and death (<18 y: 0.00 [0.00-0.28]; 18 to <40 y: 0.05 [0.01-0.20]; 40 to <50 y: 0.09 [0.00-0.51]; 50 to <65 y: 0.34 [0.07-0.99]; and ≥65 y: 2.08 [0.67-4.48]). Similar trends were observed for other AESIs, including serious infections, herpes zoster, malignancies (excluding nonmelanoma skin cancer [NMSC]), NMSC, deep vein thrombosis, and venous thromboembolism. Data from the variable-dose cohort generally showed similar trends.

Conclusions

This final long-term abrocitinib integrated safety analysis with >9600 PYs of exposure in 3850 pts with moderate-to-severe AD demonstrates consistently low rates of AESIs through up to 6.5 years of abrocitinib treatment. Rates of AESIs in pts treated with abrocitinib generally reflected those observed in real-world studies in pts with AD and are consistent with previously reported integrated safety data cuts, supporting the established benefit-risk profile of abrocitinib for moderate-to-severe AD. IRs tended to be higher in older pts; age is a known risk factor for the AESIs included in this analysis. No new safety signals were identified.

Table. Summary of AEs and AESIs in the Consistent-Dose Cohort

AEs, IR (95% CI)[a]	Abrocitinib 100 mg QD (n=1053) (PYs=2562.3)	Abrocitinib 200 mg QD (n=1999) (PYs=4497.2)	All Abrocitinib (N=3052) (PYs=7059.5)
All AEs	142.32 (132.99-152.12)	214.15 (204.26-224.40)	183.58 (176.62-190.74)
SAEs	5.65 (4.75-6.67)	6.30 (5.58-7.09)	6.07 (5.50-6.68)
Death	0.11 (0.02-0.33)	0.19 (0.09-0.37)	0.16 (0.09-0.29)
Severe AEs	5.40 (4.53-6.39)	5.63 (4.95-6.38)	5.55 (5.00-6.13)
TEAE resulting in permanent discontinuation	6.43 (5.49-7.48)	8.22 (7.41-9.10)	7.57 (6.95-8.24)
Infections			
Serious infections	2.00 (1.50-2.63)	2.17 (1.77-2.65)	2.11 (1.79-2.48)
Herpes zoster	2.50 (1.92-3.20)	4.15 (3.57-4.81)	3.55 (3.11-4.02)
Herpes simplex	3.68 (2.95-4.52)	5.34 (4.66-6.08)	4.73 (4.22-5.28)
Tuberculosis	0.00 (0.00-0.14)	0.06 (0.01-0.19)	0.04 (0.01-0.12)
Malignancies			
Adjudicated malignancies	0.46 (0.24-0.80)	0.47 (0.30-0.72)	0.47 (0.32-0.65)
Adjudicated malignancies (excluding NMSC)	0.23 (0.08-0.49)	0.39 (0.23-0.61)	0.33 (0.21-0.49)
NMSC	0.23 (0.08-0.50)	0.09 (0.02-0.22)	0.14 (0.07-0.25)
Cardiovascular events			
MACE	0.27 (0.11-0.55)	0.28 (0.15-0.48)	0.27 (0.17-0.42)
Pulmonary embolism	0.11 (0.02-0.33)	0.22 (0.10-0.40)	0.18 (0.09-0.30)
Deep vein thrombosis	0.11 (0.02-0.33)	0.04 (0.01-0.16)	0.07 (0.02-0.16)
Hematologic events			
Thrombocytopenia[b]	0.04 (0.00-0.14)	0.24 (0.12-0.42)	0.16 (0.09-0.29)
Lymphopenia[c]	0.04 (0.00-0.21)	0.34 (0.20-0.56)	0.23 (0.14-0.37)
Neutropenia[d]	0.00 (0.00-0.14)	0.02 (0.00-0.12)	0.01 (0.00-0.08)

AE, adverse event; AESI, adverse event of special interest; CI, confidence interval; IR, incidence rate; MACE, major adverse cardiovascular event; NMSC, nonmelanoma skin cancer; PY, patient-year; QD, once daily; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

[a] IRs are defined as the number of patients with an AE per 100 PYs.

[b] Platelet count of $<75\times10^3/\mu L$.

[c] Lymphocyte count of $<0.5\times10^3/\mu L$.

[d] Neutrophil count of $<1.0\times10^3/\mu L$.

EADV CONGRESS
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30 SEP - 3 OCT 2026

Abstract N°: 1904

Effectiveness and Safety of Tralokinumab in Korean Patients with Atopic Dermatitis: A Multicenter Retrospective Study

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease that significantly impairs patients' quality of life. Tralokinumab, a selective interleukin-13 (IL-13) inhibitor, has demonstrated efficacy and safety in clinical trials; however, real-world data (RWD) in Korean patients remain limited. This study aimed to evaluate the effectiveness and safety of tralokinumab in Korean patients with moderate-to-severe AD in a real-world clinical setting, with a particular focus on head and neck involvement.

Materials and Methods
This multicenter retrospective study included patients aged≥12 years with AD who received tralokinumab at three hospitals in Korea. Clinical outcomes were assessed at baseline, week 16, and week 48 using the Eczema Area and Severity Index (EASI) and Investigator's Global Assessment (IGA). Head and neck involvement was evaluated using Head and Neck EASI (H&N EASI).

Results
A total of 46 patients were included. Mean baseline EASI was 25.59± 7.08. At week 16, 67.4%, 65.2%, 13.0%, and 10.9% of patients achieved EASI-50, EASI-75, EASI-90, and IGA 0/1, respectively. At week 48, response rates were sustained, with 60.9%, 58.7%, 21.7%, and 28.3% achieving EASI-50, EASI-75, EASI-90, and IGA 0/1, respectively. For head and neck lesions, H&N EASI-75 was achieved in 23.9% at week 16 and 39.1% at week 48, indicating overall improvement, although responses were lower compared to other body regions. Adverse events were reported in 34.8% of patients, with AD exacerbation being the most common.

Conclusions
Tralokinumab demonstrated sustained effectiveness and an acceptable safety profile in Korean patients with moderate-to-severe AD in a real-world setting.

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Abstract N°: 1949

Determination of a head and neck response criterion as an optimal treatment target for patients with atopic dermatitis with head and neck involvement

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Introduction

Atopic dermatitis that involves the head and neck region (H&N AD) is particularly burdensome due to its high visibility and is associated with impaired quality of life (1). H&N AD can be more challenging to treat than other affected body areas. Tralokinumab, a high-affinity, fully human IgG4 monoclonal antibody that neutralizes interleukin-13, has demonstrated effectiveness in treating H&N AD in both clinical trials and real-world studies (2). No defined optimal treatment target exists to guide health care professionals in treating patients with H&N AD. Here, a clinically relevant response criterion for Eczema Area and Severity Index (EASI) H&N score is determined in a cohort of tralokinumab-treated patients, which can serve as a meaningful treatment target for patients with H&N AD.

Materials and Methods

This *post hoc* analysis includes as-observed data from 252 adult patients with moderate-to-severe AD enrolled in the Phase 3 study ECZTRA 3 (E3) (3) who received tralokinumab therapy for 32 weeks, 188 of whom continued treatment in the open-label extension study ECZTEND (4) for up to136 weeks. H&N AD was assessed using the EASI H&N score (range 0–7.2), an area-specific sub score of whole-body EASI. In the absence of an area-specific measure, the validated Investigator's Global Assessment (IGA) score was used as a comparator to EASI H&N score.

At the time point with the highest correlation between IGA and EASI H&N scores in E3 (Week 32), patients were categorized by IGA score as either responders (IGA 0/1) or non-responders (IGA>1). Patients were then categorized per the following potential EASI H&N response criteria: 0.5, 0.75, 1.0, 1.25, 1.5, 1.75, and 2.0. A 2x2 table was constructed for each EASI H&N response criteria, and the positive predictive value (PPV) of EASI H&N response vs. IGA 0/1 response was calculated to determine a meaningful response criterion for EASI H&N score (5). The response criterion was further supported by evaluating Dermatology Life Quality Index (DLQI) 0/1 response per timepoint by Fisher's exact test with an α=0.05.

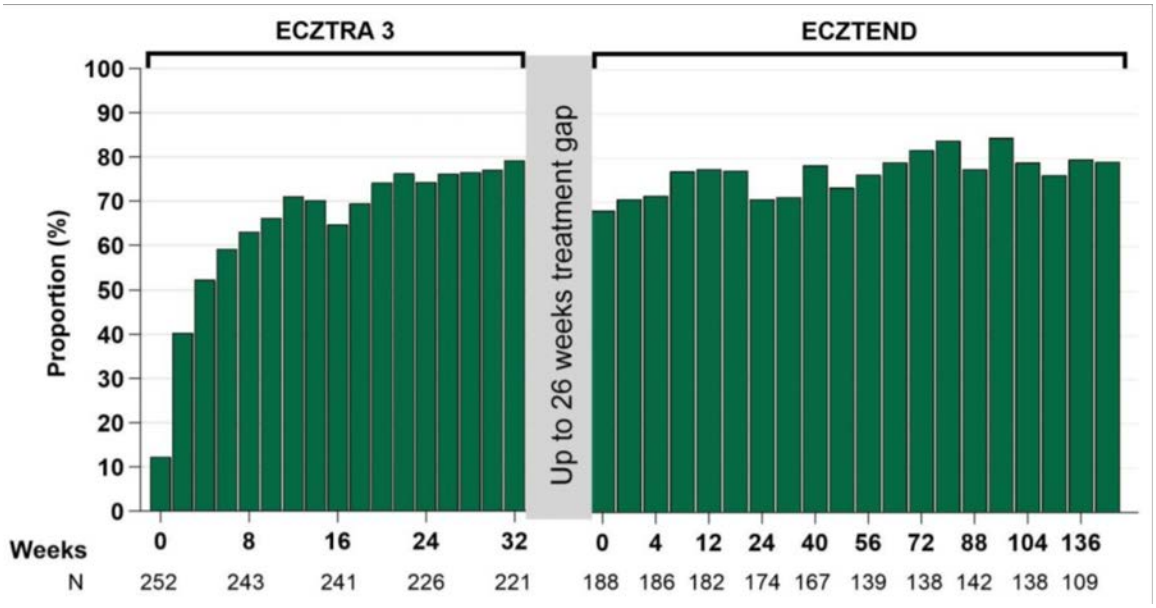
Results

At E3 baseline the mean age was 39.8 (SD±15.33) years, mean duration of AD was 27.9 (SD±16.41) years, and mean EASI H&N score was 2.8 (SD±1.54).

PPVs for EASI H&N response criteria formed two distinct groups: 60.0–65.2% for EASI H&N 2.00–1.00, and 73.0–77.1% for EASI H&N 0.75–0.50. As the largest difference between calculated PPVs was observed for H&N EASI scores between 0.75 and ≤1, an EASI H&N score <1 was selected as the best threshold for a meaningful response criterion while balancing simplicity of application and communicating an absolute target to patients.

Proportions of patients with EASI H&N <1 increased from 12% at baseline to 71% at Week 12, and 80% at Week 32 in E3 (Fig. 1). In ECZTEND, proportions of patients with EASI H&N <1 ranged from 68–96%. The proportion of patients with EASI H&N <1 who also had a DLQI score of 0/1 (constituting minimal disease activity) increased from 0% at baseline to 33% at Week 16, remained stable during E3, and increased further during ECZTEND to ~40–50%. Proportions of patients with DLQI 0/1 were significantly higher for those with EASI H&N <1 vs. those with EASI H&N ≥1 at most timepoints, with a difference ranging from 4–28% during E3 and 20–37% during ECZTEND.

Figure 1: Proportion of patients with EASI H&N score <1 in ECZTRA 3 and ECZTEND



Conclusions

An EASI H&N score <1 was determined to be a meaningful response criterion, with clinical relevance supported by significant differences in quality of life in those achieving EASI H&N <1 compared with those with EASI H&N ≥1. An EASI H&N <1 response criterion may serve as an optimal treatment target in AD patients with H&N involvement.

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Abstract N°: 1951

Health-Related Quality of Life and work productivity improvements with topical delgocitinib vs oral alitretinoin in Chronic Hand Eczema: phase 3 DELTA FORCE results

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Introduction

Chronic Hand Eczema (CHE) can significantly impact patients' Health-Related Quality of Life (HRQoL). In the 24-week phase 3 head-to-head DELTA FORCE trial (NCT05259722), topical delgocitinib cream demonstrated superior efficacy and a more favourable safety profile compared with oral alitretinoin in patients with moderate to severe CHE. Here, we report on HRQoL, work productivity, and daily activity impairment outcomes from DELTA FORCE.

Materials and Methods

Patients were randomly assigned to receive either topical delgocitinib cream 20 mg/g or oral alitretinoin. The Hand Eczema Impact Scale (HEIS), Dermatology Life Quality Index (DLQI), EuroQol-5 Dimensions-5 Levels (EQ-5D-5L), and Work Productivity and Activity Impairment (WPAI) scores were assessed through Week 24. Least squares mean changes and between-group differences in treatment groups were reported.

Results

Patient characteristics were well balanced between the delgocitinib (n=250) and alitretinoin (n=253) arms. Mean (standard deviation [SD]) baseline scores of HEIS, DLQI, EQ-5D-5L, work productivity loss, and daily activity impairment in the delgocitinib arm were 2.40 (0.81), 12.70 (6.35), 0.67 (0.23), 41.06 (28.58), and 49.50 (26.20), respectively (Table 1). Mean (SD) baseline scores of HEIS, DLQI EQ-5D-5L work productivity loss, and daily activity impairment in the alitretinoin arm were 2.51 (0.76), 12.90 (6.07), 0.63 (0.26), 43.13 (28.49), and 51.70 (25.24), respectively (Table 1).

At week 24, least squares mean (standard error [SE]) improvements were greater for delgocitinib compared with alitretinoin for HEIS (-1.29 [0.09] vs -0.79 [0.09]; difference of -0.50 [95% CI: -0.70, -0.30], p<0.001), DLQI (-7.10 [0.54] vs -4.6 [0.54]; difference of -2.50 [95% CI: -3.69, -1.38], p<0.001), EQ-5D-5L (0.17 [0.02] vs 0.10 [0.02]; difference of 0.07 [95% CI: 0.03, 0.10], p<0.001), work productivity loss (-13.48 [2.35] vs -7.85 [2.36]; difference of -5.63 [95% CI: -10.80, -0.46], p=0.033), and daily activity impairment
(-23.80 [2.49] vs -15.10 [2.49]; difference of -8.70 [95% CI: -14.13, -3.30], p=0.002) (Table 1).

Table 1 Changes in EQ-5D-5L, DLQI, HEIS, and WPAI scores from baseline to Week 24 in patients with moderate to severe CHE enrolled in the DELTA FORCE trial, treated with topical delgocitinib cream or oral alitretinoin, and between-treatment differences in change from baseline at Week 24 (Δ change).

Outcome	Baseline		Week 24		
	Reported value *mean (SD)*		Change from baseline *mean (SE)*		Δ change[a] LS Mean (95% CI)
	Delgocitinib	Alitretinoin	Delgocitinib	Alitretinoin	
EQ-5D-5L	0.67 (0.23)	0.63 (0.26)	0.17 (0.02)	0.10 (0.02)	0.07 (0.03, 0.10)[b]
DLQI	12.70 (6.35)	12.90 (6.07)	-7.10 (0.54)	-4.60 (0.54)	-2.50 (-3.69, -1.38)[b]
HEIS	2.40 (0.81)	2.51 (0.76)	-1.29 (0.09)	-0.79 (0.09)	-0.50 (-0.70, -0.30)[b]
WPAI					
Work productivity loss	41.06 (28.51)	43.13 (28.49)	-13.48 (2.35)	-7.85 (2.36)	-5.63 (-10.80, -0.46)[c]
Daily activity impairment	49.50 (26.20)	51.70 (25.24)	-23.80 (2.49)	-15.10 (2.49)	-8.70 (-14.13, -3.30)[d]

CI: confidence interval; DLQI: Dermatology Life Quality Index, EQ-5D-5L: EuroQol-5 Dimensions-5 Levels; HEIS: Hand Eczema Index Impact Scale; LS: Least squares; SD: standard deviation; SE: standard error; WPAI: Work Productivity and Activity Impairment.
Note: [a] Between-treatment difference in change from baseline at Week 24 (delgocitinib cream vs oral alitretinoin); [b] $p<0.001$; [c] $p=0.033$; [d] $p=0.002$.

Conclusions

In DELTA FORCE, topical delgocitinib cream showed superior improvements in HRQoL compared with oral alitretinoin. Furthermore, work productivity and daily activity impairment improved to a larger extent. These findings indicate that delgocitinib cream may serve as a valuable topical treatment option for patients with moderate to severe CHE in routine care, prior to the need for systemic therapy.

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Abstract N°: 1960

Signals of Phenotypic Differences of Atopic Dermatitis Stratified by Age in a Danish Cohort from the General Population

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Introduction

Background

Atopic dermatitis (AD) is chronic inflammatory skin disorder present across all ages(1). Understanding clinical phenotypes according to age may guide AD treatment choice in personalized medicine. Previous literature was primarily hospital-based(2)

Objective

Investigating AD phenotypic differences according to age categories in adults from the general population.

Materials and Methods

This analysis was based on data from patients with AD, who were part of a larger 12-months observational cohort study of patients with AD, psoriasis, alopecia areata or vitiligo. (ct.govNCT06319781). AD participants were recruited from the general population via social media, and eligible if >18 years and physician-verified AD diagnosis. Data collected included demographics and AD severity score using the Eczema Area and Severity Index (EASI) system. EASI is a tool, ranging from 0 to 72, used to measure the extent and severity of atopic eczema. It evaluates four body regions—head/neck, trunk, upper and lower extremities by assessing the percentage of skin affected and the intensity of the four morphology entities erythema, edema/papulation, excoriation, and lichenification.

For this analysis, participants were stratified according to three age definitions: A) age at baseline: young adults (18–30 years), intermediate adults (>30–40 years), older adults (>40–60 years), and senior adults (>60 years); B) age of AD onset: pediatric-onset (≤12 years), teen-onset (>12–18 years), adult-onset (>18–60 years), and geriatric-onset (>60 years); and C) lifetime duration of AD: ≤30 years or >30 years.

Statistical analyses were performed using R version 4.4.1.

Results

A total of 56 AD participants were included. The mean age was 39.35 years, and 75% were female (Table 1).

A) Phenotypes by 'Age at baseline':
Location: the most common AD sites were upper extremities (85.7%) in young adults and intermediate adults (86.7%), the head-neck region and upper extremities in older adults (69.6%) and the head-neck region fin senior adults (100%) (Figure 1B). Compared with young adults, older age groups showed a tendency towards more frequent head-neck and trunk involvement, whereas upper extremity involvement was less frequent in older and senior adults.
Morphology and extend: the mean EASI was lowest for the younger adults (1.89 (SD 1.99) vs 5.47(SD 8.90), 4.68(SD 7.42), 5.42(SD 6.74) for intermediate, older and senior adults, respectively.

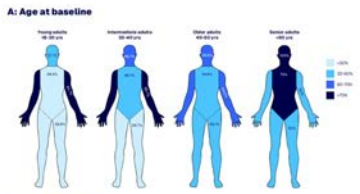
B) Phenotypes by 'Age of AD onset':
Location: the most common site of current AD were upper extremities (89.2%) for pediatric-onset AD, head-neck (71.4%) for teen-onset AD, head-neck (75% for adult-onset AD, and head-neck (100%) and upper extremities (100%) for geriatric onset AD (Figure 1A). Compared with pediatric-onset AD, teen-onset, adult-onset and geriatric-onset AD showed a tendency towards more frequent head-neck involvement.
Morphology and extend: The mean EASI was highest for the pediatric-onset age group (EASI 4.49 (SD 6.69) vs. 2.40 (SD 2.69), 2.02 (SD 1.17) and 2.45 (2.76)) for teen-onset, adult-onset, and geriatric-onset, respectively.

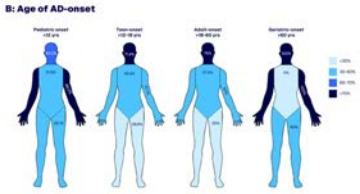
C) Phenotypes by 'duration of AD':
Location: Most common sites of AD in the group with the longest lifetime duration of AD (>30 yrs) were upper extremities (84.6%) and head-neck (73.1%)(Figure 1C).
Morphology and extend: The group with the longest lifetime duration (>30 yrs) was characterized by a higher percentage with all four body regions affected (7.1 % vs 26.9 %), and a higher mean EASI (5.75 (SD 7.62) vs. 1.95 (SD 1.77)).

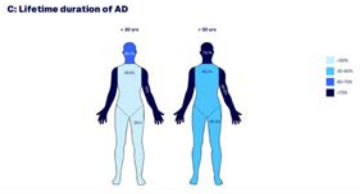
Table 1. Baseline characteristics

	Participants with atopic dermatitis (N=56)
Sex	
n (%)	56 (100.0%)
Female	42 (75.0%)
Male	14 (25.0%)
Age at baseline	
n (%)	56 (100.0%)
Mean (SD)	39.35 (13.08)
Median (Q1, Q3)	38.28 (29.52, 47.99)
Min - Max	18.44 - 73.91
Age at time of diagnosis	
n (%)	54 (96.4%)
Mean (SD)	11.68 (18.68)
Median (Q1, Q3)	2.25 (0.00, 15.35)
Min - Max	0.00 - 73.91
Disease duration (years since diagnosis)	
n (%)	54 (96.4%)
Mean (SD)	27.88 (16.03)
Median (Q1, Q3)	29.26 (14.46, 39.97)
Min - Max	0.00 - 61.60
Fitzpatrick skintype	
n (%)	56 (100.0%)
I	4 (7.1%)
II	16 (28.6%)
III	26 (46.4%)
IV	9 (16.1%)
V	1 (1.8%)
AD Severity	
EASI	
Mean (SD)	4.25 (6.90)
Median (Q1, Q3)	1.70 (0.60, 4.03)
Min - Max	0.00 - 33.60
EASI disease severity	
1. Mild AD: EASI<=7	47 (83.9%)
2. Moderate AD: EASI 7.1 - <=21	7 (12.5%)
3. Severe AD: EASI>=21.1	2 (3.6%)
Comorbidities	
Hay fever	
No	35 (62.5%)
Yes	21 (37.5%)
Asthma	
No	41 (73.2%)
Yes	15 (26.8%)
Other allergies	
No	55 (98.2%)
Yes	1 (1.8%)
AGE DEFINITION A,B,C	
A: Age at baseline	
n (%)	56 (100.0%)
1. Young adults: Age at baseline: 18-30 years	14 (25.0%)
2. Intermediate adults: Age at baseline: >30-40 years	15 (26.8%)
3. Older adults: Age at baseline: >40-60 years	23 (41.1%)
4. Senior adults: Age at baseline: >60 years	4 (7.1%)
B: Age of AD-onset	
n (%)	54 (96.4%)
1. Pediatric-onset: Age at time of diagnosis: <=12 years	37 (68.5%)
2. Tween/teen-onset: Age at time of diagnosis: >12-18 years	7 (13.0%)
3. Adult-onset: Age at time of diagnosis: >18-60 years	8 (14.8%)
4. Geriatric-onset: Age at time of diagnosis: >60 years	2 (3.7%)
C: Lifetime AD duration (years since diagnosis)	
n (%)	54 (96.4%)
1. AD duration <= 30 years	28 (51.9%)
2. AD duration > 30 years	26 (48.1%)

Figure 1A-C. Distribution of AD lesions in participants according to age categories.
The given % represent the percentages of participants, who have AD lesions in either of the four illustrated body regions 1) Head and neck, 2) Trunk, 3) Upper extremities, 4) Lower extremities. E.g. 85.7% of participants, who belong to the age category of young adults (18-30 yrs) at baseline, have AD lesions on upper extremities. The 85.7% accounts for total upper extremities (both arms in total). E.g. 71.4% of participants, who had teen-onset AD (>12-18 yrs), have AD lesions in the head and neck area in present time at baseline. Color scale illustrates percentage-categories of participants affected in either of the four above body regions.







Conclusions
In this population-based adult cohort, age-related differences in lesion distribution, morphology and extend were observed, but these findings should be interpreted cautiously given the small subgroup sizes. Larger studies are needed to confirm whether distinct age-related AD phenotypes exist.

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Abstract N°: 1967

Are we only scratching the surface of the Week 8 to 12 Flare?

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Introduction

Atopic dermatitis (AD) and Nodular prurigo (NP) are chronic inflammatory dermatoses characterised by intense pruritus, recurrent flares, and detrimental impacts on quality of life. Nemolizumab, a monoclonal antibody targeting interleukin-31 receptor α-chain (IL-31RA), presents a novel therapeutic option demonstrating significant reductions in pruritus and disease severity in AD and NP.[1] In clinical practice, certain patients develop a generalised exfoliative dermatitis between week 8 to 12 of treatment. We aim to characterise this observation and explore potential factors contributing to this flare.[2]

Materials and Methods

A prospective cohort of 26 patients (aged 24–78 years) (13 Males and 13 females) were included. Three patients had co-existing NP and one patient with a lichenoid drug reaction were commenced on Nemolizumab. All patients had received phototherapy and one systemic agent prior to inclusion. Three patients with AD were bio-naïve, ten patients had failed at least 1 biologic treatment or Janus Kinase (JAK) inhibitor, two patients had failed three JAK inhibitors as well as three biologic treatments prior to commencing Nemolizumab. Baseline Dermatology Life Quality Index (DLQI), Eczema Area Severity Index (EASI) and Peak Pruritus Numeric Rating Scale (PP-NRS) were recorded for patients. At week 16, the same measures were collected for comparison.

Results

Among the 26 patients, baseline DLQI ranged from 5-27; EASI ranged from 21-54.6; PP-NRS 4-10. The mean reduction in PP-NRS was 6.0 points. 91% of patients achieved a clinically meaningful ≥4-point reduction in itch. Improvements in erythema, oedema, lichenification, excoriation, area involvement were observed in approximately 64% of patients demonstrating improvements in EASI. Reductions in DLQI ranged from 5 to 18 points, while reductions in EASI ranged from 2.4 to 53.8.

Despite concomitant treatment with moderately potent topical corticosteroids/ topical cortico-immunomodulators, 7/26 patients developed exfoliative dermatitis between week 8 to 12, with PP-NRS ranging from 0-5, DLQI 6-26 and EASI 1.6-16.6. This included 2 patients who had received prior treatment with 3 biologics and 3 JAKi had sub-erythrodermic dermatitis, 2 patients had prior systemic therapy, the remainder had prior Biologics. The patients required a rescue tapering course of oral steroids +/- Delgotcitinib topically.

Conclusions

Within the cohort of 26 patients commencing nemolizumab, 91% achieved rapid improvements in pruritus with 64% achieving meaningful improvement in AD. Transient skin flares were observed in approximately one-third of patients between week 8 to 12, presenting as suberythrodermic exfoliative dermatitis. Despite the exfoliative flare that happened in 27% of patients treated, all patients who flared showed clinically meaningful improvement in their PP-NRS. The findings highlight the efficacy and tolerability of nemolizumab, while also drawing attention to a week 8 to 12 flare phenomenon and subsequent management. Further work is required to identify the cohort of patients at risk of generalised exfoliative dermatitis to optimise patient management.

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Abstract N°: 1975

One year efficacy and safety findings for pediatric and adolescent patients with moderate-to-severe atopic dermatitis receiving dupilumab in the Canadian phase IV prospective, observational study (CANDID).

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Introduction
Currently, limited data are available on long-term use of dupilumab in patients with moderate-to-severe atopic dermatitis (AD) in a Canadian real-world setting. The aim of this analysis was to report 1 year (12-month) effectiveness and safety data for pediatric and adolescent patients with moderate-to-severe AD receiving dupilumab as part of the CANDID study (phase 4 AD dupilumab Canada study).

Materials and Methods
CANDID (NCT06099704) is an ongoing, 18-month, long term, prospective, observational study of adults/adolescents/children (aged ≥ 6 years at baseline) with moderate-to-severe AD who initiated dupilumab in real-world settings according to Canadian-specific prescribing guidelines. Effectiveness outcomes evaluated at baseline and months 3, 6, 12, and 18 included scores for 75% improvement in Eczema Area and Severity Index (EASI-75), body surface area (BSA) involvement, Children's Dermatology Life Quality Index (CDLQI), Hospital Anxiety and Depression Scale (HADS), Sleep Disturbance Numerical Rating Scale (SD NRS), and Peak Pruritus Numeric Rating Scale (PP NRS). Safety events were collected from the time of signed informed consent.

Results
One year (12-month) data were obtained from 50 pediatric and adolescent patients (aged 6-17 years) enrolled into the CANDID study. After dupilumab initiation, mean improvements in effectiveness outcome measures from

baseline to month 12 were 85% for EASI-75 (from 23.5 to 3.6), 82% for BSA (from 33.5% to 6.0%), 65% for CDLQI (from 14.4 to 5.1), 40% for HADS (from 14.1 to 8.4), 70% for SD NRS (from 6.1 to 1.8), and 59% for peak pruritus NRS (from 7.8 to 3.2). No new safety concerns were identified at 12 months.

Conclusions

In a Canadian real-world setting, dupilumab demonstrated robust and sustained long-term effectiveness in pediatric and adolescent patients with moderate-to-severe AD across multiple disease domains, including AD signs, symptoms, and quality of life. Safety was consistent with the known dupilumab safety profile.

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Abstract N°: 2007

Children's atopic dermatitis significantly impairs parental quality of life: Severity matters

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Introduction
Atopic dermatitis (AD) is a common chronic inflammatory skin disease in children that significantly impairs the quality of life (QoL) of the entire family. This study aimed to assess the impact of pediatric AD on parental QoL and to analyze its correlation with disease severity assessed using the SCORAD (SCOring Atopic Dermatitis) index.

Materials and Methods
This prospective, analytical, cross-sectional, single-center study was conducted between January and October 2025. Children aged 2 months to 17 years with atopic dermatitis (AD) were included. Parental quality of life was assessed using the Family Dermatology Life Quality Index (FDLQI), translated into a local dialect, and administered to both parents after obtaining informed consent. Collected data included age, sex, disease duration, and AD severity according to the SCORAD index. Correlations were analyzed using Spearman's correlation coefficient.

Results
A total of 96 children were included (mean age: 2 years), along with 96 mothers and 90 fathers. The mean disease duration was 12 months. The mean SCORAD score was 31, with 37.5% mild, 27.1% moderate, and 35.4% severe forms. The mean parental FDLQI score was 7.5, indicating a moderate impact on QoL, with an extremely large impact observed in 4.2% of parents. FDLQI scores were significantly higher among mothers than fathers (10 vs. 5; $p < 0.01$). A strong positive correlation was found between parental FDLQI and SCORAD scores (rho = 0.939; $p < 0.01$), with no significant correlation with children's age or disease duration.

Conclusions
Childhood atopic dermatitis has a major impact on parental quality of life, proportional to disease severity.These findings highlight the need for a comprehensive, family-centered management approach. Beyond controlling skin lesions, particular attention should be given to parental burden through therapeutic education, psychological support, and individualized support strategies adapted to each parent's role.

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Abstract N°: 2017

Clinical Efficacy and Longitudinal Scalp Microbiome Changes Induced by an Ampamide-Containing Shampoo in Patients with Seborrheic Dermatitis

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Introduction
Seborrheic dermatitis (SD) is a chronic inflammatory dermatosis of scalp, associated with *Malassezia* dysbiosis and increased sebum production. Although AMPamide has emerged as a potential therapeutic agent due to its anti-inflammatory and sebum-regulating effects, its real-world clinical efficacy and its impact on the scalp microenvironment remain to be established. Therefore, this study aimed to investigate the clinical efficacy and longitudinal changes in the scalp microbiome following the application of an AMPamide-containing shampoo in patients with SD.

Materials and Methods
In this four- week observational study, 30 patients with SD were enrolled. The patients utilized an AMPamide-containing shampoo as their primary scalp treatment. Clinical efficacy was quantified through sebum measurement and standardized severity scales. To evaluate microbial shifts, bacterial and fungal communities were sequenced, with comparative analysis performed on α- and β-diversity and specific *Malassezia* distribution.

Results
At the end of the four-week period, a statistically significant decline in sebum levels and clinical scores was observed, particularly concerning erythema, scaling, and pruritus. Microbiome analysis revealed that while bacterial architecture remained largely unchanged, fungal α-diversity improved significantly. Notably, β-diversity analysis indicated a therapeutic recalibration of the fungal community, highlighted by a reduction in the *M. restricta to M. globosa* ratio.

Conclusions
AMPamide-containing shampoo effectively mitigates SD symptoms while promoting the restoration of fungal homeostasis. These results highlight its potential as a promising non-steroidal option for stabilizing the scalp microbiome and managing chronic seborrheic dermatitis.

Keywords: AMPamide, Bacteria, Fungus, Microbiota, Seborrheic Dermatitis

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Abstract N°: 2052

Effect of CFTR-Regulated Th17 Cell Activation on the Skin Barrier in Atopic Dermatitis

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Introduction
To investigate whether cystic fibrosis transmembrane conductance regulator (CFTR) affects the skin barrier function and inflammatory process of atopic dermatitis (AD) by regulating Th17 cell activation.

Materials and Methods
The AD model of Balb/c mice was established by applying calcipotriol on the back and randomly divided into control group, model group, CFTR knockdown group, CFTR overexpression group and hydrocortisone intervention group. The severity of the disease was evaluated by dermatitis score and ear swelling degree; H&E staining, Masson staining and transmission electron microscopy were used to observe the skin histopathology and ultrastructure; The proportion of Th17 and Treg cells in peripheral blood was detected by flow cytometry; The expression of CFTR protein in skin tissue was detected by RT-qPCR and Western blot. The effects of CFTR on cell proliferation, apoptosis, cell cycle, collagen synthesis and IL-17 secretion were analyzed.

Results
Compared with the control group, the dermatitis score and ear swelling degree of AD model group were significantly increased, and the skin showed pathological changes such as epidermal hyperplasia, inflammatory cell infiltration, increased collagen deposition, structural disorder of stratum corneum and desmosomes reduction, while the proportion of Th17 cells in peripheral blood was increased and the proportion of Treg cells was decreased. CFTR knockdown exacerbated all the above pathological manifestations, while CFTR overexpression significantly alleviated AD symptoms, improved skin barrier structure, and reversed the imbalance of Th17/Treg ratio. In vitro experiments showed that TNF-α + IFN-γ intervention could inhibit the viability of HaCaT cells, promote apoptosis, cause G0/G1 arrest, reduce collagen I synthesis, and promote IL-17 secretion. Knockdown of CFTR aggravated these injury effects, while overexpression of CFTR could enhance cell viability, inhibit apoptosis, promote cell cycle progression, increase collagen synthesis and reduce IL-17 release.

Conclusions
CFTR plays a protective role in the development of AD, and its mechanism may be related to enhancing keratinocyte function, maintaining skin barrier integrity, regulating Th17/Treg immune balance and inhibiting inflammatory response. CFTR may become a potential target for AD treatment.

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Abstract N°: 2062

Barriers to basic emollient therapy in atopic dermatitis: evidence from a cross-sectional survey of a persistent care gap

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Introduction
Basic emollient therapy (BET) is a fundamental component of atopic dermatitis (AD) management, yet its real-world implementation remains uncertain despite strong guideline recommendations.

Objectives

To identify discrepancies between guideline recommendations and clinical practice and to evaluate key barriers limiting effective implementation of BET.

Materials and Methods
A cross-sectional survey was conducted in 2024 in Germany among healthcare professionals involved in AD care. The questionnaire addressed prescribing practices, perceived relevance of BET, and patient- and physician-related barriers. Participants included dermatologists, pediatricians, and non-physician experts specialized in AD. Data were analyzed descriptively.

Results
Among 123 respondents, BET was almost universally regarded as essential (82.9%). However, reported prescription quantities were markedly below guideline-recommended levels, indicating substantial underuse in routine care.

Implementation was primarily limited by systemic and economic barriers. Financial burden on patients was reported by 66.1% of participants, while 80.7% identified poor adherence and 54.1% doubts about effectiveness as key patient-related obstacles. On the physician side, uncertainty regarding legal frameworks (56.0%) and insufficient knowledge of treatment options (57.8%) were major limiting factors.

Despite available reimbursement pathways for children, non-prescription products were frequently recommended,

suggesting a shift away from guideline-based prescribing. Notably, cost transparency was low and a majority of respondents reported uncertainty regarding reimbursement regulations.

A large proportion of participants (71.6%) indicated that age-independent reimbursement would substantially improve BET implementation.

Conclusions

This study reveals a pronounced gap between guideline recommendations and real-world practice of BET in AD. The findings suggest that inadequate implementation is driven less by clinical uncertainty than by systemic barriers, particularly economic constraints and regulatory complexity. Addressing these structural limitations—especially through improved reimbursement policies and greater cost transparency—may be critical to optimize long-term disease control.

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Abstract N°: 2086

Reasons for Non-Adherence to Emollients Among Adult Patients with Atopic Dermatitis

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Introduction

Emollients play a key role in the basic therapy of atopic dermatitis (AD). Busy lifestyles, application site discomfort, and economic barriers significantly reduce adherence to regular use among adults.

The aim of this study was to identify factors associated with poor adherence to emollients among adults with AD – a patient population with inherently poor compliance.

Materials and Methods

The study included an analysis of 300 negative reviews (1–3 stars) about emollients (2023–2025) from major marketplaces and an anonymous online survey of subscribers to a social media channel on AD patient experiences. The survey was conducted using a web-based platform, and statistical analysis was performed in STATISTICA 10 using the chi-square test with Yates' correction at a significance level of $p<0.05$.

Results

A survey of 60 adult patients with AD revealed critically poor adherence to emollient use, despite an understanding of their mechanism of action: only 18 patients (30%) followed the optimal regimen of 1–2 times daily over the entire body, 11 (18%) applied only after bathing, 7 (12%) applied emollients locally to dry areas, 18 (30%) on symptom recurrence, and 4 (7%) applied 2-3 times a week.

The primary barrier to consistent use was the requirement for frequent re-application, noted by 28 (46%) adults, uncomfortable texture by 22 (37%), economic barriers by 29 (48%), and **lack of understanding of the importance** by 5 (8%). The volume of emollient use highlighted thedeviation from clinical recommendations (up to 500 ml per week): 33 patients (55%) indicated that 500 ml lasted 1–1.5 months, 15 (25%) – up to 6 months, and only 12 (20%) demonstrated regular application, using up every 7–10 days.

Many patients failed to maintain daily application: 25 (41%) considered the daily routine tiring, resulting in missed applications; 7 (11%) applied emollients sporadically, with pauses of up to several days; whereas 28 (46%) showed regular adherence. Application site discomfort, specifically stickiness, was reported as a barrier by 13 (22%) respondents, and 18 (30%) reported a film on the skin, which correlates with the analysis of reviews on marketplaces. 186 (62%) of negative reviews noted excessive oiliness, stickiness and an occlusive effect after application, expressed in such terms as "disgusting sensations," "a feeling of a greasy film on the body," and "an oily sensation on the face." These sensations provoked an immediate desire to remove the product from the skin ("I want to wash it off quickly"). For adult patients with their busy lifestyles, such inconveniences become an additional incentive to skip applications, as the procedure requires time for absorption and creates discomfort under clothing. Along with this, an important behavioral characteristic of adult patients is high search activity: 37 (61%) changed emollient brands.

In view of all of the above, the subjective assessment of the therapeutic effect of emollients in adult patients was low: minimal improvement was reported by 17 respondents (28%), a variable response ("sometimes it helps, sometimes not") was reported by 9 patients (15%), and no effect was observed by 2 patients (3%), highlighting a significant dissonance between clinical expectations and the actual perception of therapy.

Conclusions

In adult patients with AD, adherence to emollient therapy remains extremely low, despite an understanding of their role in restoring the skin's barrier function. The main barriers are interconnected and mutually reinforcing: a busy lifestyle with time constraints and fatigue from daily routine; high cost, correlated with the recommended dosage, requiring substantial ongoing costs; application site discomfort (stickiness, greasiness, filmy sensation), which, given time constraints, leads to missed applications and an active search for alternatives.

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Abstract N°: 2090

Assessment of the impact of hypoallergenic diet on SCORAD index in children with atopic eczema

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Introduction

Atopic eczema significantly impairs the quality of life of toddler-aged children and their families. Although hypoallergenic diets are widely prescribed, their actual impact on disease severity remains insufficiently studied, particularly with respect to different degrees of dietary restriction.

Objective. To evaluate the influence of hypoallergenic diet stringency on atopic eczema severity, measured by the SCORAD index, in children aged 1–2.5 years.

Materials and Methods

A prospective analysis included 62 children (29 girls, 33 boys) aged 1–2.5 years with exacerbation of atopic eczema diagnosed according to the Hanifin–Rajka criteria. Disease severity was assessed using the SCORAD index (median 34 [28; 47] points; moderate 25–50 points – 44 children, severe >50 points – 18 children). Parents completed questionnaires on diet adherence, excluded food groups, exacerbation frequency, and confirmed food allergy status. Statistical analysis was performed using STATISTICA 10 with the Mann–Whitney U test ($p<0.05$).

Results

A hypoallergenic diet was followed by 37 (60%) children: minimal restriction (1–2 food groups) – 20 (32%), SCORAD median 34 [27; 46]; moderate restriction (3–4 groups) – 13 (21%), 31 [26; 34]; strict restriction (≥5 groups) – 4 (7%), 34 [31; 56]. No significant differences in SCORAD were found between diet types (minimal vs moderate: $p=0.6$; minimal vs strict: $p=0.8$; moderate vs strict: $p=0.3$). Children with confirmed food allergy (n=19) had a SCORAD of 32 [26; 34], whereas those without allergy (n=18) had 38 [28; 48] ($p=0.07$). Disease severity decreased with age: 1–1.5 years (moderate – 19, severe – 9); 1.6–2 years (20, 5); 2.1–2.5 years (5, 4).

Conclusions

A hypoallergenic diet of any stringency does not significantly affect atopic eczema severity as measured by SCORAD. The absence of a correlation with confirmed food allergy and the age-related decline in severity support an individualized approach with allergy testing rather than routine dietary restrictions, in order to prevent nutritional deficits while optimizing therapy.

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Abstract N°: 2096

Rapid Improvement with Topical Delgocitinib in Severe Refractory Atopic Dermatitis: A Case Report

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by recurrent eczematous lesions, intense pruritus, and significant impairment in quality of life. Although biologic agents and Janus kinase (JAK) inhibitors have substantially expanded the therapeutic armamentarium for moderate-to-severe AD, a subset of patients continues to experience incomplete or fluctuating responses to treatment. Combination therapeutic approaches may therefore represent a valuable option in refractory disease. Delgocitinib is a topical pan-JAK inhibitor that has demonstrated efficacy in the treatment of AD through inhibition of multiple cytokine signaling pathways involved in disease pathogenesis, including interleukin (IL)-4, IL-13, and IL-31. We report a case of severe refractory AD successfully treated with the combination of topical delgocitinib and systemic upadacitinib.

Case Presentation

A 24-year-old patient with a longstanding history of severe AD was referred to our clinic for persistent widespread eczematous lesions and severe pruritus associated with marked impairment in quality of life. Previous treatments included high-potency topical corticosteroids and topical calcineurin inhibitors, which provided only transient and partial benefit. Histopathological examination of a lesional skin biopsy revealed spongiosis, acanthosis, parakeratosis, and superficial perivascular lymphocytic infiltrates with occasional eosinophils, supporting the diagnosis of AD. Given the severity of the disease, systemic therapy was started. The patient was first treated with dupilumab, which resulted in partial improvement but persistent active lesions and pruritus. Therapy was subsequently switched to the oral JAK inhibitor abrocitinib, leading to an initial clinical response followed by secondary loss of efficacy. The patient was then transitioned to upadacitinib 30 mg daily. Although pruritus improved, cutaneous manifestations remained largely unchanged, with persistent eczematous plaques and fluctuating disease activity. The overall therapeutic response was therefore considered unsatisfactory. To optimize disease control, topical delgocitinib was introduced off-label and applied twice daily to affected areas while systemic upadacitinib was continued. Written informed consent for off-label treatment was obtained from the patient. Remarkably, within 15 days of combination therapy initiation, the patient demonstrated substantial clinical improvement, including marked reduction in erythema, lichenification, and pruritus. The extent and severity of skin lesions significantly decreased, accompanied by notable improvement in quality of life. No adverse events were observed during follow-up.

Conclusion

The addition of topical delgocitinib to systemic upadacitinib therapy resulted in rapid and clinically significant improvement in a patient with severe refractory AD. This case supports further investigation of combined topical and systemic JAK inhibition as a potential therapeutic strategy in difficult-to-treat AD.

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Abstract N°: 2101

Follicular Atopic Dermatitis in Dark Skin: A Pediatric Case

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Introduction

Atopic dermatitis (AD) is a widespread inflammatory skin disorder that occurs across various ethnic populations. The clinical appearance of AD may vary in people with dark skin. We report a rare case of follicular atopic dermatitis in a dark phototype, highlighting its diagnostic challenges.

Case Presentation

A 14-year-old female presented with pruritic, skin-colored lesions diffusely distributed, developing over more than 10 years. There was a positive family history of allergic rhinitis. She denied any history of prior drug intake, scalp scaling, joint pain or swelling, or palmo-plantar thickening. Cutaneous examination revealed skin phototype V with discrete, purplish to brownish follicular scaly papules distributed over the trunk, back, and both upper and lower limbs. The mucosae, nails, scalp, palms, and soles were spared. Systemic examination was unremarkable. Differential diagnoses considered included follicular atopic dermatitis, follicular psoriasis, and follicular lichen planus. Dermoscopic examination showed a white-brown background, normal-appearing terminal hairs in the center, perifollicular desquamation, multiple dots vessels with heterogeneous distribution, and hemorrhagic crusts. Histopathological examination was performed and showed findings consistent with eczema. Based on the patient’s history, particularly the positive family history of atopy, together with the clinical, dermoscopic, and histopathological findings, a diagnosis of follicular atopic dermatitis was established. The patient was treated with a topical combination of white petrolatum and betamethasone until resolution of the lesions, followed by a proactive regimen including hygiene and regular moisturizing measures. The clinical course was marked by significant improvement in pruritus and regression of the lesions after 3 months.

Conclusion

Atopic dermatitis is a common inflammatory skin condition whose clinical presentation varies according to skin phototype and ethnicity. In individuals with fair skin, AD typically presents as erythematous lesions that are easily visible due to the contrast with the surrounding skin. However, in people with darker skin types, lesions may appear violaceous, grayish, or dark brown, with less visible erythema and more intense pruritus, which can delay diagnosis. In addition, follicular atopic dermatitis represents a distinct clinical variant, frequently observed in patients with dark skin, and characterized by keratotic follicular papules distributed over the extensor surfaces and trunk. The dermoscopic findings previously described in atopic dermatitis include structureless erythema, scaling, and patchy dotted vessels. However, in dark skin phototypes, these features may be less visible, as demonstrated in our case. To the best of our knowledge, dermoscopic features of follicular atopic dermatitis are rarely reported in the literature. As illustrated in our case, this follicular pattern may contribute to diagnostic difficulty due to its resemblance to other follicular dermatoses. In fact, it may mimic lichen planus and follicular psoriasis. In our patient, the diagnosis of lichen planus was excluded by the history of atopy, the round morphology of papules,

the absence of Wickham’s striae, Koebner phenomenon, and mucosal or scalp involvement, as well as the presence of eczematous rather than lichenoid histological changes. Follicular psoriasis was also considered; however, its characteristic dermoscopic and histopathological psoriasiform features were absent.

Our case highlights the diagnostic challenges of atopic dermatitis in patients with dark skin. Although uncommon, follicular atopic dermatitis should be considered in the differential diagnosis of follicular pruritic eruptions in darker phototypes. Dermoscopy and histopathological analysis are valuable complementary tools that enhance diagnostic accuracy, facilitate differentiation from similar disorders, and support appropriate management.

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Abstract N°: 2130

Enhanced External Counter-puslation therapy improves eczema control

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Introduction

Background Patients with atopic dermatitis (AD) and erythematous skin disease are often treated with topical treatment containing corticosteroids. However, long term use of topical corticosteroid is well known for its potential side-effects. Enhanced external counter-pulsation (EECP) therapy is a non-invasive method to improve perfusion of vital organs. It operates by applying ECG-triggered pressure to the lower extremities during diastole by means of air-filled cuffs, thus, augmenting diastolic blood flow and reducing systolic afterload. These, in turns, increases blood flow to the organs. It has been proved to be effective in increasing the nitrite oxidase level in blood circulation, which has antiatherogenic, antithrombotic and anti-inflammatory effects. There are various studies showing that vascular inflammation is associated with increased Th2 response in moderate -to-severe AD patients. By improving the circulation via EECP, we hypothesize that it potentially reduces inflammation and improves AD control.

Materials and Methods

We aim to evaluate the efficacy and safety of EECP therapy in eczema control compared to wet wrap therapy.

It is a prospective single-centre randomized controlled study. Adult patients with clinical diagnosis of atopic dermatitis/eczema are screened for eligibility after informed consent. They are assigned into EECP arm (Steno) versus wet wrap arm. In EECP arm ,each patient receives 3 sessions of 45-minute EECP per week as 1-cycle. In Wet wrap therapy arm (WWT), each patient receives 3-days of wet wrap therapy using aqueous cream, 45-minutes per day ,in a week.

Patients are assessed by EASI score (eczema assessment severity index) on day 0 and Day 7. On day 7, if the EASI score is larger than 10 or BSA larger than 10%, patient will receive another 3 sessions of EECP in subsequent week and being reassessed on day 14 and one-week post-treatment (end of study assessment).

The EASI score, DLQI (dermatological life quality index) , blood for cell count and IgE level are recorded on day 0,7 ,14 and end of study visits.

All patients are allowed to continue the prior existing treatment during the study period including topicals and systemic treatment.

This study is approved by the local ethnic committee.

Results

A total of 35 patients (1M:1F), mean age 33.3 years +/-13.7 , range 19-64 with AD are recruited; 17 in EECP arm, 18 in wet wrap arm.

On analysis, the patients received EECP have shown significant improvement than those in wet-wrap therapy alone. At week 1 post EECP, 58.8% (10/17) subjects in EECP arm who has received 3 sessions, achieved EASI25 (25% reduction in EASI score) compared to only 22.2%(4 /18) wet wrap arm (p=0.027*).

Furthermore, for subjects who have received EECP (up to 6 sessions), significantly more subjects (11 out of 17, 64.7%) achieved EASI25 compared to wet wrap therapy only (4/18,22.2%, p=0.011*).

In EECP arm , 58.8% (10/17) patients experienced 5% or more Body surface area (BSA) improvement/reduction compared to 33.3% (6/18) patients in WWT (p<0.001*) .

At end of treatment visit, 64.7% (11/17) patients reported more than 3 score improvement in quality of life (DQLI) compared 50% (9/18) patients in WWT (p<0.05*).

No major adverse event is reported and patients tolerate the EECP procedures.

Conclusions

Enhanced external compress pulsation(EECP) can be considered as adjuvant non-pharmaceutical therapy to enhance AD control, Further studies with larger sample size and combined treatment with topical regime are recommended.

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Abstract N°: 2134

Drug survival of conventional versus advanced systemic therapies in atopic dermatitis: A real-world cohort study.

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease requiring systemic therapy in moderate-to-severe cases. Conventional immunosuppressants, such as cyclosporine and methotrexate have historically been first-line options; however, their role has been challenged by the emergence of advanced therapies with improved efficacy and safety profiles. Real-world data comparing treatment persistence between conventional and advanced therapies remain limited.

Materials and Methods
We conducted a retrospective observational cohort study including patients with moderate-to-severe AD who initiated cyclosporine or methotrexate as first-line systemic therapy. Drug survival of conventional systemic therapies was assessed using Kaplan–Meier analysis. In addition, for the subgroup of patients requiring therapeutic escalation, drug survival of advanced therapies (biologics or JAK inhibitors) was also evaluated.

Results
A total of 113 patients were included (mean age 33.7 ± 13.4 years; 53.1% female), of whom 88.5% (100/113) initiated cyclosporine. Median treatment duration for conventional therapies was 20.5 weeks (IQR 8–32). Drug survival was low, with 96.0% (96/100) of patients discontinuing treatment, mainly due to lack of efficacy (68.8%, 66/96). No significant differences in drug survival were observed between cyclosporine and methotrexate (log-rank test, $p>0.05$). Following discontinuation, 76.0% (73/96) of patients escalated to advanced therapies, including biologics in 57.5% (42/73) and JAK inhibitors in 42.5% (31/73). Advanced therapies demonstrated improved drug survival, with 64.4% (47/73) of patients remaining on treatment during follow-up. Median follow-up after initiation of advanced therapy was 38 weeks (IQR 24–84.8), with a mean follow-up of 64.3 weeks. Kaplan–Meier analysis confirmed higher treatment persistence for advanced therapies, with no significant differences between biologics and JAK inhibitors (log-rank test, $p >0,05$).

Conclusions
Conventional systemic therapies in AD show poor drug survival in real-world clinical practice. In contrast, advanced therapies demonstrate substantially improved treatment persistence. These findings support reconsidering the role of conventional agents as bridging therapies rather than long-term treatment options.

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Abstract N°: 2141

A Th17-enriched pain endotype in atopic dermatitis: evidence from a coculture with circulating memory CLA⁺ T-cell responses

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Introduction

Background

Atopic dermatitis (AD) has been classically defined as a Th2-driven disease. However, increasing evidence supports marked immunological heterogeneity. While itch has been extensively studied, cutaneous pain remains underexplored and poorly understood at the mechanistic level.

Materials and Methods

Objectives

To characterize the immunological basis of cutaneous pain in AD, focusing on cytokine responses of skin-homing (CLA⁺) T cells and the contribution of non-Th2 pathways.

Methods

Peripheral T cells from non-treated adult moderate to severe AD patients were stratified by pain severity. Purified circulatingCLA⁺ and CLA⁻ memory T cells subsets were stimulated with staphylococcal enterotoxin B (SEB) in a coculture with autologous lesional epidermal cell suspensions. Cytokine production was quantified at 24h and correlated with pain intensity. Patients were further stratified into Th2-high and Th2-low endotypes based on IL-13 levels.

Results

Results

SEB-stimulated CLA⁺ T cells from patients with higher pain exhibited significantly increased IL-17A production, with clear differences between no-pain and severe-pain groups. This association was restricted to CLA⁺ cells, with no differences in CLA⁻ populations. SEB-induced IL-17A in CLA⁺ T cells levels correlated positively with pain severity (r=0,45), but no with the Il-17A produced by CLA- T cells of the same patients, while IL-22 showed correlation (r=0.47) without significant intergroup differences. Most Th2 cytokines were not associated with pain, and IL-31 was higher in patients without pain. Importantly, the IL-17A–pain association was analyzed in patients

stratified in Th2 high/low depending on their mean levels of SEB-induced IL-13 production in the coculture of CLA^+ T cells. The the IL-17A–pain association was restricted to Th2-low patients (r=0,60), whereas Th2-high patients with pain showed broader cytokine upregulation, suggesting immune co-activation.

Conclusions

Conclusions

Cutaneous pain in AD is associated with a Th17-enriched immune signature in circulating skin-homing CLA^+ T cells activated by SEB, supporting the existence of a distinct “pain endotype” beyond classical Th2 inflammation. These findings challenge the Th2-centric paradigm and suggest that pain may identify patients with partial Th2-independence, potentially explaining heterogeneous therapeutic responses. This immunological profile may contribute to persistent pain despite Th2-targeted therapies, suggesting that current treatments may incompletely address key inflammatory pathways in this subgroup.

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Abstract N°: 2144

From conception to lactation: patient-reported treatment patterns, disease course, and breastfeeding complications in women with atopic dermatitis

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Introduction

Atopic dermatitis (AD) affects a substantial proportion of women of reproductive age, yet guidance on its safe and effective management during pregnancy remains limited. Concerns regarding the safety of therapeutic interventions during pregnancy often lead to treatment modification or discontinuation, which may adversely affect disease control. Despite the clinical relevance of this issue, real-world data on the course of AD during

pregnancy, patient-driven treatment behaviors, and maternal outcomes remain scarce.

This study aims to characterize self-reported treatment modification patterns, trimester-specific disease activity, and postpartum outcomes, including breastfeeding-related complications, in women with AD.

Materials and Methods

This multicenter, cross-sectional, survey-based study was conducted across 11 Atopic Dermatitis Centers of Reference and Excellence (ADCAREs) in 9 countries and included women with physician-diagnosed AD who are or had been pregnant within the last 3 years. A 36-item questionnaire assessed disease severity, trimester-specific course, treatment use and modification, exacerbation triggers, healthcare utilization, and outcomes of pregnancy. Descriptive statistics were performed.

Results

A total of 92 women (mean age 31.2±5.9 years; mean age at conception 29.0±5.9 years) of diverse ethnicity (50.0% [46/92] White/Caucasian, 21.7% [20/92] Middle Eastern, 10.9% [10/92] South Asian, 8.7% [8/92] East Asian) were included. Pre-pregnancy AD severity was mild in 42.5% (34/80), moderate in 47.5% (38/80), and severe in 10.0% (8/80).

Disease worsening peaked in the second trimester (53.2%, 41/77), compared with 44.9% (35/78) in the first and 45.5% (35/77) in the third trimester, consistently exceeding the proportion of patients reporting improvement (12.8% [10/78], 9.1% [7/77], and 10.4% [8/77] in the first, second, and third trimester, respectively).

Treatment modification upon pregnancy confirmation was substantial. Among topical corticosteroid users, 67.1% (47/70) altered therapy, including discontinuation (24.3%, 17/70), reduction to flare-only use (30.0%, 21/70), or switching to lower potency (11.4%, 8/70). High discontinuation rates were also observed for topical calcineurin inhibitors (63.2%, 12/19), biologics (63.6%, 7/11), and systemic immunosuppressants (75.0%, 3/4), whereas emollient use remained stable (97.0%, 65/67).

Among patients experiencing exacerbation (n=49), reported triggers included stress (55.1%, 27/49) and treatment modification or discontinuation (44.9%, 22/49). Increased healthcare utilization during pregnancy due to the AD was reported by 56.4% (44/78), with the highest consultation rate in the second trimester (81.8%, 36/44).

Following delivery, AD improved in 43.4% (33/76), remained unchanged in 28.9% (22/76), and worsened in 27.6% (21/76). Pregnancy outcomes were favorable, with 94.9% (74/78) live births and 90.5% (67/74) healthy infants.

Breastfeeding was initiated by 91.8% (67/73) of participants (median duration 6 months), yet eczema of the breast was reported by 40.0% (26/65), and 75.4% (52/69) required AD-specific treatment during lactation.

Conclusions

Treatment modification during pregnancy is highly prevalent and associated with increased AD exacerbations, particularly in the second trimester. However, these exacerbations do not result in adverse pregnancy outcomes, which remain largely favorable. The high burden of postpartum disease activity and breastfeeding-related complications further highlights an unmet need for optimized, continuous disease management during pregnancy. These findings underscore a clinically relevant treatment gap and the importance of improved counseling to maintain disease control during pregnancy and lactation without compromising maternal or fetal safety.

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Abstract N°: 2151

Effectiveness and drug survival of dupilumab after discontinuation of methotrexate or cyclosporin as a first systemic treatment: Results from the UK-Irish A-STAR register

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Introduction

While advanced therapies have transformed atopic dermatitis (AD) management, access in many European countries is guided by treatment pathways that require an inadequate response to conventional systemic therapy before initiation of advanced therapies. In the UK and most other European countries patients typically initiate either methotrexate (MTX) or cyclosporin (CyA) prior to commencing an advanced systemic agent We therefore studied the association between prior conventional systemic choice/failure and the effectiveness as well as drug survival of dupilumab as second line systemic treatment.

Materials and Methods

A-STAR is a prospective, longitudinal register and examines the safety and effectiveness of systemic treatment in AD patients in real-world settings. Adult and paediatric A-STAR patients who received dupilumab as second systemic treatment and were previously only exposed to either MTX or CyA were included. Treatment effectiveness outcomes were time to EASI-50, -75 and -90. Patients were censored at 12 months. A Cox-proportional hazard model with covariate adjustment was used to study the association between prior conventional systemic treatment discontinuation and the treatment effectiveness and drug survival of dupilumab. Covariates include age, sex, disease duration and EASI at drug initiation as well as date of drug initiation. Prior exposure to CyA was used as the reference treatment.

Results

221 patients on dupilumab who had previous exposure to either CyA or MTX (68 and 153, respectively) were included. When assessing baseline characteristics, MTX-exposed patients were more likely to be <12 years old ($p=0.001$) with earlier AD onset ($p<0.001$). CyA-exposed patients demonstrated higher baseline disease severity and patient-reported outcomes (EASI, PP-NRS, POEM: all $p<0.001$). Using prior CyA exposure as reference, the time to achieve EASI-50, -75 and -90 was comparable between the groups (aHR (95% CI): EASI-50: 1.08 (0.72-1.61), $p=0.8$; EASI-75: 0.95 (0.60 - 1.51), $p=0.6$; EASI-90: 0.71(0.40-1.25), $p=0.1$; Figures 1a-c). While not reaching statistical significance, a lower discontinuation rate was noted in patients with prior exposure to MTX (aHR (95% CI): 0.51(0.25–1.02); Figure 1.d).

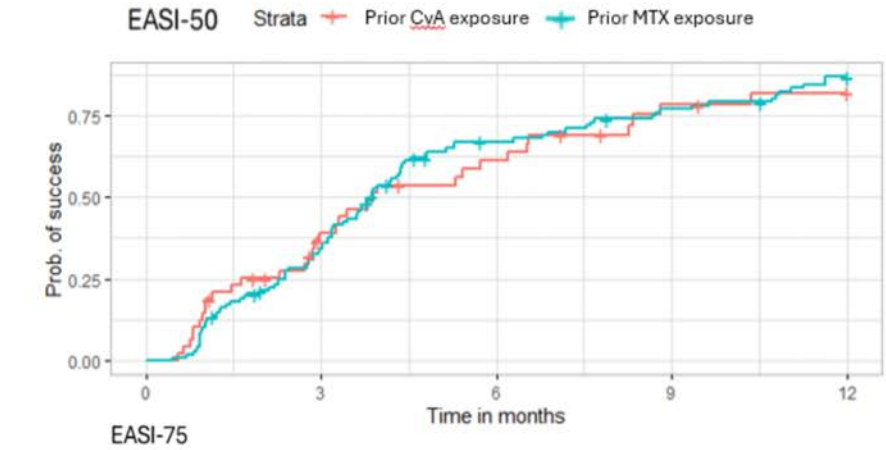

Figure 1a

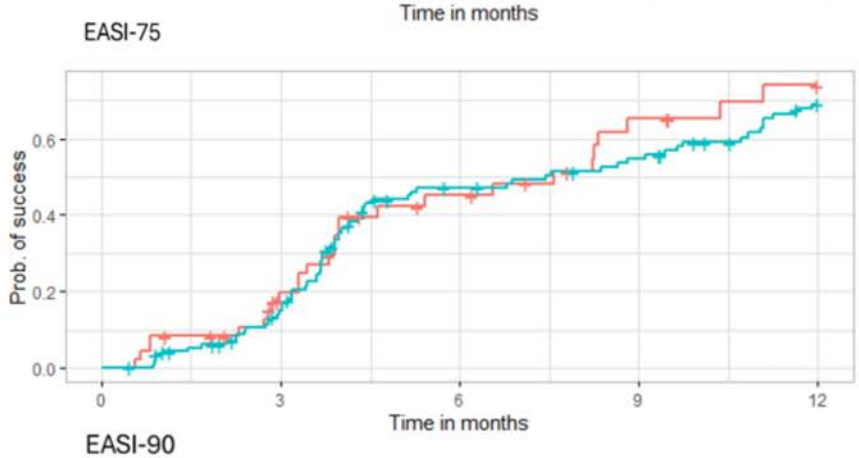

Figure 1b

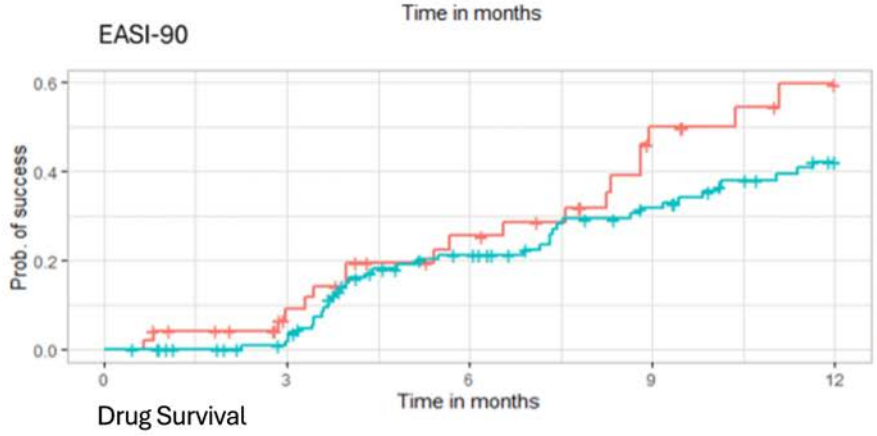

Figure 1c

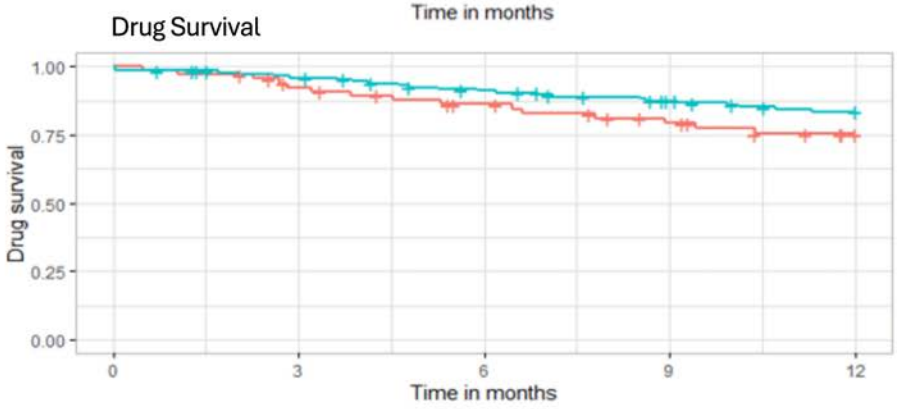

Figure 1d

Figures 1a-d: Time to achieve EASI-50, -75, -90 and drug survival on dupilumab stratified by prior conventional systemic treatment exposure (cyclosporin or methotrexate) in patients with atopic dermatitis

Conclusions

There is no observed difference in response to dupilumab when comparing AD patients with prior exposure to either CyA or MTX. However, the difference in drug persistence following MTX exposure warrants further research.

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Abstract N°: 2192

Real-world effectiveness of delgocitinib cream in adults with moderate to severe Chronic Hand Eczema: interim analysis after 8 weeks of treatment in the German REACHED study

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Introduction

Chronic Hand Eczema (CHE) is a multifactorial inflammatory skin disease often characterised by itch and pain, leading to substantial impairment in quality of life. Delgocitinib cream, a nonsteroidal topical pan-Janus kinase inhibitor, is approved for adults with moderate to severe CHE in more than 37 countries, including Europe and the United States. Its broad mechanism of action and minimal systemic exposure have been extensively studied and confirmed in several large multicentre trials. However, real-world data on the effectiveness of delgocitinib cream in patients with CHE are lacking.

The objective of this study was to describe the first real-world evidence on the short-term (8-week) effectiveness of delgocitinib cream 20 mg/g in adults with moderate to severe CHE, based on an interim analysis of the German REACHED non-interventional study.

Materials and Methods

REACHED is a prospective, observational study enrolling CHE patients deemed suitable for treatment with delgocitinib cream (20 mg/g). Patient enrolment began on 06 June 2025 and is expected to conclude on 30 June 2026. Treatment effectiveness was evaluated by comparing baseline and Week 8 values for the modified Physician Global Assessment (mPGA) scale (0='clear'; 1='almost clear'; 2='mild', 3='moderate'; 4='severe'), the Hand Eczema Severity Index (HECSI) score (0='clear'; 1-16='almost clear'; 17-37='moderate'; 38-116='severe'; ≥117='very severe'), the Dermatology Life Quality Index (DLQI) score (effect on patient's life: 0-1='no effect at all'; 2-5='small effect'; 6-10='moderate effect'; 11-20='very large effect'; 21-30='extremely large effect'), and itch/pain numerical rating scales (NRSs; 0='no itch/pain'; 10='severe itch/pain'). Data reported as observed.

Results

At the interim data cut-off (03 March 2026), a total of 79 sites were participating in Germany, with Week 8 data available for up to 97 patients, depending on the endpoint. At baseline, the mean (standard deviation [SD]) age was 50.2 (15.7) years, with the majority being female (62.9% [61/97]). CHE severity was classified as mild (mPGA 2; 7.4% [5/68]), moderate (mPGA 3; 64.7% [44/68]), or severe (mPGA 4; 27.9% [19/68]), with a mean (SD) HECSI score of 62.4 (50.2; n=72). The mean (SD) DLQI score was 14.5 (6.8; n=88), and the mean (SD) itch and pain NRS scores were 6.5 (2.6; n=88) and 5.5 (2.7; n=88), respectively.

After just 8 weeks of treatment with delgocitinib cream, marked improvements were observed across all assessed measures, with a notable shift toward less severe CHE categories. CHE severity rated as clear (mPGA 0) was reported in 4.3% (3/70) of patients, almost clear (mPGA 1) in 24.3% (17/70), mild (mPGA 2) in 32.9% (23/70),

moderate (mPGA 3) in 31.4% (22/70), and severe (mPGA 4) in 7.1% (5/70), with a total of 28.6% (20/70) classified as clear or almost clear (mPGA0/1 at Week8). The mean (SD) HECSI score decreased to 30.8 (36.3; n=67), a change of -28.6 points from baseline (95% confidence interval [CI]: -37.6, -19.7; n=62). A 75% improvement in HECSI (HECSI 75) was achieved by 35.5% (22/62) of patients. Mean (SD) DLQI, itch NRS, and pain NRS scores decreased to 7.9 (6.6; n=88), 4.1 (2.8; n=90), and 2.9 (2.6; n=90), with respective changes from baseline of -6.5 points (95% CI: -7.9, -5.1, n=81), -2.1 points (95% CI: -2.7, -1.5, n=82), and -2.7 points (95% CI: -3.3, -2.0, n=82). The treatment was well tolerated, all reported adverse events were non-serious, and all but one AE were mild or moderate, reaffirming the favourable safety profile of delgocitinib.

Table 1 Effectiveness of delgocitinib cream (20 mg/g) in patients with CHE: interim results from the German REACHED non-interventional study demonstrating changes in mPGA, HECSI, DLQI, itch NRS, and pain NRS scores from baseline to Week 8.

	Delgocitinib cream 20 mg/g	
	Baseline	**Week 8**
mPGA, n (%)	*N=68*	*N=70*
0 *(Clear)*	0 (0.0)	3 (4.3)
1 *(Almost clear)*	0 (0.0)	17 (24.3)
2 *(Mild)*	5 (7.4)	23 (32.9)
3 *(Moderate)*	44 (64.7)	22 (31.4)
4 *(Severe)*	19 (27.9)	5 (7.1)
0/1 *(Clear/almost clear)*	0 (0.0)	20 (28.6)
HECSI, mean (SD)	*N=72*	*N=67*
Reported value	62.4 (50.2)	30.8 (36.3)
Change from baseline	–	-28.6
DLQI, mean (SD)	*N=88*	*N=88*
Reported value	14.5 (6.8)	7.9 (6.6)
Change from baseline	–	-6.5
Itch NRS, mean (SD)	*N=88*	*N=90*
Reported value	6.5 (2.6)	4.1 (2.8)
Change from baseline	–	-2.1
Pain NRS, mean (SD)	*N=88*	*N=90*
Reported value	5.5 (2.7)	2.9 (2.6)
Change from baseline	–	-2.7

DLQI: Dermatology Life Quality Index; HECSI: Hand Eczema Severity Index; mPGA: modified Physician Global Assessment; N: number of patients at each timepoint; n: number of patients in each mPGA severity category; %: percentage of patients in each mPGA severity category; NRS: Numerical Rating Scale; SD: standard deviation.

Conclusions

Interim results from the REACHED demonstrate show short-term effectiveness of delgocitinib cream in adults with moderate to severe CHE, with considerable improvements in mPGA, HECSI, DLQI, and NRS scores after the first 8 weeks of treatment. This interim analysis provides early real-world evidence supporting the use of delgocitinib cream in CHE management and complements clinical data from the DELTA trials.

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Abstract N°: 2201

Perceptions and attitudes towards the value of vaccination among patients with atopic dermatitis (AD) and dermatologists in Spain

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Introduction
Adults with atopic dermatitis (AD), especially those on systemic immunosuppressants, face increased risk of vaccine-preventable diseases. Inactivated vaccines are recommended and show a positive risk-benefit profile (1–3). As vaccination is not mandatory in Spain, uptake depends on a prescription from a healthcare professional and the patient acceptance. This study explores the awareness on vaccine-preventable diseases' risks, perceptions about safety, the value of vaccination in the post-COVID era, and perceived barriers to vaccination among patients with AD and dermatologists in Spain

Materials and Methods
A non-interventional, cross-sectional study was conducted from June to October 2025 using 2 anonymous online, close-ended questionnaires for dermatologists and AD patients ≥18 years. The protocol was Ethics Committee–approved, and participation was supported by the Spanish Academy of Dermatology (AEDV) and AADA patient association

Results
A total of 78 dermatologists (≈4% of AEDV members) and 134 patients (≈11% of AADA members) participated. Among dermatologists, 47.7% had >20 years' experience, 85.9% worked in public hospitals, and 35.9% were part of monographic immune-dermatology units. Most patients (83.6%) have lived with AD for >10 years; 76.9% were women, mean age 40 years, and 66.4% held a university degree.

53.7% of patients used corticosteroids and/or immunomodulators (tacrolimus, pimecrolimus), 52.2% used emollients, 37.3% biologics (dupilumab, lebrikizumab, tralokinumab), and 14.2% JAK inhibitors (abrocitinib, baricitinib, upadacitinib). <10% used azathioprine, cyclosporine, methotrexate or received no treatment, and 4.5% received phototherapy.

Overall, dermatologists and patients showed a positive perception of vaccination: 94.9% of dermatologists and 62.0% of patients considered it important/very important. Both groups identified the main HCPs responsible for informing/recommending vaccines as dermatologists (85.9%, 76.1%), primary care physicians (73.1%, 54.5%) and preventivists (73.1%, 38.1%).

Only 57.7% of dermatologists felt adequately trained to inform/recommend vaccines. Among patients, 69.4% were unaware of vaccines recommended for them beyond COVID-19, and 50.0% reported sufficient knowledge to decide on vaccination. Dermatologists and patients agreed that patients are not proactive in asking for vaccine

information.

Dermatologists most often recommended the shingles (76.9%), flu (75.6%) and pneumococcal (70.5%) vaccines. Patient-reported vaccination status: ≈40% for shingles and pneumococcal, and 56.6% for flu in the last year. Notably, 33.3% were willing to get the RSV vaccine and 83.9% were unwilling to receive COVID-19 vaccination. Active refusal was 19.6% for flu and <9% for other vaccines.

49.7% of dermatologists were unaware of their patients' vaccination status. Patients on biologics showed higher vaccination rates than those on other treatments.

Main barriers identified by both were lack of dermatologist recommendation, fear of side effects, flares or treatment interactions. Dermatologists (42.3%) also cited lack of time during visits, and 43.6% perceived patient rejection, although only 17.2% of patients reported ever rejecting a recommended vaccine.

Dermatologists highlighted opportunities including specific training in vaccination, stronger active dermatologist recommendations, improved vaccination pathways in hospitals/primary care, and greater involvement of dermatology nurses and hospital pharmacists.
The survey was considered useful by 77.9% of patients and 53.3% of dermatologists

Conclusions
Dermatologists and AD patients show high trust in vaccination. However, limited patient awareness, lack of specialist recommendations and safety concerns remain modifiable barriers. Dermatologist proactiveness is key to improving vaccination coverage. Lack of time and insufficient vaccine-related knowledge mean recommendations depend on individual initiative or patient proactivity, creating inequities in access

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Abstract N°: 2213

Comparative Safety of Systemic Therapies for Atopic Dermatitis: A FAERS Analysis of Cutaneous and Serious Adverse Events from 2021–2025

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Introduction

Systemic therapies for atopic dermatitis (AD), including type 2 (TH2) pathway biologics and Janus kinase (JAK) inhibitors, are increasingly used across age groups. While individual agents such as dupilumab have well-characterized safety profiles, comparative real-world data on cutaneous adverse events (AEs) across systemic AD therapies—including within the TH2 biologic class—remain limited.

Materials and Methods

A retrospective pharmacovigilance analysis of the FDA Adverse Event Reporting System (FAERS) from 2021–2025 was conducted. Reports involving six systemic AD therapies (dupilumab, omalizumab, tezepelumab, upadacitinib, tofacitinib, and baricitinib) were identified. Cutaneous AEs were analyzed using proportional reporting ratio (PRR) and reporting odds ratio (ROR), with subgroup analyses restricted to AD-indicated reports. Chi-squared tests and multivariable logistic regression were used to identify predictors of cutaneous and serious AEs (death, hospitalization, life-threatening event, intervention, or disability). TH2 intra-class comparisons were conducted across all cutaneous AE reports, as AD-indicated cases comprised <2% of omalizumab and tezepelumab reports. Co-reported non-cutaneous AEs were also analyzed.

Results

Among >153,000 cutaneous AE reports, dupilumab accounted for the majority (131,379) and had the lowest proportion of serious AEs (6.5%), compared with JAK inhibitors such as upadacitinib (57%) and tofacitinib (84.9%) (Table 1).

Among TH2 biologics, dupilumab demonstrated the most favorable serious AE profile (6.5% serious, 2.4% hospitalized) compared with omalizumab (43.6% serious, 14.6% hospitalized) and tezepelumab (36.2% serious, 10.1% hospitalized) (Table 1). Adjusted analyses showed higher odds of serious AEs for omalizumab and tezepelumab compared with dupilumab (OR 19.9, 95% CI 18.4–21.5 and OR 12.5, 95% CI 9.4–16.8, respectively; both $p < 0.001$), reflecting predominantly non-AD populations.

In AD-restricted analyses (n = 102,616), dupilumab-associated cutaneous AEs were primarily disease-consistent (pruritus 9.8%, dry skin 4.6%, exfoliation 2.6%), suggesting target-specific effects. However, eczema rebound flares showed a strong signal (ROR 37.3), representing the strongest signal in the dataset.

JAK inhibitors demonstrated higher odds of serious AEs (e.g., upadacitinib OR 27.7, 95% CI 22.9–33.6, p<0.001 compared with dupilumab) and broader co-reported AEs, including acne, fatigue, headache, and infections.

Drug	Drug Class	Total Reports	Serious AEs	Hospitalized	Death
Dupilumab	TH2 Biologic	131,379	6.5%	2.4%	0.1%
Omalizumab	TH2 Biologic	7,571	43.6%	14.6%	0.4%
Tezepelumab	TH2 Biologic	545	36.2%	10.1%	0.2%
Upadacitinib	JAK Inhibitor	6,834	56.5%	20.1%	1.4%
Tofacitinib	JAK Inhibitor	7,069	84.9%†	40.2%†	24.9%†
Baricitinib	JAK Inhibitor	505	40.4%	19.2%	0.8%

Table 1. Reporting Summary and Serious Outcomes by Drug. AE = adverse event. Serious AE defined per FAERS criteria: death, hospitalization, life-threatening event, required intervention, or disability. † Tofacitinib rates should be interpreted with caution due to potential reporting bias following the 2021 ORAL Surveillance trial. TH2 intra-class comparisons conducted across all cutaneous AE reports; AD-indicated cases comprised <2% of omalizumab and tezepelumab reports.

Conclusions

Dupilumab was associated with fewer serious AEs and primarily disease-consistent cutaneous reactions but showed a strong signal for eczema rebound. JAK inhibitors demonstrated higher rates of serious and systemic AEs. Within the TH2 class, higher serious AE reporting for omalizumab and tezepelumab likely reflects older, comorbid populations rather than true safety differences. Findings should be interpreted in the context of known FAERS reporting biases. These findings highlight clinically meaningful differences in safety profiles across systemic AD therapies that may inform treatment selection and underscore the need for prospective evaluation of rebound phenomena.

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Performance of an AI-Based Atopic Dermatitis Severity Model Across In-Clinic and At-Home Imaging Modalities

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Introduction

Image-based deep learning approaches have been applied to severity assessments in inflammatory skin diseases to reduce inter-rater variability and enable remote evaluation. This has even been applied to the Eczema Area and Severity Index (EASI), which is a healthcare authority accepted assessment of atopic dermatitis (AD) disease severity. Translation to clinical trials requires evidence that model performance generalizes across independent datasets and across imaging modalities with differing quality and clinical context. For ease of data collection, an AI model for EASI estimation would ideally be run on photos taken by patients at home, but photos taken in the clinic can offer more standardization and higher quality.

Materials and Methods

To compare the use of in clinic vs at home photos for AI EASI estimation, we characterized the generalizability of an AI-based AD severity model using an independent observational dataset. This dataset comes from an 8-week observational study that included the comparison of high-resolution in-clinic photography with at-home mobile photography (27 participants; 18 AD, 10 controls). Specifically, the photographs including standardized baseline and week-8 in-person single-lens reflex (SLR) photography (taken in a clinic), as well as bi-weekly at-home mobile photography.

EASTMAN-AD is a deep learning model trained on a large, proprietary decentralized dataset of dermatologist-scored whole-body image sets (405 AD participants; 46,332 images across 1,053 image sets). The model uses an attention-based architecture with a Vision transformer (ViT) encoder to aggregate information from multiple body-region images and output a continuous whole-body EASI estimate. Without retraining, the model was applied to the SLR and mobile photos from the independent 8-week observational study. Agreement between AI-derived scores and dermatologist photo assessments was evaluated using intraclass correlation coefficients (ICC) and mean absolute error (MAE).

Results

On a holdout test set from the proprietary training dataset, the EASTMAN-AD achieved good agreement of the EASI score with dermatologist photo-based scoring (ICC range 0.67–0.75), comparable to dermatologist-to-dermatologist agreement for photo assessment (ICC ≈0.70). This established the expected performance range of the model relative to human raters. In the independent observational study, dermatologist-assigned EASI scores demonstrated excellent agreement across assessment modalities, with ICCs ranging from 0.88 to 0.97 between in-person examination, in-clinic photography, and at-home mobile images. When compared with dermatologist scores from each imaging modality, the EASTMAN-AD achieved ICCs of 0.80

for single-lens reflex images and 0.71 for at-home mobile photographs, with mean absolute error approximately 3.1–3.7 EASI points *(Fig 1)*. The observed differences across modalities mirrored known reductions in visual and contextual information from live examination to photographs. Participant adherence to required photo tasks exceeded 97%, supporting feasibility of longitudinal remote image collection.

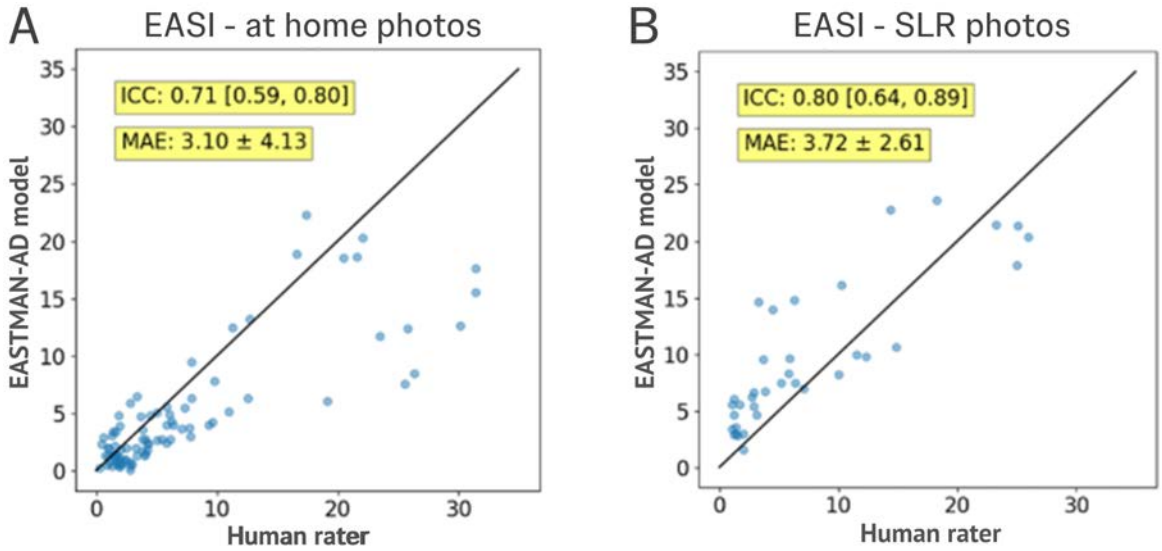

Fig 1. EASTMAN-AD model performance. (A) Human rater vs AI EASI estimation on at home photos, (B) Human rater vs AI EASI estimation on SLR photos.

Conclusions

EASTMAN-AD an attention-based AI model trained on a large, purpose-built dataset maintained good agreement of the EASI score with dermatologist assessment of images taken in-clinic and at-home when evaluated on an independent cohort. These findings support the generalizability of photo-based AI severity assessment in AD and its potential role as a scalable approach for hybrid and decentralized clinical trials. Future studies will also assess EASI scores comparability among AI models from home photos, with the current standard of in-person clinical exams.

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Staphylococcus aureus Endotoxins Mechanisms of Action Cause Inflammation and Pruritus in Atopic Dermatitis

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Introduction

Staphylococcus aureus (*S. aureus*) colonizes the skin of most adult and pediatric patients with atopic dermatitis (AD) and plays a central role in disease pathogenesis and exacerbation.[1] *S. aureus* contributes to progression along the AD disease continuum from AD disease initial onset at AD Bacterial Colonization Stage (ADBCS) through AD disease at AD Bacterial Infection Stage (ADBIS). Antibiotic use to control bacterial microbiome and the *S. aureus* component of AD may be limited due to antibiotic resistance and safety concerns, particularly in pediatric populations.[2,6,7] *S. aureus* releases endotoxins that are known to act directly on skin cells and sensory nerves. The endotoxins stimulate IL-36 release, that activates MYD88 signaling to drive T-cell–mediated inflammation.[3] They also stimulate V8 protease, that activates PAR1 receptors on sensory nerves to cause pruritus independent of histamine.[4] Shifts in the skin microbiome toward pathogenic *S. aureus* and away from commensal flora are associated with increased AD disease severity and flares.[5] Despite these well-established *S. aureus* endotoxin mechanisms, no currently approved AD therapeutic is able to target these mechanisms. The ideal AD therapeutic should target the four key interconnected AD problems of *S. aureus*, inflammation, pruritus, and xerosis.[1,7] An unmet need exists across all age groups for a topical agent that is safe, has minimal side effects, excellent patient tolerability and directly targets all four AD problems.

Materials and Methods

S. aureus endotoxin–driven mechanisms across ADBCS and ADBIS were reviewed against the current AD therapeutic landscape to identify agents capable of simultaneously treating the four key interconnected AD problems of *S. aureus*, inflammation, pruritus, and xerosis. Zabalafin, a first of its kind all-natural topical multi-target therapeutic drug platform, contains multiple bioactive compounds with multiple mechanisms of action that directly target the four key interconnected problems of AD. In Phase 2a studies in adults and children as young as 2 years, zabalafin demonstrated favorable efficacy, minimal side effects and patient tolerability across AD disease at ADBCS and the more difficult to treat AD disease at ADBIS. A 16-week double-blind, vehicle-controlled Phase 2b trial is ongoing, evaluating twice-daily topical zabalafin in two populations: mild-to-moderate AD disease at ADBCS (standard AD population) and AD disease at ADBIS. Prespecified efficacy endpoints include vIGA clear/almost clear with ≥2-point improvement, EASI 50/75, pruritus NRS ≥4-point change, SIRS, infection status, and POEM quality-of-life improvement ≥6-point change. A parallel microbiome analysis is evaluating effects on dysbiosis and skin barrier restoration in all participants.

Results

Interim observations from the ongoing zabalafin AD Phase 2b trial show consistent trends toward separation

between treatment and control arms across all prespecified efficacy parameters (vIGA, EASI 50/75, pruritus NRS, SIRS, infection status, POEM). No drug-related adverse events have been reported. These emerging trends parallel the zabalafin AD Phase 2a program. Final analyses upon study completion should confirm these interim blinded results.

Conclusions

These findings reinforce *S. aureus* toxin-driven mechanisms (IL-36/MYD88 inflammation; V8 protease/PAR1 pruritus) as central contributors to the AD disease process and underscore the importance of directly targeting these pathways. Zabalafin is the first multitarget therapeutic designed to engage all four of the interconnected problems of AD: *S. aureus*, inflammation, pruritus, and xerosis. Zabalafin has the potential to support a singular comprehensive approach to AD management independent of infection status across adult and pediatric populations.

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Abstract N°: 2257

KT-621, an Oral STAT6 Degrader, Improves Pruritus and Sleep in Patients With Moderate-to-Severe Atopic Dermatitis: Phase 1b Results

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Introduction

Atopic dermatitis (AD) is a chronic Type 2 inflammatory skin disease driven by interleukin (IL)-4 and IL-13 signaling through signal transducer and activator of transcription 6 (STAT6). IL-31, a cytokine downstream of IL-4/IL-13/STAT6 pathway activation, is a key mediator of pruritus in AD. Pruritus and associated sleep disruption are the most problematic symptoms for patients with AD, leading to a major impact on quality of life (QoL). KT-621 is a first-in-class, once-daily oral small molecule STAT6 protein degrader with high selectivity. The objective of this analysis was to determine the effects of KT-621 across Type 2 biomarkers and clinical endpoints, including patient-reported outcomes (PROs) assessing pruritus, sleep, and QoL, from a Phase 1b, open-label trial in patients with moderate-to-severe AD (NCT06945458).

Materials and Methods

Adults with moderate-to-severe AD (Eczema Area and Severity Index [EASI] ≥16; Validated Investigator Global Assessment for Atopic Dermatitis™ [vIGA-AD] ≥3) received KT-621 once daily (100 mg and 200 mg cohorts) for 28 days with 14-day follow-up. Week (Wk) 4 assessments included STAT6 protein degradation in blood and lesional skin, change in Type 2 serum biomarkers, clinical activity, and PROs. Clinical activity assessments included achievement of ≥50% and ≥75% improvement in EASI (EASI-50; EASI-75), vIGA-AD response (0 or 1 with ≥2-grade improvement from baseline), and percent change in SCORing Atopic Dermatitis (SCORAD). PROs, first measured on Day 8, included SCORAD itch and sleeplessness components; Peak Pruritus Numerical Rating Scale (PP-NRS); Patient Oriented Eczema Measure (POEM), including itch and sleep subdomains; and Dermatology Life Quality Index (DLQI). The minimal clinically important difference [MCID] for both POEM and DLQI has been defined as ≥4-point reduction from baseline.

Results

In total, 22 patients received KT-621 (100 mg, n=10; 200 mg, n=12). At baseline, mean EASI was 24.9, 54.5% had vIGA-AD=3, 45.5% had vIGA-AD=4, mean SCORAD=60.1, mean PP-NRS=7.5, mean POEM=18.6, and mean DLQI=11.6. KT-621 achieved rapid, deep STAT6 degradation, with median reductions of 97.5% in blood and 93.6% in lesional skin at Wk 4, and marked suppression of Type 2 inflammatory biomarkers. KT-621 reduced circulating levels of the pruritogenic cytokine IL-31 by 56.0% and 54.1% (100 mg and 200 mg cohorts, respectively), representing the first clear demonstration of serum IL-31 suppression by an agent targeting the IL-4/IL-13 pathway. At Wk 4, mean EASI improvement was 62.6% overall (ie, for both dose groups), with 76.2% and 28.6% achieving EASI-50 and EASI-75, respectively; mean improvement in SCORAD was 48.2%. Overall, 19.0% of patients achieved a vIGA-AD response at Wk 4. Overall, POEM total score improved by a mean of 9.3 points from baseline, with 72.7% achieving the MCID; DLQI improved by a mean of 8.1 points from baseline, with 61.1% achieving the

MCID. PP-NRS improved as early as Day 8 with mean percent change of 40.2% at Wk 4 (Figure 1A). Improvements in SCORAD-Itch (44.0% overall) and POEM-Itch (41.3% overall) were also demonstrated at Wk 4 (Figure 1A). SCORAD-Sleeplessness improved as early as Day 8, with 75.5% improvement at Wk 4 (Figure 1B). Similarly, improvements were seen for POEM-Sleep (47.1% overall) (Figure 1B). KT-621 was well tolerated, with no serious or severe adverse events, no related treatment-emergent adverse events (TEAE), no TEAEs leading to discontinuation, and no clinically relevant laboratory or ECG abnormalities.

Conclusions

KT-621 achieved rapid and consistent improvements across AD clinical and patient-reported endpoints, including reductions in disease severity, pruritus and sleep disruption, resulting in improved QoL. Reduction in pruritus was associated with marked decreases in serum IL-31, a key pruritogenic cytokine, demonstrating that inhibition of Type 2 inflammation through STAT6 degradation improves a key clinical manifestation of AD.

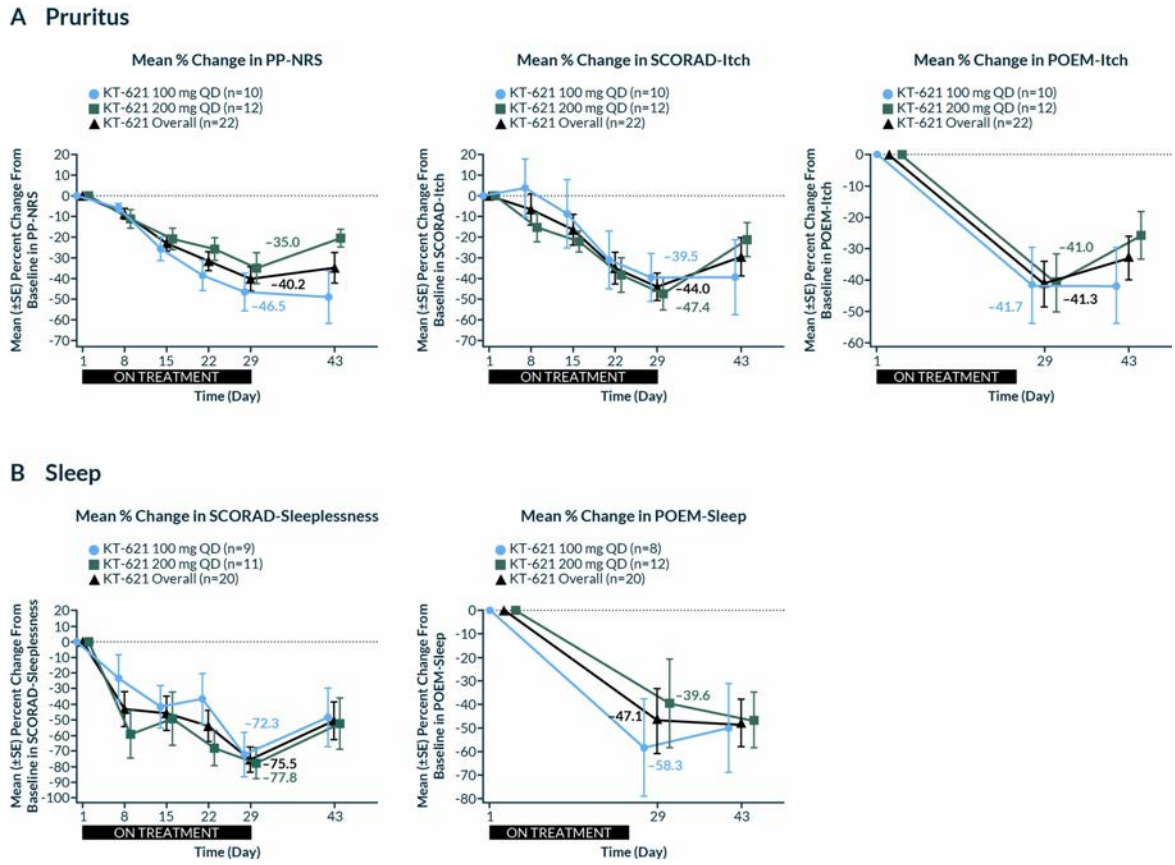

Figure 1. Improvements in Pruritus and Sleep With KT-621 in Adults With Moderate-to-Severe Atopic Dermatitis in the Phase 1b Trial. Outcomes by dose group and overall with once-daily dosing for 28 days starting on Day 1: (A) mean percent change from baseline in Peak Pruritus Numerical Rating Scale (PP-NRS), SCORing Atopic Dermatitis (SCORAD)-Itch, and Patient Oriented Eczema Measure (POEM)-Itch; (B) mean percent change from baseline in SCORAD-Sleeplessness and POEM-Sleep.

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Abstract N°: 2267

Evaluation of delgocitinib cream in chronic hand eczema: Early Real-World Experience

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Introduction

Delgocitinib cream is available for treatment of adult moderate-to-severe chronic hand eczema in Europe since 2024[1] and in the United Kingdom in 2025 for the treatment of adults with moderate-to-severe chronic hand eczema (CHE)[2].

The goal of this review was to describe baseline characteristics, treatment exposure, and early real-world outcomes for patients commenced on twice-daily delgocitinib cream, at three dermatology centres in the UK.

Materials and Methods

Retrospective review of routinely documented clinical data for adults started on delgocitinib cream. Patients without at least four weeks' follow up of outcome data were excluded.

Results

Baseline hand eczema severity index (HECSI)[3] scores were available for 11/16 patients, with a median of 52.5 out of 360 (range 15–91). Usage data indicated a 60 g standard size pack lasted a median of 76 days in this cohort. Phenotypic presentation included atopic (including pomphylx; n = 10), psoriasiform (n = 3), hyperkeratotic (n = 2), and mixed irritant / allergic (n = 1).

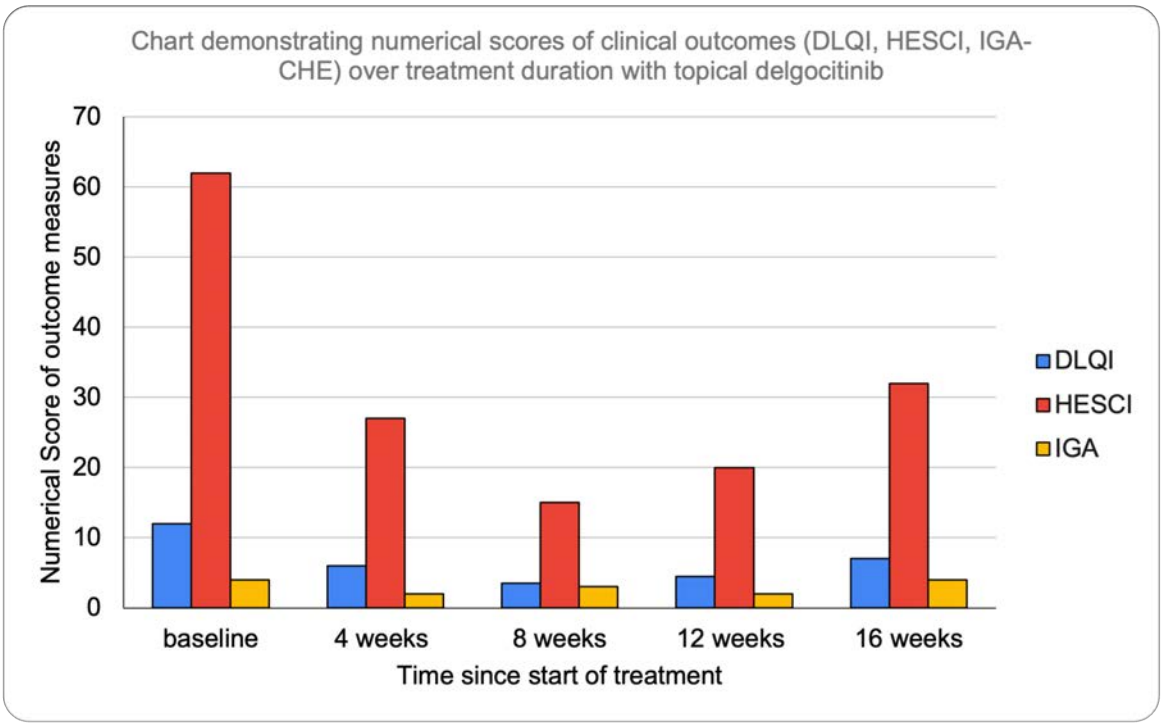
Investigator Global Assessment of Chronic Hand Eczema (IGA-CHE)[4] scores were variable, with no clear change from baseline, likely reflecting limitations of categorical scoring. Median HECSI scores showed a 48.4% reduction by week 16 (from 62 to 32), with a plateau observed between weeks 4 and 16 (Fig 1). Dermatology life quality index (DLQI)[5] improved similarly, decreasing from a median of 16 to 7 (9 points) over 16 weeks.

These were both comparable to trial data, with DELTA 1 reporting a percentage change of 56.5% in HECSI and -7.6 change in gross DLQI score at week 16[6].

Qualitative feedback was generally positive, highlighting meaningful improvements in quality of life given the functional importance of the hands. One patient reported sustained disease control over 16 weeks compared to prior topical corticosteroids. One experienced recurrent irritant-type flares requiring oral prednisolone, and another discontinued treatment after two tubes due to perceived lack of efficacy. Overall, two patients discontinued within the first 16 weeks for this reason. Two patients reported no improvement in itch, and no adverse effects were documented.

Practically, our data demonstrates that majority of improvement or lack thereof is noticeable at week 4, meaning that patients should be counselled to use the cream for at least 4 weeks, followed by clinical review and assessment.

Notably, contrary to the DELTA studies, no cases of COVID-19 or nasopharyngitis were reported in this cohort.



Conclusions

In this small, heterogeneous real-world cohort, early outcomes with delgocitinib cream appear consistent with clinical trial data, with clinically meaningful improvements in both disease severity and quality of life observed in a subset of patients. The absence of COVID-19 or nasopharyngitis likely reflects sample size and differing background infection rates (DELTA studies conducted during the COVID-19 pandemic). The observed plateau in HECSI improvement between weeks 4 and 16 may help clinicians counsel patients on expected treatment timelines and set realistic goals.

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Time to clinical and itch improvement in patients with atopic dermatitis treated with advanced therapies and current clinical control

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by recurrent eczematous lesions and intense pruritus, with a substantial impact on quality of life. The introduction of advanced therapies, including biologics and Janus kinase inhibitors (JAKi), has enabled more ambitious treatment goals and treat-to-target approaches focused on optimal disease control. However, real-world data on how rapidly patients perceive meaningful improvement in skin lesions and pruritus after starting advanced therapy remain limited, particularly regarding direct comparisons between therapeutic classes. The aim of this study was to estimate the time from initiation of advanced therapy to clinically meaningful improvement in skin lesions and pruritus in patients with AD who had achieved current clinical control.

Materials and Methods

We conducted a retrospective, multicentre observational study including patients aged ≥12 years with confirmed AD who had initiated and continuously maintained a single line of advanced therapy, either a biologic or a JAKi, and presented clinical control at the inclusion visit, defined as EASI ≤7 or pruritus NRS ≤4. Time zero was defined as the date of initiation of the index treatment, and the final time point corresponded to the inclusion visit. During a face-to-face interview, patients reported the number of days until clinically relevant milestones, including marked improvement of skin lesions and mild or absent pruritus. Sociodemographic characteristics, AD severity measures and patient-reported outcomes were also collected, including IGA, BSA, EASI, SCORAD, pruritus and sleep NRS, POEM, DLQI and ADCT.

Results

A total of 85 eligible patients with AD were included; 60.0% were male, with a mean age of 38.4 ± 16.8 years and a mean age at disease onset of 11.8 ± 17.6 years. At baseline, patients had moderate-to-severe AD, with a mean EASI of 21.9 ± 10.3 and a mean pruritus NRS of 7.6 ± 2.4. Pruritus was reported as the most bothersome symptom by 76.2% of patients. From treatment initiation to the inclusion visit, disease severity and quality of life improved significantly: mean EASI decreased from 22.0 ± 10.3 to 2.0 ± 3.4, pruritus NRS from 7.6 ± 2.4 to 1.8 ± 2.2, POEM from 19.4 ± 6.5 to 4.1 ± 3.2, and DLQI from 13.4 ± 7.0 to 2.3 ± 2.5 ($p<0.001$). Marked improvement of skin lesions was reported after a mean of 59.6 ± 74.6 days, while improvement of pruritus occurred after a mean of 62.8 ± 139.3 days. The first area to become lesion-free was most commonly the upper limbs, reported by 38.1% of patients, whereas the last areas to clear were the face/eyelids and lower limbs, reported by 23.8% and 22.6% of patients, respectively. Treatment satisfaction was high, with a mean PGIS score of 6.4 ± 0.7 out of 7.

69.4% of patients received biologics and 30.6% received JAKi. Compared with patients treated with biologics, those receiving JAKi reported a significantly shorter time to marked improvement of skin lesions, 22.2 ± 37.9 versus 77.0 ± 81.0 days, $p<0.001$, and pruritus, 14.9 ± 23.6 versus 84.3 ± 162.8 days, $p<0.001$.

Conclusions

In this real-world cohort of patients with AD achieving current clinical control under advanced therapy, pruritus was the most bothersome symptom before treatment initiation. Patients perceived marked improvement of skin lesions and pruritus after approximately two months on average, although improvement was substantially faster with JAKi, occurring within approximately two to three weeks, than with biologics. These findings may help clinicians schedule early follow-up visits, align patient expectations and anticipate treatment optimization decisions.

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Abstract N°: 2285

Lebrikizumab as a treatment for moderate-to-severe atopic dermatitis: a structured literature review

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease affecting up to 13% of children and 5% of adults (Meledathu, 2025). It is characterized by pruritus and eczematous lesions, frequently associated with asthma and allergic rhinitis. Its pathophysiology involves skin barrier dysfunction and type 2 immune response, mediated by IL-4 and IL-13. Despite the availability of biologics targeting type 2 inflammation, evidence on the long-term efficacy and safety of selective IL-13 inhibition is limited. Lebrikizumab (LBK), a monoclonal antibody and selective IL-13 inhibitor, was approved by the European Medicines Agency in 2023 for patients ≥12 years (Drucker, 2024). This study synthesizes the most recent evidence on the efficacy and safety of LBK in moderate-to-severe AD.

Materials and Methods

An integrative review was conducted on the efficacy and safety of LBK in moderate-to-severe AD. The search was performed in LILACS and PubMed databases, using the descriptors “atopic dermatitis”, “lebrikizumab”, “IL-13”, “monoclonal antibody”, “efficacy” and “safety”, combined by Boolean operators (AND/OR). Studies published from 2022 to 2026, in English and Portuguese, evaluating LBK were included, comprising randomized trials, extension studies, systematic reviews, and safety analyses. Duplicate studies, those without full text, with insufficient data, or unrelated to the topic were excluded. Selection was performed by reading titles, abstracts, and full texts. Of 34 studies initially identified, 9 composed the qualitative analysis. Efficacy outcomes (improvement of lesions and pruritus) and safety (adverse events and tolerability) were assessed.

Results

The most recent data derive from the phase III ADvocate 1 and 2 trials (Silverberg et al., 2023, NEJM) and the ADhere study (Simpson et al., 2023). In ADvocate trials, LBK showed significant superiority over placebo at week 16, with EASI-75 of 52–59% vs. 16–18% ($p<0.001$) and IGA 0/1 of 33–43% vs. 11–13%, maintaining consistency across subgroups, including those previously exposed to systemic therapies. Clinical response was maintained up to 52 weeks with maintenance every 2 or 4 weeks. In ADhere, combination with topical corticosteroid enhanced efficacy, with EASI-75 around 70% at week 16, suggesting an additive effect. Early and sustained pruritus reduction was observed, with significant NRS improvement at 2–4 weeks (Blauvelt et al., 2023), preceding lesion resolution. The safety profile was consistent with other type 2 pathway biologics, with predominantly mild-to-moderate events; conjunctivitis incidence appears lower than with dupilumab, possibly due to selective IL-13 inhibition (Wollenberg et al., 2023). Extension data (52–76 weeks) confirm sustained efficacy without new safety signals (Silverberg et al., 2024). Outcomes are summarized in Table 1.

TABLE 1. Main outcomes of lebrikizumab studies

Study (author/year)	Design	n	Intervention	EASI-75 (%)	IGA 0/1 (%)	Highlights
Silverberg et al., 2023 (ADvocate 1)	Phase III, RCT	~424	Lebrikizumab vs placebo	59 vs 16	43 vs 13	Significant response at week 16
Silverberg et al., 2023 (ADvocate 2)	Phase III, RCT	~427	Lebrikizumab vs placebo	52 vs 18	33 vs 11	Consistency across populations
Simpson et al., 2023 (ADhere)	Phase III, RCT	~211	Lebrikizumab + topical corticosteroid	~70	—	Greater efficacy in combination therapy
Blauvelt et al., 2023	Secondary analysis	—	Lebrikizumab	—	—	Early pruritus reduction (2–4 weeks)
Silverberg et al., 2024	Extension	—	Maintenance	Sustained	Sustained	Efficacy up to 52–76 weeks

RCT: randomized controlled trial; EASI-75: ≥75% improvement in Eczema Area and Severity Index; IGA 0/1: Investigator Global Assessment 0 (clear skin) or 1 (almost clear).

Conclusions

Lebrikizumab represents a significant advance in the management of moderate-to-severe AD from 12 years of age. Selective IL-13 inhibition is associated with rapid onset of action and high efficacy. Phase III trials consolidated a positive and population-consistent clinical response at week 16, with superiority over placebo, both as monotherapy and combined with topical corticosteroids. The therapy promotes sustained pruritus reduction, measurable from the second week, preceding lesion resolution. Its safety and tolerability profile is similar to other biologics targeting type 2 inflammation, with predominantly mild adverse events, such as local injection-site reactions and nasopharyngitis. The selectivity of IL-13 pathway blockade may explain the lower conjunctivitis incidence. These findings, combined with durability up to 76 weeks under spaced administration, highlight its relevance as a targeted option. Direct comparative studies are needed to define its positioning among available biologic therapies.

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A Gentle Cleanser and Barrier-Restoring Moisturiser Regimen in Mild-to-Moderate Atopic Dermatitis: Biophysical, Clinical, and Quality-of-Life Evidence from a Prospective Baseline-Controlled Study

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disorder affecting up to 20% of children and 3–5% of adults globally, imposing a substantial burden on quality of life. Its pathophysiology is rooted in epidermal barrier dysfunction - characterised by elevated transepidermal water loss (TEWL), reduced stratum corneum hydration, alkaline skin pH, and increased susceptibility to microbial colonisation. Despite emollient-based skincare being a cornerstone of AD management guidelines, rigorous multi-endpoint clinical evidence for specific barrier-restoring regimens — particularly in populations with Fitzpatrick skin types III–V — remains limited. This study addresses that gap by comprehensively evaluating a soap-free cleanser and a filaggrin-technology & Ceramide based moisturiser as a daily maintenance regimen in subjects with mild-to-moderate AD.

Objectives: To evaluate the efficacy of a barrier-restoring cleanser and moisturiser regimen in improving skin hydration, reducing TEWL, normalising skin pH, improving AD severity, and enhancing patient quality of life over a four-week treatment period.

Materials and Methods

A monocentric, open-label, prospective baseline-controlled study enrolled 70 adults (aged 18–60; Fitzpatrick skin types III–V) with mild-to-moderate AD (SCORAD 15–35; lesional Corneometer ≤30 AU). Subjects applied the test regimen twice daily for four weeks. Assessments were conducted at baseline, 30 minutes post-first application, Week 2, and Week 4. Primary endpoints were skin hydration (Corneometer CM 825) and TEWL (Tewameter TM 300) on lesional and non-lesional skin. Secondary endpoints included SCORAD, skin surface pH, Visioscan Tropography texture parameters (SEsc, SEsm, SEw, SEr), and subject self-assessment. Exploratory endpoints comprised the Dermatology Life Quality Index (DLQI), itch NRS, and Corneofix desquamation index. All efficacy analyses used the Per Protocol population (N=64).

Results

A rapid and pronounced improvement in lesional skin hydration was observed within 30 minutes of first application (+86.95%, $p<0.001$), sustained at +52.36% above baseline at Week 4 ($p<0.001$). Non-lesional hydration improved progressively, reaching +39.37% at Week 4 ($p<0.001$). Lesional TEWL decreased by 14.77% at 30 minutes post-application and by 12.81% at Week 4 ($p<0.001$), indicating genuine structural barrier repair beyond surface occlusion. Lesional skin pH declined from 6.35 (alkaline/barrier-impaired) to 5.80 at Week 4 (−8.53%, $p<0.001$), approaching physiological range. SCORAD demonstrated a remarkable 77.52% reduction from baseline by Week

4 (mean: 21.41 → 4.73; p<0.001), approaching near-clear skin status. Skin surface texture improved significantly: scaliness (SEsc) −28.72% and wrinkle parameter (SEw) −13.19% at Week 4 (both p<0.001). Itch NRS decreased by 43.44% at Week 4 (p<0.001), and DLQI fell from 3.55 to 0.98 — reaching the 'no effect on quality of life' category (−64.32%, p<0.001). No product-related adverse events were recorded throughout the study.

Conclusions

This multi-endpoint prospective study demonstrates that a daily barrier-restoring cleanser and moisturiser regimen produces rapid, sustained, and objectively measurable improvements across the full spectrum of AD pathophysiology — including hydration, barrier integrity, skin pH, disease severity, and patient quality of life. The 77.52% reduction in SCORAD and near-complete restoration of quality of life by Week 4 are particularly compelling in a population with Fitzpatrick types III–V, where evidence remains underrepresented. These findings reinforce the pivotal role of optimised daily skincare in AD management and support its integration as an evidence-based therapeutic foundation alongside pharmacological treatment.

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Extent of Cutaneous Involvement as a Marker of Systemic Inflammation and Metabolic Dysregulation in Seborrheic Dermatitis

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Introduction
Seborrheic dermatitis (SD) is a chronic inflammatory skin disorder traditionally linked to Malassezia colonization and sebaceous gland activity. Recent evidence suggests that SD may represent a cutaneous manifestation of systemic inflammation and metabolic dysregulation. Associations between SD and hypertension, cardiovascular disease, and metabolic syndrome have increasingly been reported, potentially mediated by chronic low-grade inflammation involving cytokines such as IL-6 and TNF-α. However, evidence regarding the relationship between the extent of cutaneous involvement and metabolic burden remains limited. This study aimed to investigate whether the number of affected anatomical sites and disease severity are associated with systemic inflammatory markers (CRP) and metabolic parameters including HbA1c, HOMA-IR, and lipid profile.

Materials and Methods
This cross-sectional observational study included 118 patients diagnosed with SD. Disease severity was quantified using the modified Seborrheic Dermatitis Area and Severity Index (SEDASI). Demographic variables (age, sex, height, weight, body mass index) and laboratory parameters—including fasting glucose, insulin, HOMA-IR, HbA1c, lipid profile, C-reactive protein (CRP), and erythrocyte sedimentation rate (ESR)—were collected. Associations between the number of involved anatomical sites (scalp, face, ear, trunk) and metabolic/inflammatory markers were analyzed.

Results
The most common involvement pattern was simultaneous scalp and facial involvement (36.4%). According to modified SEDASI scores, patients were classified as Mild (n=38), Moderate (n=41), Advanced (n=27), or Severe (n=12). Significant differences among severity groups were observed for fasting glucose and CRP levels, with higher values detected in Advanced and Severe disease categories. Also, the number of involved anatomical sites showed significant positive correlations with HbA1c, CRP, total cholesterol, HOMA-IR, LDL cholesterol, and fasting glucose. Family history of diabetes mellitus was significantly associated with greater disease severity.

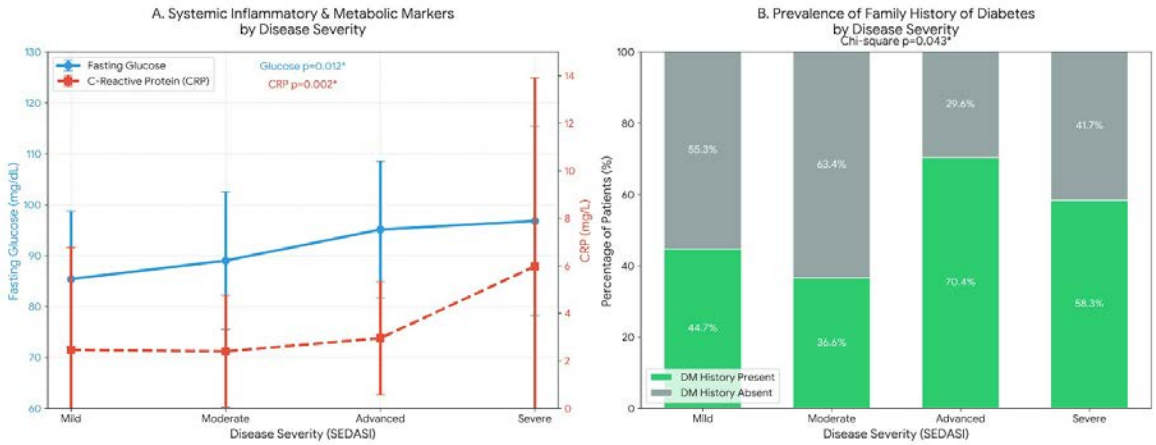

Figure 1 Association between disease severity and systemic factors. (A) Trends in Fasting Glucose and C-Reactive Protein (CRP) levels across different disease severity groups (Mild to Severe). A significant increase in both metabolic (Glucose, P=0.012) and inflammatory (CRP, P=0.002) markers is observed as disease severity worsens. (B) Stacked bar chart showing the prevalence of family history of diabetes mellitus (DM) among severity groups. The proportion of patients with a positive family history significantly increases in the Advanced and Severe groups (P=0.043).

Conclusions

This study demonstrates that SD, particularly when involving multiple anatomical sites, is significantly associated with systemic inflammatory activity and metabolic dysregulation. Patients with multiregional involvement showed significantly higher HbA1c, HOMA-IR, CRP, and LDL levels, suggesting that the extent of cutaneous involvement may serve as a clinically meaningful indicator of underlying metabolic impairment. The strongest association was observed with HbA1c, supporting the hypothesis that chronic glycemic load contributes to broader lesion dissemination through mechanisms involving sebaceous lipogenesis and inflammation. Severe SD was also associated with elevated CRP levels, reinforcing the concept that SD may represent part of a broader systemic inflammatory continuum rather than a purely superficial dermatologic disorder. Additionally, family history of diabetes mellitus correlated with higher disease severity. Although limited by its cross-sectional single-center design, the study highlights the importance of metabolic screening in patients with widespread or severe SD.

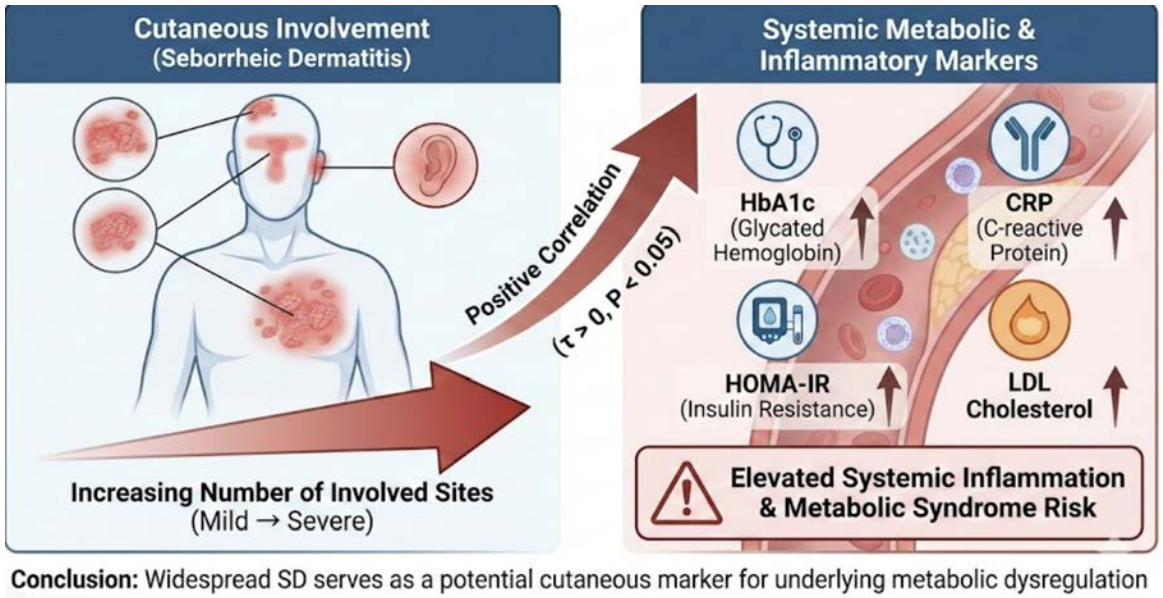

Figure 2

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Agree to Disagree: Patient vs. Investigator-assessed severity of Atopic Dermatitis in a Danish Adult Population-based Cohort

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Introduction

Background

Atopic Dermatitis (AD) is a relapsing inflammatory skin disease affecting both children and adults(1). The literature on severity distribution and comparing severity scoring methods in the general population is scarce(2). Agreement, although in various degrees, between different AD severity scoring methods have been reported in previous validation studies(3).

Accurate assessment of AD severity guides both daily treatment choices and trial design and results in clinical drug development. Traditionally, AD severity has been investigator assessed using scoring systems e.g. Eczema Area and Severity Index (EASI)(4). In recent years, there has been a tendency towards incorporating patient-reported outcome measures, to measure the patient's subjective burden of AD. Patient-reported severity scores offer advantages in feasibility and scalability of data collection.

Objective

To investigate how AD severity is distributed in a Danish population-based adult cohort when assessed by investigator-based, patient-reported, and hybrid severity instruments (Table 1).

Materials and Methods

The population-based AD-cohort was part of a larger 12-months observational cohort study (ct.govNCT06319781). Participants were recruited via social media, and eligible if >18 years and physician-verified AD diagnosis. Data collected included demographics, blood samples and AD severity score systems. AD severity was evaluated by investigator-assessed severity score (EASI, vIGA-AD, TIS), self-reported severity score according to POEM, and hybrid severity score SCORAD (3–6)(Table 1).

Table 1. AD severity score systems

SEVERITY SCORE SYSTEM BASED ON	
Investigator assessment	EASI vIGA-AD TIS
Patient-reported assessment	POEM
Hybrid assessment (investigator-assessed + patient-reported itch and sleep)	SCORAD

Eczema Area and Severity Index (EASI), Investigator Global Assessment (vIGA-AD), Three Item Severity (TIS), Patient Oriented Eczema Measure (POEM). SCOring Atopic Dermatitis (SCORAD).

Table 1

Results

A total of 56 AD participants were included. The mean age was 39.35(SD 13.08), min 18.44 – max 73.91), and 75% were female (Table 2, Baseline Characteristics). The AD severity degree data presented was based on the baseline visit.

Mild AD: investigator-assessed severity score systems identified 83.9% as mild AD using EASI, 96.4% using vIGA-AD, and 44.6% using TIS. Patient-reported assessment identified 14.5% as mild AD using POEM, while the hybrid score SCORAD identified 51.8% as mild AD (Figure 1A–E).

Moderate AD: investigator-assessed severity score systems identified 12.5% as moderate AD using EASI, 0% using vIGA-AD, and 48.2% using TIS. Patient-reported assessment identified 52.7% as moderate AD using POEM, while the hybrid score system SCORAD identified 37.5% as moderate AD.

Severe AD: investigator-assessed severity score systems identified 3.6% as severe AD using EASI, 3.8% using vIGA-AD, and 7.2% using TIS. Patient-reported assessment identified 32.8% as severe (and very severe) AD using POEM, while the hybrid score system SCORAD identified 10.7% as severe AD.

Table 2: Baseline characteristics

	Participants with atopic dermatitis (N=56)
Sex	
n (%)	56 (100.0%)
Female	42 (75.0%)
Male	14 (25.0%)
Age at baseline	
n (%)	56 (100.0%)
Mean (SD)	39.35 (13.08)
Median (Q1, Q3)	38.28 (29.92, 47.99)
Min - Max	18.44 - 73.91
Age at time of diagnosis	
n (%)	54 (96.4%)
Mean (SD)	11.68 (18.68)
Median (Q1, Q3)	2.25 (0.00, 15.35)
Min - Max	0.00 - 73.91
Disease duration (years since diagnosis)	
n (%)	54 (96.4%)
Mean (SD)	27.88 (16.03)
Median (Q1, Q3)	29.26 (14.46, 39.97)
Min - Max	0.00 - 61.60
Fitzpatrick skintype	
n (%)	56 (100.0%)
I	4 (7.1%)
II	16 (28.6%)
III	26 (46.4%)
IV	9 (16.1%)
V	1 (1.8%)
Comorbidities	
Hay fever	
No	35 (62.5%)
Yes	21 (37.5%)
Asthma	
No	41 (73.2%)
Yes	15 (26.8%)
Other allergies	
No	55 (98.2%)
Yes	1 (1.8%)

Figure 1 A-E. Pie charts for mild-moderate-severe AD using the different severity score systems
Figure 1A: EASI, 1B: vIGA-AD, 1C: TIS, 1D: SCORAD, 1E: POEM.



Table 2 and Figure 1A-E

Conclusions

These findings show substantial differences between investigator-assessed, patient-reported, and hybrid AD severity measures in a population-based adult cohort. Investigator-assessed tools tended to classify disease as

milder than patient-reported measures, while SCORAD yielded intermediate results. Acknowledging previous validation studies, the choice of severity instrument may still materially influence cohort characterization and interpretation in epidemiologic studies and clinical trials.

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Comprehensive Assessment of Skin Barrier Dysfunction in Chronic Hand Eczema in Patients Eligible for Delgocitinib: A Non-Invasive Comparative Study

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Introduction
Chronic hand eczema (CHE) is a highly prevalent and burdensome condition characterized by persistent inflammation and impaired skin barrier function. Objective, non-invasive assessment of barrier parameters may provide valuable insights into disease mechanisms and support therapeutic decision-making, particularly in the era of targeted treatments such as topical JAK inhibitors. The aim of this study was to evaluate and compare skin barrier function parameters between lesional and non-lesional skin in patients with chronic hand eczema who are candidates for initiation of delgocitinib.

Materials and Methods
This observational study included adult patients diagnosed with chronic hand eczema (CHE) of at least 6 months' duration, evaluated in a tertiary dermatology center and considered eligible for treatment with delgocitinib. The etiology of CHE was classified as irritant, allergic, atopic, protein contact dermatitis, unknown, or mixed, according to clinical and diagnostic criteria. Skin barrier function was assessed using standardized, non-invasive techniques in both lesional and adjacent non-lesional skin within the same patient. The following parameters were evaluated: transepidermal water loss (TEWL), stratum corneum hydration (SCH), skin temperature, erythema and melanin indices, skin elasticity (R0, R2, R7), and electrical impedance parameters (mix, mix phase, Z). All measurements were performed under controlled environmental conditions using validated devices. Comparative intra-individual analyses between lesional and non-lesional skin were conducted.

Results
A total of 6 patients with chronic hand eczema were included, with a mean age of 34.0 ± 12.1 years, being 83.3% female. Lesional skin showed a trend toward higher TEWL (18.0 vs 17.8), increased erythema (358.6 vs 330.3) and higher skin temperature (32.7 vs 32.05). Elasticity parameters showed a trend to higher R2 (0.91 vs 0.72) and R7 (0.58 vs 0.46) in lesional skin. Electrical impedance parameters showed variability, with lower mix values (5.39 vs 6.28) and markedly lower Z values (142.2 vs 329.1), No consistent pattern was observed for SCH.

Conclusions
Chronic hand eczema is associated with multidimensional alterations in skin barrier function, supporting the central role of barrier dysfunction and highlighting the potential of non-invasive biomarkers for objective disease characterization and for guiding and monitoring response to targeted therapies such as delgocitinib.

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Ruxolitinib Cream Use to Delay or Prevent Treatment Escalation in Adults With Moderate Atopic Dermatitis Eligible for Systemic Therapy: Results From the TRuE-AD4 Study

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Introduction

Following the failure of topical corticosteroids (TCS) and topical calcineurin inhibitors (TCI) in adults with moderate atopic dermatitis (AD), treatment often requires escalation to systemic therapy. In the TRuE-AD4 phase 3b study (NCT06238817), 1.5% ruxolitinib (selective Janus kinase [JAK] 1/JAK2 inhibitor) cream applied twice daily (BID) for 8 weeks was well tolerated and quickly reduced the signs, symptoms, and quality-of-life burden associated with moderate AD versus vehicle in patients post-TCS and -TCI. Disease control achieved with ruxolitinib cream was maintained to Week 24. This analysis investigated the long-term (24-week) disease control and safety of as-needed ruxolitinib cream treatment in TRuE-AD4 with respect to remaining on topical therapy and preventing progression of AD to levels that typically require systemic therapy.

Materials and Methods

Patients aged ≥18 years with AD, an Investigator's Global Assessment (IGA) of 3, Eczema Area and Severity Index (EASI) >7, itch numerical rating scale (NRS) ≥4, Dermatology Life Quality Index (DLQI) score >10, and 10% to 20% affected body surface area (BSA) post-TCS and -TCI were randomized (2:1) to 1.5% ruxolitinib cream BID or vehicle for 8 weeks. At Week 8, patients who achieved a ≥50% reduction in EASI score from baseline (EASI-50)

continued to apply study cream for up to 16 additional weeks in the vehicle-controlled extension (VCE), but only as needed (stopping treatment 3 days after lesion clearance). Patients not achieving EASI-50 by Week 8 or patients for whom EASI-50 was not maintained were eligible to enter an escape arm, whereby ruxolitinib cream was applied open-label.

Results

Of 241 patients initially randomized to ruxolitinib cream or vehicle (mean age, 39 y; 54% female; mean [SD] EASI, 12.6 [4.1]; mean [SD] affected BSA, 15.1% [3.0%]), 154 of 160 (96.3%) and 60 of 81 (74.1%) completed the 8-week, continuous, vehicle-controlled treatment period, respectively, and 121 (75.6%) and 20 (24.7%) responded to treatment (EASI-50) and entered the 16-week, double-blind, as-needed VCE period. More patients on vehicle versus ruxolitinib cream who completed Week 8 did not achieve EASI-50 and thus entered the escape arm (66.7% vs 20.8%). By Week 8, more patients in the vehicle group versus ruxolitinib cream group (14.8% vs 1.9%) met the typical criteria for escalation to systemic therapy (IGA score >3, EASI score >16, itch NRS score >4, BSA >10%, and DLQI score >10), which represents an 87% reduction in risk with ruxolitinib cream. In the VCE period, 84.3% of patients who applied ruxolitinib cream at least once completed treatment, and few patients entered the escape arm (11.6%); 3 patients (2.5%) met the criteria for systemic therapy. Disease control was also evident with the mean reduction in affected BSA from baseline (15.1%) to Week 8 (2.5%) being maintained at Week 24 (2.5%) with as-needed application of ruxolitinib cream. During the 4-week intervals between study visits in the as-needed treatment period, patients in the ruxolitinib cream group spent a mean of 15.8% to 24.3% of time off treatment owing to lesion clearance. Ruxolitinib cream was well tolerated in the double-blind as-needed period, with few application site reactions (1.7%). No patients in the as-needed treatment period discontinued owing to a treatment-emergent adverse event.

Conclusions

This study enrolled adults with moderate AD post-TCS and -TCI, who may otherwise have been eligible for systemic therapy. With 16 weeks of as-needed use following 8 weeks of continuous use, ruxolitinib cream maintained disease control and tolerability in most of these patients, with few patients meeting criteria typically used for progression to systemic therapy. These findings suggest that ruxolitinib cream is an effective topical therapy that can be used intermittently as needed to delay or prevent progression to systemic therapy in patients with moderate AD.

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Long-Term Safety and Pharmacokinetics of Ruxolitinib Cream in Adults With Moderate Atopic Dermatitis Eligible for Systemic Therapy: 24-Week Results From the TRuE-AD4 Study

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Introduction
Effective treatment of patients with moderate atopic dermatitis (AD) after failure of topical corticosteroids (TCS) and topical calcineurin inhibitors (TCI) has typically required escalation to systemic therapy that exposes patients to considerations related to such treatments. The TRuE-AD4 phase 3b study (NCT06238817) showed that ruxolitinib (selective Janus kinase [JAK]1/JAK2 inhibitor) cream was well tolerated and quickly reduced the signs and symptoms of moderate AD after failure of TCS and TCI. Disease control achieved with ruxolitinib cream was maintained to Week 24, potentially delaying or preventing the need for systemic therapy. A safety warning for serious infections, major adverse cardiovascular events (MACE), thromboembolic events, malignancies, and mortality accompanies most of the US and Canadian labels of JAK inhibitors for inflammatory conditions, based on findings with the systemic pan-JAK inhibitor tofacitinib in patients with rheumatoid arthritis. However, none of these events occurred in this 24-week study. The present analysis further investigated the long-term (24-week) safety of ruxolitinib cream in TRuE-AD4, with a particular focus on systemic (eg, hematologic) effects associated with JAK inhibition in the context of ruxolitinib pharmacokinetics.

Materials and Methods
TRuE-AD4 included adults (aged ≥18 y) with an Investigator's Global Assessment score of 3), Eczema Area and Severity Index (EASI) score >7, itch numerical rating scale ≥4, Dermatology Life Quality Index score >10, and 10% to 20% affected body surface area post-TCS and -TCI. Patients were randomized (2:1) to twice-daily 1.5% ruxolitinib cream or vehicle for 8 weeks, at which time patients who achieved a ≥50% reduction in EASI score from baseline (EASI-50) could continue to apply study cream for up to 16 additional weeks on an as-needed basis (stopping treatment 3 days after lesion clearance). Patients not achieving EASI-50 by Week 8 or patients for whom EASI-50 was not maintained were eligible to enter an escape arm, whereby ruxolitinib cream was applied open-label.

Results
Of 160 patients who applied ruxolitinib cream in the 8-week, continuous, vehicle-controlled (VC) treatment period, 121 continued applying ruxolitinib cream in the double-blind as-needed VC extension period and 32 switched to the open-label escape arm at the start of the as-needed period. Consistent with no serious infections,

MACE, thromboembolic events, malignancies, or mortality in the 24-week study, there were no clinically meaningful changes from baseline in mean hemoglobin, neutrophil, or platelet levels. Similarly, median ruxolitinib plasma concentrations remained ≥4-fold lower than the threshold associated with JAK-mediated myelosuppression (half-maximal inhibitory concentration of 281 nM following thrombopoietin stimulation in adult whole blood in vitro) throughout the continuous treatment period (Week 2, 57.4 nM; Week 8, 47.0 nM) and decreased during the as-needed period (Week 24, 18.0 nM). Among 6 patients with ≥1 ruxolitinib concentration measurement >281 nM, there were no clinically relevant changes in hematologic parameters and no clinical sequelae. Overall, there was no observed correlation between steady-state ruxolitinib concentration quartiles and hemoglobin, neutrophil, or platelet levels in the VC period.

Conclusions

In adults with moderate AD post-TCS and -TCI, low ruxolitinib plasma concentrations throughout the 24-week study suggested that physiologically meaningful systemic JAK inhibition is highly unlikely. Correspondingly, no MACE, malignancy, serious infections, thromboses, fatalities, or clinically meaningful changes in hematologic parameters occurred during the study. Occasional outliers in plasma concentrations were not associated with clinical sequelae. These findings suggest ruxolitinib cream can be used to treat patients otherwise eligible for systemic therapy without exposing them to potential risks associated with these therapies.

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Abstract N°: 2353

Ruxolitinib Cream in Moderate Atopic Dermatitis Across Disease Severity Thresholds: Insights From Randomized Trials and Real-World Data

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Introduction
Moderate atopic dermatitis (AD) represents a clinically heterogeneous disease state, with severity inconsistently defined across clinical trials, treatment guidelines, and real-world practice. Defining moderate AD is multifactorial and may rely on objective severity scores, disease extent (ie, body surface area [BSA] involvement), symptom burden, quality-of-life (QoL) impairment, and/or prior treatment history. This heterogeneity complicates therapeutic decision-making and escalation strategies. Across randomized clinical trials and real-world settings, ruxolitinib (Janus kinase [JAK] 1/JAK2 inhibitor) cream has demonstrated clinically meaningful efficacy in patients with moderate AD, including those with substantial disease burden and features commonly necessitating consideration of systemic therapy. The objective of this analysis was, for the first time, to evaluate the consistency of efficacy outcomes with ruxolitinib cream across a myriad of moderate AD definitions using data from randomized trials and real-world claims.

Materials and Methods
An analysis was conducted using data from patients with moderate AD enrolled in 4 randomized, double-blind, vehicle-controlled phase 3 studies, complemented by retrospective real-world claims analyses. Moderate disease was defined using prespecified and post hoc criteria, including an Investigator's Global Assessment score of 3 and baseline Eczema Area and Severity Index (EASI) ≥16 as well as affected BSA, patient-reported symptom severity, QoL impairment, and prior use of advanced AD therapies. Efficacy outcomes included achievement of ≥75%

improvement in EASI (EASI-75) and ≥4-point improvement in itch numerical rating scale score (itch NRS4) as well as changes in itch NRS, affected BSA, and dermatology-specific QoL scores (eg, Dermatology Life Quality Index and Children's version [DLQI/CDLQI]). Real-world outcomes from the Optum Research Database and Healthcare Integrated Research Database (HIRD) included treatment patterns and subsequent use of systemic therapies following initiation of ruxolitinib cream.

Results

Randomized pivotal trials (TRuE-AD1, TRuE-AD2, TRuE-AD3, and TRuE-AD4) included 1820 patients aged 2 to 88 years with mild to moderate AD and claims databases included 2820 patients aged ≥12 years. Although affected BSA was limited to ≤20% in all pivotal studies per inclusion criteria, other disease severity assessments were heterogeneous at baseline (EASI range, 0.6−40.0; DLQI/CDLQI range, 0−30.0; itch NRS score range, 0−10.0 [by visit]). Across all randomized trials, ruxolitinib cream consistently demonstrated greater clinical improvement versus vehicle in all definitions of moderate AD. Treatment effects were observed as early as Week 2 and were maintained through Week 8, including in patients meeting higher objective severity thresholds, those with substantial symptom burden, and those otherwise eligible for systemic therapy. Improvements were consistent across efficacy endpoints, including EASI-75, itch NRS4, BSA involvement, and QoL measures. When current itch (ie, no recall) was assessed in TRuE-AD4, improvement with ruxolitinib cream versus vehicle was observed as quickly as 15 minutes after first application. Real-world claims analyses from the HIRD showed that most patients (>90%) initiating ruxolitinib cream (mean of 2.4 ruxolitinib cream fills [60-g tubes]) did not have a first claim for biologic therapy in 18 months of follow-up.

Conclusions

Across randomized clinical trials, ruxolitinib cream demonstrated robust and consistent efficacy across heterogeneous definitions of moderate AD. This efficacy was reflected in real-world claims data showing few patients with moderate AD escalated to biologic therapies after initiating ruxolitinib cream. Together, these findings highlight the role of ruxolitinib cream as an effective treatment option across the moderate AD disease spectrum, challenging current treatment paradigms, including in patients who may otherwise be considered for systemic therapy escalation.

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Atopic Dermatitis and Life Course Disruption: Evidence From a Multidimensional International Survey (TOPiQAL)

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory disease with well-documented symptomatic and quality-of-life burden. Given the substantial impairment in quality of life, AD may also affect long-term life trajectory, including education, career, and family planning. The aim of this analysis was to assess the association between Patient-Oriented Eczema Measure (POEM)-defined severity and life course disruption, including domain-level structural impact, in adults with AD.

Materials and Methods
In the TOPiQAL study, adults from 5 countries (France, Germany, Italy, Spain, United Kingdom) with self-reported, physician-diagnosed AD completed an online survey incorporating validated patient-reported outcome measures. Disease severity was assessed using POEM and categorized as mild, moderate, or severe. Life course disruption was evaluated using the Dermatology Long-Term Life Impact Measure (DLLIM) total score and domain-level analyses. Comparative analyses were performed across severity groups.

Results
A total of 5295 adults with AD were included (mild, n=1838; moderate, n=2296; severe, n=1161). Mean (SD) DLLIM scores increased across severity categories (mild, 8.46 [9.72]; moderate, 14.19 [10.65]; severe, 16.96 [11.24]; $P<0.001$), with the largest increment between mild and moderate disease. Among patients with mild, moderate, and severe disease, limitations in professional careers were reported by 19.70%, 36.98%, and 41.43% of patients, respectively ($P<0.001$). Negative impact on family life was reported by 17.74%, 37.85%, and 44.62% of patients, respectively ($P<0.001$). A barrier to parenthood was reported by 15.94%, 31.88%, and 36.52% of patients, respectively ($P<0.001$). Self-confidence impairment was reported by 34.00%, 54.49%, and 69.77% of patients, respectively ($P<0.001$). Moderate and severe groups demonstrated overlapping levels of structural disruption across domains.

Conclusions

Life course disruption in AD increases with clinical severity but rises most markedly at the transition from mild to moderate disease. Moderate AD is associated with substantial impact closely approximating severe disease. These findings suggest that long-term life disruption emerges earlier in the course of disease than traditionally assumed and should be considered in clinical management strategies.

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Abstract N°: 2368

Patient Treatment Preferences in Atopic Dermatitis: Best–Worst Scaling Results From an International Study (TOPiQAL)

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by substantial symptom burden, particularly itch. Although multiple topical and systemic therapies are available, limited data exist on how patients prioritize treatment attributes in real-world decision-making and whether these preferences differ according to disease severity. Understanding patient preferences may enhance shared decision-making and treatment satisfaction. The aim of this analysis was to quantify treatment attribute preferences in adults with AD using a best–worst scaling (BWS) approach and to compare preferences between moderate and severe disease as defined by the Patient-Oriented Eczema Measure (POEM).

Materials and Methods
In the TOPiQAL study, adults from 5 countries (France, Germany, Italy, Spain, United Kingdom) with self-reported, physician-diagnosed AD participated in an online survey and completed a BWS (also termed maximum difference scaling) module assessing key treatment attributes of available therapies. Attributes included speed and magnitude of itch improvement, skin clearance, mode of administration (corticosteroid-free topical cream, oral tablet, subcutaneous injection), treatment frequency, monitoring requirements, and risk of severe adverse events. Preference weights were estimated using hierarchical Bayes methods and rescaled to a 0 to 10 importance score to allow direct comparison across attributes and patient groups. Analyses were restricted to patients with moderate and severe AD and stratified by POEM-defined severity.

Results
A total of 3457 adults with moderate (n=2296) or severe (n=1161) AD were included. Speed of itch improvement was the most influential attribute, with rapid relief within minutes (moderate, 7.95; severe, 8.70) and within a few days (moderate, 7.93; severe, 8.36) receiving the highest mean importance scores. The likelihood of substantial itch reduction (60% at 2–3 months) ranked next (moderate, 7.07; severe, 7.15). A corticosteroid-free topical cream was preferred over oral tablet and subcutaneous injection (moderate, 5.06; severe, 4.89), while subcutaneous injection was the least preferred route of administration. Safety monitoring requirements and treatment frequency

had low importance (scores <3.2). Preference patterns were largely consistent across POEM-defined severity groups.

Conclusions

In this international BWS analysis, rapid itch relief, particularly within minutes, was the dominant driver of treatment preference in adults with AD, consistently ranking above the importance of long-term outcomes such as skin clearance. Non-invasive administration, particularly corticosteroid-free topical therapy, was strongly favored across severity levels over oral and injectable options. These findings indicate that fast-acting anti-pruritic therapy and non-invasive administration are the primary drivers of treatment preference in AD, independent of disease severity, and should be prioritized as key attributes.

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Abstract N°: 2369

Patient Profile and Multidimensional Burden of Atopic Dermatitis: Results From an International Survey (TOPiQAL)

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory disease associated with substantial physical and psychosocial burden. Although severe AD is recognized as highly impactful, the burden of moderate disease remains insufficiently characterized. The aims of this analysis were to characterize multidimensional patient-reported burden across disease severity categories as defined by the Patient-Oriented Eczema Measure (POEM) as well as to evaluate whether impairment escalates proportionally with clinical severity in adults with AD and whether this burden persists despite disease control with treatment.

Materials and Methods
In the TOPiQAL study, adults from 5 countries (France, Germany, Italy, Spain, United Kingdom) with self-reported, physician-diagnosed AD completed an online survey incorporating validated patient-reported outcome (PRO) measures, including POEM, Dermatology Life Quality Index (DLQI), Dermatological Mental Load Questionnaire (DMLQ), Patient Unique Stigmatization Holistic tool in Dermatology (PUSH-D), and Dermatology Long-Term Life Impact Measure (DLLIM), as well as a PRO measure for disease control similar to the Atopic Dermatitis Control Tool (ADCT-like). Descriptive and comparative analyses were performed across mild, moderate, and severe POEM categories.

Results
A total of 5295 adults with AD were included (mild, n=1838; moderate, n=2296; severe, n=1161); 59.3% of patients were female. Overall mean (SD) age was 40.41 (14.31) years and mean (SD) affected body surface area among patients with mild, moderate, and severe disease was 4.90% (4.86%), 7.51% (6.64%), and 10.55% (8.79%), respectively (P<0.001). Mean (SD) DLQI increased significantly across severities (mild, 7.05 [6.84]; moderate, 11.83 [7.07]; severe, 14.41 [7.49]; P<0.001). Similar patterns were observed for stigmatization (PUSH-D) scores (12.84 [16.44], 22.11 [18.02], 26.02 [19.57]; P<0.001) and life impact (DLLIM) scores (8.46 [9.72], 14.19 [10.65], 16.96 [11.24]; P<0.001). DMLQ also increased significantly across groups (mild, 16.61 [3.55]; moderate, 18.20 [3.74]; severe, 20.03 [4.35]; P<0.001). Across treatment groups, a substantial proportion of patients (78.4%) remained

uncontrolled as per the ADCT-like definition. Uncontrolled patients consistently showed markedly higher burden across all PROs, including quality of life, stigma, and mental load. Notably, this elevated burden persisted despite treatment, including among patients receiving systemic or advanced therapies.

Conclusions

Multidimensional burden increased significantly across POEM-defined severity categories. Patients with moderate AD exhibited levels of quality-of-life impairment, stigma, mental burden, and life trajectory impact approaching those with severe disease, indicating that clinically meaningful burden is already present below the conventional severe threshold. It is important to note that this significant burden persists despite treatment and is strongly associated with uncontrolled disease, which was observed in 3 out of 4 patients, and thereby highlights the potential limitations of current management based on clinical severity alone. These findings also serve as a reminder that patients with moderate AD experience a clinically relevant burden with an impact on their daily lives.

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Use of Topical Corticosteroids One Year Prior to Referral and One Year After First Consultation in Patients with Atopic Dermatitis

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Introduction
Topical corticosteroids (TCS) are first-line therapy in atopic dermatitis (AD) and are effective when used appropriately. However, concerns about potential side effects may potentially contribute to suboptimal TCS use in primary care. This study investigates dispensed TCS in referred patients during the year prior to referral and the year after the first consultation at a tertiary dermatology outpatient clinic for AD.

Materials and Methods
This retrospective cohort study included 119 patients diagnosed with AD referred to a tertiary dermatology outpatient clinic in the period between 2021 and 2023. For each patient data were extracted from Shared Medication Record and all dispensed TCS products were assessed for the year prior to referral and the year following the first consultation. TCS products were categorized by potency group (I-IV), and both total amounts dispensed (grams), and potency distribution were analyzed.

Results
A substantial proportion of patients (33.6%) had no dispensed TCS in the year prior to referral. Overall TCS use increased following the first consultation. Significant increases were observed in mean use of TCS group II among children aged 0-5 years (+157%, p = 0.03) and of TCS group III among adults (+114%, p = 0.02). After assessment, 55% of referred AD patients were managed with optimized topical therapy and 40% initiated systemic treatment.

Conclusions
These findings suggest that a substantial proportion of patients with AD may not have received fully optimized topical treatment before referral. Following specialist consultation, TCS use increased, and treatment was optimized, with more than half of patients managed with topical therapy. This highlights a potential for improved disease control through optimized topical treatment in primary care and may reduce the need for specialist referral.

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Abstract N°: 2393

Impact of genital involvement on disease severity and quality of life in patients with atopic dermatitis

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease with heterogeneous clinical presentation and variable anatomical distribution. Genital involvement is often underreported in clinical practice due to patient embarrassment, lack of active questioning, and limited physical examination of this area. However, lesions in this location may have a relevant impact on symptoms, quality of life, sexual wellbeing and treatment needs. The aim of this study was to evaluate the clinical profile, disease severity and patient-reported burden of AD patients with genital involvement.

Materials and Methods
A cross-sectional study was conducted including consecutive patients with AD attending a specialized AD clinic at a tertiary hospital. Sociodemographic and clinical variables, atopic comorbidities, lesion distribution, previous treatments, physician-reported severity scores, and patient-reported outcomes were collected. Patients were classified according to the presence or absence of genital involvement. Disease severity was assessed using IGA, BSA, EASI and SCORAD. Symptom burden and quality of life were evaluated using NRS pruritus, NRS sleep, POEM, DLQI, ADCT, WHO-5 and Skindex-mini.

Results
A total of 313 patients with AD were included, of whom 55 patients, 17.6%, presented genital lesions. Patients with genital involvement showed significantly greater objective disease severity than those without genital involvement, with higher IGA scores (2.85 vs 1.64; $p<0.001$), BSA involvement (34.42 vs 12.45; $p<0.001$), EASI scores (20.80 vs 9.01; $p<0.001$) and SCORAD scores (52.78 vs 31.89; $p<0.001$). Patients with genital involvement also reported greater symptom burden, with higher NRS pruritus scores (7.29 vs 5.31; $p<0.001$) and higher NRS sleep disturbance scores (5.40 vs 2.98; $p<0.001$). Patient-reported outcomes were significantly worse in this group, including higher POEM (19.03 vs 12.89; $p<0.001$), DLQI (11.33 vs 7.12; $p=0.001$), ADCT (14.94 vs 9.67; $p<0.001$) and Skindex-mini scores (11.80 vs 9.20; $p=0.015$).

Genital involvement was associated with a more extensive anatomical distribution of AD lesions, including more frequent involvement of the face and eyelids (68.5% vs 41.5%; $p<0.001$), scalp (36.4% vs 10.5%; $p<0.001$), upper limbs (76.4% vs 52.7%; $p=0.001$), lower limbs (81.8% vs 44.6%; $p<0.001$), gluteal region (85.5% vs 12.8%; $p<0.001$) and hands (50.0% vs 29.8%; $p=0.005$). Patients with genital involvement also had a higher prevalence of asthma (50.0% vs 30.5%; $p=0.006$) and allergic rhinitis (56.6% vs 37.5%; $p=0.010$). Previous use of oral corticosteroids (66.7% vs 40.6%; $p<0.001$) and ciclosporin (37.0% vs 21.9%; $p=0.019$) was more frequent in this group, as was treatment modification at the study visit (67.3% vs 31.2%; $p<0.001$).

Conclusions

Genital involvement in AD was present in nearly one in five patients and was associated with greater clinical severity, more extensive anatomical involvement, higher symptom burden, poorer disease control and worse quality of life. These findings support the need for systematic assessment of genital lesions in AD consultations and suggest that genital involvement may help identify patients with greater disease complexity and therapeutic needs.

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Abstract N°: 2406

Divergent systemic treatment–associated, trajectories of type 2 inflammatory diseases in atopic dermatitis

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Introduction

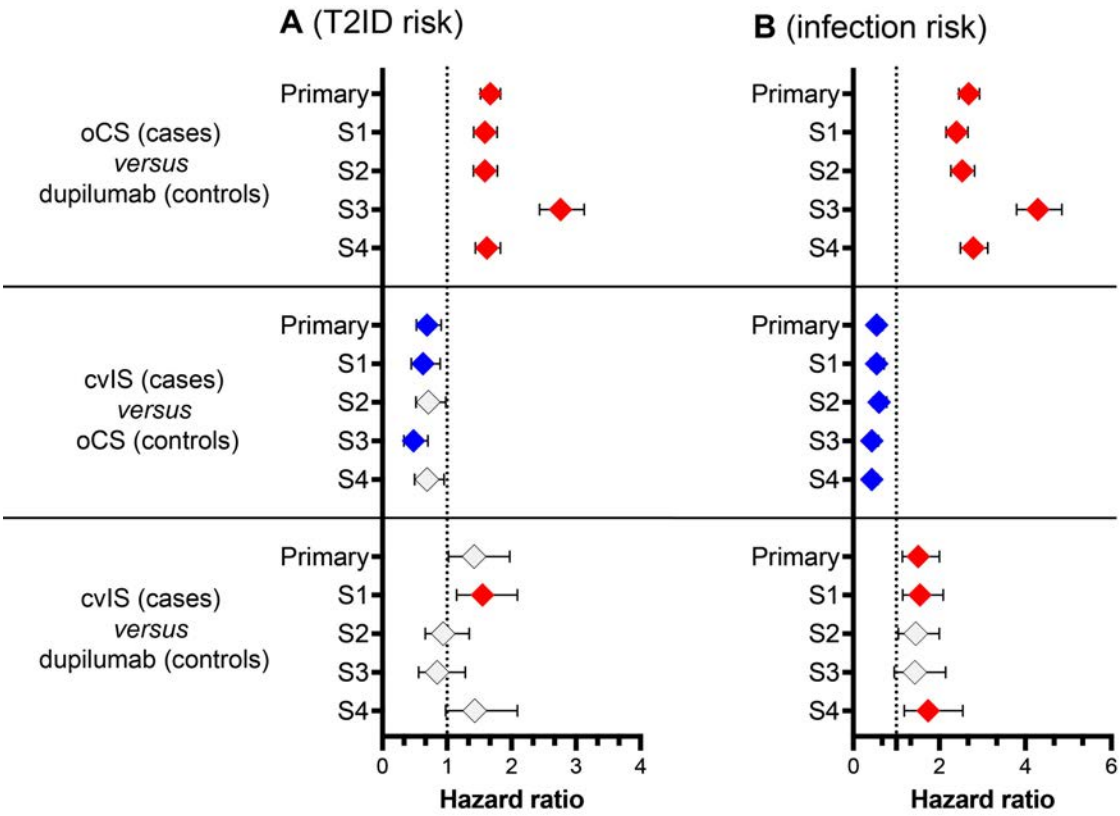
Patients with atopic dermatitis (AD) have an increased risk of developing subsequent type 2 inflammatory diseases (T2IDs). Indirect evidence suggests that systemic therapies, particularly biologics, may exert disease-modifying effects; however, whether treatments alter long-term T2ID trajectories remains unclear.

Materials and Methods

We performed retrospective cohort analyses using TriNetX data under established IRB-exempt procedures. Three AD treatment groups were defined: oral corticosteroids (oCS), conventional systemic immunosuppressants (cvIS), and dupilumab. Drug exposure defined the index event. Propensity score matching (PSM) balanced baseline characteristics, and four sensitivity analyses tested robustness. Outcomes included incident T2IDs, infections (positive control), and varicose veins (negative control). All pairwise treatment comparisons were evaluated.

Results

Before matching, approximately 76,000 oCS-treated, 20,000 dupilumab-treated, and 2,200 cvIS-treated patients were identified. After PSM, covariates were well balanced across all comparisons. In the primary analysis, oCS-treated patients had a higher incidence of new-onset T2IDs than dupilumab-treated patients (75.7 vs. 44.4 per 1,000 person-years). A similar pattern was observed for infections, while the negative control outcome showed no difference. Compared with oCS, cvIS was associated with a lower incidence of subsequent T2IDs (47.6 vs. 67.2 per 1,000 person-years), with consistent findings in two of four sensitivity analyses. Infections were also less frequent among cvIS-treated patients than among oCS users. Compared with dupilumab, cvIS showed a modest, non-significant increase in T2ID incidence, with inconsistent results in sensitivity analyses.



Risk of type 2 inflammatory diseases in patients with atopic dermatitis (AD) treated with (i) oral corticosteroids (oCS), (ii) dupilumab, (iii) of conventional immunosuppressants (cvIS). (A) T2ID and (B) infection risks are depicted. Hazard ratios (HRs) and 95%-confidence intervals for the primary analysis (1 day to 18 months after index) and sensitivity analyses (S1: 3 -18 months, S2: mandating a 6-months minimal-baseline-time-window, S3: mandating a second drug exposure at 3-18 months after the first documentation, S4: exclusion of outcomes at data retrieval – instead of the default option). To correct for multiple testing, Bonferroni correction (α=0.017) was used. Red indicates increased, blue decreased and white unchanged disease risks.

Conclusions

Overall, dupilumab was associated with the lowest risk of subsequent T2IDs and infections, cvIS with intermediate risk, and oCS with the highest risk. In addition to established efficacy and safety considerations, differences in long-term T2ID and infection risk may be relevant when selecting systemic therapies for AD.

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Abstract N°: 2409

Trajectory and genetic correlation mapping of cross-disease risks following incident type 2 inflammatory diseases

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Introduction

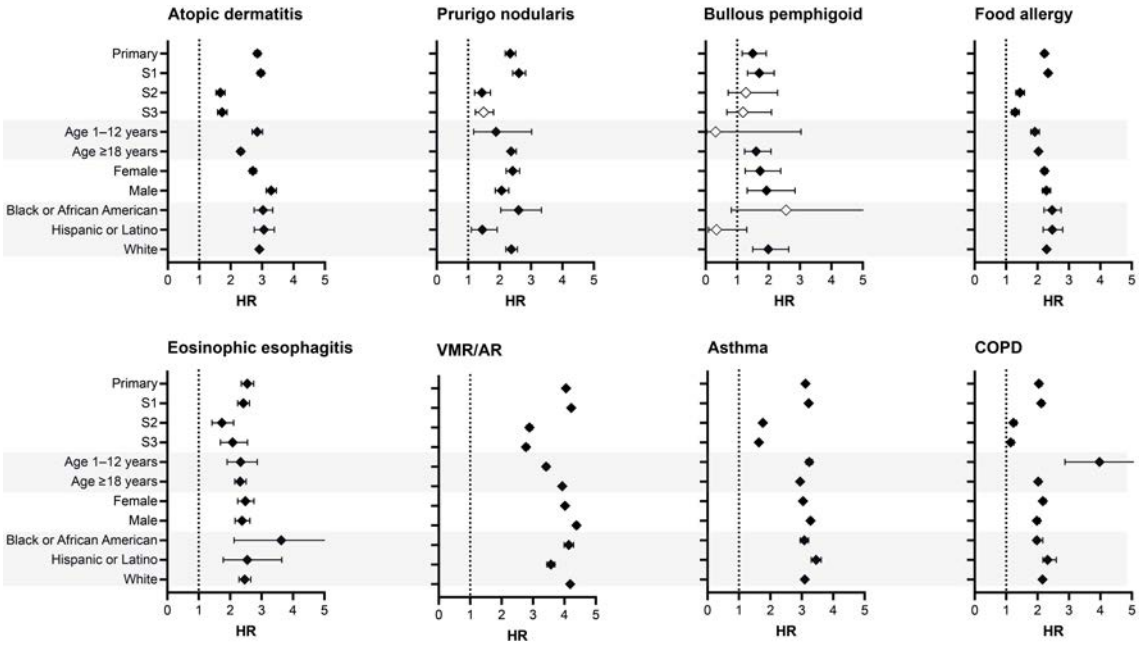
Type 2 inflammatory diseases (T2IDs) such as atopic dermatitis (AD), asthma, food allergy, eosinophilic esophagitis (EoE), chronic sinusitis (CS), and others, are immune-mediated conditions that frequently co-occur across organ systems and contribute to substantial disease burden. While the atopic march has long served as a conceptual model for T2ID progression, it remains unclear whether this linear sequence captures the broader comorbidity structure of T2IDs.

Materials and Methods

In this study, we systematically analyzed comorbidity patterns across nine T2IDs using two complementary methodological approaches: Large-scale real-world data (RWD) from over 129 million electronic health records and genome-wide genetic correlation, including data from three novel (asthma, chronic sinusitis and allergic rhinitis) metanalyses of genome-wide association studies.

Results

Retrospective matched cohort analyses revealed a highly interconnected disease network in which CS emerged as a central driver of downstream comorbidities, increasing the risk of multiple other T2IDs across diverse patient populations. AD, food allergy, and vasomotor and allergic rhinitis also showed strong cross-disease effects. Subgroup analyses uncovered notable age-, sex-, and race-specific disparities. Genetic correlation analyses supported shared heritability among many disease pairs and integration with RWD allowed to infer directionality. While some disease pairs showed discordant findings between genetic correlation and RWD, most associations aligned across both methodologies.



Risk of type 2 inflammatory diseases in patients with incident chronic sinusitis compared to non-type 2 inflammatory diseases controls. Hazard ratios (diamonds) and 95% confidence intervals (error bars) for the risk of developing other type 2 inflammatory diseases (T2IDs) in patients with chronic sinusitis (CS) versus non-T2ID controls. Each panel represents the indicated T2ID as an outcome, and each row shows results from the primary analysis, sensitivity analyses (S1-S3), and subgroup analyses stratified by age, sex, and race/ethnicity. Black diamonds indicate statistically significant results; open diamonds represent non-significant results. Alternating row shading is used to visually separate subgroup levels. Abbreviations: AD, atopic dermatitis; PN, prurigo nodularis; VMR/AR, vasomotor and allergic rhinitis; EoE, eosinophilic esophagitis; CS, chronic sinusitis; COPD, chronic obstructive pulmonary disease; BP, bullous pemphigoid.

Conclusions

Together, our results highlight that T2ID progression extends beyond the atopic march and is shaped by a complex and heterogeneous network of interactions. This work provides a data-driven framework to guide risk stratification, inform early preventive strategies, and prioritize upstream disease targets within the type 2 inflammatory spectrum.

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Abstract N°: 2411

Two cases of refractory hyperkeratotic eczema on feet were successfully treated with stapokibart

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Introduction

Endogenous hyperkeratotic eczema is characterized by chronic well-demarcated hyperkeratosis and painful fissures on the hands and feet, often involving the plantar region. It occurs mostly in middle-aged and elderly people without obvious irritant exposure, and its cause is unknown.The disease has inconsistent curative effect, slow effect, easy recurrence and drug resistance. As a refractory inflammatory disease, it causes physical and mental pain and greatly affects patients' quality of life.This study reports two cases of endogenous eczema only on the feet. The patients had severe pruritus that affected their quality of life. Previous treatments with topical glucocorticoids, calcineurin inhibitors, oral retinoids, antihistamines and traditional Chinese medicine showed no obvious effect. After using stapokibart (a Chinese-made fully human monoclonal antibody blocking IL-4 and IL-13 signaling), pruritus and skin lesions improved significantly. This result provides a new idea for the treatment of hyperkeratotic eczema.

Case Presentation

Case 1

A 52-year-old female bank clerk with unremarkable past medical history and no history of allergic rhinitis, asthma or other allergic diseases presented with an 8-year recurrent pruritic foot rash aggravated for 2 months. The rash initially involved the left heel with severe pruritus. Multiple previous diagnoses included eczema and tinea pedis. Treatments with topical glucocorticoids, calcipotriol, local block therapy, oral retinoids, antihistamines and tripterygium wilfordii relieved symptoms temporarily but relapses persisted. The condition deteriorated again with severe itching 2 months prior to presentation.Physical examination revealed erythematous plaques, hyperkeratosis with scales, and partial ulceration and crusting on the right foot. Skin pathology showed epidermal hyperkeratosis, acanthosis, mild epidermal spongiotic edema, perivascular chronic inflammatory infiltration in the superficial dermis, and scattered eosinophils, consistent with eczema. The patient received initial stapokibart 600 mg, followed by 300 mg every 2 weeks. Marked improvement of rash and pruritus was observed after 4 weeks of treatment.

Case 2

A 49-year-old male teacher with unremarkable past medical history presented with a 2-year recurrent pruritic rash on the right foot. The lesion originated on the right foot with intractable pruritus. Recurrence remained despite multiple oral and topical medications. Oral abrocitinib 2 mg once daily for half a year showed poor efficacy. Dermatological examination showed plantar plaques with marked hyperkeratosis, fissures and yellow crusts, without obvious vesicles or pustules. Pathological findings were consistent with eczematous changes. The patient was treated with stapokibart and achieved satisfactory clinical efficacy after 8 weeks.

Conclusion

Hyperkeratotic eczema presents with variable clinical manifestations, a protracted and intractable course, and a

complex etiology, with some cases being difficult to treat. The therapeutic response to stapokibart in certain patients indirectly suggests that a subset of such eczema may be driven by Th2-mediated inflammatory responses. Further studies with enlarged sample sizes and long-term follow-up are warranted to verify the efficacy and safety of stapokibart.

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Abstract N°: 2436

Real-world disease burden and treatment outcomes in Chinese patients with moderate-to-severe atopic dermatitis: A stratified analysis of the ChinaSTAD registry

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Introduction
The prevalence of AD in China has increased over the last three decades, yet real-world data on disease management remain limited. This analysis from the China Atopic Dermatitis Registry Study (NCT05023668) evaluated clinical characteristics, treatment patterns, and 12-month longitudinal outcomes in patients uncontrolled by topical therapy, stratified by systemic treatment.

Materials and Methods
ChinaSTAD is a large-scale, prospective, observational registry. Eligible participants were aged ≥12 years with moderate-to-severe AD (SCORing AD [SCORAD] score ≥25) inadequately controlled by topical therapies. Assessments occurred at baseline (BL) and months 1, 4, 8, and 12. Effectiveness endpoints included SCORAD, Peak Pruritus Numerical Rating Scale (PP-NRS), and the Atopic Dermatitis Control Tool (ADCT; control defined as <7). The analysis focused on a systemic treatment naïve population (no prior systemic history). Within this group, we further analyzed a subset of systemic treatment initiators (started systemic therapy at BL).

Results
A total of n=10,000 participants were enrolled. In the systemic treatment naïve subpopulation (n=8,535; mean age 42.7±20.5 years), the cohort exhibited a heavy disease burden with a mean SCORAD of 53.3±16.0 and 89.7% remaining uncontrolled (ADCT ≥7). A total of 56.5% of participants reported allergic comorbidities, with allergic rhinitis (64.1% among patients who reported allergic comorbidities) being the most common. Baseline treatments were dominated by topical anti-inflammatory therapy (64.9%) and antihistamines (56.6%), while foundational moisturizing therapy was used by only 30.5%. Among systemic treatment initiators (n=2,957), the distribution of therapy classes at BL was predominantly biologic therapy (74.5%, n=2,112), followed by Janus kinase (JAK) inhibitors (15.3%, n=435) and oral conventional immunosuppressive therapy (7.7%, n=219). Dupilumab

accounted for nearly all biologic prescriptions (n=2,109; 74.4% of all initiators). Over 12 months, the mean SCORAD score for initiators decreased significantly from 55.3±16.1 to 12.9±11.9 ($p<0.001$). Correspondingly, the proportion of participants achieving disease control (ADCT <7) rose from 7.4% at BL to 90.6% at month 12. Progressive improvements were also seen in mean PP-NRS (7.3±2.1 to 1.7±1.6) and DLQI (11.6±6.7 to 2.6±3.3). Longitudinal analysis revealed a notable real-world shift toward treatment intensification; in the systemic treatment naïve subpopulation, dupilumab utilization increased from 25.6% at BL to 36.6% by month 12, while topical therapy, antihistamine, and traditional Chinese medicine use declined sharply.

Conclusions

Patients in China with moderate-to-severe AD face a profound clinical burden characterized by a significant treatment gap in foundational care. Real-world practice shows a transition toward systemic therapies. Systemic treatment, predominantly with dupilumab, demonstrated robust effectiveness in routine care, enabling over 90% of systemic initiators to achieve disease control over 52 weeks.

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Abstract N°: 2437

Severity-Dependent Associations Between Atopic Dermatitis and Systemic Comorbidities: A Nationwide Cohort Analysis

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Introduction

Atopic dermatitis (AD) is a systemic inflammatory disorder associated with multiple organ system comorbidities. However, data on how these risks vary with AD severity remain limited. This study aimed to evaluate the relationship between AD severity and the risk of systemic diseases, including malignancies, cardiovascular, autoimmune, and infectious conditions.

Materials and Methods

Analysis of the Korean National Health Insurance data (2015–2022) stratified AD patients into mild (n=3,162,685), moderate-to-severe (n=156,849), and controls (n=1,037,265). Multivariable Cox proportional hazards models assessed hazard ratios (HR) for various systemic diseases.

Results

Compared to controls, both mild and moderate-to-severe AD patients had increased risks of ischemic heart diseases (mild: HR 1.020 ; moderate-to-severe: HR 1.331), cerebrovascular diseases (mild: HR 1.053 ; moderate-to-severe: HR 1.247), skin cancers (mild: HR 1.533 ; moderate-to-severe: HR 2.509), hematologic malignancies (mild: HR 1.094 ; moderate-to-severe: HR 3.274), and various infections, with substantially higher risks in the moderate-to-severe group.

Conclusions

There is a strong, severity-dependent association between AD and systemic comorbidities. These results highlight the necessity for comprehensive systemic assessment and integrated management strategies to improve outcomes for AD patients.

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Initiating biologics in atopic dermatitis: Global practices and recommendations from the AMAZE project

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Introduction

Biologic therapies are approved for the treatment of moderate-to-severe atopic dermatitis (AD), but optimal treatment strategies in real-world clinical practice are not well defined. Many practical considerations remain to be addressed, including the initiation process, transition from other treatments, and long-term management. The AMAZE (Advancing Management of Atopic dermatitis and ecZEma) project aimed to explore real-world approaches to the use of biologics for AD and to identify best practices to support dermatologists in optimising patient care.

Materials and Methods

AMAZE was chaired by a Global Steering Committee (GSC) of six leading dermatologists and nurse practitioners, representing a wide range of academic, clinical, and healthcare system perspectives from multiple continents. The study included a global online survey of 150 dermatologists with recent experience in prescribing biologics from North America, Europe and Japan. Findings were interpreted by the GSC and further discussed during four regional expert discussion meetings (15 dermatologists). The survey results, expert consensus, and a narrative literature review were used to develop a set of best practice recommendations.

Results

The survey findings revealed considerable regional variation in biologic initiation, transition strategies, and follow-up schedules, driven by local guidelines and reimbursement policies. For example, while 47% of clinicians plan for long-term biologic use (>1 year), Japanese respondents often anticipate shorter treatment durations (4–12 months), perhaps reflecting national guideline wording on treatment discontinuation after sustained remission. Transition practices from conventional systemic therapy to biologic also varied, with 49%, 33%, and 18% of clinicians reporting that they overlap treatments, transition between treatments directly without overlap, or use a washout period, respectively. European respondents preferred to discontinue conventional systemic therapies before biologic initiation, whereas overlap strategies were more common in North America and Japan. Early follow-up (<4 weeks) was reported by 36% of survey respondents, although this was largely driven by dermatologists in Japan due to healthcare system requirements. Expert-informed recommendations (**Table**) emphasised the importance of establishing patient-centered treatment goals focused on long-term disease control, individualised transition strategies when switching from conventional systemic therapies, structured follow-up with formal assessment of treatment response around 12–16 weeks after biologic initiation, and proactive management of flares through use of emollients and topical anti-inflammatory therapies.

Conclusions

The AMAZE project highlighted the absence of a single global standard for initiating and managing biologics, underscoring the need for flexible, region-specific strategies to improve the real-world use of advanced systemic therapies in AD. A set of expert-informed recommendations was proposed to provide practical guidance on individualised, patient-centered approaches to initiating and managing biologic therapy in routine clinical practice.

Best practice recommendations and supporting literature*
Treatment goals and expectations for biologic therapy
At treatment initiation, clinicians and patients should agree on achievable, patient-centered, long-term goals aimed at improving disease signs/symptoms and quality of life, with clear communication that biologics provide long-term disease control rather than cure [1-8].
Clinicians should be equipped with shared decision-making skills and use time-efficient consultations to engage patients as partners in care, providing clear, evidence-based guidance to support collaborative decisions and ongoing adjustment of treatment goals with biologics [1, 2, 4-7, 9-11].
Clinicians should provide accessible, tailored patient education on biologics that is individualised to patient needs and preferences, using appropriate formats such as written materials, images, videos, or digital resources to support understanding of treatments and skincare [2-4, 7, 10-13].
Transitioning patients to biologic therapy
In the absence of strong evidence supporting a single approach, clinicians should adopt personalised transition strategies when initiating a biologic, tailoring initiation to individual patient and disease characteristics, including disease severity, current and prior treatments, prior treatment response, adverse events, and local reimbursement criteria [4, 14].
When initiating a biologic, clinicians should assess the need for treatment overlap and establish a clear plan for tapering or discontinuing any ongoing conventional systemic therapy; a limited period of overlap may be appropriate for agents with short half-lives, such as cyclosporine, when safety and tolerability allow, with timing of tapering or discontinuation guided by achievement of disease control or a predefined timeframe [14].
Follow-up after starting biologic therapy
In the early period following biologic initiation (≤8 weeks), follow-up visits should emphasise patient education as well as treatment adherence, injection technique, and safety monitoring; evaluation of treatment effectiveness should generally be performed at later predefined assessment timepoints [7].
Treatment effectiveness for biologics should be assessed at predefined timepoints; treatment response should be evaluated using both clinician- and patient-reported outcomes, such as BSA, EASI, IGA, DLQI, PP-NRS, and SD-NRS, at approximately 3 months (12–16 weeks) after biologic initiation, recognising that some patients may not yet have achieved peak treatment response and may respond later [1, 2, 4-7, 15, 16].
After achievement of clinical remission with biologics, periodic review should be maintained; during the maintenance phase, follow-up visits should be scheduled every 6 months, or as clinically indicated, to monitor treatment efficacy, safety, and adherence [4, 6].
Clinicians should apply consistent, evidence-based clinical practices while individualising treatment decisions to each patient's needs, to support high-quality care and minimise unwarranted variability in biologic management across all points of care.
Managing flares and use of concomitant medications while on biologic therapy
Clinicians should optimise background therapy by maintaining, where necessary, ongoing use of emollients and intermittent topical therapies that target inflammation to support sustained remission [2-5, 7, 9-13, 17].
Clinicians should educate patients about the flaring nature of the disease, emphasising that flares are an inherent part of the disease course and that topical therapies remain essential even when systemic therapies, including biologics, are used.
Clinicians should guide appropriate flare management while on a biologic by providing clear instructions for short-term use of TCS, TCI, topical phosphodiesterase inhibitors, topical JAK inhibitors, or topical aryl hydrocarbon receptor modulators for localised flares, as clinically appropriate [4, 6]

BSA, body surface area; EASI, Eczema Area and Severity Index; JAK, Janus kinase; IGA, Investigators' Global Assessment; DLQI, Dermatology Life Quality Index; PP-NRS, Peak Pruritus Numerical Rating Scale; SD-NRS, Sleep Disturbance Numerical Rating Scale; TCS, topical corticosteroids; TCI, topical calcineurin inhibitors. *References that support aspects of the best practice recommendation but do not necessarily address all elements. 1. Agache I, et al. Allergy. 2021;76(4):988-1009; 2. Saeki H, et al. J Dermatol. 2025;52(2):e70-e142 ; 3. Ko HC, et al. Ann Dermatol. 2025;37(4):216-27; 4. Torres T, et al. Drugs Context. 2021;10; 5. Yew YW, et al. Ann Acad Med Singap. 2024;53(11):670-82; 6. Yeung J, et al. J Am Acad Dermatol. 2023;89(2):372-5; 7. Ameen A, et al. Dermatol Ther (Heidelb). 2024;14(9):2299-330; 8. Wollenberg A, et al. J Eur Acad Dermatol Venereol. 2022;36(9):1409-31; 9. Davis DMR, et al. J Am Acad Dermatol. 2024;90(2):e43-e56 ; 10. Chu DK, et al. Ann Allergy Asthma Immunol. 2024;132(3):274-312; 11. Wollenberg A, et al. J Eur Acad Dermatol Venereol. 2022;36(11):1904-26; 12. Lapeere H, et al. Acta Clin Belg. 2024;79(1):62-74; 13. Steinhoff M, et al. J Dermatolog Treat. 2023;34(1):2251622; 14. de Wijs LEM, et al. J Eur Acad Dermatol Venereol. 2021;35(3):e221-e3; 15. Pereyra-Rodriguez JJ, et al. Acta Derm Venereol. 2023;103:adv12314; 16. De Bruin-Weller M, et al. Acta Derm Venereol. 2023;103:adv5382; 17. Alakeel A, et al. Clin Cosmet Investig Dermatol. 2022;15:1435-45.

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Comparative transcriptomic analysis across mild, moderate, and severe atopic dermatitis and implications for treatment development.

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Introduction

Atopic dermatitis (AD) is a common chronic inflammatory skin disease, affecting approximately 10–20% of children and 2–10% of adults worldwide (1). Notably, even mild disease (reported by approximately 27% of adults with AD (2)) is associated with a substantial impact on quality of life. Current severity classification relies predominantly on global disease measures, which may underestimate disease burden in patients with localized moderate-to-severe lesions, resulting in some individuals being classified as having mild disease despite severe lesional involvement (3). While transcriptomic profiles of lesional skin in patients with moderate-to-severe AD have been well characterized, comparable data in patients with mild-to-moderate disease remain limited. Although the use of biological therapies for AD is increasing globally, their application remains largely restricted to patients with moderate-to-severe disease, leaving many patients with locally severe disease reliant on topical treatments, which often provide limited disease control.

Materials and Methods

In total, 72 matched lesional and non-lesional skin biopsy samples were collected from 39 patients participating in a Dutch clinical trial. Lesional and non-lesional skin biopsies were collected across AD severities. The samples were profiles using bulk RNA sequencing and jointly analyzed with samples from the TREATgermany cohort (GEO ID GSE157194). The clustering of samples was inspected using PCA, followed by differential gene expression and pathway analysis using GSEA to compare lesional vs. non-lesional samples.

Results

The mild-to-moderate study population had a mean age of 22.6 years (SD 3.8) and a mean body mass index of 22.3 kg/m² (SD 3.1). Based on the Investigator's Global Assessment (IGA) and objective SCORAD (oSCORAD), the majority of the Dutch patients were classified as having mild AD (69.2% and 51.3%, respectively), compared with moderate disease (30.8% and 48.7%, respectively). The transcriptomic profiles of the study population were consistent with previously reported eczema datasets. Within the mild-to-moderate cohort, transcriptomic features were largely comparable when the samples were stratified by global severity measures (EASI, IGA, and SCORAD). In contrast, stratification by local SCORAD, enriched with a more severe population from the TREATgermany cohort reflecting lesional severity,

revealed distinct transcriptomic differences.

Conclusions

Patients with mild-to-moderate AD exhibited transcriptomic profiles comparable to those of moderate-to-severe AD when stratified by global severity measures. In contrast, local severity measures were more strongly associated with transcriptomic variation than overall disease severity. Overall, these results suggest that patients with limited overall disease but moderate-to-severe local involvement may be appropriate candidates for inclusion in studies of biological and systemic therapies. Expanding eligibility criteria for certain clinical trials may be especially relevant in early-phase research, where enrollment of treatment-naïve patients with moderate-to-severe disease is increasingly challenging.

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Abstract N°: 2491

Successful Management of Refractory Dermatitis Herpetiformis with Dupilumab

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Introduction

Dermatitis herpetiformis (DH) is a chronic, intensely pruritic autoimmune bullous disease considered the cutaneous manifestation of gluten-sensitive enteropathy. While a strict gluten-free diet (GFD) and oral dapsone are the cornerstones of treatment, management becomes challenging when patients are intolerant to dapsone or when the diet alone is insufficient to control skin symptoms.

Materials and Methods

A 51-year-old male with a history of celiac disease, strictly adherent to a GFD and medicated with mesalazine (3g/day), presented with a 2-month history of severely pruritic papulovesicular lesions on the scalp, extensor surfaces of the limbs, trunk, and buttocks.

Results

An incisional skin biopsy revealed a subepidermal blister with neutrophilic microabscesses at the dermal papillary tips and a perivascular lymphoid infiltrate. Direct immunofluorescence (DIF) demonstrated granular IgA (++) and C3 (+) deposits at the dermo-epidermal junction and within the dermal papillae, confirming the diagnosis of DH. Oral dapsone was initiated and titrated up to 100mg/day. However, treatment was discontinued after one month due to significant hepatotoxicity (transaminases exceeding three times the upper limit of normal). Subsequent therapies, including topical dapsone, maximum-dose oral antihistamines, and mirtazapine (30mg/day), yielded only a partial clinical response. Given the refractory nature of the pruritus and the recurrence of lesions despite GFD adherence, dupilumab was started (600mg loading dose followed by 300mg every 14 days). The patient achieved sustained clinical remission of lesions and complete resolution of pruritus within the first weeks of treatment, with no adverse events reported.

Conclusions

Dapsone is the first-line systemic treatment for DH, but its side effect profile (e.g., hemolysis, methemoglobinemia, and hepatotoxicity) can limit its use. In cases of dapsone intolerance and strict GFD adherence, therapeutic options are limited. Recent evidence suggests that the IL-4/IL-13 signaling pathway may play a role in the inflammatory cascade and pruritus of various immunobullous diseases. This case adds to the growing body of evidence that dupilumab may be a safe and effective alternative for managing refractory DH.

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Ruxolitinib Cream Maintains Improvements in Patient-Reported Symptom and Quality of Life Outcomes When Used As Needed in Adults With Moderate Atopic Dermatitis Eligible for Systemic Therapy: Long-Term Results From the TRuE-AD4 Study

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Introduction
Following the failure of topical corticosteroids (TCS) and topical calcineurin inhibitors (TCI) in patients with moderate atopic dermatitis (AD), treatment often requires escalation to systemic therapy to address AD signs, symptoms, and the associated quality-of-life (QoL) burden. The TRuE-AD4 phase 3b study in adults with moderate AD (NCT06238817) found that ruxolitinib cream was well tolerated and quickly reduced the signs, symptoms, and QoL burden versus vehicle when applied twice daily (BID) for 8 weeks. Clinician-assessed improvements in AD signs were maintained with as-needed application to Week 24. This analysis evaluated the maintenance of patient-reported symptom and QoL improvements with as-needed ruxolitinib cream application to Week 24.

Materials and Methods
Patients aged ≥18 years with AD, an Investigator's Global Assessment (IGA) of 3, Eczema Area and Severity Index (EASI) >7, itch numerical rating scale (NRS) ≥4, Dermatology Life Quality Index (DLQI) score >10, and 10% to 20% affected body surface area (BSA) post-TCS and -TCI were randomized (2:1) to 1.5% ruxolitinib cream BID or vehicle for 8 weeks. At Week 8, patients who achieved a ≥50% reduction in EASI score from baseline (EASI-50) continued to apply study cream for up to 16 additional weeks, but only as needed (stopping treatment 3 days after lesion clearance). Patients not achieving EASI-50 by Week 8 or patients for whom EASI-50 was not maintained were eligible to enter an escape arm, whereby ruxolitinib cream was applied open-label. Assessments in this analysis included itch NRS, skin pain NRS, Patient-Oriented Eczema Measure (POEM), Patient-Reported Outcomes Measurement Information System (PROMIS) sleep-related impairment and sleep disturbance, DLQI, and Work Productivity and Activity Impairment – AD (WPAI-AD).

Results
Of 241 patients initially randomized to ruxolitinib cream or vehicle in the vehicle-controlled (VC) period, 121 and

20, respectively, achieved EASI-50 and applied study cream at least once as needed in the double-blind VC extension period. Among patients who continued with ruxolitinib cream, median age was 35.0 years and 62.0% were female; mean (SD) EASI, and affected BSA at baseline were 12.2 (3.8) and 15.1% (3.0%), respectively. Symptom improvements assessed by mean itch NRS and mean skin pain NRS from baseline (7.3 and 6.8, respectively; 7-day average of daily recall) to Week 8 (1.9 and 1.4; 7-day average of daily recall) were maintained to Week 24 (2.4 and 1.6; weekly recall). The proportion of patients with a POEM score of 0−2 (clear/almost clear; baseline, 0%) at Week 8 (43.7%) was similarly maintained at Week 24 (34.3%). Regarding sleep quality, the proportions of patients achieving a ≥6-point improvement from baseline in PROMIS sleep-related impairment score and PROMIS sleep disturbance score at Week 8 (62.1% and 65.3%, respectively) were maintained at Week 24 (63.9% and 68.5%) among those with a score ≥14 at baseline. QoL improvement assessed by DLQI score from baseline (19.3) to Week 8 (3.5) was maintained at Week 24 (3.4). Improvements in absenteeism, presenteeism, work impairment, and activity impairment assessed by WPAI-AD from baseline (8.7%, 47.1%, 50.1%, and 56.5%, respectively) to Week 8 (3.8%, 10.2%, 12.1%, and 11.3%) were maintained at Week 24 (3.8%, 9.9%, 11.9%, and 11.2%).

Conclusions

With 16 weeks of as-needed use following 8 weeks of continuous use, ruxolitinib cream maintained improvements in patient-reported symptom and QoL outcomes in adults who would otherwise be eligible for systemic therapy. These findings suggest that ruxolitinib cream is an effective topical therapy option that could delay or prevent progression to systemic therapy in patients with moderate AD.

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COMBINED BIOLOGIC AND JANUS KINASE INHIBITOR THERAPY FOR RECALCITRANT SEVERE ATOPIC DERMATITIS: A REAL-WORLD CASE SERIES

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Introduction

Atopic dermatitis (AD) is a chronic heterogeneous inflammatory dermatosis which frequently has a substantial impact on quality of life. Although monotherapy use of biologics and Janus kinase inhibitors (JAKi) have transformed management, a subset of patients experience primary or secondary failure to these agents despite optimised topical therapy. Evidence supporting off-label combination therapy remains limited.

Objectives

To evaluate the effectiveness and safety of combined biologic and JAKi therapy in patients with recalcitrant severe AD in a real-world setting.

Materials and Methods

Hospital records of patients with AD initiated on a biologic or JAKi from 2021 onwards were retrospectively screened to identify cases receiving ongoing dual therapy. Eleven patients were identified of which 10 had reached 3 months follow-up with documented severity scores and one patient discontinued therapy due to side effects. Demographic data, prior treatments, disease severity (Eczema Area and Severity Index (EASI) and Dermatology Life Quality Index (DLQI), and adverse events were collected before and after initiation of dual therapy.

Patient number	Age (years)	Sex	Race	Comorbidities	Previous systemic treatments	Treatment prior to dual therapy	Dual therapy	Scores before dual therapy	Efficacy assessment on dual therapy	Scores after dual therapy on last review	Follow-up period (weeks)	Adverse effects on dual therapy
1	25	M	White British	-	Ciclosporin (PF) Methotrexate (PE)	Dupilumab 300 mg 2- weekly (40 weeks)	Dupilumab 300mg 2-weekly + Upadacitinib 15mg daily	EASI 13 DLQI 19	n/a	EASI 2 DLQI 0	9 Discontinued Upadacitinib due to side effects	Fatigue, Abdominal bloating
2	24	F	White British	Severe Asthma (previous ITU admission), allergic bronchopulmonary aspergillosis	UVB phototherapy (PF) Ciclosporin (PF) Methotrexate (PF) Azathioprine (PF)	Dupilumab 300mg 2-weekly (293 weeks)	Dupilumab 300mg 2-weekly + Upadacitinib 15mg daily	EASI 19.5 DLQI 9	EASI 4.8 DLQI 7 (week 24)		24	-
3	25	M	Asian	Asthma	Ciclosporin (PF)	Upadacitinib 30mg daily (70 weeks)	Upadacitinib 30mg daily + Dupilumab 300mg 2-weekly	EASI 17.4 DLQI 14	EASI 12 DLQI 11 (week 17)	-	17	-
4	25	M	White British	Anxiety, depression with psychosis, insomnia, hay fever, bilateral cataract surgery, variant of Guillain Barre syndrome, iron deficiency anaemia	Ciclosporin (E) Tralokinumab (PF)	Lebrikizumab 250mg 4-weekly (62 weeks)	Lebrikizumab 250mg 4-weekly + Abrocitinib 200mg daily	EASI 10 DLQI 3	EASI 5.5 DLQI 8 (week 19)	-	19	-
5	27	F	White British		Ciclosporin (PE) Methotrexate (SE)	Lebrikizumab 250mg 4-weekly (48 weeks)	Lebrikizumab 250mg 4-weekly + Abrocitinib 200mg daily	EASI 20 DLQI 18	EASI 1 DLQI 2 (week 20)	-	20	-
6	22	F	Chinese	Alpha Thalassaemia, depression	Ciclosporin (PF) Dupilumab (SF) Upadacitinib (SE)	Abrocitinib 200mg daily (43 weeks)	Abrocitinib 200mg daily + Lebrikizumab 250mg 4-weekly	EASI 12.9 DLQI 27	EASI 2.7 DLQI 6(week 19)	EASI 0.6 DLQI 7	67	Intermittent facial flares, element of urticaria
7	26	F	White British	Hay fever	Ciclosporin (E) Dupilumab (SE)	Abrocitinib 200mg daily (10 weeks)	Abrocitinib 200mg daily + Lebrikizumab 250mg 4-weekly	EASI 15.3 DLQI 25	EASI 2.2 DLQI 4 (week 26)	EASI 1.4 DLQI 3	44	-
8	23	M	Asian	Nil	UVB phototherapy (PF) Ciclosporin (PF) Methotrexate (PE) Azathioprine (PF) Tralokinumab (PF)	Lebrikizumab 250mg 4-weekly (16 weeks)	Lebrikizumab 250mg 4-weekly + Upadacitinib 15mg daily (increased to 30mg daily on week 23)	EASI 9 DLQI 10	EASI 5.2 DLQI 3 (week 12)	EASI 4.5 DLQI 1	59	Slight dry eyes
9	48	F	White British		Ciclosporin (E) Upadacitinib (SE)	Abrocitinib 100mg daily (2 weeks)	Abrocitinib 200mg daily + Tralokinumab 300mg 2-weekly	EASI 15 DLQI 20	EASI 1.5 DLQI 4 (week 17)	-	17	-
10	21	M	Pakistani	Asthma, recurrent PVL-staph aureus infection, previous hepatitis B infection	UVB phototherapy (SE) Ciclosporin (E, SE) Methotrexate (PF) Azathioprine (PF) Dupilumab (SF) Upadacitinib (PF)	Abrocitinib 200mg daily (25 weeks)	Abrocitinib 200mg daily + Tralokinumab 300mg 2-weekly	EASI 49.5 DLQI 19	EASI 8 DLQI 14 (week 17)	EASI 0.9 DLQI 4	92	Raised ALT
11	27	F	Asian	Nil	UVB phototherapy (PF) Ciclosporin (PF) Methotrexate (PF) Dupilumab (PF)	Upadacitinib 30mg daily (110 weeks)	Tralokinumab 300mg 2-weekly + Upadacitinib 30mg daily	EASI 8 DLQI 10	EASI 4 DLQI 10 (week 16)	-	16	Mild facial acne, intermittent headache, possible drug induced lichenoid eruption secondary to tralokinumab but likely de novo presentation

Abbreviations: PF = primary failure, SF = secondary failure, E = effective, PE = partially effective, SE = Side effects, (-) not available

Table 1. Patient characteristics, previous systemic treatments and severity scores

Results

Eleven patients were included in the study (6 female and 5 male, average age 26.6, range 21-48) who had failed multiple prior systemic therapies, including ciclosporin, methotrexate, and monotherapy biologics or JAKi. Combination therapies included dupilumab and upadacitinib (n=3), lebrikizumab and abrocitinib (n=4), lebrikizumab and upadacitinib (n=1), tralokinumab and abrocitinib (n=2) and tralokinumab and upadacitinib (n=1). Follow-up period ranged from 16 to 92 weeks. Baseline severity scores were compared in those who had efficacy assessments at ≥12 weeks following initiation of combination therapy (table 1). Overall mean baseline EASI and DLQI scores prior to starting dual therapy were 17.66 and 15.5 respectively which improved to 4.69 and 6.9. Four patients on the following combination treatments abrocitinib and lebrikizumab (n=2), lebrikizumab and Upadacitinib (n=1) and tralokinumab and abrocitinib (n=1) had further review (range 44-92 weeks) with updated EASI and DLQI scores of 0.6 and 7, 1.4 and 3, 4.5 and 1, and 0.9 and 4 respectively (table 1).

Adverse effects were generally mild including fatigue (n=1), intermittent facial flares (n=1), urticaria (n=1), dry eyes (n=1), headache (n=1), gastrointestinal symptoms (n=1), acneiform eruptions (n=1) and transient liver enzyme elevation (n=1). One patient on dupilumab and upadacitinib despite good response discontinued upadacitinib at week 9 due to fatigue and abdominal bloating but continued to maintain control on week 23 follow-up.

	Dupilumab + Upadacitinib	Lebrikizumab + Abrocitinib	Lebrikizumab + Upadacitinib	Tralokinumab + Abrocitinib	Tralokinumab + Upadacitinib
Total, n	2	4	1	2	1
Age (mean ± SD)	24.5 ± 0.71	25±2.16	23	34±19	27
Male, n (%)	2 (33)	1 (25)	1	1 (50)	0
Atopic comorbidities, n (%)	2 (33)	2 (50)	0	1 (50)	0
Baseline severity scores on monotherapy prior to initiation of dual therapy					
EASI, mean	18.45	14.55	9	32.25	8
DLQI, mean	11.5	18.25	10	19.5	10
Efficacy assessment at ≥12 weeks after initiation of dual therapy					
EASI, mean	8.4	2.85	5.2	4.75	4
DLQI, mean	9	6.25	3	9	10

EASI = Eczema Area and Severity Index, DLQI = Dermatology Life Quality Index

Table 2. Mean patient characteristics, baseline severity scores and efficacy assessment scores

Conclusions

Dual therapy may provide synergistic benefit by targeting several inflammatory pathways involved in AD pathogenesis. Our findings align with other case series[1], however variability in response and long-term safety remain important considerations. The optimal duration of dual therapy and risk of relapse following withdrawal of one of the treatments requires further investigation. Limitations of this study include the small number of patients, incomplete documentation of severity scores (including Patient Oriented Eczema Measure (POEM), Peak Pruritus Numerical Rating Scale (PP-NRS), Investigator Global Assessment (IGA) and inconsistent follow-up intervals due to constraints in service capacity.

In our cohort, combined biologic and JAKi therapy appear to be an effective and generally well-tolerated option for patients with recalcitrant, severe, AD who have failed or been intolerant of conventional systemic therapies and biologic/JAKi monotherapy. Larger prospective studies are needed to establish long-term safety, durability of response and treatment sequency strategies.

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Abstract N°: 2513

Impact of Dupilumab on Bone Mineralization Biomarker and Growth Metrics in Children Aged 2 to Under 12 Years With Moderate-to-Severe Atopic Dermatitis

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Introduction

Dupilumab has been shown to increase bone alkaline phosphatase (B-ALP), a marker of bone formation, and the proportion of short-stature children gaining at least 5 height percentiles in patients aged 6–<12 years with severe atopic dermatitis (AD). In these patients, B-ALP strongly correlated with total serum alkaline phosphatase (T-ALP). We evaluated the effects of dupilumab on T-ALP (as a proxy for bone mineralization) and changes in growth metrics (height percentile and growth velocity) among children aged 2–<12 years with moderate-to-severe AD.

Materials and Methods

Two phase 3 trials (LIBERTY AD PEDS [NCT03346434] and LIBERTY AD PRESCHOOL [NCT03345914]) included children 2–<6 years old (moderate-to-severe AD) and 6–<12 years old (severe AD), randomized to placebo or dupilumab (2–<6 years: 200/300 mg every 4 weeks ; 6–<12 years: 300 mg every 4 weeks or 200 mg every 2 weeks). T-ALP was measured at baseline, Week 4, and Week 16. Height percentile and velocity at Week 16 were assessed in patients below the 50th height percentile at baseline; velocity (cm/year) was derived from reported Week 16 data. Analyses were stratified by age group, sex, and pooled dupilumab doses vs placebo.

Results

Dupilumab significantly increased T-ALP from baseline to Week 16 vs placebo across all age groups. LS mean change based on treatment difference (dupilumab vs. placebo) for ages 2–<6 years was +48.1 U/L (n=77; 95% CI 24.5, 71.8; *P*<0.0001); for 6–<12 years, +27.7 U/L (n=177; 95% CI 17.4, 37.9;*P*<0.0001). In children aged 2–<12 years, dupilumab treatment effect was +36.1 U/L vs. placebo (n=254, 95% CI 25.5, 46.8; *P*<0.0001), with a lower absolute level increase in girls (+28.3 U/L, n=124) than in boys (+45.3 U/L, n=130); both *P*<0.0001. T-ALP levels remained within reference ranges.

Among children below the 50th height percentile, dupilumab improved mean height percentile at Week 16. For

ages 2–<6 years, mean (SD) height percentile increase was 13.7 (26.4) with dupilumab (n=37) vs 3.1 (22.4) with placebo (n=35), *P*=0.0693. For ages 6–<12 years, dupilumab (n=95) increased height percentile by 3.5 (12.0) vs placebo (n=66) 0.1 (9.6), *P*=0.0468. Pooled ages 2–<12 years showed a significant mean height percentile increase of 6.4 (17.8) with dupilumab vs 1.1 (15.2) with placebo, *P*=0.0163; girls 4.0 (14.7) vs 1.1 (13.3), *P*=0.2847; boys 8.6 (20.1) vs 1.2 (16.6), *P*=0.0253.

Height velocity of children below the 50th height percentile also increased over 16 weeks with dupilumab vs placebo. For ages 2–<6 years, mean (SD) height velocity was 15.6 (22.6) cm/year with dupilumab (n=37) vs 6.6 (14.2) cm/year with placebo (n=35), *P*=0.0441. Among children 6–<12 years, height velocity was 7.9 (9.7) cm/year with dupilumab (n=95) vs 6.2 (10.5) cm/year with placebo (n=67), *P*=0.3155. In the pooled 2–<12 year group, dupilumab significantly increased mean height velocity: 10.0 (14.8) vs 6.3 (11.8) cm/year, *P*=0.0347; boys: 12.1 (18.9) vs 5.8 (8.7) cm/year, *P*=0.0147; mean height velocity in girls did not differ between dupilumab and placebo.

Conclusions

In girls and boys aged 2–<12 years with moderate-to-severe AD, 16 weeks of dupilumab treatment vs placebo increased T-ALP, suggesting enhanced bone mineralization and growth. Among children with shorter stature, dupilumab was associated with greater gains in growth metrics than placebo. Notably, despite height percentile and velocity changes being more pronounced in boys, girls showed nominal increases in height percentile with dupilumab vs placebo. These results support dupilumab's potential to enhance bone mineralization and growth. Longer-term studies are needed to assess sustained benefits across ages and sexes.

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Abstract N°: 2556

Comparative Safety of Biologics in Moderate-to-Severe Atopic Dermatitis: Network Meta-analysis

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with significant morbidity. Biologic therapies targeting the IL-4/IL-13 pathway have improved outcomes in moderate-to-severe AD. However, comparative safety across available biologics remains unclear due to the absence of head-to-head randomized trials.

Materials and Methods

A systematic review and network meta-analysis were conducted following PRISMA guidelines. Phase 3 randomized, double-blind, placebo-controlled trials evaluating biologic monotherapy in patients aged ≥12 years were included. Outcomes at 16 weeks included treatment-emergent adverse events (TEAEs), serious adverse events (SAEs), and adverse event-related discontinuation. Random-effects models were used to estimate risk ratios (RRs) with 95% confidence intervals.

Results

Nine trials including 3,525 participants were analyzed. All treatments were connected through placebo. No biologic increased the risk of TEAEs, SAEs, or discontinuation compared with placebo. Lebrikizumab was associated with fewer TEAEs (RR 0.84, 95% CI 0.72–0.97), while dupilumab and tralokinumab showed no significant differences. SAEs and discontinuation events were infrequent, with wide confidence intervals.

Conclusions

No clinically meaningful differences in short-term safety were identified among IL-4/IL-13 biologics at 16 weeks. Current evidence is limited by short follow-up and low event rates. Treatment decisions should consider factors beyond short-term safety, including efficacy and patient preferences.

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Abstract N°: 2583

The impact of barrier-restoring therapy with emollients on quality of life and exacerbation frequency in children with atopic dermatitis

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Introduction

Atopic dermatitis (AD) is the most common inflammatory skin disease in the pediatric population, affecting 15–20% of children in developed countries. Its chronic relapsing course, negative impact on quality of life, and contribution to the "atopic march" necessitate the search for effective and safe disease management strategies. Standard topical anti-inflammatory therapy (glucocorticosteroids, calcineurin inhibitors) effectively controls flares, but long-term use is limited by the risk of adverse effects. The pathogenesis of AD is primarily driven by epidermal barrier dysfunction caused by filaggrin gene mutations, stratum corneum dyslipidemia, and type 2 inflammation activation. Theoretically, regular use of emollients (moisturizing agents) can restore the lipid mantle and reduce transepidermal water loss; however, evidence for their use as monotherapy to prevent relapses in children with moderate-to-severe AD after achieving remission remains limited. The aim of this prospective study was to evaluate the efficacy and safety of daily twice-daily barrier-restoring therapy with emollients for preventing flares in children aged 3–9 years with moderate-to-severe AD in the remission phase.

Materials and Methods

The prospective study included 42 children aged 3–9 years (mean age 6.1±1.7 years; boys 57.1%, n=24) with moderate-to-severe atopic dermatitis (baseline SCORAD after remission 2.4±0.6 points). After resolution of the acute phase with topical corticosteroids (7–10 days), all patients applied a body-wide emollient twice daily for 3 months. In the event of a flare, short-term (up to 5 days) reintroduction of topical corticosteroids was permitted. SCORAD, the Children's Dermatology Life Quality Index (CDLQI), the frequency of flares requiring topical corticosteroids, and adverse events were assessed.

Results

At baseline (after corticosteroid therapy), the mean SCORAD was 2.4±0.6 points, and the mean CDLQI was 3.8±1.1 points. After 3 months of emollient monotherapy, the mean SCORAD decreased to 1.0±0.2 points ($p<0.001$). Complete remission (SCORAD <1.5 points) was achieved in 39 out of 42 children (92.9%). The mean CDLQI decreased to 1.9±0.5 points ($p<0.001$); 88.1% (n=37) showed no clinically significant impact of AD on quality of life. Flares requiring topical corticosteroids occurred in 4 patients (9.5%) – associated with respiratory infections (n=3) and psycho-emotional stress due to changing kindergartens (n=1). No adverse events (burning, contact dermatitis) were observed.

Conclusions

Regular twice-daily application of emollients in children aged 3–9 years with moderate-to-severe atopic dermatitis

after achieving remission leads to complete clinical remission in 92.9% of cases, significantly improves quality of life (reduction in CDLQI from 3.8 to 1.9 points), and limits the frequency of flares requiring topical corticosteroids to 9.5% over a three-month follow-up period. These findings support the inclusion of barrier-restoring therapy as a maintenance protocol in the management of this age group.

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Abstract N°: 2612

Ruxolitinib Cream Reduced High Symptom and Quality-of-Life Burden in Adults With Moderate Atopic Dermatitis After Failure of Topical Corticosteroids and Topical Calcineurin Inhibitors: Item-Level Patient-Reported Outcome Results From TRuE-AD4

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Introduction
In the phase 3b TRuE-AD4 study (NCT06238817) in adults with moderate atopic dermatitis (AD) after failure of topical corticosteroids (TCS) and topical calcineurin inhibitors (TCI), ruxolitinib cream was well tolerated and improved AD signs, symptoms, and overall patient-reported outcomes versus vehicle. This analysis identified the most burdensome symptom and quality-of-life (QoL) impairments at baseline and assessed their resolution with ruxolitinib cream.

Materials and Methods
Patients aged ≥18 years with AD, an Investigator's Global Assessment of 3, Eczema Area and Severity Index >7, itch numerical rating scale ≥4, Dermatology Life Quality Index (DLQI) score >10, and 10% to 20% affected body surface area post-TCS and -TCI were randomized (2:1) to twice-daily 1.5% ruxolitinib cream or vehicle for 8 weeks. Symptom and QoL burden were assessed via component items of the DLQI, Patient-Oriented Eczema Measure (POEM), and EuroQol 5-Dimension 5-Level (EQ-5D-5L) questionnaires. Item thresholds for high burden were defined as "a lot" or "very much" for DLQI, ≥5 affected days in the last week for POEM, and a score of 3 (moderate problem) to 5 (extreme problem or unable to do) for the EQ-5D-5L. For each item, the proportion of patients who resolved from a high burden category at baseline to a non–high-burden category after ruxolitinib cream versus vehicle treatment was assessed by chi-square test.

Results

Patients (n=241) had a median (range) age of 37.0 (19−88) years, and 54.4% were female. At baseline, items most frequently categorized as having high symptom or QoL burden were itchy/sore/painful/stinging skin (99.6% of patients), embarrassment or self-consciousness because of skin (85.9%), skin influence on clothing choice (77.6%), and skin influence on social/leisure activities (74.7%) among items of the DLQI; itchy skin (89.2%), dry/rough skin (86.7%), flaking skin (72.6%), and cracked skin (68.5%) among items of the POEM; and pain/discomfort (55.2%) among dimensions of the EQ-5D-5L. As early as the first assessment at Week 2, a significantly greater proportion of patients who applied ruxolitinib cream versus vehicle reported resolution of high burden for all of the most frequent high burden items at baseline, including itchy/sore/painful/stinging skin (74.1% vs 28.6% of patients; $P<0.0001$), embarrassment or self-consciousness because of skin (77.0% vs 37.3%; $P<0.0001$), skin influence on clothing choice (72.4% vs 35.3%;$P<0.0001$), and skin influence on social/leisure activities (85.6% vs 51.0%; $P<0.0001$) among items of the DLQI; itchy skin (66.2% vs 22.6%;$P<0.0001$), dry/rough skin (68.3% vs 25.0%; $P<0.0001$), flaking skin (83.1% vs 37.3%; $P<0.0001$), and cracked skin (82.1% vs 40.4%; $P<0.0001$) among items of the POEM; and pain/discomfort (79.5% vs 35.9%;$P<0.0001$) among dimensions of the EQ-5D-5L. At Week 8, resolution of high symptom or QoL burden was maintained or increased with ruxolitinib cream for itchy/sore/painful/stinging skin (84.0% vs 50.0% with vehicle; $P<0.0001$), embarrassment or self-consciousness because of skin (91.7% vs 61.2%; $P<0.0001$), skin influence on clothing choice (89.9% vs 61.9%; $P<0.0001$), and skin influence on social/leisure activities (91.0% vs 75.0%; $P=0.0105$) among items of the DLQI; itchy skin (83.0% vs 43.1%; $P<0.0001$), dry/rough skin (78.9% vs 41.7%; $P<0.0001$), flaking skin (86.7% vs 48.7%; $P<0.0001$), and cracked skin (87.7% vs 51.4%; $P<0.0001$) among items of the POEM; and pain/discomfort (91.8% vs 68.8%; $P=0.0016$) among dimensions of the EQ-5D-5L.

Conclusions

Adults with moderate AD in TRuE-AD4 had substantial symptom and QoL burden associated with itch/pain, skin appearance, and impairment of daily activities that was quickly and significantly reduced with ruxolitinib cream. These findings suggest that ruxolitinib cream can effectively address the most burdensome symptom and QoL effects in addition to controlling the signs associated with the disease, and thus may delay or prevent progression to systemic therapy in patients with moderate AD.

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Abstract N°: 2633

Topical Tofacitinib versus Topical Tacrolimus for Mild to Moderate Pediatric Facial Atopic Dermatitis in Skin of Colour: A Randomized Non-inferiority Study

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Introduction
Atopic dermatitis is a chronic, relapsing and pruritic condition predominantly affecting children. Facial involvement is particularly common and has a significant impact on quality of life. Topical therapies including emollients and corticosteroids remain the mainstay of treatment; however, their long-term use is limited by adverse effects, highlighting the need for steroid-sparing options. Topical calcineurin inhibitors such as tacrolimus are well-established, but are often associated with application-site reactions. Topical tofacitinib, a Janus kinase inhibitor, has emerged as a potential alternative; however, direct comparative evidence in pediatric facial atopic dermatitis, particularly in skin of colour, remains limited.

Materials and Methods
Objectives:
To compare the efficacy and safety of topical tofacitinib 2% ointment with tacrolimus 0.1% ointment in pediatric patients with mild-to-moderate facial AD.

Methods:
This prospective, randomized, open-label, active-controlled non-inferiority study included 56 children aged 2–18 years with mild to moderate facial atopic dermatitis, defined as vIGA scores of 2–3 and EASI <21. Patients were randomized 1:1 to receive topical tofacitinib 2% twice daily or tacrolimus 0.1% once daily for 8 weeks. Outcomes were assessed at baseline and at weeks 2, 4, and 8 using validated Investigator Global Assessment (vIGA), Eczema Area and Severity Index (EASI), Patient-Oriented Eczema Measure (POEM), and Children's Dermatology Life Quality Index (CDLQI). Primary endpoints were ≥2-point reduction in vIGA and achievement of EASI-75 at week 8.

Results
At week 8, ≥2-point reduction in vIGA was achieved in 89.3% of patients receiving tofacitinib versus 78.6% receiving tacrolimus, with no statistically significant difference (p=0.32). EASI-75 was achieved in 64.2% and 71.4%, and EASI-90 in 42.8% and 50% of patients in the tofacitinib and tacrolimus groups, respectively, with no statistically significant differences (p=0.41), supporting non-inferiority. Tofacitinib demonstrated significantly earlier pruritus reduction at week 2 (p=0.04). Both treatments were well tolerated, with no significant adverse effects observed.

Conclusions
Topical tofacitinib 2% ointment demonstrated non-inferior efficacy to tacrolimus 0.1% ointment in mild-to-moderate pediatric facial atopic dermatitis. It was associated with faster pruritus relief and a slightly superior tolerability profile with improved local tolerability. While tacrolimus remains an established standard of care, topical tofacitinib emerges as a promising steroid-sparing alternative, particularly in pediatric patients with skin of colour. Larger controlled studies are required to further validate these findings.

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Abstract N°: 2635

2-year data on effectiveness and quality of life in patients treated with upadacitinib in clinical practice – results from the UP-TAINED study

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Introduction

Upadacitinib (UPA) is a selective JAK-inhibitor approved for the treatment of moderate to severe Atopic Dermatitis (AD) and seven other indications. Interim data from the German real-world study UP-TAINED has been published before[1-3]. This analysis of the UP-TAINED study evaluates the clinical effectiveness and impact on quality of life (QoL) in patients treated with UPA up to 2 years.

Materials and Methods

UP-TAINED [NCT05139836] is a prospective post-marketing, multicenter, observational study for UPA as approved per local label for the treatment of AD in Germany. Treatment decisions were made at the discretion of the patients' physicians independently of and prior to study enrolment.
For this interim analysis patients treated with either UPA 30 mg or 15 mg for up to 2 years were included. Analyzed parameters include absolute and relative Eczema Area and Severity Index (EASI), several patient-reported disease and QoL parameters e.g., Atopic Dermatitis Control Tool (ADCT), (Children's) Dermatological Quality of Life Index (DLQI), and Worst Pruritus-Numeric Rating Scale (WP-NRS; 0-10). As observed data are presented as mean/median or percentage of patients with 95 % confidence interval [CI], where appropriate. Data cut-off for this interim analysis was the 31st of Oct 2025.

Results

Baseline data was available for 625 patients with a mean age of 40.4 years, 87.8% were between 18 and 64 years old, and 45% were female. Disease severity parameters at baseline were EASI 21.5 [20.39; 22.52; n=618], WP-NRS 6.8 [6.61; 7.04; n=465] and DLQI 13.6 [13.03; 14.17; n=561]. Significant improvements were observed after 1 year of treatment, indicated by 69.4% [63.0; 75.3; n=161/232] of patients achieving disease control, defined as ADCT < 7, 72.8% [67.2; 78.0; n=201/276] achieving an EASI ≤3, 44.8% [37.7;52.1; n=87/194] achieving WP-NRS 0/1, 39.3% [32.8;46.0; n=88/224) achieving DLQI 0/1. Minimal Disease Activity (MDA), defined as EASI ≤3 and WP-NRS 0/1, was achieved by 36.3% [29.0; 43.1; n=78/215].
At 2 years of upadacitinib treatment, disease control was achieved by 77.7% [67.9; 85.6; n=73/94], EASI ≤ 3 by 71.6% [63.2; 79.1; n=96/134], WP-NRS 0/1 55.4% [63.2; 79.1; n=46/83], DLQI 0/1 45.7% [35.4; 56.3; n=43/94], and

MDA by 34% [24.7; 44.3; n=33/97]. 81.1% [64.5; 93.0; n=27/33] of patients who reached MDA had a DLQI of 0/1 at 2 years. Validated Investigator Global Assessment (vIGA) score of ≤1 for face and hand was achieved by 75.0% [63.0; 84.7; n=51/68 and 86.8% [74.7; 94.5; n=46/53 patients at 2 years, respectively.
Adverse events (AEs) were reported for 336 patients (53.7%), serious AEs for 38 (6.1%) whereas AEs leading to discontinuation or break were reported for 18 (2.9%) and 60 (9.6%) patients, respectively. The most frequent AEs (> 4%) were dermatitis atopic (25.2%), nasopharyngitis (6.4%), acne (6.2%) and influenza like illness (4.2%).

Conclusions

Patients receiving upadacitinib over the 2-year period showed improvements in effectiveness and QoL, with low rates of discontinuation or break due to UPA related AEs. These findings support and reinforce the growing evidence of Upadacitinib's effectiveness in a real-world setting. Moreover, the analysis indicates the value of striving for high treatment goals like Minimal Disease Activity (MDA) to improve QoL and reduce the impact of AD on patients' daily life for favorable long-term treatment outcomes in clinical practice.

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Severe Eczematous Dermatitis on Cultured Skin Grafts

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Introduction

Cultured skin grafts are an established therapeutic option for patients with extensive burns when donor skin availability is limited[1]. While their efficacy in achieving durable skin coverage has been widely demonstrated, little is known about late inflammatory complications arising in these areas. The concept of the *immunocompromised district* (ICD), introduced by Ruocco, describes cutaneous regions with altered local immune responses secondary to prior injury, predisposing them to the development of localized dermatoses[2]. We report a case of eczematous dermatitis confined to autologous cultured skin grafts, supporting their potential role as ICDs.

Case Presentation

A 17-year-old male with a history of extensive childhood burns involving 65% of the total body surface area was treated with autologous cultured skin grafts combined with conventional split-thickness skin grafts. Eight years after grafting, he developed well-demarcated erythematous, scaly, and intensely pruritic plaques located exclusively on areas covered by cultured grafts on the upper limbs, lower limbs, and feet.
Skin unaffected by burns and areas treated with conventional grafts were spared. Histopathological examination showed findings consistent with eczematous dermatitis.

The lesions initially improved with topical and systemic corticosteroids, although recurrence occurred after treatment withdrawal, leading to corticosteroid dependence. Partial clinical improvement was achieved with ciclosporin; however, persistent lesions and severe pruritus remained (EASI 13.6; pruritus NRS 7). Owing to inadequate disease control, treatment with dupilumab was initiated.

This patient was among the first individuals in Andalusia to receive autologous cultured skin grafts, during the early implementation of this technique. To our knowledge, this represents the first reported case of late inflammatory complications specifically affecting cultured skin grafts.

Conclusion

Previous reports have described isolated cases of eczematous dermatitis arising on conventional skin grafts, interpreted as manifestations of the ICD phenomenon[3-5]. However, no similar cases involving cultured skin grafts have been identified in the literature. Our findings suggest that cultured grafts may behave as immunologically altered cutaneous regions susceptible to chronic localized inflammation. Persistent barrier dysfunction and changes in the local immune microenvironment may contribute to this phenomenon. Awareness of this potential complication is important for both clinical management and long-term follow-up of patients treated with advanced

skin replacement therapies.

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Multi-strain probiotic in the comprehensive treatment of atopic dermatitis in young children

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Introduction

Atopic dermatitis (AD) is the most common chronic inflammatory skin disease in the pediatric population, affecting up to 20% of young children. Standard therapy includes topical glucocorticosteroids, calcineurin inhibitors, and antihistamines; however, it does not always provide sustained symptom control and is associated with a risk of adverse effects with long-term use. In recent decades, evidence has accumulated regarding the role of gut dysbiosis in the pathogenesis of AD, making microbiota modulation with probiotics a promising approach. Nevertheless, the heterogeneity of strains, doses, and study designs prevents definitive conclusions regarding the clinical efficacy and safety of probiotics in children with AD, which underscores the relevance of the present study.

Materials and Methods

A randomized controlled trial was conducted. The study included 148 children aged 3 months to 3 years (mean age 1.8±0.9 years; boys 54.7%, n=81) with a verified diagnosis of AD (moderate severity, baseline SCORAD index 22.4±3.8 points). Patients were randomized into an intervention group (n=95) and a control group (n=53). The study design included a 1-month run-in period, during which all patients underwent a diagnostic elimination diet with food diaries, received antihistamines and topical therapy (emollients twice daily, topical corticosteroids as needed). At the end of the run-in period, the clinical efficacy of baseline therapy was assessed in both groups; no statistically significant differences were found between the groups. Subsequently, children in the intervention group received a multi-strain probiotic (7 strains at a titer of 10^9 CFU: Lactobacillus casei, L. rhamnosus, Streptococcus thermophilus, L. acidophilus, Bifidobacterium breve, B. infantis, B. longum with fructooligosaccharides), one sachet per day with meals for 30 days, in addition to baseline therapy. The control group continued to receive only baseline therapy without the probiotic. Efficacy was assessed using the SCORAD index (a reduction of ≥50% from baseline was considered a clinically significant response) and the rate of achieving remission (SCORAD <10 points); safety was assessed by recording adverse events.

Results

At baseline, the mean SCORAD in the intervention group was 22.1±3.9 points, and in the control group — 22.9±3.6 points ($p>0.05$). After 30 days of therapy, remission (SCORAD <10 points) was achieved in 89.5% of patients (n=85) in the intervention group, with the mean SCORAD decreasing to 6.9±0.5 points ($p<0.001$ compared to baseline). In 10.5% (n=10), periodic new rashes persisted, but their intensity was significantly lower than at baseline. In the control group, improvement in skin symptoms (SCORAD reduction ≥50%) was achieved in 75.5% (n=40), with a mean SCORAD of 7.3±0.4 points; in 24.5% (n=13), active manifestations of AD persisted (SCORAD 14.1±0.8 points), which was significantly higher than in the intervention group ($p=0.003$). Complete remission (SCORAD <5 points) was documented in 61.1% (n=58) of the intervention group versus 37.7% (n=20) of the control group. No adverse events related to probiotic intake (diarrhea, constipation, flatulence, skin

reactions) were reported in any case; parents of all patients in the intervention group noted good tolerability of the preparation.

Conclusions

The inclusion of a multi-strain probiotic in the comprehensive treatment of atopic dermatitis in children aged 3 months to 3 years significantly increases the clinical efficacy of therapy: remission was achieved in 89.5% of patients in the intervention group versus 75.5% in the control group, with the mean SCORAD decreasing to 6.9±0.5 points. The absence of adverse reactions confirms the favorable safety profile of the probiotic in young children, suggesting that multi-strain probiotics can be considered a promising addition to baseline therapy for AD in pediatric practice.

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The Eczema Shadow Report: A Patient-Led Assessment of the Multidimensional Burden of Atopic Dermatitis — Evidence from French and International Studies

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Introduction

Atopic dermatitis (AD) affects nearly 4 million people in France and millions worldwide. Despite its prevalence, its real-life burden remains systematically underestimated by healthcare systems and policymakers. The French Eczema Association (AFE) — an independent patient organization founded in 2011 — initiated and coordinated this Shadow Report as a **patient-driven counter-narrative**: a rigorous, evidence-based document that gives voice to what official health policies have long failed to capture. This initiative reflects 15 years of AFE commitment to breaking patient isolation and placing lived experience at the heart of dermatological evidence.

The objective had to quantify, from a **patient perspective**, the multidimensional burden of AD across nine life domains: occupational, social, affective, sexual, mental health, stigmatization, life trajectory, caregiver impact, and treatment satisfaction.

Materials and Methods

Patient-led synthesis of peer-reviewed studies (2013–2026) conducted in collaboration between the AFE and the EMMA research group, combining French national surveys (N up to 2,271 adult patients) and international data including the *Scars of Life* project (N>10,000; 27 countries), a suicidal ideation case-control study (N=23,191 adults), and multi-country burden assessments (5–8 countries). Validated PRO instruments included the DMLQ, ABS-F, EczemaPartner, DLQI and POEM. Patient testimonials were systematically integrated as primary evidence.

Results

Work absenteeism affected 26% of AD patients (~21 days/year), reaching 0.8 days/week in severe AD. Social avoidance was reported by 33% of severe vs. 8% of mild AD patients. Sexual life was impaired in 55% of moderate-to-severe patients. Perceived stress was elevated in 80% of severe AD patients; 46% reported excessive daytime sleepiness, yet fewer than 15% had received psychological support. Depression risk reached 53% in severe AD; 13% reported suicidal ideation vs. 8% in controls, rising to 29% when AD onset occurred in childhood. Childhood-onset AD was associated with greater lifelong stigmatization and a 4-fold higher need for psychological follow-up in adulthood. Caregiver burden was nearly 3-fold higher in parents of severe vs. mild AD children. Treatment satisfaction remained critically low (2.84/5); shared decision-making was reported by only 18% of patients.

Conclusions

This patient-initiated Shadow Report demonstrates that AD exerts a profound, severity-dependent burden extending far beyond the skin — across occupational, psychological, relational, sexual and familial dimensions, consistent across countries. Patients call for systematic psychological screening, expanded therapeutic education, genuine shared decision-making, and urgent recognition of AD as a global public health priority.



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Tapinarof Cream 1% Once Daily in Atopic Dermatitis: Individual Patient EASI Responses from Pooled ADORING 1 and ADORING 2 Phase 3 Clinical Trials

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Introduction

Tapinarof cream 1% is a non-steroidal, topical aryl hydrocarbon receptor agonist approved by the Food and Drug Administration for the treatment of atopic dermatitis (AD) in adults and children down to 2 years of age, as well as for plaque psoriasis in adults. In two pivotal AD trials, ADORING 1 and ADORING 2, tapinarof cream 1% monotherapy demonstrated statistically significant efficacy versus vehicle in patients with AD as well as favorable safety and tolerability. This pooled analysis evaluated individual patient-level Eczema Area and Severity Index (EASI) responses to tapinarof cream 1% once daily (QD) across multiple timepoints to characterize clinical improvement in patients with AD.

Materials and Methods

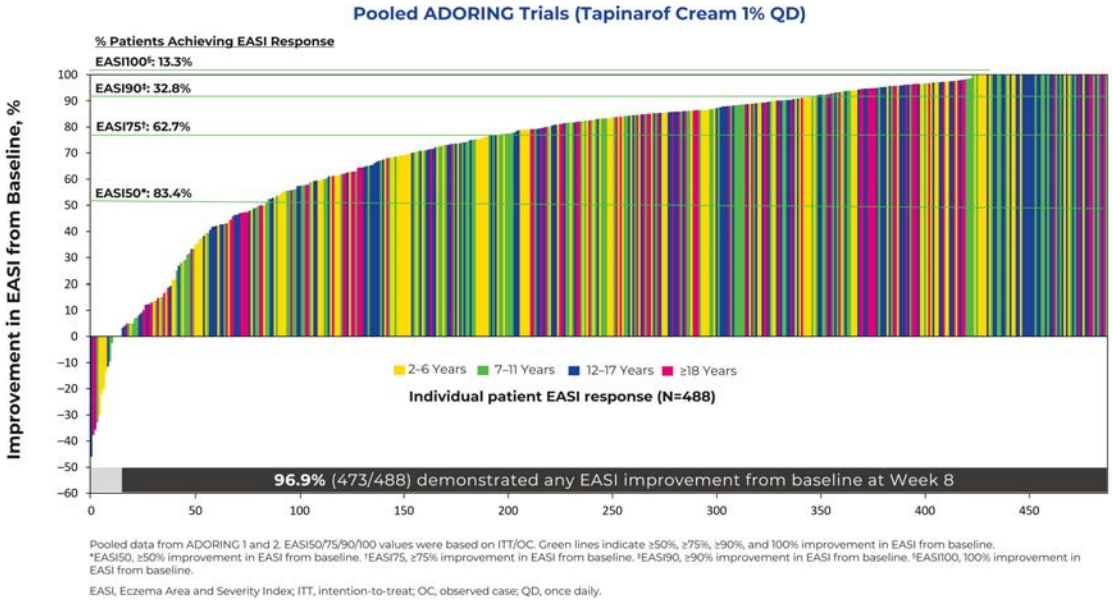
Pooled data were analyzed post hoc from the ADORING 1 and ADORING 2 trials, two identical, double-blind, randomized, vehicle-controlled, phase 3 multicenter trials conducted across sites in the United States and Canada. Eligible patients were adults and children aged ≥2 years with a confirmed diagnosis of AD, a Validated Investigator Global Assessment for AD (vIGA-AD™) score ≥3, an EASI score ≥6, and 5%–35% body surface area (%BSA) involvement at both screening and baseline. Participants were randomized in a 2:1 ratio to receive tapinarof cream 1% or vehicle QD for 8 weeks. EASI responses at different thresholds (EASI50, EASI75, EASI90, and EASI100) were assessed at Weeks 1, 2, 4, and 8 in the intent-to-treat population (all randomized patients).

Results

The pooled population included 813 patients (541 patients treated with tapinarof cream 1% and 272 patients treated with vehicle). Overall, 80.4% of patients were pediatric (2–17 years). At baseline, patients had a mean EASI score of 12.9, a mean %BSA of 16.8%, and mean Peak Pruritus-Numeric Rating Scale (PP-NRS) score of 6.7, and 87.0% of patients had a vIGA-AD™ of 3. At Week 8, statistically significantly more tapinarof-treated than vehicle-treated patients achieved a vIGA-AD™ response (45.9% vs 15.9%, $P<0.0001$), based on MI-estimand analyses, defined as vIGA-AD™ score of 0 or 1 and ≥2 grade improvement from baseline. At Week 1, the first assessment, 84.6% of tapinarof-treated patients had a measurable improvement in EASI; this increased to 96.9% at Week 8. Individual EASI responses at Week 8 in tapinarof-treated patients are illustrated in **Figure 1**. The proportion of patients achieving EASI response rates with tapinarof were statistically significant versus vehicle as early as Week 2, and continued through Week 8: EASI50 (83.4% vs 46.6%, P<0.0001), EASI75 (62.7% vs 25.6%, $P<0.0001$), EASI90

(32.8% vs 9.4%, *P*<0.0001), and EASI100 (13.3% vs 3.6%, *P*<0.0001).

Figure1. Individual Patient Percent EASI improvement From Baseline at Week 8



Pooled data from ADORING 1 and 2. EASI50/75/90/100 values were based on ITT/OC. Green lines indicate ≥50%, ≥75%, ≥90%, and 100% improvement in EASI from baseline.
*EASI50, ≥50% improvement in EASI from baseline. †EASI75, ≥75% improvement in EASI from baseline. ‡EASI90, ≥90% improvement in EASI from baseline. §EASI100, 100% improvement in EASI from baseline.

EASI, Eczema Area and Severity Index; ITT, intention-to-treat; OC, observed case; QD, once daily.

Conclusions

Tapinarof monotherapy demonstrated rapid and sustained clinical improvements across multiple EASI thresholds over time in adult and pediatric patients with AD down to the age of 2 years.

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Diagnostic Challenge in Severe Atopic Dermatitis: Drug-Associated Lymphomatoid Reaction or Unmasked Cutaneous T-Cell Lymphoma?

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory disease whose diagnostic and therapeutic management may be challenging, with cutaneous T-cell lymphomas (CTCLs) as an important differential diagnosis. With the use of advanced therapies for severe AD, atypical lymphoid infiltrates and overt CTCLs, particularly mycosis fungoides (MF) and Sézary syndrome (SS), have been reported in patients treated with monoclonal antibodies and Janus kinase inhibitors (JAKi).

We report 5 cases of patients with severe AD who developed atypical lymphoid infiltrates while receiving advanced therapies.

This case series highlights the importance of accurate diagnosis and a thorough diagnostic work-up to exclude CTCL, including repeated skin biopsies for as long as diagnostic suspicion persists.

Case Presentation

We present 5 patients with severe AD who developed epidermotropic lymphoid infiltrates suggestive of MF during treatment with different advanced therapies.

Three patients had childhood-onset AD, histologically confirmed in two cases before starting advanced therapies. They had Th2-associated comorbidities. During treatment —week 31 of lebrikizumab, week 12 of tralokinumab, and week 44 of upadacitinib— they experienced disease worsening, leading to skin biopsies that revealed histopathological findings suggestive of MF. Treatment was discontinued, and later repeat biopsies showed histological findings compatible with AD.

Two patients had recently diagnosed AD, histologically confirmed in only one case. One patient experienced clinical worsening at week 20 of abrocitinib treatment, and a skin biopsy was performed, revealing findings suggestive of MF. These were initially interpreted as a lymphomatoid reaction, and treatment was switched to tralokinumab. A repeat biopsy performed two months later again confirmed the diagnosis of MF.

The remaining patient experienced worsening at week 10 of tralokinumab treatment. Skin biopsy revealed histopathological findings suspicious for MF. Tralokinumab was discontinued and the patient received treatment for MF, achieving a favorable clinical response.

Conclusion

AD is a chronic inflammatory disease characterized by recurrent flares. Management of severe AD is complex and transient or sustained exacerbations may represent a significant therapeutic and diagnostic challenge. It is important to recognize that atypical lymphocytes have been described in skin biopsies performed during disease exacerbations in patients treated with advanced therapies.

The transition from AD, as an inflammatory disease, to an infiltrate with atypical features or to a lymphoid neoplasm is complex, and the underlying pathogenic mechanisms remain unclear.

Two main pathogenic hypotheses have been proposed:

- Benign lymphomatoid reactions, reversible after treatment discontinuation.
- Unmasking of a true CTCL previously concealed under a diagnosis of AD. This may occur through progression of lymphoid infiltrates due to disruption of the Th1/Th2 balance, or as a consequence of JAKi - related immunosuppression.

The main histological differences are summarized in Table 1. However, in clinical practice, these findings often overlap, making diagnosis challenging.

Given the complexity of the differential diagnosis, a high index of suspicion should be maintained in late-onset AD and in patients who fail to respond to treatment or develop sustained exacerbations or atypical clinical features during therapy. Skin biopsies should be repeated as often as necessary when clinical suspicion persists. In the presence of atypical lymphoid infiltrates, treatment discontinuation followed by repeat biopsy should be considered. Close clinical follow-up is essential to determine whether these findings represent a benign lymphomatoid reaction or true MF, and, in the latter scenario, whether MF was present from the outset, concealed under the diagnosis of AD, or emerged in the setting of severe AD.

	Atopic Dermatitis	Lymphoid reaction	Mycosis fungoides
Acanthosis, parakeratosis, spongiosis	+	+	+
Intraepithelial T-cell lymphocites	-	Atypical lymphocites sprinkled in upper epidermal layer	Atypical lymphocites lined in basal layer of epidermis
Disregulated CD4: CD8 ratio	-	+	+
Loss of CD2, CD3, CD5	-	-	+
CD30+ expression	-	+	Late disease stage

Table 1. Main histological differences between atopic dermatitis, lymphoid reaction and mycosis fungoides.

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Efficacy of An Emollient Plus Containing a New Mix Active, Niacinamide and Thermal Water on Sleep Quality and Pruritus in Pruritic Dermatoses

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Introduction

Chronic pruritus and scratching significantly impacts sleep quality and overall quality of life (QoL) in patients with pruritic dermatoses, including atopic dermatitis (AD), exacerbating the itch-scratch cycle. Emollients, and especially emollients“plus” that contains active, non-medicated substances, are recommended in AD management as they have been proven to improve AD lesions, repair skin barrier, reduce inflammation and itch, and thus improve globally QoL. This study aimed to evaluate the efficacy of an emollient plus containing a new mix active, niacinamide and thermal water on sleep disturbances and itching in patients with pruritic dermatoses.

Materials and Methods

A 4-week, open-label, monocenter study was conducted in 50 adult subjects with stable pruritic dermatoses and sleep disturbances. Participants applied the investigated product twice daily. Sleep quality (awakenings due to itching, overall fatigue), itching, scratching, and mental well-being were assessed using NRS, patients’ diaries and validated scales.

Results

Significant improvements were observed rapidly. Average daily pruritus reduced significantly after 3 days for all patients (-54% by week 4) and even more for AD patients (-59%), as well as peak pruritus. The number of awakenings due to itching significantly decreased from Day 3, with an improvement up to day 10 (-42%) for all patients. SCORAD sleep loss decreased by 69% after 4 weeks for AD patients.

Conclusions

The investigated product demonstrated significant efficacy in reducing itch and related sleep disturbances and enhancing overall quality of life in patients with pruritic dermatoses. These findings support its use as an effective dermocosmetic for managing pruritic conditions.

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Co-creation of Patient Educational Materials for dermatology Phase 1b Clinical Studies: Improving patient perception and willingness to participate

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Introduction

Inclusion of patients in first in human studies is referred as Phase 1b. Phase 1b (Ph1b) studies are expanding options to advance dermatology treatments, yet patient participation remains challenging due to complexities surrounding effective patient-facing communication and education on , Ph1b-specific concepts, safety concerns, and expectations. Traditional educational materials often fail to address patient-specific concerns and barriers. Here we describe the co-creation of patient-centered educational materials for Ph1b studies with dermatology patient advocacy groups.

Materials and Methods

A four-phase co-creation approach was implemented: (1) Initial patient survey via Carenity, a patient engagement and research platform, exploring perceptions of Ph1b motivations to join, barriers, and information needs for Ph1b participation; (2) Development of draft educational materials (video and brochure) based on survey insights; (3) Feedback collection on draft materials via the Within3 document review platform ; (4) Patient advisory panels with atopic dermatitis (AD) (National Eczema Association, n=7) and hidradenitis suppurativa (HS) (HS Connect, n=8) patient advocates for iterative refinement.

Results

The Carenity survey recruited 234 participants across France (n=99), UK (n=83), and US (n=52), covering five conditions including asthma (n=57), psoriasis (n=47), rheumatoid arthritis (n=52), lupus (n=43), and Crohn's disease (n=35). It revealed primary barriers to participate in Ph1b studies: fear of side effects (64%), lack of information (41%), uncertain benefits (30%), and time commitment (25%). Key motivators included potential health benefits (83%) and helping others (62%). Regional differences emerged: US patients prioritized practical concerns (travel, compensation) equally with risks, while European patients focused primarily on risks. Patient panels identified critical gaps in the draft materials, including the need for clearer reassurance on risks and explanations on study procedures, practical information on logistics, and emotional support considerations. Primary information that would help patients decide whether to participate included risk and side effects (43%), a clear understanding of research methods and procedures (19%), time commitment (18%), and travel requirements (17%). A first draft of patient information material (leaflet and video) gathering these elements was created and proposed to patient a panel of 13 AD or HS patients.

This initial draft of patient information material achieved high comprehension scores within the 13 probed

participants on clinical study concepts, single or multiple dose ascension and practical consideration. Moreover, 12 out of 13 respondents reported feeling confident or very confident in their understanding of what a Ph1b clinical study is and what participating involves. However, AD and HS advocates recommended enhanced visual design, simplified terminology, timestamps for video navigation, and clearer separation of benefits from risks. Besides improved visuals, final materials including a video and a leaflet incorporated an emphasis on frequent monitoring, involvement of specialized care team, withdrawal rights, region- and study-specific practical information, comprehensive safety processes, and clearer benefit/risk sections.

Conclusions

Co-creation with AD and HS patient advocates revealed critical insights into Ph1b perception, particularly regarding needs for information on safety aspects and practical study considerations. Patient review led to simplified and enhanced material understandability while preserving meaningful information for potential studies participants and without creating confusion with the actual informed consent. The materials are now being implemented across multiple Ph1b dermatology studies allowing to evaluate their impact on patient comprehension and recruitment rates.

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Abstract N°: 2732

A new addition to the dermatology registries: HEBest, the German Registry for Chronic Hand Eczema

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Introduction

Hand eczema is among the most common dermatological conditions, with a prevalence of approximately 4% (point prevalence) to over 9% (1-year prevalence) in the general population. Chronic hand eczema (CHE) is defined as eczema of the hands persisting for at least three months or recurring at least twice per year. In addition to visible skin changes, symptoms such as pruritus, pain, and functional impairment substantially reduce patients' quality of life. Due to marked limitations in occupational, domestic, psychological, and social functioning, CHE is associated with a considerable individual disease burden and high patient needs. Furthermore, CHE has relevant health-economic and socio-medical consequences. Particularly in the occupational context, the disease and its symptoms may impair work ability, lead to sick leave, or even necessitate a change of profession. In recent years, advances in the treatment of CHE have been achieved, including new topical therapies. However, there remains a gap in the systematic assessment of real-world care in routine clinical practice.

Against this background, the German hand eczema registry HEBest was developed. Its aim is the structured, long-term documentation of clinical, therapeutic, and patient-reported data on CHE. The registry is conceptually aligned with established dermatological registries such as PsoBest. In Germany, a growing registry landscape in dermatology has emerged, beginning with the German psoriasis registry PsoBest in 2008, which has enrolled more than 27,000 patients. Subsequent registries include CoronaBest, TreatGermany, HSBest, and more recently VitiBest (vitiligo), ADBest (atopic dermatitis), PPBest (pustular psoriasis), and GPCBest (chronic prurigo). Internationally, registry research is increasingly recognized as a key contributor to real-world evidence.

HEBest was developed and initiated in accordance with international standards for registry research and the criteria of the German Network for Health Services Research.

Materials and Methods

HEBest is a multicenter, prospective, non-interventional observational study. Both dermatology practices and

clinics can participate. Adult patients with a clinical diagnosis of chronic hand eczema are eligible. Data are collected via a web-based platform with pseudonymized documentation. A baseline assessment is conducted at study entry, followed by regular follow-ups every 3–6 months. The observation period is currently two years, with a planned extension.

Themes	Parameter (examples)
Demographics	Age, sex, education, BMI, occupation, smoking status
Dermatological history and disease characteristics	Duration, onset, relapses, triggers, comorbidities, protective measures
Clinical presentation:	Localization, symmetry, morphology, severity (pruritus, pain)
Objective severity	HECSI, PGA
Subjective severity	DLQI, pruritus-NRS, WPAI:CHE, HEIS
Occupational exposure	Wet work, chemical exposure, glove use
Allergy diagnostics	Patch test, prick test
Comorbidities	Foot eczema, cardiovascular diseases ...
Previous therapies	Topical, phototherapy, systemic
Current therapy	Substance, dosage, duration
Treatment response	Improvement, stability, worsening
Adverse events	Type and severity
Work ability	Sick days, incapacity for work

Table 1. Summary of study variables across key clinical and demographic domains

Results

The planned registry will provide real-world data on diagnosis, classification, and treatment of CHE. In particular, differences between clinical subtypes, care settings, and therapeutic strategies can be better characterized. Furthermore, the registry may serve as an important basis for the development of evidence-based guidelines and future clinical and translational research projects. Given the substantial individual and socioeconomic burden of CHE, there is a strong need for robust real-world data. Structured data collection within a registry can make a significant contribution in this regard. In the long term, HEBest may help to refine individualized treatment strategies and further develop preventive measures, particularly in occupational settings.

Conclusions

The goal of the established Hand Eczema Registry is the systematic collection and analysis of real-world data on the epidemiology, disease burden, and care landscape, as well as the efficacy and safety of therapeutic interventions in patients with chronic hand eczema. In terms of content, HEBest focuses on real-world disease courses, clinical subtypes, disease burden, and “patient needs.” In addition, current treatment standards and outcomes are recorded, with optional evaluation of efficacy and safety (including future therapeutics) as well as a forward-looking focus on pharmacovigilance-related issues.

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Abstract N°: 2767

Dupilumab in prurigo nodularis: 3-months follow-up insights into GLOBOSPIN, a global observational study

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Introduction
Prurigo nodularis (PN) is a chronic inflammatory disease that profoundly impacts quality of life. GLOBOSPIN was the first global real-world observational study aiming to characterise the use patterns and effectiveness of dupilumab in patients with PN during the first 3-month observation period.

Materials and Methods
The GLOBOSPIN 18-month, multinational, observational study (NCT05991323) enrolled 108 patients aged ≥18 years with prurigo nodularis who were prescribed dupilumab based on physician decisions made independently of study participation, according to country-specific prescribing information. Assessments were performed at baseline and every 3 months. Effectiveness of dupilumab was evaluated using the Investigator's Global Assessment of Chronic Prurigo Activity and Stage (IGA-CPG; 0 (clear) – 4 (severe)).

Results
The proportion of patients achieving IGA-CPG Activity score of 0/1 was 4.1% at baseline, increasing to 32.9% at 3 months. The proportion of patients with an IGA-CPG Activity score of 3 (67.6%) or 4 (27.0%) at baseline, decreased to 32.9% and 4.3% at 3 months, respectively. The proportion of patients achieving IGA-CPG Stage score of 0/1 was 4.1% at baseline, increasing to 35.7% at 3 months. The proportion of patients with an IGA-CPG Stage score of 3 (58.1%) or 4 (17.6%) at baseline, decreased to 24.3% and 0% at 3 months, respectively.

Conclusions
The results of this study provide broader real-world insights on the efficacy of dupilumab treatment in reducing itch and lesion count in patients with PN, with substantial improvements observed at the first assessment timepoint of 3 months after treatment initiation.

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Abstract N°: 2783

Stress-induced Neurotensin Upregulation in Sensory Neurons Mediates the Exacerbation of Chronic Allergic Itch

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Introduction

Atopic dermatitis (AD) is characterized by a debilitating itch-scratch cycle that perpetuates skin inflammation. While psychological stress is a clinically proven trigger for AD exacerbation, the precise molecular mechanisms by which stress modulates peripheral sensory neurons remain elusive. Traditional views emphasize central neuroendocrine pathways, but emerging evidence suggests direct stress-induced remodeling of the peripheral nervous system. This study utilizes a longitudinal transcriptomic approach to identify the sensory neuron-derived mediators that drive stress-exacerbated AD.

Materials and Methods

We established a stress-exacerbated AD model using MC903 (calcipotriol) to induce chronic dermatitis in mice, followed by the application of standardized psychological stress. Itch behavior was quantified via automated scratching bouts, and skin severity was assessed through clinical manifestations and histopathological analysis. To capture the dynamic transcriptional landscape of sensory neurons, bulk RNA sequencing (RNA-seq) was performed on trigeminal ganglia (TG) at multiple time points: Baseline, AD-induction, and post-stress application. Data were analyzed to identify differentially expressed genes (DEGs) and functional pathways associated with neurogenic inflammation.

Results

MC903 treatment induced transcriptional changes in the peripheral nervous system. Notably, expression of the neurotensin (Nts) gene increased as early as day 3, followed by upregulation of the NP3 neuron marker Nppb at day 4 and Il31ra at day 5. Inflammatory genes such as Ccl8, Cxcl9, and Ptgs2 also showed marked elevation from day 4. Both 3-day restraint and chronic unpredictable stress upregulated Nts expression in TGs, indicating stress-induced neurotensin regulation.

Functionally, intradermal injection of neurotensin into cheek skin induced rapid-onset scratching behavior, sustained up to 60 minutes. This acute pruritic response was significantly suppressed by co-treatment with a neurotensin receptor 1 (NTSR1) antagonist. To assess chronic effects, neurotensin or vehicle was intradermally co-administered daily during the 6-day topical MC903 treatment. Neurotensin significantly enhanced scratching on days 3, 4, and 6 and exacerbated dermatitis, including increased mast cell infiltration. Finally, pharmacologic inhibition of NTSR1 via intraperitoneal injection of SR-48692 attenuated both spontaneous scratching and skin inflammation in MC903-treated mice.

Conclusions

Our findings demonstrate that neurotensin induction in sensory neurons—triggered by stress or MC903—drives itch and amplifies skin inflammation in a murine AD model. Our data suggest the neurotensin–NTR1 pathway as a potential therapeutic target in AD, particularly for stress-induced exacerbations.

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Abstract N°: 2799

Real-world budget-impact of ruxolitinib cream in moderate atopic dermatitis in Germany: evidence from nationwide statutory health insurance claims data (Forschungsdatenzentrum Gesundheit; FDZ)

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Introduction

Atopic dermatitis is a chronic, inflammatory skin disease associated with substantial epidemiological, clinical, and economic burden. In Germany, adult prevalence is estimated at approximately 1.3 to 4.2%. Patients, particularly those with moderate-to-severe disease, frequently experience significant impairment in quality of life primarily attributable to eczematous lesions and persistent pruritus. Disease management typically follows a stepwise approach according to disease severity and response to initial therapy, including topical therapies and targeted systemic treatment with biologics or Janus kinase (JAK) inhibitors. Topical JAK inhibition represents a novel, nonsteroidal therapeutic option for patients with moderate atopic dermatitis. As introducing new therapies may lead to additional financial pressure on healthcare budgets, this study aims to assess the budgetary implications of the introduction of ruxolitinib cream for the treatment of moderate atopic dermatitis from the perspective of the German statutory health insurance.

Materials and Methods

A cohort-based budget impact model was developed to estimate the total annual treatment costs over a five-year time horizon under two scenarios: a reference scenario without ruxolitinib cream and a scenario in which ruxolitinib cream was introduced into the German healthcare market. The analysis was conducted using a decision-analytic modelling framework with weekly cycles, enabling the representation of disease progression and treatment pathways across clinically relevant severity states. The target population comprised patients with moderate dermatitis who were eligible for advanced systemic therapies. Comparators included currently available targeted treatments, such as biologics and systemic JAK inhibitors approved for this indication in accordance with German treatment guidelines. Epidemiological data, real-world treatment patterns and market share estimates were derived from healthcare claims data (2021 – 2023) obtained from the Research Data Center Health of the Federal Institute for Drugs and Medical Devices (Forschungsdatenzentrum Gesundheit am Bundesinstitut für Arzneimittel und Medizinprodukte; FDZ/BfArM). This recently established database provides access to nationwide statutory health insurance claims data covering approximately 90% of the population in Germany for research purposes. Key input parameters including population estimates and transition probabilities were complemented by evidence from national and international guidelines as well as published literature. Costs included drug acquisition, routine monitoring, and costs associated with adverse events. Drug acquisition costs were obtained from publicly available national drug price databases, while monitoring costs were based on outpatient reimbursement tariffs. Scenario analyses explored alternative assumptions regarding population size, treatment

uptake, and market share development. Deterministic and probabilistic sensitivity analyses were conducted to assess uncertainty surrounding key model parameters.

Results

Over a five-year time horizon, preliminary results based on publicly available data and expert-based market shares indicated that introduction of ruxolitinib cream is a cost savings. Scenario analyses showed consistent results. Further analyses incorporating real-world data from FDZ are currently ongoing.

Conclusions

The introduction of ruxolitinib cream for adult patients with moderate atopic dermatitis may be associated with cost savings, supporting the favorable economic profile and thereby informing healthcare decision-making.

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Abstract N°: 2815

Paradoxical Hair Loss During Dupilumab Therapy: A Case Highlighting Immune Imbalance

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Introduction

Dupilumab, a fully human IgG4 monoclonal antibody that targets the IL-4 receptor α subunit shared by IL-4 and IL-13 receptors, has significantly enhanced outcomes in moderate-to-severe atopic dermatitis (AD) by suppressing Th2-dependent type 2 inflammation and reducing the need for broad immunosuppression. However, expanding real-world experience continues to reveal adverse effects, including emerging reports of alopecia. This report details the occurrence of de novo hair loss during dupilumab therapy and explores potential immunological mechanisms linking AD and alopecia areata (AA).

Case Presentation

A 25-year-old male with AD since infancy presented with a severe flare unresponsive to topical corticosteroids and cyclosporine (up to 400 mg/day). Baseline severity and burden were high (EASI 32.2, IGA 4, DLQI 11), with no active AD lesions on the scalp and no personal or family history of AA. Following the exclusion of contraindications, dupilumab was initiated. At week 12, the patient developed sudden hair loss of the frontal scalp and beard, accompanied by erythematous, scaly plaques with excoriations (SALT 31); trichoscopy revealed features characteristic of an AA. Dupilumab was discontinued, and a topical high-potency corticosteroid (clobetasol) solution was initiated. Four weeks later, due to substantial AD activity (EASI 26, IGA 4, DLQI 10), upadacitinib was commenced, resulting in concurrent clinical improvement in AD and hair regrowth; complete regrowth was observed at 6 months.

Conclusion

AD and AA frequently coexist (approximately 15–20% of AA patients have AD; 38% report atopy), suggesting shared immunopathogenesis. Although Th2 blockade may benefit AA in certain contexts, dupilumab can paradoxically precipitate AA through Th1/Th17-axis dysregulation, IFN-α–related pathways, autoreactive CD8+ T-cell activity and AA-like drug reactions characterized by erythema/scaling and potential sebaceous gland atrophy. This case highlights the dual and unpredictable effects of IL-4/IL-13 inhibition on hair follicles and supports vigilant monitoring and individualized therapeutic adjustments when dupilumab-associated alopecia is suspected.

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Abstract N°: 2816

Abrocitinib modulates multi-axis immune activation in moderate-to-severe AD patients who failed Dupilumab

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Introduction

While Dupilumab is highly effective in treating patients with atopic dermatitis (AD), complete or near-complete clearance is only achieved in approximately one-third of patients. Systemic JAK inhibitors have emerged as an effective alternative treatment due to their ability to target multiple inflammatory pathways. This open-label study aims to assess the clinical efficacy and effect on skin biomarkers of Abrocitinib, an oral JAK1-inhibitor, in treating patients with moderate-to-severe AD who previously failed Dupilumab.

Materials and Methods

Nineteen (19) adult patients with moderate-to-severe AD (vIGA-AD≥2) with persistent facial erythema (Cohort A; n=7) or unsatisfactory trunk/limbs response (Cohort B; n=12) after ≥12 weeks treatment with Dupilumab were enrolled in the study. Baseline inclusion criteria included a modified vIGA-AD≥2 and either ≥1% BSA with at least moderate facial erythema for Cohort A or ≥3% BSA on trunk and/or limbs for Cohort B. Following a 2-6-week washout period, patients received Abrocitinib 100 mg daily for 12 weeks. Reduction of baseline in Eczema Area and Severity Index (EASI) total score at Week 12 was the primary endpoint and was evaluated every 4 weeks. Tape-strips were collected from lesional and non-lesional facial and body skin at baseline and lesional skin after 12 weeks and from 20 anatomically matched healthy controls. Differentially expressed genes (DEGs; fold change/FCH>2, $p<0.05$) were evaluated using RNA-seq.

Results

Significant reduction from baseline in EASI was observed at weeks 2, 4, 8, and 12, with a 5.7 and 7.2-point reduction achieved at week 12 in cohorts A and B respectively. Cohort A showed significant improvements in facial vIGA-AD and BSA at all timepoints, while Cohort B showed significant improvements in trunk and limbs vIGA-AD and BSA at all timepoints. At week 12 versus baseline, 1,144 DEGs (655 upregulated, 489 downregulated) were identified in lesional facial skin, and 94 DEGs (46 upregulated, 46 downregulated) in lesional body skin. With treatment, facial skin showed a marked and significant reduction in Th1 (IRF1, MX1, OASL, CXCL9/10/11, IL12B) and Th17 (CXCL3, S100A7A/8/9/12) inflammation, with more modest modulation of Th22 and Th2 pathways, showing overall decreases approaching significance (SERPINB1/4, S100P, STAT6, FLG). In body skin, significant reductions were primarily observed in markers of innate immunity (XCL1/2) and Th1 activation (OASL, CXCL9/10/11, IL12B), with no significant changes in the Th2 axis.

Conclusions

These findings suggest that persistent erythema following Dupilumab is likely caused by a confluence of immune axes including Th1, Th17 and potential Th22 activation in face and predominant Th1 driven inflammation in body. These notable clinical and transcriptomic improvements suggest that Abrocitinib may be effective in treating patients with non–Th2-dominant or heterogeneous inflammatory profiles by broadly reducing multi-pathway inflammation through JAK1 inhibition.

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Abstract N°: 2828

Comparative efficacy of upadacitinib and nemolizumab with background topical therapy in adults and adolescents with moderate-to-severe atopic dermatitis: a placebo-anchored matching-adjusted indirect comparison

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by eczematous rash and itch. Advances in systemic therapies enabled targeted modulation of immune pathways that drive AD. Upadacitinib (UPA), a Janus kinase 1 inhibitor, and nemolizumab (NEMO), an interleukin-31 receptor alpha antagonist, are both approved for the treatment of moderate-to-severe AD. Given the absence of head-to-head trials of UPA versus NEMO, a placebo-anchored matching-adjusted indirect comparison (MAIC) was conducted to compare the efficacy of UPA versus NEMO in adults and adolescents with moderate-to-severe AD.

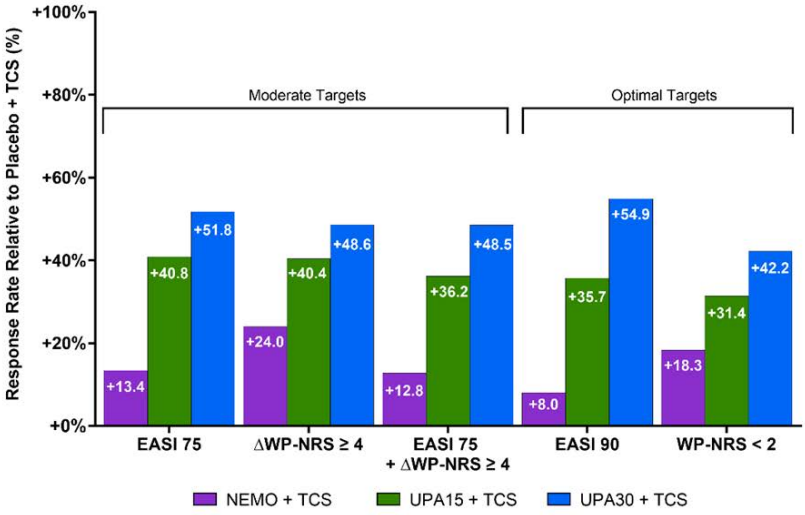
Materials and Methods

Individual patient-level data were collected from the AD Up phase 3 trial (NCT03568318), in which adults and adolescents with moderate-to-severe AD received UPA 15mg (UPA15), UPA 30mg (UPA30), or placebo in combination with topical corticosteroids (TCS) for a 16-week double-blind treatment period. Individual data were not available for NEMO; aggregate-level data were collected from the ARCADIA 1 and 2 phase 3 trials (NCT03985943/NCT03989349), in which adults and adolescents with moderate-to-severe AD received NEMO 30mg or placebo in combination with TCS with or without topical calcineurin inhibitors for a 16-week double-blind treatment period. Selection criteria included Eczema Area and Severity Index (EASI) ≥ 16, Investigator Global Assessment (IGA) of moderate/severe, Worst Pruritus Numerical Rating Scale (WP-NRS) ≥ 4, and body surface area (BSA) ≥ 10%. Upadacitinib patients were weighted to match NEMO baseline characteristics, including disease severity measures (EASI, IGA, WP-NRS, BSA, Scoring AD), demographics (age, weight, sex, race), and quality of life (Dermatology Life Quality Index [DLQI]/children's DLQI). Outcome measures included the Aiming High in Eczema/Atopic Dermatitis (AHEAD) recommendations[1] for moderate treatment targets (≥ 75% improvement in EASI [EASI 75], WP-NRS improvement ≥ 4 [ΔWP-NRS ≥ 4], EASI 75 + ΔWP-NRS ≥ 4) and optimal treatment targets (≥ 90% improvement in EASI [EASI 90], WP-NRS < 2). Response rates were estimated for the matched UPA cohort and compared against NEMO using placebo-adjusted rates, with statistical comparisons based on the risk difference (RD).

Results

UPA demonstrated statistically significant superiority over NEMO across all outcomes at Week (W) 16, with benefits emerging by W2. At W16, matching-adjusted response rates for UPA were numerically higher than those reported for NEMO for EASI 75 (NEMO: 42.9%; UPA15: 68.3% | UPA30: 79.2%), EASI 90 (25.6%; 48.4% | 67.6%), ΔWP-NRS ≥ 4 (41.9%; 54.2% | 62.4%), WP-NRS < 2 (29.6%; 40.1% | 50.8%), and EASI 75 + ΔWP-NRS ≥ 4 (23.4%; 45.5% | 57.8%). Placebo-adjusted response rates were higher for UPA15 and UPA30 versus NEMO for EASI 75 (UPA15: +40.8% | UPA30: +51.8% vs NEMO: +13.4%), EASI 90 (+35.7% | +54.9% vs +8.0%), ΔWP-NRS ≥ 4 (+40.4% | +48.6% vs +24.0%), WP-NRS < 2 (+31.4% | +42.2% vs +18.3%), and EASI 75 + ΔWP-NRS ≥ 4 (+36.2% | +48.5% vs +12.8%) (Figure); RDs were statistically significant ($p < 0.001$) for these comparisons. Statistically significant RDs favoring UPA were observed at W2 for ΔWP-NRS ≥ 4 (UPA15 vs NEMO: RD = 10.7% [95% CI: 2.9, 18.4]; UPA30 vs NEMO: RD = 20.1% [95% CI: 12.0, 28.1]) and WP-NRS < 2 (9.9% [3.7, 16.2]; 15.4% [8.9, 22.0]), and at W4 for EASI 75 (39.2% [30.4, 48.0]; 51.3% [42.9, 59.6]), EASI 90 (23.4% [16.3, 30.4]; 42.2% [34.6, 49.8]), and EASI 75 + ΔWP-NRS ≥ 4 (27.1% [19.3, 34.9]; 38.8% [30.8, 46.8]). Statistically significant differences for UPA15 and UPA30 versus NEMO were sustained through W16 for all outcomes assessed.

Figure. Placebo-adjusted response rates for both moderate and optimal treatment targets at Week 16



EASI, Eczema Area and Severity Index; EASI 75/90, ≥ 75%/90% improvement in EASI score; NEMO, nemolizumab; TCS, topical corticosteroids; UPA15, upadacitinib 15mg; UPA30, upadacitinib 30mg; WP-NRS, Worst Pruritus Numerical Rating Scale. Note: Topical background therapy in the ARCADIA 1 & ARCADIA 2 trials was also with or without topical calcineurin inhibitors. UPA15 vs NEMO and UPA30 vs NEMO RDs were statistically significant for all outcome measures ($p < 0.001$).

Conclusions

Based on trials that included background topical therapy, adults and adolescents with moderate-to-severe AD achieved higher rates of moderate and optimal treatment targets with UPA15 and UPA30 compared with NEMO as early as W2 and through W16 in this placebo-anchored MAIC.

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Abstract N°: 2844

Baseline Characteristics of Atopic Dermatitis Patients and Treatment Efficacy: First Results from the TREAT Austria Registry

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Introduction

Atopic dermatitis (AD) is the most frequent chronic inflammatory skin disease affecting up to 20% in children and 10% in adults in high income countries. Moderate–to-severe disease significantly impairs patient's quality of life and requires long-term treatment strategies including standard topical anti-inflammatory therapies along with systemic classical immunosuppressants or modern targeted treatment options, such as biologics and Januskinase (JAK) inhibitors. Here, we present a first interim data analysis of the TREAT Austria registry including patient's characteristics, disease severity, comorbidities, treatment regimens as well as quality of life in patients with AD.

Materials and Methods

Patients with moderate-to-severe AD with or without systemic treatment were included. Besides demographic characteristics of patients, details about comorbidities, information about treatment regimen and response to treatment, as well as data on quality of life were evaluated. Follow-up visits were conducted at 3- to 6-month intervals, consistent with standard clinical practice. Disease severity was assessed using the Eczema Area and Severity Index (EASI), and the Investigator's Global Assessment (IGA). As patient-oriented scores, we used patient-oriented eczema measure (POEM), disease life quality index (DLQI) and numerical rating scale (NRS) itch to assess burden of disease as well as atopic dermatitis control test (ADCT) for disease control. For statistical analysis, baseline patient characteristics were summarized using descriptive statistics and presented by mean and standard deviation or by median and interquartile range for metric variables. For categorial variables the number of patients and percentage (n, %) were reported. Outcomes were analyzed using Mann-Whitney U test for not normally distributed data. A value of $p \leq 0.05$ was considered significant. Statistical analysis was performed with PRISM (Graph Pad, San Diego, CA, USA) version 10.0 for Macintosh.

Results

At baseline, our study population included 170 patients (86 female and 84 male) with a mean age of 37.5 years. Around 30% of the patients showed one allergic comorbidity, and more than 50% showed two or more with allergic rhino-conjunctivitis being the most prevalent allergic comorbidity (Table 1). In terms of body weight, most patients (64.1%) had a BMI within the normal weight range of 18.5 – 24.9. Considering additional cardiovascular risk factors, the majority of patients were non-smokers (62.4%), and 62% reported no other relevant cardiovascular risks. Only 13.5% of patients had arterial hypertension (Table 1). Evaluation of laboratory parameters revealed that IgE (954.0 (178.0/3420.0) kIU/L) was the only marker with a notable deviation from the reference range. As measures for disease severity, mean EASI and IGA scores at baseline were 11.68 ± 11.48, and 2.346 ± 1.1, respectively. Both scores significantly declined at the first follow-up visit (EASI 5.2± 6.6 and IGA 1.640

± 1.051). Likewise, patient-oriented scores including POEM, DLQI, NRS itch and ADCT showed a significant decrease from baseline to follow-up visits. When treatment modalities at baseline were reviewed, we found that 84.1% of the patients received topical and 72.0% received systemic treatment. Of the latter, the vast majority (68.6%) were treated with biologic agents. At the first follow-up visit, the percentage of systemically treated patients had increased to 88.2% with a larger proportion of patients receiving biologics (60%) as compared to JAK-inhibitors.

Table 1: Demographic data

Sex (n=170)	**n**	**%**
m	84	49.4%
f	86	50.6%
Age, years (n=170)		
mean±SD	37.47±14.45	
BMI (n=92)		
	n	**%**
Normal (18.5 – 24.9)	59	64.1%
Overweight/obese (≥25)	33	35.9%
Age of onset (years) (n=169)		
mean±SD	7.77 ± 12.47	
	n	**%**
0 – 5	125	75.3%
6 – 18	21	12.7%
19 – 40	14	8.4%
>40	6	3.6%
Family history of AD (n=114)		
	n	**%**
Positive	50	43.9%
Negative	64	56.1%
Smoking (n=93)		
	n	**%**
Current smoker	16	17.2.%
Former smoker	19	20.4%
Non-smoker	58	62.4%
Patients with/without allergic comorbidities (n=162)		
	n	**%**
No allergic comorbidity	26	16.0%
1 allergy	53	32.7%
2 or more allergies	83	51.3%
Allergic comorbidities (n=268)		
	n	**%**
Bronchial asthma	63	23.5%
Contact allergies	33	12.3%
Food allergies	55	20.5%
Allergic rhino-conjunctivitis	98	36.6%
Atopic eye disease	19	7.1%
Cardiovascular risk factors /diseases (n=163)		
	n	**%**
No cardiac risk factors	101	62.0%
Coronary heart disease	4	2.5%
Myocardial infarction	2	1.2%
Stroke	1	1.2%
Hyperlipidemia	18	11.0%
Hypertension	22	13.5%
Diabetes	5	3.1%
DVT	1	0.6%
Other	8	4.9%

Table 1: Demographic data

Conclusions

The TREAT Austria registry presents real-life data of baseline demographic characteristics, clinical, and therapeutic outcome of patients with moderate-to-severe AD. Treatments showed significant clinical efficacy with improvements in both clinical and patient-reported outcomes.

These findings emphasize the importance of individualized therapy in the management of AD to optimize treatment outcomes.

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Abstract N°: 2862

Identification and characterization of exhausted T cells in atopic dermatitis using high-dimensional spectral flow cytometry

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Introduction

T cell exhaustion is induced by chronic antigen exposure and characterized by sustained expression of inhibitory receptors and impaired effector function. It is well established in cancer and chronic infections and is increasingly recognized as a potential contributor to autoimmune and chronic inflammatory diseases. However, its role in dermatological conditions, specifically atopic dermatitis (AD), remains poorly defined. AD is characterized by persistent immune activation and a predominantly Th2-driven inflammatory profile, suggesting that chronic antigenic stimulation may contribute to immune-exhaustion states (Figure 1). Despite this, exhausted T cells in AD and their clinical relevance remain understudied.

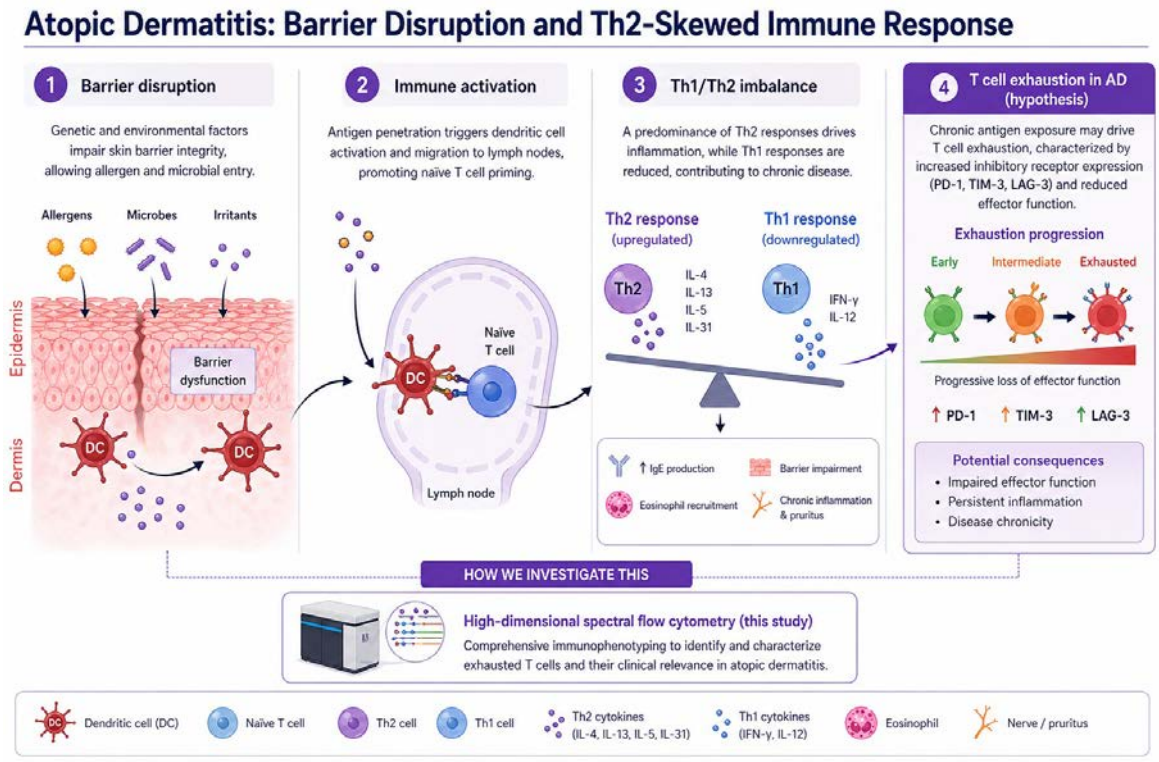

Figure 1: Barrier disruption, Th2-skewed inflammation, and progression toward T cell exhaustion in atopic dermatitis. Schematic overview of atopic dermatitis pathogenesis, showing how barrier dysfunction and immune activation lead to a predominantly Th2-driven response. Chronic antigen

exposure sustains inflammation and immune dysregulation, which may drive the gradual development of T cell exhaustion, characterized by increased expression of inhibitory receptors (e.g., PD-1, TIM-3, LAG-3) and reduced effector function. In this study, exhaustion-associated profiles are investigated using high-dimensional spectral flow cytometry.

Materials and Methods

Peripheral blood samples were collected from adult patients with moderate-to-severe AD and age- and sex-matched healthy controls. Inclusion criteria comprised AD diagnosis according to UK Working Party criteria, childhood onset (<13 years), and validated Investigator Global Assessment (vIGA-AD ≥3). Healthy controls had no history of AD or other self-reported atopic diseases, namely asthma, allergic rhinitis, and food allergy. Exclusion criteria included BMI >30, recent systemic immunosuppressive therapies, chronic infections, malignancies, prolonged antibiotic use, and other inflammatory or infectious diseases. Washout periods were 12 weeks for biologicals, 4 weeks for conventional systemics and JAK inhibitors, and 1 week for prednisolone. PBMCs are being isolated and analyzed using a spectral flow cytometry panel for exhaustion-associated markers (PD-1, TIM-3, CTLA-4, LAG-3), activation markers (CD25, OX40), and differentiation markers (CXCR3, CCR6, CRTh2). Initial validation in healthy controls evaluated marker resolution, signal distribution, and gating robustness.

Results

A total of 26 AD patients were included, with a mean age of 39 ± 15.1 years (range 20–72), and 38.5% females. Disease severity by vIGA-AD classified patients into 10 moderate, 8 severe, and 8 very severe cases, with a mean EASI of 22.9 ± 13.3. Regarding atopic comorbidities 61% of patients reported asthma, 69% allergic rhinitis, and 46% food allergy. Most patients had previous systemic treatment: 2 patients (7.7%) received one treatment, 19 (73.1%) two or more, and 5 (19.2%) had no previous immunosuppressants. Prior use of biologics and JAK inhibitors was observed in 7 (26.9%) and 2 (7.7%) patients, respectively. Initial validation of the flow cytometry panel in healthy controls demonstrated robust identification and clear separation of major T cell populations, including CD4+ and CD8+ subsets. Exhaustion-associated markers such as PD-1, TIM-3, and TIGIT showed expected expression patterns across T cell compartments, supporting sensitivity and specificity. The panel also enabled characterization of Th1- and Th2-associated subsets, providing context for interpreting exhaustion profiles in AD. Differential baseline expression of inhibitory receptors was observed between individuals, revealing heterogeneity in exhaustion-associated profiles even under healthy conditions. Patient sample analysis is ongoing to determine whether exhaustion-associated profiles are enriched in AD and associated with disease severity.

Conclusions

This study establishes a high-dimensional framework to identify and characterize T cell exhaustion in AD. Panel validation confirmed robust identification of exhaustion-associated markers, while differentiation markers enabled assessment of exhaustion profiles across relevant T cell subsets. Ongoing analyses will determine whether these profiles are enriched in AD and relate to disease severity. This work aims to refine the understanding of immune dysregulation in AD and support more targeted therapeutic strategies.

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Abstract N°: 2863

One year efficacy and safety findings for skin of colour patients with moderate-to-severe atopic dermatitis receiving dupilumab in the Canadian phase IV prospective, observational study (CANDID).

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Introduction

Currently, limited data are available on long-term use of dupilumab in skin of colour (SOC) patients with moderate-to-severe atopic dermatitis (AD) in a Canadian real-world setting. The aim of this analysis was to report 1 year (12-month) effectiveness and safety data for SOC patients with moderate-to-severe AD receiving dupilumab as part of the CANDID study (phase 4 AD dupilumab Canada study). For this analysis, skin of colour was defined by self-reported ethnicity (African; Asian; Hispanic; Middle Eastern; Indigeneous; mixed ethnicity) rather than Fitzpatrick phototype classification, to align with current recommendations for equitable patient representation.

Materials and Methods

CANDID (NCT06099704) is an ongoing, 18-month, long term, prospective, observational study of adults/adolescents/children (aged ≥ 6 years at baseline) with moderate-to-severe AD who initiated dupilumab in real-world settings according to Canadian specific prescribing guidelines. Effectiveness outcomes evaluated at baseline and months 3, 6, 12, and 18 included scores for 75% improvement in Eczema Area and Severity Index (EASI-75), body surface area (BSA), Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI), Hospital

Anxiety and Depression Scale (HADS), Sleep Disturbance Numerical Rating Scale (SD NRS), and Peak Pruritus Numeric Rating Scale (PP NRS). Safety events were collected from the time of signed informed consent.

Results

One year (12-month) data were obtained from 106 SOC patients (76 adults and 30 pediatric/adolescents aged 6-17 years) enrolled into the CANDID study. After dupilumab treatment initiation, mean improvements in effectiveness outcome measures from baseline to month 12 were 87% for EASI-75 (from 24.0 to 3.1), 83% for BSA (from 34.0% to 5.9%), 71% for DLQI (from 16.7 to 4.9), 57% for CDLQI (from 14.3 to 6.1), 34% for HADS (from 17.0 to 11.2), 65% for SD NRS (from 6.6 to 2.3), and 57% for PP NRS (from 7.9 to 3.4). No new safety concerns were identified at 12 months.

Conclusions

In a Canadian real-world setting, dupilumab demonstrated robust and sustained long-term effectiveness in SOC patients with moderate-to-severe AD across multiple disease domains, including AD signs, symptoms, and quality of life. Safety was consistent with the known dupilumab safety profile.

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Abstract N°: 2890

Atopic Dermatitis in Indigenous Communities: Barriers to Care and Teledermatology Solutions

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Introduction
Indigenous communities in Canada experience higher atopic dermatitis prevalence alongside profound barriers to dermatologic care, shaped by historical and ongoing structural inequities related to colonization. These barriers include historical trauma, geographic isolation, unsafe water, inadequate housing, and cultural safety gaps. Despite significant disease burden, Indigenous participants comprise only 0.91% of atopic dermatitis clinical trial enrollment. This review synthesizes evidence on prevalence, assessment approaches, access barriers, and intervention models, centering Indigenous perspectives and structural determinants of health.

Materials and Methods
A systematic search of five databases identified six studies; an environmental scan catalogued 49 programs. No randomized trials specific to atopic dermatitis management in Indigenous populations exist. Dermatologic conditions affected 16.6-53.5% of Indigenous populations, exceeding general rates. Barriers emerged across four domains: systemic (historical trauma, research exclusion), geographic (remote locations accessible only by plane or ice roads), resource-related (water insecurity, mold exposure, medication costs), and cultural safety deficits (limited Indigenous providers, dismissal of traditional healing). Promising interventions included Indigenous Extension for Community Healthcare Outcomes telementoring, hybrid models combining community navigators with electronic consultations, outreach rotations, and co-designed care pathways. Most programs reported positive outcomes but lacked standardized metrics for wait times, disease control, or equity stratification.

Results
Improving atopic dermatitis care for Indigenous communities requires approaches beyond clinical service delivery. Findings support the importance of addressing upstream determinants such as water security and housing, strengthening cultural safety training, Indigenous governance following Ownership-Control-Access-Possession principles, and developing standardized equity-focused evaluation metrics. Dermatologists can contribute through advocacy, adapting care to patients' material realities, and partnering with communities to co-design sustainable models of care.

Conclusions
Improving atopic dermatitis care for Indigenous communities requires approaches beyond clinical service delivery. Findings support the importance of addressing upstream determinants such as water security and housing, strengthening cultural safety training, Indigenous governance following Ownership-Control-Access-Possession principles, and developing standardized equity-focused evaluation metrics. Dermatologists can contribute through advocacy, adapting care to patients' material realities, and partnering with communities to co-design sustainable

models of care. Effective atopic dermatitis care for Indigenous communities demands more than teledermatology. It requires addressing systemic barriers including water insecurity, housing conditions, and cultural safety gaps while centering Indigenous governance and traditional healing practices.

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Abstract N°: 2919

Association Between the COVID-19 Pandemic and Atopic Dermatitis Incidence: A Systematic Review and Meta-Analysis of 1,477,955 Cohort Patients

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease marked by immune dysregulation and impaired barrier function, affecting up to 20% of children and 10% of adults worldwide. These immunologic alterations may increase vulnerability to infections, including SARS-CoV-2. While biologically plausible, the association between AD and COVID-19 infection risk remains unclear, with conflicting evidence across observational studies. Understanding this relationship is critical for guiding clinical risk stratification during pandemics. We therefore conducted a systematic review and meta-analysis to evaluate whether AD increases susceptibility to COVID-19.

Materials and Methods
We systematically searched PubMed, Embase, and the Cochrane Central Register of Controlled Trials for observational studies published until 12 April 2025. A random-effects model was used to generate pooled odds ratios (ORs) and 95% confidence intervals (CIs). We measured the certainty of the evidence using GRADE assessment.

Results
A total of eight studies and 1,477,955 patients were included, of whom 93,744 (6.34%) had AD. No significant association was observed between atopic dermatitis and the risk of COVID-19 infection (OR: 1.05; 95% CI: 0.80–1.38; p = 0.714; GRADE: low). Considerable heterogeneity was observed among the included studies (I^2 = 93%).

Conclusions
This meta-analysis found no significant association between AD and the risk of COVID-19 infection, suggesting that AD is not an independent risk factor for acquiring SARS-CoV-2. However, further prospective studies

employing standardized definitions and rigorous adjustment for potential confounders are warranted to clarify this relationship.

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Abstract N°: 2933

Beyond EASI: development of a clinical model based on IGA and pruritus to identify patients with poorly controlled atopic dermatitis

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Introduction
Morphological severity does not always reflect the real impact of atopic dermatitis (AD). In clinical practice, stratification based on the *Eczema Area and Severity Index* (EASI) may underestimate patients with high disease burden. The aim was to assess this limitation and determine whether a model based on the *Investigator's Global Assessment* (IGA) and pruritus improves identification of patients with clinically relevant uncontrolled disease at the first visit.

Materials and Methods
Cross-sectional study in a specialized AD unit. Consecutive patients attending their first visit were included. Clinically relevant uncontrolled disease was defined as EASI ≥21, *Dermatology Life Quality Index* (DLQI) >10, or *Atopic Dermatitis Control Tool* (ADCT) ≥7. EASI was compared with a combined IGA–pruritus model using logistic regression, ROC curves, bootstrap validation, and decision curve analysis.

Results
A total of 257 patients were included (37.6 ± 20.4 years; 54.5% female). Among those with available data (n = 180), 77.8% had clinically relevant uncontrolled disease, and 52.9% of these had EASI <21. The IGA–pruritus model showed better discrimination than EASI (AUC 0.900 vs 0.833), particularly in patients with EASI <21 (0.872 vs 0.692; p = 0.0003). A clinical calculator, using a threshold ≥0.50, showed 93.2% sensitivity and 65.0% specificity, identifying 77 additional patients (44.8%).

Conclusions
EASI alone may underestimate patients with AD and clinically relevant uncontrolled disease. A model based on IGA and pruritus, implemented in a calculator, may improve identification and support clinical prioritization.

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Abstract N°: 2964

Beyond EASI: residual sleep abnormalities and psychological burden in adult patients treated with dupilumab for severe atopic dermatitis – a prospective observational study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by eczematous lesions and intense pruritus, leading to sleep impairment, psychological distress, and reduced quality of life. In routine practice, treatment success is commonly assessed using skin severity, pruritus, and quality-of-life endpoints. However, it remains uncertain whether improvement in cutaneous lesions fully corresponds to patient-centered outcomes. The objective of this study was to assess multidimensional patient-reported outcomes in adults with severe AD treated with dupilumab, with particular focus on residual sleep abnormalities and psychological burden despite clinical skin response.

Materials and Methods

We analyzed a prospective cohort of 20 adult patients with severe AD (defined as Eczema Area and Severity Index [EASI] ≥21.0) treated with dupilumab. Disease severity and patient-reported outcomes were assessed at baseline, week 8, and week 16 using EASI, Pruritus Numerical Rating Scale (P-NRS), Dermatology Life Quality Index (DLQI), Hospital Anxiety and Depression Scale - anxiety subscale (HADS-A), Hospital Anxiety and Depression Scale - depression subscale (HADS-D), and Athens Insomnia Scale (AIS). Treatment response was evaluated using absolute and relative changes as well as predefined endpoints, including EASI75, defined as at least 75% improvement in EASI, EASI90, defined as at least 90% improvement in EASI, P-NRS reduction of at least 4 points, DLQI reduction of at least 4 points, AIS <6, and HADS-A/HADS-D <8. Correlations between changes in patient-reported outcomes were assessed. Exploratory analyses were performed to identify factors associated with incomplete response. All statistical analyses were performed using R software, version 4.6.0 (R Foundation for Statistical Computing, Vienna, Austria).

Results

At baseline, patients presented substantial disease burden, with median EASI of 28.2 (interquartile range [IQR] 21.0-32.9), P-NRS of 8.0 (IQR 8.0-9.0), DLQI of 22.5 (IQR 16.8-25.3), AIS of 12.5 (IQR 10.0-17.0), HADS-A of 10.5 (IQR 6.8-15.0), and HADS-D of 9.0 (IQR 8.0-12.0). At week 16, EASI75 and EASI90 were achieved by 17 patients (85%) and 15 patients (75%), respectively. P-NRS improvement of at least 4 points was achieved by 19 patients (95%) and DLQI improvement of at least 4 points by 18 patients (90%). However, patient-centered response remained incomplete in a relevant subgroup. Despite achieving EASI75, 7/17 patients (41.2%) did not reach AIS <6, 5/11 patients (45.5%) with elevated baseline HADS-A did not normalize below 8 points, and 3/13 patients (23.1%) with elevated baseline HADS-D did not normalize below 8 points. Similar residual burden was observed among EASI90 responders: persistent sleep impairment occurred in 6/15 patients (40%), persistent anxiety burden

in 4/10 (40%), and persistent depressive burden in 2/11 (18.2%). Improvement in pruritus correlated with improvement in DLQI at week 16 (rho = 0.534; p = 0.015). Improvement in AIS correlated with improvement in HADS-A (rho = 0.712; p < 0.001) and HADS-D (rho = 0.538; p = 0.014). Exploratory analyses did not identify robust baseline predictors of incomplete patient-centered response after correction for multiple comparisons.

Conclusions

Dupilumab treatment resulted in marked improvement in adults with severe AD, but classical indicators of disease severity did not uniformly correspond to sleep and psychological outcomes. These findings suggest that assessment of treatment success in severe AD should include measures of residual patient-reported burden. This approach may identify patients requiring additional supportive interventions (multidisciplinary specialist team). These findings confirm that atopic dermatitis is an extremely complex, multifactorial disease.

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Abstract N°: 2974

Extracellular Vesicles with High PD-L1 and E-cadherin Expression for Atopic Dermatitis Treatment by Regulating CD4+Tissue-Resident Memory T Cells

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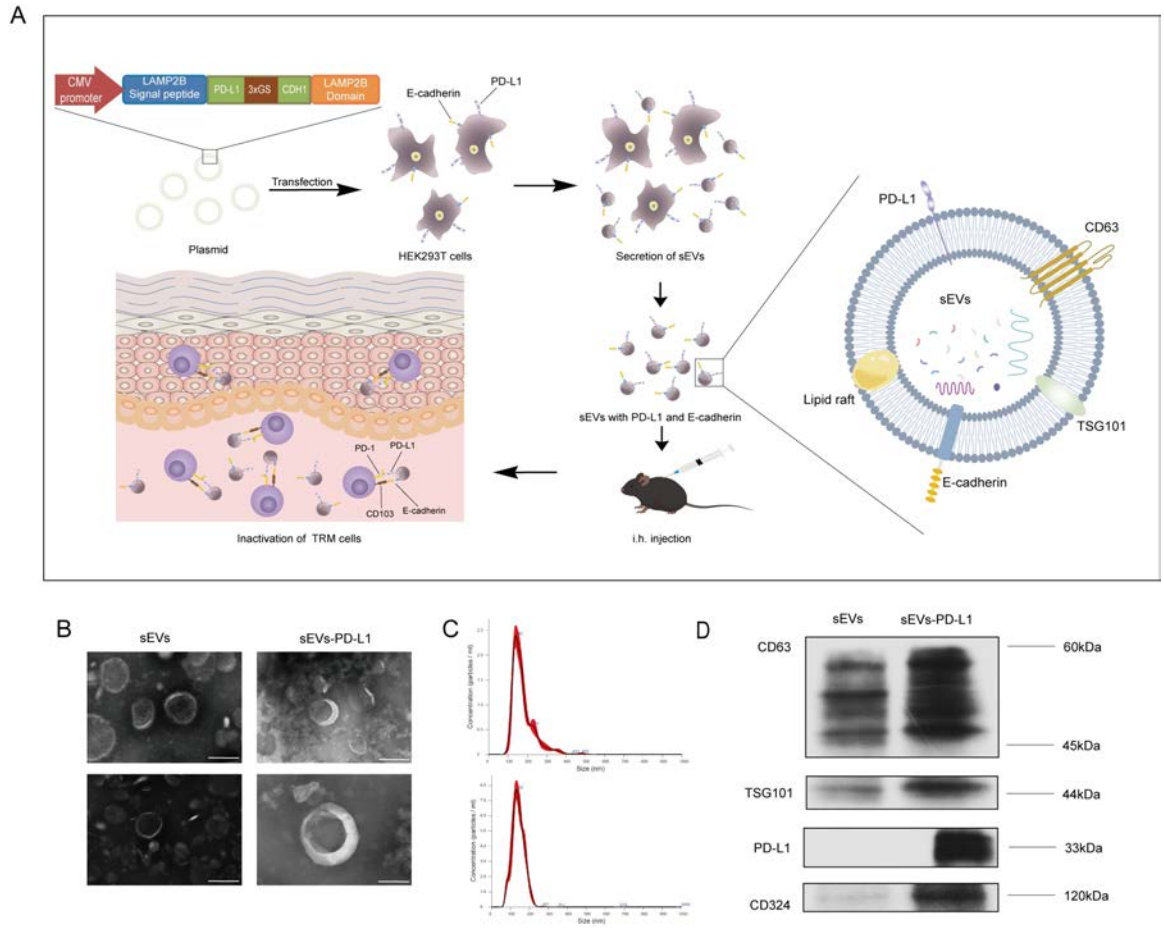
Introduction

Introduction: Atopic dermatitis (AD) is a chronic inflammatory skin disease that imposes significant physical discomfort, psychological stress, and financial strain on patients due to its recurrent nature. Current treatments, while effective for some, often fail to provide long-term relief, particularly for those who experience frequent relapses. The persistence of $CD4^+$tissue-resident memory T (TRM) cells in lesional skin has been implicated in the chronicity and recurrence of AD. Targeting these $CD4^+$ TRM cells offers a promising strategy to mitigate the inflammatory response and reduce the frequency of flare-ups. Our study aims to evaluate the therapeutic efficacy of sEVs-PD-L1, engineered to target $CD4^+$ TRM cells, in an OVA-induced relapse model of AD, with the goal of developing a novel treatment approach to address the issue of AD recurrence.

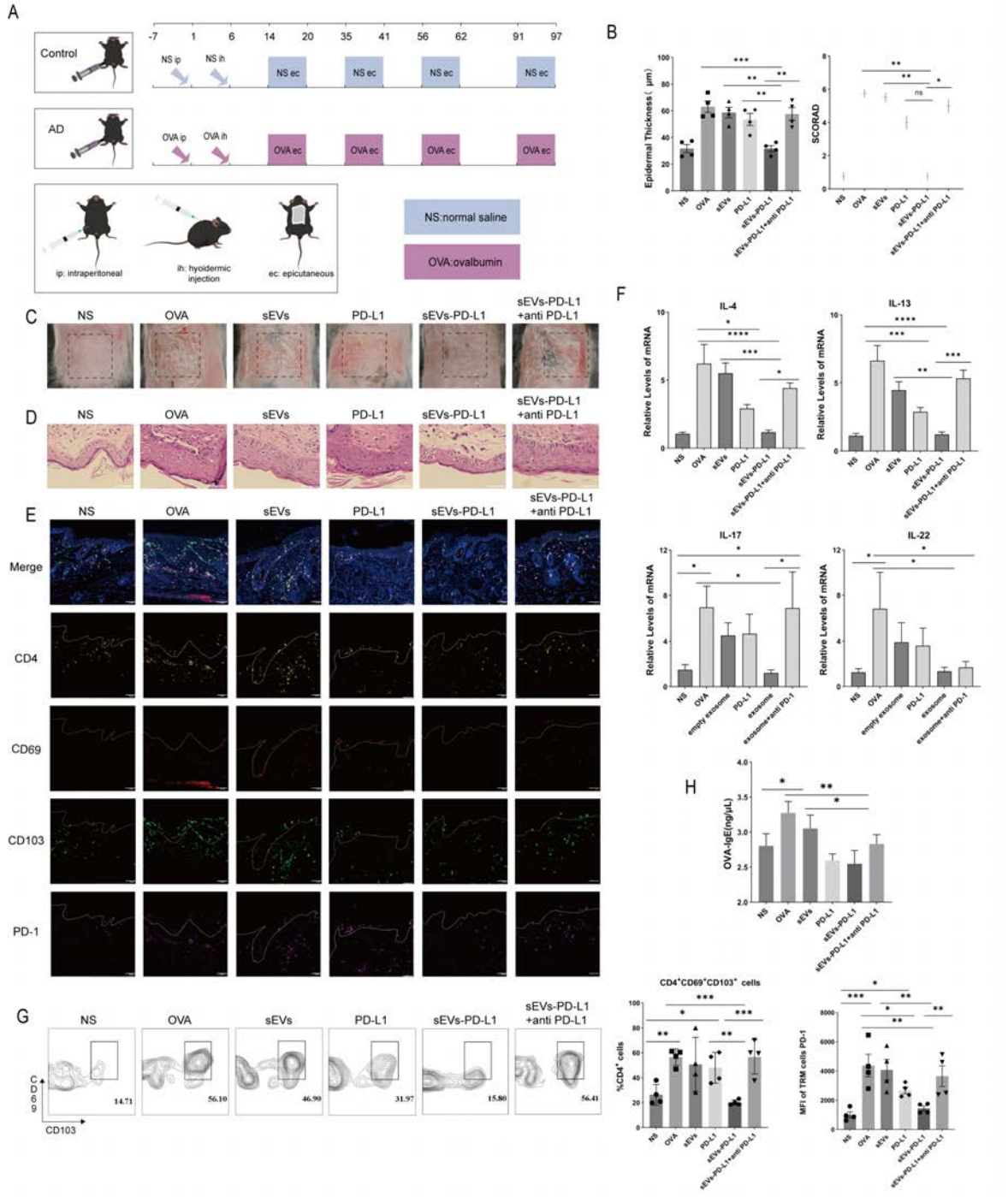
Materials and Methods

Materials & Methods: We constructed an OVA-induced relapse model of AD in female C57BL/6 mice. sEVs-PD-L1, engineered to express high levels of PD-L1 and E-cadherin, was used to target $CD4^+$ TRM cells. Efficacy was evaluated by assessing skin lesion severity, SCORAD scores, histopathological changes, and cytokine levels. Safety was examined through tissue morphology, immune cell infiltration, and major organ functions.



Results

Results: sEVs-PD-L1 significantly reduced skin lesion severity, SCORAD scores, and pathological changes such as acanthosis, parakeratosis, and hyperkeratosis. It outperformed blank sEVs and PD-L1 protein alone in reducing $CD4^+$ TRM cell infiltration and modulating local inflammation. Safety assessments in healthy mice revealed no significant changes in tissue structure, cellular morphology, immune cell infiltration, or major organ functions, indicating good biocompatibility. Additionally, sEVs -PD-L1 significantly lowered OVA-specific IgE levels in peripheral blood, an effect that was abrogated upon administration of anti-PD-L1 antibody.



Conclusions

Conclusions: sEVs-PD-L1 demonstrated significant therapeutic potential in reducing TRM cell infiltration and modulating local inflammatory levels in AD lesions, with good safety profiles. This approach offers a promising strategy for treating refractory AD and warrants further investigation into its clinical application and underlying mechanisms.

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Abstract N°: 3022

The clinical impact of atopic dermititis on sleep disorders

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by epidermal barrier dysfunction, pruritus and increased susceptibility to to cutaneous infections Affecting 15–20% of children and about 10% of adults, it is the most common chronic inflammatory skin condition in the population.

AD has a genetic predisposition and beyond its cutaneous manifestations, it is frequently associated with various comorbidities, among which sleep disorders represent a notably prevalent and impactful concern.

While the relationship between atopic dermatitis and sleep disorders has been demonstrated in numerous studies, it has not yet been fully elucidated.

The aim of our study was to investigate the impact of atopic dermatitis on patients' sleep quality in Georgian population.

Case Presentation

The study was conducted over 12 months and included 347 patients with atopic dermatitis, recruited from dermatology consultations that referred to our clinics.

Participants completed the questionnaire collecting demographic and clinical data, including age, sex, duration and severity of AD. Symptom intensity—specifically pruritus and pain—were assessed alongside sleep quality, which was evaluated using the Pittsburgh Sleep Quality Index (PSQI). Statistical analyses were performed to identify correlations between clinical parameters and sleep disturbances.

Totally 347 patients participated in the study, consisting of 211 (61%) females and 136 (39%) males, with a mean age of 17.3 ± 4.2 years. Notably, 58% of participants presented with moderate-to-severe atopic dermatitis, and 68% reported moderate-to-severe pruritus (VAS ≥ 5).

Assessments via the PSQI revealed that 61% of the patients experienced poor sleep quality (score ≥ 5). The primary sleep disturbances identified were nocturnal awakenings (57%), sleep-onset latency (34%) and morning fatigue (23%).

Among the clinical parameters evaluated, a significant association was identified between nocturnal pruritus and impaired sleep quality ($r = 0.96$; $p < 0.001$), underlining the impact of pruritus on sleep quality in patients with atopic dermatitis. Furthermore, skin pain was correlated with the frequency of nocturnal awakenings ($r = 0.52$; $p = 0.001$). A comparative gender analysis further revealed a significantly higher prevalence of sleep-onset latency in female patients compared to males.

Conclusion

Optimizing the management of sleep-related comorbidities in AD patients requires a multidisciplinary approach involving dermatologists and sleep medicine specialists. Special attention should be given to high-risk patients, particularly those with severe pruritus or psychological comorbidities.

Clinical practice should prioritize targeted screening for high-risk patiants, particularly those exhibiting severe pruritus, persistent nocturnal disturbances, or concurrent psychological comorbidities, to facilitate early intervention and improve overall health-related quality of life.

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Abstract N°: 3033

Multi-Axis Modulation of Atopic Dermatitis Pathophysiology by a Defined Live Biotherapeutic Consortium: Selective Staphylococcus aureus Suppression, Epidermal Barrier Restoration, and Inflammatory Attenuation

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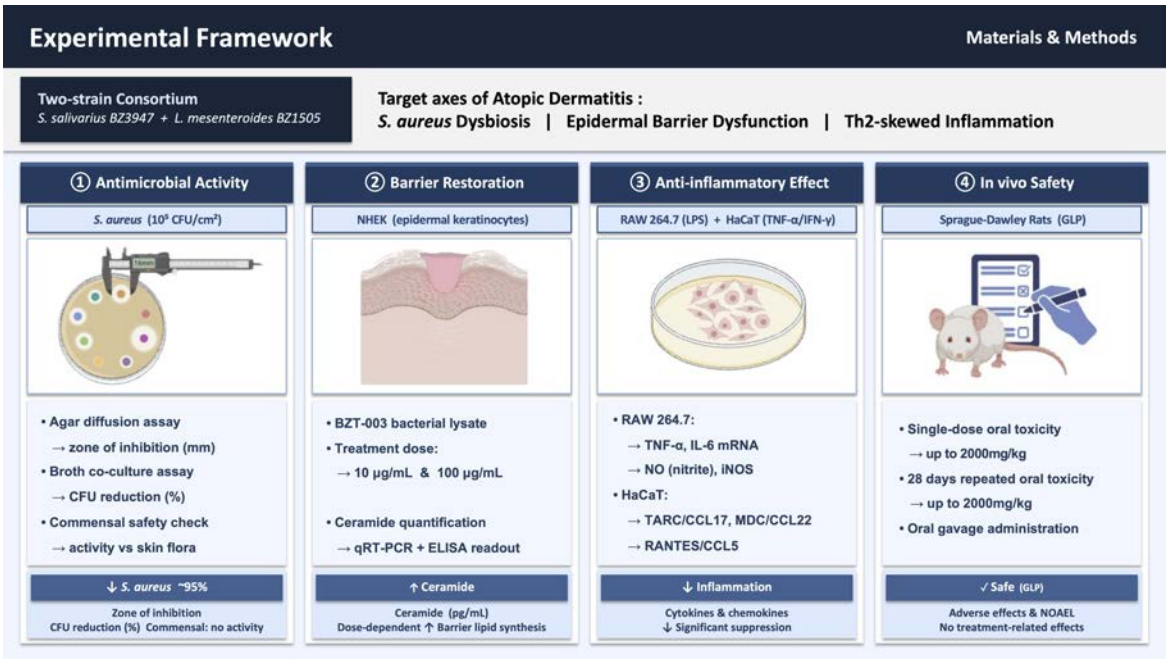
Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease sustained by *S. aureus* dysbiosis, epidermal barrier dysfunction, and Th2-skewed immune activation. Notably, *S. aureus* colonizes only 5–15% of healthy skin yet exceeds 90% in AD lesional skin, with colonization burden correlating with disease severity and flare frequency. High density *S. aureus* elaborates delta-toxins and superantigens that damage keratinocytes, suppress filaggrin, and amplify type 2 inflammation. Conventional therapies address downstream inflammation without correcting this dysbiosis, while antibiotic approaches carry resistance risks and deplete commensal flora essential for barrier homeostasis. Microbiome-based live biotherapeutic products (LBPs) address these limitations: selective *S. aureus* suppression with commensal preservation supports barrier recovery, reduces resistance liability, and allows combination with existing therapies for synergistic benefit. Here, we evaluated BZT-003, a defined two-strain consortium of *Streptococcus salivarius* BZ3947 and *Leuconostoc mesenteroides* BZ1505, for its capacity to suppress *S. aureus*, restore barrier lipid synthesis, and attenuate inflammatory signaling in multiple*in vitro* AD models and *in vivo* safety studies.

Materials and Methods

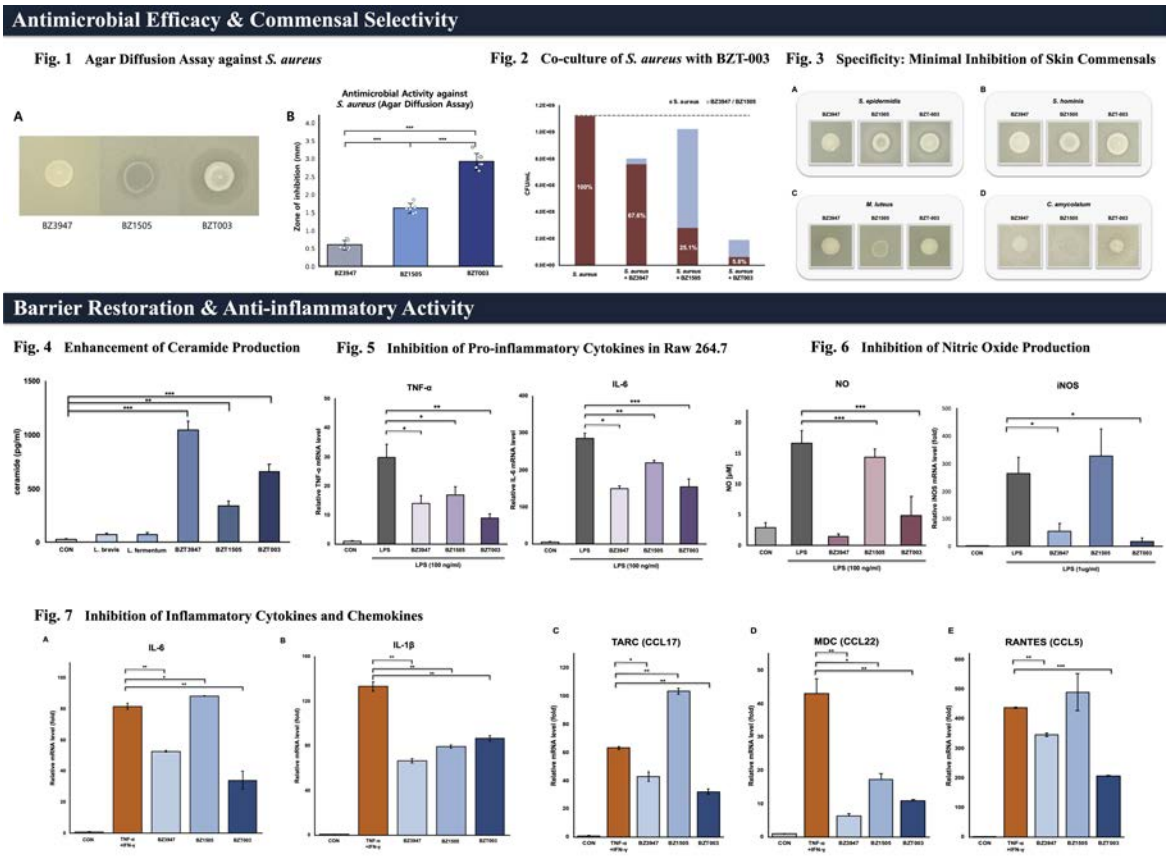
Antimicrobial activity was assessed by agar diffusion assay against*S. aureus* (10^5 CFU/cm² on soft agar overlay) and by broth co-culture at a 1:1 ratio for 24 h with viable count enumeration. Target specificity was evaluated against representative skin commensals (*S. epidermidis*, *S. hominis*, *C. amycolatum*, *M. luteus*). Barrier restoration was measured by ceramide quantification in normal human epidermal keratinocytes (NHEK) treated with bacterial lysates at protein concentrations of 10 and 100 μg/mL. Anti-inflammatory effects were assessed in LPS-stimulated RAW 264.7 macrophages, measuring TNF-α and IL-6 transcripts, NO production via nitrite accumulation, and iNOS expression, and in TNF-α/IFN-γ-stimulated HaCaT keratinocytes, measuring pro-inflammatory cytokines (IL-6, IL-1β) and Th2-associated chemokines (TARC, MDC, RANTES). *In vivo* safety was evaluated by GLP-compliant single-dose and 28-day repeated oral toxicity studies in Sprague-Dawley rats at doses up to 2,000 mg/kg.



BZT-003 was assessed across three pathological axes of atopic dermatitis: selective S. aureus suppression, epidermal barrier restoration (ceramide synthesis in NHEK), and anti-inflammatory activity in LPS-stimulated RAW 264.7 macrophages and TNF-α/IFN-γ-stimulated HaCaT keratinocytes. In vivo safety was evaluated in Sprague-Dawley rats (GLP-compliant).

Results

In agar diffusion assays, BZT-003 produced a synergistically enlarged zone of inhibition against *S. aureus* compared with either strain alone, while showing no activity against skin commensals, indicating selective specificity. In broth co-culture, BZT-003 reduced *S. aureus* colony-forming units by approximately 95%, compared with 32.4% for BZ3947 and 72.9% for BZ1505 individually, revealing potent synergistic bacterial killing. BZT-003 also promoted barrier recovery: ceramide levels in NHEK cells increased dose-dependently, reaching approximately 650 pg/mL at 100 μg/mL lysate; BZ3947 alone reached 1,100 pg/mL, reflecting strain-specific contributions to barrier lipid synthesis. In LPS-stimulated macrophages, BZT-003 significantly suppressed TNF-α and IL-6 transcripts, reduced nitrite accumulation, and downregulated iNOS expression. In TNF-α/IFN-γ-stimulated HaCaT keratinocytes, BZT-003 attenuated IL-6 and IL-1β expression and markedly suppressed Th2-associated chemokines TARC, MDC, and RANTES. Finally in oral toxicity studies, no treatment-related adverse effects were observed at any dose level, establishing a favorable preclinical safety profile.



BZT-003 selectively suppressed S. aureus by 95% in broth co-culture while sparing skin commensals. In NHEK, ceramide production increased ~4-fold at 100 µg/mL vs. untreated control. BZT-003 also reduced NO production and iNOS expression in LPS-stimulated macrophages, and attenuated pro-inflammatory cytokines (IL-6, IL-1β) and Th2-associated chemokines (TARC, MDC, RANTES) in stimulated HaCaT keratinocytes. Data are mean ± SD (n = 3); *p<0.05, **p<0.01, ***p<0.001 vs. stimulated control.

Conclusions

BZT-003, as a defined two-strain consortium, targets the core pathological axes of AD—*S. aureus* dysbiosis, barrier dysfunction, and Th2-skewed inflammation within a single formulation. Selective *S. aureus* suppression with commensal preservation, dose-dependent ceramide upregulation, and broad attenuation of pro-inflammatory and Th2-associated mediators demonstrate a mechanism distinct from conventional immunosuppressive approaches. Together with a favorable GLP safety profile, these data support BZT-003 as a disease-modifying live biotherapeutic product candidate for AD.

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Abstract N°: 3042

Real-World Disease Burden and Treatment Patterns in Patients with Atopic Dermatitis and Limited Skin Involvement Who Meet Criteria for Advanced Systemic Therapy in the US and Canada

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Introduction
Despite the approval of multiple advanced systemic therapies (ASTs), patients with moderate to severe atopic dermatitis (AD) remain undertreated, with particularly limited real-world data on disease burden and AST use in moderate AD. This study describes the AD symptoms and AST initiation in patients with moderate AD in the United States and Canada.

Materials and Methods
This retrospective study analyzed data from TARGET-DERM AD, a US and Canadian longitudinal registry, including patients with moderate AD assessed by clinicians, enrolled between January 25, 2019, and October 30, 2025. Moderate AD diagnosis (index) was defined ≥1 assessment with Body Surface Area (BSA) 10–40% or BSA <10% and Patient Oriented SCORing Atopic Dermatitis (PO-SCORAD) lesion on the hand, foot, or face within ±3 months of BSA measure. This study sample included patients who had moderate AD at index and no AST use for 9 months prior to index. Patients were stratified into two cohorts based on whether AST was initiated within 6 months of index: 1) AST initiators and 2) non-initiators. Patient demographics and clinical characteristics were summarized descriptively. Severity was assessed clinically using the validated Investigator's Global Assessment (vIGA-AD) score. Patient assessments included Patient-Oriented Scoring AD (PO-SCORAD) overall, PO-SCORAD Sleep, PO-SCORAD Itch, Patient Reported Outcomes Measurement Information System (PROMIS)-Worst Itch, and Patient Oriented Eczema Measure (POEM) scores. Higher scores indicated greater disease severity and burden. Time-to-AST initiation was assessed during a 24-month follow-up period; discontinuation was assessed among those initiating AST. Outcomes were analyzed using the cumulative incidence function.

Results
Among patients with moderate AD, the median (interquartile range (IQR): Q1–Q3) age was 27.0 (13.0–52.0) years overall (N=2,289), 28.0 (16.0–52.0) among AST initiators (N=304), and 22.0 (7.0–46.0) among non-initiators (N=822). Despite being diagnosed with moderate AD, the majority were non-initiators (73.0%). Patients were predominantly non-Hispanic white and female. The median (IQR) BSA% was 10.0 (5.0-20.0) overall, 17.0 (10.0–26.0) among initiators, and 10.0 (3.3–18.0) among non-initiators; BSA% was higher in AST initiators than in non-initiators (standardized mean difference=0.7). At assessment, vIGA-AD and PO-SCORAD classified most patients as moderate across cohorts (overall: 48.6%/40.4%; AST initiators: 65.5%/49.1%; non-initiators: 48.8%/39.6%). Substantial disease burden was observed across cohorts; overall and AST initiator/non-initiator median (IQR)

scores for itch (PROMIS-Worst Itch: 7.0 (4.0–9.0), 8.0 (6.0–9.0), 7.0 (5.0–9.0); PO-SCORAD Itch: 3.6 (1.5–7.0), 6.7 (3.1–7.9), 4.2 (1.8–7.0)), sleep disturbance (PO-SCORAD Sleep: 2.0 (0.2–5.9), 4.1 (1.0–6.6), 1.9 (0.2–5.9)); and overall disease impact (POEM: 10.0 (5.0–15.0), 15.0 (11.0–20.0), 10.0 (5.0–15.0)). At assessment, the most common comorbidities were asthma (overall: 27.7%; AST initiators: 26.0%; non-initiators: 25.6%) and allergic rhinitis (20.0%; 18.4%; 21.8%). Among those with no prior AST use (N=1,327), the proportion of AST initiators after moderate AD diagnosis increased over 24 months; however, overall AST initiation was low (3, 6, 12, 18, 24 months: 22.3%, 25.8%, 30.6%, 34.6%, 38.0%). By 24 months, 38.0% of the cohort initiated AST, and 37.1% of these patients discontinued treatment within the same period.

Conclusions

Patients with moderate AD experienced substantial itch, sleep disturbance, and overall disease burden, underscoring that moderate disease severity should not be falsely regarded as minimal impact on patients' lives. Despite this burden, fewer than 4 in 10 patients initiated AST over 24 months, and over one-third of initiators subsequently discontinued, highlighting a meaningful treatment gap in real-world management of moderate AD with important implications for clinical practice and guideline adherence.

Table 1. Patient demographics and clinical characteristics at moderate AD assessment, overall and by AST initiation status

Characteristic	Overall (N = 2,289)	AST initiators (n = 304)	Non-initiators (n = 822)
Demographics			
Age in years, Median (IQR)	27.0 (13.0–52.0)	28.0 (16.0–52.0)	22.0 (7.0–46.0)
Female, n (%)	55.5	58.1	55.8
Race/ethnicity, n (%)			
Non-Hispanic White	57.7	53.3	59.8
Non-Hispanic Black	12.9	13.9	12.6
Hispanic or Latino	12.4	15.2	14.5
Asian	10.9	11.5	7.3
Other	6.2	6.1	5.7
Disease Assessment			
BSA%, Median (IQR)	10.0 (5.0–20.0)	17.0 (10.0–26.0)	10.0 (3.3–18.0)
BSA category, n (%)			
< 10%	34.2	10.9	41.5
10 – <20%	36.7	43.8	35.8
20 – <30%	16.6	23.4	13.4
30 – <40%	8.8	15.5	6.7
40%+	3.7	6.6	2.7
PO-SCORAD category, n (%)			
Mild	53.8	40.0	55.4
Moderate	40.4	49.1	39.6
Severe	5.7	10.9	5.0
PO-SCORAD lesion location, n (%)			
Hand	56.9	67.9	58.5
Foot	45.6	52.8	48.4
Face	48.1	37.7	45.2
vIGA-AD category, n (%)			
Clear	0.4	2.6	15.7
Almost clear	14.4	0.0	0.5
Mild	26.0	11.2	26.6
Moderate	48.6	65.5	48.8
Severe	10.5	20.7	8.4
Disease Burden			
Itch, Median (IQR)			
PROMIS-Worst Itch	7.0 (4.0–9.0)	8.0 (6.0–9.0)	7.0 (5.0–9.0)
PO-SCORAD Itch	3.6 (1.5–7.0)	6.7 (3.1–7.9)	4.2 (1.8–7.0)
Sleep, Median (IQR)			
PO-SCORAD Sleep	2.0 (0.2–5.9)	4.1 (1.0–6.6)	1.9 (0.2–5.9)
Severity, Median (IQR)			
POEM	10.0 (5.0–15.0)	15.0 (11.0–20.0)	10.0 (5.0–15.0)

Interquartile range (IQR) indicates the range between the 25th (Q1) and 75th (Q3) percentiles. Abbreviations: AD, atopic dermatitis; AST, advanced systemic therapy; BSA, Body Surface Area; N, total number of patients; n, number of patients in the specified subgroup; POEM, Patient Oriented Eczema Measure; PO-SCORAD, Patient Oriented SCORing Atopic Dermatitis; PROMIS, Patient Reported Outcomes Measurement Information System; vIGA-AD, validated Investigator's Global Assessment For categorical variables, percentages may not add up to 100% due to rounding.

EADV CONGRESS
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Abstract N°: 3053

Efficacy and Practical Considerations of Wet Wrap Therapy in Atopic Dermatitis: An Indian Clinical Experience

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Introduction

Wet wrap therapy (WWT) is an effective adjunct in atopic dermatitis (AD), but its use in India remains limited due to
practical challenges.



Materials and Methods

To evaluate the efficacy, safety, and feasibility of WWT in Indian patients with moderate-to-severe AD.

A prospective observational study of 24 patients with moderate-to-severe AD was conducted. All received standard

therapy with adjunctive WWT using cotton-based wraps. SCORAD, pruritus (VAS), and sleep disturbance were assessed at baseline and after 7–14 days. Compliance and adverse effects were recorded. Informed consent was obtained from all patients.



Results

Mean SCORAD reduced from 48.2 to 22.4 (~53% reduction, $p < 0.001$). Pruritus improved from 8.1 to 3.2 within 1 week, with better sleep in 85% patients. WWT was well tolerated; mild folliculitis occurred in ~8% (2/24). Compliance
was good in ~71% (17/24), with reduced adherence in hot weather.

Conclusions

WWT is a safe, cost-effective, and rapidly effective adjunct for moderate-to-severe AD in Indian settings. Simple, climate-adapted protocols and patient counselling can improve acceptance and outcomes in routine practice.

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Abstract N°: 3068

Effectiveness and Safety Data of Dupilumab in Adolescent and Adult Patients With Atopic Dermatitis: Real-World Insights 3 Years Into the GLOBOSTAD Multinational Prospective Observational Study

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Introduction
GLOBOSTAD (NCT03992417) is an ongoing, 5-year, multinational, prospective, observational registry study that included adult and adolescent (aged ≥12 years) patients with moderate-to-severe atopic dermatitis (AD) at baseline, who initiated dupilumab in real-world clinical practice according to their local country-specific prescribing guidelines.[1,2] The aim of this analysis was to provide interim effectiveness and safety data for patients who completed up to 3 years of observation in GLOBOSTAD.

Materials and Methods
Data were included for pooled adult and adolescent patients who completed up to 3 years of observation in GLOBOSTAD. Assessments were conducted at baseline, 3 months (3 months; ±1 month), 6 months (±2 months), then every 6 months (±2 months) up to 36 months (3 years). All analyses are descriptive and data are reported as observed.

Results
Of the 953 patients enrolled in GLOBOSTAD, 343 (36.0%) discontinued. The main reason for study discontinuation was withdrawal of consent by the patient (119/953; 12.5%). A total of 753, 626, and 528 patients completed ≥1 assessment at 12 months, 24 months, and 36 months, respectively, with a mean (standard deviation; SD) duration of dupilumab therapy of 29.1 (11.23) months. In the overall population, mean (SD) Eczema Area and Severity Index (EASI) score decreased (improved) from 25.1 (12.84) at baseline to 4.7 (10.1), 3.4 (7.54), and 2.9 (5.15) at 12mo, 24mo, and 36mo, respectively; EASI scores were similar in adult (n = 886) vs adolescents (n = 13): 25.2 (12.86) vs 21.3 (10.78) at baseline; 4.7 (10.14) vs 3.4 (3.06) at 12 months; 3.4 (7.60) vs 2.3 (3.07) at 24 months; and 2.9 (5.18) vs 1.3 (0.91) at 36 months. In the overall population, mean (SD) SCORing AD (SCORAD) total score decreased (improved) from 60.3 (16.42) at baseline to 18.7 (14.39), 16.1 (14.26), and 14.3 (13.91) at 12 months, 24 months, and 36 months, respectively; SCORAD scores were similar in adult (n = 886) vs adolescents (n = 13): 60.3 (16.43) vs 59.2 (16.71) at baseline; 18.7 (14.43) vs 19.8 (12.40) at 12 months; 16.1 (14.26) vs 15.9 (15.13) at

24 months; and 14.3 (13.98) vs 14.2 (8.00) at 36 months. Of the 953 enrolled patients, 480 (50.4%) had any adverse event (AE), of whom 42 (4.4%) had any serious AE. A total of 41/953 (4.3%) patients had any AEs leading to permanent treatment discontinuation, and 2/953 (0.2%) patients had any AEs leading to death (unrelated to dupilumab). A total of 235/953 (24.7%) patients had ≥1 AE considered related to dupilumab therapy by the investigator. The most common dupilumab-related AEs were ocular in nature, specifically conjunctivitis (61/953 patients; 6.4%) and allergic conjunctivitis (60/953; 6.3%). In most patients, the severity of dupilumab-related AEs were mild (163/235; 69.4%) or moderate (95/235; 40.4%), with few patients (6/235; 2.6%) having severe dupilumab-related AEs. At the end of the 3-year observation period, dupilumab-related AEs were reported to be recovered/resolved (152/234 patients; 65.0%), not recovered/not resolved (52/234; 22.2%), recovered with sequelae (0/234; 0%), recovering/resolving (52/234; 22.2%), unknown (13/234; 5.6%), and fatal (0/234; 0%).

Conclusions

In this analysis of real-world data for patients with moderate-to-severe AD at baseline treated with dupilumab for up to 3 years in the observational GLOBOSTAD registry, dupilumab resulted in sustained improvements in AD severity according to SCORAD total score. Safety was consistent with the known dupilumab safety profile. The most common dupilumab-related AEs were conjunctivitis and allergic conjunctivitis. Most dupilumab-related AEs were of mild or moderate severity.

References:

1. Calzavara-Pinton P, et al. Adv Ther. 2023;40:5366-82.
2. Calzavara-Pinton P, et al. Adv Ther. 2025;42:720-33.

EA DV CONGRESS
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Abstract N°: 3084

Adult Patients With Moderate-to-Severe Atopic Dermatitis Treated With Dupilumab Achieve Sustained Optimal Control of Signs and Symptoms: Results From a 5-Year Open-Label Extension Study

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Introduction

Given the chronic nature of atopic dermatitis (AD) and variable therapeutic response, understanding whether continuous treatment can deliver sustained control of signs and symptoms is essential for clinical practice. Recent consensus frameworks for treatment targets in AD define optimal goals, such as Eczema Area and Severity Index (EASI) score ≤3, Peak Pruritus Numeric Rating Scale (PP-NRS) score ≤4, and Investigator's Global Assessment (IGA) score 0/1 to optimize patient outcomes.

Most publications analyzing the potential of advanced systematic therapies to achieve these outcomes have reported data up to 52 weeks, creating uncertainty about the maintenance of efficacy with continuous treatment over longer periods in chronic disease like AD. This analysis evaluated the efficacy of dupilumab in achieving optimal control in signs and symptoms over 5 years in adults with moderate-to-severe AD.

Materials and Methods

In LIBERTY AD OLE (NCT01949311), adult patients (≥18 years of age) received dupilumab 300 mg every week/every 2 weeks via subcutaneous injection. We assessed the proportion of patients achieving optimal control of signs and symptoms as defined by a) IGA score ≤2 or EASI score ≤7; b) IGA score 0/1 or EASI score ≤3; c) PP-NRS score ≤4; and d) PP-NRS score 0/1 (no to almost no itch). All analyses were descriptive.

Results

Of 2,677 patients, 334 patients (12.5%) completed treatment up to Week 260. The most common reasons for

withdrawal included regulatory approval of dupilumab (810 of 1,380 [58.7%]), patient withdrawal (248 of 1,380 [18.0%]), adverse events (116 of 1,380 [8.4%]), and patient withdrawal due to lack of efficacy (58 of 1,380 [4.2%]).

Dupilumab achieved optimal control of signs in most patients based on a) IGA score ≤2 or EASI score ≤7 at Week 48 (1,647 of 1,760 [93.6%]), and up to 5 years (211 of 225 [93.8%]); and b) IGA score 0/1 or EASI score ≤3 at Week 48 (1,274 of 1,760 [72.4%]), a proportion that increased over time and up to 5 years (186 of 225 [82.7%]). Dupilumab also achieved optimal control of itch based on c) PP-NRS score ≤4 at Week 48 in most patients (1,117 of 1,280 [87.3%]), and for up to 5 years (144/164 [87.8%]); and based on d) PP-NRS score 0/1 (no to almost no itch) in 38.4% of patients (491/1280) at Week 48 and 38.4% up to 5 years (63/164). Safety was consistent with the known dupilumab safety profile.

Conclusions

In adult patients with moderate-to-severe AD, continuous dupilumab treatment demonstrates sustained optimal control of signs and symptoms over 5 years, achieving goals defined by consensus frameworks for treatment targets in AD.

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Abstract N°: 3085

Longitudinal laboratory profile of patients with moderate-to-severe atopic dermatitis treated with lebrikizumab or tralokinumab in real-world clinical practice

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Introduction

Atopic dermatitis is a chronic inflammatory skin disease associated with high clinical burden and frequent need for systemic therapy. Targeted IL-13 inhibition with tralokinumab and lebrikizumab has expanded the therapeutic landscape for moderate-to-severe disease. Unlike conventional immunosuppressants or JAK inhibitors, IL-13 inhibitors are not expected to require intensive laboratory monitoring, although real-world longitudinal data on routine analytical parameters remain limited.

The objective of this study is to describe the longitudinal evolution of routine laboratory parameters in patients with moderate-to-severe atopic dermatitis treated with tralokinumab or lebrikizumab in real-world clinical practice, and to explore their clinical response over follow-up.

Materials and Methods

We conducted a real-world observational study including patients with moderate-to-severe atopic dermatitis treated with tralokinumab or lebrikizumab in a tertiary hospital. Demographic data, clinical severity scores and routine laboratory parameters were collected at baseline and during follow-up. For the main analysis, early follow-up was defined as weeks 8–12 and long-term follow-up as weeks 40–52.

Clinical outcomes included EASI, SCORAD, BSA, IGA, DLQI, pruritus NRS and sleep NRS. Laboratory parameters included blood count, eosinophils, neutrophils, lymphocytes, liver enzymes, renal function, lipid profile, IgE, LDH and neutrophil-to-lymphocyte ratio. Paired comparisons were performed within each treatment group and changes from baseline were compared between groups. Analyses were considered exploratory.

Results

A total of 56 patients were included: 34 treated with tralokinumab and 22 with lebrikizumab. Baseline age, EASI, SCORAD, IGA, DLQI and pruritus intensity were similar between groups, although baseline BSA was higher in the tralokinumab group.

At weeks 8–12, both treatments were associated with significant clinical improvement. In the tralokinumab group, mean EASI decreased from 24.2 ± 13.5 to 11.3 ± 13.1 ($p<0.001$), while in the lebrikizumab group it decreased from 21.8 ± 1.4 to 4.4 ± 3.6 ($p<0.001$). Pruritus NRS also improved significantly in both groups.

Overall, routine laboratory parameters remained stable during follow-up. No consistent clinically relevant changes were observed in liver enzymes, renal function, lipid profile, leukocyte counts, IgE or LDH. A mild early increase in eosinophil count was observed in the tralokinumab group, although without evidence of a broader hematological safety signal. Isolated statistically significant changes in selected parameters, such as total cholesterol, ALT/GPT or GGT, were small and not consistent over time.

Conclusions

In this real-world cohort of patients with moderate-to-severe atopic dermatitis, treatment with tralokinumab or lebrikizumab was associated with clinical improvement and an overall stable laboratory profile during follow-up. These findings support the favourable analytical safety profile of IL-13 inhibitors in routine practice. Comparative efficacy results should be interpreted cautiously due to the observational design, baseline differences and limited sample size at later visits.

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Abstract N°: 3086

Camoteskimab, a novel anti-IL-18 monoclonal antibody, demonstrates proof-of-concept in atopic dermatitis (AD) in a phase 2a clinical trial

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Introduction

Atopic dermatitis (AD) is a chronic-relapsing inflammatory skin condition. The disease is characterized by pruritus and skin barrier dysfunction, but disease pathogenesis is complex and multifactorial with involvement of Th1, Th2, Th17 and Th22 pathways.

Interleukin-18 (IL-18) is a pleiotropic cytokine with a causative role in the pathophysiology of AD through innate and adaptive inflammatory pathways. This study evaluated the clinical effect of camoteskimab, a novel anti-IL-18 monoclonal antibody, in patients with AD.

Materials and Methods

This phase 2a, multicenter, randomized, double-blind, placebo-controlled trial evaluated the efficacy, safety, and tolerability of camoteskimab in adults with moderate-to-severe AD, followed by an open-label extension.

Eligible participants were adults (≥18 years) with a confirmed diagnosis (≥1 year) of moderate-to-severe AD (EASI ≥12; IGA score ≥3), who were candidates for systemic therapy or for whom topical treatments are otherwise medically inadvisable. Participants were randomized 1:1:1 to receive camoteskimab 300 mg Q4W, a single 300 mg dose, or placebo by IV infusion to Week 16 (Part 1), followed by all arms receiving camoteskimab 300 mg Q8W through Week 32 (Part 2). Participants remained blinded to their assignment in Part 1. Rescue therapy was not allowed in Part 1. Participants with a history of ≤2 prior systemic therapies were eligible.

The primary efficacy endpoint was the percent change from baseline in EASI. Secondary endpoints included EASI-75, IGA 0/1, and Peak Pruritus Numerical Rating Scale (PP-NRS) response, and the assessment of the safety of camoteskimab vs placebo in participants with AD. Analyses were conducted on the mITT and completer (excludes participants using rescue medication) populations.

Results

62 participants were randomised and treated: 18 in the Q4W group, 22 in the single-dose group and 22 in the placebo group. Demographics were generally balanced across subgroups and treatment arms (mean age 46.7 years, 52% female). At baseline, 43 participants (68%) had moderate disease and 19 (32%) had severe disease as assessed using the EASI (< 25 vs ≥ 25). Mean baseline EASI score was 22.2.

At the end of Part 1 (W16), both camoteskimab arms demonstrated significantly greater EASI improvement compared with placebo. LS mean percent change from baseline (excluding rescue) was –61% (95% CI: –79, –42; p

< 0.05) for the Q4W group and –57% (95% CI: –74, –41; p < 0.05) for the single-dose group, compared to –32% (95% CI: –49, –15) for placebo. The improvement in EASI for both camoteskimab arms was observed as early as Week 4. EASI scores continued to improve reaching a mean ~80% reduction in Part 2. EASI75 and IGA0/1 response rates also improved over time with camoteskimab reaching 62-64% and 46-57% respectively in the completer analysis. PP-NRS improvements correlated with patients achieving IGA 0/1 responses. Notably, all six participants with prior inadequate response to anti–IL4/IL13 biologics achieved clinically meaningful improvement in EASI PCFB (-50% to -98%) after treatment with camoteskimab, with 4/6 achieving ≥EASI-87.

Camoteskimab was well tolerated through 32 weeks. In Part 1, TEAE incidence was 39% (Q4W), 50% (single dose) and 59% (Pbo). In Part 2, TEAEs occurred in 32–40% of participants. AEs were mostly mild or moderate. Serious and severe TEAEs occurred infrequently and were not treatment related. There was no safety signal of concern. There were no related AEs leading to discontinuation and no reports of conjunctivitis.

Conclusions

Camoteskimab delivered clinically meaningful and durable efficacy, including in biologics refractory patients, with an infrequent dosing regimen and a leading safety profile. Results support a differentiated mechanism of action offering an orthogonal alternative to Th2-targeted therapies. Further evaluation in a Ph2b dose-ranging trial is ongoing.

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Abstract N°: 3102

Sleep Matters: The Bedtime Impacts of Atopic Dermatitis on Pediatric Patients

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Introduction
Adequate sleep is essential, yet pruritus-driven sleep disturbance is common in children with atopic dermatitis (AD) and is associated with impaired functioning and quality of life for patients and caregivers. Real-world evidence from practitioner and caregiver surveys in pediatric AD remains limited, and although many studies emphasize nighttime sleep disruption, fewer comprehensively characterize the associated daytime functional impacts. This study characterized sleep disturbance and sleep-related impairment in children <12 years using caregiver-reported outcome measures.

Materials and Methods
This analysis used data from the Adelphi Real World Pediatric AD Wave II Disease Specific Programme™ (DSP), an independent cross-sectional survey with retrospective elements, conducted in the United States (May-Dec 2025). The DSP is owned and conducted by Adelphi Real World; Eli Lilly and Company subscribed to the data but was not the sponsor. Physicians were recruited through fieldwork partners and completed online surveys and patient record forms (PRFs) for consecutively consulting patients with provider-confirmed AD. Caregivers completed voluntary self-administered surveys for patients <12 years old. Analyses were descriptive. Sleep outcomes were assessed using the Patient-Reported Outcomes Measurement Information System (PROMIS) Parent Proxy Sleep Disturbance and Sleep-Related Impairment Short Forms, with a 7-day recall period, and AD-impacted sleep numeric rating scales (NRS, 0=no sleep to 10=perfect sleep; last 24 hours and 7 days). Study limitations included cross-sectional design, caregiver reports, and non-probability sampling.

Results
Data are presented for 169 patients aged <12 years (mean age 5.9 [standard deviation (SD) 3.6] years; 53% female) with current moderate-to-severe AD. Mean (SD) time since diagnosis was 2.8 (2.8) years (n=101). Provider-rated AD severity was moderate in 132 (78%) and severe in 37 (22%) patients. Among caregiver-reported data (n=51), the mean (SD) worst itch (24-hour, 0-10 scale) was 5.2 (2.9). Mean (SD) PROMIS Parent Proxy Sleep Disturbance and Sleep-Related Impairment scores were 62.3 (6.9) and 53.7 (9.3), respectively (n=49, 50). Sleep

Disturbance scores were >1 SD worse than population norms (mean 50 [SD 10], indicating greater nighttime sleep problems than the normal population. Over the past 7 days, caregivers (n=51) reported their child had (sometimes; always/almost always) “difficulty falling asleep” (55%; 18%), “a problem with his/her sleep” (51%; 12%), and “trouble sleeping” (45%; 16%). Moderate AD-related sleep impact was reported over the last 24 hours and past 7 days, with mean (SD) NRS scores of 5.1 (2.8) and 5.2 (2.7), respectively. Caregivers also reported daytime impairment (sometimes; always/almost always), including their child “was sleepy during the daytime” (43%; 0%) and “had a hard time concentrating because he/she was sleepy” (22%; 4%).

Conclusions

AD is associated with sleep disturbance and sleep-related impairment, representing a high burden for patients and families. In this critical period, this burden may be underrecognized in routine visits, reflecting an unmet need in pediatric AD. These findings reinforce the importance of clinician–caregiver discussions about sleep as part of pediatric AD management - particularly given the prominence of nighttime sleep disruption.

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Abstract N°: 3104

From neurogenic inflammation to improved well-being: efficacy of a light-textured emollient "plus" in atopic dermatitis

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Introduction

Atopic Dermatitis (AD) is a chronic inflammatory skin disorder characterized by intense pruritus and a significant alteration of well-being. Beyond visible skin lesions, patients experience persistent sensations of discomfort, leading to scratching behavior that further impairs the skin barrier and perpetuates the itch-scratch cycle. Increasing evidence highlights the role of neurogenic inflammation in AD, where activation of cutaneous sensory nerves and release of neuropeptides such as substance P contribute not only to pruritus but also to heightened skin reactivity and reduced skin comfort. While emollients remain the cornerstone of AD management, their ability to address both barrier dysfunction and neurocutaneous components remains a key challenge.

This study aimed to assess the efficacy, tolerability and impact on well-being of a novel light-textured emollient "plus", designed to support the skin barrier while contributing to the reduction of neurocutaneous reactivity and improving skin comfort.

Materials and Methods

The evaluation combined one in vitro study and two open-label, intra-individual clinical studies.

Neuro-soothing potential was assessed in vitro using a neuron–keratinocyte co-culture model of neurogenic inflammation, by quantifying neuronal substance P release.

A first clinical study evaluated tolerability and improvements in clinical signs and functional symptoms in 21 adult subjects with mild to moderate AD (SCORAD 15–30) following 28 days of use. Outcomes included ocular, peri-ocular and cutaneous tolerability, AD severity (SCORAD and clinical scoring), skin barrier function (TEWL), pruritus and skin comfort (patient-reported outcomes), quality of life (DLQI), and cosmetic acceptability.

A second clinical study assessed the cooling effect of the emollient after a single application by measuring skin temperature using infrared thermography in 12 healthy subjects.

Results

Targeting neurogenic inflammation: the emollient significantly reduced neuronal substance P release by 52%, supporting a modulatory effect on neurogenic inflammation involved in pruritus.

Restoring skin barrier and improving clinical signs: after 4 weeks of twice-daily application, significant improvements in AD severity and skin barrier function were observed. SCORAD decreased by 33% ($p<0.001$), while TEWL was reduced by 28%, indicating improved barrier function. Clinical signs were significantly improved, including skin irritation (-42%), erythema (−49%), desquamation (−50%), dryness (−42%) and skin roughness (−40%) (all $p<0.001$).

Relieving pruritus and improving skin comfort: a marked reduction in pruritus was reported (−71%), accompanied by a significant improvement in skin comfort ($p<0.001$), reflecting a reduction in cutaneous discomfort and sensory irritation.

Improving well-being and quality of life: quality of life was significantly improved, with a 51% reduction in DLQI ($p<0.001$), highlighting the positive impact of the product on overall well-being. Cosmetic acceptability was rated as very good, with 90% of subjects reporting an immediate soothing effect.

Providing immediate cooling and soothing effect: instrumental measurements demonstrated a rapid cooling effect, with a mean skin temperature reduction of −2.3°C observed within 3 minutes after application.

Conclusions

This light-textured emollient "plus" demonstrated a reduction of neurogenic inflammation, as shown by decreased substance P release in vitro. These effects were associated with significant improvements in pruritus, skin barrier function and disease severity in atopic dermatitis, contributing to improved skin comfort and overall well-being. Rapid cooling, high cosmetic acceptability and improved skin comfort contributed to overall well-being. The combination of clinical efficacy and light texture may support better adherence in daily use. Overall, these findings highlight the relevance of targeting neurogenic inflammation while optimizing well-being and sensory experience in atopic skin care.

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Abstract N°: 3113

Baseline Disease Burden and High Treatment Persistence at Six Months with Lebrikizumab in Moderate-to-Severe Atopic Dermatitis: A Real-World Analysis from a Canadian Patient Support Program

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Introduction
Lebrikizumab, an interleukin-13 inhibitor approved for moderate-to-severe atopic dermatitis (AD), has shown efficacy in phase 3 trials. However, real-world evidence on the use of lebrikizumab remains limited. This study characterizes baseline demographics and disease severity profiles and examines six-month treatment persistence, including its associations with baseline characteristics, among individuals with AD receiving lebrikizumab in routine clinical practice in Canada.

Materials and Methods
This retrospective, observational study analyzed data from adolescents aged ≥12 to <18 years and ≥40 kg and adults aged ≥18 years with moderate-to-severe AD who consented to participate in the Canadian Ebglyss® Patient Support Program and received at least one dose of lebrikizumab, enrolled between 19 August 2024 and 29 August 2025. The following baseline information was analyzed descriptively for the cohort: 1. demographics, 2. prior use of advanced therapy (AT) (≥1 AD-approved biologic or Janus kinase inhibitor [JAKi]), 3. disease severity assessed using Eczema Area and Severity Index (EASI), Body Surface Area (BSA), Pruritus Numeric Rating Scale (NRS), Investigator's Global Assessment (IGA), and Dermatology Life Quality Index (DLQI) (collected for insurance purposes). Six-month treatment persistence—calculated as the time from the index date to the treatment end date, derived from patient self-reports collected at standardized follow-up timepoints—was estimated using Kaplan–Meier analysis, overall and according to prior AT exposure. Persistence was stratified by AT status (AT-naïve or AT-experienced) based on prior AD-approved AT medication history; patients with missing AT data (n=114) were excluded. Associations between baseline characteristics and treatment persistence were evaluated using a multivariate Cox proportional hazards model, with hazard ratios (HRs), 95% confidence intervals (CIs), and p-values reported; $p<0.05$ was considered statistically significant.

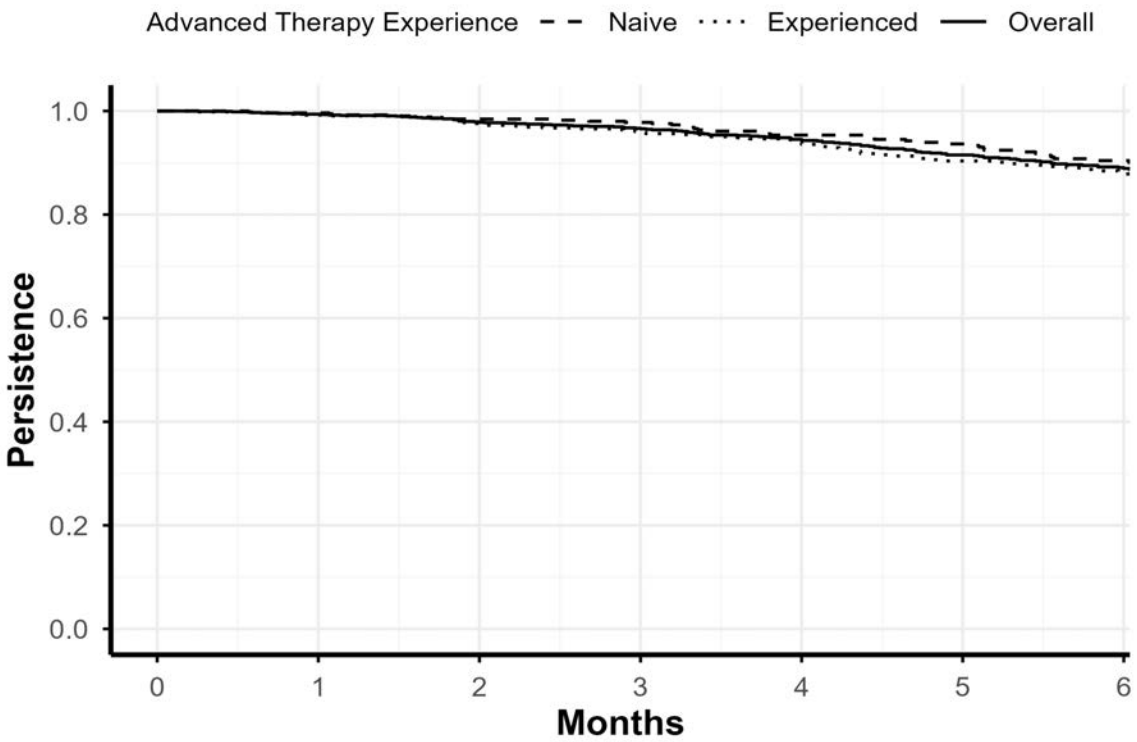
Results
Among 1,358 eligible patients, 93.7% were adults, 50.4% were male, and the mean (SD) age was 43.4 (19.0) years. Among those with available data (n=1,244), 54.4% were AT-experienced (biologics: 86.7%, most commonly

dupilumab [72.8%]; JAKi: 43.4%; categories were not mutually exclusive), and 45.6% were AT-naïve. Among the 54.4% (n=677) AT-experienced patients, the number of prior approved AT use was 1=63.1% (427/677), 2=28.5% (193/677), and ≥3=8.4% (57/677). Baseline disease burden was generally comparable between AT-naïve and AT-experienced patients and was reflective of moderate-to-severe AD (mean [SD]: EASI 22.2 [8.9] vs 20.4 [10.5]; BSA 29.1 [19.7] vs 28.8 [19.9]; pruritus NRS 8.3 [1.8] vs 7.7 [2.0]; IGA 3.5 [0.5]vs 3.4 [0.6]; DLQI 19.8 [5.6] vs 18.3 [6.6]). At baseline, a slightly higher proportion of AT-naïve vs AT-experienced patients had severe disease: EASI >21 (severe to very severe) in 42.1% vs 35.6%; IGA 4 (severe) 49.6% vs 44.4%. Overall six-month treatment persistence was 88.9% (95% CI, 86.9–91.0) and was comparable between AT-naïve (90.4% [87.5–93.5]) and AT-experienced patients (87.9% [84.9–90.9]). No significant associations were observed between treatment persistence and baseline characteristics, including age, gender, prior AT exposure, or disease severity (EASI and IGA categories; all p>0.05).

Conclusions

In this first Canadian real-world analysis of lebrikizumab-treated patients with moderate-to-severe AD, baseline disease burden was similarly high across AT-naïve and AT-experienced patients, with slightly greater severity among AT-naïve patients by EASI and IGA categories. Six-month treatment persistence was high, regardless of prior AT experience. No baseline characteristics were significantly associated with persistence. These findings support the real-world durability of lebrikizumab in routine clinical practice and may help inform clinical management and decision-making in moderate-to-severe AD.

Figure 1: Six-Month Lebrikizumab Treatment Persistence in Patients with Moderate-to-Severe Atopic Dermatitis, Overall and by Prior Advanced Therapy Exposure: Kaplan–Meier Analysis



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Abstract N°: 3139

Real-World Impact of Achieving Optimal Versus Moderate Treatment Targets on Patient Outcomes: Analysis of the PPD CorEvitas Atopic Dermatitis Registry

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Introduction

The Aiming High in Eczema/Atopic Dermatitis consensus recommendations were recently established to define moderate and optimal treatment targets for patients with atopic dermatitis (AD). Previous analyses have suggested that achieving optimal versus moderate treatment targets is associated with better patient outcomes. However, most analyses were conducted in clinical trial populations and data from real-world settings are needed. To confirm if these findings are observed in clinical practice, we examine if similar associations between treatment targets and patient outcomes are observed in the real-world PPD™ CorEvitas™ AD Registry.

Materials and Methods

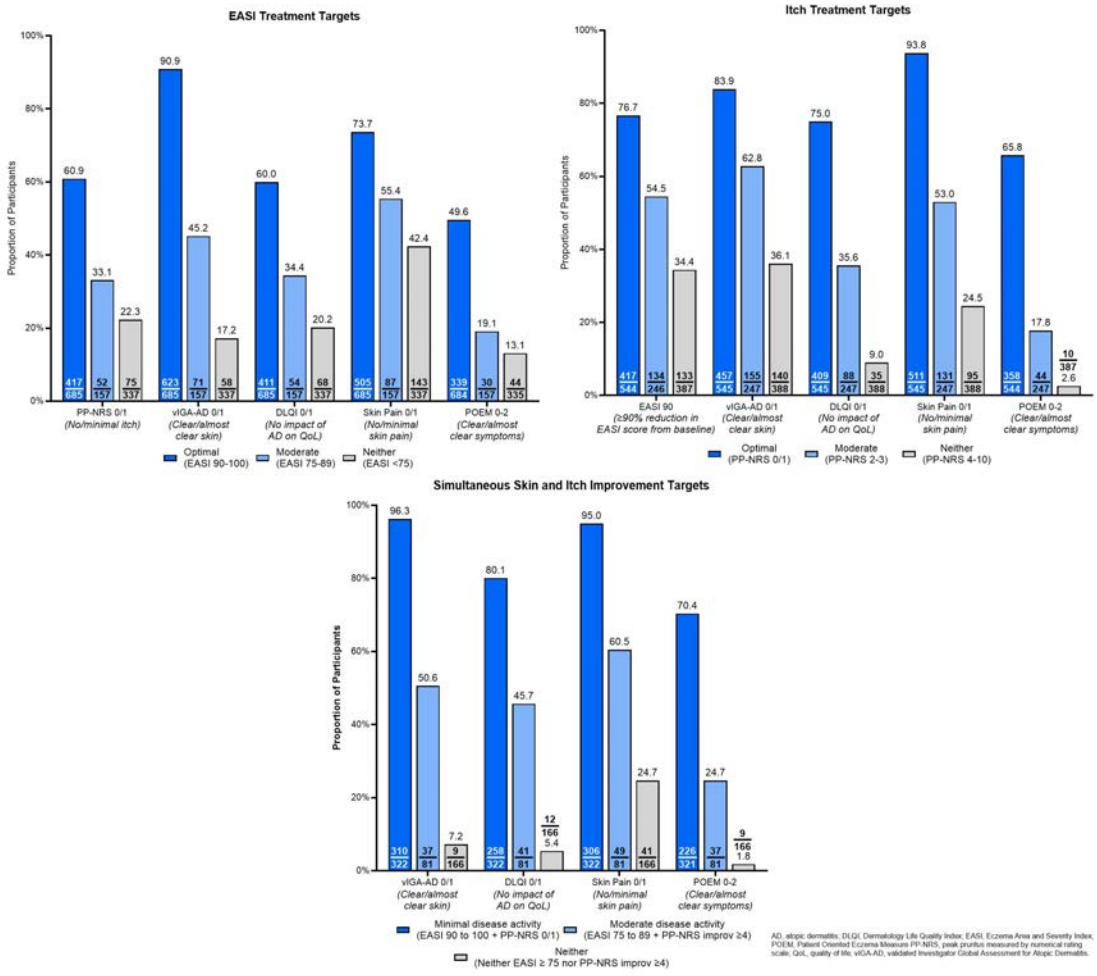
This analysis includes participants from the PPD™ CorEvitas™ AD Registry who initiated an advanced systemic therapy (AST; dupilumab, tralokinumab, lebrikizumab, nemolizumab, abrocitinib, or upadacitinib) and maintained that therapy at their 6-month follow-up visit. Participants were stratified at the 6 month visit by optimal and moderate treatment targets based on Eczema Area and Severity Index (EASI) percent improvement from baseline for skin (EASI 90 to 100; EASI 75 to 89) and Peak Pruritus Numeric Rating Scale (PP-NRS) for itch (PP-NRS 0 to 1 [no/minimal itch]; PP-NRS 2 to 3 [mild itch]). Participants were also stratified by optimal and moderate skin & itch improvement: EASI 90 to 100 & PP-NRS 0 to 1 (minimal disease activity [MDA]) and EASI 75 to 89 & PP-NRS improvement ≥4, respectively. Participants achieving neither the optimal nor the moderate targets were also described. The proportion of participants reporting outcomes corresponding to no/minimal disease burden at the 6 month visit were described: validated Investigator Global Assessment for AD 0/1 (clear or almost clear skin), Dermatology Life Quality Index 0/1 (no impact of AD on quality of life), Skin Pain Numeric Rating Scale 0/1 (no/minimal skin pain), and Patient Oriented Eczema Measure 0 to 2 (clear or almost clear patient-reported eczema). Outcomes for each stratum are reported as observed with no imputation. Safety was not assessed in this analysis.

Results

A total of 1182 participants were included in this analysis. Participants reporting outcomes corresponding to no/minimal disease burden was highest in those participants reporting optimal treatment targets, with response

rates 1.3 to 3.7 times those of participants reporting moderate treatment targets **(Figure 1)**. Response rates ranged from 50% to 91% for participants achieving EASI 90 to 100 compared to 19% to 55% for those reporting EASI 75 to 89. Similarly, response rates were higher for participants with no/minimal itch (range: 66% to 94%) versus mild itch (range: 18% to 63%). When considering simultaneous skin & itch improvement, response rates were 70% to 96% for those who reported MDA (EASI 90 to 100 & PP-NRS 0 to 1) compared to 25% to 61% for those who reported the moderate target (EASI 75 to 89 & PP-NRS improvement ≥4).

Figure 1. Achievement of Outcomes by Treatment Targets



Conclusions

These real-world findings suggest that meeting optimal, rather than moderate, skin and itch treatment targets is associated with meaningfully better patient outcomes at 6 months in AD.

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Abstract N°: 3156

Evaluating the Quality of Eczema Documentation in Outpatient Letters Against NICE QS44 Standards

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Introduction

Atopic dermatitis (eczema) is a chronic inflammatory skin condition affecting both children and adults. It is characterized by dry, itchy, and inflamed skin, significantly impacting quality of life. The National Institute for Health and Care Excellence (NICE) Quality Standard QS44 outlines key recommendations for the assessment, management, and long-term care of individuals with eczema (NICE, 2013). However, effective management requires clear, structured, and comprehensive documentation in outpatient clinic letters to the patient's general practitioner, to ensure continuity of care and adherence to evidence-based guidelines.

The NICE Quality Standard QS44 outlines evidence-based recommendations for the assessment and management of childhood eczema, including comprehensive assessment, stepped management, psychological wellbeing, and provision of emollients and written information. Previous studies highlight inconsistencies in clinical documentation for eczema, which may lead to suboptimal management and fragmented care (Langan et al., 2020). High-quality documentation is essential for effective communication between healthcare professionals, patient education, and treatment adherence (NICE, 2022).

This audit will assess whether outpatient letters meet NICE QS44 standards and identify areas for improvement. Findings will inform strategies to enhance documentation quality, ensuring best-practice care for eczema patients.

Materials and Methods

A retrospective audit of 34 paediatric dermatology clinic letters was conducted over a three-month period (November 2024–January 2025). Letters were assessed against NICE QS44 standards, including documentation of diagnostic assessment (age of onset, triggers, family history, previous treatments and treatment efficacy), disease severity assessment, psychological impact, provision of written information, and emollient recommendations.

Results

Documentation quality varied considerably across domains. Age of eczema onset was documented in 26.5% (9/34) of letters, while potential triggers and family history of atopy were recorded in only 5.9% (2/34) each. Previous treatments were documented in 32.4% (11/34), although treatment efficacy was recorded in 54.5% (6/11) of these cases. Disease severity assessment was documented in 50.0% (17/34), and affected body areas were described in 76.5% (26/34). Psychological impact and quality of life considerations were not documented in any clinic letter (0/34). Written eczema management information was not provided to caregivers in any case (0/34). Regarding emollient management, bath/shower emollients and soap substitutes were recommended in 55.9% (19/34) of patients, while appropriate emollient prescription dosage guidance to general practitioners was absent in all letters (0/34). Follow-up arrangements were documented in 88.2% (30/34) of clinic letters.

Conclusions

This audit identified substantial variability and significant gaps in compliance with NICE QS44 standards in

paediatric eczema clinic documentation, particularly in psychosocial assessment, caregiver education, and emollient prescribing guidance. We propose a multi-faceted intervention; firstly, the introduction of a standardised eczema clinic letter template incorporating NICE QS44 prompts (**Figure 1**). Secondly, the routine use of the Children's Dermatology Life Quality Index (cDLQI) and provision of pre-prepared written educational materials. Thirdly, structured documentation of emollient prescribing included in the templace. These interventions may improve consistency, documentation quality, and adherence to evidence-based eczema care with improved communication with the general practitioner.

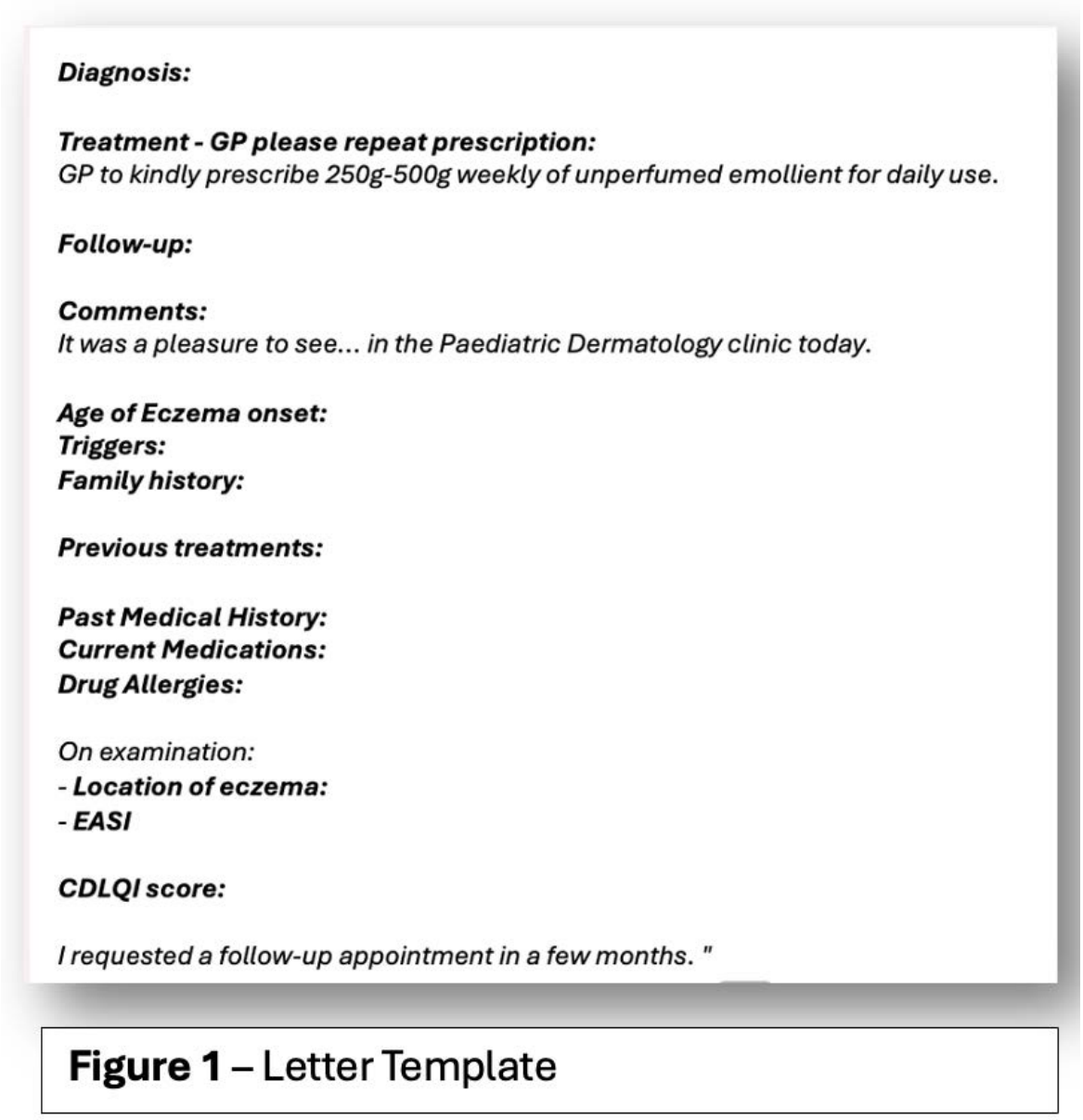

Figure 1 - Letter Template for Eczema Letter Standardisation.

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Abstract N°: 3159

Impact of Lebrikizumab on Dermatology-Related Emergency Department Visits in Patients with Moderate-to-Severe Atopic Dermatitis: A Real-World Study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with intense pruritus, sleep disturbance, impaired quality of life, and frequent healthcare utilization. Patients with uncontrolled moderate-to-severe AD may require repeated emergency department (ED) visits due to severe flares, secondary infections, or uncontrolled symptoms. Lebrikizumab, a selective interleukin-13 inhibitor, has demonstrated significant efficacy in clinical trials; however, real-world data regarding its impact on urgent healthcare resource utilization remain limited. The aim of this study is to evaluate whether initiation of lebrikizumab reduces the number of dermatology-related ED visits in patients with AD in routine clinical practice.

Materials and Methods

A retrospective real-world study was designed including initially 25 patients with moderate-to-severe AD treated with lebrikizumab at a tertiary dermatology center. Dermatology-related ED visits occurring in the months before and after treatment initiation will be recorded and compared. Clinical severity and patient-reported outcomes, including Eczema Area and Severity Index (EASI), Body Surface Area (BSA), Investigator Global Assessment (IGA), Numeric Rating Scale for itch (NRS itch), and sleep disturbance (NRS sleep), will be collected at baseline and follow-up visits. Descriptive and comparative analyses will be performed to evaluate changes in clinical outcomes and ED utilization following treatment initiation.

Results

Preliminary data suggest a reduction in dermatology-related ED visits after initiation of lebrikizumab, accompanied by improvement in disease severity and patient-reported symptoms. Final quantitative analyses, including detailed clinical outcome measures and comparative results between pre- and post-treatment periods, will be completed as patient follow-up progresses and will be presented in the final poster.

Conclusions

This real-world study aims to explore the potential impact of lebrikizumab not only on clinical severity of AD but also on urgent healthcare utilization. Reduction in ED visits may reflect improved disease control and decreased healthcare burden in patients with moderate-to-severe AD treated with targeted biologic therapy.

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Abstract N°: 3169

Discordance Between Low Body Surface Area Involvement and High Itch Burden Among EczemaWise Users

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Introduction
EczemaWise is a mobile health tracking app designed for individuals with eczema and caregivers to record symptoms, body surface area (BSA) involvement, and patient-reported disease burden over time. Although BSA is commonly used to quantify the extent of eczema, symptom burden, particularly itch, may remain substantial even when BSA involvement is low. This analysis evaluated the prevalence of low BSA with concurrent high itch among EczemaWise users.

Materials and Methods
We conducted a descriptive analysis of EczemaWise users with self- or caregiver-reported eczema tracking data. The user-level sample included 1,599 individuals with at least 5 paired BSA and itch tracking events in the app. BSA was reported as the percentage of body surface area affected by eczema, and itch was reported using a 0 to 10 Numeric Rating Scale (NRS). Low BSA/high itch events were defined as observations with low BSA involvement (<10%) and high itch (NRS ≥5). We summarized user demographics and the proportion of users experiencing at least one or recurrent low BSA/high itch events.

Results
Among the 1,599 users with ≥5 paired BSA/NRS events, 86.9% were individuals self-reporting their own eczema, 12.3% were caregivers reporting for a child, and 0.8% were caregivers reporting for another individual.Longitudinal tracking showed substantial variation in both affected BSA and itch burden over time. Most users recorded at least one event with BSA involvement >10% (83.0%), while 63.1% recorded at least one event with BSA involvement ≤10%. Similarly, 91.7% recorded at least one event with itch NRS <5, while 87.7% recorded at least one event with itch NRS ≥5. Overall, 39.8% of users experienced at least one discordant event characterized by low BSA involvement (≤10%) and high itch (NRS ≥5), and 18.0%, corresponding to 288 users, experienced at least three such events. The mean patient age was 35.8 years among self-reporting users and 7.9 years among caregiver-reported users. The mean PO-SCORAD score was 32.4, consistent with moderate eczema severity. Most users were female (76.9%) and resided in metropolitan areas (88.6%). Among users reporting race, 62.8% identified as White, 17.0% as Asian, 5.1% as Black, and 6.5% as more than one race; 11.8% reported Hispanic ethnicity. Users with at least one low BSA/high itch event were significantly older than users without such an event, with mean ages of 34.8 and 30.7 years, respectively ($p < 0.001$). They also had a higher proportion of female users (86.8% vs. 75.8%; $p < 0.001$), a lower proportion of Hispanic users (9.6% vs. 13.2%; $p = 0.034$), and slightly lower mean PO-SCORAD scores (31.0 vs. 33.2; $p = 0.006$). Race distribution also differed significantly between groups ($p = 0.007$), with a higher proportion of White users among those with at least one low BSA/high itch event (67.0% vs. 60.0%).

Conclusions
In this real-world mobile health tracking sample, a meaningful subset of EczemaWise users reported high itch despite low BSA involvement. These findings highlight discordance between eczema extent and symptom burden and suggest that low BSA does not necessarily indicate low disease impact. Clinical and patient-reported assessments should include itch evaluation even when visible or reported affected surface area is limited.

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Abstract N°: 3179

Adult-Onset Atopic Dermatitis Mimicking Deficiency-Related Dermatosis Following Whipple Procedure

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Introduction

Adult-onset atopic dermatitis is an increasingly recognized clinical entity that may present with atypical morphology and distribution compared to childhood disease, often creating diagnostic challenges. In adults, eczematous eruptions must be differentiated from a broad spectrum of inflammatory, infectious, and nutritional dermatoses. Patients with severe malnutrition or malabsorption may develop deficiency-related skin manifestations that clinically mimic eczema, including erythematous-squamous plaques, fissures, erosions, and pruritus.

Following Whipple procedure (pancreaticoduodenectomy), patients are at risk of exocrine pancreatic insufficiency, malabsorption, and multiple nutritional deficiencies, particularly involving zinc, niacin, essential fatty acids, and proteins. These deficiencies can lead to complex dermatologic manifestations that overlap with inflammatory dermatoses such as atopic dermatitis. Distinguishing between primary inflammatory eczema and secondary nutritional dermatoses is essential, as management and prognosis differ significantly.

Case Presentation

We present the case of a 44-year-old woman with a history of Whipple resection performed in July 2025 with significant history of severe exocrine pancreatic insufficiency and severe protein-calorie malnutrition. She was admitted for evaluation of a generalized, intensely pruritic skin eruption with a fluctuating course. The lesions appeared in recurrent self-limited episodes lasting approximately two weeks and alternated with periods of complete remission. The patient also reported an involuntary weight loss of approximately 10 kilograms during the previous six months, despite preservation of appetite.Dermatological examination revealed a generalized eruption consisting of erythematous-squamous plaques, some of them exudative, associated with painful fissures involving the palms, soles, and popliteal fossae. Several lesions showed secondary hyperpigmentation and intense pruritus. Multiple round-to-oval ulcerations with fibrinous deposits were also identified on the gluteal region and lower legs.

Given the clinical appearance and the patient’s nutritional status, several differential diagnoses were considered, including acrodermatitis enteropathica secondary to zinc deficiency, pellagra associated with niacin deficiency, necrolytic migratory erythema, and severe atopic dermatitis. The association between chronic pancreatic disease, malnutrition, and cutaneous manifestations raised the suspicion of a deficiency-related dermatosis.A skin biopsy was performed and the histopathological examination revealed features consistent with eczema. Laboratory testing showed elevated serum IgE levels, leading to the diagnosis of atopic dermatitis. The patient was treated with topical corticosteroids and intensive emollient therapy, leading to significant clinical improvement of the cutaneous lesions and pruritus.Further review of the histopathological examination and immunohistochemical studies from the previously resected duodenopancreatectomy specimen supported the diagnosis of type I

autoimmune chronic pancreatitis associated with IgG4-related disease.

In this context, genetic testing for cystic fibrosis transmembrane conductance regulator (CFTR) mutations was recommended in order to exclude underlying cystic fibrosis presenting in adulthood.

Conclusion

The case highlights the importance of a multidisciplinary approach involving dermatology, gastroenterology, pathology, and nutrition specialists. Although, in this case, the initial diagnoses considered were dermatoses associated with complications from the large surgical procedure, we must always keep in mind a broader range of differential diagnoses.The unique aspect of this case lies in the adult-onset of atopic dermatitis following Whipple resection in a patient without prior history of atopy and the association between IgG4-related pancreatitis and atopic dermatitis.

EADV CONGRESS
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Abstract N°: 3191

Efficacy and Safety of Crisaborole 2% Ointment in mild to moderate Atopic Dermatitis

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Introduction
Atopic dermatitis is a common chronic inflammatory skin disorder affecting up to 20% of children and approximately 3% of adults, with most cases being mild to moderate in severity. Long term topical therapeutic options remain limited. Crisaborole 2% ointment is a non steroidal phosphodiesterase 4 (PDE 4) inhibitor with anti inflammatory properties. This study aimed to evaluate the efficacy and safety of Crisaborole 2% ointment in patients with mild to moderate atopic dermatitis.

Materials and Methods
This prospective clinical trial was conducted at the Department of Dermatology and Venereology in a tertiary hospital, Dhaka, Bangladesh; over a 12 month period following ethical approval. A total of 226 patients with mild to moderate atopic dermatitis were enrolled and randomly assigned to receive either Crisaborole 2% ointment or placebo. Follow up assessments were performed at weeks 4, 8 and 12. Twenty patients were lost to follow up; therefore , 206 patients (103 in each group) were included in the per protocol analysis. Data were analyzed using SPSS version 26.

Results
Baseline demographic and clinical characteristics were comparable between the two groups ($p>0.05$). The mean Investigators Static Global Assessment (ISGA) score significantly decreased in the Crisaborole group from baseline to week 12 (2.32 vs 0.89; $p<0.001$). At week 12, a significantly higher proportion of patients achieved clinical improvement in the Crisaborole group compared with the placebo group (63.1% vs 44.7%; $p=0.008$). Both groups demonstrated a low incidence of adverse effects, which was slightly higher in the Crisaborole group (10.7% vs 5.8%).

Conclusions
Crisaborole 2% ointment is an effective and well tolerated treatment option for mild to moderate atopic dermatitis, with minimal adverse effects.

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Abstract N°: 3204

Association between atopic dermatitis treatment intensity and asthma control in patients with atopic dermatitis and concomitant asthma: a cross-sectional questionnaire-based study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by eczematous lesions and pruritus. AD often coexist with asthma, reflecting shared immunologic mechanisms, that is type 2 inflammation.

The therapeutic options for AD have evolved substantially with the introduction of systemic immunomodulatory and biologic therapies. These treatments modulate key inflammatory pathways implicated in both AD and asthma and may, therefore, potentially influence asthma outcomes. However, studies on the association between AD treatment intensity and asthma control is limited.

The aim of the study was to investigate the association between AD treatment intensity and asthma control in patients with AD and concomitant asthma.

Materials and Methods

This cross-sectional study was conducted in May 2020. An online questionnaire was sent to adults (≥18 years) with a hospital-verified diagnosis of AD (International classification of diseases, 10th edition (ICD-10) code L20.x) registered in the Danish National Patient Register between January 1st, 2000, and December 31st, 2019. Eligibility for inclusion in this study required a self-reported asthma diagnosis.

The primary outcome was asthma control assessed by the Asthma Control Questionnaire (ACQ-5), where the minimal clinically important difference (MCID) is 0.5. Linear region models were performed to assess the association between AD treatment groups (topicals, UV therapy, conventional systemic treatment, biologics (dupilumab) or no AD treatment ever) and ACQ-5 scores. Multivariable analyses adjusted for potential confounders, including AD severity (patient-oriented eczema measure (POEM), patient-oriented scoring atopic dermatitis (PO-SCORAD)), sociodemographic (age, sex, body mass index (BMI)), lifestyle factors (smoking, alcohol, and physical activity), and clinical characteristics (age of disease onset, family history and allergic rhinitis). Results were reported as regression coefficient (β) with 95% confidence intervals (CI) and p-values <0.05 were considered statistically significant.

Results

A total of 16,718 patients with AD were invited and 7,044 (42.1%) patients completed the questionnaire. Of these,

2,742 (44.3%) reported physician-diagnosed asthma and were, therefore, included in the study. Regarding AD treatment intensity, 649 (25.6%) had received topical treatment only, 259 (10.2%) had received UV therapy, 1,476 (58.1%) had received conventional systemic treatment and 155 (6.1%) had received treatment with biologics. Childhood onset of AD was reported by 92.6% of participants, while 77.6% reported childhood onset of asthma. Family disposition to AD and asthma was reported in 49.9% and 50.0% of participants, respectively.

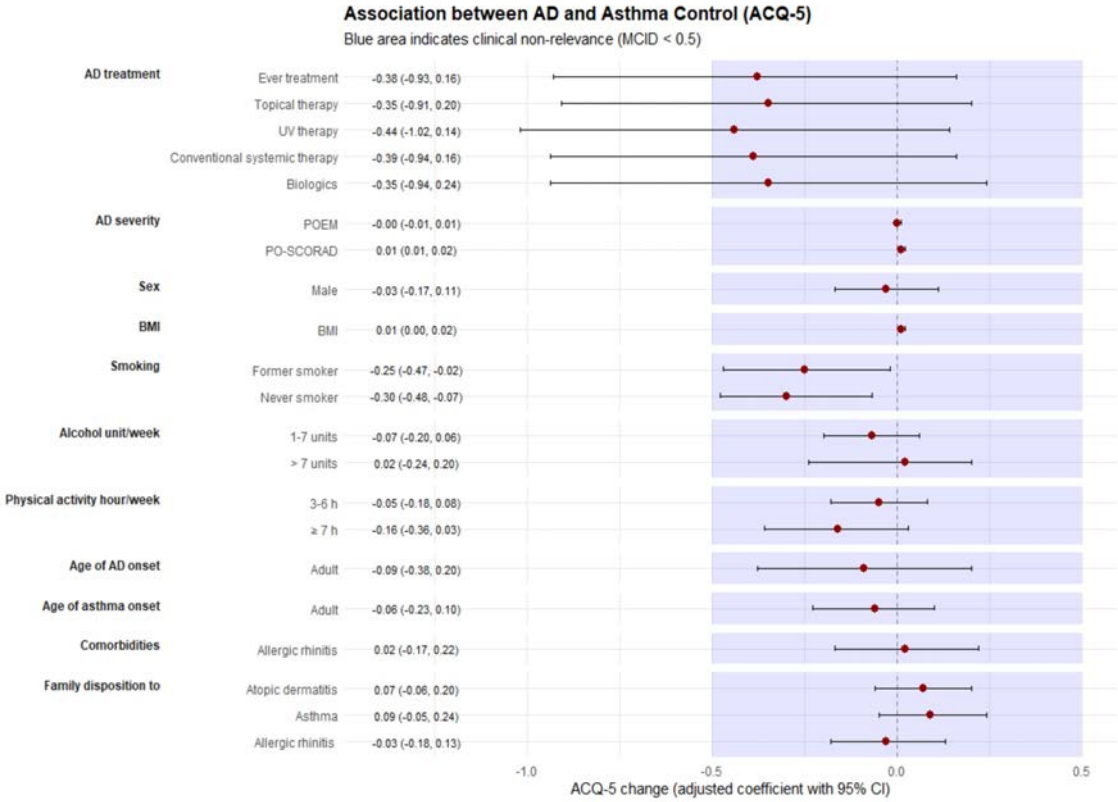
In the unadjusted analysis, ever treatment for AD was associated with lower ACQ-5 scores compared to no treatment ever (β = -0,32; 95% CI -0.57 to -0.06; p=0.017). Within AD treatment groups, topical treatment, UV therapy and conventional systemics were all significantly associated with lower ACQ-5 scores. After adjusting for potential confounders, the associations were no longer statistically significant.

AD disease activity measured by PO-SCORAD, remained an independent predictor of asthma control, even after adjusting for confounders (β = 0.01, 95% CI 0.01 to 0.02, p <0.001) (Figure 1). Smoking and higher BMI were both significantly associated with higher ACQ-5 scores.

Conclusions

PO-SCORAD was independently associated with poorer asthma symptom control, however the effect sizes were below clinically significance. This suggests that although a statistically significant skin-lung axis exists, other factors, most notably smoking, exert a more substantial clinical impact on asthma symptoms.

Figure 1: Association between atopic dermatitis and asthma control



Reference groups: No treatment ever, female, current smoker, 0 unit/week alcohol, 0-2 hour/week activity, childhood onset, no rhinitis and no family disposition.

Abbreviations: ACQ-5: Asthma control questionnaire, AD: Atopic dermatitis, BMI: Body mass index, POEM: Patient-oriented eczema measure, PO-SCORAD: Patient-oriented scoring atopic dermatitis

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Abstract N°: 3205

Safety and Efficacy of Oral Roflumilast for Chronic Hand Eczema (HERO): A Double-Blind Randomized Controlled Trial

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Introduction

Chronic hand eczema (CHE) is a disabling inflammatory skin disease with limited treatment options. Topical roflumilast is FDA-approved for atopic dermatitis and psoriasis, and oral roflumilast has shown efficacy in psoriasis, supporting exploration of oral phosphodiesterase-4 inhibition in CHE. This study assessed efficacy and safety of oral roflumilast versus placebo in adults with moderate-to-severe CHE.

Materials and Methods

This was a company-independent multicenter, double-blinded, randomized, placebo-controlled, phase II trial with open-label extension. Patients with untreated, moderate-to-severe CHE were randomized 1:1 to oral roflumilast 500 µg once daily or placebo for 16 weeks, with open-label roflumilast from week 16 to 28. Throughout the study period, patients were allowed to use moisturizing agents. Primary endpoint was ≥75% reduction in hand eczema severity index (HECSI75) at week 16. Key secondary outcomes included HECSI50/90/100 at week 28. Safety and tolerability were monitored throughout the study period.

Results

A total of 41 adult patients with CHE were randomized (roflumilast, n=19; placebo, n=22). Patient characteristics were well-balanced. At baseline, the roflumilast group had a median HECSI score of 40.0 (interquartile range: 30.5, 49.0), compared with 56.5 (34.0, 57.8) in the placebo group. By week 16, the median HECSI score in the roflumilast group had decreased to 9.5 (6.2, 46.8), corresponding to a 76.3% HECSI score reduction from baseline. In contrast, the placebo group decreased to a median HECSI score of 42.0 (IQR 21.0, 70.0), representing a 25.7% reduction (p=0.30). At week 16, HECSI75 was achieved by 26.3% (n=5/19) treated with roflumilast and 18.2% (n=4/22) treated with placebo (p=0.71). At week 28, 42.1%, 5.3%, and 0.0% treated with roflumilast achieved HECSI50, HECSI90, and HECSI100 versus 45.5%, 18.2%, and 9.1% treated with placebo, respectively; none showed an advantage for roflumilast (all nominal p-values >0.05). Adverse events were consistent with the established safety profile of roflumilast, with transient gastrointestinal symptoms and headache reported more frequently in the roflumilast group. No treatment-related serious adverse events occurred during the trial. However, there was an unexpected pregnancy in the placebo arm.

Conclusions

In this phase 2 trial, CHE improved over 28 weeks in both the oral roflumilast and placebo groups, with no statistically significant difference between treatments. Roflumilast was generally well-tolerated.

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Abstract N°: 3211

Lebrikizumab Safety in Pediatric Patients with Moderate-to-Severe Atopic Dermatitis: Results from the Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study ADorable-1 through Week 16.

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Introduction

Pediatric atopic dermatitis (AD) remains a substantial societal burden with a need for safe, well-tolerated therapies. We evaluate the safety of lebrikizumab (LEB) in pediatric populations from the ADorable-1 study.

Materials and Methods

ADorable-1, a double-blind, randomized, placebo-controlled, Phase 3 study, assesses efficacy and safety of LEB plus low-to-mid potency TCS vs PBO plus low-to-mid potency TCS in participants aged 6 months to <18 years with moderate-to-severe AD. Participants were randomised 2:1 to LEB or PBO for 16 weeks and stratified by age upon enrolment (6months–<18 years), by disease severity, indicated by an IGA score of 3 vs 4, as well as by geographical region (USA/EU/Other). Dosing was based on participants weight summarised as: ≥40kg, 500mg at W0 and W2, then 250mg Q2W from W4-16; 15–<40kg, 250mg at W0, then 250mg Q4W from W2-16; 6–<15kg, 125mg at W0, then 125mg Q4W from W2-16. Participants aged 12–<18 years, weighing ≥40kgs were excluded from the study. Descriptive statistics were used for the analysis of safety data.

Results

The mean age of participants was 7.7 years (Cohort 1 (6<18 years) 9.06 years (2.25 SD); Cohort 2 (6 months <

6years; ≥6kg) 3.29 years (1.54 SD)); 49.6% were female; 75.1% had a baseline IGA of 3. Participants were enrolled globally (US 16.5%, Europe 18.7%, rest of world 64.7%). 26.2%, 6.3% and 59.2% were Asian, Black or African American and White, respectively. In the LEB and PBO groups, respectively, prior asthma, allergic rhinitis, and food allergy were reported by 25.3% vs 28.0%, 37.1% vs 49.2%, and 31.4% vs 35.6%. No notable trends or clinically important differences in vital signs and growth across the treatment groups were observed.

There were no reported AEs leading to treatment discontinuation and 1.2% vs 2.5% reported serious AEs in the LEB and PBO groups, respectively. Most AEs were mild (37.1% vs 29.7%), moderate (18.8% vs 27.1%) or severe (1.2% vs 2.5%) in severity, between LEB and PBO, respectively. The most common treatment-emergent adverse events (TEAEs) were upper respiratory tract infections (9.4% vs 7.6%) and nasopharyngitis (7.8% vs 8.5%), respectively. AEs of special interest (AESIs) included the known ADR conjunctivitis (cluster; 7.3% vs 5.1%) and herpes infection (oral herpes and eczema herpeticum; 0.4% vs 0.8%), with no events of herpes zoster or parasitic infection were reported.

One participant reported a TEAE of eosinophilia*. No eosinophilic-related disorders or confirmed opportunistic infections were noted between groups. Mild events of injection site reactions were reported by 2.0% vs 2.5% of participants respectively, with no injection site pain reported.

Conclusions

Safety findings through Week 16 in this pediatric population are consistent with the established LEB profile in adults, adolescents ≥40 kg and in children as young as 6 months of age with moderate-to-severe AD. Safety characterization in the youngest cohort (<2 years) will be strengthened as enrolment completes.

Table 1. Summary of adverse events, treatment-emergent adverse events of special interest, and other events of special interest.

	LEB + TCS N=245	PBO + TCS N=118
TEAE	140 (57.1%)	70 (59.3%)
TEAE by severity**		
Mild	91 (37.1%)	35 (29.7%)
Moderate	46 (18.8%)	32 (27.1%)
Severe	3 (1.2%)	3 (2.5%)
Death	0	0
Serious adverse event	3 (1.2%)	3 (2.5%)
TEAE related to study treatment	32 (13.1%)	9 (7.6%)
Discontinuation from study treatment due to adverse event (including death)	0	0
Infections	96 (39.2%)	50 (42.4%)
Herpes infections (oral herpes and eczema herpeticum)	1 (0.4%)	1 (0.8%)
Parasitic infections	0	0
Skin infections	6 (2.4%)	10 (8.5%)
Conjunctivitis cluster	18 (7.3%)	6 (5.1%)
Keratitis cluster	0	0
Hypersensitivity (narrow term/algorithm search)		
Potential immediate events (events occurred on the day of injection)	2 (0.8%)	1 (0.8%)
Potential non-immediate events (events occurred after the day of injection)	18 (7.3%)	16 (13.6%)
Injection-site reactions	5 (2.0%)	3 (2.5%)
Injection-site pain	0	0
Malignancies	0	0
Atopic dermatitis exacerbation	3 (1.2%)	6 (5.1%)
Suicide/self-injury	0	0

Note: Broad classification encompasses preferred terms within the narrow classification. Infections are defined using the MedDRA preferred terms from the infection and infestations system organ class. The overall safety population is composed of all randomized participants from Cohorts 1 and 2 who received ≥1 dose of study treatment and who either complete or have an opportunity to complete treatment through Week 16. A TEAE is defined as an event that first occurred or worsened in severity after baseline and on or prior to the date of the last visit within the specified treatment period. All data are n (%). The study is still ongoing, enrolling participants <2 years old. *ADorable-1 is an ongoing trial; study grouping and percentages were removed to prevent unblinding when there is a single event reported. There was one reported occurrence of Eosinophilia. Eosinophil-related AEs are defined using specific MedDRA preferred terms specified in the PSAP. **Patients with multiple occurrences of the same event are counted under the highest severity. Abbreviations: LEB, lebrikizumab; PBO, placebo; TCS, topical corticosteroid; N, number of patients in the analysis population; n, number of patients in the specified category; TEAE, Treatment-Emergent Adverse Event; MedDRA, Medical Dictionary for Regulatory Activities.

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Abstract N°: 3213

Evaluation of a novel emollient plus providing protection against allergens and pollution, and relieving pruritus in atopic dermatitis

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Introduction

Atopic dermatitis (AD) affects millions of patients worldwide and significantly impairs quality of life. AD is characterized by skin barrier dysfunction, leading to the release of keratinocyte- and mast cell–derived alarmins, including thymic stromal lymphopoietin (TSLP), which directly both activates sensory neurons involved in pruritus and promotes type 2 inflammation.

Barrier disruption enhances the penetration of allergens, pathogens, and irritants and contributes to exaggerated immune responses. Moreover, AD patients frequently exhibit IgE reactivity to environmental allergens, microbes, or food proteins, which can trigger or worsen disease flares, sustaining a pathogenic cycle of chronic inflammation and skin discomfort.

Therefore, this study evaluated the protective effect against allergens and pollution of a balm emollient plus (AD balm) formulated with a biomimetic lipid phase, the ability of an incorporated active ingredient to modulate TSLP production, and the AD balm clinical efficacy in reducing pruritus.

Materials and Methods

The effect of the active ingredient on TSLP production was evaluated using an atopic-like in vitro model of human primary keratinocytes stimulated with IL-4, TNF-α and poly(I:C). TSLP secretion was quantified by ELISA. Dexamethasone served as a positive control.

The physical protective effect of the AD balm against allergens was assessed using four different allergens—house dust mite (Der p1), cat (Fel d1), mold (Alt a1) and peanut (Ara h2)—labelled with a fluorophore. Human shaved scalp explants were topically pre-treated with the AD balm before allergen application. Allergen skin penetration was evaluated in follicular infundibulum areas by image analysis.

Protection against pollution was evaluated on the forearms of 10 healthy subjects. Water or the AD balm was applied, followed by exposure to 1 µm carbon particles. After washing, residual particles were quantified by colorimetric analysis (L*).

Open-label clinical efficacy study of the AD balm on pruritus was evaluated in 30 adults with chronic or chronically relapsing atopic dermatitis and significant itching (Numerical Rating Scale [NRS] ≥4/10). After a 3-day washout period, the balm was applied to the forearm. Pruritus soothing was assessed immediately (1 second) by satisfaction, and after 1 minute and 1 hour using the NRS. Soothing efficacy was also self-assessed after 10 hours

and after 7 days of twice-daily application to the face and body using a questionnaire.

Results

The active ingredient significantly inhibited TSLP secretion by human keratinocytes (−73%) compared with the atopic-like control, with an efficacy comparable to dexamethasone.

On scalp explants, the AD balm provided a significant physical barrier against allergens, reducing cutaneous accumulation by −71% for house dust mite, −92% for cat, −81% for mold and −85% for peanut allergens. On healthy subjects, protection against pollution was also observed, with a 80% reduction in residual carbon particles versus water.

On atopic subjects, the AD balm demonstrated pruritus soothing from 1 second, reported by 100% of subjects. Itch intensity was significantly reduced by 55% after 1 minute and 82% after 1 hour. The effect persisted throughout the day, with 96% of subjects still reporting pruritus relief after 10 hours. After 7 days of twice-daily use, more than 95% of subjects reported relief discomfort.

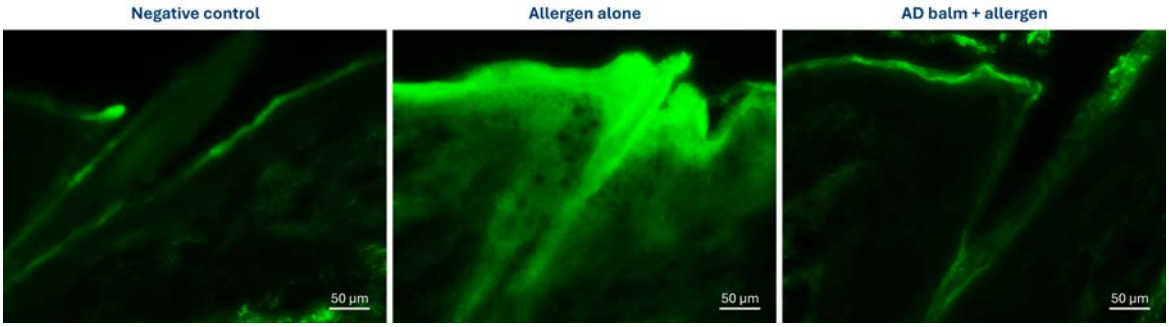

Figure 1. Pictures of human scalp explants (sections) showing the repartition of fluorescence in the epidermis and the hair follicle after the application of fluorescent Der p1 on untreated skin (allergen alone) and after application and removal of AD balm (AD balm + allergen). Negative control shows the autofluorescence of the skin.

Conclusions

This novel AD emollient balm provides rapid and long-lasting relief of pruritus and skin discomfort in patients with atopic dermatitis. These clinical benefits may be partly explained by the inhibition of keratinocyte-derived TSLP by the active ingredient, and by the biomimetic lipid-replenishing phase. By forming a physical barrier that limits allergen and pollution penetration, the balm may contribute to sustained skin protection and help reduce the risk of flare-ups. Overall, this AD balm represents an effective supportive care to improve skin comfort and quality of life in patients with atopic dermatitis.

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Abstract N°: 3216

A novel emollient plus significantly improves skin condition and pruritus in contact dermatitis

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Introduction

Contact dermatitis is a frequent inflammatory dermatosis characterized by erythematous, pruritic lesions occurring after exposure to an exogenous agent. Two main entities are distinguished: irritant contact dermatitis, driven by direct non-immunological cutaneous inflammation, and allergic contact dermatitis, a T cell-mediated delayed hypersensitivity reaction that occurs upon re-exposure. Clinical features include erythema, scaling and pruritus; acute cases may present with vesicles/bullae, whereas chronic disease may lead to lichenification and fissuring.

This study aimed to evaluate the tolerance and effectiveness of a balm emollient plus (containing active ingredients) on discomfort (including pruritus) and overall skin condition in adults with contact dermatitis.

Materials and Methods

This single-centre, open-label clinical study conducted under dermatological supervision included 32 adults (19-65 years old) with allergic (n=15) or irritant (n=17) contact dermatitis. Participants had Fitzpatrick phototypes III-V and diverse ethnic backgrounds (Caucasian 13%, Asian 3%, Indian 25%, African 44%, mixed 16%). In half of the participants, disease onset was >6 months before inclusion. Participants with allergic contact dermatitis had used topical corticosteroids prior to inclusion but remained symptomatic, supporting study eligibility.

At visit 1 (D0), participants refrained from applying skincare products other than routine hygiene. After acclimatization, a dermatologist evaluated affected areas (face and/or body), scoring clinical signs (xerosis and roughness; 0-9 scale) and disease extent (palm units). Participants self-assessed functional symptoms (discomfort, pruritus, intensity of urge to scratch, and impact on daily activities) using 0-9 scales and an 11-point numerical rating scale (NRS, 0-10). The investigational emollient and a daily log were provided for home use.

On D7, participants repeated the functional symptom self-assessments at home.

At visit 2 (D28), compliance was checked and clinical and self-assessments were repeated. Adverse events, concomitant treatments and product tolerance were recorded using investigator evaluation and a participant self-administered questionnaire.

Results

Over 28 days, participants applied the balm to affected areas a mean of twice daily. Dermatologist-assessed skin condition improved markedly by D28, with statistically significant reductions in xerosis (-73%), roughness (-71%) and extent of affected areas (-73%) (each with $p<0.001$ versus D0).

Functional symptoms improved significantly as early as D7, with further gains by D28. Discomfort decreased by -76% at D7 and -91% at D28; pruritus by -70% and -89%; and urge to scratch by -73% and -88%, respectively (each with $p<0.001$ versus D0). Consistently, limitations in work and personal activities due to itching decreased by -71% at D7 and -91% at D28 (each with $p<0.001$ versus D0).

The product was very well tolerated and was highly appreciated.

Conclusions

In this open-label study in adults with irritant or allergic contact dermatitis, twice-daily use of a balm emollient plus for 28 days was well tolerated and associated with substantial improvements in clinician-rated skin condition and patient-reported symptoms, particularly pruritus and urge to scratch, with a concomitant reduction in daily activity impairment. These findings support this balm emollient plus as a useful adjunctive skincare option for contact dermatitis-related skin impairment and discomfort.

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Abstract N°: 3226

Real-World Utilization of Upadacitinib in Atopic Dermatitis and Achievement of Minimal Disease Activity in China: 1-Year Interim Analysis of REACH-AD Study

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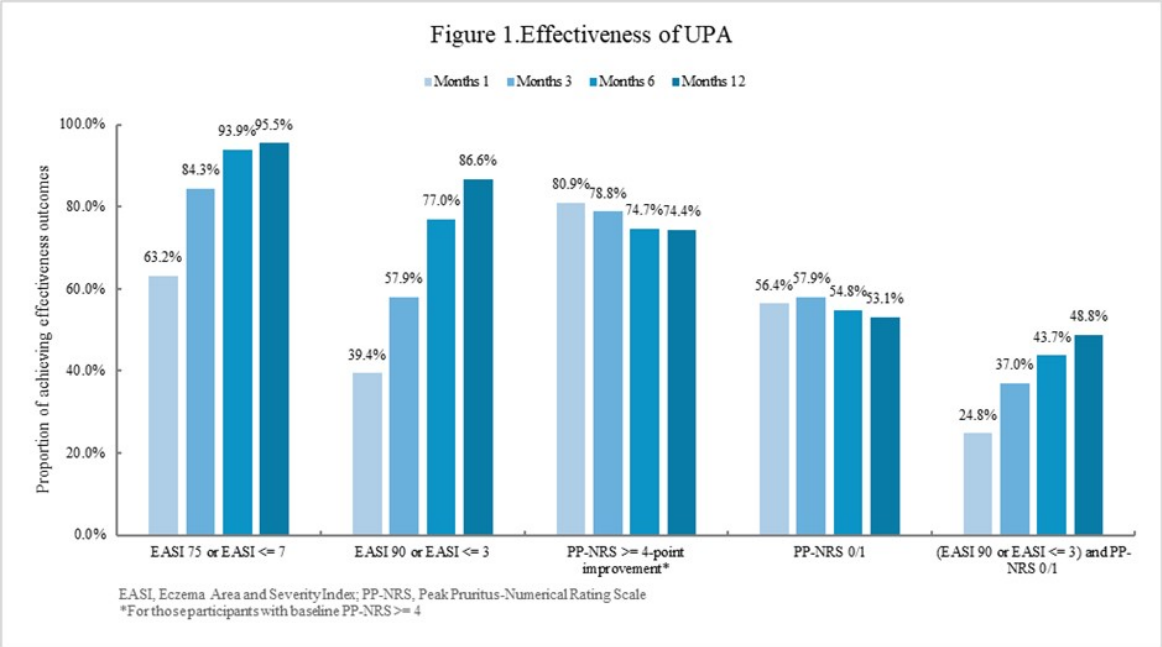
Introduction
Upadacitinib (UPA), which has been approved for the treatment of moderate-to-severe atopic dermatitis (AD), is supported by an increasing number of real-world evidence in Chinese patients. This study characterizes UPA utilization in AD clinical practice and evaluates its effectiveness using achievement of the minimal disease activity (MDA) target derived from the AHEAD consensus.

Materials and Methods
The REACH-AD study (P24-965) is an ongoing, prospective observational study enrolling 1,000 patients from 40 atopic dermatitis centers over a 1-year period. The primary outcome is to characterize upadacitinib utilization patterns, while key secondary outcomes include EASI and PP-NRS. Exploratory analyses assess achievement of the AHEAD consensus-derived targets. The MDA combines treat-to-target principles with patient / clinician shared decision-making principle and is defined as the composite outcomes of EASI 90 or ≤3 + PP-NRS 0/1 in this report. This analysis presents data on upadacitinib utilization and effectiveness collected over the whole study period among the first 500 patients, with a data cutoff of March 2, 2026.

Results
This analysis included 500 AD patients (14.8% adolescents). The top reason for starting UPA was the inadequate disease cpntrol (99.2%). 493 (98.6%) initiated UPA 15 mg and 7 patients (1.4%) applied 30 mg. At 1 year, 75.2% (376/500) reported with UPA 15 mg treatment and 4 patients (0.8%) applied 30 mg. There were 73.6% (368/500) patients remained with no interruption during the whole study, with median time 12.0 months (IQR, 11.7-12.0), mean time 10.47 months (Min-Max, 0.13-12.0). At 12 months, 95.5% of patients achieved EASI 75 or ≤7, and 86.6% achieved EASI 90 or ≤3. PP-NRS improvement ≥4 was observed in 74.4% patients, and PP-NRS 0/1 in 53.1% patients. The composite outcome of MDA (EASI 90 or ≤3 + PP-NRS 0/1) was observed in 48.8% patients (Figure 1). Drug-related AEs (10.6 E/100PY), AEs leading to discontinuation (6.4 E/100PY), and SAEs (1.4 E/100PY) were low; no deaths occurred.



Conclusions

This interim analysis demonstrates that UPA treatment of AD patients in China real world clinical practice results in durable persistence and optimal MDA achievement. The safety profile was consistent with previously reported data, and no new safety signals were identified.

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Abstract N°: 3236

Atopic Dermatitis Is Associated With Caries Risk But Not Gum Disease In Dutch Adults

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Introduction

Atopic dermatitis (AD) shows characteristics of a systemic disease and has been associated with an array of different comorbidities. Limited evidence suggests a link between atopic dermatitis and oral health, potentially mediated by factors like mucosal barrier dysfunction, mouth breathing alongside xerostomia, similar Th2 immune signalling, and side effects of immunosuppressive medication. Thus, the objective of this study was to assess the association of AD with oral health outcomes, considering AD severity and atopic multimorbidity in the adult Dutch general population.

Materials and Methods

This cross-sectional study within the population-based Lifelines Cohort from the Northern Netherlands assessed lifetime AD through self-reported, physician-diagnosis and AD severity via the Patient Oriented Eczema Measure (POEM). Atopic multimorbidity referred to the lifetime presence of asthma, rhinitis, or both, alongside AD. Oral health outcomes included the presence of gum disease, defined as gingivitis or periodontitis, and a caries risk score (CRS), integrating both direct (teeth brushing frequency, eating frequency and xerostomia) and indirect (current smoking, alcohol use, dental check-ups, age <22 or >65 years, and socioeconomic status) cariogenic factors on a scale of 0-11. The association of AD with presence of gum disease was analysed using binary logistic regression, while linear regression was used to assess the association of AD with the CRS, including adjustment for respectively relevant covariates. For both outcomes, subgroup analyses were conducted according to AD severity and atopic multimorbidity.

Results

We enrolled 26,991 participants, of which 2,391 (8.9%) reported AD. Prevalence of gum disease was higher among participants with AD than those without (44.8% vs. 42.5%, $P = 0.032$), while there were no significant differences in regards to the CRS with a median score of 3 points in both groups. We found no association of AD with presence of gum disease (adjusted Odds ratio (aOR) 1.07, 95% Confidence Interval (CI) 0.97–1.19, $P = 0.193$). Similarly, subgroup analyses showed no significant associations (Figure 1). However, AD was associated with a higher CRS (adjusted β 0.13, CI 0.05–0.21, $P < 0.001$) and in subgroup analysis by AD severity, the association remained significant only in moderate-to-severe AD (adjusted β 0.18, CI 0.02–0.34, $P = 0.027$), but not in mild AD. Compared to those without AD, participants with AD and atopic multimorbidity and those with AD only showed a similar association with the CRS (adjusted β 0.13, CI 0.03–0.24, $P = 0.011$ vs. adjusted β 0.13, CI 0.02–0.25, $P = 0.021$; Figure 1).

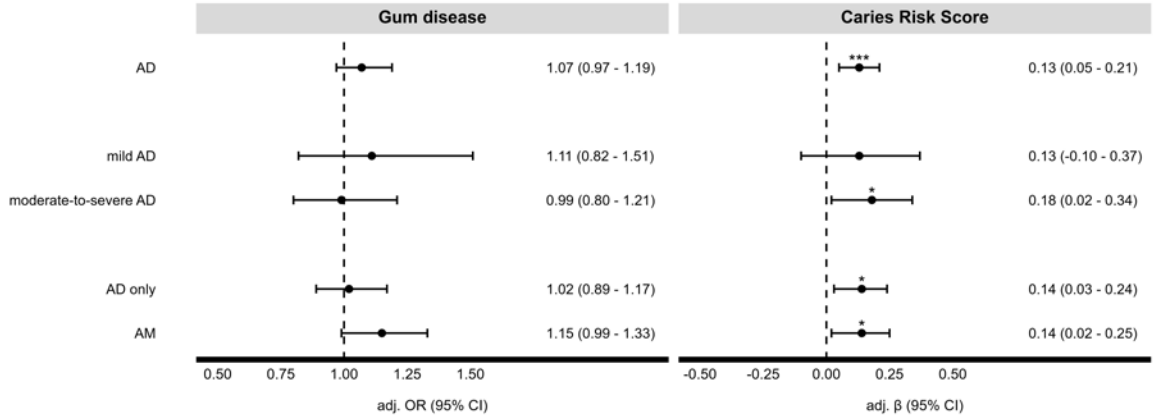

Figure 1. Association of atopic dermatitis with gum disease and Caries Risk Score, including subgroup analysis by severity and atopic multimorbidity. Associations with gum disease were analysed using binary logistic regression with adjustments for age, sex, income, education, current smoking, alcohol use, ICS use, diabetes presence and teeth brushing frequency. Associations with the CRS were analysed using linear regression with adjustments for age, sex, income, education, ICS use, diabetes presence. These multivariate regression models were fitted based on the Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC). All regression analyses utilized the no AD group as reference. Statistically significant results are indicated *P < 0.05 and ***P < 0.001. AD = atopic dermatitis, AM = atopic multimorbidity, OR = Odds Ratio, CI = Confidence Interval.

Conclusions

This is the first study exploring associations of AD with oral health outcomes in the Dutch general population. Presence of AD, especially moderate-to-severe disease, was associated with slightly higher caries risk, while atopic multimorbidity did not play a role in this association. This may reflect impaired oral hygiene behaviour, plaque accumulation, and medication-related effects, which can promote an acidogenic oral biofilm and enamel demineralization. In contrast, gum diseases are multifactorial conditions driven not only by plaque but also by microbial composition, immune response, and other susceptibility factors, potentially explaining the absence of an association with AD. To further clarify the behavioural, biological and treatment-related mechanisms underlying oral health outcomes in AD, longitudinal studies in clinically validated populations using objective dental assessments are needed.

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Abstract N°: 3237

Caregiver Impressions of Disease and Change in Infants and Children Aged 6 Months to 5 Years With Moderate-to-Severe Atopic Dermatitis

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Introduction
For infants and young children with atopic dermatitis (AD), assessment of disease activity and impact often relies on caregiver observations, as patients may be too young to reliably report symptoms and respond to questions. In clinical studies, caregiver assessments offer a complementary measure to evaluate treatment effects on behalf of patients. We assessed global caregiver impressions of AD severity and improvement of symptoms in patients aged 6 months to 5 years with moderate-to-severe AD treated with dupilumab for 16 weeks.

Materials and Methods
Children aged 6 months to 5 years with moderate-to-severe AD were enrolled in LIBERTY AD PRESCHOOL (NCT03346434), a randomized, double-blind, placebo-controlled, phase 3 clinical trial of dupilumab. Patients received weight-tiered subcutaneous dupilumab (bodyweight 5 to <15 kg: 200 mg; 15 to <30 kg: 300 mg) or matched placebo, plus low-potency topical corticosteroids, every 4 weeks for 16 weeks. Caregivers were asked to rate their child's symptoms throughout the treatment period according to the Caregiver Global Impression of Disease scoring (CGID; 1 – no symptoms, 2 – mild, 3 – moderate, 4 – severe, 5 – very severe) and compare their child's eczema to baseline symptoms using the Caregiver Global Impression of Change (CGIC; 1 – much better, 2 – moderately better, 3 – a little better, 4 – no change, 5 – a little worse, 6 – moderately worse, 7 – much worse). The proportions of caregivers giving a score of 1 and/or 2 were compared between the dupilumab and placebo groups using a Cochran–Mantel–Haenszel test stratified by region, baseline disease severity, and baseline weight group.

Results
This analysis included 162 patients, of whom 83 were randomized to dupilumab and 79 were randomized to placebo. According to the CGID scoring, 17.8% more caregivers in the dupilumab group reported "mild or no

symptoms" after 2 weeks of treatment compared with the placebo group (22.9% dupilumab vs 5.1% placebo; *P*=0.0015). By Week 16 of treatment, 46.3% more caregivers in the dupilumab group reported "mild or no symptoms" compared with the placebo group (51.8% dupilumab vs 5.5% placebo; *P*<0.0001). According to the CGIC scoring, 21.7% more caregivers in the dupilumab group described their child's symptoms as "much better" after 2 weeks of treatment compared with the placebo group (21.7% dupilumab vs 0% placebo; *P*<0.0001). By Week 16 of treatment, 40.6% more caregivers in the dupilumab group described symptoms as "much better" compared with the placebo group (45.0% dupilumab vs 4.4% placebo; *P*<0.0001). Safety was consistent with the known safety profile of dupilumab.

Conclusions

Caregivers reported meaningful changes in AD severity in infants and young children aged 6 months to 5 years treated with dupilumab. Significantly better ratings were given in the dupilumab group compared with placebo as early as Week 2, with consistent improvements observed throughout 16 weeks of treatment.

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Biologics versus JAK Inhibitors in Atopic Dermatitis: Baseline Data from the German ADBest-TREAT Registry

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Introduction

Systemic treatment of atopic dermatitis (AD) is a key element of advanced guideline-based care. The aim of the current study was to characterize the pretreatment and demographic characteristics of patients with AD receiving biologics or Janus kinase inhibitors (JAKi) in the German national AD registry ADBest-TREAT.

Materials and Methods

The ADBest-TREAT registry is a German national treatment registry which was established in 2024. It addresses the growing global need for real-world data from routine clinical care. Adults with AD are eligible for enrollment when switching to or starting a new systemic therapy.
Clinical outcomes were measured with the Eczema Area and Severity Index (EASI), patient-reported outcomes with the Dermatology Life Quality Index (DLQI), and Numeric Rating Scales (NRS) for sleep impairment, peak pruritus, and pain.
Data extraction was conducted in April 2026. After data cleaning and plausibility checks, descriptive statistical analyses were performed using IBM SPSS Statistics version 29.0.1.0.

Results

A total of 226 patients were included in the analysis. Of these, 35 patients (15%) were treated JAKi and 191 patients (85%) were treated with biologics. Within the JAKi group, the most frequently prescribed agent was Abrocitinib (n=17), followed by Upadacitinib (n=14) and Baricitinib (n=4). Among patients receiving biologics, Dupilumab was the most commonly used treatment (n=106), followed by Lebrikizumab (n=60), Tralokinumab (n=24), and Nemolizumab (n=1).
At enrollment, 24% of patients had previously received JAKi or biologics. Among the patients who were newly prescribed a JAKi (n=35), previous therapy most commonly included Dupilumab (n=13), Upadacitinib (n=3), Abrocitinib (n=2), and Tralokinumab (n=2). Prior exposure to Baricitinib and Lebrikizumab was reported in one patient each. Among patients who were newly treated with biologics (n=191), most frequent prior treatments were Dupilumab (n=18), Tralokinumab (n=8), Baricitinib (n=3), Lebrikizumab (n=2), and Upadacitinib (n=1).
Most patients receiving JAKi were classified as having severe disease (48.6%), followed by moderate (28.6%), mild (8.6%) and very severe disease (2.9%). In the biologic group, moderate disease was most common (45%), followed by severe (35.1%) and mild (5.8%) disease. 1.6% and 1% were rated as clear and almost clear, respectively.
The most common clinical subtype in both cohorts was the eczematous/disseminated subtype (62.9% in the JAKi group and 51.3% in the biologics group), followed by head-and-neck involvement (40% in the JAKi group and

42.9% in the biologics group) and flexural eczema (40% in the JAKi group and 54.5% in the biologics group).
Disease burden measures at baseline varied slightly between treatment groups. Mean DLQI (14.1 vs. 13.5) and EASI (17.6 vs. 15.1) were higher in the JAKi group and peak pruritus NRS (6.5 vs. 6.6), sleep impairment NRS (5.6 vs. 5.3) and peak pain NRS (4.5 vs. 4.2) were slightly higher in the biologics group.
Patients treated with JAKi were younger than those receiving biologics (mean age of 36.6 vs. 39.1 years), and the JAKi group showed a higher proportion of male patients (63% vs. 47%). In both groups, the chronic disease trajectory predominated, with a higher proportion in the biologics group (71.4% vs. 81.2%).

		Patients receiving a JAK inhibitor (n = 35)		Patients receiving a biological (n = 191)	
		n	n %	n	n %
Sex	Female	13	37 %	102	53 %
	Male	22	63 %	89	47 %
Age average (mean)		36.6 years		39.1 years	
Age > 65 years (n / median)		2	65 years	12	71.8 years
Disease trajectory	Chronic	25	71.4 %	155	81.2 %
	Thrust-based / relapsing	4	11.4 %	17	8.9 %
Clinical type	Acral accentuated	3	8.6 %	35	18.3 %
	Flexural	14	40 %	104	54.5 %
	Vesicular, dyshidrosiform	2	5.7 %	28	14.7 %
	Erythroderm	3	8.6 %	13	6.8 %
	Eczematous, disseminated	22	62.9 %	98	51.3 %
	Head and neck	14	40 %	82	42.9 %
	Prurigo-like	6	17.1 %	20	10.5 %
	Superinfected and weeping	2	5.7 %	9	4.7 %
	Nummular	0	0 %	8	4.2 %
Smoking status	Ex smoker <10 years not smoked	5	16.7 %	24	14.6 %
	Ex smoker ≥ 10 years not smoked	4	13.3 %	20	12.2 %
	Never smoked	14	46.7 %	86	52.4 %
	Smoker	5	16.7 %	28	17.1 %
Peak Pruritus last 24h (mean)		6.5		6.6	
Sleep impairment last 24h (mean)		5.3		5.6	
Peak pain last 24h (mean)		4.2		4.5	
DLQI (mean)		14.1		13.5	
EASI (mean)		17.6		15.1	

Conclusions

Patients with AD started on biologics or JAKi showed a substantial burden consistent with the indication for advanced systemic therapy. The differences between the two groups in terms of age, gender, and quality of life can be associated with the specific safety profile of JAKi, which leads to more frequent use among younger patients and men, and a markedly higher objective and subjective disease burden. Overall, clear guideline-based treatment patterns were observed, reflecting a high-quality care.
Continued data collection and further analyses are essential to better understand the factors driving physicians' preference for biologics versus JAKi and the differential choices among JAKi in routine practice.

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Abstract N°: 3248

Tolerability and efficacy of an emollient "Plus" containing Aquaphilus Dolomiae and Dextran sodium sulfate extracts in improving long-term atopic skin condition of infants and children

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Introduction

Atopic dermatitis (AD) is the most common chronic inflammatory skin disorder in infants and children, with a significant impact on the quality of life. Emollients are considered as the first-line therapy of AD management. Their prolonged application has been shown to improve skin condition, patient's quality of life and space-out flare-ups. These products must be safe, effective, and suitable for infants and children. This study aimed to assess the tolerability and efficacy of an emollient "Plus" containing *Aquaphilus Dolomiae* and *Dextran sodium sulfate* extracts, intended to improve long-term atopic skin condition.

Materials and Methods

12 infants from 3 to 23 months and 21 children from 24 months to 11 years old were included in a 6-month open clinical study. Main inclusion criteria were mild AD with SCORAD between 10 and 24 included, xerosis intensity ≥ 2 (scale 0-3) and pruritus intensity ≥ 3 (scale 0-10), and at least one peak of xerosis and pruritus per month reported by the subjects/parents during the 3 previous months. Assessments included tolerability, AD severity (SCORAD index), quality of life (Dermatology Life Quality Index for children and infants; CDLQI, IDQOL), number of peaks of xerosis and pruritus, tolerability, and cosmetic acceptability questionnaire.

Results

After 6 months of twice-daily use on face and body, tolerability was assessed as very good by the investigators (dermatologist and pediatrician). AD severity significantly improved with a SCORAD index decrease by –99% ($p<0.0001$). Xerosis and pruritus respectively decreased by 98% and 99% ($p<0.0001$) and a significant improvement in quality of life was observed (CDLQI: +96% ($p<0.0001$), IDQOL: +76%, ($p=0.0005$)). While at baseline, subjects/parents reported a mean number of 8 peaks of xerosis and pruritus during the 3 previous months, almost all (31/33) did not report any peak during the study. The cosmetic acceptability of the product was very good.

Conclusions

The efficacy results of this study demonstrate the benefit of an emollient "Plus" in improving the long-term management of atopic skin condition in infants and children. Moreover, its very good tolerability and acceptability by the subjects and their parents could help to ensure long-term compliance.

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Abstract N°: 3250

Lebrikizumab-associated ocular surface disease in atopic dermatitis patients: a prospective study from the BioDay registry

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Introduction
Lebrikizumab-associated ocular surface disease (LAOSD) is a common side effect in atopic dermatitis (AD) patients treated with lebrikizumab. The aim of this study was to investigate the effect of lebrikizumab treatment on ocular surface disease (OSD) and conjunctival goblet cells (GCs) in AD patients, as well as the effect of ophthalmic treatment on LAOSD.

Materials and Methods
This prospective cohort study included moderate-to-severe AD patients treated with lebrikizumab in a daily practice registry. Dermatological and ophthalmological assessments were performed at baseline (start of lebrikizumab), week 4, and week 28, between September 2024 and February 2026. Patients were categorized as biologic-naive and biologic-experienced based on prior treatment with dupilumab and/or tralokinumab. OSD severity was assessed using the Utrecht Ophthalmic Inflammatory and Allergic disease (UTOPIA) score. LAOSD was defined as a ≥3-point increase in the UTOPIA score compared to baseline. Conjunctival impression cytology was performed to study the quantity of conjunctival GCs.

Results
A total of 26 patients were included, of whom 69.2% (n=18/26) were biologic-naive and 30.8% (n=8/26) were biologic-experienced. OSD characteristics were observed in all patients at baseline, while only 46.2% (n=12/26) reported ocular symptoms. Median baseline UTOPIA scores did not differ significantly between biologic-naive and biologic-experienced patients (3.0 [IQR 2.0-4.0] vs. 3.5 [IQR 3.0-4.8], respectively, p=0.144). The use of ophthalmic medication increased significantly during lebrikizumab treatment, from 3.8% (n=1/26) of patients at baseline to 61.9% (n=13/21) at week 28. During 28 weeks of lebrikizumab treatment, 30.8% (n=8/26) of patients developed LAOSD (n=5 biologic-naive and n=3 biologic-experienced) after a median of 5.0 weeks (IQR 5.0-9.0). At baseline, conjunctival GC numbers were significantly lower in both biologic-naive and biologic-experienced patients compared to healthy controls (p=0.030 and p=0.026, respectively). GC numbers remained stable between baseline and week 28 in lebrikizumab-treated AD patients.

Conclusions

This study shows that OSD is highly prevalent in moderate-to-severe AD patients before initiating biologic treatment. During 28 weeks of lebrikizumab treatment, 30.8% of patients developed LAOSD despite intensive ophthalmological monitoring and treatment. Conjunctival GC numbers remained stable during 28 weeks of lebrikizumab treatment. Overall, these findings underscore the need for dermatologists to be aware of LAOSD in AD patients treated with lebrikizumab.

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Abstract N°: 3256

Tolerability and efficacy of a dermo-cosmetic product containing Aquaphilus dolomiae and Broussonetia extracts dedicated to pruritus associated with localized dry skin in atopic infants and children

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Introduction

Atopic dermatitis (AD) is the most common chronic inflammatory skin disorder in infants and children. Dry skin and pruritus are the main features of AD. Repeated itchy periods can significantly impact patients' daily life. We developed a dermo-cosmetic product containing two active ingredients, *Aquaphilus dolomiae* and *Broussonetia* extracts, dedicated to pruritus associated with localized dry skin. We investigated the tolerability and efficacy of the product in infants and children with AD.

Materials and Methods

A monocentric and open study has been conducted on 32 infants and children aged from 8 months to 11 years old. The product was applied four times a day on localized dry and pruritic areas of the body and/or face for 22 days. Four visits were performed (D1, D3, D8, and D22). Inclusion criteria included AD according to United Kingdom Working Party definition, localized dry and pruritic areas with an intensity of xerosis ≥ 2 (moderate) on a 0-3 scale and a pruritus intensity (on average over the previous 24 hours) ≥ 4 for children and ≥ 1 for infants on a 0-10 numerical rating scale (NRS) on at least one localized area. The primary objective was to assess the tolerability of the product. Secondary objectives included pruritus intensity evaluation, physical and functional signs assessment, Local SCORAD on a target area, cosmetic acceptability questionnaire, and standardized photographs.

Results

Tolerability was assessed as excellent by the investigators (dermatologist and pediatrician). At baseline, the mean pruritus intensity on average over the previous 24 hours was 5.3 and a significant decrease was observed at each timepoint: - 74% at D3 ($p<0.0001$), - 85 % at D8 ($p<0.0001$) and - 100 % at D22 ($p<0.0001$). AD severity on a target area was significantly improved as Local-SCORAD decreased by -53% at D3 ($p<0.0001$), by -66% at D8 ($p<0.0001$) and by -96% at D22 ($p<0.0001$) as well as xerosis decreased by -59% at D3 ($p<0.0001$), by -72% at D8 ($p<0.0001$) and by -99% at D22 ($p<0.0001$). Finally, the cosmetic acceptability as well as the perceived efficacy on pruritus just after application was judged very good.

Conclusions

Tolerability and efficacy results as well as the cosmetic acceptability of this dermo-cosmetic product demonstrated its benefit in the prompt relief of significant pruritus associated with dry skin in atopic pediatric population.

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Abstract N°: 3271

Risk of cancer in atopic dermatitis exposed to Janus kinase inhibitors, a systemic review and meta-analysis

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Introduction
Cancer risk following exposure to Janus kinase(JAK) inhibitors in atopic dermatitis (AD) patients is not certain. The aim of this study is to evaluate the current evidence on the risk of cancer in AD patients treated with JAK inhibitors.

Materials and Methods
We searched PubMed, Web of Science, EMBASE, and ClinicalTrial.gov for original articles for their inception to september 2025 and screened them by inclusion criteria and exclusion criteria. The relative risk (RR) and risk difference for incident cancer were calculated by random-effects meta-analysis. Bias was assessed by the Cochrane Risk of Bias Tool 2.

Results
16 studies with 8791 people were included. The meta-analysis demonstrated no significant differences in the risk of cancer between patients with AD who received treatment with JAK inhibitor and patients with AD received placebo or dupilumab, the RR was 0.89 (95% CI, 0.45–1.76 ; p=0.13). The result was similar when non-melanoma skin cancer (NMSC) was excluded from the analysis, the RR was 0.58 (95% CI, 0.26–1.30; p=0.5) and NMSC alone, the RR was 1.34 (95% CI, 0.5–3.57; p=0.61).

Conclusions
Our meta-analysis suggests that JAK inhibitor have little-to-no effect on the occurrence of cancer in AD patients vs. comparators. These findings could provide reference for clinicians when using JAK inhibitors in AD patients.

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Abstract N°: 3290

Systemic Treatment Outcomes for Severe Atopic Dermatitis in Children Aged Under 12 Years: Interim Results From the PEDISTAD Registry

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Introduction

Real-world studies can offer clinicians insight into the long-term effectiveness and safety of systemic therapies in pediatric patients with atopic dermatitis (AD). Here, we report the long-term effects of systemic therapies on clinician-reported outcomes in children aged under 12 years with severe AD.

Materials and Methods

PEDISTAD (NCT03687359), an ongoing, international, observational, 10-year registry, enrolled patients with moderate-to-severe AD aged under 12 years who were receiving/were candidates for systemic treatment. This 6-year (2019–2025) interim analysis reports the effect of systemic therapies on mean Eczema Area and Severity Index (EASI) total score and the percentage affected body surface area (BSA) for children with severe AD. Data were collected at therapy start and last available observation. Patients were categorized by the treatment they received — dupilumab, methotrexate, or cyclosporine —and only counted if they remained on that treatment. The adverse event rate, discontinuation rate, and treatment duration were also evaluated. Data are presented as observed.

Results

At the time of this analysis, 1,072, 845, 649, 521, 256 and 17 moderate-to-severe AD patients had completed their 1, 2, 3, 4, 5, and 6 year visit, respectively**.** Of these 142, 40, and 54 patients with severe AD received dupilumab, methotrexate, and cyclosporine, respectively. For dupilumab, methotrexate, and cyclosporine, the mean EASI change from start of treatment to the last available observation was −24.3 (baseline = 29.3; $P < 0.0001$), −15.7 (30.1; $P < 0.0001$), and −10.2 (29.2; $P = 0.0009$), respectively. The mean percentage BSA change was −38.7 (baseline = 51.8; $P < 0.0001$), −25.3 (54.8; $P = 0.0003$), and −13.4 (53.0; $P = 0.0080$), respectively.

The proportion of children experiencing adverse events when treated with dupilumab, methotrexate, and cyclosporine was 35.9%, 30.0%, and 35.2%, respectively. For dupilumab, methotrexate, and cyclosporine, the discontinuation rates were 37.9%, 77.5%, and 96.3%, respectively, and the mean (SD) treatment exposure was 21.6 (17.7), 21.8 (17.2), and 10.9 (8.8) months, respectively.

Conclusions

Children with severe AD aged under 12 years have a high disease burden at baseline. Those treated with dupilumab had a numerically greater improvement in clinician-reported AD disease assessments and lower discontinuation rates when compared to those treated with methotrexate and cyclosporine.

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Abstract N°: 3295

From complementary pruritogenic pathway modulation to clinical improvement: multidimensional evaluation of an emollient containing Rhealba oat and Helichrysum g. in adult atopic dermatitis

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disorder characterized by erythema, xerosis and intense pruritus, which often worsens at night and disrupts sleep. Its pathophysiology involves barrier impairment closely linked to type 2 inflammation and pruritogenic mediators. Emollients are a cornerstone of AD management, aiming to repair skin barrier and reduce itch. This study was designed to assess effectiveness of a cream containing Rhealba Oat and *Helichrysum gymnocephalum (H.g.)* in adults with AD using a multidimensional approach that combined clinical assessments of AD severity, objective, device-based monitoring of nocturnal scratching through a wearable device, and patient-reported outcomes capturing pruritus intensity, its impact on quality of life, and sleep quality. In parallel, anti-inflammatory properties of both extracts were investigated *in vitro*.

Materials and Methods

A monocentric, open-label study was conducted comprising a 7-day run-in period without application of the product, followed by 28 days of once-daily application of the emollient containing Rhealba oat and *Helichrysum g*. A multidimensional assessment strategy was implemented. Clinically, AD severity was evaluated using SCORAD. In parallel, patients were equipped with wrist-worn wearable devices to provide objective, continuous monitoring of nocturnal scratching, capturing frequency and duration of scratching episodes. In addition, patient-reported outcomes were collected to document pruritus intensity and its impact on quality of life through a validated questionnaire, the Chronic Itch Burden Scale, as well as perceived sleep quality and sleep disturbances. In vitro, anti-inflammatory properties of the extracts were investigated using complementary models, including inhibition of IL-8 and TSLP release and STAT phosphorylation assay in Th2-stimulated normal human epidermal keratinocytes (NHEKs). A sensory neuron–keratinocyte co-culture model was also used to examine nerve growth and Brain Natriuretic Peptide (BNP) both associated with pruritic context of the pathophysiology.

Results

After 4 weeks of night cream application compared to D1, SCORAD score decreased significantly with mean decreases of 53.2% ($p < 0.0001$), with notable reductions in pruritus and sleep disturbances (74.1% and 85.6%, respectively, $p<0.0001$). In addition, mean target SCORAD scores decreased similarly over time for both left and right limbs, with significant differences on D36 vs. D1: -44.0% ($p = 0.0013$) for left limbs and -43.4% ($p = 0.0024$) for right limbs. Wearable device measurements showed a significant decrease in nocturnal scratching and duration of scratching episodes, along with improved sleep efficiency ($p=0.0224$). This significant improvement in pruritus was confirmed by the patients who also noted a significant improvement in their quality of life. Specifically, scores decreased for the urge to scratch ($p=0.0005$) and scratch-related pain ($p=0.0001$). Scores related to the negative

impact of itch on mental health, such as bad mood, stress, and anger, also decreased ($p<0.0001$; $p=0.0005$ and $p=0.0088$ respectively). The patients also noticed a significant reduction in the impact of sleep problems on daily activities ($p=0.0001$).

Furthermore, both extracts significantly decreased TSLP and IL-8 release. *H.g.* extract modulated immunological responses, decreasing the pSTAT6/STAT6 ratio in Th2-challenged NHEKs and inhibited BNP release and neuronal sprouting in the sensory neuron-keratinocyte model stimulated by IL-31.

Conclusions

This complementary approach, combining clinical evaluation, objective wearable data and patients' own experience, demonstrates that a Rhealba oat and *Helichrysum g.* night cream effectively reduces AD severity, nocturnal scratching and sleep impairment and improves quality of life. Consistent *in vitro* evidence on inflammatory and pruritogenic pathways further supports its use as a target in atopic dermatitis.

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Balancing thrombotic risk and therapeutic benefit: baricitinib for severe atopic dermatitis in a patient with systemic lupus erythematosus and prior thromboembolism

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Introduction

Janus kinase (JAK) inhibitors have emerged as an effective therapeutic option for moderate-to-severe atopic dermatitis (AD). However, concerns regarding venous thromboembolism (VTE) remain an important limitation in clinical practice following regulatory safety warnings on thrombotic and cardiovascular adverse events associated with this drug class. Patients with systemic lupus erythematosus (SLE) represent a particularly challenging population, as SLE itself is associated with an increased baseline thrombotic risk. We report a case of severe AD successfully treated with baricitinib in a patient with SLE and a history of inferior vena cava thrombosis and deep vein thrombosis, highlighting the importance of individualized risk–benefit assessment and multidisciplinary management.

Case Presentation

A 52-year-old man with SLE, diagnosed at the age of 22 and previously complicated by lupus nephritis, was referred for evaluation of severe AD. His previous SLE treatment included systemic corticosteroids, chloroquine, cyclophosphamide, and methotrexate. During the 2010s, he developed deep vein thrombosis and inferior vena cava thrombosis, requiring long-term anticoagulant therapy with low-molecular-weight heparin, later switched to apixaban in 2017. Cutaneous manifestations of SLE had not previously been documented. Since 2011, the patient had experienced recurrent intensely pruritic eczematous lesions predominantly involving the dorsal hands, forearms, trunk, and lower legs, partially responsive to topical corticosteroids and tacrolimus ointment, but with frequent relapses. In 2021, marked worsening occurred with severe lichenification, pachydermic and prurigo-like lesions, accompanied by significant impairment in quality of life. Laboratory evaluation demonstrated persistent eosinophilia and markedly elevated total IgE levels reaching 45,770 kIU/L, with polysensitization to inhalant and food allergens. Patch testing was positive for carbamates, formaldehyde, thimerosal, and methyldibromo glutaronitrile. Despite treatment with methotrexate 10 mg weekly, topical corticosteroids, tacrolimus, antihistamines, and emollients, the disease remained poorly controlled. At dermatological assessment in February 2024, the patient presented with extensive lichenification of the hands, wrists, lower legs, and prurigo nodules on the upper extremities, with SCORAD 52, EASI 27, Itch-NRS 6/10, and DLQI 14. Following multidisciplinary evaluation involving dermatology and immunology specialists, baricitinib 4 mg daily was initiated despite the history of VTE, while therapeutic anticoagulation with apixaban was continued. A rapid clinical response was observed within the first month of therapy, with reduction of pruritus and visible improvement of lichenification. After six months of treatment, SCORAD decreased from 52 to 19.7, with near-complete regression of eczematous lesions and marked improvement in quality of life. During follow-up of more than two years, the patient maintained sustained remission of AD and SLE without recurrence of VTE events or other serious adverse effects. Mild transient nausea and laboratory hypercholesterolemia were noted during treatment, while renal function remained stable. In March 2025, the patient was hospitalized for influenza-associated pneumonia, requiring temporary discontinuation of baricitinib. Despite treatment interruption, no significant flare or worsening of AD occurred.

Conclusion

This case highlights the successful use of baricitinib for severe AD in a patient with SLE and a history of inferior vena cava thrombosis and deep vein thrombosis, emphasizing the importance of individualized therapeutic decision-making and multidisciplinary management.

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Abstract N°: 3309

Lichenified atopic eczema of the feet with excellent clinical response to lebrikizumab

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease with a substantial impact on patients' quality of life, particularly when presenting as localized, intensely lichenified eczema that is refractory to conventional therapy. Lichenified eczema of the dorsal and plantar feet represents a therapeutic challenge due to severe pruritus, recurrent flares, and poor response to topical treatments. In recent years, biologic therapies targeting the IL-13 pathway have expanded treatment options for patients with moderate-to-severe AD who fail to respond to traditional systemic agents. We present the case of a patient with long-standing, treatment-refractory lichenified chronic eczema of the feet who achieved excellent clinical improvement with lebrikizumab.

Case Presentation

A 69-year-old woman presented with a 10-year history of lichenified chronic eczema predominantly affecting the dorsal, lateral, and plantar aspects of the feet, with severe pruritus and recurrent exacerbations despite conservative management. Since 2016, she had undergone patch testing twice with negative results. At presentation, she exhibited well-demarcated, intensely lichenified eczematous plaques with significant symptoms.

Given the severity and lack of response to topical therapy, multiple skin biopsies were performed. All showed features consistent with chronic eczema: regular epidermal hyperplasia, spongiosis, hyperkeratosis, and hypergranulosis, without findings suggestive of allergic contact dermatitis or psoriasis. The final diagnosis was atopic dermatitis presenting as chronic lichenified eczema localized to the feet.

The patient had previously received numerous treatments, including potent topical corticosteroids, short courses of oral corticosteroids, acitretin, wet wraps, intensive emollients, and oral cyclosporine, without achieving adequate disease control. Due to the severity, functional impact, and therapeutic refractoriness, advanced targeted therapy was considered, and lebrikizumab was initiated in May 2025.

After four months of treatment, the patient showed marked improvement, with complete resolution of pruritus, significant reduction of plantar lesions, and a substantial improvement in quality of life. She continued on maintenance lebrikizumab (250 mg every 4 weeks), maintaining a complete and stable clinical response without any relevant adverse events.

Conclusion

This case highlights the therapeutic challenge of chronic lichenified eczema of the feet, a clinical presentation often resistant to both topical and conventional systemic therapies. In our case, lebrikizumab showed rapid, sustained efficacy with an excellent safety profile, enabling complete control of cutaneous lesions and resolution of pruritus in a patient with long-standing, treatment-refractory AD. This case supports the role of targeted biologic therapies such as lebrikizumab as a key option for patients with severe, localized, and difficult-to-manage AD.

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Abstract N°: 3335

Targeted Management of Pediatric Atopic and Diaper Dermatitis Using a Multifunctional Regenerating Cream: Addressing Skin Barrier Dysfunction and Microbiome Imbalance

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Introduction

Atopic dermatitis and diaper dermatitis are two of the most prevalent dermatologic conditions in pediatric populations, stemming largely from compromised skin barriers and microbial imbalances.

Materials and Methods

This study explores the relevance of a multifunctional regenerating cream as a therapeutic adjunct in the management of these conditions. The cream contains a combination of madecassoside, panthenol, and a mineral complex, alongside Tribioma—a probiotic blend with potential anti-Staphylococcus aureus activity. In atopic dermatitis, where barrier dysfunction and Staphylococcus colonization exacerbate inflammation, this formulation supports both epidermal renewal and microbial modulation. In cases of diaper dermatitis, the cream's occlusive and reparative properties protect the skin from moisture-related irritation and Candida overgrowth. Its non-greasy texture and antimicrobial components provide effective daily barrier maintenance. Evidence from clinical assessments and caregiver feedback reinforces its utility in relieving symptoms and improving skin integrity.

Results

A significant improvement in the clinical condition was observed in 77.8% of children using the product. Overall symptom severity changes of erythema, scaling, dyspigmentation, fissures and edema assessed were assessed at baseline and follow up visit that took place after at least 14 days of twice daily product applying. This improvement was particularly pronounced among patients whose initial condition was classified as moderate or severe, with 92.2% to 94.2% of these patients respectively experiencing a noticeable recovery.

Conclusions

The multifunctional regenerating cream emerges as a comprehensive, microbiome-conscious solution for managing these age-specific dermatoses.

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Abstract N°: 3355

Methotrexate enhances the efficacy of tralokinumab in severe atopic dermatitis.

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Introduction

Atopic dermatitis is a chronic, inflammatory, and itchy disease. In mild cases, the disease can be controlled with topical therapy. In patients with moderate to severe exacerbation, systemic treatment, including modern biological therapies, becomes necessary. Tralokinumab is a human monoclonal antibody directed against IL-13. Its safety and efficacy have been confirmed in numerous clinical trials. Positive effects of the therapy can be observed after prolonged use.

Case Presentation

We present two patients with severe atopic dermatitis who were treated with tralokinumab and methotrexate. The first patient is a 58-year-old man with severe atopic dermatitis since early childhood, chronic hepatitis B treated with Entecavir, inoperable bilateral cataracts, a history of hypertension and contact allergy. Due to the condition of his skin, he had been treated repeatedly with short courses of systemic steroid therapy and cyclosporine. Treatment with tralokinumab was initiated in November 2024 with disease severity of BSA 57%, EASI 53.8, and SCORAD 74.4. During this treatment, exacerbations of the skin condition were observed, requiring the reintroduction of systemic glucocorticosteroids. It was only after the addition of methotrexate between in July 2025 that resolution of inflammation was achieved, along with a significant, stable improvement in skin lesions: BSA 6%, EASI 2.7 (94.98% reduction), SCORAD 31.2. The next patient is a 48-year-old woman in whom atopic dermatitis was diagnosed at the age of 30. The lesions were most severe in the upper half of the body, particularly on the face. Following the failure of cyclosporine and methotrexate, tralokinumab was added to methotrexate therapy in January 2026. Remission of the skin lesions was achieved after 12 weeks. The patient continues monotherapy with tralokinumab.

Conclusion

In patients with severe atopic dermatitis treated with tralokinumab, the temporary addition of methotrexate allows for faster remission of skin lesions.

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Abstract N°: 3377

Uncovering the Multidimensional Burden of Atopic Dermatitis Through the Patient Voice: Insights from a U.S. Survey Using Validated Patient-Reported Outcome Measures

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Introduction

Background: Atopic dermatitis (AD) is assessed by visible skin involvement and flare frequency, which underestimates patient burden across psychological and functional domains. Validated patient-reported outcome (PRO) instruments offer a more comprehensive assessment of disease impact.

Objective: To characterize the burden of AD using validated PROs and identify gaps between patient experience and clinical assessment that influence treatment decisions.

Materials and Methods

Patient Voice Dynamix™: Atopic Dermatitis U.S. 2025 included a survey of 304 AD patients and interviews with eight AD patients, with a parallel European study readout in June 2026. PRO measures included the Dermatology Life Quality Index (DLQI), Patient-Reported Impact of Dermatological Diseases (PRIDD), EQ-5D-5L, Work Productivity and Activity Impairment (WPAI), Generalized Anxiety Disorder-7 (GAD-7), and Patient Health Questionnaire-9 (PHQ-9).

Results

AD imposes a substantial burden beyond skin symptoms. Nearly half of patients report a large or extremely large impact on quality of life, with health utility scores below U.S. population norms that worsen with disease severity. PRIDD identifies a pronounced non-physical burden, particularly among patients with moderate disease, where psychological, social, and life responsibilities impacts exceed physical burden. Work impairment is driven by presenteeism. Mental health burden is underrecognized: among patients not self-reporting anxiety or depression related to AD, 17% and nearly 25% meet moderate-to-severe thresholds on GAD-7 and PHQ-9, respectively. Patients of color report greater quality of life, mental health, and sleep impairment.

Conclusions

Validated PROs reveal the overlooked burden of AD that is discordant with traditional clinical assessments. Integrating PROs into routine practice can improve recognition of unmet needs and support patient-centered AD management.

Why this changes practice:

Validated patient-reported outcome measures reveal substantial, often unrecognized physical, psychological, and functional burden in atopic dermatitis that is frequently discordant with physician assessment based on visible severity alone. Routine integration of multidimensional PROs can improve recognition of unmet needs, support earlier treatment escalation, and enable more holistic patient-centered management of AD.

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Abstract N°: 3379

Quantifying the Impact of Itch and Skin Lesion Severity on Quality of Life in Atopic Dermatitis: A Longitudinal Analysis of the ARCADIA Trials

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by pruritus, eczema, and substantial impairment in quality of life (QoL). While clinical trials have demonstrated treatment-related improvements in signs and symptoms, the extent to which these improvements translate into meaningful QoL benefits remains an important clinical question. Conceptual disease models suggest that itch and eczema influence QoL both directly and indirectly through intermediate domains.

The objective is to quantify the relationship between improvements in itch and skin severity and QoL outcomes in AD.

Materials and Methods
Patients with moderate-to-severe AD from the ARCADIA pivotal studies (NCT03985943, NCT03989349) were pooled for analysis (N=1728; mean age 34.1 years; 49% female). Descriptive statistics were produced and longitudinal modelling was used to estimate mean QoL at baseline, week 8, and week 16 according to itch intensity, skin lesion severity, and treatment (nemolizumab vs placebo; both with background topical corticosteroids of low/medium potency with or without topical calcineurin inhibitors). QoL was measured through the Dermatology Life Quality Index (DLQI; range 0 to 30). Itch intensity was assessed using the Peak Pruritus Numerical Rating Scale (PP-NRS; 0-10), and skin lesion severity using the Eczema Area and Severity Index (EASI; range 0-72). Mixed effects models with unstructured covariance matrices, random intercepts, and time-by-covariate interactions were used to estimate least squares means of DLQI according to each predictor with 95% confidence intervals.

Results
Both itch and skin lesion severity were significantly associated with DLQI ($p<0.01$), with higher signs and symptom burden corresponding to worse QoL. Itch intensity demonstrated a strong and graded association with QoL. Representative PPNRS values were modeled to reflect severity categories defined as mild (2), moderate (5), and severe (7). At week 16, LS mean DLQI was 4.7 (4.37–5.1) for mild itch, 8.8 (8.44–9.15) for moderate itch, and 11.5 (11.01–11.99) for severe itch, corresponding to a ~4.1-point difference between mild and moderate itch and a ~6.8-point difference between mild and severe itch (Figure 1)

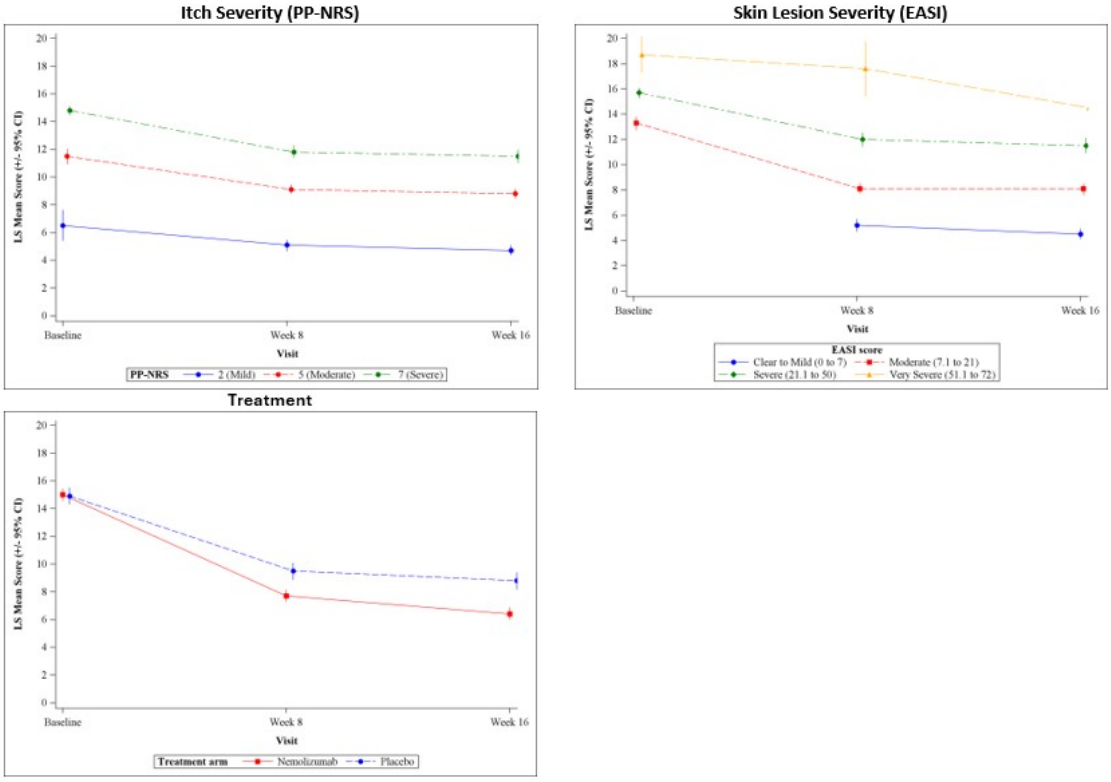
Skin lesion severity, via EASI, demonstrated a clear monotonic relationship with DLQI at week 16, with LS mean DLQI scores increasing from 4.5 (95% CI: 4.11–4.95) in patients with clear-to-mild disease (EASI 0–7), to 8.1 (7.59–8.51) for moderate (7.1–21), 11.5 (10.92–12.13) for severe (21.1–50), and 14.5 (12.32–16.60) for very severe

disease (51.1–72).

Treatment with nemolizumab resulted in significantly greater QoL improvement versus placebo at week 16, with LS mean DLQI scores of 6.4 (5.99–6.88) and 8.8 (8.17–9.40), respectively.

Notably, itch intensity demonstrated a substantial impact on QoL across relatively narrow severity categories, highlighting its importance as a key driver of QoL impairment alongside skin lesion severity.

Figure 1. LS Mean DLQI at Week 8 and 16 by Itch Severity (PP-NRS), Skin Lesion Severity (EASI), and Treatment



Abbreviations: CI = Confidence interval; EASI = Eczema Area and Severity Index; LS = Least square; PP-NRS = Peak Pruritus Numerical Rating Scale. Notes: Lines for selected EASI categories begin after baseline due to trial inclusion criteria and distribution of observed values, which limited representation of lower severity categories at earlier timepoints.

Conclusions

Improvements in itch and skin lesion severity are associated with meaningful QoL gains in AD. These findings highlight itch as a key and independent driver of QoL impairment, reinforcing its importance as a therapeutic target and patient-relevant endpoint in clinical trials. Further analyses are warranted to evaluate the durability of DLQI benefits over extended follow-up and to assess mediating pathways, including the role of sleep, using formal mediation analyses, as well as to better understand the relative and independent contributions of itch and skin lesion severity to QoL.

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Abstract N°: 3383

Flip-flop phenomenon - from iksekizumab to dupilumab with apremilast.

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Introduction

The 'flip-flop' phenomenon refers to the paradoxical shift between atopic and psoriatic phenotypes, which is being observed with increasing frequency in connection with biologic therapies. Biologics that block IL-17 or IL-23 bring about an atopic phenotype, whilst dupilumab may trigger the appearance of psoriatic lesions.

Case Presentation

A 53-year-old patient, an employee in the metallurgical industry, suffering from bronchial asthma, an allergy to house dust mites, nasal polyps and severe plaque psoriasis was treated with ixekizumab under the National Health Funds. As the psoriasis subsided, polymorphic skin lesions began to appear, including papules, excoriations, erosions and vesicles, accompanied by severe generalised pruritus. Treatment with ixekizumab was suspended, and the patient was referred to hospital for diagnostic investigations. Atopic dermatitis and concomitant allergic contact dermatitis were diagnosed. Topical glucocorticoids were initially used, but this did not result in lasting improvement. Systemic rescue therapy with glucocorticosteroids led to short-term remission and recurrence of the disease after discontinuation of the drug. Due to the interruption in ixekizumab treatment, psoriasis flared up. Upon resumption of treatment under the National Fund Programme, remission of psoriatic lesions was achieved, with exacerbation of atopic lesions. After 8 months of treatment with cyclosporine, no sustained improvement was achieved. An attempt was then made to alleviate the symptoms using phototherapy, but exposure to 311 nm UVB radiation proved ineffective. Ultimately, dupilumab was introduced, which yielded good results in terms of skin lesions and nasal polyps. Due to a relapse of psoriasis, oral apremilast was added. Ultimately, the patient's condition is managed with dupilumab and apremilast.

Conclusion

The flip-flop phenomenon is the reason for modifying biological therapy in patients suffering from chronic inflammatory skin conditions. Treatment should be tailored to the individual patient.

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Abstract N°: 3406

Efficacy of amlitelimab in improving head and neck atopic dermatitis in Phase 2 and 3 trials: Results from COAST-1, COAST-2, SHORE, and ATLANTIS

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Introduction

Atopic dermatitis (AD) can impact several regions of the body, including the head, neck, and eyelids, which remain challenging to treat. Amlitelimab (SAR445229) is a fully human, non-depleting, anti-OX40 ligand (OX40L) monoclonal antibody that blocks OX40L during the inflammatory prequel, which is upstream of T-cell expansion and inflammatory cytokine production in AD. The efficacy and safety of amlitelimab have been evaluated in Phase 2 and Phase 3 trials including the duplicate monotherapy trials, COAST-1 (NCT06130566) and COAST-2 (NCT06181435), and in SHORE (NCT06224348) in combination with topical corticosteroids and/or topical calcineurin inhibitors (TCS/TCI). Across all three studies, the primary endpoint of validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) 0/1 at Week 24 was achieved. In a preliminary analysis of ATLANTIS (NCT05769777), a long-term, open-label, Phase 2 study, amlitelimab was generally well tolerated and demonstrated progressive efficacy. Amlitelimab has previously demonstrated efficacy in improving head and neck AD in the Phase 2b STREAM-AD trial. Here we report the efficacy of amlitelimab on head, neck, and eyelid lesions across COAST-1, COAST-2, SHORE, and ATLANTIS in participants with moderate-to-severe AD.

Materials and Methods

COAST-1, COAST-2, and SHORE were Phase 3, randomised, double-blind, placebo-controlled trials. ATLANTIS is an ongoing Phase 2, open-label, single-arm, long-term study (268 weeks; ~5 years). In the Phase 3 trials, eligible participants aged ≥12 years were randomised 2:1:1 to receive subcutaneous amlitelimab with a 500 mg loading lose (LD) followed by 250 mg every-4-weeks (Q4W), amlitelimab Q12W + LD, or placebo for 24 weeks. In ATLANTIS, enrolled pts aged ≥12 years receive 250 mg subcutaneous amlitelimab Q4W + LD. In all studies, doses were halved for participants <40 kg. TCS/TCI use was required in SHORE and permitted in ATLANTIS. In COAST-1, COAST-2, and SHORE**,** the proportion of pts with head and neck AD achieving ≥75% improvement from baseline

in head and neck Eczema Area and Severity Index sub-score (EASI-75) and the proportion of pts with eyelid AD rated by a physician as ‘clear’ or ‘improved’ at Week 24 were evaluated. In an interim analysis of ATLANTIS (data cut-off Nov 3, 2025), head and neck EASI-75 was evaluated at Week 52. Pts were considered non-responders after rescue/prohibited medications/procedures or early discontinuation due to lack of efficacy. Missing data were imputed as non-responder. P-values are nominal.

Results

At Week 24, a greater proportion of pts achieved head and neck EASI-75 with both amlitelimab dosing regimens compared with placebo in COAST-1 (Q4W [N=274]: 39.8%, Q12W [N=141]: 36.9% vs placebo [N=143]: 20.3%; p<0.01) and COAST-2 (Q4W [N=281]: 42.7%, Q12W [N=141]: 39.0% vs placebo [N=137]: 24.1%; p<0.01). In COAST-1, 47.3% (p=0.07) and 55.4% (p<0.01) of pts in Q4W (N=169) and Q12W (N=92) dosing regimens, respectively, were rated by a physician as having ‘clear’ or ‘improved’ eyelid AD at Week 24 compared with 34.1% of pts with placebo (N=88). In COAST-2, a greater proportion of pts had eyelid AD rated as ‘clear’ or ‘improved’ with Q4W (N=167; 58.1%) and Q12W dosing (N=85; 47.1%) compared with placebo (N=80, 31.3%; p<0.05). In SHORE, a greater proportion of pts in both dosing regimens achieved head and neck EASI-75 (Q4W [N=307]: 55.4%, Q12W [N=151]: 57.0% vs placebo [N=154]: 39.6%; p<0.01) and eyelid AD rated by a physician as ‘clear’ or ‘improved’ (Q4W [N=190]: 78.9%, Q12W [N=86]: 76.7% vs placebo [N=88]: 58.0%; p<0.05). In pts with up to 52 weeks of amlitelimab treatment in ATLANTIS (N=560), 53.4% of pts achieved head and neck EASI-75.

Conclusions

Improvements in AD signs and severity in head, neck, and eyelid regions were observed with amlitelimab across multiple trials with Q4W and Q12W dosing regimens, demonstrating a clinically meaningful benefit to multiple anatomical sites, including challenging-to-treat regions.

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Abstract N°: 3415

Efficacy of Upadacitinib in Patients With Itch-Dominant Atopic Dermatitis: A Post-Hoc Analysis from the Phase 3 Measure Up 1 and Measure Up 2 Trials

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Introduction

Atopic dermatitis (AD) is a chronic, systemic inflammatory disease, characterized by eczematous skin lesions and intense itch. Itch is reported as the most burdensome symptom of AD, and is associated with sleep disturbance, pain, and diminished quality of life. Patients with AD vary in itch intensity and extent of skin lesions, resulting in a range of clinical phenotypes. The itch-dominant phenotype, present in approximately a quarter of all patients with AD, is characterized by severe itch symptoms with mild-to-moderate skin lesions (Chovatiya R, et al. *Ann Allergy Asthma Immunol*. 2021;127(1):83–90.e2). The oral, selective, Janus kinase inhibitor, upadacitinib (UPA), is approved for the treatment of moderate-to-severe AD in patients ≥12 years old. This post hoc analysis of the pivotal phase 3 Measure Up clinical trials evaluates the efficacy of UPA in achieving optimal clinician reported outcomes (ClinRO), patient reported outcomes (PRO), and minimal disease activity (MDA) in patients with itch-dominant AD at baseline.

Materials and Methods

In the phase 3 Measure Up 1 and Measure Up 2 trials, patients aged 12-75 years with moderate-to-severe AD (≥10% of body surface area [BSA] affected by AD, Eczema Area and Severity Index [EASI] score of ≥16, validated Investigator's Global Assessment for AD [vIGA-AD] score of ≥3, and Worst Pruritus Numerical Rating Scale [WP-NRS] score of ≥4) were randomized 1:1:1 to receive UPA 15 mg (UPA15), UPA 30 mg (UPA30), or placebo (PBO) once daily for 16 weeks. Outcomes were assessed in patients with mild-to-moderate extent of skin involvement and severe itch at baseline (ie, itch dominant phenotype), defined as BSA ≤40% and WP-NRS ≥7. All efficacy results for optimal ClinRO, PRO, and MDA outcomes as shown in Table 1 were reported for the integrated patient population from both trials and based on nonresponder imputation. Safety for UPA in AD has been reported previously and was not assessed in this analysis.

Results

A total of 435 patients (PBO, n=156; UPA15, n=140; UPA30, n=139) presented with an itch-dominant phenotype at baseline, comprising 26% of the total population across both trials. Baseline mean (SD) EASI, BSA (%), WP-NRS, and Dermatology Life Quality Index (DLQI) scores were 21.9 (5.5), 28.1 (8.1), 8.2 (0.9), and 17.3 (6.9), respectively, with the latter indicating a very large effect on patients'' lives. At week 16, higher rates of skin clearance and itch relief were achieved with UPA15 or UPA30 treatment versus PBO, with many simultaneously achieving no/minimal itch and clear/almost clear skin (MDA). More patients treated with UPA vs PBO achieved no/minimal itch (WP-NRS 0/1) at week 16 (UPA15: 30.0%, UPA30: 54.0%, PBO: 4.5%). Optimal skin clearance outcomes of EASI ≤3 and EASI 90 were achieved by more patients on UPA 15 (59.3%; 52.1%) and UPA30 (76.3%; 72.7%) than on PBO (12.8%; 9.6%) at week 16. Outcomes for MDA, including simultaneous achievement of EASI ≤3 with WP-NRS 0/1 and EASI 90 with WP-NRS 0/1 were greater for UPA15 (24.3%; 22.9%) and UPA30 (50.4%; 48.9%), compared with PBO (3.2%; 2.6%) at week 16. Additionally, more patients treated with UPA versus PBO achieved no/minimal impact of AD on sleep (Atopic Dermatitis Impact Scale Sleep Question 2 [ADerm-IS Sleep Q2] 0/1; UPA15: 45.9%, UPA30: 57.4%, PBO: 10.6%), no/minimal skin pain (Atopic Dermatitis Symptom Scale [ADerm-SS Skin Pain] 0/1; UPA15: 39.7%, UPA30: 60.0%, PBO: 11.7%), and no impact of AD on quality of life (DLQI 0/1; UPA15: 26.1%, UPA30: 48.9%, PBO: 5.6%) at week 16.

Table 1. Achievement of Efficacy Endpoints at Week 16

Outcome	Placebo N = 156	UPA 15 mg N = 140	UPA 30 mg N = 139
Skin and Itch, % (n)			
EASI ≤ 3	12.8 (20)	59.3* (83)	76.3* (106)
EASI 90	9.6 (15)	52.1* (73)	72.7* (101)
WP-NRS 0/1	4.5 (7)	30.0* (42)	54.0* (75)
Minimal Disease Activity, % (n)			
EASI ≤ 3 + WP-NRS 0/1	3.2 (5)	24.3* (34)	50.4* (70)
EASI 90 + WP-NRS 0/1	2.6 (4)	22.9* (32)	48.9* (68)
Other Patient Reported Outcomes, % (n/N)			
DLQI 0/1	5.6 (8/143)	26.1* (35/134)	48.9* (64/131)
ADerm-IS Sleep Q2 0/1	10.6 (16/151)	45.9* (62/135)	57.4* (74/129)
ADerm-SS Skin Pain 0/1	11.7 (18/154)	39.7* (54/136)	60.0* (81/135)

*Nominal *P* value <.0001.
Nominal *P* values are based on Mantel-Haenszel tests adjusted for study and age.
Data are reported for the integrated patient population from Measure Up 1 and Measure Up 2; missing data were handled using non-responder imputation (NRI).
EASI 90 was defined as 90% improvement in EASI score from baseline.
EASI ≤ 3 corresponds to clear or almost clear skin.
WP-NRS score of 0/1 corresponds to no (0) or minimal (1) itch.
DLQI score of 0/1 corresponds to no impact of AD on quality of life.
ADerm-IS Sleep Question 2 assesses impact of AD on sleep and a score of 0/1 corresponds to no (0) or minimal (1) impact of AD on sleep.
ADerm-SS Skin Pain score of 0/1 corresponds to no (0) or minimal (1) skin pain.

ADerm-IS, Atopic Dermatitis Impact Scale; ADerm-SS, Atopic Dermatitis Symptom Scale; EASI, Eczema Area and Severity Index; DLQI, Dermatology Life Quality Index; NRI-NC, nonresponder imputation with no multiple imputation for assessments missing due to COVID-19; UPA, upadacitinib; WP-NRS, Worst Pruritus Numerical Rating Scale.

Conclusions

In itch-dominant patients with moderate-to-severe AD, more patients treated with UPA vs PBO achieved optimal treatment targets for itch relief, skin clearance, and MDA. Patients also reported no/minimal impact of AD on sleep, pain, and quality of life, suggesting that UPA provides meaningful benefits in daily lives of patients with itch-dominant AD.

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Abstract N°: 3417

Amlitelimab reduces atopic dermatitis (AD)-associated biomarkers in participants with moderate-to-severe AD: Results from Phase 3 COAST-1, COAST-2, and SHORE trials

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Introduction

Amlitelimab (SAR445229) is a fully human, non-depleting, anti-OX40 ligand (OX40L) monoclonal antibody that blocks OX40L during the inflammatory prequel which is upstream of T-cell expansion and inflammatory cytokine production in atopic dermatitis (AD). Amlitelimab inhibits T-cell–dependent pathogenic inflammation without depleting T cells. The efficacy and safety of amlitelimab has been evaluated in Phase 3 duplicate monotherapy trials, COAST-1 (NCT06130566) and COAST-2 (NCT06181435), and SHORE (NCT06224348) in combination with topical corticosteroids and/or topical calcineurin inhibitors (TCS/TCI). Across all 3 studies, the primary endpoint of validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) 0/1 at Week 24 was achieved. Progressive improvements in clear skin, disease severity, and itch, without plateau, were observed through Week 24 and amlitelimab was generally well tolerated. Here, the effect of amlitelimab treatment on AD-associated type 2 biomarkers (total IgE, TARC, IL-13, IL-31, blood eosinophil count), type 3 (IL-22, IL-17A) and type 1/3 (IL-12p40) biomarkers, as well as lactate dehydrogenase (LDH), an established AD severity-associated biomarker, was evaluated.

Materials and Methods

Eligible participants (aged ≥12 years) were randomly assigned 2:1:1 to subcutaneous amlitelimab 250 mg every-4-weeks (Q4W) with a 500 mg loading dose (+LD), 250 mg every-12-weeks (Q12W) +LD, or placebo for 24 weeks (doses [including LD] were halved for participants weighing <40 kg). In SHORE, all participants were on background TCS/TCI. Serum biomarkers (IgE, TARC, IL-13, IL-31, IL-22, IL-17A, IL-12p40) were measured from baseline to Week 24. Blood eosinophils and serum LDH were evaluated every 4 weeks. IL-31 was measured in COAST-2 only. For all other biomarkers, COAST-1 and COAST-2 data were pooled. Biomarker analyses included participants with a baseline and at least 1 post-baseline biomarker measurement.

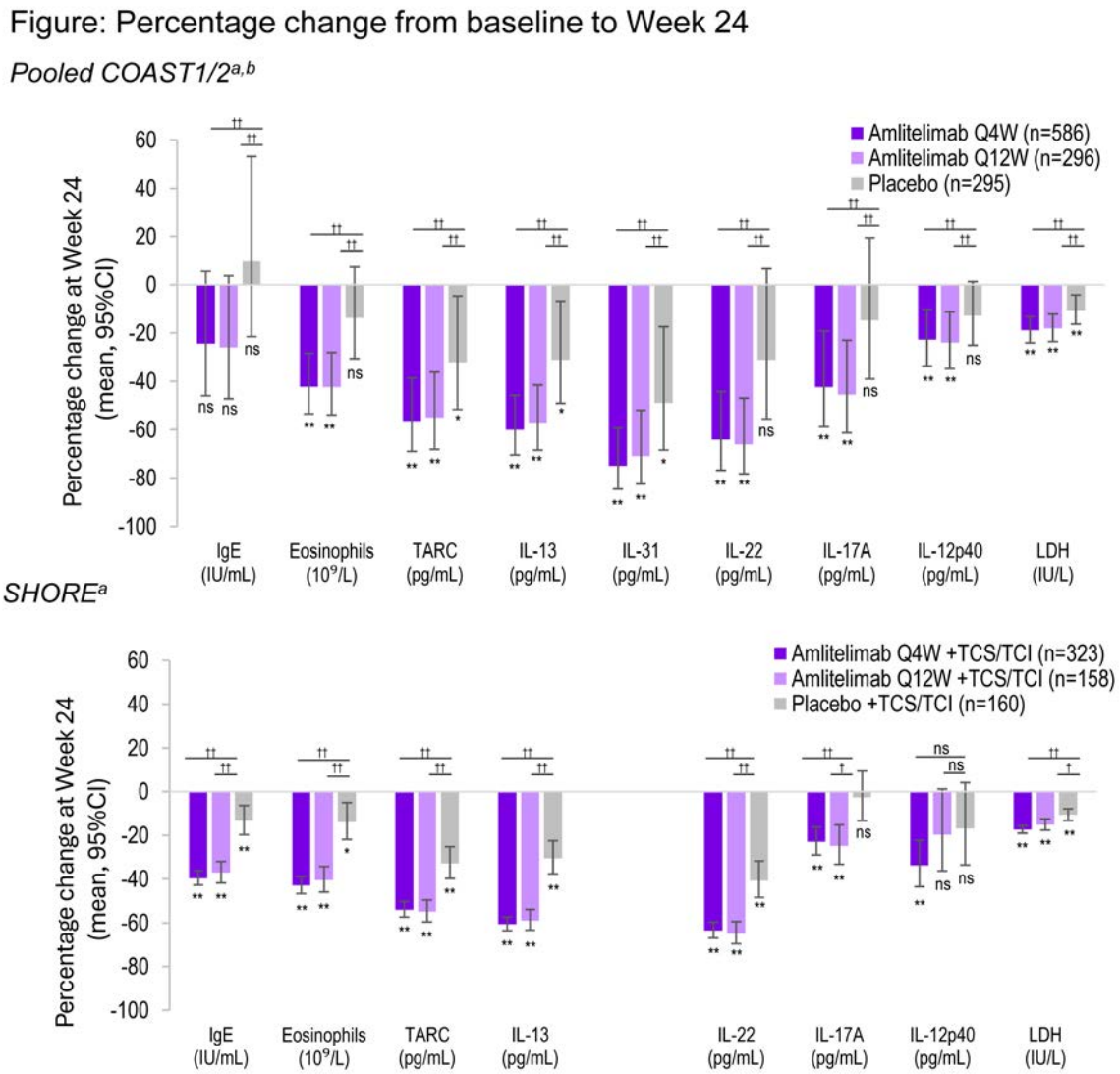
Results

Baseline biomarker levels were generally balanced across treatment arms in the 3 trials (COAST-1, N=601; COAST-2, N=589; SHORE, N=643), with the exception of the COAST-2 placebo arm, which showed lower baseline levels of blood eosinophils and serum LDH, IgE, and TARC than the amlitelimab arms. Between-group comparisons (amlitelimab Q4W or Q12W vs placebo) at Week 24 demonstrated significant reductions in type 2 biomarkers (total IgE, TARC, IL-13, blood eosinophils; $p<0.001$; Figure) in pooled COAST-1 and -2, and SHORE, as well as IL-31 (COAST-2 only). Significant between-group differences were consistently observed for type 3 biomarkers, with reductions ($p<0.05$) in IL-22 and IL-17A across trial analyses. IL-12p40 (a subunit of IL-12 [type 1], and IL-23 (type 3)] was significantly reduced with amlitelimab vs placebo ($p<0.001$) in the pooled COAST-1 and -2 data, whereas similar reductions were not seen in SHORE. Reductions in serum LDH levels with both amlitelimab dosing regimens were also observed compared with placebo ($p<0.05$). In pooled COAST-1 and -2, as well as in SHORE, eosinophils and LDH showed significant reductions with amlitelimab Q4W and Q12W vs placebo as early as Week 4 ($p<0.05$).

Conclusions

Across Phase 3 randomised clinical trials, amlitelimab treatment resulted in significant reductions in relevant AD biomarkers, including type 2-associated IgE, blood eosinophil count, TARC, IL-13, IL-31, and type 3-associated IL-22 and IL-17A, with mixed results observed for the type 1/3-associated cytokine IL-12p40. Reductions in LDH were observed, consistent with reduction of inflammation and disease improvement. Similar magnitudes of reduction were observed for both the Q4W and Q12W dose regimens, with effects observed as early as Week 4. Together, these significant reductions in AD-associated biomarkers support targeting the OX40L/OX40 costimulatory axis as a potential therapeutic approach for the chronic, heterogeneous inflammation driving AD pathogenesis.

Figure: Percentage change from baseline to Week 24



a. The p-value reflects the within-group comparison of post-treatment vs baseline biomarker values,

derived from the model on the log10 scale, or tests whether the differences in log10-fold changes between amlitelimab groups and placebo are statistically significant. All reported p-values are nominal and are not adjusted for multiplicity across biomarkers. b. IL-31 not available for COAST-1; therefore, IL-31 data are from COAST-2 participants only. † p≤0.05, † † p≤0.001 vs placebo. *p<0.05, **p≤0.001 vs baseline.

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Abstract N°: 3420

COMPARATIVE DRUG SURVIVAL, REASONS FOR DISCONTINUATION, AND PREDICTORS OF TREATMENT PERSISTENCE FOR DUPILUMAB AND UPADACITINIB IN ATOPIC DERMATITIS: A 297-PATIENT MULTICENTRE AUSTRALIAN STUDY

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with substantial impairment in quality of life and increased healthcare utilisation. Dupilumab and Upadacitinib are advanced systemic therapies approved for the treatment of moderate-to-severe AD and represent important alternatives to conventional systemic agents. However, real-world comparative studies on drug survival remain limited, particularly in Australian populations. This multicentre study aims to compare drug survival, treatment persistence, discontinuation patterns, and predictors of treatment discontinuation between Dupilumab and Upadacitinib in AD.

Materials and Methods

A total of 297 patients with moderate-to-severe AD treated with Dupilumab (n = 255), Upadacitinib (n = 11), or both (n = 31) were identified across six tertiary referral centres in Australia through retrospective registry and medical record review. Baseline demographic and clinical variables including age, sex, disease duration, atopic comorbidities, biologic exposure, EASI score, and treatment history were collected. Kaplan–Meier analyses were performed to estimate drug survival, and Cox proportional hazards models were used to identify predictors of treatment discontinuation.

Results

At data lock, 73 of 286 patients (26.0%) treated with Dupilumab had discontinued therapy, compared with 20 of 42 patients (47.6%) treated with Upadacitinib. Discontinuation patterns differed between therapies, with Dupilumab discontinuation most commonly related to loss to follow-up, patient preference, and reduced treatment efficacy, whereas Upadacitinib discontinuation was predominantly driven by loss of efficacy and treatment-related adverse events. Herpetic infections were a common side effect with Upadacitinib, whereas ophthalmic adverse events were more frequently associated with Dupilumab (Figure 1). Drug survival for Dupilumab was 95.4% at 26 weeks, 88.0% at 52 weeks, and 82.6% at 104 weeks, with persistence maintained beyond 200 weeks of follow-up. In comparison, Upadacitinib drug survival was 78.0% at 26 weeks, 75.5% at 52 weeks, and 56.1% at 104 weeks. Treatment line appeared to influence drug survival, with Dupilumab demonstrating higher persistence when used as first-line advanced therapy, whereas Upadacitinib demonstrated comparatively higher drug survival when utilised as a second-line or later therapy following prior advanced systemic treatment. In both univariable and multivariable analyses, Upadacitinib was associated with a higher risk of treatment discontinuation compared with Dupilumab. For Dupilumab, biologic-naïve status, longer disease duration, and the presence of atopic comorbidities were significant predictors of longer drug survival.

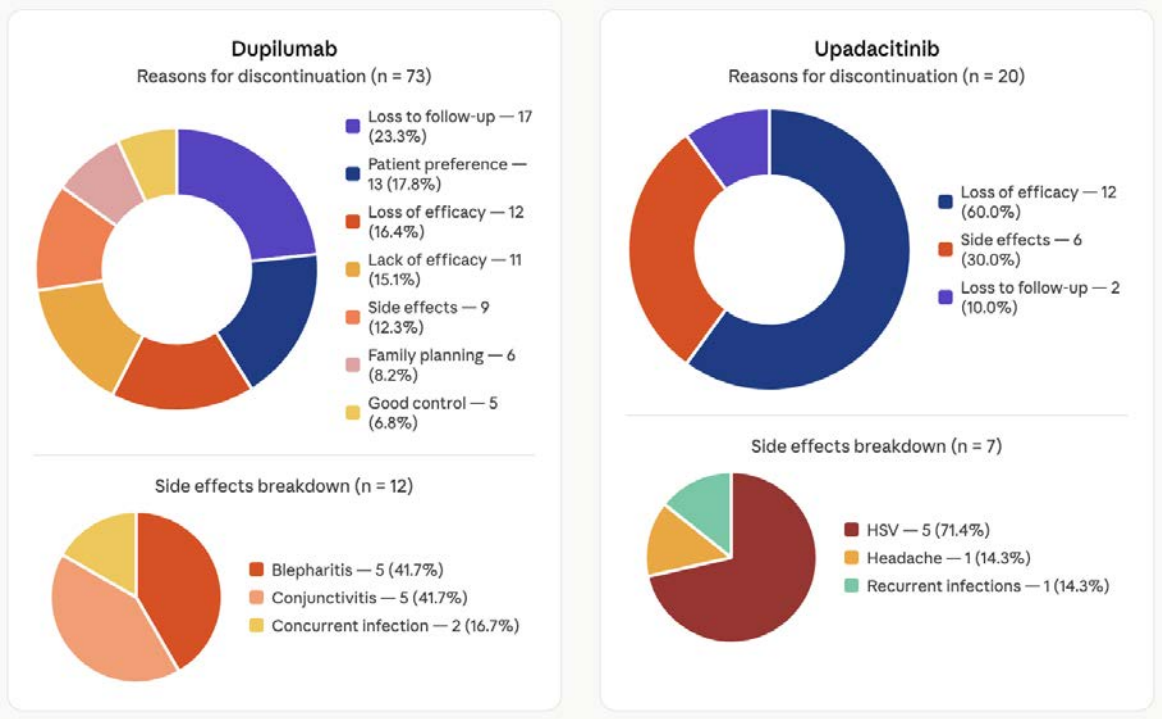

Figure 1. Reasons for treatment discontinuation and adverse event profiles among patients receiving Dupilumab and Upadacitinib for atopic dermatitis

Conclusions

These findings suggest that Dupilumab provides more durable treatment persistence and higher drug survival compared with Upadacitinib in real-world AD management. The higher discontinuation rate observed with Upadacitinib may in part reflect its use in more treatment-refractory or biologic-experienced patients, in addition to differences in adverse event profiles between therapies. Upadacitinib may offer more rapid symptom control and may be preferable in selected patients requiring faster disease improvement or with concomitant inflammatory conditions, whereas Dupilumab may be more suitable for patients with broader atopic comorbidities and those prioritising long-term treatment persistence. Our findings suggest that treatment sequencing may play an important role in long-term outcomes in AD, with Upadacitinib potentially representing an effective option for patients with treatment-resistant disease or prior biologic exposure, while Dupilumab may provide greater durability as a first-line advanced systemic therapy (Figure 2). These real-world multicentre Australian data provide clinically relevant insights to support treatment selection, sequencing of advanced systemic therapies, and optimisation of long-term outcomes in AD.

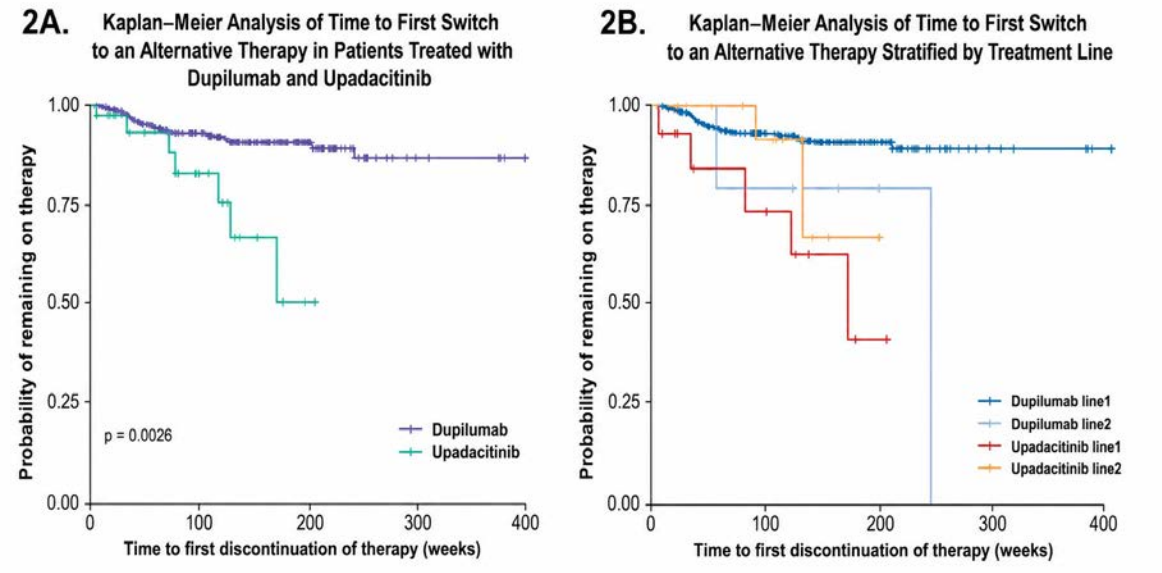

Figure 2. Kaplan–Meier Curves Demonstrating Time to First Discontinuation of Therapy for Dupilumab

and Upadacitinib Overall (2A) and Stratified by Treatment Line (2B)

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Abstract N°: 3425

Efficacy of amlitelimab in improving atopic dermatitis in participants who have failed or are naïve to advanced systemic therapy: Post hoc analysis from pooled COAST-1, COAST-2, and SHORE Phase 3 trials

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Introduction

Therapeutic options for individuals with moderate-to-severe atopic dermatitis (AD) have advanced in recent years to include treatments such as biologics and Janus Kinase (JAK) inhibitors. However, many individuals do not respond adequately to these advanced systemic therapies. Amlitelimab (SAR445229) is a fully human, non-depleting, anti-OX40 ligand (OX40L) monoclonal antibody that blocks OX40L during the inflammatory prequel, which is upstream of T-cell expansion and inflammatory cytokine production in AD.[1] The efficacy and safety of amlitelimab have been evaluated in Phase 3 duplicate monotherapy trials, COAST-1 (NCT06130566) and COAST-2 (NCT06181435), and in SHORE (NCT06224348) in combination with topical corticosteroids and/or topical calcineurin inhibitors (TCS/TCI). Across all 3 studies, the primary endpoint of validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) 0/1 at Week 24 was achieved. Progressive improvements, without plateau, were observed in skin clearance, disease severity, and itch through Week 24, and amlitelimab was generally well tolerated. Here, the efficacy of amlitelimab was evaluated in participants in COAST-1, COAST-2, and SHORE who failed prior advanced systemic therapies, as well as in those who were naïve to advanced systemic therapies.

Materials and Methods

COAST-1, COAST-2, and SHORE are Phase 3, randomised, double-blind, placebo-controlled trials. Eligible participants aged ≥12 years were randomised 2:1:1 to receive subcutaneous amlitelimab with a 500 mg loading dose (LD) followed by 250 mg every-4-weeks (Q4W), amlitelimab Q12W +LD, or placebo for 24 weeks (doses halved for participants <40 kg). In SHORE, all participants were on background TCS and/or TCI. Subgroup analyses evaluated the proportion of participants who achieved vIGA-AD 0/1 and Eczema Area and Severity Index (EASI)-

75 at Week 24 based on prior advanced systemic therapy failure (inadequate efficacy or intolerance to biologic or oral JAK inhibitor for AD) and advanced therapy-naïve status. As data from the 3 trials were pooled, participants were considered nonresponders after use of prohibited medications and study intervention discontinuation due to lack of efficacy. For Shore study only, participants were also considered nonresponders after use of rescue medication. All missing data were imputed as nonresponders. As no multiplicity adjustment was applied to the pooled analyses, all p-values are nominal.

Results

Across the 3 trials, 1833 participants were randomised and exposed to treatment. In participants with prior advanced therapy failure (placebo, n=80; amlitelimab Q12W, n=59; amlitelimab Q4W, n=136), a greater proportion of Q12W and Q4W amlitelimab-treated participants achieved vIGA-AD 0/1 at Week 24 (22.0% and 24.3%, respectively) compared with placebo (8.8%; Q12W, p=0.07 and Q4W, p=0.02 vs placebo). Similarly, a greater proportion of amlitelimab-treated participants who had prior advanced therapy failure achieved EASI-75 (Q12W, 37.3%; Q4W, 43.4%) compared with placebo (23.8%; Q12W, p=0.09 and Q4W, p=0.01 vs placebo). In participants naïve to advanced therapy (placebo, n=355; amlitelimab Q12W, n=364; amlitelimab Q4W, n=718), higher vIGA-AD 0/1 response rates at Week 24 were observed with amlitelimab Q12W (32.4%) and Q4W (29.2%) vs placebo (16.9%; p≤0.0001 for both comparisons), as well as higher EASI-75 response rate with amlitelimab (Q12W: 51.1%, Q4W: 48.5%) vs placebo (31.0%; p≤0.0001 for both comparisons).

Conclusions

In these pooled post hoc analyses, amlitelimab demonstrated consistent and progressive efficacy over 24 weeks in both participants who had previously failed advanced systemic therapy or were naïve to advanced systemic therapy. These results suggest that targeting the OX40L/OX40 pathway with amlitelimab may benefit individuals with moderate-to-severe AD regardless of prior advanced systemic therapy failure.

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Abstract N°: 3431

Title: Disease Patterns of Atopic Dermatitis with Pre- vs. Post-Pubertal Onset: A Machine Learning-Based Exploration of Clinical Heterogeneity and Immune Endotypes

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Introduction
Atopic dermatitis (AD) demonstrates marked heterogeneity according to age at onset, a factor that critically shapes disease trajectory and immune endotype. Taking 12 years as the threshold, this study investigated the immunological, clinical, and exposure-related differences between patients with pre-pubertal and post-pubertal onset AD, with the aim of providing a basis for stratified management and early prevention.

Materials and Methods
A total of 312 patients with AD were enrolled and stratified into a pre-pubertal onset group (≤12 years, n=169) and a post-pubertal onset group (>12 years, n=143). Comparisons were conducted on serum cytokine profiles, clinical severity and quality-of-life scores, complete blood counts, lesional skin microbiota, allergen sensitization patterns, family history, and non-specific clinical signs. LASSO regression and 12 machine learning classifiers (including Logistic-Ridge, SVM, and XGBoost) were employed to identify core discriminative variables and to construct predictive models. Model performance was evaluated using 5-fold stratified cross-validation, and SHAP (SHapley Additive exPlanations) analysis was applied to interpret feature contributions.

Results
Patients with pre-pubertal onset AD exhibited a mixed Th2/Th1/Th17 inflammatory pattern, characterized by significantly elevated levels of CCL22, CCL26, and IL-13, accompanied by higher eosinophil counts, greater Staphylococcus colonization, polysensitization to allergens, and a stronger family history of atopy. Clinically, this group was more frequently associated with flexural dermatitis, neck folds, and dry skin. In contrast, post-pubertal onset patients displayed a Th2-skewed endotype with more pronounced disease severity, greater impairment of quality of life and sleep, and a higher prevalence of truncal and special-site eruptions and wool intolerance. Machine learning analysis identified 25 key variables. The Logistic-Ridge model yielded the highest area under the curve (AUC) of 0.88, with satisfactory calibration and superior net clinical benefit. SHAP analysis identified CCL26 and high parental education level as the strongest predictors, followed by truncal rash, CCL22, limb rash, eosinophil count, and poor wool tolerance.

Conclusions
Systematic differences in immune endotypes, clinical phenotypes, and exposure backgrounds exist between patients with pre-pubertal and post-pubertal onset AD. The 25-variable Logistic-Ridge model provides a robust and interpretable framework for discriminating between these two patient populations, highlighting the potential for age-at-onset-driven risk stratification to inform early prevention and individualized therapeutic strategies.

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Abstract N°: 3437

ATOPIC DERMATITIS AND CHRONIC STRESS AS FACTORS REDUCING QUALITY OF LIFE AND PROFESSIONAL PERFORMANCE IN MILITARY PERSONNEL, WITH THE DEVELOPMENT OF AN INTELLIGENT MONITORING AND MANAGEMENT SYSTEM

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Introduction

Atopic dermatitis is a chronic inflammatory skin disease accompanied by itching, sleep disturbances, and a relapsing course. Chronic stress plays a significant role in modulating the immune response and can exacerbate the severity of dermatological manifestations. For military personnel, stress is systemic, leading to a reduced quality of life and professional performance. Given the lack of tools for early prognosis, the development of digital solutions for monitoring and managing patient conditions is a pressing issue.

Case Presentation

Research objective. To assess the impact of chronic stress on the course of atopic dermatitis, quality of life, and professional performance in military personnel, as well as to substantiate the development of an intelligent monitoring and personalized management system.

Materials and Methods.

A study was conducted on 240 military personnel with atopic dermatitis. Disease severity was assessed using the SCORAD scale, stress levels using the Perceived Stress Scale (PSS), and quality of life using the DLQI index. Professional performance was evaluated via a questionnaire. Correlation and regression analysis methods were used ($p<0.05$).

Results.

A statistically significant positive correlation was found between the level of chronic stress and the severity of atopic dermatitis ($r>0.4$; $p<0.05$). An increase in stress levels was found to be associated with a decrease in quality of life (DLQI) scores and professional performance. Patients with high stress levels demonstrated more pronounced clinical manifestations and reduced work capacity. The data obtained allowed for the identification of key predictors for the development of an intelligent monitoring system.

Conclusion

Chronic stress is a significant factor in the exacerbation of atopic dermatitis and the reduction of quality of life and professional performance in military personnel. The study substantiates the need to implement an intelligent monitoring and personalized management system aimed at the early detection of exacerbation risks and the optimization of therapeutic and preventive measures.

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Abstract N°: 3438

Long-Term Efficacy of Extending Dosing Interval of Stapokibart (Anti-IL-4Rα) in Chinese Adults with Moderate-to-Severe Atopic Dermatitis: 52-Week Results of a Phase II, Multicenter, Open-Label, Single-Arm Study

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Introduction
Atopic dermatitis (AD) is the most common chronic inflammatory skin condition. For patients with moderate-to-severe disease, its chronic and relapsing course significantly impairs quality of life. Stapokibart is a humanized anti-interleukin-4 receptor alpha (anti-IL-4Rα) monoclonal antibody that has been approved for adults with moderate-to-severe AD in China. This study aimed to evaluate the long-term efficacy of extending dosing interval of stapokibart in patients with moderate-to-severe AD.

Materials and Methods
This multicenter, open-label, single-arm phase II trial (NCT06116565) employed a response-adaptive design. Eligible patients received stapokibart 600 (loading dose)-300 mg every two weeks (Q2W) for the first 12 weeks. Based on treatment response at week 12, nonresponders (did not achieve ≥50% improvement from baseline in Eczema Area and Severity Index score [EASI-50]) were withdrawn from study, slow responders (achieved EASI-50 but not EASI-75 or Investigator's Global Assessment score of 0 or 1 [IGA 0/1]) continued Q2W dosing, and fast responders (achieved EASI-75 or IGA 0/1) were switched to Q4W. At week 36, a further adaptation was made: fast responders achieving EASI-90 or IGA 0/1 were switched from Q4W to Q8W, slow responders achieving EASI-90 or IGA 0/1 were switched to Q4W, while others continued their original regimens until week 52.

Results
A total of 262 patients were enrolled and received ≥1 dose of stapokibart. Of these, 256 patients completed the 12-week treatment. Among them, 10 (3.9%) patients were withdrawn due to nonresponse, 63 patients (24.6%) were identified as slow responders and continued Q2W dosing, and 183 patients (71.5%) were identified as fast responders and were switched to an extended Q4W dosing interval. A total of 232 patients completed the 36-week treatment and continued into the 52-week dosing period. Between weeks 36 and 52, 77.0% (141/183) of patients receiving Q4W were further stepped down to Q8W, and 44.4% (28/63) of patients receiving Q2W dosing were switched to Q4W. In the Q2W-Q4W-Q8W and Q2W-Q2W-Q4W groups, EASI-75 response rates at week 36 were 98.6% and 96.4%, respectively, and by week 52 they were 91.2% and 96.4%, showing no marked decline (Figure 1a). IGA 0/1 response rates at week 36 were 90.8% and 85.7%, and by week 52 they remained high at 75.7% and 78.6%, respectively (Figure 1b). In the Q2W-Q4W-Q4W and Q2W-Q2W-Q2W groups, EASI-75 response rates were 56.3% and 66.7% at week 36, which increased to 79.3% and 83.9% by week 52 (Figure 1a). The IGA 0/1 response rates at week 36 were 0% in both groups, rising to 55.2% and 22.6% by week 52, respectively (Figure 1b).

Conclusions
Extending the dosing interval of stapokibart based on efficacy response demonstrated sustained efficacy. These findings support the use of response-guided dosing interval extension as a viable long-term management strategy for moderate-to-severe AD.

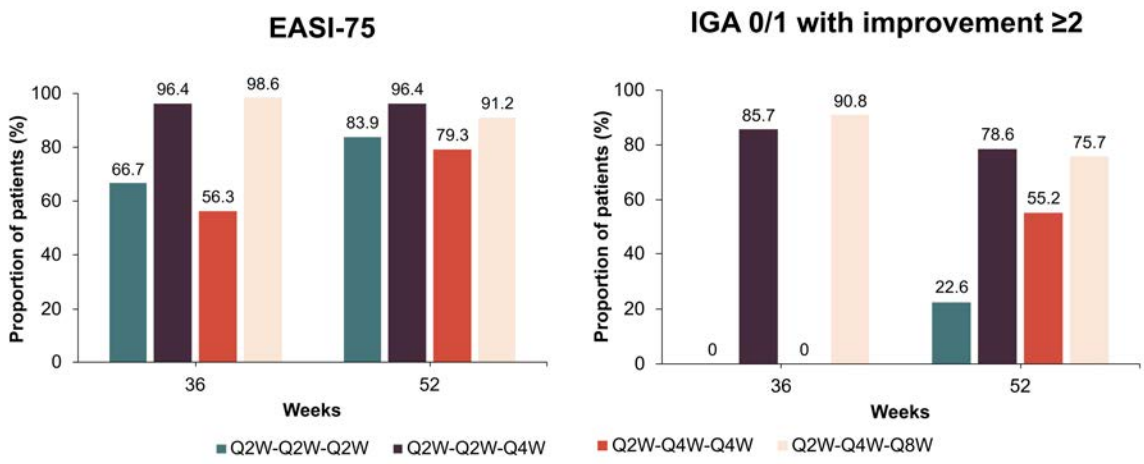

Figure 1. Proportions of patients achieving EASI-75 (a) and IGA 0/1 with ≥2-point improvement (b).

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Abstract N°: 3446

Evolving Treatment Dynamics and Persistent Unmet Need in Atopic Dermatitis: Insights from EU5 Dermatologists

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Introduction

The treatment landscape for atopic dermatitis (AD) has rapidly expanded with the introduction of advanced systemic therapies, including biologics and JAK inhibitors. Despite these innovations, heterogeneity in the disease, variability in severity, treatment response, and patient eligibility continue to challenge optimal disease management across EU5 markets.

Objectives: To assess current treatment patterns, unmet needs, and perceptions of recently approved and emerging therapies among dermatologists managing AD patients in the EU5.

Materials and Methods

Data are drawn from the RealTime Dynamix™ Atopic Dermatitis EU5 Q1 2026 insights, based on a quantitative survey of 250 dermatologists across France, Germany, Italy, Spain, and the UK, conducted between January and February 2026. The study evaluates patient unmet need, prescribing drivers, treatment utilization and satisfaction, and perceived barriers to the use of advanced systemic therapies.

Results

Nearly two-thirds of the adult AD patient population is moderate-to-severe, reinforcing their role as the primary candidates for advanced systemic therapies. Among surveyed physicians, 52% of adult moderate-to-severe AD patients who are treated with a prescription are treated with an advanced systemic therapy. Overall, pharmacologic treatment rates are high across all markets (85%-91%). Despite the wide range of therapies currently available, one-third of dermatologists continue to report a significant unmet need for new AD treatments.

The competitive landscape is increasingly dynamic and fragmented. Dupilumab maintains a leading position, currently garnering 47% of advanced systemic brand share; however, newer agents, including upadacitinib (15%) and lebrikizumab (14%), capture disproportionate new prescription share, signaling growing physician willingness to adopt alternative mechanisms. This shift reflects both expanding therapeutic optionality and a lack of clearly differentiated and universally effective treatments.

Treatment decision-making is driven by efficacy in skin clearance for all advanced systemic therapy options, efficacy in itch reduction (nemolizumab), safety profile (dupilumab and tralokinumab), and mechanism of action (lebrikizumab, nemolizumab). Dermatologists increasingly place an emphasis on mechanism-based differentiation as the number of available options grows. While satisfaction with currently available therapies is moderate to high (7.1 to 8.6 out of 10), the absence of strong preference for any single agent and emphasis on MOA differentiation suggests recent innovations are perceived as incremental rather than transformative.

Barriers to broader and earlier adoption of advanced systemic therapies persist, with 32% of physicians expressing

concerns about long-term safety with upadacitinib, 27% with abrocitinib, and 22% with baricitinib. Nearly one-quarter of physicians report that dupilumab faces patient concerns regarding needle phobia, and nemolizumab continues to face familiarity challenges with 22% of physicians and reimbursement barriers with 16% of physicians. These factors may contribute to delayed initiation and conservative use, even in patients who may benefit from earlier intervention.

At the same time, awareness of recently approved and emerging therapies is nearly universal, with 96% of dermatologists reporting unaided awareness of newly approved AD treatments. This underscores strong engagement with innovation while also reflecting an increasingly crowded and complex treatment landscape.

Conclusions

Although the AD treatment landscape is increasingly competitive, unmet need remains high, particularly in moderate-to-severe disease, due to ongoing challenges with efficacy, safety, patient selection, and access. Future differentiation depends on improved durable efficacy, enhanced safety and patient targeting. High awareness of emerging therapies highlights strong physician demand for novel treatments to address these persistent unmet needs.

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Abstract N°: 3451

ENV-294, a First-in-Class Oral Rac2 Modulator, Demonstrates Deep, Durable Efficacy with a Favorable Safety Profile in Moderate-to-Severe Atopic Dermatitis: Results from a Phase 1b Open-Label Study

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease driven by immune dysregulation spanning multiple endotypes, yet most approved therapies predominantly target the Th2/IL-4/IL-13 axis. ENV-294 is a first-in-class oral small molecule derived from a plant source that acts as an allosteric, non-degrading molecular glue selectively stabilizing the Rac2:RhoGDI complex—a previously unliganded intracellular GTPase that integrates upstream immune signals across Th1, Th2, and Th17 effector pathways. ENV-294 was safe and well tolerated in a randomized, placebo-controlled Phase 1 SAD/MAD study (n=72) with no clinically meaningful safety signals. Here we report efficacy and safety results from the Phase 1b open-label study of ENV-294 in adults with moderate-to-severe AD.

Materials and Methods

Adults (≥18 years) with moderate-to-severe AD received ENV-294 800mg once-daily (QD) for 28 days, followed by a 14-day off-treatment period (Day42). Primary endpoints included safety and tolerability. Efficacy endpoints included validated-Investigator's Global Assessment (vIGA), Eczema Area and Severity Index (EASI), SCORing AD (SCORAD), EASI-50/75/90 response rates, peak-pruritus numerical rating scale (PP-NRS), and Patient-Oriented Eczema Measure (POEM).

Results

All enrolled patients (N=9) completed treatment. At baseline, mean±SD EASI was 21.0 ±4.1, BSA 24.7% ±16.3, SCORAD 53 ± 7.5 and PP-NRS 6.8 ±1.7. ENV-294 was well tolerated with no serious adverse events (SAEs) and no treatment-related AEs; the sole AE was a mild, unrelated headache. No clinically significant laboratory changes, ECG abnormalities, or signs of immunosuppression were observed. Efficacy emerged rapidly and deepened through the 14-day off-treatment period, consistent with durable immune modulation. Mean EASI improvement reached 68% at Day 28 and 85% at Day 42, with all 9 patients (100%) meeting the EASI-50 threshold by Day 42. EASI-75 and EASI-90 were achieved in 44% and 33% of patients at Day 28, increasing to 78% and 56% by Day 42. Composite disease burden improved substantially: SCORAD 44% at Day 28 and 62% at Day 42. vIGA 0/1 (clear/almost clear) was achieved by 33% and 44% of patients at Days 28 and 42, respectively, including two patients who reached fully clear skin (vIGA=0). Patient-reported outcomes likewise improved: PP-NRS 20% at Day 28 and 38% at Day 42; POEM 35% at Day 28. Skin and plasma concentrations of ENV-294 exceeded the EC50 for target engagement approximately 5-fold.

Conclusions

ENV-294 achieved rapid, deep, and durable clinical responses across all efficacy endpoints with a favorable safety profile and no signals of immunosuppression. These findings provide a compelling rationale for advancing ENV-294 into Phase 2 development across the full spectrum of moderate-to-severe AD.

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Abstract N°: 3459

Real-World Efficacy and Drug Survival of Dupilumab in Atopic Dermatitis: Evaluating Patient Outcomes Under National Reimbursement Policy Mandates

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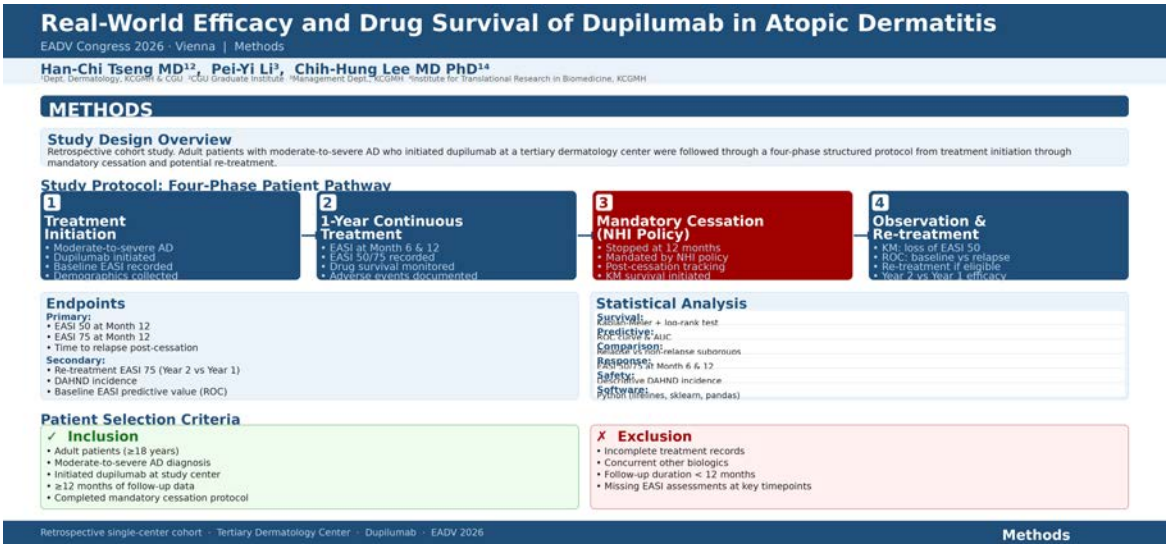
Introduction

Dupilumab demonstrates robust efficacy in moderate-to-severe atopic dermatitis (AD). However, regional reimbursement policies mandate treatment cessation after 1 year of continuous therapy, creating forced interruptions whose long-term clinical consequences remain poorly characterized. This study aimed to evaluate dupilumab outcomes, drug survival, and the clinical impact of policy-mandated treatment interruptions in a real-world retrospective single-center cohort.

Materials and Methods

A retrospective cohort analysis was conducted at a tertiary dermatology center. Patients with moderate-to-severe AD who initiated dupilumab were followed through a structured protocol comprising: (1) treatment initiation, (2) 1-year continuous treatment, (3) mandatory cessation per national reimbursement policy, and (4) observation and potential re-treatment. Efficacy was assessed using EASI 50 and EASI 75 at Month 12. Post-cessation survival analysis was performed using Kaplan-Meier methodology, with time to relapse (loss of EASI 50) as the primary endpoint. Baseline EASI as a predictor of relapse was evaluated by ROC analysis. Safety monitoring included assessment of dupilumab-associated head and neck dermatitis (DAHND).

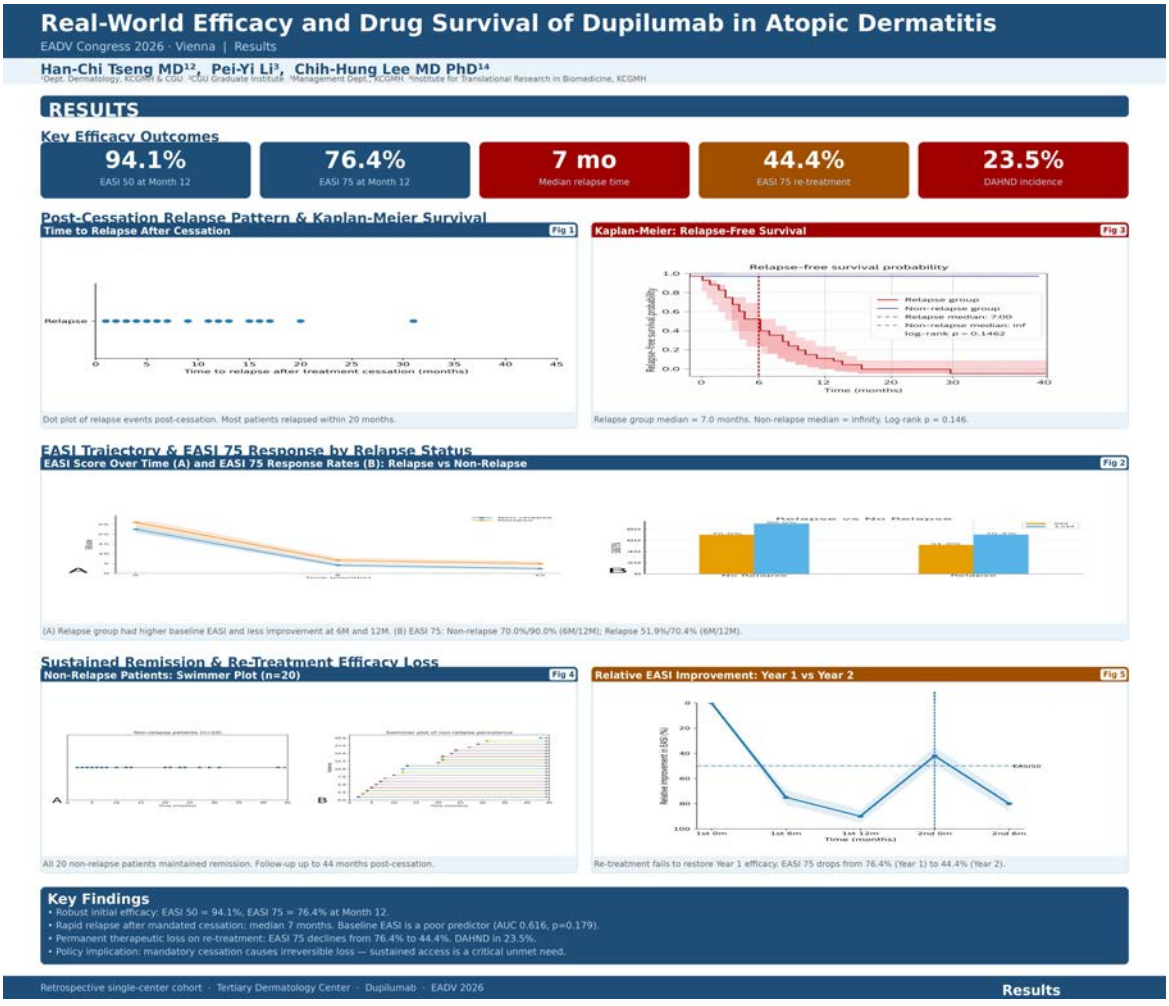


Results

At Month 12, 94.1% of patients achieved EASI 50 and 76.4% achieved EASI 75, confirming robust efficacy under continuous standard administration. Following mandatory cessation, Kaplan-Meier analysis demonstrated rapid disease relapse, with a median time to loss of EASI 50 of approximately 7 months post-cessation. Upon re-initiation (Year 2), re-treatment efficacy was substantially diminished: EASI 75 response declined to 44.4%, compared to 76.4% during the initial continuous treatment year. Baseline EASI demonstrated limited predictive value for long-term relapse (AUC = 0.616, p = 0.179). DAHND was observed in 23.5% of the cohort.

Key Findings:

- Robust efficacy interrupted: Year 1 therapeutic trajectories are artificially halted by mandates
- Rapid relapse: Median time to relapse of 7 months post-cessation
- Permanent therapeutic loss: Re-treatment EASI 75 response = 44.4% (vs. 76.4% at Year 1)
- Targeted safety monitoring: DAHND observed in 23.5% of the cohort



Conclusions

Policy-mandated dupilumab cessation results in rapid disease relapse and permanently degraded re-treatment efficacy, representing a critical and underappreciated consequence of reimbursement-driven interruptions. These real-world findings highlight a substantial unmet medical need for sustained, uninterrupted access to dupilumab in moderate-to-severe AD. Reimbursement policies should be re-evaluated in light of the long-term therapeutic loss imposed by mandatory cessation paradigms.

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Abstract N°: 3465

Long-term safety and efficacy (up to 152 weeks) of nemolizumab in ARCADIA open-label long-term extension study in adults and adolescents with moderate-to-severe atopic dermatitis.

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Introduction

Long-term clinical data are essential to establish sustained efficacy and safety of atopic dermatitis (AD) treatment. The ARCADIA long-term extension study (NCT03989206; 200-week duration) aimed to evaluate the safety and efficacy of nemolizumab in adults and adolescents with moderate-to-severe AD. Previously presented data suggested that nemolizumab showed continuous improvements in itch, skin lesions and sleep through week (W)104 with a favourable safety profile in patients with moderate-to-severe AD. Herein, we report safety data in all treated patients and efficacy data up to W152 at the time of the new data cut-off (July 2025).

Materials and Methods

This prospective, multicentre, open-label, long-term extension study enrolled nemolizumab-previously experienced [NPE] or nemolizumab-naïve [NN] participants from ARCADIA 1&2 phase 3 and other nemolizumab studies. Participants received nemolizumab 30mg every 4 weeks alongside background topical corticosteroids (low/medium potency) with or without topical calcineurin inhibitors. Efficacy endpoints included Investigator's Global Assessment (IGA) score of 0/1 (clear/almost clear), ≥50%/≥75%/≥90% improvement from baseline in the Eczema Area and Severity Index (EASI-50/EASI-75/EASI-90), ≥4-point improvement from lead-in baseline in visual analogue scale (VAS) Pruritus and in VAS Sleep loss of SCORing Atopic Dermatitis (SCORAD) score, SCORAD VAS Pruritus score <2, ≥4-point improvement from lead-in baseline in Dermatology Life Quality Index (DLQI) score, and DLQI score of 0/1. Efficacy outcomes are presented using as-observed (AO; observed cases [OC]; no imputations were made for missing data) analyses, and multiple imputation (MI) under a missing-at-random (MAR) assumption was conducted as a sensitivity analysis.

Results

Of 1901 treated participants, 1268 (67%) had completed W104 and 995 (52%) had completed W152 at the time of data cut-off. Of 1164 NPE participants and 737 NN participants, 72 (6%) and 39 (5%) respectively discontinued the study due to adverse events. At W152, the proportion of NPE and NN participants achieving efficacy outcomes (OC analysis) was 65% and 67% for IGA 0/1, 97% and 97% for EASI-50, 88% and 91% for EASI-75, and 72% and 75% for EASI-90, respectively; 88% and 86% achieved a ≥4-point improvement from lead-in baseline in SCORAD VAS Pruritus, 73% and 68% achieved a SCORAD VAS Pruritus score <2, 92% and 90% achieved a ≥4-point improvement from lead-in baseline in DLQI, and 57% and 59% achieved a DLQI score of 0/1, respectively. At W152, the proportion of NPE and NN participants achieving efficacy outcomes (MI analysis for MAR data) was 57% and 56% for IGA 0/1, 74% and 70% for EASI-50, 61% and 59% for EASI-75 and 46% and 46% for EASI-90, respectively. Improvements in sleep parameters mirrored those observed in itch parameters. The most frequently reported adverse events were nasopharyngitis, COVID-19, and dermatitis atopic. Exposure-adjusted incidence rates for any treatment emergent adverse events were 105 participants/100 person years (NPE) and 111 participants/100 person years (NN). Safety results corroborated those previously reported.

Conclusions

Long-term nemolizumab treatment was effective through W152 and well tolerated with a low study discontinuation rate due to adverse events. Sustained and continuous improvements were observed in skin lesions, itch relief, sleep disturbance and quality of life.

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Abstract N°: 3473

Achieving Minimal Disease Activity in Atopic Dermatitis is Associated with Improvements in Patient-Reported Outcomes, Irrespective of Actual Treatment Status

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Introduction

Atopic dermatitis (AD) is a chronic, inflammatory disease characterized by agonizing pruritus and recurrent eczematous lesions. The burden of AD affects all aspects of life including patients' psychological well-being, social functioning, sleep and work productivity. Consequently, treatment paradigms are focusing more on patient-centered goals. Minimal Disease Activity (MDA), a combined measure defined by physician-reported Eczema Area and Severity Index, EASI ≤3, and patient-reported 3-day-recall pruritus via Numeric Rating Scale, pNRS ≤1, is such a treatment target. It reflects a state in which the disease has negligible impact on patient's life. This study aimed to quantify the association between achieving MDA and psychosocial patient-reported outcomes in a large, real-world registry cohort of patients with AD, further stratified for patient visits with and without active systemic therapy (ST).

Materials and Methods

Longitudinal data from 2,367 adult patients from the TREATgermany registry, a prospective, non-interventional cohort study of patients with moderate-to-severe AD, were used. The correlations between the psychosocial outcomes Dermatology Life Quality Index (DLQI, range 0-30), depressive symptoms (CES-D, range 0-60), fatigue (FSS range 1-7), sleep disturbance (sleep, range 0-10), and the Work Limitations Questionnaire (WLQ; index score 0-28.6%) and EASI were analyzed. For each patient visit, a binary variable was created to indicate whether the MDA criterion (EASI ≤3 and pNRS ≤1) were met. The association of achieving MDA with the psychosocial outcomes was investigated. The relationship was analyzed using multiple linear regression models up to the 14th visit (n= 19,086 data points), with MDA status as the primary predictor. All models were adjusted for the confounding effects of age, sex, and visit number. To explore the influence of treatment, the analysis was stratified into two subgroups: data from visits where patients were receiving ST and data from visits where they were not.

Results

At registry inclusion, the mean age of the patients was 39.9 years, 53.7% were male. Patients exhibited a mean EASI of 14.9 and a mean pNRS of 5.72. The EASI was positively correlated (r=0.5 each) with pruritus, DLQI, and sleep. Strong positive correlations were also observed between pruritus and DLQI (r=0.7), pruritus and sleep (r=0.8), DLQI and sleep (r=0.7) and CES-D and WLQ (r=0.7). Initially, only 6% of all patients met the MDA criteria, this proportion increased to 25.1% by the 4th follow-up visit (after ~1.5 years), indicating an overall improvement

in disease control within the registry cohort over time. In ~85% of these visits' patients were on ST. The regression analyses revealed that achieving MDA was associated with improvements across all investigated outcomes, regardless of actual treatment status. In the subgroup of visits where patients were on ST, achieving MDA was associated with a mean reduction of 5.2 points in DLQI, a 5.2-point reduction in CES-D, and a 2.3-point reduction in sleep compared to not achieving MDA. For visits without ST, the observed effects were similar. Substantial improvements were also observed consistently for fatigue and work limitations in both the treated and untreated subgroups.

Conclusions

This large-scale, real-world analysis demonstrates that regardless of the current treatment status, achieving a state of MDA is associated with positive effects across multiple domains of life. Nonetheless, MDA is achieved to a greater extent in the ST group than in the group without therapy. The strong correlations between pruritus, sleep disturbance, and impaired quality of life further emphasize the interconnected nature of the disease burden. These findings underscore the dual importance of effective therapy to accelerate improvement and the validity of MDA as a comprehensive treatment goal to restore patients' overall well-being that should be considered in daily practice.

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Abstract N°: 3480

Characterization Of Intrinsic Atopic Dermatitis Revisited Using Multiplex Allergy Diagnostics

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Introduction

The so-called „extrinsic atopic dermatitis" (EAD) with increased total serum IgE (tIgE), atopic comorbidities and/ or specific sensitizations has been described in 75-80% of patients, lack of these features as „intrinsic AD" (IAD). The respective definition and rate of IAD vary within the literature. We aimed to re-evaluate IAD using multiplex allergy diagnostics.

Materials and Methods

Specific sensitizations of AD patients from the CK-CARE ProRaD cohort Bonn (n=826) were analyzed using multiplex assays (ISAC ImmunoCAP, Thermo Fisher). Strict IAD was defined as: 1.) tIgE age-dependent normal (age>15 y: ≥100 IU/ml), 2.) no atopic comorbidities (no asthma, no allergic rhinitis, no allergic conjunctivitis, no food allergy), 3.) no specific sensitizations measured by multiplex allergy diagnostics. Pseudo-IAD was defined as 1.+2, but sensitizations detected in the ISAC. The associations of IAD with clinical severity as measured by EASI and epidemiological features were analyzed using binary logistic regression and Factor analysis of mixed data followed by hierarchical clustering using Ward´s criterion.

Results

Only 7% featured strict IAD (n=59), 3% pseudo-IAD (n=25) and 90% (n=742) an EAD with a mean tIgE of 26, 58,

2,853 IU/ml, respectively. Atopic comorbidities were reported by 81% (n=670). An increased tIgE was detected in 73% (n=606) of patients, specific sensitizations in 85% (n=700).

Compared to EAD, both strict IAD and pseudo IAD were associated with (i) younger age (0-11 years, OR=3.30 [95% CI: 1.50; 7.27] for strict IAD, OR=4.63 [1.62;13.28] for pseudo-IAD), (ii) mild disease with an EASI≤7 (OR=2.88 [1.58; 5.26], OR=3.22 [1.27; 8.15]); (iii) less and distinct atopic stigmata. Strict IAD was additionally associated with (i) female gender (OR=2.55 [1.40; 4.67]); (ii) less eosinophilia (OR=0.26 [0.09; 0.74]), (iii) no parental atopic diseases (OR=2.46 [1.44; 4.20]), (iv) shorter disease duration (OR=0.89 [0.81; 0.98]/ per 5 years) and (v) living in a household ≥4 persons (OR=2.01 [1.18; 3.43]).

Conclusions

We identified a much lower rate of IAD than previously reported using strict definitions and new multiplex allergy diagnostics. Pseudo-IAD might represent a transient form between strict IAD and EAD. Traits associated with IAD point towards the development of specific sensitizations and EAD within an immunological march in severe and longstanding AD. The growing spectrum of sensitive allergy diagnostics including additional assays considering also sensitizations against auto-allergens and microbial allergens might enable us to unravel an even higher rate of sensitizations further reducing the rate of "true" strict IAD.

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Abstract N°: 3501

Long-Term Efficacy and Safety of Anti-IL-4Rα Stapokibart for Adolescents With Moderate-to-Severe Atopic Dermatitis: An Open-Label Extension Study of a Phase 3 Clinical Trial

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Introduction
Stapokibart, a novel monoclonal antibody targeting IL-4Rα, has been approved for the treatment of adults with moderate-to-severe atopic dermatitis (AD) in China. A phase 3 trial (NCT06277765) revealed high efficacy and favorable safety in adolescents with moderate-to-severe AD. At week 18, significantly higher proportions of patients receiving stapokibart than placebo achieved ≥75% improvement from baseline in the Eczema Area and Severity Index score (EASI-75; 73.9% vs. 43.3%) and Investigator's Global Assessment score of 0 or 1 with ≥2-point reduction from baseline (IGA 0/1; 57.1% vs. 25.0%). This open-label single-arm trial aimed to evaluate the long-term efficacy and safety in adolescents with AD.

Materials and Methods
This was an open-label extension study of the randomized phase 3 trial, which included an initial 18-week double-blind treatment period followed by a 36-week open-label treatment period and an 8-week safety follow-up

period. Adolescents with AD who participated in the parent study and completed the end-of-treatment visit were eligible to enroll voluntarily in this extension study. As the parent study remained blinded at the start of the extension study, to maintain blinding integrity, patients originally randomized to the stapokibart group received stapokibart 300 mg plus a matching volume of placebo subcutaneously (SC) for the first dose; patients from the placebo group received stapokibart 600 mg SC. All subsequent doses were stapokibart 300 mg SC. Dosing frequency followed the parent study protocol: Q2W for patients with baseline weight ≥60 kg and Q3W for those with baseline weight 30 to <60 kg. Data from both weight groups were pooled for analysis. Treatment-emergent adverse events (TEAEs) were analyzed in all stapokibart-exposed patients, encompassing the stapokibart-stapokibart group during weeks 0-62 and the placebo-stapokibart group during weeks 18-62.

Results

A total of 174 patients were enrolled in this extension study, including 116 in the stapokibart-stapokibart group (Q2W, n=50; Q3W, n=66) and 58 (Q2W, n=26; Q3W, n=32) in the placebo-stapokibart group. Two patients in the stapokibart-stapokibart group lacked post-dosing efficacy data and were excluded from efficacy analyses. EASI-75 response rates in the stapokibart-stapokibart group continued to increase during the extension study, reaching 87.4% and 93.5% at weeks 36 and 54, respectively; IGA 0/1 response rates were 60.4% and 66.7%. In the placebo-stapokibart group, EASI-75 response rates increased rapidly following stapokibart administration, reaching 86.0% and 96.4% at weeks 36 and 54; IGA 0/1 rates were 56.1% and 75.0%, respectively. During the follow-up period after completion of treatment, responses rates remained high in both the stapokibart-stapokibart and placebo-stapokibart groups, with EASI-75 rates of 85.8% and 98.1% and IGA 0/1 rates of 60.4% and 74.1% at week 62, respectively (Figure 1). Totally 545 TEAEs occurred in 144 (80.9%) patients (297.2 per 100 person-years); the majority were mild or moderate. The most common TEAEs (≥5/100 person-years) were upper respiratory tract infection (38.2%, 58.9/100 person-years), proteinuria (7.9%, 9.3/100 person-years), uric acid blood increased (6.7%, 7.6/100 person-years), abdominal pain (6.7%, 7.6/100 person-years), albumin urine present (3.9%, 6.5/100 person-years), pyrexia (6.2%, 6.0/100 person-years), blood bilirubin increased (5.1%, 6.0/100 person-years), acne (5.1%, 6.0/100 person-years), and cough (4.5%, 6.0/100 person-years). No TEAEs led to premature treatment discontinuation, study withdrawal, or death.

Conclusions

Stapokibart demonstrated robust efficacy and a favorable safety profile in adolescents with moderate-to-severe AD, with clinical benefits sustained in both groups up to 10-11 weeks after the last dose.

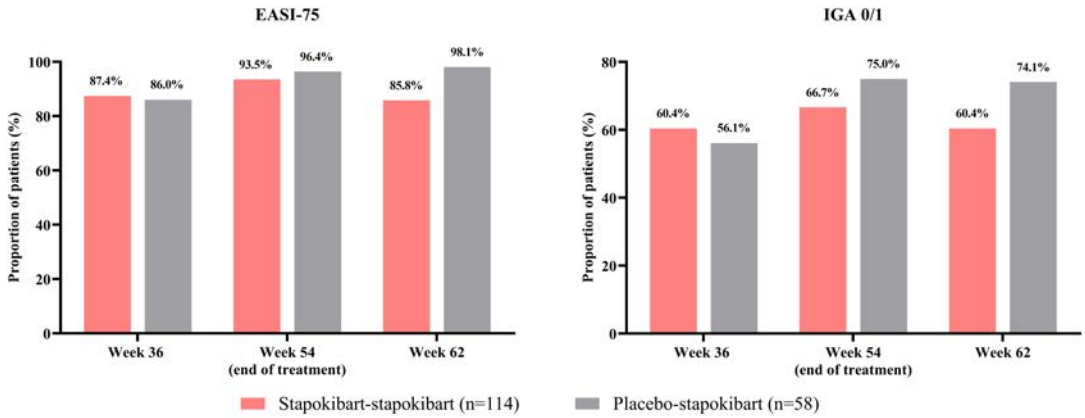

Figure 1 Proportions of patients achieving ≥75% improvement from baseline in the Eczema Area and Severity Index score (EASI-75) and Investigator's Global Assessment score of 0 or 1 with ≥2-point reduction from baseline (IGA 0/1) at weeks 36, 54, and 62.

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Clinical Benefits of an emollient containing Rhealba Oat and Helichrysum g. in the management of Atopic Dermatitis in skin of color: From Eczema Control to Dyspigmentation

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Introduction

Atopic dermatitis (AD) is a common chronic inflammatory disease in patients with skin of color (SOC). Individuals with phototypes IV-VI (Fitzpatrick scale) display specific clinical features: lesions are often less erythematous and more lichenified, sometimes predominantly papular, with a more frequent involvement of extensor areas of the limbs which may contribute to delayed diagnosis and underestimation of disease severity. Flares are frequently followed by post-inflammatory pigmentary changes (hyper- or hypopigmentation), resulting in persistent dyspigmentation and substantial aesthetic concerns, with a significant impact on quality of life. While emollients are a cornerstone of AD management, evidence remains limited regarding their specific impact on AD in SOC, particularly on post-inflammatory lesions. This clinical study aimed to assess the efficacy and tolerability of an emollient containing Rhealba Oat and *Helichrysum gymnocephalum* in infants, children and adults with phototypes IV–VI presenting mild-to-moderate AD, including as exploratory endpoints the assessment of dyspigmentation.

Materials and Methods

59 subjects aged 2 months to 45 years were included in a 4-week, monocentric, open-label clinical study. Main inclusion criteria were: mild to moderate AD with SCORAD between 15 and 30, xerosis intensity ≥ 2 (moderate; 0–3 scale), and pruritus intensity ≥ 3 (average for the last 3 days/nights; 0-10 visual analogic scale). The tested emollient was applied once daily. Assessments were performed at Day (D)1, D8 and D29 and included: AD severity (SCORAD, PO-SCORAD using Eczema Care+ app) and AD control (Atopic Dermatitis Control Tool; ADCT), pruritus, quality of life (Dermatology Life Quality Index for adults [DLQI], Children [CDLQI], and Infants [IDQOI]); tolerability evaluation and acceptability questionnaire. Exploratory endpoints focusing on post inflammatory dyspigmentation in adult subjects included the extent of dyschromic areas (based on SCORAD parameter A), as well as the intensity of pigmentation of one target post inflammatory hyperpigmentation (HPI) lesion (0-3 clinical scale) and image analysis (texture and pigmentation parameters) using high-resolution photographs (SKINCAM PRO).

Results

AD severity significantly improved, with SCORAD decreasing by 37% at D8 and 62% at D29 ($p<0.001$ at all timepoints). Xerosis and lichenification were significantly reduced, by 31% and 30% at D8 and by 54% and 47% at D29, respectively ($p<0.001$ at all timepoints). Pruritus and insomnia decreased by 44% and 64% at D8 and by 71% and 89% at D29 respectively ($p<0.001$ at all timepoints). PO-SCORAD showed a sustained reduction in AD severity of 52.8% at D8 and 75% at D29 ($p<0.001$ at all timepoints). In parallel, a clinically relevant improvement in AD control was observed at the end of the study with an ADCT score decrease of −8.11 points and a total score of 3.74 at D29, indicating adequately controlled AD. After 4 weeks of daily use, the extent of areas affected by dyschromia decreased by 33%, and pigmentation intensity (HPI) was significantly reduced, by 30.4% ($p=0.0059$).

A significant improvement in quality of life was observed at D29 ($p<0.001$). Tolerability of the emollient was assessed as good by the investigator. Subjects or parents were very satisfied by the cosmetic qualities and the efficacy of the product. Finally, image analysis in adult subjects showed an improvement of color homogeneity and a smoothing of skin texture at the end of the study.

Conclusions

These results demonstrate the benefit of an emollient containing Rhealba Oat and *Helichrysum g.* in improvement in AD severity, symptoms, disease control and quality of life in patients with SOC, with good tolerability and cosmetic acceptability. Moreover, exploratory data suggest a positive effect of the product on post-inflammatory dyspigmentation and support its specific benefit as an adjunctive care in this population prone to pigmentary sequelae.

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Abstract N°: 3509

Tolerance and efficacy of a new emollient dedicated to the face containing Rhealba oat and Helichrysum g. in the long-term management of atopic dermatitis: an open-label, monocentric study

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease with a significant impact on the quality of life. Involvement of the face is very common and clinically significant, as facial skin is thinner, more exposed to environmental aggressors, and more visible, resulting in greater discomfort, stigmatization, and psychosocial burden for patients. The essential requirements for an emollient are safety, efficacy and good cosmetic acceptability, in order to ensure optimal compliance. A new gel cream emollient with a light texture specifically dedicated to the face and containing Rhealba oat and *Helichrysum gymnocephalum* has been developed. The aim of this study was to assess the long-term tolerance, and efficacy of this new emollient product in subjects with atopic dermatitis on the face.

Materials and Methods

33 adult subjects aged 18 to 67 years (mean age: 41) were included in a 3-month open clinical study. Main inclusion criteria were: AD with Local-SCORAD (L-SCORAD) ranging between 3 to 8, xerosis intensity ≥ 1 (mild) on a 0-3 scale, pruritus intensity ≥ 2 (on average over the previous 3 days on 0-10 numeric rating scale/ NRS) and at least one peak of xerosis and pruritus per month reported by the subjects during the 3 previous months. Tested emollient was applied twice daily. Assessments were performed at Day (D)1, D4, D8, D29, and D85 and included tolerance evaluation, AD severity (L-SCORAD), pruritus and discomfort assessment (NRS), quality of life (Dermatology Life Quality Index; DLQI), and number of peaks of xerosis and pruritus.

Results

After 3 months of twice-daily use, the emollient's tolerance was assessed as very good by the dermatologist. AD severity significantly improved with a L-SCORAD decrease by -62% at D4, -75% at D29 and - 92% at D85 ($p<0.0001$ at all timepoints). Xerosis was significantly decreased by -76% at D4 and D29and -96% at D85 ($p<0.0001$ at all timepoints). Pruritus (average intensity over the previous 3 days) decreased by 87% at D4, -89% at D29 and 97% at D85 ($p<0.0001$ at all timepoints). Moreover, pruritus and discomfort decreased immediately after the first use of the product by respectively 88% and 86% ($p<0.0001$). A significant improvement in quality of life was observed (DLQI; -86% at D85, $p<0.0001$) and the product was judged as effective and very effective for 97% of the subject after 3 months of use. Finally, none of the subjects reported any peak of xerosis and pruritus during the study.

Conclusions

The efficacy results of this study demonstrate the benefit of this new gel cream emollient dedicated to the face in

improving the long-term management of atopic skin condition. Moreover, its light texture combined with its very good tolerability, could help to ensure long-term compliance.

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Abstract N°: 3515

Benefit of an emollient containing Rhealba oat and Helichrysum g. in combination with tacrolimus 0.1% in patients with eyelid atopic dermatitis: a randomized, intra-individual, split-face study

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease with a significant impact on quality of life. Eyelid involvement is common and particularly challenging due to the thinness, high sensitivity and visibility of the periocular skin. Topical calcineurin inhibitors (TCI), such as tacrolimus, are recommended for eyelid AD flare-ups treatment to avoid steroid-related adverse effects on such a sensitive area. However, burning and pruritus are frequently reported, especially at treatment initiation, and may negatively affect patient comfort and adherence. A new emollient cream specifically dedicated to the eyelid area, containing Rhealba oat and *Helichrysum gymnocephalum (H.g),* has been developed. The aim of this study was to assess the benefit of this new product, when applied in association with tacrolimus 0.1% in subjects suffering from eyelid AD flare-up.

Materials and Methods

33 adult subjects aged 18 to 50 years (mean: 28 yrs) were included in a 2-week, intra-individual, randomized, split-face clinical study. Main inclusion criteria were eyelid atopic dermatitis flare-up with bilateral involvement of similar extend and intensity requiring TCI treatment (Tacrolimus 0.1%) initiated within the previous 24hrs; xerosis intensity ≥1 (mild) and erythema =2 (moderate) on a 0-3 scale; pruritus intensity and discomfort's sensation ≥4 (on average over the past 24hrs on 0-10 numeric rating scale, NRS). Eyelids were randomized to receive twice daily treatment with either TCI alone or a combination of TCI and tested emollient (applied 2hrs prior to TCI). Assessments were performed at Day (D)1, D3, D5, D8, and D15 and included pruritus and discomfort assessments (NRS), AD severity (L-SCORAD), investigator and subject global assessment of evolution of eyelid AD (IGA and SGA), tolerability, as well as cosmetic acceptability and perceived efficacy questionnaires.

Results

The results showed a significantly greater improvement in pruritus (mean and maximal intensity over the past 24hrs) at all timepoints (except D15), on the eyelid treated with the combination TCI and tested emollient compared to the eyelid treated by TCI alone (At D3: mean pruritus intensity: −48% vs −33%; p=0.0018). Discomfort intensity decreased by 77% (p<0.0001) immediately after the first emollient application on D1, and a significantly greater improvement in discomfort (mean intensity) was observed at D5 in favor of the combination versus TCI alone (p=0.0229). AD severity improved on both eyelids, with a significantly greater reduction in L-SCORAD at D3 on the eyelid treated with the combination TCI-tested emollient compared with TCI alone (−53% vs −41%; p=0.0018). A significantly greater improvement in erythema was also observed in favor of the combination at D3 and D5 (−47% vs −36%, p=0.0156 at D3; −74% vs −62%, p=0.0078 at D5), as well as in xerosis at D3 (−58% vs −40%; p=0.0039). An improvement in eyelid AD was observed by the investigator in 67%

of subjects at D3 on the eyelid treated with the product combination, versus 46% on the eyelid treated with TCI alone. After 2 weeks of twice-daily use in association with Tacrolimus 0.1%, the tolerability of the emollient was assessed as very good by the dermatologist. Cosmetic acceptability of the tested emollient was rated as very good. Subjects reported the product as effective in limiting the occurrence of skin discomfort and supporting the adherence of the medical treatment.

Conclusions

These results demonstrate the benefits of a new emollient cream specifically dedicated to the eyelid area, containing Rhealba oat and *H.g.*, when used in combination with tacrolimus 0.1%, providing faster relief of pruritus and discomfort and improvement of AD severity. Its very good tolerability and cosmetic acceptability suggest that this supportive care product may help improve patient comfort and support treatment adherence in the management of eyelid atopic dermatitis.

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Abstract N°: 3516

Eczema burden beyond the skin: psychological, socioeconomic, and occupational outcomes in US adults

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Introduction
Eczema, including atopic dermatitis (AD), is increasingly recognised as a chronic systemic condition with consequences well beyond the skin. Adult eczema has been linked to depression, anxiety, occupational impairment, and reduced quality of life, yet most analyses rely on single-year surveys or administrative cohorts that cannot simultaneously address psychological, healthcare access, socioeconomic, and occupational outcomes within the same contemporary population. Few studies adequately account for the non-atopic multimorbidity disproportionately affecting adults with eczema, and its downstream economic consequences (cost-related medication non-use, food insecurity, housing-cost hardship) have rarely been quantified in a unified framework. Thus, here we quantify the multidimensional burden associated with current eczema in US adults and assess its heterogeneity by socioeconomic status, sex, and race/ethnicity.

Materials and Methods
We pooled 2021 and 2024 National Health Interview Survey sample-adult data (n=62,019), the two most recent years in which the itchy-rash/eczema item was fielded. Current eczema was defined as a self-reported itchy rash due to eczema or atopic dermatitis in the past 12 months. Twenty outcomes were grouped a priori into six thematic blocks: atopic comorbidities; mental health (including Kessler-6 serious psychological distress, K6≥13); perceived health; barriers to care; socioeconomic precarity; and occupational impact. Design-based multivariable logistic regression using Taylor-series linearisation under the NHIS complex survey design estimated adjusted odds ratios (OR) controlling for age, sex, race/ethnicity, education, and a disability-weighted non-atopic comorbidity score. Prespecified sensitivity analyses added atopic comorbidities and income/insurance to the adjustment set, and we tested interaction with poverty, sex, and insurance, and conducted supplementary race/ethnicity-stratified analyses.

Results
Current eczema had a weighted prevalence of 10.8% (n=6,802). Adults with eczema had higher adjusted odds across every examined outcome domain: any atopic comorbidity (OR 2.63, 95% CI 2.43–2.85), asthma (2.12, 1.96–2.29), respiratory allergy (2.38, 2.21–2.55), and food allergy (2.62, 2.41–2.85); serious psychological distress (2.02, 1.77–2.30), frequent anxiety (1.84, 1.72–1.97), frequent depression (1.89, 1.73–2.07), and life dissatisfaction (1.90, 1.55–2.33); poor/fair self-rated health (1.60, 1.46–1.76); cost-related medication non-adherence (1.98, 1.79–2.20), delayed medical care due to cost (1.72, 1.55–1.91), and difficulty doing errands (1.76, 1.58–1.96); food insecurity (1.39, 1.23–1.57), SNAP receipt (1.22, 1.09–1.36), and inability to pay housing costs (1.49, 1.26–1.76); work limitation (1.65, 1.52–1.79) and ≥5 missed workdays (1.28, 1.16–1.40). Estimates were stable across 2021 and 2024 and attenuated by only 8–15% after additional adjustment for atopic comorbidities, indicating that these associations persisted. Adding income and insurance to the model changed estimates by less than 5% for every outcome. Associations were broadly consistent across poverty, insurance, sex, and race/ethnicity subgroups, with modest amplification below 200% of the federal poverty level for atopic comorbidity and work limitation.

Conclusions

In a large, contemporary, nationally representative US sample analysed with proper complex-survey variance estimation, current eczema is independently associated with substantial psychological, access-related, socioeconomic, and occupational burden that persists after adjustment for non-atopic and atopic multimorbidity. Findings support a broader, more integrated approach to adult eczema that couples skin-directed therapy with routine screening for psychological distress and financial toxicity in dermatology encounters.

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Effectiveness and Safety of Lebrikizumab in Moderate-to-Severe Atopic Dermatitis in Routine Care: Data from the TREATgermany Registry

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Introduction
Lebrikizumab, a high-affinity monoclonal antibody targeting interleukin-13, has demonstrated robust efficacy and safety in phase 3 trials in moderate-to-severe atopic dermatitis (AD). However, routine care data on treatment pattern, effectiveness and safety remain limited.

Objectives:
To evaluate clinical effectiveness and safety of lebrikizumab in routine care in Germany.

Materials and Methods
Data were analyzed from the TREATgermany registry. Adult AD patients initiating lebrikizumab until December 2024 were included. Real-world use was assessed by baseline characteristics, prior systemic therapy (switchers vs. non-switchers), and treatment persistence. Effectiveness outcomes included Investigator Global Assessment (IGA), Eczema Area and Severity Index (EASI), objective SCORAD (oSCORAD), and multiple patient-reported outcomes (PROs), including Patient Oriented Eczema Measure (POEM), Recap of atopic eczema (RECAP), peak pruritus (PP), Dermatology Life Quality Index (DLQI), and retrospectively reported well-controlled (i.e., causing only minor symptoms) and completely controlled (i.e., causing no symptoms) weeks within the previous 12 weeks. Safety was assessed by adverse event reporting. A severity-based subgroup ("trial-like cohort") with baseline EASI ≥16 was analyzed to contextualize results with phase 3 trials.

Results
Among 108 patients initiating lebrikizumab, follow-up data were available for 80 patients. Fifty-four patients (50%) switched from prior systemic therapy, while 54 (50%) were therapy-naïve or off systemic therapy for ≥4 weeks. Switchers more frequently had asthma (55.8%) than non-switchers (23.4%; p=0.001). Baseline disease severity was notably higher in non-switchers (mean EASI 10.3 ± 9.0 vs 18.6 ± 10.0). Both subgroups reached comparably low absolute EASI and oSCORAD over the treatment period at 3 and 6 months. However, the interpretation of the data is limited by two small patient populations with different baseline characteristics.

In the overall cohort, mean EASI decreased from 14.8 at baseline to 5.6 at 3 months (-62%) and 3.0 (-80%) at 6 months. EASI-75 was achieved by 37.1% of patients at 3 months and 66.7% at 6 months. Improvements were also observed in oSCORAD, IGA, PGA, and all PRO measures, including POEM (–7 and –8 points), RECAP (–7.3 and –7.8 points) and DLQI (–7 and -7.1 points) at 3 and 6 months, respectively. Patients reported a more than doubled

number of well- and completely controlled weeks within the past 12 weeks over the treatment period.

The trial-like cohort (n=32, mean baseline EASI 25.9) showed similar patterns, with mean EASI reductions to 6.4 (-75.3%) and 3.8 (-85.3%) at 3 and 6 months, respectively, with EASI-75 rates of 60% and 70%.

The most frequently reported adverse event was conjunctivitis, occurring in 13 patients (20,3%). %). In five of these patients conjunctivitis had been reported with previous dupilumab treatment. Other adverse events were infrequent and mostly mild or moderate. No new safety signals were detected. Overall, these observations support the conclusion that lebrikizumab has a manageable safety and tolerability profile in daily practice.

Conclusions

In routine care, lebrikizumab demonstrates favorable effectiveness and safety consistent with randomized controlled trials. Taken together, these data from TREATgermany support its role as an effective treatment option in patients with moderate-to-severe AD, including those previously treated with other systemic therapies.

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Abstract N°: 3550

Dupilumab Improves Patient and Caregiver Quality of Life and Productivity Among Adolescents with Moderate-to-Severe Atopic Dermatitis in Clinical Practice: 1-Year Results From the RELIEVE-AD-PEDs Study

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Introduction

Treatment of moderate-to-severe atopic dermatitis (AD) with dupilumab has been shown to significantly improve quality-of-life (QoL), and sleep quality thus reducing the burden of disease experienced by adolescents and their caregivers in clinical trials and real-world studies. This analysis evaluated dupilumab's impact on QoL and productivity among adolescent patients with moderate-to-severe AD and their caregivers based on one-year interim data from the RELIEVE-AD-PEDs real-world study.

Materials and Methods

RELIEVE-AD-PEDs is an ongoing, prospective, longitudinal survey study of pediatric patients aged 6m – 17y with moderate-to-severe AD who initiated dupilumab, and their caregivers, recruited from DUPIXENT MyWay®, a patient support program. This analysis included all enrolled adolescent patients aged 12-17 years and their caregivers. Eligible patients from the USA and their caregivers completed surveys at baseline before dupilumab initiation and at multiple time points after dupilumab initiation. The impact of AD on patient's QoL was evaluated with the Children's Dermatology Life Quality Index (CDLQI) range 0-30, with a minimal clinically important difference (MCID) of 6 points. Caregiver and family burden was further assessed using the Dermatitis Family Impact questionnaire (DFI; range 0-30; higher scores indicate greater impact). Sleep disturbance was assessed using the Patient-Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance score. The Work Productivity and Activity Impairment Questionnaire (WPAI) was used to assess absenteeism, presenteeism, productivity impairment and activity impairment for adolescent patients in terms of classroom attendance and caregivers in terms of work. Outcomes were self-reported by adolescent patients and caregivers, respectively.

Results

At the time of this interim analysis, 126 of 314 patients (40.1%) initiating dupilumab completed 12 months of dupilumab treatment and responded to the Month 12 survey. Mean (standard deviation [SD]) CDLQI total score improved from 11.9 (6.5) at baseline to 4.4 (5.5) at Month 12 ($p<0.001$). 74.8% achieved the MCID for CDLQI at Month 12. Caregiver-reported DFI had improved from a mean (SD) score of 9.3 (6.6) at baseline to 2.9 (5.1) at Month 12 ($p<0.001$), with 83.3% of the caregivers reporting normal QoL (DFI 0/1) vs 33.8% at baseline ($p<0.001$). Sleep disturbance was reported as moderate or severe in 57.0% of adolescents at baseline, vs 20.6% at Month 12 ($p<0.001$). Caregiver sleep disturbance was reported to be moderate or severe in 19.1% at baseline, which improved to 8.7% by Month 12 ($p<0.01$). Absenteeism, presenteeism, total productivity impairment and total

activity improvement were all substantially improved at the time of the Month 12 survey vs baseline for caregivers in terms of work and adolescent patients in terms of classroom attendance.

Conclusions

In this real-world study, the majority of adolescent patients with moderate-to-severe AD and their caregivers achieved meaningful improvement in QoL, as well as impact on sleep, after 12 months of dupilumab treatment. Furthermore, most of the adolescent patients and their caregivers reported substantial improvement in work/school productivity and activities at Month 12.

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Abstract N°: 3552

OX40/OX40L Clinical Response Lag: A Systematic Review And Pharmacodynamic Analysis Of Amiltelimab, Rocatinlimab, And Ivarmacitinib. Proposing A New "Delayed Onset" Classification System For T-Cell Rebalancing Therapies In Atopic Dermatitis

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Introduction

OX40/OX40L pathway inhibitors (amlitelimab, rocatinlimab, ivarmacitinib) are a newer class of T-cell rebalancing therapies for moderate-to-severe atopic dermatitis (AD). Unlike conventional biologics such as dupilumab, which show onset within 2–4 weeks, these agents consistently show a "response lag" of 8 to 16 weeks. No formal framework currently exists to describe or predict this delayed onset. This review quantifies that response lag, identifies its pharmacodynamic drivers, and proposes a practical classification system.

Materials and Methods

A systematic search of PubMed, ClinicalTrials.gov, and EMBASE (2018–2026) identified 12, phase 2b/3 trials involving 3,847 patients treated with amlitelimab (4 trials), rocatinlimab (5 trials), or ivarmacitinib (3 trials). EASI-75, IGA 0/1, and peak pruritus NRS scores were extracted at weeks 2, 4, 8, 12, 16, and 24. Pharmacodynamic data included $OX40^+$ memory T-cell suppression, Treg restoration, and serum OX40L levels. Mixed-effects modeling determined time-to-response thresholds. "Response lag" was defined as time from first dose to achieving ≥15% absolute EASI reduction above placebo.

Results

All three agents showed minimal EASI-75 separation from placebo at week 4 (mean difference 4.2%, 95% CI –1.1 to 9.5). By week 12, separation accelerated significantly to 24.7% (95% CI 18.3–31.1, $p<0.001$), peaking at week 24 with a difference of 38.9% (95% CI 31.2–46.6). Median time to first meaningful response was 10.3 weeks for amlitelimab (IQR 8.1–13.2), 11.6 weeks for rocatinlimab (IQR 9.0–14.1), and 9.1 weeks for ivarmacitinib (IQR 7.2–11.5). Peak $OX40^+$ $CD4^+$ T-cell suppression (>75% reduction) occurred at weeks 14–18, coinciding with maximal Treg expansion (2.8-fold, $p=0.002$). A new "Delayed Onset" classification system is proposed: Class D1 (partial lag, response by week 8), Class D2 (full lag, response between weeks 8 and 16), and Class D3 (prolonged lag, response after week 16). Across all trials, 71% of eventual responders met D2 criteria. Predictors of longer lag included baseline OX40L >450 pg/mL (hazard ratio for early response 0.41, $p=0.003$) and prior cyclosporine use (HR 0.58, $p=0.01$).

Conclusions

OX40/OX40L inhibitors have a consistent, predictable response lag of 8 to 16 weeks, driven by gradual T-cell rebalancing rather than immediate cytokine blockade. The proposed D1–D3 classification system offers clinical guidance to prevent premature treatment discontinuation. Lack of early response does not indicate treatment failure. An 18-week minimum therapeutic trial is recommended before switching therapies.

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Sustained Disease Control Among Adolescents with Moderate-to-Severe Atopic Dermatitis Treated with Dupilumab in Clinical Practice: 1-Year Results From the RELIEVE-AD-PEDs Study

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Introduction

Treatment with dupilumab has been shown to be effective and have a favorable safety profile in controlling moderate-to-severe atopic dermatitis (AD) in clinical trials and real-world studies. This analysis evaluated the long-term effectiveness of dupilumab in adolescents (12-17 years old) with moderate-to-severe AD based on one-year interim data from the RELIEVE-AD-PEDs real-world study.

Materials and Methods

RELIEVE-AD-PEDs is an ongoing, prospective, longitudinal survey study of pediatric patients aged 6m – 17y with moderate-to-severe AD who initiated dupilumab, recruited from DUPIXENT MyWay®, a patient support program. This analysis includes all adolescents aged 12-17 years who enrolled in the program. Eligible patients from USA completed surveys at baseline before dupilumab initiation and at multiple time points (1, 3, 6, 9 and 12 months) after dupilumab initiation. Disease control was assessed using the Atopic Dermatitis Control Tool (ADCT; range 0–24, minimally clinically important difference [MCID] >3 points, score <7 indicating 'controlled disease'; one-week recall period). Severity of AD symptoms were assessed by Patient-Oriented Eczema Measure (POEM; range 0–28, MCID >6 points) and a numeric rating scale (NRS) for itch (range 0-10, MCID >4 points), both with a one-week recall period, as well as number of flares in the past 4 weeks. Treatment satisfaction was also assessed. Outcomes were self-reported by adolescent patients.

Results

At the time of this interim analysis, 126 of 314 patients (40.1%) initiating dupilumab completed 12 months of dupilumab treatment and responded to the Month 12 survey. The mean patient age was 15.1 years (standard deviation [SD] 1.5), 55.4% were female, 59.9% White, and the mean (SD) age at AD diagnosis was 4.6 (5.1) years old. At the Month 12 survey, 111/126 (88.1%) were still using dupilumab. Mean (SD) total ADCT score decreased from 13.3 (5.3) at baseline to 4.9 (4.6, $p<0.001$). 84.0% of patients achieved ADCT MCID at Month 12 and the proportion of patients reporting 'controlled disease' increased from 12.1% at baseline to 57.9% at 2 weeks ($p<0.001$), and 73.8% at Month 12 ($p<0.001$). At baseline, the proportion of patients reporting >2 AD flares in the past 4 weeks was 51.3%, versus 15.1% at Month 12 ($p<0.001$). The proportion of patients achieving the POEM or itch NRS MCID at Month 12 was 81.2% and 65.2%, respectively. Lastly, 88.1% of patients reported being extremely, very, or somewhat satisfied with treatment at 12 months.

Conclusions

In this real-world study, most adolescent patients with AD reported controlled disease 2 weeks after initiating dupilumab treatment. Disease control and treatment satisfaction were sustained during the 12-month follow-up period.

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Abstract N°: 3563

Clinical Efficacy and Barrier-Restoring Benefits of Adjuvant Moisturizer Therapy for Mild Pediatric Atopic Dermatitis: A Prospective Study

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Introduction
The pathogenesis of atopic dermatitis (AD) is fundamentally driven by epidermal barrier dysfunction, elevated transepidermal water loss, and chronic pruritus. Emollients remain the cornerstone of non-pharmacological management, acting to restore barrier integrity and enhance stratum corneum hydration. This prospective study aimed to evaluate the clinical efficacy, safety, and barrier-repairing benefits of a specific moisturizer as an adjuvant therapy in children aged 0-12 years with mild AD, providing objective evidence for its clinical utility.

Materials and Methods
This open-label, prospective, self-controlled study enrolled children aged 0-12 years with mild AD (SCORAD < 25). Participants applied the moisturizer to target lesions twice daily for 28 days. Scheduled evaluations occurred at baseline (D0), Day 7, Day 14, and Day 28. The primary endpoint was the change in SCORAD score from baseline to D28. Secondary endpoints included the Peak Pruritus Numerical Rating Scale (PP-NRS), transepidermal water loss (TEWL), stratum corneum hydration (SCH), and the Children's Dermatology Life Quality Index (CDLQI).

Results
Among 22 enrolled participants, 21 completed the 28-day study (age 0-6 years, n=13; 7-12 years, n=8), with one withdrawal due to an unrelated intercurrent urticaria. SCORAD scores progressively declined from 19.21±4.42 at baseline (D0) to 15.78±5.85 (D7), 14.83±6.64 (D14), and 10.90±7.61 (D28) (all $P < 0.05$ vs. baseline; **Figure 1A**). Median PP-NRS scores improved significantly, dropping from 4.0 (D0) to 3.0 (D7) and stabilizing at 2.0 (D14-D28), indicating rapid and sustained pruritus relief (overall $P < 0.001$; **Figure 1B**). Patient quality of life also improved, with median CDLQI dropping from 7.0 at baseline to 3.0 at D28 ($P < 0.001$; **Figure 1C**). Biophysical assessments revealed a significant increase in median SCH (20.67 to 57.33; $P < 0.001$) and a concurrent decrease in median TEWL (28.77 to 16.91; $P < 0.01$) from D0 to D28 (**Figure 1D**). No product-related adverse events were observed.

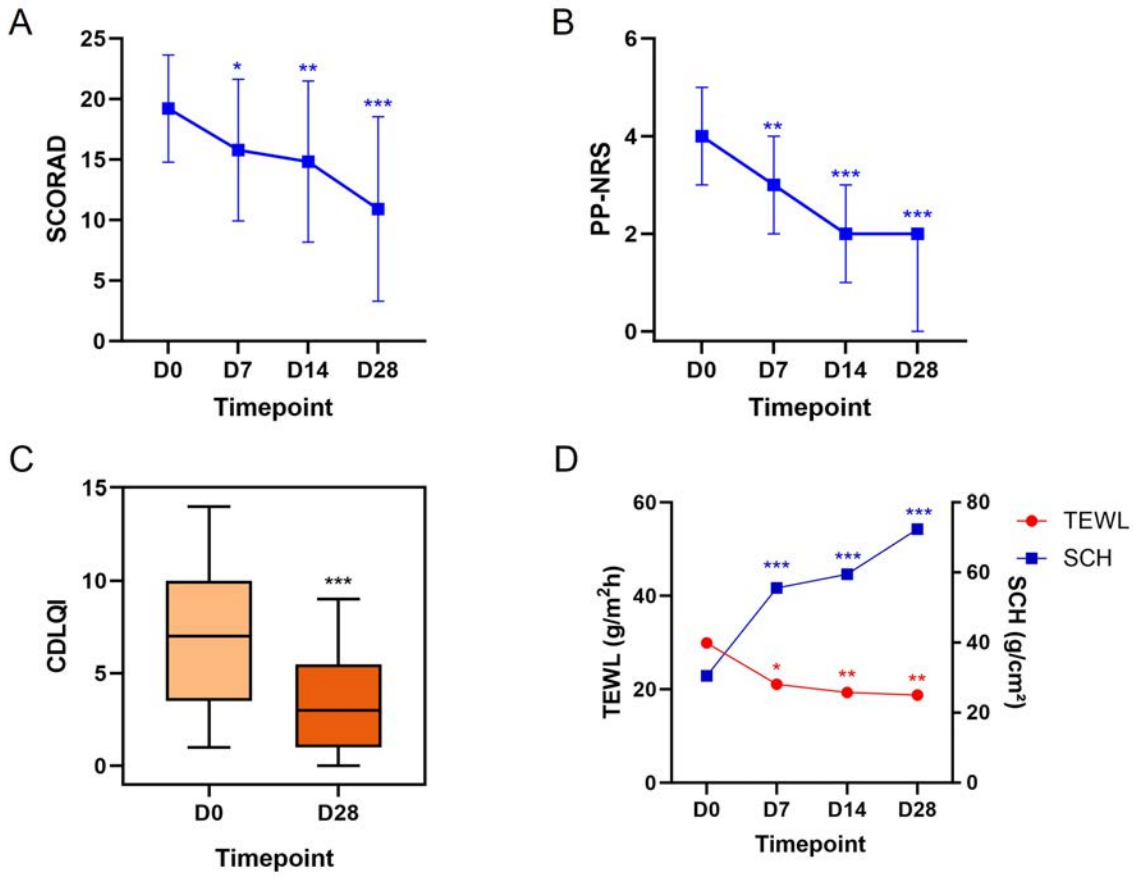

Figure1

PP-NRS, Peak Pruritus Numerical Rating Scale; TEWL, transepidermal water loss; SCH, stratum corneum hydration; CDLQI, Children's Dermatology Life Quality Index; *P < 0.05, **P < 0.01, ***P < 0.001.

Conclusions

The evaluated moisturizer provides significant adjuvant therapeutic benefits for mild AD in children aged 0-12 years. It delivers rapid and sustained improvements in skin lesions and pruritus, significantly improving the patients' quality of life. These clinical benefits are closely associated with its efficacy in repairing the skin barrier function, evidenced by decreased transepidermal water loss and continuously increased stratum corneum hydration. The intervention was well-tolerated, confirming its utility in pediatric AD management.

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Abstract N°: 3582

Characterizing the Atopic Dermatitis-COPD Overlap: Clinical Profile, Biomarker Phenotyping, and Dupilumab Eligibility in a Descriptive Cohort

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Introduction

Atopic dermatitis (AD) and chronic obstructive pulmonary disease (COPD) are chronic inflammatory conditions that may coexist in older adults, yet the clinical and biomarker profile of patients with both diseases is poorly characterized. With dupilumab now approved for moderate-to-severe AD and for COPD with type 2 inflammation (blood eosinophils ≥300 cells/µL), characterizing AD-COPD patients eligible for shared type 2-targeted therapy has immediate clinical relevance.

Materials and Methods

We conducted a single-center descriptive study of 29 patients with concurrent AD and, physician-diagnosed COPD between 2020 and 2025. Patients with a concurrent asthma diagnosis were excluded. Demographic, clinical, treatment, comorbidity, and biomarker data were extracted from medical records. AD severity was assessed using the Eczema Area and Severity Index (EASI). COPD severity was classified by GOLD spirometry stage and exacerbation history (GOLD 2026 Group E: ≥1 moderate or severe exacerbation in the preceding 12 months). Continuous variables are reported as medians and interquartile ranges (IQRs).

Results

The cohort was balanced by sex (14 male, 48%), with a median age of 73 years (IQR= 62-85) and BMI of 25.0 kg/m^2(IQR= 24.0 -26.9). Fourteen (48%) were never-smokers; among 15 ever-smokers, median exposure was 35 pack-years. Median baseline EASI was 3.0 (IQR=2.0-6.0). Current AD treatment was predominantly topical; only 1 (3%) was on systemic therapy (upadacitinib) and 1 had previously received dupilumab. Median blood eosinophils were 200 cells/µL (IQR=100-300). Spirometry was available in 14 (48%); among those tested, median FEV1 was 66% predicted and 10/14 (71%) had GOLD 2-3 airflow limitation. Twelve (41%) met GOLD 2026 Group E criteria. Ten (34%) had blood eosinophils ≥300 cells/µL; 3/14 with spirometry (21%) met both biomarker and GOLD 2-3 criteria. Among those with both biomarker positivity and Group E status, 5 (17%) had a candidate biomarker-positive exacerbator phenotype potentially amenable to dupilumab. Hypertension (59%), cardiovascular disease (48%), hyperlipidemia (28%), and malignancy (24%) were common; allergic rhinitis was present in 17%.

Conclusions

Patients with coexisting AD and COPD demonstrate mild skin disease but substantial pulmonary

and cardiometabolic morbidity. Identifying these patients in the dermatology setting may inform shared type 2-targeted therapy and support coordinated multidisciplinary care. Larger, prospective studies are needed to validate these findings.

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Abstract N°: 3591

AtopicHealth: Quality of care for patients with atopic dermatitis in Germany between 2010 and 2026

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Introduction

The national care study on atopic dermatitis (AD), 'AtopicHealth2' (2017–2019), found no improvement in the care situation of patients with AD compared with 'AtopicHealth1' (2010). New treatments are now available in Germany. The 'AtopicHealth3' study (2024–2026) aims to analyse whether, as measured by validated indicators, the care situation for patients with AD in Germany has changed over time.

Materials and Methods

The Germany-wide, multicentre cross-sectional study AtopicHealth3 collected clinical data, AD severity (SCORAD), dermatology-related quality of life (DLQI), treatments, preventive behaviour and patient-defined treatment benefit (PBI) from randomly selected dermatology practices and clinics. A key focus was on the patients' perspective. The care situation was assessed using previously employed quality indicators and compared with earlier studies.

Results

The questionnaire sets, fully completed by 73 centres by March 2026, were analysed. Of the 839 patients, 56.1% identified as female, 43.7% as male and 0.2% as diverse. The mean age was 42 years. The mean SCORAD of 37.7 was lower than the SCORAD for AtopicHealth2 (45.4) and AtopicHealth1 (42.3, on a scale from 0 = none to 103 = maximum severity of AD). The mean DLQI score was 7.9, compared with 8.5 in the two previous studies (0 = no impairment to 30 = maximum impairment of dermatology-related quality of life). The proportion of patients with high severity (SCORAD > 50) was 29.7%, compared with 41.6% in AtopicHealth2 and 32.2% in AtopicHealth1. The mean PBI was 2.5 (AtopicHealth2: 2.2 and AtopicHealth1: 2.4; scale from 0=none to 4=maximum patient-defined treatment benefit). The use of guideline-based systemic therapy was more common in 2024–2026 than in previous studies (44.3% of patients had received systemic therapy 'to date'; 35.3% had 'ever used' it in 2017–19, in each case according to doctors' reports).

Conclusions

Compared with the studies from 2010 and 2017–19, outcome indicators show an improvement in the quality of care for patients with AD in dermatological practice in Germany. These improvements were observed in conjunction with the introduction and use of innovative medicines. The results presented are preliminary, as data collection is still ongoing; the final results will be presented at EADV 2026.

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Abstract N°: 3598

Reaching the Target: Real-World Attainment and Prognostic Value of International Eczema Council Low Disease Activity States in a Cohort of Patients with Atopic Dermatitis Treated with Upadacitinib

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Introduction

Recent International Eczema Council (IEC) consensus definitions have introduced standardized thresholds for low disease activity (LDA) and very low disease activity (vLDA) in atopic dermatitis (AD), aiming to harmonize treatment targets across clinical trials and real-world practice. However, data on the attainment of these outcomes in patients treated with upadacitinib in routine clinical settings remain limited, and the clinical implications of achieving these targets are still poorly understood.

Materials and Methods

We conducted a retrospective observational study including adult patients with moderate-to-severe AD treated with upadacitinib in a real-world setting. LDA was defined as EASI ≤7 plus peak pruritus numerical rating scale (PP-NRS) ≤4, and vLDA (equivalent to previous definition of Minimal Disease Activity [MDA]) as EASI ≤3 plus PP-NRS ≤1, in accordance with IEC consensus definitions. Baseline demographic and clinical variables were collected, and exploratory analyses were planned to evaluate associations between outcome achievement, drug survival, and potential predictors.

Results

A total of 60 patients were included. Median age was 29 years (IQR 23–37), and 31% were female. At baseline, median EASI was 24 (IQR 18–30), and median PP-NRS was 8 (IQR 6–9). At week 16, 83.7% of patients achieved LDA (n available =43). This increased to 86.1% at week 24 (n available =36), and was maintained in 76.9% of patients at week 52 (n available = 26). Regarding vLDA, 65.1% of patients achieved this outcome at week 16, decreasing to 55.6% at week 24, and increasing again to 65.4% at week 52. Achievement of LDA at week 52 was associated with improved drug survival (log-rank p=0.03). A similar trend was observed for LDA at week 16, although this did not reach statistical significance (p=0.19). No significant differences in drug survival were observed according to LDA achievement at earlier time points. In contrast, achievement of vLDA was not associated with improved drug survival at most time points, with the exception of week 52, where a significant association was observed (p=0.02). In exploratory univariable analyses for LDA achievement within the first 6 months, female sex, prior dupilumab exposure, and baseline lactate dehydrogenase (LDH) levels showed p<0.20 and were entered into a multivariable Firth logistic regression model together with age. Prior dupilumab exposure was independently associated with lower odds of achieving LDA within the first 6 months (OR 0.1, 95% CI 0.006–0.83; p=0.035), as were higher baseline LDH levels (OR per unit increase 0.97, 95% CI 0.95–0.99; p=0.042). Prior dupilumab use was also independently associated with lower odds of achieving vLDA within the first 6 months (OR 0.2, CI 95% 0.04-0.74, p=0.02).

Conclusions

IEC-defined LDA and vLDA were frequently achieved in this real-world cohort of patients with AD treated with upadacitinib, and week-52 target achievement was associated with improved drug

survival. Prior dupilumab exposure and higher baseline LDH levels were associated with reduced likelihood of achieving LDA within the first 6 months. These findings support the use of IEC targets as clinically meaningful benchmarks in routine clinical practice. However, the limited sample size and low number of discontinuation events warrant cautious interpretation and confirmation in larger cohorts.

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Abstract N°: 3605

Drug survival and reasons for treatment switching in severe atopic dermatitis: a single-centre observational analysis

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Introduction
Advanced systemic therapies, including biologics and Janus kinase (JAK) inhibitors, have substantially expanded treatment options for severe atopic dermatitis (AD). However, a considerable proportion of patients fail to achieve sustained disease control and require treatment modification or discontinuation. Real-world data on drug survival and treatment switching remain limited.

Materials and Methods
This single-centre study included adult and paediatric patients with severe AD. Eligibility criteria included EASI ≥20; adult patients were additionally required to have documented treatment failure, contraindications, or intolerance to cyclosporin A. Advanced therapies were introduced sequentially within the national reimbursement programme: dupilumab (2021), upadacitinib and baricitinib (2022), abrocitinib and tralokinumab (2023), and lebrikizumab (2025). Among 188 treated patients, 31 (16.5%) discontinued or switched therapy and were included in the present analysis.

Results
The study cohort comprised 16 males (51.6%) and 15 females (48.4%), with a mean age of 24.8±10.7 years (range: 6–53 years), baseline EASI of 34.0±12.4, and DLQI of 19.7±5.6. Twenty-two patients (71.0%) switched to another advanced therapy, whereas 9 (29.0%) discontinued treatment without subsequent switching. Dupilumab was the most frequently used first-line advanced therapy (77.4%), followed by tralokinumab (9.7%), upadacitinib (9.7%), and abrocitinib (3.2%).
At week 16, among patients with available follow-up data (n=23), EASI-50, EASI-75, and EASI-90 responses were achieved in 82.6%, 26.1%, and 13.0% of patients, respectively. Mean DLQI improvement at week 16 was 10.7±6.2 points. The most common reason for treatment discontinuation was lack of effectiveness (45.2%), followed by adverse events (29.0%), family planning (12.9%), and patient-related reasons (12.9%). Adverse events leading to discontinuation included conjunctivitis, alopecia, eosinophilia, angioedema, and dyspnoea. Four patients (12.9%) required three consecutive advanced therapies. Median drug survival was 34.0 weeks (IQR: 16.0–53.0).

Conclusions
Treatment switching and discontinuation were common despite meaningful clinical improvement, highlighting the challenges of long-term disease control in severe AD and the unmet need for improved treatment sequencing strategies.

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Abrocitinib reduces pathogenic skin-resident memory T cells and restores barrier integrity in atopic dermatitis: a biopsy-based analysis from the JADE MOA trial

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin condition driven by persistent immune activation, in which memory T cells play a central role in disease chronicity and recurrent flares. Abrocitinib, a selective JAK1 inhibitor approved by the FDA for moderate-to-severe AD, has demonstrated strong clinical efficacy in the form of skin clearance, itch mitigation and overall flare reduction. We previously showed in an *ex vivo* model that abrocitinib reduces T cell numbers, including cutaneous memory T cells. Here, we sought to confirm and extend these findings in lesional skin biopsies from patients enrolled in the JADE MOA clinical trial.

Materials and Methods

To assess how abrocitinib-treatment influences epidermal barrier integrity and pathogenic immune cell populations associated with flares, we examined lesional skin biopsies from 17 AD patients enrolled previously in the monotherapy JADE MOA trial (NCT03915496, [1]). Patients received abrocitinib (100 mg or 200 mg) or placebo once daily over 12 weeks. Samples were collected at baseline (day 1) and week 12, and analyzed by (immuno-) histomorphometry.

Results

Abrocitinib treatment increased Claudin-1 expression, reaching statistical significance at the 200 mg dose, and similarly up-regulated keratin expression, with the more pronounced effect again observed among patients receiving the higher dose. Immune cell activation was assessed in both the dermis and epidermis. $CD3^+$ T cell numbers were significantly reduced by 200 mg abrocitinib in the dermis. Tissue-retained $CD3^+CD45RO^+$ memory T cell numbers — including $CD69^+$ cells, which may also represent an activated subset — also declined significantly in both compartments among patients receiving the 200 mg dose. Tissue-resident memory $CD3^+CD69^+CD103^+$ T cells showed a trend toward reduction, as did circulation-derived $CD3^+CD45RO^+CLA^+$ memory T cells, though to a lesser extent. The effect of 100 mg abrocitinib on these cell populations among both tissue compartments was less pronounced. Placebo-associated changes varied and did not reflect the consistent treatment-related patterns observed with abrocitinib treatment

Conclusions

Taken together, our findings indicate that abrocitinib combines restoration of barrier integrity with broad

suppression of the pathogenic memory T cell pool, affecting both tissue-resident and circulation-derived subsets. These effects were most pronounced at 200 mg, while the lower dose showed similar directional trends. This dual impact on structural and immunologic disease drivers provides a mechanistic basis for sustained disease control and supports the potential of abrocitinib to convey lasting mechanistic changes to atopic dermatitis pathophysiology, as reported on elsewhere [2].

[1] Guttman-Yassky, E et al. *Allergy*.2024;79(5):1258-1270.
[2] Guttman-Yassky, E et al., Sustained on- and off-treatment disease control in patients with moderate-to-severe atopic dermatitis following 12-week open-label once-daily abrocitinib 200 mg: post-hoc analysis of the phase 3 JADE REGIMEN study. Poster presented at: Winter Clinical Dermatology Conference – Hawaii; 2026 Jan 16–21; Maui, Hawaii.

EA DV CONGRESS
VIENNA
30 SEP - 3 OCT 2026

Abstract N°: 3617

Development and validation of MATCHE-Q, a self-administered screening tool for chronic hand eczema: a prospective multicentre blind diagnostic study with item reduction analysis

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Introduction

Chronic hand eczema affects 4-6% of European adults and remains the leading occupational dermatosis, yet 30-50% of patients never receive formal diagnosis. Existing self-assessment tools show critical limitations: symptom-based questionnaires generate false-positives (PPV as low as 38%), while direct self-report tools (NOSQ-2002) underestimate prevalence by 30-60%. No validated self-screening tool integrates correction for palmoplantar psoriasis, the main diagnostic pitfall. This gap justifies developing a prospectively validated questionnaire for reliable diagnostic classification before dermatological consultation.

Materials and Methods

Prospective multicentre single-blind study (156 patients, 9 centres, 8 French regions). MATCHE-Q developed through tripartite process: patient focus group (Association Française de l'Eczéma), expert dermatologist validation, and statistical engineering. Questionnaire: 13 items, 4 blocks—P (prerequisite, −20 if no lesions), A (atopy, 0 to +2), B (psoriasis correction, 0 to −3), C (clinical, 0 to +12). Total score −3 to +14; thresholds: <4 (no CHE), 4-7 (possible), ≥8 (probable). Blinding: patients completed questionnaire in sealed envelope before consultation; dermatologists examined without access, diagnosed per Diepgen 2009 criteria. Analysis: sensitivity, specificity, predictive values, likelihood ratios, ROC, Youden index. Item reduction: OR <2.0 and frequency difference <15 percentage points

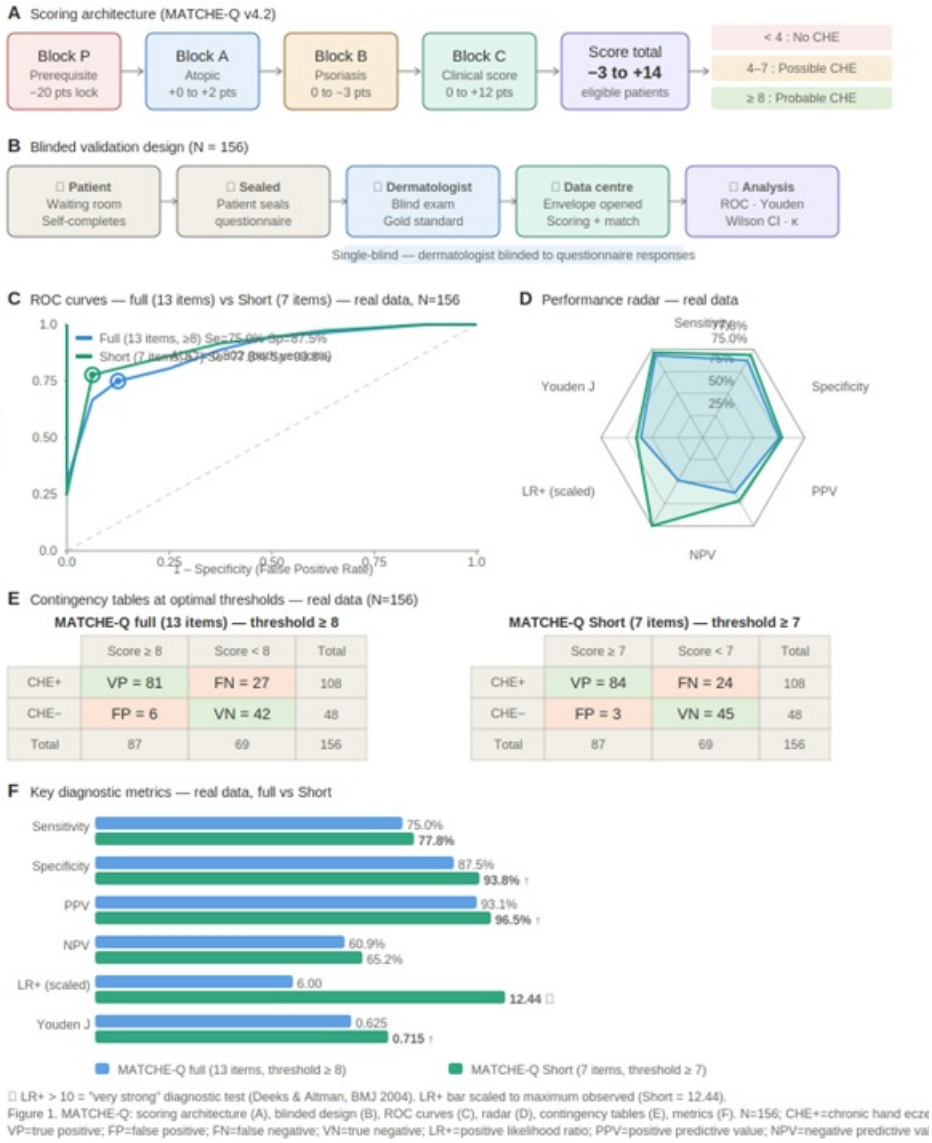
Results

Among 156 included patients, 108 CHE positive (prevalence 69.2%), mean age 43.0 ± 13.8 years, 56.7% female. Mean MATCHE-Q score significantly higher in CHE positive (8.9 ± 2.8, range 2 to 14) versus CHE negative (3.2 ± 5.5, range −15 to +10). A priori classification: 24 patients (15.4%) classified "no CHE" (score less than 4), 42 (26.9%) "possible CHE" (score 4 to 7), 90 (57.7%) "probable CHE" (score greater than or equal to 8). Among 90 "probable CHE" patients, 87 confirmed by dermatologist (class-level positive predictive value 96.7%). ROC analysis: optimal threshold at score greater than or equal to 8 (Youden index 0.625, AUC 0.804), exact convergence with a priori "probable CHE" threshold. Complete diagnostic performance: sensitivity 75.0% (95% CI: 66.1 to 82.2%), specificity 87.5% (75.3 to 94.1%), positive likelihood ratio 6.00, Cohen's kappa 0.557. Item discrimination analysis: four items with OR less than 2.0 and frequency difference less than 15 points (Q2 allergic background OR 1.40, Q5 nail signs OR 0.43, Q10 dichotomised continuous OR 0.94, Q11 vesicles OR 0.86) identified for removal. MATCHE-Q Short (seven items, score −2 to +11, threshold greater than or equal to 7): superior performance across all discrimination indicators: sensitivity 77.8% (69.1 to 84.6%), specificity 93.8% (83.2 to 97.9%), AUC 0.804 (identical), positive likelihood ratio 12.44, Youden index 0.715, positive predictive value

96.6% (90.3 to 98.8%), false positives reduced from six to three. Positive likelihood ratio of 12.44 exceeds threshold of 10 qualifying test as "very strong diagnostic evidence" per Deeks and Altman criteria.

Conclusions

MATCHE-Q and its short version are the first French hand eczema self-screening tools validated in multicentre setting with blinding procedure. MATCHE-Q Short achieves a positive likelihood ratio of 12.44 (threshold >10 for very strong diagnostic evidence). Optimal ROC threshold (≥8) exactly matches the a priori "probable eczema" threshold, validating the tripartite calibration process. Unlike NOSQ-2002 (epidemiological surveillance, Se 70.3%, Sp 99.8%), MATCHE-Q integrates correction blocks for psoriasis and atopy, with individual diagnostic purpose. Its moderate negative predictive value (65.2%) confirms positioning as triage tool, not exclusion instrument. Next steps: external validation and digital adaptation with photographic references.



	Score ≥ 8	Score < 8	Total
CHE+	VP = 81	FN = 27	108
CHE−	FP = 6	VN = 42	48
Total	87	69	156

	Score ≥ 7	Score < 7	Total
CHE+	VP = 84	FN = 24	108
CHE−	FP = 3	VN = 45	48
Total	87	69	156

LR+ > 10 = "very strong" diagnostic test (Deeks & Altman, BMJ 2004). LR+ bar scaled to maximum observed (Short = 12.44).

Figure 1. MATCHE-Q: scoring architecture (A), blinded design (B), ROC curves (C), radar (D), contingency tables (E), metrics (F). N=156; CHE+=chronic hand eczema; CHE−=non-CHE; Se=sensitivity; Sp=specificity; AUC=area under the curve; VP=true positive; FP=false positive; FN=false negative; VN=true negative; LR+=positive likelihood ratio; PPV=positive predictive value; NPV=negative predictive value.

MATCHE-Q diagnostic validation. (A) Scoring architecture: four functional blocks (Block P, prerequisite lock; Block A, atopic background; Block B, psoriasis-correction penalty; Block C, clinical score) generating a total score of −3 to +14 for eligible patients, with a priori classification thresholds. (B) Blinded five-step validation procedure ensuring dermatologist independence from questionnaire responses. (C) ROC curves for MATCHE-Q full (13 items, blue, threshold ≥ 8) and MATCHE-Q Short (7 items, teal, threshold ≥ 7); AUC = 0.804 for both versions; optimal thresholds marked with open circles; dashed diagonal = AUC 0.50 reference. (D) Hexagonal radar chart comparing six diagnostic metrics across full and short versions. (E) Contingency tables at optimal thresholds; N = 156 patients. (F) Horizontal bar comparison of key metrics; ★ LR+ > 10 denotes ‘very strong’ diagnostic evidence

(9), bar scaled to maximum observed LR+ (12.44). CHE = chronic hand eczema; TP = true positive; FP = false positive; FN = false negative; TN = true negative; LR+ = positive likelihood ratio; PPV = positive predictive value; NPV = negative predictive value.

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Abstract N°: 3620

Tolerance and efficacy of a new emollient eyelid balm containing Rhealba oat and Helichrysum g. in eyelid eczema

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Introduction

Eyelid eczema, whether of atopic, allergic or irritant origin, is a frequent condition in dermatological practice and is particularly challenging to manage due to the thinness and high reactivity of periocular skin. In this sensitive area, therapeutic options are limited and long-term use of topical treatments is often constrained by tolerability or cosmetic concerns. There is therefore a need for well-tolerated, effective emollient formulations specifically designed for the eye contour, to help restore the skin barrier and relieve pruritus and discomfort. A new emollient balm specifically dedicated to the eyelid area, containing Rhealba oat and *Helichrysum g.,* has been developed. The objective of this study was to evaluate the dermatological and ophthalmological tolerance and efficacy of this product in adults with dry eyelid eczema.

Materials and Methods

34 adult subjects aged 19 to 63 years (mean age: 38 years) were included in a 3-week, open-label clinical study. Main inclusion criteria were dry eyelid eczema of atopic, allergic or irritant origin, with xerosis ≥ 2 (mild) or 3 (moderate) on a 0–4 scale, erythema = 2 (mild), discomfort and pruritus ≥ 3 on 0–10 numeric rating scales (NRS). The eyelid balm was applied twice daily. Assessments were performed at Day (D)1, D4, D8 and D22, and included dermatological and ophthalmological tolerance, evaluation of physical and functional signs, pruritus and discomfort (NRS), global efficacy and cosmetic qualities and acceptability questionnaires.

Results

After 3 weeks of twice-daily use, both cutaneous and ophthalmological tolerance of the eyelid balm were assessed as very good by the dermatologist and the ophthalmologist. A rapid and sustained improvement of physical signs was observed by the investigator: xerosis significantly decreased by 59% at D4, 61% at D8 and by 81% at D22 ($p<0.0001$ at all timepoints), while erythema decreased by 68% at D4, 78% at D8 and by 94% at D22 ($p<0.0001$ at all timepoints). Functional signs were also significantly improved, from the first application in burning sensation (−57% at D1, Timm; $p<0.01$), itching (−66% at D1, Timm; $p<0.0001$) and sensation of warmth (−71% at D1, Timm; $p<0.05$). Pruritus (average intensity over the last 24 hours, NRS) decreased by 69% at D4, 74% at D8 and 95% at D22 ($p<0.0001$ at all timepoints), while discomfort decreased by 75% at D4, 82% at D8 and 97% at D22 ($p<0.0001$ at all timepoints). After 21 days of use, 97% of subjects rated the product as effective or very effective. Finally, cosmetic acceptability was evaluated as very good, with subjects reporting their skin as comfortable and soothed.

Conclusions

These results demonstrate the benefit of this new emollient eyelid balm, which combines very good dermatological and ophthalmological tolerance with rapid and sustained improvement of symptoms and clinical signs of dry eyelid eczema and very good cosmetic acceptability, supporting its use as a valuable supportive care option in the management of dry eyelid eczema.

EADV CONGRESS
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Abstract N°: 3652

Changes in lipidomic profile following treatment of atopic dermatitis with dupilumab and correlation with abundance of staphylococcal species

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Introduction

Atopic dermatitis (AD) is characterized by skin barrier dysfunction and altered lipid composition, particularly dysregulation of ceramides. The effects of the IL-4Rα inhibitor, dupilumab, on stratum corneum lipids and its association with staphylococcal colonization remain incompletely understood.
The aim of this study was to characterize changes in stratum corneum lipid composition in lesional and nonlesional skin of patients with AD before and after dupilumab therapy, and to explore associations with abundance of staphylococcal species and disease severity.

Materials and Methods

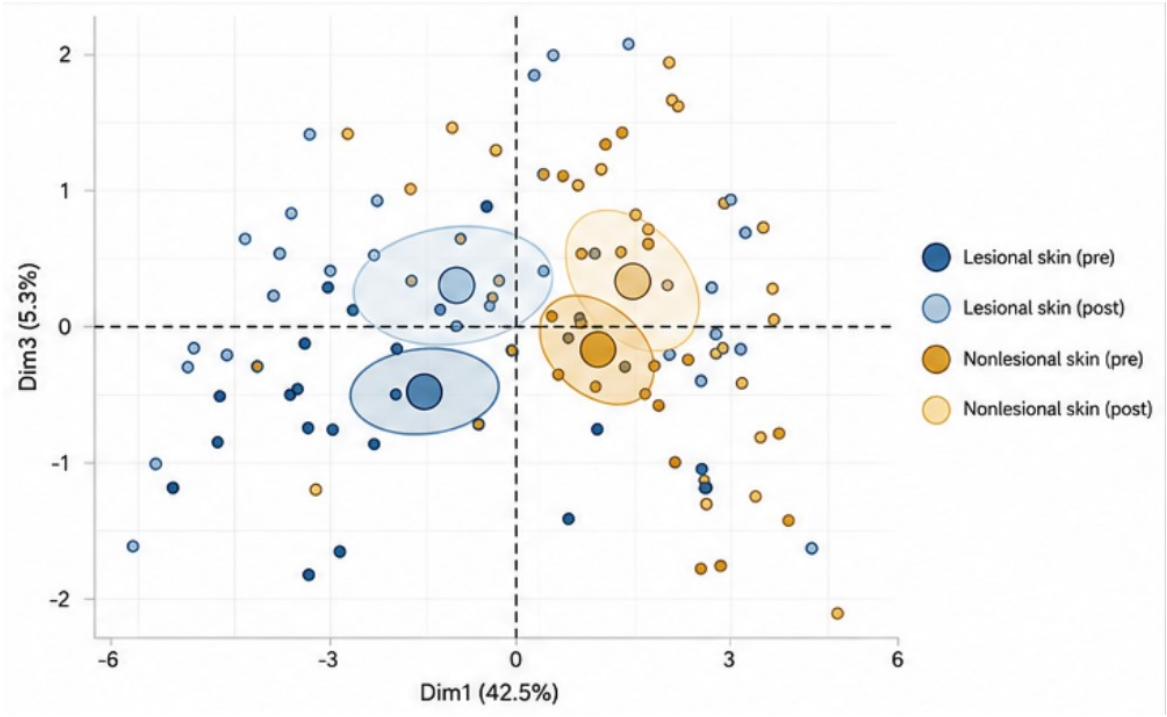
Tape strips were collected from lesional and nonlesional skin from 27 AD patients at baseline and after 16 weeks of dupilumab therapy. Lipidomic profiling was performed using liquid chromatography–mass spectrometry. Lipidomics was correlated with staphylococcal species colonization assessed by *tuf* sequencing and disease severity assessed by Eczema Area and Severity Index (EASI).

Results

At baseline, lesional skin exhibited increased relative abundance of cholesterol and reduced relative abundance of ceramides compared with nonlesional skin. Several ceramide subclasses, including short chained NS and NdS ceramides were increased in lesional skin, whereas long chained EOS ceramides were reduced.

Dupilumab treatment significantly improved disease severity with a mean reduction in EASI score of 70.0%. Clinical improvement was paralleled by alterations in lipid composition, with increases in long-chain EO ceramides (EOS and EOH). The number of differentially abundant lipids between lesional and nonlesional skin decreased following treatment from 244 to 105, reflecting partial normalization of the lesional lipidomic profile, although post treatment lipid composition was more strongly influenced by sampling site than by treatment.

No significant correlations were observed between relative abundance of *Staphylococcus aureus* and ceramide levels. However, abundance of *Staphylococcus lugdunensis*, a coagulase-negative staphylococci, were associated with specific ceramides, including an inverse correlation with EOS ceramides and positive correlations with NS ceramides ($r > 0.4$, adjusted $p < 0.05$). Improvement following treatment correlated with alterations in multiple ceramides, particularly reductions in NH and NS subclasses.



Principal component analysis (PCA) of stratum corneum ceramide profile in atopic dermatitis (AD) before and after dupilumab treatment. Samples clustered primarily according to sampling site (lesional vs. nonlesional skin) rather than treatment status. Despite partial normalization of the lipid profile following treatment, lesional and nonlesional skin remained distinct, suggesting that local disease activity has a greater impact on stratum corneum lipid composition than systemic IL-4Rα inhibition.

Conclusions

AD lesional skin demonstrated marked alterations in lipid and ceramide profile compared to nonlesional skin, characterized by increased cholesterol levels and changed ceramide composition. Although dupilumab induced partial normalization of the lipid profile, the differences between lesional and nonlesional skin remained more pronounced than the treatment-induced changes, suggesting that local disease activity has a greater impact on the stratum corneum lipid profile than systemic IL-4Rα inhibition.

Interestingly, only limited associations were observed between lipid alterations and the cutaneous staphylococcal colonization. In particular, no significant correlations were identified with *S. aureus*.

Together, these findings indicate that important barrier abnormalities persist despite clinical improvement with dupilumab and support a continued role for barrier-targeted interventions in management of AD.

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Abstract N°: 3653

Burden and Patient-Reported Outcomes in Adults with Hand/Foot Atopic Dermatitis: Real-World Data from the Atopic Dermatitis Wave II Disease Specific Programme

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Introduction
Hand/foot involvement in atopic dermatitis (AD) can be associated with high functional and psychosocial burden, but this is not well characterized in real-world populations. We assessed clinical burden and patient-reported outcomes (PROs) in adults with hand/foot AD using real-world data.

Materials and Methods
Data were drawn from an interim cut of the Adelphi Real World Nurse Practitioner and Physician Assistant (NPPA) Atopic Dermatitis Wave II Disease Specific Programme™, a cross-sectional real-world US survey with elements of retrospective data collection (2025-26). Eli Lilly and Company subscribed to the data and was not the study sponsor. NPPAs affiliated with dermatology or allergy practices completed patient record forms for consecutive adults with NPPA-confirmed AD. Hand/foot involvement was identified by NPPA report in patient record forms. Key outcomes included NPPA-reported disease severity and reasons for severity, and patient-reported disease control (Atopic Dermatitis Control Tool [ADCT]) and quality of life (QoL) (Dermatology Life Quality Index [DLQI]). Analyses included descriptive summaries and unadjusted between-group comparisons conducted using Student's t-test, ANOVA, Mann-Whitney U, Kruskal-Wallis, Fisher's Exact, and Pearson's Chi-Squared.

Results
319 (56.9%) patients had AD involvement of the hands/feet, and 242 (43.1%) did not. Demographics were similar between groups, including age (43.2 vs 42.1 years, p=0.4475), sex (52.5% vs 57.7% female, p=0.2248), and race (74.9% vs 69.8% White, p=0.1803; 17.2% vs 18.6% Black/African American/African/Caribbean, p=0.6782).

Among patients with hand/foot involvement, commonly affected sites included hands (excluding fingers; 87.7%), fingers (46.9%), wrists (57.0%), feet (excluding toes; 42.2%), toes (13.7%), and ankles (41.2%).

Patients with hand/foot involvement had a greater mean body surface area affected (21.0 vs 10.9, p<0.0001) and were more likely to have moderate-to-severe disease (Investigator's Global Assessment 3-4; 60.5% vs. 36.0%, p<0.0001). Reasons for severity were more frequently reported in patients with hand/foot involvement, including itch intensity (76.8% vs 61.6%, p<0.0001), itch control level (69.0% vs 57.0%, p=0.0036), body surface area affected (62.1% vs 49.2%, p=0.0023), and highly visible areas affected (34.2% vs 17.8%, p<0.0001).

Patients with hand/foot involvement were more likely to be flaring at assessment (42.0% vs 30.2%, p=0.0040) and to experience severe flares (50.0% vs 26.0%, p=0.0002). They were also more likely to report their work was affected by their AD (35.7% vs 14.6%, p<0.0001).

PRO data were available for 36 patients with hand/foot involvement and 38 without. Moderate or greater DLQI impact was reported by 52.8% of patients with hand/foot involvement and by 47.4% without. Mean DLQI scores were similar between groups (6.5 vs 5.6, p=0.3611), but disease control was worse with hand/foot involvement (ADCT 9.9 vs 7.1, p=0.0385).

Recent symptom burden was higher with hand/foot involvement. In the past 7 days, patients with hand/foot involvement more frequently reported at least moderate symptoms (75.0% vs 43.2%, p=0.0058) and at least one day of intense itching (86.1% vs 56.8%, p=0.0056) and were at least moderately bothered (77.8% vs 44.4%, p=0.0037). Psychosocial burdens were common and similar across groups (embarrassment 69.4% vs 71.1%, p=0.3365; self-consciousness 66.7% vs 68.4%, p=0.8789).

Conclusions

Hand/foot involvement in AD is associated with greater NPPA-reported disease severity, more frequent and severe flares and higher recent symptom burden. While QoL impact and psychosocial burden were similar across groups, based on a smaller subset of patients with PRO data, patients with hand/foot involvement experienced poorer disease control than those without. These findings highlight an unmet need for improved management in this subgroup in real-world practice.

Study funded by Eli Lilly & Company

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Abstract N°: 3670

Dupilumab Modulates Circulating Immune Cells and Normalizes the Phenotype of Tregs in Atopic Dermatitis

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Introduction

Although atopic dermatitis (AD) primarily manifests in the skin, the immune dysregulation underlying moderate-to-severe disease is systemic, with significant abnormalities in circulating immune cell populations. Dupilumab, an anti–IL-4Rα monoclonal antibody, produces robust clinical improvement in AD and is associated with rapid and sustained changes in skin and serum biomarkers. However, functional flow cytometry studies characterizing circulating immune cell frequencies and cytokine production after dupilumab treatment remain limited. In this study, we used high-dimensional spectral flow cytometry to comprehensively profile adaptive and innate immune compartments in patients with AD before and after dupilumab treatment.

Materials and Methods

Spectral flow cytometry was performed on peripheral blood mononuclear cells from 46 adults with AD before and after dupilumab treatment. No patients received other systemic therapies within 4 weeks before or during the study. Paired pre- and post-treatment differences were assessed using paired t-tests.

Results

Participants were 39.1 ± 16.2 (mean ± SD) years old and received dupilumab for 31.8 ± 21.7 weeks. At baseline, CD4, CD8, and B cell populations showed higher expression of Ki67, GATA3, IL-4, IL-13, IL-17, IL-21, and IL-22 in skin-homing (CLA+) cells compared to systemic (CLA-) cells.

After dupilumab treatment, Ki67 expression decreased significantly in skin-homing CD4 (9.2% to 7.0%, p=0.023) and CD8 (12.6% to 8.3%, p=0.005) T cells without changing overall lineage frequencies. Th2-associated markers decreased in CD4 and CD8 T cells, including **GATA3** (CD4: 12.3% to 7.3%, p=0.003; CD8: 8.1% to 3.1%, p<0.0001), **IL-4** (CD4: 3.1% to 2.4%, p=0.047), and **IL-13** (CD4: 5.7% to 4.1%, p=0.006; CD8: 7.4% to 4.2%, p=0.002). Additional inflammatory cytokines were also significantly reduced, including **IL-21** (CD4: 10.1% to 8.0%, p=0.024; $CD8^+$:5.7% to 4.2%, p=0.026), **IL-2** (CD4: 34.5% to 31.7%, p=0.038) and **IL-17** (CD4: 7.4 to 4.1%, p=0.002). IFN-γ expression was unchanged after dupilumab (CD4: 22.7% to 21.9%, p=0.787; CD8: 26.5% to 28.4%, p=0.610).

While the total number of Tregs ($FOXP3^+$) was unchanged after dupilumab treatment, they displayed a significant decrease in **Ki67** (CLA^+: pre 20.5% vs post 15%, p<0.01, n=41), pathogenic **GATA3** (CLA^+: pre 29.6% vs post 17.9%, p<0.0001), as well as pro-inflammatory cytokines **IL-4** (CLA^+: pre 23.4% vs post 17.1%, p<0.01 n=37), **IL-13** (CLA^+: pre 17.2% vs post 12.4%, p<0.01), and **IL-2** (CLA^+: pre 28.1% vs post 22.9%, p<0.01). IL-10 production remained unchanged. To validate these findings in skin, qualitative immunofluorescence (IF) was performed on tissue samples of AD patients at baseline and after treatment, showing a substantial reduction of both $FOXP3^+$ and $GATA3^+$ double-positive Tregs.

Reduced Ki67 production was also observed in B (4.4% to 2.8%, p<0.0001), NK (19.5% to 13.0%, p=0.002), and NKT cells (4.6% to 2.8%, p<0.0001), with decreased expression of **IL-4** (NK: 13.7% to 10.8%, p=0.029; B: 5.5% to 2.2%, p=0.001), **IL-4Rα** (NK: 2.3% to 1.2%, p=0.034), **IL-13** (NK: 11.3% to 7.7%, p=0.049; B: 1.6% to 1.0%, p=0.001), **IL-13Rα** (NK: 1.0% to 0.6%, p=0.029; B: 6.7% to 3.5%, p=0.003), and **OX40L** (NK: 4.9% to 3.7%, p=0.030).

Conclusions

These data show that dupilumab broadly reshapes circulating immunity in AD, reducing markers of proliferation, activation, Th2-, Th17-, and Tfh-associated immunity across $CD4^+$ effector T cells, $CD8^+$ T cells, Tregs, B cells, NK cells, and NKT cells. In contrast, IFN-γ was not significantly affected, suggesting relative preservation of Th1 immunity. Dupilumab was associated with phenotypic normalization of Tregs, including reduced GATA3 expression and reduced pro-inflammatory cytokine production, suggesting an additional mechanism of immune normalization beyond suppression of the canonical Th2 pathway.

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Abstract N°: 3694

Increased risk of herpes infections with JAK inhibitor treatment in patients with atopic dermatitis: Results from the ADVANCES cohort study (2022-2025)

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Introduction
New and effective targeted systemic immune-modulating drugs (IMDs) are available to treat atopic dermatitis (AD), but their comparative risk of herpes in clinical practice has not been fully characterized. Using US commercial and Medicaid claims data, we sought to compare the risk of herpes simplex virus (HSV) infection and herpes zoster (zoster) among patients with AD initiating treatment with a JAK-inhibitor vs. a Th2 cytokine-inhibitor using the ADVANCES safety monitoring system.

Materials and Methods
We report findings from the ADVANCES system, a multi-year propensity score (PS) matched, sequential monitoring system. We implemented a new-user, active comparator cohort study design using nationwide US insurance claims data (Dec 2021-June 2025), including commercial and Medicaid enrollees. New users of upadacitinib or abrocitinib (JAK-inhibitors) constituted the exposure group. Initiators of dupilumab or tralokinumab (Th2 cytokine-inhibitors) were the comparator group. Patients with pre-existing herpes or herpes anti-viral treatment use were excluded. The outcome was the first occurrence of HSV requiring antiviral treatment or zoster in the 180 days following treatment initiation. Conjunctivitis was assessed as a positive control outcome given a known elevated risk with Th2 cytokine-inhibitors. After 1:2 propensity score-matching relative risks (RR) were computed with 95% confidence intervals. We report 6-month risks and risk ratios (RR) from as-started analyses, emulating an intention-to-treat design.

Results
After 1:2 PS-matching, the study included 2,025 JAK-inhibitor initiators (mean age 41, 56% female, 57% White) and 4,040 cytokine-inhibitor initiators. The 6-month risk of HSV or zoster for JAK-inhibitors vs. Th2 cytokine-inhibitors was 1.3% vs. 0.6%, resulting in a risk ratio of RR (95% CI) 2.2 (1.3-3.9). The risk of zoster in particular for JAK-inhibitors was 0.5% vs. 0.2% among Th2 cytokine-inhibitor initiators, resulting in a risk ratio of 2.9 (1.1-7.5). There were 3 eczema herpeticum events among JAK-inhibitors and 1 among cytokine-inhibitor users. Patients treated with a JAK-inhibitors had a decreased risk of conjunctivitis compared to Th2 cytokine-inhibitors (0.6; 0.5-0.8). The risk of herpes infection was similar when prior dupilumab use was allowed among JAK-inhibitor users

(2.2; 1.4-3.5).

Conclusions

Patients with AD who started treatment with a JAK-inhibitor had a 2.9-fold increased 6-month risk of zoster and a 2.2-fold increased risk of herpes simplex infections compared to patients treated with Th2 cytokine-inhibitors. Absolute risk of these herpes infections was low across both treatment groups.

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Abstract N°: 3696

The BEACON platform trial in atopic dermatitis: a new blueprint for evaluating therapeutics in dermatology?

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Introduction

Therapeutics for common inflammatory skin diseases such as atopic dermatitis (AD) are evolving rapidly. In the absence of key head-to-head trials, there has been a reliance on network meta-analyses to determine the relative effectiveness and tolerability of treatments which can be limited by indirect comparisons across heterogeneous patient populations with variable study endpoints. A recent paradigm shift in trial design and delivery enables the efficient generation of direct comparative evidence. Adaptive multi-arm, multi-stage (MAMS) platform trials such as STAMPEDE and RECOVERY facilitate interim analyses and adaptive modifications under a master protocol including the incorporation of new arms, continually changing the 'standard of care'. Here we describe the first MAMS platform trial in dermatology, the BEACON trial.

Materials and Methods

Trial design:

The BEACON trial (Best systemic treatments for adults with atopic eczema over the long term) is a UK Government funded pragmatic, phase IV, UK-wide, multicentre, assessor blind, randomised controlled one year trial comparing the effectiveness, tolerability and cost effectiveness of systemic treatments for adults with moderate to severe atopic dermatitis. Recruitment started in January 2024 with ciclosporin as the control (only UK

licensed ‘standard’ conventional systemic therapy) and methotrexate (most commonly used systemic in the UK) and dupilumab (‘novel’ biologic) as pair-wise comparators.

No futility criteria were included for early arm termination before the one-year analysis, as evaluating the long-term effectiveness and tolerability of these commonly prescribed therapies remains informative; however, only one arm will subsequently continue as the platform’s standard of care control for future comparisons. Any switch in the control treatment will be determined by factors including relative effectiveness, tolerability, drug survival and patient satisfaction. These aspects are ‘a priori’ defined in the master protocol but may evolve over time. Any new treatments or treatment combination deemed to have the potential to challenge the current standard of care will be considered for incorporation into BEACON. There has been an initial focus on licenced therapies but there is potential to incorporate investigational products from phase II upwards in the future. Abrocitinib was added as the first new arm in BEACON in February 2025 as an exemplar JAKi. New arms have been/ will be industry funded.

Results

BEACON platform as an enabling framework for related research:

A qualitative study is running within BEACON to establish participant expectations and experiences with the aim of improving the platform and also translating results into clinical practice. Embedded longitudinal biosampling aims to characterise the molecular events underpinning drug activity and outcomes on treatment with a view to informing the design of novel treatments and personalised medicine approaches to management. Parallel longitudinal image capture is forming a library for future research. Patients are able to co-consent in to the UK AD registry A-STAR to facilitate longer term follow up post-trial.

Conclusions

The ambition of this platform trial is to improve the ‘standard of care’ in atopic dermatitis. Similar innovative trial platforms are likely to become common place across inflammatory skin disease in the future given the profusion of new therapies and significant timescales required for individual drug comparative trials set up. Our approach represents a faster and more efficient method to change practice for patient benefit.

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Retinoid-induced filaggrin suppression as a key mechanism of skin barrier impairment: translational evidence supporting rapid barrier recovery with a filaggrin-supportive dermocosmetic formulation

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Introduction

Topical retinoids, particularly tretinoin, are widely used in dermatology but are frequently associated with irritation, xerosis, desquamation, and increased transepidermal water loss (TEWL). These adverse effects are mechanistically linked to retinoid-induced alterations in epidermal differentiation, including marked suppression of filaggrin expression [1–4]. Retinoic acid downregulates filaggrin through transcriptional repression of the profilaggrin gene and inhibition of enzymatic processing required for filaggrin maturation, even at very low concentrations [2,3]. Filaggrin deficiency is also a hallmark of atopic dermatitis, leading to impaired barrier integrity, reduced natural moisturizing factor, and increased TEWL [5,6], indicating convergent mechanisms of barrier disruption between retinoid-treated skin and atopic-prone skin.

Materials and Methods

To investigate the relationship between topical retinoid-induced skin irritation and filaggrin expression, and to evaluate whether a dermocosmetic formulation containing barrier-supportive and filaggrin-enhancing ingredients can accelerate barrier recovery and restore filaggrin expression, a translational approach was applied. An ex vivo human skin model of barrier disruption induced by sodium lauryl sulfate was used to mimic atopic dermatitis–like conditions. Skin explants were treated with a dermocosmetic formulation combining panthenol (5%), soybean glycerides with shea butter unsaponifiables, emollient lipids (sweet almond oil, paraffinum liquidum, petrolatum), lanolin derivatives, beeswax and fatty alcohols, designed to support epidermal differentiation, lipid replenishment and barrier repair. Filaggrin expression was assessed by immunofluorescence and semi-quantitative analysis. In parallel, a clinical study evaluated the formulation in skin sensitized by topical tretinoin 0.025%, using instrumental measurements of hydration (corneometry), TEWL, image analysis and participant-reported outcomes, from 1 hour up to 28 days after application.

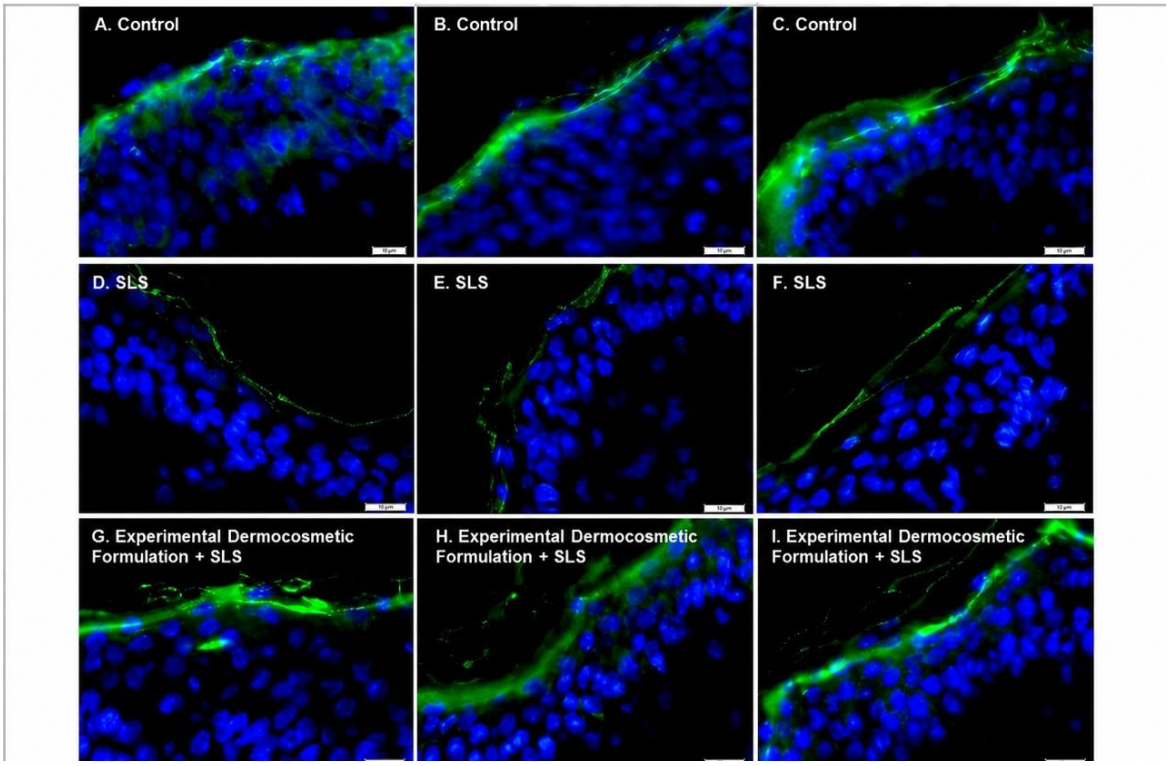

Figure 1. Immunofluorescence assessment of filaggrin protein expression in human skin explants incubated with the evaluated product (Experimental Dermocosmetic Formulation) and subjected to barrier disruption with 5% sodium lauryl sulfate (SLS). A–C – histological section of untreated ex vivo skin (Control). D–F – histological section of ex vivo skin treated with 5% SLS. G–I – histological section of ex vivo skin treated with the evaluated product (Experimental Dermocosmetic Formulation) and 5% SLS. Filaggrin is labeled in green, and blue staining represents cell nuclei (DNA). The scale bar corresponds to 10 µm.

Results

Chemical barrier disruption induced a pronounced reduction in filaggrin expression (−79.8% vs. basal control; $p < 0.0001$). Treatment with the dermocosmetic formulation led to a rapid and significant recovery of filaggrin synthesis, with a 358.7% increase compared with the damaged control ($p < 0.0001$). In tretinoin-sensitized skin, instrumental measurements demonstrated a significant improvement in barrier function within the first hours after application, with reductions in TEWL observed as early as 1–6 hours, depending on the anatomical site, alongside early increases in skin hydration. These effects were sustained after 28 days, with further reductions in TEWL, dryness and desquamation. The early functional recovery is consistent with rapid barrier reinforcement mediated by the lipid-rich formulation, followed by normalization of epidermal differentiation and filaggrin expression.

Conclusions

Topical retinoids induce early and marked suppression of filaggrin, representing a central mechanism underlying skin barrier impairment and irritation. The evaluated dermocosmetic, formulated with filaggrin-supportive and barrier-restorative ingredients, demonstrated not only restoration of filaggrin synthesis but also early barrier recovery within hours, as evidenced by instrumental TEWL measurements. These findings support its use as an adjunctive strategy for rapid barrier repair in tretinoin-treated skin and as supportive care in filaggrin-deficient, sensitive or atopic dermatitis–prone skin.

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The Burden, Measurement, and Management of Fatigue in Atopic Dermatitis: A Scoping Review

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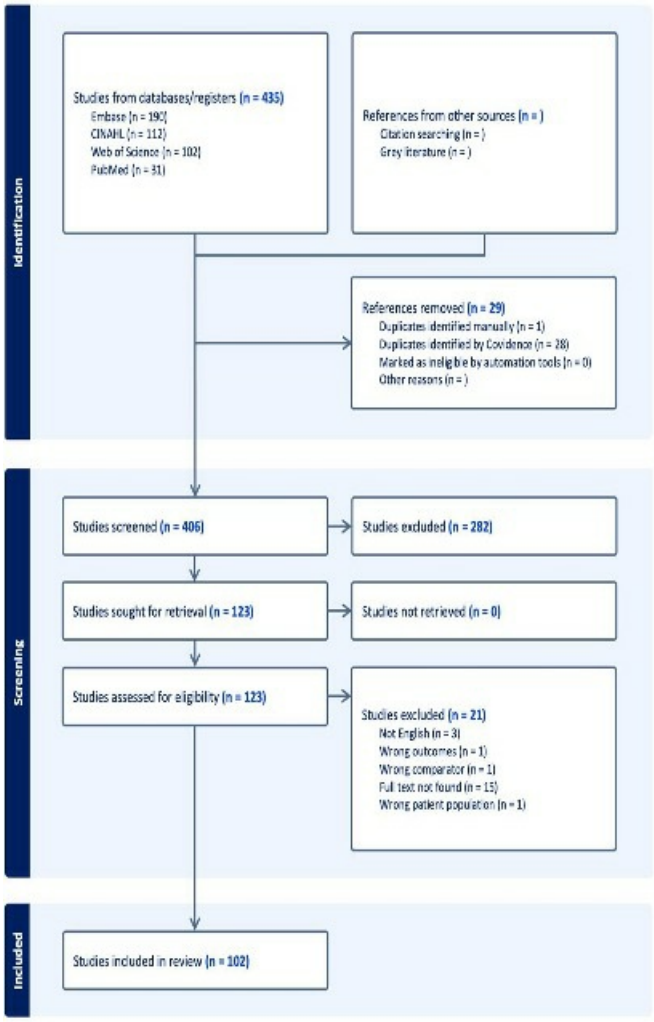
Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease with effects extending well beyond the skin. Fatigue and sleep disturbance are major systemic burdens, leading to profound behavioral and cognitive complications. AD-related fatigue starts a vicious cycle of reduced treatment adherence that worsens overall disease severity. A comprehensive summary of the quantitative prevalence, measurement tools, and multidisciplinary management strategies for AD-related fatigue is currently lacking. The objective of this scoping review is to systematically map the quantitative burden, measurement instruments, and the efficacy of pharmacological and non-pharmacological interventions for AD-related fatigue.

Materials and Methods
This scoping review followed PRISMA-ScR guidelines and used the Arksey and O'Malley framework. Systematic searches of PubMed, Embase, CINAHL, and Web of Science identified observational studies, clinical trials, and methodological papers. Data extraction focused on the quantitative prevalence of sleep loss, measurement methodologies, objective physiological metrics, and clinical outcomes following systemic and behavioural interventions in pediatric and adult groups.

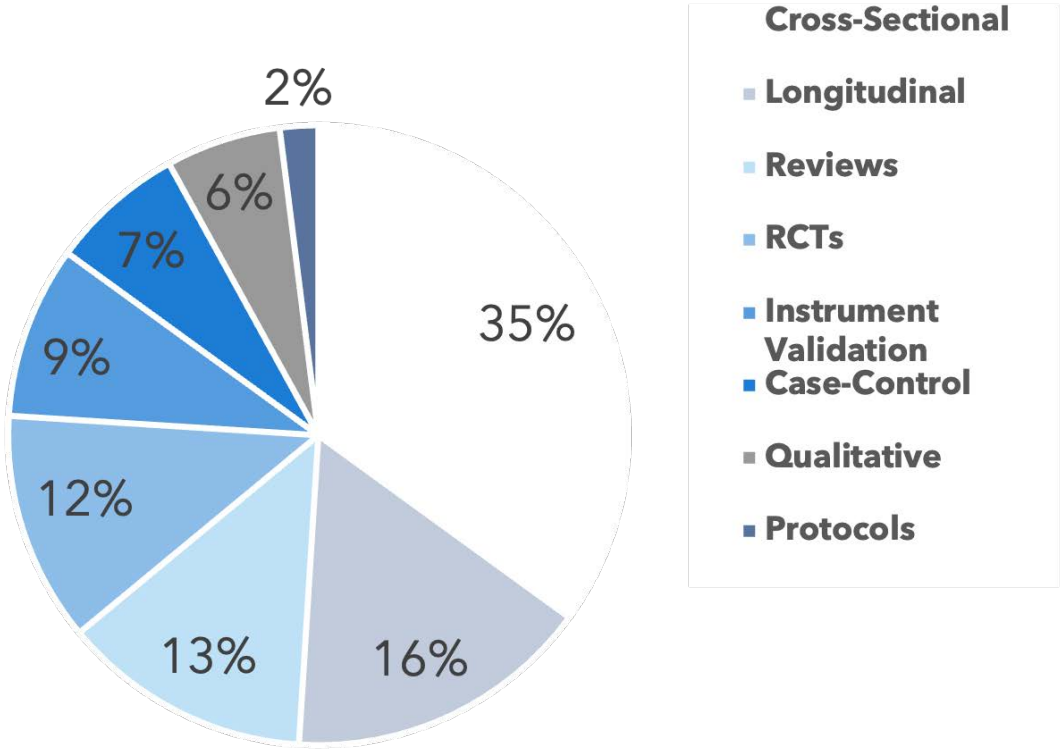


Results

Fatigue is a severity-dependent burden with measurable systemic effects. In pediatric groups, 62% of children report near-constant itch, and 42% lose more than one hour of sleep nightly. As a result, 23% of pre-schoolers with severe AD show significant behavioral symptoms, compared to 5% of matched controls. In adults, AD is strongly associated with impairment across five specific fatigue domains: general, physical, reduced activity, reduced motivation, and mental fatigue. The secondary caregiver burden is high, with 75% of parents reporting AD-related fatigue, and 66% experience emotional distress.

Measurement methodologies remain highly fragmented. Approximately half of the literature relies on legacy HOME-validated instruments (e.g., POEM, SCORAD, DLQI). While standardized, these tools lack a granular assessment of sleep architecture and specific fatigue parameters. Targeted tools, such as PROMIS, FACIT-Fatigue, and the Atopic Dermatitis Sleep Scale (ADSS), offer greater detail but face significant barriers to adoption in trial settings and daily practice due to the administrative burden of completion. Objective measures, including actigraphy and EEG polysomnography, constitute a minority in the literature and remain largely confined to ongoing clinical trials rather than to day-to-day patient care. However, when utilized, objective data reveal infants with AD record nearly double the overnight movements compared to controls (19.2 vs. 11.2) and significantly increased nighttime awakenings (3.5 vs. 1.9 times), which doubles maternal sleep-onset latency (27.1 vs. 12.8 minutes).

Therapeutically, systemic agents exhibit specific efficacy profiles. JAK inhibitors provide a rapid, uncoupled onset, driving clinically meaningful improvements in FACIT-F scores by week 2, frequently before full skin clearance. IL-4/13 inhibitors significantly restore sleep continuity, while IL-31 inhibitors provide targeted neuro-immunological itch blockade. At the same time, non-pharmacological interventions remain critical, fatigue-driven drops in topical treatment use highlight the value of behavioral interventions such as habit reversal training to break the nighttime itch-scratch cycle and stabilize sleep.



Conclusions

Fatigue is a primary systemic burden in AD, strongly associated with cognitive impairment, behavioral issues, and caregiver distress. In clinical practice, comprehensive management may benefit from targeting fatigue individually as a distinct symptom, combining rapid-acting systemic therapies with structured psychosocial interventions. To support this approach, future research should focus on bridging the gap between complex clinical trial measurements and practical, objective tools viable for routine patient care, ultimately establishing fatigue as a primary, measurable endpoint.

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Value of Achieving Absolute Score Treatment Targets in Atopic Dermatitis: Outcomes from Measure Up 1 and 2 Upadacitinib Trials

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Introduction

Atopic dermatitis (AD) is a chronic, inflammatory skin disease that impacts multiple dimensions of patients' lives. There is a growing interest in optimal treatment targets and absolute score thresholds, as demonstrated by minimal disease activity (MDA) defined by the Aiming High in Eczema/Atopic Dermatitis (AHEAD) recommendations and more recently by very low disease activity (vLDA) defined by the International Eczema Council (IEC). Both AHEAD and IEC advocate for the attainment of stringent outcomes to elevate the standard of care for AD. Further research is needed to characterize the value of these optimal/stringent score thresholds compared to suboptimal/less-stringent score thresholds. This study aimed to understand the value of achieving these optimal absolute score targets vs suboptimal criteria of disease activity on patient-reported outcomes (PROs).

Materials and Methods

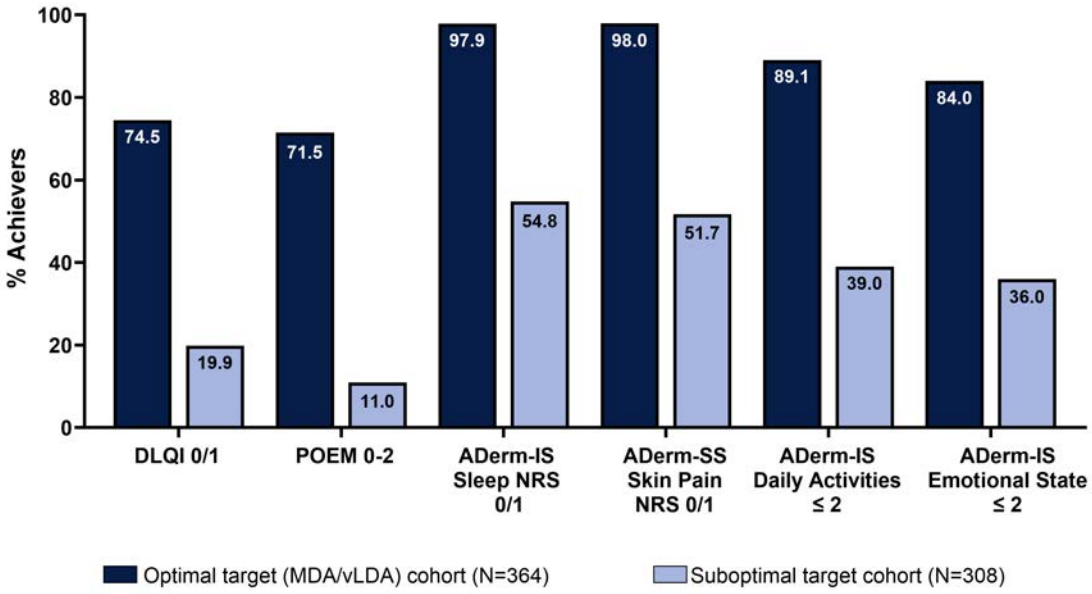
This is a post-hoc analysis of integrated data from 2 upadacitinib (UPA) phase 3 studies—Measure Up 1 (NCT03569293) and Measure Up 2 (NCT03607422). Patients received UPA 15 mg (UPA15), UPA 30 mg (UPA30), or placebo for a 16-week double-blind (DB) period, followed by a blinded extension (BE) period up to Week 260. Among patients with baseline Eczema Area and Severity Index (EASI) > 7 and Worst Pruritus Numeric Rating Scale (WP-NRS) > 4, those who achieved optimal skin and itch score targets (MDA/vLDA, defined here as EASI ≤ 3 and WP-NRS 0/1) or suboptimal skin and itch score targets (LDA per IEC definitions), which allow for residual disease activity (EASI ≤ 7 and WP-NRS ≤ 4) at Week 16 were selected and analyzed as 2 mutually exclusive groups. To characterize the value of absolute score targets, the proportion of patients achieving PRO responses corresponding to no/minimal disease were described, including: Dermatology Life Quality Index (DLQI) 0/1, Patient-Oriented Eczema Measure (POEM) 0-2, Atopic Dermatitis Impact Scale (ADerm-IS) Sleep NRS 0/1, Atopic Dermatitis Symptom Scale (ADerm-SS) Skin Pain NRS 0/1, ADerm-IS Daily Activities ≤ 2, and ADerm-IS Emotional State ≤ 2 at Week 16. Observed case analysis was used.

Results

Among 672 patients with both baseline EASI > 7 and WP-NRS > 4, 364 achieved optimal targets (MDA/vLDA: EASI ≤ 3 and WP-NRS 0/1), and 308 achieved suboptimal targets (EASI ≤ 7 and WP-NRS ≤ 4) at Week 16. More

patients achieving MDA/vLDA vs suboptimal targets reported PRO responses corresponding to no impact on quality of life (DLQI 0/1: 74.5% vs 19.9%), clear/almost clear symptoms (POEM 0-2: 71.5% vs 11.0%), no/minimal sleep disturbance (ADerm-IS Sleep NRS 0/1: 97.9% vs 54.8%), no/minimal skin pain (ADerm-SS Skin Pain NRS 0/1: 98.0% vs 51.7%), no/minimal impact of AD on daily activities (ADerm-IS Daily Activities ≤ 2: 89.1% vs 39.0%), and no/minimal impact of AD on emotional well-being (ADerm-IS Emotional State ≤ 2: 84.0% vs 36.0%) at Week 16.

Figure 1. Patients achieving optimal PRO outcomes at Week 16 based on achievement of MDA/vLDA



Note: Optimal target (MDA/vLDA) cohort defined as patients achieving EASI ≤ 3 and WP-NRS 0/1 at Week 16. Suboptimal target cohort defined as patients achieving EASI ≤ 7 and WP-NRS ≤ 4 at Week 16. Suboptimal EASI ≤ 7 and WP-NRS ≤ 4 group excludes patients who achieved MDA/vLDA (EASI ≤ 3 and WP-NRS 0/1); these two groups are non-overlapping and mutually exclusive. Restricted to both baseline EASI > 7 and WP-NRS > 4. Abbreviations: ADerm-IS, Atopic Dermatitis Impact Scale; ADerm-SS, Atopic Dermatitis Symptom Scale; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; MDA, minimal disease activity; NRS, numerical rating scale; POEM, Patient-Oriented Eczema Measure; PRO, patient-reported outcome; vLDA, very low disease activity; WP-NRS, Worst Pruritus Numerical Rating Scale.

Conclusions

These findings suggest that achieving optimal treatment targets (MDA/vLDA), rather than suboptimal targets, is associated with clinically relevant improvements in patient outcomes, including quality of life, sleep, pain, and emotional health outcomes, in patients with moderate-to-severe AD.

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Which EASI Response Is Relevant to Pediatric Patients With Atopic Dermatitis From a Patient's Perspective?

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Introduction
Achieving clinically meaningful treatment goals is a key objective in managing patients with atopic dermatitis (AD). Eczema Area and Severity Index (EASI) is one of the most used physician-assessment tools for assessing the severity and extent of AD in clinical trials. Previous reports in adults show that an EASI response between EASI-50 (50% improvement from baseline) and EASI-75 (75% improvement from baseline) is associated with clinically meaningful improvements in most patient-reported outcomes. This analysis reports which EASI threshold correlates best with clinically meaningful changes in patient- and caregiver-reported outcomes in pediatric patients with AD.

Materials and Methods
This post-hoc analysis included all dupilumab-treated patients aged 6 months to 17 years with AD from three phase 3, randomized, placebo-controlled studies in patients with AD: LIBERTY AD PRESCHOOL (moderate-to-severe AD; NCT03346434), LIBERTY AD PEDS (severe AD; NCT03345914), and LIBERTY AD ADOL (moderate-to-severe AD; NCT03054428). Repeated-measures regression analyses were used to assess the relationship between change in EASI and clinically meaningful difference in Infants' Dermatitis Quality of Life Index (IDQoL), Children's Dermatology Life Quality Index (CDLQI), Patient-Oriented Eczema Measure (POEM), SCORing Atopic Dermatitis (SCORAD), pruritus Visual Analog Scale (VAS), SCORAD sleep loss VAS, and Peak Pruritus Numeric Rating Scale (PP-NRS) from baseline.

Results
Linear regression showed that IDQoL ≥6-point improvement (PI)/CDLQI ≥6-PI, POEM ≥6-PI, SCORAD pruritus VAS ≥2-PI, SCORAD sleep loss VAS ≥2-PI, and PP-NRS ≥3-PI were achieved with the following percent change from baseline in EASI, respectively: 53%/52%, 39%, 36%, 36% and 78% (6 months to 5 years), 97%, 58%, 49%, 55% and 82% (6 to 11 years) and 76%, 48%, 51%, 54% and 83% (12 to 17 years). Logistic regression showed that, in patients aged 6 months to 5 years, the probabilities of achieving clinically meaningful responses were highly likely at EASI-50 and increased only modestly at higher response thresholds (EASI-75, EASI-90, and EASI-100) across IDQoL/CDLQI (range 0.81–0.99) , POEM (range 0.82–0.96), SCORAD pruritus VAS (range 0.87–0.98), and PP-NRS (range 0.89–0.98). The greatest gains in clinically meaningful responses were observed when moving from EASI-50

to EASI-75, with minimal additional benefit beyond EASI-75. Similar trends were observed in patients aged 6 to 11 years and 12 to 17 years, with the likelihood of clinically meaningful improvement increasing slightly with higher EASI responses across these patient- and caregiver-reported outcomes.

Conclusions

An EASI response between EASI-50 and EASI-75 is associated with a high probability of clinically meaningful improvements in patient- and caregiver-reported outcomes in pediatric patients with AD, a treatment goal that is visually quantifiable by physicians and meaningful for patients. Achievement of EASI-90 or EASI-100 was associated with slightly greater probabilities of clinically meaningful improvements in patient- and caregiver-reported outcomes, however, they were only marginally higher than with EASI-75. Identifying the level of EASI threshold associated with clinically meaningful improvement in pediatric patients further provides clinicians with valuable insights for guiding treatment decisions and managing patient expectations effectively in clinical practice.

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Abstract N°: 3717

Comparative Efficacy of 1.5% Ruxolitinib Cream Versus Systemic Therapies in Moderate Atopic Dermatitis

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Introduction

Adults with moderate atopic dermatitis (AD) inadequately controlled with topical corticosteroids (TCS) or topical calcineurin inhibitors (TCI) are often escalated to systemic therapy. Ruxolitinib cream (1.5%), a topical Janus kinase (JAK)1/JAK2 inhibitor, previously demonstrated efficacy in mild to moderate AD (TRuE-AD1/2) and was recently evaluated in TRuE-AD4, a phase 3b study exclusively enrolling adults with moderate AD and inadequate response, intolerance, or contraindication to both TCS and TCI. The aim of this analysis was to evaluate the comparative efficacy of 1.5% ruxolitinib cream versus approved systemic therapies in moderate AD using TRuE-AD4 data.

Materials and Methods

A systematic literature review conducted on September 9, 2024, identified phase 3 randomized controlled trials of biologics and oral JAK inhibitors in moderate AD (including mixed populations with mild or severe AD). A feasibility assessment confirmed a connected evidence network of 21 trials (including TRuE-AD4) for monotherapy regimens without concomitant TCS and TCI, 7 of which reported outcomes for the moderate AD population. Fixed-effect network meta-analyses (NMAs) were conducted in a Bayesian framework for ≥75% and ≥90% improvements in Eczema Area and Severity Index scores (EASI-75 and EASI-90, respectively), Investigator's Global Assessment Treatment Success (IGA-TS; defined as an IGA score of 0 or 1, with a ≥2-grade improvement from baseline), and ≥4-point improvement in the itch numerical rating scale, as reported at the timepoint of the primary endpoint of each trial. The NMAs were performed for patients with moderate AD (ie, intention-to-treat patients in TRuE-AD4 and subgroups of patients with moderate AD in comparator trials). Between-trial heterogeneity in baseline patient characteristics and vehicle/placebo response was accounted for in sensitivity analyses through baseline risk adjustment, where feasible.

Results

In the moderate AD population, 1.5% ruxolitinib cream demonstrated efficacy comparable to dupilumab, abrocitinib, and upadacitinib for EASI-75 and IGA-TS. For EASI-90, 1.5% ruxolitinib cream demonstrated efficacy comparable to upadacitinib, but comparisons to other treatments were not feasible as this outcome was not reported for those therapies in the moderate AD subgroup. Data for ≥4-point improvement in the itch numerical rating scale in the moderate AD population were limited to dupilumab and upadacitinib, both of which demonstrated efficacy comparable to 1.5% ruxolitinib cream. Baseline risk-adjusted results were consistent with unadjusted findings.

Conclusions

In patients with moderate AD inadequately controlled with TCS and TCI, 1.5% ruxolitinib cream demonstrated efficacy comparable to approved systemic therapies across clinical and patient-reported outcomes. Results should be interpreted with caution owing to cross-trial differences in patient populations and definitions of moderate AD, including differences in baseline disease severity such as body surface area, EASI, and IGA scores between TRuE-AD4 and comparator trials. These data support ruxolitinib cream as an effective non-systemic treatment option for patients with moderate AD.

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Real-world effectiveness of topical delgocitinib in chronic hand eczema: a case series

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Introduction

Chronic hand eczema (CHE) is a relapsing inflammatory condition with significant functional and quality-of-life impairment. Topical delgocitinib, a pan–Janus kinase inhibitor, has demonstrated efficacy in clinical trials, but real-world data remain limited, particularly in routine clinical settings.

The aim of this study was to evaluate the effectiveness of topical delgocitinib in routine clinical practice in patients with CHE non-responsive to topical corticosteroids.

Materials and Methods

We conducted an observational case series including 15 adult patients with CHE (5 males, 10 females; mean age 47.35 years; mean disease duration 6.9 years) treated with topical delgocitinib. Clinical subtypes included hyperkeratotic fissured eczema (n=6), dyshidrotic/pompholyx type (n=4), nummular eczema (n=4), and pulpitis (n=1), with one patient presenting overlapping clinical features. Patients were assessed at baseline and at weeks 4 and 16 using validated outcome measures: Investigator's Global Assessment for CHE (IGA-CHE), Hand Eczema Severity Index (HECSI), Hand Eczema Symptom Diary (HESD; itch and pain), and Dermatology Life Quality Index (DLQI). Adjunctive measures, including emollients and trigger avoidance, were maintained. Changes from baseline were analyzed using paired statistical tests. Analyses at week 16 were performed on evaluable patients only, as two patients had not yet reached this timepoint.

Results

At week 4, most patients showed early clinical improvement, with associated rapid and sustained improvement of itch and pain. Mean IGA-CHE decreased from 3.07 at baseline to 1.23 at week 4 and 0.58 at week 16. Disease severity, as measured by HECSI, improved from 78.15 at baseline to 31.38 at week 4 and 13.92 at week 16, with a statistically significant reduction from baseline to week 16 ($p < 0.001$). At week 16, 75.7% achieved HECSI-75 response, with 36.9% reaching HECSI-90, and all patients achieving at least HECSI-50 improvement. Symptom burden showed marked reductions: mean NRS itch decreased from 9.12 at baseline to 4.46 at week 4 and 1.30 at week 16, while NRS pain decreased from 8.64 to 3.92 and 0.92, respectively. Quality of life improved consistently, with DLQI scores decreasing from 22.92 at baseline to 11.61 at week 4 and 2.62 at week 16. Clinical response varied according to individual factors, particularly occupational exposure and allergen avoidance. Patients with ongoing occupational exposure showed more fluctuating responses, whereas those with effective trigger avoidance achieved more sustained improvement. Treatment was generally well tolerated, with no major safety concerns observed.

Conclusions

In this real-world Italian case series, topical delgocitinib demonstrated rapid onset of action on pruritus and sustained clinical improvement in patients with recalcitrant CHE, confirming and extending evidence from clinical trials. These findings suggest that delgocitinib may represent a valid therapeutic for patients who failed corticosteroid or need a steroid-sparing first-line approach to optimize long-term outcomes.

EADV CONGRESS
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Abstract N°: 3741

Development of an anti-IL-13 antibody with best-in-class potency and half life

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Introduction

Type 2 inflammatory pathway inhibition is safe and effective in the treatment of atopic dermatitis, with approved drugs targeting the cytokine IL-13 and its receptor IL-4R. Newer IL-13 antagonists in clinical development (zumilokibart) leverage half-life extension to improve patient convenience, compliance, and drug exposure, with recent trials demonstrating a clear exposure benefit in the depth of clinical response. We note that even in these trials the maximally efficacious dose of IL-13 inhibition has yet to be reached. To achieve maximal efficacy we have developed an IL-13 inhibitor capable of deeper inhibition, with anticipated best-in-class half life, affinity, and bioavailability compared to current commercial and clinical-stage IL-13 inhibitors.

Materials and Methods

Using our GLIMPSE antibody language model, we generated highly specific, novel antibody candidates with overlapping epitopes to known IL-13 inhibitors. Combined with experimental data, GLIMPSE enables systematic improvement of molecular properties, including increased affinity, half-life enhancement, manufacturing and formulation optimization, and reduced predicted immunogenicity. Briefly, affinity data for each intermediate and final candidate antibody was generated via surface plasmon resonance (SPR, Carterra LSA-XT) with final antibody candidates IC50 evaluated in HEKBlue IL-4/13R reporter cells. The candidates were also evaluated using a panel of standard developability assays to assess stability and manufacturability, and run through a 28 day pharmacokinetic study in Tg32/hFcRn transgenic mice.

Results

A final set of 14 Fv sequences were derived over multiple rounds of diversity and optimization engineering. Affinity of all candidate sequences was measured less than 200pM, with top sequences in the single digit picomolar range. An overall reduction for predicted manufacturing liabilities and similar or better stability was also achieved for each sequence. These antibodies reduced IL-13 signaling in HEKBlue reporter cells to the lower limit of quantification for the assay. Critically, ten of the fourteen sequences demonstrated longer half lives than clinical counterparts, with the top sequences demonstrating Tg32 mouse half lives of ~24 days (an increase of ~40% compared to zumilokibart).

Conclusions

Inhibition of Th2 inflammation, and particularly blockade of IL-13, is currently the most effective biologic therapy for AD. As multiple IL-13 blocking antibodies have entered the clinic, it has become clear that increased drug exposure (via improved potency and longer half life) drives increased efficacy. From the set of IL-13 inhibitors described here we expect a final candidate to meaningfully increase both affinity and half life relative to current clinical candidates. Along with improved stability and manufacturability we expect this molecule to drive deeper clinical responses and further improve patient outcomes for AD and other Th2 mediated diseases.

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Abstract N°: 3743

Lebrikizumab improves clinical outcomes and reduces serum TARC in biologic-naive and biologic-experienced patients with atopic dermatitis: 16-week real-world data from the BioDay Registry

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Introduction

Lebrikizumab, a selective interleukin-13 inhibitor, has demonstrated efficacy and a favorable safety profile in clinical trials for atopic dermatitis (AD). However, prospective real-world evidence (RWE), particularly in biologic-experienced patients, remains limited. Therefore, this study evaluated the 16-week effectiveness and safety of lebrikizumab in patients aged ≥12 years with moderate-to-severe AD in routine clinical practice.

Materials and Methods

We conducted a prospective multicenter observational cohort study within the Dutch BioDay Registry. Primary endpoints included the Eczema Area and Severity Index (EASI), Investigator's Global Assessment (IGA), Numeric Rating Scale (NRS) for weekly Pruritus, Dermatology Life Quality Index (DLQI), and Recap of Atopic Eczema (RECAP) at week 16. Secondary endpoints included achievement of EASI≤7, IGA≤1, NRS Pruritus≤4, and DLQI≤5 at week 16. Additional outcomes included head and neck EASI subscore and a combined absolute cutoff for low disease activity (LDA), defined as EASI≤7 and weekly NRS Pruritus≤4. Adverse events (AEs) were summarized descriptively. In addition, serum levels of AD severity biomarker thymus- and activation-regulated chemokine (TARC) were evaluated. Mixed models were used for continuous and dichotomous outcomes, with multiple imputation to handle missing data. Subgroup analyses were performed comparing biologic-naïve and biologic-experienced patients.

Results

A total of 129 patients were included. Mean age was 35.4 years (SD 14.4), 62.8% were male, and 83.7% had ≥1 atopic comorbidity. Overall, 57 patients (44.2%) were biologic-experienced, having previously received dupilumab and/or tralokinumab. At week 16, mean EASI decreased from 13.7 (95% CI: 12.4–15.1) to 5.3 (95% CI: 4.0–6.7), NRS Pruritus from 6.6 (95% CI: 6.2–7.0) to 3.9 (95% CI: 3.5–4.3), DLQI from 14.2 (95% CI: 12.8–15.6) to 6.3 (95% CI: 5.0–7.6), RECAP from 17.0 (95% CI: 15.5-18.4) to 9.4 (95% CI: 8.0-10.8). In addition, head and neck EASI subscore decreased from 21.2% (95% CI: 18.4-23.8) to 9.2% (95% CI: 6.5-11.9), while median serum TARC levels decreased from 1286.9 pg/mL (95% CI: 1050.5–1576.6) to 438.8 pg/mL (95% CI: 350.4–At week 16, 88.8% (95% CI: 71.4–96.2) achieved EASI≤7, 62.6% (95% CI: 51.2–72.7) achieved NRS Pruritus≤4, 49.4% (95% CI: 39.4-59.5) achieved LDA, 46.7% (95% CI: 35.6–58.2) achieved DLQI≤5, and 24.1% (95% CI: 16.1–34.3) achieved IGA≤1. Stratified efficacy results in biologic-naïve and biologic experienced patients, are shown in **Figure 1**. In total, 107 AEs were reported in 82 patients (63.6%), of which 95.3% were mild to moderate. The most common AE was conjunctivitis, occurring in 40 patients (31.0%), including 4 cases (3.1%) of severe conjunctivitis with limbitis. Treatment discontinuation before week 16 occurred in 7 patients (5.4%) due to AEs (n=2), AEs combined with ineffectiveness (n=1), administration issues (n=2) and patient wish (n=2).

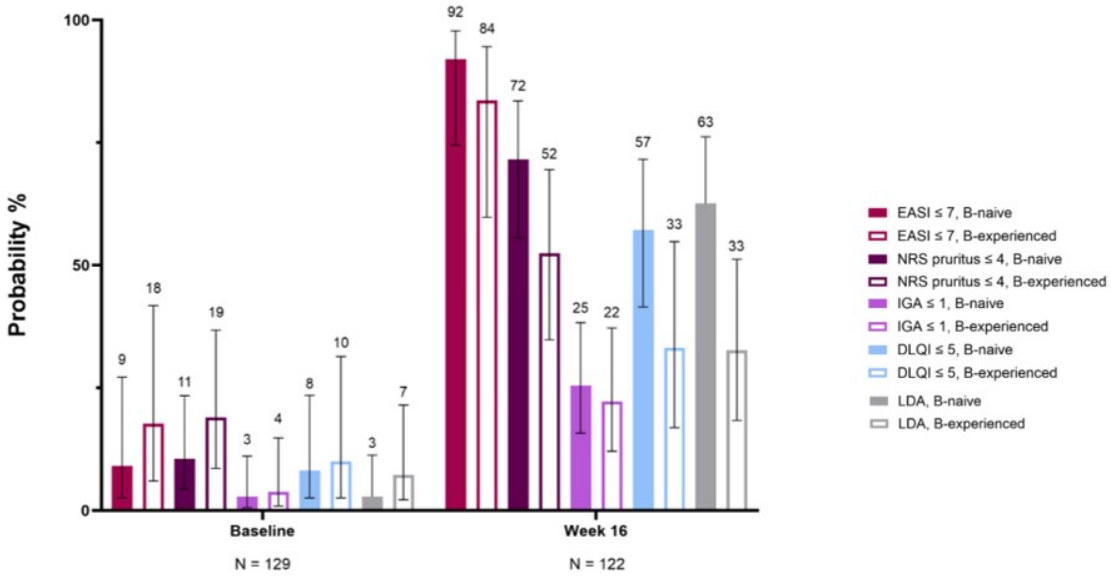

Figure 1. Estimated probabilities of achieving predefined absolute cut-off scores indicative of controlled atopic dermatitis (AD) at baseline and week 16, stratified by prior biologic (dupilumab and/or tralokinumab) use. Outcomes include EASI ≤7, NRS Pruritus ≤4, IGA ≤1, DLQI ≤5 and low-disease activity (LDA). Error bars represent 95% confidence intervals. Differences between biologic-naive and biologic-experienced patients were statistically significant for EASI ≤7, NRS Pruritus ≤4 and LDA (likelihood ratio test, $p<0.05$), but not for IGA ≤1 and DLQI ≤5.

Conclusions

In this prospective real-world cohort of moderate-to-severe AD patients, lebrikizumab led to clinically meaningful improvements in disease severity, symptoms, and quality of life over 16 weeks. Improvements were observed in across biologic-experienced and biologic-naïve subgroups and was accompanied by a marked reduction in serum TARC levels. Although treatment discontinuation due to AEs was low and most AEs were mild-to-moderate, severe ocular surface disease occurred in a small number of patients.

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Suicidal behavior in 108,675 Children and Adolescents with Atopic Dermatitis: A Swedish Nationwide Matched Cohort Study

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Introduction

Atopic dermatitis (AD) has been associated with adverse mental health outcomes, including suicidal behaviour. Yet whether this reflects increased occurrence or greater lethality of suicidal events remains unresolved.

The objective of this study is to quantify the incidence and case-fatality of suicidal behaviour among children and adolescents with AD compared with matched population-based controls.

Materials and Methods

We conducted a nationwide matched cohort study including individuals aged 0–18 years with specialist-diagnosed AD (2007–2024), matched by birth year and sex to up to five controls. The primary outcome was first suicidal behaviour (suicide attempt or completed suicide). Incidence rates (IRs), incidence rate ratios (IRRs), and hazard ratios (HRs) were estimated using Poisson and Cox regression models with attained age as the timescale, adjusted for sex and calendar period. Analyses were stratified by age and sex. Case-fatality was defined as the proportion of suicidal events resulting in death, i.e. deaths divided by the total number of suicide attempts and suicides, and estimated using exact 95% confidence intervals.

Results

The cohort included 108,675 children and adolescents with AD and 690,343 reference individuals. During follow-up, 1,341 first events of suicidal behaviour occurred among individuals with AD, including 1,321 suicide attempts and 29 deaths by suicide; corresponding numbers among reference individuals were 7,477 events, including 7,383 suicide attempts and 143 deaths by suicide.

AD was associated with a consistently increased incidence of suicidal behaviour, evident across adolescence. Both relative (HR) and absolute (IR) measures showed this pattern. In individuals aged 15–18 years, hazard ratios were 1.16 (95% CI 1.07–1.25) in females and 1.15 (1.02–1.30) in males, with similar estimates in those aged 10–14 years, while estimates in children aged 0–9 years were less precise.

Absolute risks were higher in AD compared with controls. The incidence rate for the composite outcome was 1.31 per 1000 person-years (95% CI 1.24–1.38) in individuals with AD and 1.10 per 1000 person-years (1.07–1.12) in controls, corresponding to an incidence rate ratio of 1.19 (95% CI 1.13–1.26), representing an absolute difference of approximately 0.21 events per 1000 person-years. Similar patterns were observed for suicide attempts (IRR 1.19, 95% CI 1.12–1.26), while estimates for completed suicide were less precise (IRR 1.35, 95% CI 0.90–2.01). When stratified by sex, incidence rates of suicide attempts were higher in females, whereas completed suicide was more frequent in males.

Patterns differed when examining lethality. Case-fatality was substantially higher in males than females across all age groups. Among individuals aged 15–18 years without AD, case-fatality was 1.7% (95% CI 1.4–2.1) in females and 6.1% (5.1–7.3) in males. In the corresponding AD group, case-fatality was 1.8% (1.1–2.9) in females and 8.5% (5.8–12.0) in males. Point estimates of case-fatality were consistently higher in males with AD than in controls, particularly in older adolescents.

Conclusions

AD is associated with an increased incidence of suicidal behaviour in youth, primarily driven by more frequent events- of suicide attempts rather than suicidality. Case-fatality was consistently higher in males, with the highest estimates observed in males with AD, suggesting a potentially vulnerable subgroup and highlighting the importance of sex-specific risk stratification.

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Effectiveness of Lebrikizumab as a switch from Tralokinumab in patients with moderate-to-severe atopic dermatitis: a real-world case series

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory disease predominantly mediated by the Th2 immune pathway, in which interleukin-13 (IL-13) plays a key role in its pathophysiology. Monoclonal antibodies selectively targeting this cytokine, such as tralokinumab and lebrikizumab, have emerged as directed therapeutic options. Although they share the same molecular target, they present distinct mechanisms of action that may influence clinical response. We present a group of patients who do not achieve an adequate disease control with tralokinumab, highlighting the need for rescue strategies.

Materials and Methods

Single-centre retrospective case series of patients aged ≥18 years with moderate-to-severe AD who initiated lebrikizumab following documented tralokinumab failure, defined as <50% improvement in EASI or IGA >2 at week 16 or beyond. Lebrikizumab was administered per SmPC. EASI, IGA, pruritus NRS, sleep NRS, DLQI and BSA were collected at available timepoints (weeks 6, 16 and 24) to assess treatment response.

Results

Eight patients were identified (5 female; median age 27.5 years, range 18–60). Prior systemic therapies included topical corticosteroids (8/8), ciclosporin (6/8) and dupilumab (2/8), with a median tralokinumab duration before switching of 32 weeks (range 20–92). At week 16, among 7 evaluable patients, the mean percent reduction in EASI from baseline was 65.9%, with 85.7% (6/7) achieving EASI 50 and IGA 0/1, and 28.6% (2/7) achieving EASI 75. At week 24, among 4 evaluable patients, 75% (3/4) maintained or achieved EASI 75, including 2 patients with complete clearance (EASI 0, IGA 0). Clinically meaningful improvement in pruritus NRS (≥4-point reduction) was observed in 6/7 patients with available data. One patient (12.5%) experienced secondary failure at week 24 with return to baseline disease activity and was subsequently switched to a JAK inhibitor. No serious adverse events were recorded.

Conclusions

Lebrikizumab is a humanized monoclonal antibody (IgG4) that binds with high affinity to IL-13 and selectively inhibits its signaling through blockade of the heterodimerization of the IL-4Rα and IL-13Rα1 subunits of the type 2 receptor. Its binding epitope on IL-13 differs from that of other anti-IL-13 antibodies, allowing IL-13 to retain its interaction with the decoy receptor IL-13Rα2, which is thought to promote cytokine clearance via lysosomal degradation. This differential mechanism of action may explain its efficacy in patients who do not respond to tralokinumab. Our results are consistent with those of Hagino et al. (JEADV 2025), the first prospective multicentre

series (n=13), which reported EASI 50, 75 and 90 rates of 78.6%, 42.9% and 14.3% at week 16. This evidence is further consolidated by the single-centre retrospective study from the same group (BioDrugs 2026, n=16), which demonstrated EASI 50 and EASI 75 rates of 91.7% and 83.3% respectively at week 48, with sustained improvement and a favourable safety profile.

We present a real-world case series that expands the available evidence on switching from tralokinumab to lebrikizumab, suggesting that this strategy can be effective in patients with moderate-to-severe AD refractory to the former.

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4-Week Anti-Relapse Efficacy of a Ceramide-Containing Moisturizer in Children and Adults with Atopic Dermatitis: A Global Multi-Center Study

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease characterized by barrier dysfunction, intense pruritus, and recurrent flares. Topical corticosteroids (TCS) remain first-line therapy for AD. Maintaining sustained remission remains a clinical challenge, as flares frequently recur once treatment is discontinued. This study aimed to assess the efficacy of a ceramide-containing moisturizer (CCM) formulated with ceramides NP, AP, and EOP when used over the course of 6 weeks in patients with mild to moderate AD to evaluate its anti-relapse efficacy.

Materials and Methods

This global, multi-center study enrolled both pediatric (2 months-17 years) and adult subjects (18-55 years). Subjects were required to have least one active mild-to-moderate AD lesion on the body (arms, legs, or torso) at baseline. The 6-week study included a standardized TCS phase (Fluticasone propionate 0.05% + twice daily CCM) for 7-14 days until target lesion resolution was achieved. Following this 2-week period, subjects transitioned to a maintenance regimen of twice daily CCM application, with TCS only used on an as-needed basis. Efficacy of the CCM was assessed via time to next flare and SCORAD. A flare was defined as the recurrence of active inflammatory symptoms on the target lesion requiring rescue TCS therapy, as documented in subject daily diaries. Safety was monitored through investigator-graded objective irritation and subject-reported subjective tolerance.

Results

From initial enrollment, a per-protocol population of 105 subjects was analyzed. The mean duration of TCS use required to achieve lesion resolution was 12 days. In the maintenance phase, 82 out of the 105 (78.1%) patients remained flare-free with no relapse on the target lesion for 4 weeks. Subjects achieved a statistically significant and rapid reduction in AD severity; with mean body SCORAD decreasing from 30.81 at pre-TCS baseline to 12.73 at Week 1 (during TCS induction phase) and 8.14 at Week 4, and 6.26 at Week 6 during the maintenance phase ($p < 0.001$ across all time points).

Conclusions

By preventing flare recurrence in the 4-week maintenance phase and achieving a rapid, significant reduction in SCORAD, this CCM regimen provides a strong anti-relapse effect for patients with mild to moderate AD lesions. These findings demonstrate that addressing the underlying skin barrier dysfunction plays a foundational role in managing AD across both pediatric and adult populations.

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Stringent Clinical and Patient-Reported Benefits of Upadacitinib in Patients With Moderate-to-Very Severe Hand Eczema Associated with Atopic Dermatitis: Integrated Post Hoc Analysis From Measure Up 1 and Measure Up 2 Studies

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Introduction

Hand eczema is a common inflammatory skin condition, that often occurs alongside atopic dermatitis (AD) and is associated with significant disease burden, leading to substantial impact on daily activities, social interactions, mental health, and overall health-related quality of life (HRQoL). In the Measure Up 1 and 2 studies, treatment with upadacitinib 15 mg (UPA15) and 30 mg (UPA30) resulted in greater reductions in Hand Eczema Severity Index (HECSI) scores from baseline to week 16 compared with placebo (PBO) (Simpson EL, et al. *J Eur Acad Dermatol Venereol.* 2023;37:1863–1870). This integrated post hoc analysis from Measure Up 1 and 2 evaluated achievement of stringent hand eczema responses and HRQoL outcomes with UPA among patients with at least moderate hand eczema severity (HECSI > 16) at baseline.

Materials and Methods

Measure Up 1 and Measure Up 2 were replicate, double-blind, placebo-controlled, multicenter phase 3 trials enrolling patients aged 12 to 75 years with moderate-to-severe AD. Patients were randomized 1:1:1 to receive UPA15, UPA30, or PBO once daily for 16 weeks. This post hoc analysis assessed the proportion of patients achieving the following stringent outcomes at week 16: ≥ 90% and 100% HECSI improvement (HECSI 90/100);

HECSI ≤ 16; Dermatology Life Quality Index (DLQI) or Children's Dermatology Life Quality Index (cDLQI) score of 0/1; Atopic Dermatitis Impact Scale – Daily Activities (ADerm-IS Daily Activities) score ≤ 2; Atopic Dermatitis Impact Scale – Emotional State (ADerm-IS Emotional State) score ≤ 2; and Hospital Anxiety and Depression Scale – Anxiety (HADS-A) and Depression (HADS-D) scores < 8. Nominal *P* values were derived from Mantel–Haenszel tests adjusted for study and baseline vIGA-AD scores to compare the efficacy of UPA15 and UPA30 vs PBO. Safety was not assessed in this analysis.

Table 1. Demographics and Baseline Disease Characteristics of Patients in Measure Up 1 and Measure Up 2 Stratified by Severity of Hand Eczema at Baseline.

	Clear (n = 234)	Almost Clear (n = 388)	Moderate (n = 343)	Severe (n = 555)	Very Severe (n = 159)
Age (years), mean (SD)	36.2 (17.7)	31.0 (14.3)	33.2 (15.8)	33.4 (14.6)	39.9 (16.0)
Male, n (%)	127 (54.3)	216 (55.7)	186 (54.2)	315 (56.8)	82 (51.6)
Duration of symptoms (years), mean (SD)	19.9 (14.1)	21.4 (12.6)	23.3 (13.9)	24.4 (14.1)	26.8 (16.4)
vIGA-AD, n (%)					
Moderate (3)	168 (71.8)	248 (63.9)	169 (49.3)	218 (39.3)	36 (22.6)
Severe (4)	66 (28.2)	140 (36.1)	174 (50.7)	337 (60.7)	123 (77.4)
EASI, mean (SD)	23.5 (7.6)	25.8 (9.5)	28.4 (10.8)	32.2 (12.9)	38.1 (14.9)
BSA, mean (SD)	34.6 (16.3)	42.8 (19.6)	46.9 (21.1)	52.4 (23.3)	55.4 (25.6)
HECSI, mean (SD)	0	8.1 (4.3)	26.4 (6.2)	66.6 (20.9)	160.7 (44.2)
DLQI, mean (SD)	14.9 (6.4)	16.0 (7.2)	16.9 (6.8)	17.5 (6.9)	18.3 (7.2)
cDLQI, mean (SD)	11.7 (4.1)	13.4 (6.2)	13.2 (6.4)	15.7 (6.2)	17.0 (6.9)
HADS Total Score, mean (SD)	11.8 (7.3)	12.2 (7.4)	13.2 (7.9)	13.1 (7.6)	13.5 (7.6)
ADerm-IS Daily Activities, mean (SD)	21.6 (10.6)	21.4 (10.8)	23.3 (10.7)	24.0 (10.2)	25.8 (9.8)
ADerm-IS Emotional State, mean (SD)	19.3 (8.3)	19.6 (8.1)	20.5 (8.2)	20.6 (8.1)	21.6 (7.7)

ADerm-IS, Atopic Dermatitis Impact Scale; BSA, Body Surface Area; cDLQI, Children's Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; HADS, Hospital Anxiety and Depression Scale; HECSI, Hand Eczema Severity Index; vIGA-AD, Validated Investigator Global Assessment for Atopic Dermatitis. Percentages calculated on non-missing values.

Results

A total of 1057 patients had a baseline HECSI > 16 (**Table 1**). Greater baseline hand eczema severity was associated with higher overall AD severity, larger AD-affected area, longer AD symptom duration, poorer HRQoL, and greater impact on both daily activities and emotional well-being (**Table 1**). Baseline hand eczema severity was balanced across treatment arms (**Table 2**). At week 16, a greater proportion of patients receiving UPA15 and UPA30 vs PBO achieved HECSI 90 (60.2% and 71.7% vs 10.1%) and HECSI 100 (42.7% and 54.8% vs 6.4%). Most patients receiving UPA15 and UPA30 achieved a HECSI score ≤ 16 compared with those receiving PBO (71.5% and 79.8% vs 20.2%; nominal *P* < .001 across all HECSI outcomes), reflecting achievement of clear or almost clear skin in the hands. Additionally, higher proportions of patients treated with UPA vs PBO achieved no impact on QoL (DLQI or cDLQI 0/1: 28.9% and 41.2% vs 2.6%), minimal daily activity impairment (ADerm-IS Daily Activities 0–2: 38.8% and 55.3% vs 9.0%), minimal emotional impact (ADerm-IS Emotional State 0–2: 34.7% and 50.9% vs 7.4%), and psychological well-being (HADS-A < 8 and HADS-D < 8: 42.0% and 55.8% vs 10.9%: nominal *P* < .001 across all HRQoL outcomes) (**Table 3**).

Table 2. Distribution of Baseline HECSI in Measure Up 1 and Measure Up 2.

Baseline HECSI	Placebo (N = 556) n (%)	UPA 15 mg (N = 556) n (%)	UPA 30 mg (N = 567) n (%)	Total (N = 1679) n (%)
Clear (0)	93 (16.7)	75 (13.5)	66 (11.6)	234 (13.9)
Almost clear (1 to 16)	117 (21.0)	137 (24.6)	134 (23.6)	388 (23.1)
Moderate (17 to 37)	119 (21.4)	108 (19.4)	116 (20.5)	343 (20.4)
Severe (38 to 116)	184 (33.1)	181 (32.6)	190 (33.5)	555 (33.1)
Very severe (≥ 117)	43 (7.7)	55 (9.9)	61 (10.8)	159 (9.5)

HECSI, Hand Eczema Severity Index.
Patients with missing baseline HECSI are excluded from the results.

Table 3. Results at Week 16 Among Patients With HECSI > 16 at Baseline.

	Placebo n/N (%)	UPA 15 mg n/N (%)	UPA 30 mg n/N (%)
HECSI 90[a]	35/346 (10.1)	207/344 (60.2)*	263/367 (71.7)*
HECSI 100[a]	22/346 (6.4)	147/344 (42.7)*	201/367 (54.8)*
HECSI ≤ 16	70/346 (20.2)	246/344 (71.5)*	293/367 (79.8)*
DLQI or cDLQI 0/1 [b]	9/341 (2.6)	98/339 (28.9)*	146/354 (41.2)*
ADerm-IS Daily Activities 0-2[c]	28/311 (9.0)	119/307 (38.8)*	187/338 (55.3)*
ADerm-IS Emotional State 0-2 [d]	23/309 (7.4)	105/303 (34.7)*	171/336 (50.9)*
HADS-A <8 and HADS-D <8[e]	19/174 (10.9)	74/176 (42.0)*	110/197 (55.8)*

ADerm-IS, Atopic Dermatitis Impact Scale; cDLQI, Children's Dermatology Life Quality Index; HADS-A, Hospital Anxiety and Depression Scale-Anxiety subscale; HADS-D, Hospital Anxiety and Depression Scale-Depression subscale; HECSI, Hand Eczema Severity Index; UPA, upadacitinib.
*All nominal $P < .001$; UPA vs. placebo; non-responder imputation with no multiple imputation (NRI-NC).
[a]HECSI 90/100, 90% and 100% improvement in hand eczema severity. [b]Assessed among patients with HECSI > 16 and DLQI > 1 or cDLQI > 1 at baseline. [c]Assessed among patients with HECSI > 16 and ADerm-IS Daily Activity > 2 at baseline. [d]Assessed among patients with HECSI > 16 and ADerm-IS Emotional State > 2 at baseline. [e]Assessed among patients with HECSI > 16 and HADS-A ≥ 8 or HADS-D ≥ 8 at baseline.

Conclusions

In this post hoc analysis, treatment with UPA15 and UPA30 was associated with clinically meaningful improvements in hand eczema severity compared with PBO at week 16, with most patients achieving clear or almost clear skin in the hands. These improvements were accompanied by gains in HRQoL, daily functioning, emotional well-being, and psychological health. Numerically greater benefits were observed with the 30 mg dose across clinical and HRQoL outcomes. These findings support UPA as an effective therapeutic option for patients with at least moderate hand eczema and concurrent moderate-to-severe atopic dermatitis.

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Prolongation of flare-free intervals in adults with atopic dermatitis using an active emollient formulation: a 12-month multicenter, blinded cosmetic study

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disease characterized by impaired epidermal barrier function, xerosis, pruritus, and recurrent eczematous lesions. It affects both children and adults and is associated with a substantial physical, psychological, and socioeconomic burden. The disease course is typically marked by alternating phases of remission and flare, with symptoms frequently reoccurring after discontinuation of anti-inflammatory treatment. Current management strategies therefore emphasize not only reactive treatment of acute flares, but also proactive, long-term maintenance approaches aimed at stabilizing remission, strengthening the skin barrier, and reducing the frequency and severity of relapses (Wollenberg, A et al., 2022). In this study, we investigated an emollient formulation with barrier-supportive and anti-pruritic ingredient properties (Ceramides and Licochalcone A), that may prolong symptom-free intervals and thereby improve patient quality of life.

Materials and Methods

This multicenter, blinded, cosmetic in-vivo study investigated an active emollient formulation in adults (18–70 years, n=40) with AD in remission after successful anti-inflammatory therapy. Subjects applied the formulation at least twice daily under normal use conditions for up to 12 months or until relapse. Dermatological assessments were conducted at baseline and at eight follow-up visits. Individual pre-treatment flare-free interval time was documented.

The primary outcome was time to relapse, defined by recurrent erythema, Investigator's global assessment (IGA) >1, and/or local SCORing of Atopic Dermatitis (SCORAD) >5. Continuous development of local SCORAD, IGA and Dermatology Life Quality Index (DLQI) were reported as secondary outcome.

Results

The mean pre-treatment flare-free interval was 100 days. Use of the active formulation significantly prolonged the time to relapse, with a relative extension of 186%, effectively extending individual flare-free phases by up to 279 days, with up to 348 days until relapse observed in treated subjects.

In comparison with baseline values, local SCORAD scores decreased significantly from day 28 onwards and remained improved through month 12. IGA scores showed significant long-term improvement from day 84 onward. DLQI scores improved significantly from baseline at multiple time points, indicating a sustained benefit on patient quality of life. No incompatibility or tolerability issues were reported.

Conclusions

Regular use of the active emollient formulation during remission significantly prolonged flare-free intervals in adults with atopic dermatitis and led to sustained improvements in clinical severity and dermatology-specific quality of life. The observed extension of relapse-free periods of up to nearly one year highlights the value of targeted maintenance skincare as a non-pharmacological strategy in long-term AD management. These findings support the use of the formulation as an effective adjunct in proactive disease stabilization.

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Abstract N°: 3861

The Effectiveness and Safety of Lebrikizumab in a Cohort of Real-World Patients with Moderate-to-Severe Atopic Dermatitis from the United Kingdom

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Introduction

Lebrikizumab is a monoclonal antibody licensed for moderate-to-severe atopic dermatitis (AD). It binds with interleukin IL-13 reducing IL-13Rα1/IL-4Rα formation and signalling implicated in AD pathogenesis.[1] The dosing regimen in the UK consists of 2 doses of 500mg every 2 weeks, followed by 250mg every two weeks until week 16. In complete responders, the dosing interval may be extended to 4-weekly. Real-world effectiveness and safety data for lebrikizumab in AD patients are emerging. We present the outcomes for our cohort of patients who were prescribed lebrikizumab for moderate-to-severe AD.

Materials and Methods

Patients prescribed lebrikizumab were identified through pharmacy records. Demographics, previous therapies, effectiveness, adverse events and dosing regimens for lebrikizumab were recorded retrospectively. National Institute of Health and Care Excellence (NICE) defined adequate response as at least a 50% reduction in Eczema Area and Severity Index Score (EASI 50) and at least a 4-point reduction in Dermatology Life Quality Index (DLQI) at week 16 compared with baseline.

Results

Between September 2024 and March 2026, 44 patients received lebrikizumab for AD. Five patients were excluded as they had not reached week 16 of therapy. The remaining 39 patients were included. Demographics and clinical characteristics are shown in Table 1.

The baseline mean EASI and DLQI scores were 22.2(range 5.5-48.5) and 22.7(range 8-30) indicating severe AD impact. Previous treatments included dupilumab (n=23), ciclosporin (n=20), methotrexate(n=18), azathioprine(n=11), phototherapy(n=9), tralokinumab (n=5), mycophenolate mofetil(n=4), upatacitinib (n=4), abrocitinib (n=3) and baricitinib (n=2).

At week-16, 25 patients (64%) achieved NICE efficacy criteria. Patients who continued treatment beyond week 16 were classified as treatment responders. Week-16 EASI and DLQI outcomes were available for 32 patients (82%). Four patients (10%) required 2-weekly maintenance dosing after week 16 to sustain efficacy.

Thirteen patients (33%) were biologic-naïve. Lebrikizumab demonstrated efficacy in 9 patients (69%). In the remaining biologic-experienced patients (n=26), 16(62%) patients achieved clinical response to lebrikizumab.

Seventeen patients (44%) discontinued lebrikizumab and reasons were primary treatment failure (n=5;13%), secondary failure (n=6;15%), adverse events (n=3;8%), lost to follow up (n=1;3%), patient choice (n=1,3%), death (n=1,3%). The adverse events were facial eczema with eye irritation, exacerbation of generalised eczema and dry eyes. The death was not related to lebrikizumab therapy.

Eight patients (21%) had ocular adverse effects with dupilumab or tralokinumab. Two of these patients (25%) reported ocular side effects with lebrikizumab, leading to discontinuation in one case. The remaining 6 patients (75%) had no recurrence of ocular symptoms.

Table 1: Clinical Characteristics of Patients Prescribed Lebrikizumab for AD

	Lebrikizumab (n=39)
Male, n (%)	20 (51%)
Female, n (%)	19 (49%)
Mean age, years (Range)	41 (19-89)
Mean baseline EASI (Range)	22.2 (5.5-48.5)
Mean baseline DLQI (Range)	22.7 (8-30)
Proportion of patients who satisfy NICE criteria for continuation, n (%)	25 (64%)
Primary failure leading to discontinuation, n (%)	5 (13%)
Secondary failure leading to discontinuation, n (%)	6 (15%)
Adverse events leading to discontinuation, n (%)	3 (8%)
Average treatment duration, months (range)	10 (1-25)
Biologic naïve, n (%)	13 (33%)
Previous biologic treatment(s), n (%)	27 (69%)
Previous systemic treatment(s), n(%)	32 (82%)
Previous JAK inhibitor treatment, n (%)	7 (18%)

Conclusions

In our cohort patients, lebrikizumab achieved NICE efficacy criteria in 64% of patients, with marked improvement observed at week-16 for both EASI (73%) and DLQI (71%) scores. No difference in treatment response rate was observed between biologic-naïve (69%) and biologic-experienced patients (62%). Lebrikizumab was well tolerated and adverse events are reported above. A small number of patients who developed ocular side effects with dupilumab or tralokinumab reported a clinical response to lebrikizumab without recurrence of ocular problems (75%). In patients with inadequate response following extending dosing interval to 4-weekly, continuation of 2-weekly dosing maintained clinical efficacy, suggesting a subset of patients require more frequent dosing to sustain response. Limitations of the study was incomplete reported outcome measures. New treatments with novel mechanisms of action are still required for patients with AD.

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Severe Extensive Staphylococcal Impetigo in an Adolescent with Atopic Dermatitis Following Corticosteroid Therapy

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Introduction

Atopic dermatitis (AD) is associated with a compromised skin barrier, immune dysregulation, and frequent colonization by *Staphylococcus aureus*. These factors predispose patients to secondary bacterial infection, which can mimic or complicate eczematous flares. Misdiagnosis of impetiginization as an AD flare and continued corticosteroid use may exacerbate the infection, leading to extensive disease and systemic involvement. Awareness of this "impetiginized AD" phenomenon is critical, especially in paediatric cases where steroid therapy is common.

Case Presentation

We report the case of a 13-year-old boy with a history of moderate to severe atopic dermatitis, who presented with rapidly evolving, painful, oozing, and crusted lesions covering approximately 40% of body surface area. The initial lesion appeared over the popliteal fossa while he was receiving both topical and systemic corticosteroids for presumed eczematous exacerbation. Over days, lesions spread to involve the trunk, face, and limbs, with multiple erosions, pustules, and honey-colored crusts. He experienced malaise and irritability. The initial treating team had maintained corticosteroid therapy in view of presumed eczema flare, which allowed further propagation of bacterial infection. Upon evaluation in our dermatology unit, the clinical picture was deemed consistent with extensive non-bullous staphylococcal impetigo superimposed on AD.

Corticosteroids were immediately discontinued. Empiric intravenous anti-staphylococcal antibiotic therapy was initiated (cefazolin, later adjusted per culture sensitivity). Supportive care included antiseptic wound care, emollients, systemic antihistamines, and analgesics. Within 48 hours, there was marked clinical response: reduction of erythema, cessation of exudation, diminished tenderness, and evolution of lesions into crusts and desquamation. Re-epithelialization proceeded progressively, and by day 7–8, approximately 80–90% of affected areas showed healing, leaving residual post-inflammatory hypopigmentation and mild xerosis. The patient was discharged on day 10 with full resolution of active lesions.

On day 6 of hospitalization, his elder sister developed three discrete impetiginous lesions on her arm, suggestive of household transmission. She was managed with an oral anti-staphylococcal antibiotic and topical mupirocin, achieving full clearance within five days. Both siblings and caregivers were counseled on hygiene measures (no towel sharing, short nails, hand hygiene) and barrier restoration (emollients).

This case highlights key pitfalls and lessons. First, in patients with AD, new onset of painful, exudative, crusted lesions—especially in flexural or previously inflamed areas—should prompt suspicion for bacterial superinfection rather than automatic escalation of corticosteroids. Second, systemic and topical steroids in the presence of unrecognized infection may accelerate bacterial proliferation, leading to widespread impetiginization. Third, impetigo remains transmissible; family members are at risk, hence prompt therapy and strict hygiene measures are essential to interrupt transmission. In this case, discontinuation of steroids and prompt initiation of targeted intravenous antibiotics led to rapid clinical reversal.



Multiple well defined polycyclic erythematous eroded plaques with peripheral collarette scaling and crusting over bilateral lower limbs

Conclusion

Severe impetiginization in atopic dermatitis can be a dramatic, iatrogenically amplified complication. Clinicians should maintain a low threshold for diagnosing bacterial superinfection in AD flares unresponsive to steroids. Early interruption of corticosteroids, initiation of appropriate antimicrobial therapy, and control of barrier function can prevent morbidity, systemic spread, and intra-household transmission.

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Handheld Infrared Thermography for Detecting Atopic Dermatitis Inflammation in Patients with Skin of Colour

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by pruritus, scaly lesions, and epidermal barrier dysfunction. Common clinical scoring systems (e.g., Eczema Area and Severity Index-EASI and SCORing Atopic Dermatitis-SCORAD) rely on subjective signs of inflammation such as erythema and clinician-estimated affected surface area. In individuals with darker skin tones (Fitzpatrick skin types IV-VI), erythema may be less apparent, contributing to underdiagnosis and undertreatment. Infrared thermography (IRT) is a non-invasive imaging modality that provides real-time information about cutaneous inflammation using heat emission. IRT is especially useful in providing a more objective method for identifying AD in patients with skin of colour (SoC) where erythema is difficult to visualize. Recent computational advancements have also enabled integration of artificial intelligence (AI) to assist in detecting and quantifying affected skin areas. This project aims to assess how AI-assisted thermal imaging can support the clinical assessment of AD.

Materials and Methods

Images of AD lesions were obtained from three patients with Fitzpatrick skin types IV-VI during routine clinical visits using a handheld point-of-care IRT camera. Digital and thermal images were acquired by a trained research team member on affected areas of the arms following a standardized period of abduction to minimize occlusion-related heat effects. A calibrant sticker was included in each image to enable quantitative analysis of lesion area (cm^2) and maximum temperature difference between affected skin and an adjacent control site (°C). The control site was located on unaffected skin near the AD lesions. Image analysis was performed using the ImageJ software and AI-assisted Swift Skin and Wound platform.

Results

Differences in calculated lesion area between AI-assisted and manual tracing ranged from 0.1 to 0.6 cm^2. Maximum temperature differences between affected and control sites ranged from 2.3 to 2.8 °C in thermally active regions, compared to 0.4 to 0.8 °C in the control (no lesion) regions. Although erythema was not visible on digital images of active AD lesions, lichenification and papulation were observed. Areas of increased heat emission corresponded with patient-reported pruritus and clinical signs of AD.

Conclusions

This project generates pilot data that demonstrate that IRT can non-invasively visualize cutaneous heat emission associated with inflammation in AD. These findings highlight the potential utility of handheld point-of-care IRT for

real-time detection of inflammation in patients with darker skin tones, in whom erythema is difficult to visualize. Integration of AI assistance may further enhance this approach by enabling faster quantification of affected skin areas. As an adjunct tool in clinical examination, IRT has the potential to improve diagnostic accuracy and support more equitable assessment of inflammatory conditions in patients with SoC. Visualization of affected skin areas may also enhance patient understanding, support shared decision-making, and increase engagement in care. Larger studies incorporating standardized clinical and patient-reported outcomes are needed to further validate the relationship between thermal findings and AD severity.

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Clinical phenotyping of atopic dermatitis using combined itch and lesional severity in a large French real-world cohort: psychosocial burden across four clinical phenotypes

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Introduction

Background: Atopic dermatitis (AD) presents heterogeneous clinical phenotypes (CP) defined by the combination of itch and lesional severity. Chovatiya & Silverberg (2021) identified four distinct CP subtypes in a US clinical cohort (N=592), but the psychosocial burden was not characterized using validated dermatology-specific instruments.

Objectives: To identify the Chovatiya & Silverberg CPs in a large French real-world cohort and to characterize the psychosocial burden of each CP using three validated patient-reported outcome measures: PUSH-d (stigmatization), DLLIM (life trajectory impairment), and DMLQ (mental load).

Materials and Methods

Cross-sectional analysis of the DERMPACT study (France, 2026; N=1,330 with complete data). Patients were recruited through an online self-administered questionnaire; EASI and NRS were self-reported. Four CPs were defined using validated NRS (worst itch, past 7 days; threshold ≥7 = severe) combined with EASI (threshold >7 = severe lesions): MI-ML (mild itch + mild lesions), SI-ML (severe itch + mild lesions; itch-dominant), MI-SL (mild itch + severe lesions; lesions-dominant), and SI-SL (severe itch + severe lesions). Between-group comparisons used one-way ANOVA with post-hoc Bonferroni correction. Spearman correlation assessed EASI–NRS association.

Results

The CP distribution was: MI-ML 41.8% (n=556), SI-ML 29.4% (n=391), SI-SL 18.6% (n=248), MI-SL 10.2% (n=135). The EASI–NRS correlation was modest ($r=0.31$, $p<0.001$), confirming itch-lesion dissociation. All three psychosocial instruments differed significantly across CPs (all $p<0.001$). The SI-ML itch-dominant group showed PUSH-d scores of 18.2±16.6 — 61% higher than MI-ML (11.3±14.3) and comparable to MI-SL (15.5±15.1), despite having mild lesions. DMLQ mental load was elevated across all CPs including MI-ML (16.3/32; 51% of maximum).

Conclusions

This study confirms and extends the Chovatiya & Silverberg phenotyping framework to a European real-world cohort, adding the first psychosocial characterization of each CP. The itch-dominant SI-ML group (~30% of patients) carries a psychosocial burden disproportionate to its EASI score, supporting systematic itch assessment independent of lesional severity in clinical practice. Notably, itch can induce as much stigmatization as the appearance of lesions. Clinicians must be aware that lesional severity is not the only driver of both physical and psychosocial suffering in AD patients.

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Pruritus as the primary driver of mental load in atopic dermatitis: item-level analysis of the DMLQ (DERMPACT, N=1,395

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Introduction

Chronic pruritus is central to the lived experience of patients with atopic dermatitis (AD). Beyond its sensory dimension, pruritus intensity conditions quality of life, stigmatization and psychological distress. The Dermatological Mental Load Questionnaire (DMLQ) captures a complementary construct: the cognitive and organizational burden associated with the day-to-day management of the disease. While the total DMLQ score has been validated in AD, no study had examined, on an item-by-item basis, the extent to which each domain is driven by pruritus intensity as compared with lesion severity.

Materials and Methods

Data from 1,395 adults with AD enrolled in DERMPACT, a French real-world cross-sectional study, were analysed. Mean pruritus intensity over the past 7 days (NRS, 0–10) and the Eczema Area and Severity Index (EASI, 0–72) were assessed in parallel. DMLQ items were scored from 0 to 3 (total 0–24; higher scores indicating greater mental load). Patients were categorized into four NRS quartiles: Q1 (0–3, n=366), Q2 (3–5, n=514), Q3 (5–7, n=269) and Q4 (7–10, n=246). Spearman correlation coefficients were computed between each clinical variable and both the total DMLQ score and individual item scores.

Results

Mean pruritus NRS was strongly correlated with total DMLQ ($r=0.442$, $p<0.001$, N=1,395), with a continuous dose-dependent relationship: mean DMLQ scores increased from 7.3±4.2 in Q1 (minimal pruritus) to 12.2±3.8 in Q4 (severe pruritus), corresponding to a **67% increase in mental load** (Kruskal–Wallis $p<0.001$). Seven of eight items were significantly associated with pruritus (all $p<0.001$): eczema-related intrusive thoughts (D1, $r=0.424$, strong effect), mood impact (D2, $r=0.410$, strong effect), social avoidance (D3, $r=0.341$, moderate), impaired self-esteem (D6, $r=0.296$, moderate), need for psychological support (D8, $r=0.293$, moderate), difficulty in daily management (D4, $r=0.210$, small) and dissatisfaction with support received (D5, $r=0.109$, small). D7 — access to information ($r=0.010$) — was the only non-significant item. Radar analysis confirmed a progressive, concentric and asymmetric expansion of the DMLQ profile with increasing pruritus, driven predominantly by D1, D2 and D3. In sensitivity analysis, EASI showed a substantially weaker association with total DMLQ ($r=0.297$, $p<0.001$), accounting for only 8.8% of explained variance versus 19.5% for mean NRS.

Conclusions

This item-level analysis demonstrates that mental load in AD is systematically and proportionally driven by pruritus intensity rather than lesion severity. D1, D2 and D3 form a **cognitive–emotional tripod** directly proportional to pruritus level and constitute priority targets for psychological intervention. The independence of D7 from both clinical variables suggests that information access reflects healthcare delivery quality — a universally modifiable factor. The superiority of mean weekly NRS over worst-intensity NRS (r=0.442 vs 0.423) indicates that **persistent pruritus**, more than intermittent flares, progressively depletes cognitive resources. Systematic measurement of mean weekly NRS in routine practice should be regarded as an essential entry point for mental load screening in AD, independently of EASI.

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Dupilumab in Real-World Practice: A Three-Month Analysis of Clinical and Patient-Reported Outcomes focusing on body regions in the Large German Atopic Dermatitis Registry TREATgermany

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease that manifests with regional variation, impacting the head/neck, trunk, arms, and legs with differing degrees of severity. This regional distribution contributes to the overall disease burden. Dupilumab, a monoclonal antibody targeting the IL-4 and IL-13 pathways, is a widely used systemic therapy for moderate-to-severe AD in Germany. This analysis aimed to evaluate effectiveness of dupilumab on the signs of AD across the four key body regions in the large TREATgermany registry cohort.

Materials and Methods

This retrospective, multicenter analysis included data from 512 therapy episodes (54.7% of the patients were male, mean age 39.9 years) with moderate-to-severe AD who were initiated on dupilumab therapy. Clinical effectiveness was assessed using IGA (0–4) and EASI (0–72), with regionally weighted subscores. Patient-reported outcomes at baseline and 3 months included BSA (%) and 0–10 NRS for pain, itch (average/peak), and sleep impairment (0-10 NRS).

Results

At dupilumab start visit, patients demonstrated high disease activity and a severe symptom burden. A vast majority (81.8%) presented with an IGA score of 3 (moderate, 40.6%) or 4 (severe, 41.2%), or 5 (very severe, 10.4%). The mean EASI score was 19.8, and the mean patient-reported BSA was 25.9%. Regionally, the arms were most severely affected relative to their maximum score (mean EASI 4.6, 31.9% of max), followed by the head/neck (2.0, 27.8%), trunk (5.9, 27.3%), and legs (7.3, 25.3%). The subjective burden was substantial, with high mean NRS scores of 6.9 for average itch, 6.7 for peak itch, 5.9 for sleep impairment, and 4.8 for pain. After three months of dupilumab treatment, improvements were observed. The proportion of patients achieving an IGA score of 0 (clear) or 1 (almost clear) was 29.7%. The mean total EASI score decreased by 70.7% to 5.8, and the mean patient-reported BSA decreased by 71.4% to 7.4%. This clinical improvement was consistent across all body regions, with mean EASI subscore reductions of 76.3% for the trunk (to 1.4), 71.2% for the legs (to 2.1), 69.6% for the arms (to 1.4), and 60.0% for the head/neck area (to 0.8). The therapy also led to major improvements in patient-reported symptoms: the mean average itch score decreased by 55.1% to 3.1, peak itch by 55.2% to 3.0, sleep impairment by 71.2% to 1.7, and pain by 66.7% to 1.6.

Conclusions

This large-scale, real-world analysis provides evidence that dupilumab delivers rapid improvement across all body regions for patients with moderate-to-severe AD. Within the first three months of therapy, it achieved a greater than 70% reduction in both clinician-assessed lesion severity (EASI) and patient-reported affected body surface area (BSA). This remarkable improvement in objective skin signs was mirrored by an alleviation of the most burdensome subjective symptoms, including a greater than 55% reduction in itch and pain, and a more than 70% improvement in sleep disturbance. These findings underscore dupilumab's effectiveness across all body regions for patients with moderate-to-severe AD, confirming its ability to improve both the clinical and personal aspects of this challenging disease.

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Dupilumab Demonstrates a Significantly Higher Likelihood of Achieving Improvements in Atopic Dermatitis Signs and Itch vs Nemolizumab at Week 16 in Combination With Topical Corticosteroids: Results From a Bucher Placebo-Adjusted Indirect Comparison

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Introduction

Atopic dermatitis (AD) is a chronic type 2 inflammatory disease, which often needs long-term treatment. The fully human monoclonal antibody dupilumab and the humanized monoclonal antibody nemolizumab have both demonstrated efficacy and safety in AD clinical trials. However, no head-to-head comparisons have been performed. In the absence of direct comparisons between medicinal products, Bucher indirect treatment comparisons (ITCs), in which treatment effects of the medicinal products are anchored to a common comparator (e.g. placebo), provide a robust and widely accepted method of evaluating relative efficacy. Here we report the results of a placebo-anchored Bucher ITC comparing efficacy of dupilumab plus topical corticosteroids (TCS) every 2 weeks (q2w) versus nemolizumab plus TCS every 4 weeks (q4w) for moderate-to-severe AD over 16 weeks of therapy.

Materials and Methods

A placebo-anchored Bucher ITC was conducted using data from the published phase 3 clinical trial LIBERTY AD CHRONOS (NCT02260986) and the replicate phase 3 clinical trials ARCADIA 1 (NCT03985943) and ARCADIA 2 (NCT03989349). Data at Week 16 for the following doses were used: 300 mg dupilumab + TCS q2w, or placebo + TCS (LIBERTY AD CHRONOS), and 30 mg nemolizumab + TCS q4w, or placebo + TCS (ARCADIA 1 and 2). Non-responder imputation was used in all clinical trials for the binary outcomes, which were assessed in this ITC. Outcomes at Week 16 included proportion of patients achieving Investigator's Global Assessment score 0/1 (IGA-0/1; clear/almost clear skin), ≥75% improvement from baseline in Eczema Area and Severity Index (EASI-75) and ≥4-point improvement from baseline in Peak Pruritus Numeric Rating Scale (PP-NRS Δ ≥4). Odds ratios (ORs)

with 95% confidence intervals (CIs) are reported. Meta-analysis ORs are provided for ARCADIA 1 and 2 combined. The number needed to treat (NNT) for achieving those outcomes were also computed to compare treatment benefits.

Results

Baseline disease characteristics were similar between LIBERTY AD CHRONOS and ARCADIA 1 and 2, supporting the use of Bucher ITC. Patients treated with dupilumab + TCS vs nemolizumab + TCS had a significantly higher likelihood of achieving IGA-0/1 (OR = 2.61; 95%CI 1.49, 4.57), EASI-75 (OR = 4.09, 95%CI 2.41, 6.96), and PP-NRS Δ ≥4 (OR = 1.76, 95%CI 1.02, 3.02) at Week 16. When comparing these two treatments, dupilumab + TCS demonstrated greater treatment efficacy than nemolizumab + TCS across all 3 outcomes. The NNT to observe 1 patient achieving IGA 0/1, EASI-75, and PP-NRS Δ ≥4 was 4, 3, and 3 respectively for dupilumab + TCS vs placebo + TCS, compared with 9, 8, and 5 respectively for nemolizumab + TCS vs placebo + TCS.

Conclusions

This placebo-anchored Bucher ITC analysis demonstrated that the likelihood of achieving improvements in AD signs and itch is significantly higher for patients treated with dupilumab + TCS q2w vs nemolizumab + TCS q4w at Week 16. Based on the NNT analysis, dupilumab + TCS demonstrated greater treatment efficacy across all assessed outcomes compared with nemolizumab + TCS, requiring substantially fewer patients to be treated to achieve the same clinical benefits.

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Clinical and molecular improvements in pediatric patients with atopic dermatitis treated with dupilumab: an analysis from the TREATKids registry

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Introduction

Real-world evidence on clinical and molecular outcomes of systemic therapy for pediatric atopic dermatitis remains limited.

Materials and Methods

Within the prospective TREATkids registry, we conducted an observational analysis of children and adolescents treated with Dupilumab in routine care. Baseline data from 200 and follow-up data from 124 patients were evaluated for clinician- and patient-/caregiver-reported outcomes, alongside with epidermal proteomic profiling using tape strips and the Olink® Explore Inflammation 384 (n=20) panel and 16S rRNA gene sequencing for skin microbiome assessment in subsets (n=48).

Results

At treatment initiation, disease burden was high (mean EASI 16.5; oSCORAD 44.9; peak itch PP-NRS 6.6). By month 3, EASI50/75/90 response rates were 87%, 60%, and 30%. In addition, 83% of patients achieved low disease activity (EASI ≤ 7), and 64% reported a ≥3-point reduction in peak itch. Clinical responses were sustained through months 6 and 12, with no discontinuations and conjunctivitis in 4.8%. Proteomic analyses demonstrated marked baseline upregulation of alarmins, Th2 chemokines, and tissue-remodeling markers in lesional skin, followed by downregulation of 144/161 dysregulated proteins at month 3, including CCL17/TARC, CXCL8, IL-6, IL-18, and MMPs. Microbiome profiling showed baseline dysbiosis with *Staphylococcus aureus* overabundance and reduced α-diversity, normalizing toward a non lesional–like state after therapy.

Conclusions

Overall, dupilumab was associated with rapid, sustained clinical and molecular improvement.

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Distinct Microbial Remodeling and Functional Shifts in Human Atopic Dermatitis Skin

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease linked to cutaneous microbial dysbiosis. Characterizing both the taxonomic and functional differences between lesional and non-lesional skin may clarify microbial contributions to active disease and identify novel therapeutic targets.

Materials and Methods

Twenty-one paired lesional and non-lesional skin swabs were collected from 10 AD subjects and processed for shotgun metagenomic sequencing. After QC filtering, 17 samples were analyzed unpaired (10 lesional vs. 7 non-lesional) and 12 paired (6 vs. 6). Taxonomic classification used the CosmosID pipeline. Functional profiling was performed with HUMAnN 3, which aligned reads to UniRef90 protein families and mapped them to Gene Ontology (GO) terms for community-level functional inference. Shannon alpha diversity was compared by Wilcoxon test, Bray-Curtis beta diversity by PCoA with PERMANOVA, and differential abundance by DESeq2 with Benjamini-Hochberg correction.

Results

Shannon alpha diversity did not differ between lesional and non-lesional skin, suggesting a compositional shift rather than a loss of overall diversity. At the species level, Bray-Curtis beta diversity was significantly different between cohorts (unpaired R^2 = 0.19, p = 0.001; paired R^2 = 0.21, p = 0.002). GO-pathway beta diversity showed substantially greater separation than taxonomic composition (unpaired R^2 = 0.57, p = 0.001; paired R^2 = 0.59, p = 0.003), indicating that functional divergence between lesional and non-lesional skin exceeds taxonomic divergence. *Staphylococcus aureus* mean relative abundance was higher in lesional samples. DESeq2 identified consistent enrichment of *Corynebacterium* and *Cutibacterium* species in non-lesional skin. Functionally, lesional skin was enriched in virulence- and envelope-associated pathways (type IV pilus biogenesis, type III/IV secretion, siderophore transport, cyclopropane fatty acyl–phospholipid synthase), while non-lesional skin was enriched in core metabolic functions (succinate dehydrogenase, polyphosphate metabolism, NAD(P) transhydrogenase).

Conclusions

In this pilot cohort, AD lesional and non-lesional skin harbor distinct microbial communities and functional profiles despite similar overall diversity. Lesional skin demonstrated a shift toward host-interaction, adhesion, and colonization-associated microbial functions, while non-lesional skin favored commensal metabolic activity. These disease-associated functional shifts may represent potential therapeutic targets or biomarkers of disease activity.

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Anchored matching-adjusted indirect comparison of the efficacy of dupilumab vs nemolizumab in patients with moderate-to-severe atopic dermatitis

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Introduction
Dupilumab and nemolizumab are both approved biologics for the treatment of moderate-to-severe atopic dermatitis (AD). In the absence of head-to-head clinical trial data, indirect comparisons are needed to inform clinical decision making. A previous Bucher indirect treatment comparison (ITC) showed a greater likelihood of achieving improvements in efficacy outcomes with dupilumab vs nemolizumab. However, Bucher ITCs do not account for cross-trial differences in patient populations or treatment effect modifiers, which can be addressed by anchored matching indirect treatment comparisons (MAIC). In this analysis, we performed an anchored MAIC to assess whether the comparative efficacy results for dupilumab and nemolizumab remain consistent when accounting for potential differences in baseline patient characteristics.

Materials and Methods
A placebo-anchored MAIC was performed using data from LIBERTY AD CHRONOS (NCT02260986) which evaluated dupilumab 300 mg + topical corticosteroids (TCS, N = 106) or placebo + TCS (N = 315) every 2 weeks in adult patients, and from ARCADIA1/ARCADIA2 (NCT03985943/NCT03989349) where patients aged ≥12 years received nemolizumab 30 mg + TCS (N = 620/522) or placebo + TCS (N = 321/265) every 4 weeks. Baseline covariates used to adjust data were: scores of body-mass index, Dermatology Life Quality Index (DLQI), Eczema Area and Severity Index (EASI), Peak Pruritus Numeric Rating Scale (PP-NRS), and proportion of patients with an Investigator's Global Assessment (IGA) score of 3/4 (moderate/severe). Outcomes at Week 16 included: proportion of patients achieving ≥75% improvement from baseline in EASI (EASI-75); achievement of IGA 0/1 (clear/almost clear); improvement of ≥4 points in PP-NRS score, and change from baseline in DLQI score.

Results
To compare the two trials, CHRONOS patients were down-weighted to an effective sample size of 228 for placebo and 66 for dupilumab + TCS. At Week 16, patients receiving dupilumab + TCS were significantly more likely than

those receiving nemolizumab + TCS to achieve EASI-75 (odds ratio [OR] 3.6; 95% confidence interval [CI] 1.9, 6.9), IGA 0/1 (OR 2.7; 95% CI 1.4, 5.3), ≥4-point reduction in PP-NRS score (OR 2.1; 95% CI 1.1, 3.9), as well as to experience a significantly greater improvement (decrease) in DLQI score from baseline (mean difference -2.1; 95% CI -3.9, -0.4).

Conclusions

This anchored MAIC analysis demonstrated that patients with moderate-to-severe AD receiving dupilumab + TCS were significantly more likely to achieve improvements in AD signs, itch, and quality of life compared with those receiving nemolizumab + TCS. These results are consistent with a previously published Bucher ITC comparing dupilumab and nemolizumab, providing additional evidence to support clinical decision making.

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Clinical phenotypes of atopic dermatitis exhibit distinct skin barrier profiles

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Introduction

Atopic Dermatitis (AD) is a heterogeneous disease characterized by different clinical phenotypes and alterations in skin barrier function. While barrier dysfunction is a hallmark of AD, the relationship between clinical phenotypes and skin biomechanical properties remains poorly understood.

The aim of this study was to evaluate differences in skin barrier parameters according to the clinical phenotype of AD.

Materials and Methods

A cross-sectional study including patients with AD was performed. Patients were classified according to their clinical phenotype (diffuse, flexural, erythrodermic, nummular, prurigo nodularis, and head-and-neck dermatitis). Skin barrier function was assessed using transepidermal water loss (TEWL), stratum corneum hydration (SCH), skin elasticity parameters (R2 and R7), and skin hardness measurements. Comparisons between phenotypes were performed using one-way ANOVA with Tukey-Kramer post-hoc analysis.

Results

A total of 98 patients with AD were included, with a mean age of 38.38 ± 19.78 years; 49 patients (50.0%) were female. Overall disease severity was moderate-to-severe, with mean EASI and SCORAD scores of 20.79 ± 5.91 and 48.76 ± 13.49, respectively. Patients were classified into the following clinical phenotypes: diffuse (n=31/98, 31.63%), flexural (n=33/98, 33.67%), prurigo nodularis (n=18/98, 18.37%), erythrodermic (n=9/98, 9.20%), nummular (n=4/98, 4.08%), and head-and-neck dermatitis (n=3/98, 3.05%). Significant differences between clinical phenotypes were observed in SCH ($p=0.044$), TEWL ($p=0.026$), skin hardness ($p=0.0007$), R2 elasticity ($p=0.0025$), and R7 elasticity ($p=0.0029$). Patients with prurigo nodularis exhibited significantly lower skin elasticity values compared with other AD phenotypes. Specifically, R7 values were significantly lower in prurigo nodularis compared with erythrodermic ($p=0.011$), diffuse ($p=0.003$), and flexural phenotypes ($p=0.006$). Similarly, R2 values were significantly lower in prurigo nodularis compared with erythrodermic ($p=0.014$) and diffuse phenotypes ($p=0.020$). In addition, the nummular phenotype showed significantly increased skin hardness compared with diffuse, flexural, erythrodermic, prurigo nodularis, and head-and-neck phenotypes (all $p<0.01$).

Conclusions

Distinct clinical phenotypes of AD exhibit different skin barrier profiles. Reduced skin elasticity in prurigo nodularis may reflect chronic skin remodeling and tissue alteration. These findings support the concept that clinical phenotypes of AD may represent distinct underlying biological and biomechanical patterns, potentially relevant for phenotype-oriented assessment and personalized management strategies.

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Greater skin barrier dysfunction in atopic dermatitis patients with concomitant asthma

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Introduction

Atopic Dermatitis (AD) is frequently associated with other atopic comorbidities, including asthma. Both AD and asthma are characterized by shared type 2/Th2-mediated inflammatory pathways, which may contribute to a higher systemic inflammatory burden and potentially exacerbate cutaneous inflammation and barrier damage. The pathophysiology of AD is characterized by skin barrier dysfunction, which has been associated with increased disease severity. However, the impact of asthma on skin barrier function of patients with AD remains poorly understood. The present study aimed to evaluate whether patients with AD and concomitant asthma exhibit greater impairment of skin barrier function compared with patients without asthma.

Materials and Methods

A cross-sectional study including patients with AD was performed. Patients were stratified according to the presence or absence of asthma. Clinical severity was evaluated using the Eczema Area and Severity Index (EASI), the SCORing Atopic Dermatitis (SCORAD), and Numerical Rating Scale for pruritus (NRS-itch) and sleep disturbance (NRS-sleep). Skin barrier function was assessed on non-lesional skin of the volar forearm using transepidermal water loss (TEWL), stratum corneum hydration (SCH), erythema, and skin temperature measurements.

Results

A total of 101 patients with AD were included, with a mean age of 38.38 ± 19.78 years; 49 patients (48.5%) were female. Among them, 45/101 (44.6%) presented asthma. Mean disease severity scores in the overall cohort were: EASI 20.79 ± 5.91, SCORAD 48.76 ± 13.49, NRS-itch 7.16 ± 2.76, and NRS-sleep 4.46 ± 3.96. Disease severity was comparable between patients with and without asthma, with no significant differences in EASI, SCORAD, NRS-itch, or NRS-sleep scores (all $p>0.05$). Patients with asthma showed significantly higher TEWL values in non-lesional skin compared with patients without asthma (11.90 ± 6.62 vs 9.46 ± 5.19 g/m²/h; $p=0.05$). Similarly, erythema values were significantly increased in patients with asthma (245.68 ± 90.48 vs 210.87 ± 83.45 AU; $p=0.05$). In contrast, SCH values were significantly lower in the asthma group (30.48 ± 12.57 vs 35.29 ± 11.54 AU; $p=0.05$). No significant differences were observed in skin temperature (30.89 ± 1.22 vs 30.70 ± 1.28 °C; $p=0.45$).

Conclusions

Patients with AD and concomitant asthma exhibit greater epidermal barrier dysfunction on non-lesional skin, characterized by increased TEWL and erythema and reduced SCH. These differences were observed despite similar clinical severity between groups, suggesting that asthma may be associated with an intrinsic barrier dysfunction phenotype independent of disease severity. These findings support the concept of a systemic atopic phenotype and suggest that asthma may identify a subgroup of patients with more pronounced skin barrier impairment.

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Interim 24-week real-world effectiveness of lebrikizumab in atopic hand eczema: a multicentre case series

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Introduction
Hand eczema is one of the most frequent and burdensome manifestations of atopic dermatitis (AD), often associated with marked impairment in quality of life, functional limitations, and therapeutic refractoriness. Despite the increasing use of targeted therapies in AD, evidence specifically addressing atopic hand eczema remains scarce. Lebrikizumab, a selective IL-13 inhibitor approved for moderate-to-severe AD, has demonstrated high efficacy in clinical trials; however, real-world data in patients with concomitant atopic hand eczema are currently limited. This study aimed to evaluate the 24-week effectiveness and safety of lebrikizumab in patients with moderate-to-severe atopic hand eczema treated in routine clinical practice.

Materials and Methods
Multicentre retrospective case series including adult patients with moderate-to-severe atopic dermatitis and concomitant hand eczema treated with lebrikizumab. Outcomes assessed at baseline and week 24 included EASI, HECSI, IGA-CHE, pruritus and pain NRS, DLQI and POEM. Descriptive analyses were performed using available data.

Results
Twenty-one patients were included in this interim analysis. Mean baseline EASI was 23.0. Rapid and sustained improvement was observed from week 16 onwards across clinician-reported and patient-reported outcomes. At week 24, mean EASI decreased to 3.6, corresponding to an approximate 78% reduction from baseline. EASI-75 and EASI-90 responses were achieved in approximately 67% and 47% of evaluable patients, respectively. Most evaluable patients achieved IGA-CHE 0/1, with marked HECSI improvement. Relevant reductions in pruritus NRS, pain NRS, DLQI, and POEM scores were also observed. Several patients had previous dupilumab exposure. Lebrikizumab was generally well tolerated, with conjunctivitis being the most frequently reported adverse event.

Conclusions
Lebrikizumab demonstrated marked effectiveness in patients with AD-associated hand eczema, with rapid improvement by week 16 and sustained responses through week 24. These interim real-world findings support lebrikizumab as a promising therapeutic option for difficult-to-treat atopic hand eczema.

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TALA-125, a high-affinity bispecific antibody co-neutralising IL-13 and IL-18 with an extended half-life: preclinical characterisation for atopic dermatitis

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Introduction
Interleukin-13 (IL-13) inhibition is an established therapeutic approach in atopic dermatitis (AD), but many patients fail to reach higher efficacy endpoints such as EASI90 or IGA0/1. IL-18 plays an orthogonal and non-redundant role in AD pathology, and its inhibition has recently been clinically validated in several independent phase 2 studies.

TALA-125 is a high-affinity humanized IgG1-like bispecific monoclonal antibody that binds and neutralises both IL-13 and IL-18. The IL-13 arm prevents IL-13/IL-13Rα1/IL-4Rα heterodimerization and downstream signalling while preserving binding to the IL13Rα2 decoy receptor. The IL-18 binding arm is non-competitive with the immunoregulatory IL-18 binding protein (IL-18BP) interaction. TALA-125 also contains a clinically FcRn mediated recycling and increase half-life.

Materials and Methods
TALA-125 was tested in multiple *in vitro* assays and compared to competitor antibodies binding IL-13 and IL-18. Affinity was measured by surface plasmon resonance (SPR). Multiple assays were used to assess blockade of the full signalling complex of IL-13 and IL-18 downstream signalling. For IL-13, inhibition of the downstream STAT6 signalling pathway was demonstrated in HEK293 reporter cells, phosphorylation in HT-29 cells, and inhibition of release of TARC in A549 cells. For IL-18 inhibition of downstream NFκB inhibition of endogenous IL-18 measured through IFN-gamma secretion by LPS and IL-12 stimulated PBMCs. In-vivo half-life was tested in non-human primates.

Results
As measured by SPR, TALA-125 had an affinity of <10 pM for both IL-13 and IL-18. In cell-line-based and primary assays, TALA-125 exhibited a potency similar to competitor anti IL-13 and anti-IL-18 monospecific therapies in clinical development for AD. Competitive binding assays demonstrated that TALA-125 can bind both IL-13 and IL-18 simultaneously and binding of the IL-18 arm does not compete with IL-18/IL-18BP interaction. The clearance in non-human primate studies was <2 mL/day/kg, consistent with a prolonged clinical half-life.

Conclusions
TALA-125 demonstrated similar affinity and potency for IL-13 and IL-18 in multiple assays compared to monospecific anti-IL-13 and IL-18 antibodies. Crucially, TALA-125 can neutralise both IL-13 and IL-18 in a single

molecule. These data provide compelling evidence for further clinical development of TALA-125 in AD and diseases where these two orthogonal inflammatory pathways both play a role. TALA-125 also contains amino acid substitutions designed to extend its half-life in humans by increasing binding to neonatal Fc receptor to potentially allow for convenient dosing.

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Pediatric-Origin Disease, Adult-Valued Targets: A Systematic Review of the DELTA TEEN Paradigm in Chronic Hand Eczema

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Introduction

Topical pan-JAK inhibitor that is Delgocitinib cream was found to be effective in treating from moderate to severe chronic hand eczema (CHE) in adolescents in the recently published study of DELTA TEEN. Although these JAK inhibitors are gaining popularity in all age groups, the long-term safety equation of treatment burden, infection risk and malignancy signal might be significantly different in between the adults and adolescents. This systematic review focuses on whether age differences may also affect the sustainability of treatment response and risk benefit ratio in the topical JAK1/TYK2 inhibition.

Materials and Methods

Looking back at "DELTA TEEN" our main findings were ones that came from a 2025 assessment. Alongside that it gives results from adult studies which were labelled as DELTA-1 and DELTA-2, between the years 2023 and 2025. Clear skin by the 16th week gave as one of the measures, specifically that how many of it reached an IGA-CHE score of 0 or 1. An analysis focused on the maintenance of therapeutic gains after treatment removal. Blood levels over time gave us hints about total drug presence inside the body. Safety patterns emerged through reports of infections and shifts seen in lab tests. Real-life experience added intensity to it, pulled from medicine logs that kept across Europe under TREAT NL/EU. These records highlighted the side effects of those that appeared in younger patients dealing with CHE. For those who relapsed after therapy ended, average time frames were made based on the age groups.

Results

In DELTA TEEN (N=245), IGACHE 0/1 was 38% at week 16th, compared with 42% in DELTA1 in adults. The posttreatment disease stability (mean weeks to rescue) was about 8.5 weeks in teens, compared with which was 12.1 weeks in adults at p=0.03. Systemic drug exposure of (AUC02 4) was 1.4 times higher in teenagers which is partially explained by larger body surface area to weight ratio. Infection rates were similar to (8 versus 6%), but for 2 teens those experienced herpes zoster, compared with one adult. Registry data (N=1,203) show that the rate of JAK related cutaneous infections is 2.3 time higher in patients age under the age of 18 years. Based on modelling collective drug exposure over decades, with the assumption of annual courses, appeared a higher lifetime burden which was possible in teens if symptoms come back quickly, it means doing treatment again, off and on.

Conclusions

Age matters usually when it comes to how long topical JAK inhibitors remain effective after treatment and how much of the drug ends up circulating in our system. For the adolescents, there is an additional factor that is how their shorter periods of "sovereignty," or independent treatment effect. This can lead to more persistent dosing

that changes overall long-term safety concerns. Because of this, it’s not enough to just use adult dosing and schedules, in the pediatric patients they need their own dosing measures and treatment timelines that take into account with their particular patterns of drug response and usage.

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Cutaneous Triple Barrier in Atopic Dermatitis: ex vivo, in vivo and microbiome studies

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Introduction

Skin microbiota diversity decreases in atopic dermatitis, interacting with changes in physical barrier (lower level of ceramides, *filaggrin, loricrin*) and interfering with activation of innate and adaptive immunity (1,2). Toll Like Receptors (TLR) dysregulation is associated with a switch of T Helper lymphocytes to Th2 and Th22 profiles (3), all being part of complex "inside-outside-inside" mechanisms of AD physiopathology (4).

Our objectives were to assess: A. the ceramides in the in delipidated human skin *ex vivo* before and after the application of an emulsion O/W (EM1) containing eight different ceramides and a patented vegetal extract of *Umbelliferae* stimulating antimicrobial peptide hBD2 (5). B. Same emulsion EM1 was assessed in patients with atopic dermatitis, clinical and microbiome analyses were made at baseline and at one month.

Materials and Methods

A.Human skin explants were delipidated (with acetone solution), then the EM1 (containing eight types of ceramides - short chains NS 6, NS 22, NP6, NP16, NP22, 6a, and long chain 9-EOP) was applied at T0 on the skin explant surface. Immunostaining analysis of ceramides was made at T0 and at 24h (T1). B. In an open clinical trial, patients with atopic dermatitis were included; EM1 was applied twice daily for 1 month (M1). At baseline and at M1: clinical outcome and SCORAD were assessed, associated with skin swabs for microbiome taxonomy analysis of ribosomal DNAr 16S.

Results

A. Immunohistochemistry showed a ceramides' level significantly increased at T1 (by 105%), compared to T0 ($p<0.0001$). B. In a series of 30 patients with atopic dermatitis, the mean baseline SCORAD (32.1) decreased by 75% (11.3) at M1 compared to D0 ($p<0.0001$). The diversity of the microbiome, analyzed by 16S rDNA metagenomic analysis, showed a significant increase in skin microbiome diversity ($p<0.0001$). *Actinomycetota* relative abundance increased at M1 compared to baseline, *Pseudomonadota* relativa abundance decreased at M1 vs baseline, other bacteria relative abundance remained stable between baseline and M1.

Conclusions

A.In an *ex vivo* study on delipidated human explants treated with emulsion EM1 formulated with eight types of ceramides and a patent stimulating antimicrobial peptide hBD2, immunohistochemistry assessment showed a significant increase of ceramide's level at 24h after single application, compared to baseline ($p<0.001$).
B. In a series of 30 patients with atopic dermatitis having applied EM1 for one month, the clinical and skin

microbiome assessment showed a correlation between clinical improvement and the increase of microbiome diversity at M1 compared to baseline ($p<0.0001$).

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Sustained Improvement in Atopic Dermatitis Disease Control and Treatment Satisfaction With Dupilumab in Clinical Practice: 7-Year Follow-Up Results From the RELIEVE-AD Study

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing, inflammatory skin disease in which durable disease control and sustained treatment satisfaction are essential. In the RELIEVE-AD study, adults with moderate-to-severe AD initiated dupilumab in a real-world setting. Previous analyses showed that most patients initiating dupilumab reported controlled disease and high treatment satisfaction, maintained for up to 6 years. Here, we report the 7-year outcomes of dupilumab in AD disease control and treatment satisfaction from the RELIEVE-AD study.

Materials and Methods

RELIEVE-AD is a single-arm, prospective, observational study in adults with moderate-to-severe AD prescribed dupilumab and enrolled in the US dupilumab patient support program who agreed to participate in online surveys at baseline and at Months 1, 2, 3, 6, 9, 12, 33, 48, 60, 72, and 84. The outcomes presented here are disease control, assessed using the Atopic Dermatitis Control Tool (ADCT; 6-item, total range 0–24, with a total score <7 indicating controlled disease); percentage of patients who reported no intense episodes of itching in the past week based on the corresponding ADCT item; and treatment satisfaction (using a 7-point Likert scale ranging from "extremely satisfied" to "extremely dissatisfied"); percentage of patients taking oral steroids; quality-of-life impact due to AD assessed using the Dermatology Life Quality Index (DLQI, range 0–30, with a total score 0–1 indicating no effect of AD on patient's life). Statistical significance analysis, comparing each time point with baseline, was determined using generalized estimating equations to account for correlated data from the same patients. Normal distributions with an identity link function were used for continuous outcomes, and binomial distributions with a logit link function were used for categorical outcomes. Analyses were conducted in patients who reported that they were continuing dupilumab at various time points.

Results

Of the 698 patients who completed the baseline survey, 227 completed the Month 84 survey and 156 reported continuing dupilumab treatment. Mean age at baseline was 46.2 years and 61.7% were female patients. Controlled disease (ADCT <7) was reported by 5.9% of patients at baseline, increasing to 90.4% at Month 84 ($P < 0.001$ for all time points vs baseline). The percentage of patients reporting no intense episodes of itching over the last week increased from 3.2% at baseline to 72.4% at Month 84 ($P < 0.001$ for all time points vs baseline). Oral steroid use decreased from 30.1% at baseline to 5.1% at Month 84 ($P < 0.001$ for all time points vs baseline). 56.4% of

patients reported that AD had no effect on their quality of life (DLQI total score 0/1) at Month 84 vs 1.1% at baseline. Patient satisfaction with current AD treatments improved over time, with 96.8% reporting being “extremely/very/somewhat satisfied” at Month 84 vs 17.8% at baseline.

Conclusions

In a real-world setting, the majority of adult patients with moderate-to-severe AD treated with dupilumab for 7 years reported sustained disease control, over half reported no impact of AD on their quality of life, and most patients remained satisfied with their AD treatments.

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Abstract N°: 4091

CTO1681 Suppresses Proinflammatory Cytokine Production in Stimulated Human Peripheral Blood Mononuclear Cells: Implications for Atopic Dermatitis-Associated Immune Dysregulation

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Introduction

Atopic dermatitis (AD) is characterized by chronic type 2 skewed inflammation, impaired skin barrier function, and a cytokine-rich microenvironment that facilitates aberrant microbial colonization — most notably by *Staphylococcus aureus* — and heightened susceptibility to viral invasion, including herpes simplex virus and molluscum contagiosum. Key proinflammatory mediators including TNF-α, IL-1α, IL-1β, IL-4, IL-5, IL-13, IL-17, IFN-γ, CCL2, and CXCL9 sustain the inflammatory milieu that disrupts barrier integrity, downregulates antimicrobial peptide expression, and promotes pathogen persistence. Therapeutic strategies capable of broadly attenuating this broad cytokine activation while preserving antiviral interferon responses represent an unmet clinical need in AD management. This study sought to characterize the breadth of cytokine suppression by CTO1681 using an expanded ex vivo cytokine release assay in stimulated human peripheral blood mononuclear cells (PBMCs) from healthy donors.

Materials and Methods

Normal human cryopreserved PBMCs (Lonza) from five donors of mixed age, race, and gender were treated with CTO1681 or dexamethasone as a positive control, followed by stimulation with lipopolysaccharide (LPS) or the viral mimetic Poly(I:C). Supernatants were collected at 24 hours and assessed for 29 cytokines/chemokines using Luminex multiplex technology (MAGPIX; Millipore 28-plex + TGF-β). Cell viability was confirmed via AlamarBlue at 48 hours. Statistical analysis included one-way ANOVA with multiple comparisons on individual donor data.

Results

CTO1681 demonstrated no cytotoxicity across all five donors at the concentrations tested. Across both LPS and Poly(I:C) stimulation conditions, CTO1681 significantly reduced production of 21 of 29 cytokines evaluated. Robust suppression was confirmed in both stimulation paradigms for IL-1α, IL-1β, IL-4, IL-5, IL-12p70, IL-13, IL-15, IL-18, TNF-α, CCL2/MCP-1, CCL5/RANTES, CXCL9/MIG, CXCL10/IP-10, IFN-γ, IFN-α, and PDGF. Suppression observed under LPS stimulation alone included IL-9, IL-17, CCL3/MIP-1α, GM-CSF, and FGF-2.

Conclusions

The cytokine profile suppressed by CTO1681 maps directly onto the key drivers of AD pathophysiology. Reduction of IL-4, IL-13, and IL-5 addresses the Th2-dominant inflammation that downregulates skin barrier proteins and antimicrobial peptides, thereby reducing the permissive environment for *S. aureus* colonization. Suppression of IL-17, TNF-α, IL-1β, and IFN-γ attenuates the amplified inflammatory cascade that damages tight junction integrity and facilitates viral entry. Importantly, the preservation of functionally relevant IFN-α antiviral activity suggests

CTO1681 may reduce the inflammatory burden in AD without compromising the host's capacity to resist cutaneous viral invasion. Combined with the broad suppression of chemokines including CCL2, CCL5, and CXCL9 — which coordinate immune cell recruitment and sustain chronic inflammation — CTO1681 represents a promising candidate for therapeutic investigation in AD, warranting further evaluation in skin-relevant models of barrier dysfunction and microbial challenge.

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Abstract N°: 4099

IMG-007, a non-depleting OX40 antagonist: Optimizing Peak Loading Concentration and Exposure Range to Unlock the Full Potential of OX40-OX40L Pathway Targeting in Immune Mediated Diseases

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Introduction

OX40/OX40L signaling regulates activation and survival of pathogenic T cells central to AD disease development and progression. Accordingly, monoclonal antibodies targeting the OX40/OX40L pathway have represented a promising upstream approach for the treatment of atopic dermatitis (AD) and other immune-mediated diseases. However, despite strong biological rationale, phase 3 clinical outcomes to date from investigational agents in this class suggest that the therapeutic potential of OX40 blockade has not yet been fully realized, potentially due to molecule-specific limitations in loading, dosing, exposure, and/or selection of receptor or ligand as the target in clinical trials.

Rocatinlimab, an ADCC-enhanced anti-OX40 antibody designed to deplete pathogenic OX40+ T cells with a relatively short half-life, demonstrated modest efficacy in Phase 3 e.g. ROCKET-HORIZON trial using monthly dosing (EASI-75: ~33% vs ~14% placebo at Week 24) alongside a notable MoA associated adverse event profile (aphthous ulcers, pyrexia, chills). These safety concerns may well have constrained dose escalation and contributed to suboptimal efficacy. In contrast, amlitelimab, a non–T-cell-depleting anti-OX40L antibody, demonstrated improved tolerability but also modest efficacy in Phase 3 e.g. COAST 2 trial (EASI-75 ~41% vs~17% placebo at Week 24) and the overall dose-response relationship has not been well established. Together, these results suggest that both safety-constrained exposure and insufficient pharmacologic exploration in Phase 2 may have limited the observed efficacy of earlier agents.

A next-generation anti-OX40 antibody has looked to overcome these constraints while maintaining or even potentially enhancing product safety. IMG-007 is a high-affinity IgG1 monoclonal antibody incorporating an Fc modification that silences ADCC activity, thereby avoiding Fcγ receptor-mediated T-cell depletion and reducing cytokine release-related adverse events. In addition, this design minimizes non-specific clearance, resulting in an extended half-life (~5 weeks) compared to earlier agents (~2–3 weeks), and enables exploration of higher systemic exposures with improved tolerability.

Materials and Methods

IMG-007 is being evaluated in a Phase 2b dose-ranging study that also simultaneously employs different loading dosing regimens to rapidly achieve therapeutic concentrations. Population pharmacokinetic modelling integrating data from healthy volunteers and patients predicts a broad exposure range across dose arms, with approximately 20-fold differences in trough concentrations and 4-fold differences in cumulative exposure (AUC) at Week 24.

At the highest dose, predicted peak concentrations reach approximately 136-fold above the in vitro EC90, corresponding to ~21-fold above EC90 after accounting for skin-to-plasma distribution. These exposure levels provide a unique opportunity to assess the upper bound of efficacy for OX40 pathway inhibition. Importantly, preclinical toxicology studies demonstrate substantial safety margins supporting evaluation of high exposures without anticipated dose-limiting toxicities.

Results

This study design enables, for the first time in this class, a comprehensive characterization of the exposure–response relationship, including identification of loading-speed of onset, the efficacy plateau and optimization of maintenance dosing frequency. By combining rapid attainment of therapeutic levels, sustained high exposure, and extended dosing intervals, IMG-007 may have the potential to deliver both enhanced speed of onset, clinical efficacy and improved patient convenience.

Conclusions

In summary, prior clinical outcomes in the OX40/OX40L class may reflect suboptimal exposure and other molecule-specific effects rather than target inadequacy. A strategy focused on maximizing peak loading concentration and exploring a wide exposure range—enabled by improved pharmacokinetics and safety—may unlock the full therapeutic potential of OX40-targeted therapies in immune mediated diseases.

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Abstract N°: 4118

Dupilumab Impacts Weight and Body Mass Index in Pediatric Patients With Moderate-to-Severe Atopic Dermatitis

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Introduction
Growth-related concerns have been raised in children with atopic dermatitis (AD). We have previously shown a shift toward higher weight and body mass index (BMI) percentiles in the broader pediatric AD population; however, a subset of children may still experience faltering weight. Dupilumab treatment supports bone formation and is associated with increased height in children aged 2–11 years (y) of low stature with moderate-to-severe AD. This study evaluated treatment-associated shifts in weight percentiles to assess whether dupilumab supports normalization toward age-specific reference curves. We characterized baseline weight and BMI percentile distributions and evaluated 16-week treatment-induced increases in weight percentiles among patients aged 2–<18 y with lower and higher percentiles at baseline.

Materials and Methods
Three phase 3 trials (NCT03346434, NCT03345914, NCT03054428) included children 2–<18 y with moderate-to-severe AD, randomized to placebo or dupilumab (2–<6 y: 200/300 mg q4w; 6–<12 y: 300 mg q4w or 200 mg q2w; 12–<18 y: 200 mg q2w or 300 mg q2w). Weight and BMI percentiles were evaluated relative to CDC age-specific reference curves. Baseline and Week 16 analyses were conducted overall and stratified by sex and age bands (2–<6, 6–<12, 12–<18 y). Baseline characterization included mean weight and BMI percentiles values and distribution across predefined percentile categories (<25th, <30th, <40th, >60th, >70th, >75th). Longitudinal analyses evaluated proportions achieving a ≥5 percentile point increase from baseline to Week 16, comparing dupilumab vs placebo, stratified by baseline percentile category, age group, and sex.

Results
At baseline, the pediatric AD cohort (N=622) spanned low to high weight and BMI percentiles but was skewed

above the median, with most patients in categories >60th percentiles (49.7% weight and 57.2% BMI) and a clinically relevant minority in lower percentiles, including <25th percentiles (20.3% weight and 16.6% BMI).

From baseline to Week 16, in patients aged 2 to <18 y and <25th weight percentile, dupilumab (n=69) had a higher proportion achieving ≥5-point gains than placebo (n=57), with 28.4% on dupilumab vs 7.8% on placebo (*P*=0.0052). These gains were concentrated among younger children who started in lower baseline percentiles. In the 2–<6 y subgroup, 62.5% of dupilumab-treated patients (n=16) had upward shifts vs 7.1% on placebo (n=15) (*P*=0.0024). In 6–<12 y and 12–<18 y subgroups <25th weight percentile, the proportions were smaller or showed no meaningful difference between dupilumab and placebo.

Across ages 2 to <18 y, sex-stratified analyses suggested larger dupilumab-associated gains among underweight girls (n=54) than boys (n=72) for those <25th weight percentile (girls: dupilumab 45.2% vs placebo 10.0% [*P*=0.0125]; boys: dupilumab 13.9% vs placebo 6.5% [*P*=0.4372]). Among patients starting with baseline weight >60th percentile, nonsignificant differences between dupilumab (n=165) and placebo (n=144) were observed (dupilumab: 18.6%, placebo:13.4% [*P*=0.2738]). Overall BMI change analyses from baseline to week 16 showed concordant trends with weight percentile shifts across stratifications.

Conclusions

Treatment with dupilumab supported clinically meaningful increases in weight percentiles primarily in younger children who were initially in lower baseline weight percentiles, consistent with movement toward age-expected growth trajectories. Effects were less evident or minimal in older children/adolescents and in those initially at higher baseline percentiles. These findings suggest dupilumab can address an unmet need related to growth and weight status among underweight children with AD and may provide actionable context for monitoring growth in clinical practice.

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Abstract N°: 4168

Validity and Reliability of the Turkish Version of the Recap of Atopic Eczema (RECAP) Questionnaire

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease with a heterogeneous clinical course in terms of disease severity and symptom experience. The insufficient reflection of the patient perspective in clinical assessment has increased the importance of patient-reported outcome measures. This study aimed to perform the linguistic adaptation of the Turkish version of the RECAP instrument, which evaluates disease control, and to assess its psychometric properties.

Materials and Methods
This prospective, single-center study was conducted between March 1, 2025, and April 1, 2026. Seventy patients diagnosed with atopic dermatitis according to the Hanifin and Rajka criteria were included. The sample size was determined based on the rule of 5-10 times the number of items recommended for psychometric studies. The Turkish adaptation of the RECAP instrument was performed using the forward-backward translation method. Participants completed the RECAP-TR along with the ADCT-TR, Skindeks-16, pruritus Numeric Rating Scale (NRS), and single-item patient-reported measures; disease severity was assessed using EASI and vIGA-AD. For test-retest reliability, 29 patients were reassessed after 2 weeks. Internal consistency was evaluated using Cronbach's alpha coefficient and item-total correlations. Test-retest reliability was analyzed using Spearman correlation analysis and the intraclass correlation coefficient (ICC). Construct validity was assessed using exploratory factor analysis (EFA) and confirmatory factor analysis (CFA); data suitability was examined with the Kaiser-Meyer-Olkin (KMO) coefficient and Bartlett's test of sphericity. Convergent validity was evaluated by examining the relationships between RECAP scores and other clinical and patient-reported measures using Spearman correlation analysis.

Results
The mean RECAP-TR total score was 10.19±7.31 (median: 8.50). Internal consistency analysis yielded a Cronbach's alpha coefficient of 0.927, with item-total correlations ranging from 0.707 to 0.860. In the test-retest analysis, the Spearman correlation coefficient was r=0.928 ($p<0.001$), and the ICC value was 0.927 (95% CI: 0.898-0.951). In EFA, the KMO value was 0.883, and Bartlett's test was significant ($\chi^2=378.486$; $p<0.001$). CFA results indicated good model fit (Standardized Root Mean Square Residual=0,036; Comparative Fit Index=0,994; Tucker-Lewis Index=0,992). In convergent validity analysis, a very strong positive correlation was observed between RECAP and ADCT-TR (r=0.954; $p<0.001$), and strong positive correlations were found with mean and peak pruritus NRS scores (r=0.896 and r=0.894, respectively; $p<0.001$). Although RECAP-TR scores showed a moderate positive correlation with vIGA-AD (r=0.513; $p<0.001$), they differed significantly across disease severity groups defined by EASI and vIGA-AD ($p\leq0.002$).

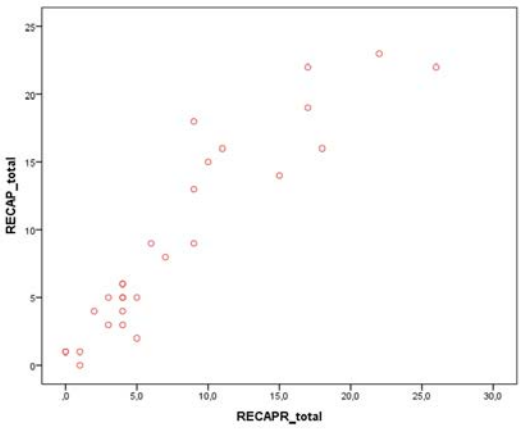

Figure 1. Scatter plot of the test–retest results of the Recap of Atopic Eczema

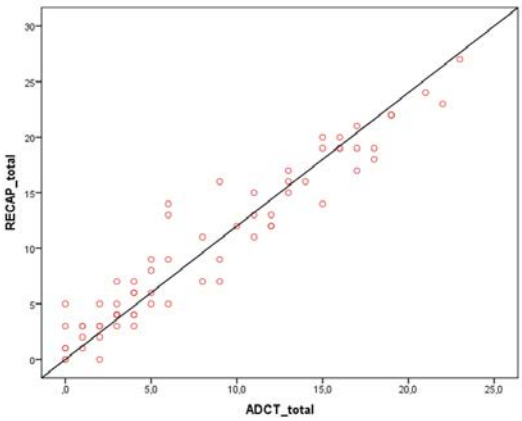

Figure 2. Scatter plot of the RECAP of Atopic Eczema and the Atopic Dermatitis Control Tool

Figure 1. Scatter plot of the pre-test and post-test results of the Recap of Atopic Eczema Figure 2. Scatter plot of the RECAP of Atopic Eczema and the Atopic Dermatitis Control Tool

Conclusions

The Turkish version of the RECAP instrument is a valid and reliable tool with high internal consistency, strong temporal reliability, and good construct and convergent validity for assessing disease control in patients with atopic dermatitis. The adaptation of this scale into Turkish will strengthen patient-centered evaluation processes in clinical practice and enable its use as a standardized patient-reported outcome measure in research.

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Abstract N°: 4178

Practice patterns and educational needs in chronic hand eczema management: a national survey of 137 French dermatologists

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Introduction

Chronic hand eczema (CHE) is the most prevalent occupational skin disease in Europe, with a reported annual prevalence of 4.7% in adults (Apfelbacher et al., 2025), accounting for a major burden of work-related disability. Despite recent advances in diagnostics (including standardized contact allergen identification), prevention, and targeted therapeutics, real-world management remains heterogeneous. New severity assessment tools and treatment algorithms introduced by the ESCD/EuroGuiDerm guidelines have not yet been characterized in routine practice. We aimed to assess current practice patterns and educational needs of French dermatologists in CHE management.

Materials and Methods

A 32-item structured online questionnaire was disseminated nationally between 24 June and 24 July 2025 through a French collaborative dermatology network, using an independent third-party platform ensuring anonymous data handling. The instrument explored five domains: demographics and CHE caseload; diagnostic workup (clinical features, patch testing, referral); clinical phenotypes and triggers; severity assessment and prescribing patterns (topical corticosteroids [TCS], alitretinoin, topical delgocitinib, off-label calcineurin inhibitors, phototherapy, ciclosporin, methotrexate, biologics, oral JAK inhibitors); and self-reported educational needs. Data were summarized using descriptive statistics.

Results

Overall, 137 dermatologists completed the survey (69% women; mean age 49 years; 56% in private practice; 70% with >10 years' experience). The mean monthly CHE caseload was 8 patients per dermatologist.

Itch, fissuring, dryness and erythema were reported by 87% as the cardinal signs prompting a CHE diagnosis. Patch testing was routinely prescribed by 88%, and atopic comorbidities were screened for by 95%; the Repeated Open Application Test was used by only 7%.

Among recognized subtypes, mixed phenotypes were the most frequently encountered in routine practice (29%), followed by hyperkeratotic (23%) and dyshidrotic (22%) variants. Leading triggers were occupational exposure (57%), frequent hand washing (52%, persisting beyond COVID-19) and irritant contact (45%). A chronic relapsing course was reported in 57% of patients; 47% required adjustment of daily activities, and 23% had taken sick leave.

TCS were prescribed regularly by 98% of respondents, of whom 53% used them as long-term maintenance therapy. Alitretinoin, the only systemic agent licensed for CHE in France, was prescribed regularly by 44%. Topical delgocitinib, recently introduced, was already used regularly by 22%, indicating early clinical uptake. Biologics and oral JAK inhibitors remained marginal (<20%, off-label).

Three actionable gaps were identified: (1) only 42% were familiar with the ESCD/EuroGuiDerm guidelines (barriers: lack of time, 56%; preference for national guidance, 51%), and 40% had attended any CHE-dedicated continuing medical education in the previous 12 months; (2) only 15% routinely used the Dermatology Life Quality Index (DLQI) for severity assessment; (3) 85% expressed a clear need for further training on targeted topical therapies.

Conclusions

French dermatologists' diagnostic practices are well aligned with European standards, while three priority areas emerge, complementing the previously published CHEMIN survey (Bernier et al., 2025): limited awareness of the ESCD/EuroGuiDerm guidelines, marked under-use of patient-reported outcomes such as the DLQI, and an evolving therapeutic landscape in which the choice between long-term TCS use and earlier introduction of novel topical agents remains driven by individual practitioner familiarity. These findings support the development of harmonized national French recommendations, routine integration of validated severity tools into clinical practice, and structured continuing medical education focused on newly approved topical therapies.

EADV CONGRESS
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Abstract N°: 4229

Three Decades of Atopic Dermatitis Burden: A Comparative Global Burden of Disease Analysis of North America and Caribbean Small Island Developing States, 1990–2023

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease and a major global contributor to non-fatal health loss. While AD epidemiology is extensively documented in North America, where rates surged in the late twentieth century before plateauing, comparative longitudinal data for Caribbean Small Island Developing States (SIDS) remain scarce. Caribbean SIDS present a unique epidemiological setting characterized by tropical climates, distinct environmental exposures, highly admixed populations, and rapid westernization. This study aims to assess long-term trends and characterize persistent geographic disparities in AD burden across North America and Caribbean SIDS from 1990 to 2023, utilizing standardized Global Burden of Disease (GBD) data.

Materials and Methods

An ecological analysis was conducted using estimates from the GBD Study 2023, accessed via the Global Health Data Exchange (GHDx) Results Tool. We extracted annual age-standardized rates for prevalence, incidence, years lived with disability (YLDs), and disability-adjusted life years (DALYs) per 100,000 population (both sexes combined) from 1990 to 2023. Data were evaluated for Canada, the United States, and 10 Caribbean SIDS (Antigua and Barbuda, Bahamas, Barbados, Bermuda, Dominica, Grenada, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, and Trinidad and Tobago). Temporal trends were assessed utilizing absolute and percentage changes over the 34-year study period.

Results

Between 1990 and 2023, the age-standardized burden of AD remained highly stable across all included jurisdictions, characterized by profound geographic disparity rather than major temporal change. In 2023, the age-

standardized AD prevalence in Caribbean SIDS averaged approximately 4,200 per 100,000, compared to 1,610.1 in the United States and 1,460.0 in Canada, representing a 2.6-fold and 2.9-fold higher prevalence in the Caribbean, respectively. Incidence, YLDs, and DALYs were consistently elevated across the Caribbean cohort compared to North America. Over time, Canada showed negligible changes in prevalence (−0.10%) and incidence (−0.2%), while the US recorded modest declines in prevalence (−0.86%) and incidence (−3.0%). Within the Caribbean cluster, rates were relatively homogeneous; Saint Kitts and Nevis registered the highest 2023 prevalence (4,211.6 per 100,000) alongside a minimal temporal increase (+0.059%), while Dominica (4,193.1) and Grenada (4,195.8) reported lower relative estimates. Across all jurisdictions, YLD rates were identical to DALY rates, confirming that AD burden is driven entirely by non-fatal disability rather than premature mortality.

Conclusions

Persistent regional geographic disparities define the long-term epidemiology of AD across the studied jurisdictions. From 1990 to 2023, Caribbean SIDS sustained an AD prevalence and disability burden roughly three times higher than North America. This persistent gradient underscores a notable "Caribbean Paradox," where an elevated disease burden persists despite potentially protective tropical factors like high ambient humidity and barrier-preserving climates. The stability of these elevated rates suggests that localized environmental drivers (such as continuous indoor allergen exposures), combined with ongoing lifestyle westernization, heavily influence disease expression. Consequently, mitigating the substantial non-fatal disability of AD in Caribbean SIDS requires tailored, region-specific public health interventions rather than frameworks extrapolated solely from North American models.

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Abstract N°: 4239

Circadian Rhythm and Nocturnal Pruritus in Atopic Dermatitis: A Literature Review Based on Evidence Indexed in PubMed/MEDLINE

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by epidermal barrier dysfunction, immune-mediated inflammation, and pruritus. Recent evidence suggests that AD should be understood as a systemic condition in which cutaneous symptoms, sleep, and biological rhythms interact bidirectionally.[1,2] Circadian rhythm influences skin functions such as stratum corneum hydration, cutaneous blood flow, transepidermal water loss (TEWL), and inflammatory reactivity.[3,4] In AD, nocturnal worsening of pruritus has a significant impact on sleep, quality of life, and disease control, with peak intensity occurring between 8:00 PM and 12:00 AM.[5] Therefore, this study aimed to evaluate the relationship between circadian rhythm and atopic dermatitis, with emphasis on nocturnal pruritus and its potential pathophysiological and therapeutic implications.

Materials and Methods

A literature review was conducted using the PubMed/MEDLINE database with descriptors related to atopic dermatitis, circadian rhythm, sleep, melatonin, skin barrier, and pruritus. Clinical, observational, experimental, omics, and review studies investigating the relationship between AD, sleep, circadian rhythm, skin barrier function, and chronobiology were included. Qualitative analysis prioritized clinical studies and systematic reviews.

Results

Findings were organized into five axes: circadian pattern of pruritus, sleep alterations, skin barrier function, molecular/metabolic mechanisms, and therapeutic implications of melatonin and chronobiology. Overall, studies indicate that nocturnal worsening of AD involves measurable temporal changes in symptoms, sleep, skin barrier function, inflammatory pathways, and metabolism.

The most consistent clinical finding was the temporal concentration of pruritus during the nighttime period. In a cross-sectional study involving 241 adults with AD, 74.69% reported higher pruritus frequency between 8:00 PM and 12:00 AM, and 62.66% identified this interval as the period of greatest intensity. Pruritus intensity positively correlated with the Eczema Area and Severity Index and the Dermatology Life Quality Index.[5] Systematic reviews demonstrated a high prevalence of sleep disturbances and a bidirectional relationship between inflammation, nocturnal pruritus, and impaired sleep quality.[9,10] In children with severe AD, an actigraphy study suggested a possible contribution of circadian misalignment to clinical worsening.[6]

Regarding the skin barrier axis, a pilot study demonstrated that patients with AD did not exhibit the physiological reduction in TEWL observed before sleep in healthy controls, with increased pre-sleep TEWL in the forearm.[7] Metabolomic and transcriptomic studies reinforced the mechanistic plausibility of this relationship by identifying circadian alterations in inflammatory and metabolic pathways, reduced expression of circadian genes in AD skin, and associations with dendritic cells.[8,11] In a murine model, day–night inversion aggravated AD-like lesions and altered clock genes.[12]

Melatonin emerged as the chronobiological intervention with the most direct clinical evidence. In a randomized

clinical trial, melatonin 3 mg/day for 4 weeks reduced SCORAD index and sleep latency in children and adolescents with AD, without reported adverse events.[13] Mechanistic studies describe antioxidant and immunomodulatory properties, as well as a possible effect on the cutaneous microbiota.[14,15]

Evidence Axis	Key Studies Indexed in PubMed	Main Findings	Scientific Interpretation
Circadian pruritus	Sang et al., 2024	In 241 adults with AD, pruritus was more frequent between 8:00 PM and 12:00 AM in 74.69% of participants and more intense during this interval in 62.66%. EASI and DLQI positively correlated with pruritus intensity.	There is direct clinical evidence of a circadian pattern of pruritus, with nocturnal peak and association with clinical severity and quality of life.
Sleep and clinical severity	Jeon et al., 2017; Moafa et al., 2025; Arif et al., 2024	Sleep disturbances are frequent in AD and are associated with pruritus and disease severity; children with severe AD showed lower daytime light exposure and delayed sleep midpoint on weekends.	Sleep should be interpreted as part of the clinical phenotype of AD, rather than merely a secondary consequence of pruritus.
Skin barrier	Iwanaszko et al., 2024; Camilion et al., 2022	TEWL decreased before sleep in controls, but did not improve — and appeared to increase — in patients with AD; sensory perception pathways accompanied the evening increase in TEWL in lesional skin.	Timed failure of the skin barrier may contribute to nocturnal worsening of eczema and pruritus.
Molecular and immunometabolic mechanisms	Ratley et al., 2024; Sun et al., 2023; Hiramoto et al., 2018; Nakao, 2020	Alterations in the circadian metabolome, lower expression of circadian genes in AD skin, association with dendritic cells, and worsening of lesions in a murine model subjected to day–night inversion were observed.	The relationship between AD and circadian rhythm involves epithelial barrier function, immunity, lipid metabolism, and core clock genes.
Melatonin and therapeutic intervention	Chang et al., 2016; Yang et al., 2025; Simon et al., 2025	Melatonin 3 mg/day for 4 weeks reduced SCORAD and sleep latency in children with AD; mechanistic studies suggest antioxidant, immunomodulatory, and cutaneous microbiota-related effects.	Melatonin is the chronobiological intervention with the most direct clinical evidence, although broader chronotherapy still requires larger prospective studies.

Table 1 – Main evidence axes, key studies, and scientific interpretation

Conclusions

The findings of this review support that atopic dermatitis has a relevant chronobiological component, particularly related to nocturnal pruritus. Sleep disturbances, skin barrier alterations, circadian genes, and metabolomic changes appear to contribute to this phenomenon. However, currently available evidence remains limited by pilot studies, exploratory analyses, and animal models. Thus, chronotherapy remains an emerging field, and prospective

studies are needed to determine whether interventions aligned with the biological clock may improve disease control.

Strength of Evidence	Topic	Justification
Most consistent	Nocturnal peak of pruritus and association with EASI/DLQI	Clinical study involving 241 adults with clear quantitative results.
Moderate	Sleep, quality of life, and AD severity	Systematic reviews and observational studies support the association, although methodological heterogeneity exists.
Exploratory-promising	Circadian TEWL, metabolome, and transcriptomics	Biologically plausible findings, but based on small samples or observational designs.
Emerging	Chronotherapy and melatonin	A positive clinical trial with melatonin in children exists, but larger studies and comparisons according to therapeutic timing are still lacking.

Table 2 – Strength of evidence according to evaluated topic. References: Simon JA, Serrano C, Kumar D, Anaya BJ, Bautista L, Torrado-Salmerón C, et al. Beyond Sleeping Disorders, the Role of Melatonin in Skin Diseases and Emerging Applications in Dermatology and Topical Therapy. Gels. 2025 Oct 27;11(11):860. Nakao A. Circadian Regulation of the Biology of Allergic Disease: Clock Disruption Can Promote Allergy. Front Immunol. 2020 Jun 12;11:1237. O'Connor C, Irvine AD, Murray D, Murphy M, Hourihane JO'B, Boylan G. Study protocol: assessing SleeP IN infants with early-onset atopic Dermatitis by Longitudinal Evaluation (The SPINDLE study). BMC Pediatr. 2022 Jun 18;22:352. Hiramoto K, Orita K, Yamate Y, Kasahara E, Yokoyama S, Sato EF. The Clock Genes Are Involved in The Deterioration of Atopic Dermatitis after Day-and-Night Reversed Physical Stress in NC/Nga Mice. Open Biochem J. 2018 Oct 12;12:87-102. Moafa TA, Mojiri ME, Alattas KK, Sumayli AM, Alnujaidi EH, Alharbi MO, et al. The Impact of Sleep Dysfunction on Inflammatory Skin Diseases: A Systematic Review. Cureus. 2025 Dec 19;17(12):e99598. Ratley G, Zeldin J, Chaudhary PP, Yadav M, Paller AS, Zee P, et al. The Circadian Metabolome of Atopic Dermatitis. J Allergy Clin Immunol. 2024 Apr;153(4):1148-1154. Sun N, Dai D, Deng S, Cai X, Song P. Bioinformatics Integrative Analysis of Circadian Rhythms Effects on Atopic Dermatitis and Dendritic Cells. Clin Cosmet Investig Dermatol. 2023 Nov 6;16:2919-2930. Arif MK, Zee PC, Paller AS, Crowley SJ, Roenneberg T, Fishbein AB. Severe atopic dermatitis, sleep disturbance, and low light exposure. Sleep. 2024 Jan 11;47(1):zsad276. Sawada Y, Saito-Sasaki N, Mashima E, Nakamura M. Daily Lifestyle and Inflammatory Skin Diseases. Int J Mol Sci. 2021 May 14;22(10):5204. Iwanaszko M, Waldeck N, Anafi R, Paller AS, Zee P, Fishbein A. Circadian rhythms in skin barrier function in atopic dermatitis: A pilot study. J Biol Rhythms. 2024 Apr;39(2):208-214. Camilion JV, Khanna S, Anasseri S, Laney C, Mayrovitz HN. Physiological, Pathological, and Circadian Factors Impacting Skin Hydration. Cureus. 2022 Aug 4;14(8):e27666. Jeon C, Yan D, Nakamura M, Sekhon S, Bhutani T, Berger T, et al. Frequency and Management of Sleep Disturbance in Adults with Atopic Dermatitis: A Systematic Review. Dermatol Ther (Heidelb). 2017 Sep;7(3):349-364. Jaworek AK, Szepietowski JC, Hałubiec P, Wojas-Pelc A, Jaworek J. Melatonin as an Antioxidant and Immunomodulator in Atopic Dermatitis—A New Look on an Old Story: A Review. Antioxidants. 2021 Jul 24;10(8):1179. Sang X, Lu J, Tan L, Zeng J, Wang D, Guo A, et al. The Circadian Rhythm of Itching among 241 Adults with Atopic Dermatitis: A Cross-sectional Study. Acta Derm Venereol. 2024 Aug 5;104:adv35427

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Abstract N°: 4251

A Novel, pH-Sensitive IL-4Rα × TSLP Bispecific Antibody for Dual Pathway Blockade and Extended Exposure in Atopic Dermatitis and Type 2 Inflammatory Diseases

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Introduction

Atopic dermatitis (AD), asthma, and chronic obstructive pulmonary disease (COPD) are heterogeneous inflammatory diseases driven by both upstream epithelial alarmin activation and downstream type 2 cytokine signaling. Thymic stromal lymphopoietin (TSLP) amplifies inflammatory responses across immune and structural cells, while the interleukin-4 receptor alpha chain (IL-4Rα) mediates IL-4- and IL-13-dependent effector signaling. Blockade of either pathway alone may leave complementary inflammatory circuits intact. In addition, target-mediated drug disposition of IL-4Rα antibodies may limit systemic exposure and dosing durability. ALX009 is a pH-sensitive IL-4Rα × TSLP bispecific antibody engineered to integrate upstream TSLP blockade, downstream IL-4/IL-13 pathway inhibition, and enhanced antibody recycling in a single molecule. This study evaluated the binding, functional activity, pharmacokinetics, and in vivo efficacy of ALX009.

Materials and Methods

Binding affinity and pH-dependent dissociation to human TSLP and IL-4Rα were assessed by surface plasmon resonance (SPR). Functional activity was evaluated in TSLP-, IL-4-, and IL-13-dependent reporter assays and CCL17 release assays in primary human peripheral blood mononuclear cells (PBMCs) stimulated with IL-4, IL-13, and TSLP, with ALX009 benchmarked against monospecific anti-TSLP and anti-IL-4Rα antibodies. Pharmacokinetics were assessed in human IL-4Rα transgenic mice, and efficacy was evaluated in a mouse ovalbumin (OVA)-induced airway inflammation model.

Results

ALX009 bound human TSLP and IL-4Rα with high affinity and retained potent activity across upstream TSLP and downstream IL-4/IL-13 signaling pathways. ALX009 demonstrated pH-dependent IL-4Rα binding, with strong engagement at physiological pH and rapid dissociation under acidic endosomal conditions. ALX009 inhibited TSLP-induced and IL-4/IL-13-induced signaling with sub-nanomolar potency, and suppressed CCL17 release from human PBMCs co-stimulated with IL-4, IL-13, and TSLP more effectively than either monospecific benchmark antibody. In human IL-4Rα transgenic mice, ALX009 showed slower clearance and prolonged half-life relative to a pH-independent reference antibody. In the OVA-induced airway inflammation model, ALX009 reduced bronchoalveolar lavage fluid (BALF) eosinophilia and systemic inflammatory biomarkers, supporting in vivo efficacy across type 2 inflammatory readouts.

Conclusions

In preclinical studies, ALX009 retained potent activity across TSLP-, IL-4-, and IL-13-driven pathways and showed prolonged systemic exposure. These findings support further evaluation of ALX009 as a long-acting therapeutic candidate for AD and other type 2 inflammatory diseases, including asthma and COPD.

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Abstract N°: 4311

Retrospective Evaluation of the Documentation of Diagnostic Criteria for Atopic Dermatitis in Patients Followed at a Dermatology Service Over a 10-Year Period

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Introduction

Atopic dermatitis is a chronic, relapsing, pruritic inflammatory skin disease associated with epidermal barrier dysfunction, immune dysregulation, and significant impact on quality of life.[3] Diagnosis remains predominantly clinical and is based on the integration of criteria such as pruritus, typical lesion morphology and distribution, chronic or relapsing course, and personal or family history of atopy.[1] Among the most widely used diagnostic systems are the Hanifin and Rajka criteria and the United Kingdom Working Party criteria, whose applicability and performance vary according to population and healthcare setting.[1 2] The aim of this study was to retrospectively evaluate the documentation of diagnostic criteria for atopic dermatitis in medical records from a university dermatology service.

Materials and Methods

This observational, retrospective, descriptive, and analytical study was "conducted at a university dermatology outpatient clinic, covering the period from 2016 to 2026. Initially, 223 patients with ICD L20.9 were identified, of whom 46 were excluded due to lack of diagnostic confirmation, resulting in a final sample of 177 medical records. Clinical variables were classified as present, absent, or not specified, and were considered present only when explicitly documented in the medical record.

Results

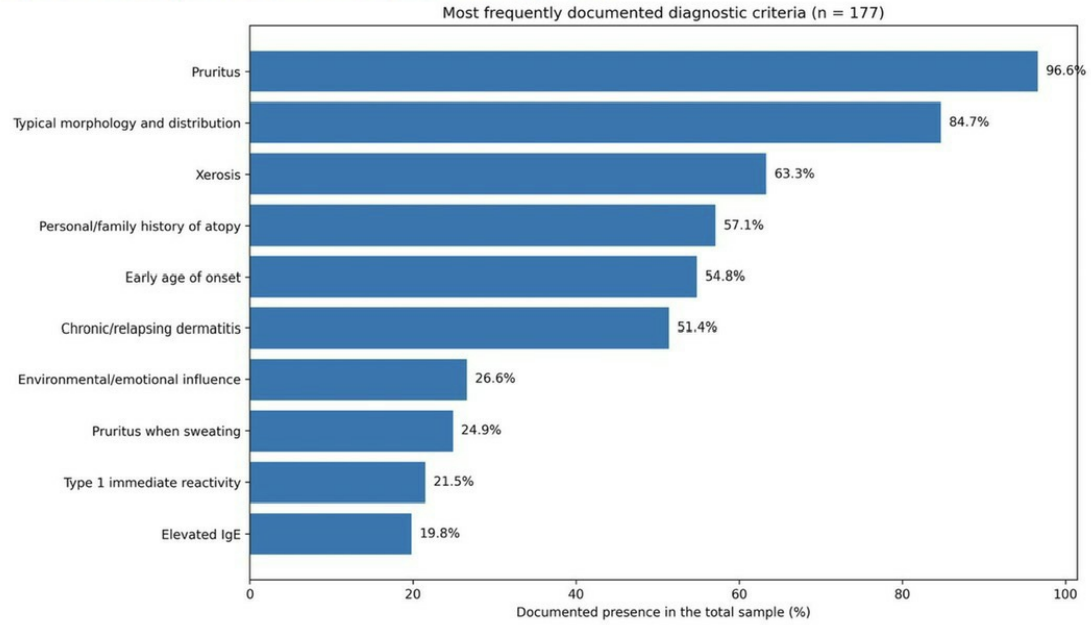
Pruritus was the most frequently documented criterion, present in 171 patients (96.6%), followed by typical lesion morphology and distribution in 150 (84.7%), xerosis in 112 (63.3%), personal or family history of atopy in 101 (57.1%), early age of onset in 97 (54.8%), and chronic/relapsing dermatitis in 91 (51.4%) (Figure 1). Among the evaluated criteria, pruritus showed the highest proportion of presence among documented cases (99.4%), followed by typical morphology/distribution (94.9%) and xerosis (84.2%). These findings corroborate the literature, which recognizes pruritus and typical lesion distribution as central elements in the clinical diagnosis of atopic dermatitis.[4]

Analysis of minor criteria demonstrated an important discrepancy between the frequency expected in the literature and the documentation observed in the medical records. Xerosis was documented in 63.3% of the sample, whereas Dennie-Morgan infraorbital fold, palmar hyperlinearity, pityriasis alba, orbital darkening, and white dermographism showed low documentation frequency. A high proportion of variables classified as not specified was observed, especially for elevated immunoglobulin E (72.3%), intolerance to wool and lipid solvents, white dermographism, and other laboratory or ophthalmologic criteria, suggesting significant retrospective underreporting (Table 1).

Variables with identical frequencies were also identified, including tendency toward hand/foot dermatitis and Dennie-Morgan infraorbital fold, both documented in 19 patients, as well as perifollicular accentuation and food

intolerance, documented in 13 patients each (Table 2). Comparison with previous studies demonstrated agreement regarding the centrality of major criteria and divergence regarding the frequency of minor criteria, traditionally more prevalent in studies using systematic application of the Hanifin and Rajka criteria (Table 3). The reviewed literature demonstrates wide variability in sensitivity and specificity among different diagnostic systems, reinforcing the relevance of standardized clinical documentation.

Figure 1. Most frequently documented diagnostic criteria (n = 177)



NS = Not specified. Bar chart showing the ten most frequently documented diagnostic criteria.

Table 1. Documentation of the ten most frequently recorded diagnostic criteria (n = 177)

Order	Criterion	Yes, n (%)	No, n (%)	NS, n (%)	Yes among documented (%)
1	Pruritus	171 (96.6)	1 (0.6)	5 (2.8)	99.4
2	Typical morphology and distribution	150 (84.7)	8 (4.5)	19 (10.7)	94.9
3	Xerosis	112 (63.3)	21 (11.9)	44 (24.9)	84.2
4	Personal or family history of atopy	101 (57.1)	33 (18.6)	43 (24.3)	75.4
5	Early age of onset	97 (54.8)	36 (20.3)	44 (24.9)	72.9
6	Chronic/relapsing dermatitis	91 (51.4)	27 (15.3)	59 (33.3)	77.1
7	Environmental/emotional influence	47 (26.6)	30 (16.9)	100 (56.5)	61.0
8	Pruritus when sweating	44 (24.9)	24 (13.6)	109 (61.6)	64.7
9	Type 1 immediate reactivity	38 (21.5)	41 (23.2)	98 (55.4)	48.1
10	Elevated immunoglobulin E	35 (19.8)	14 (7.9)	128 (72.3)	71.4

NS = Not specified. Variables considered present only when explicitly documented in the medical record.

Table 2. Variables with identical documentation frequencies across categories

Compared variable	Frequency	Tied criteria	Number of criteria
Documented presence	19	Tendency toward hand/foot dermatitis; Dennie-Morgan infraorbital fold	2
Documented presence	13	Perifollicular accentuation; food intolerance	2
Documented presence	4	Palmar hyperlinearity; anterior subcapsular cataract; facial pallor/erythema	3
Documented absence	50	Tendency toward hand/foot dermatitis; food intolerance	2
Documented absence	86	Pityriasis alba; cheilitis	2
Documented absence	104	Anterior subcapsular cataract; orbital darkening	2
Not specified	44	Xerosis; early age of onset	2
Not specified	69	Recurrent conjunctivitis; keratoconus; anterior subcapsular cataract	3

Ties identified across documented presence, documented absence, and not-specified categories.

Table 3. Comparison with previously published studies on atopic dermatitis diagnostic criteria

Study	Population or design	Main finding	Comparison with the present study
Brenninkmeijer et al., 2008 [1]	Systematic review of diagnostic	Hanifin-Rajka: sensitivity 87.9%–96.0%; specificity 77.6%–93.8%. UK Working	The present casuistry shows high frequency of major criteria, but

	criteria	Party: more validated, but with variable sensitivity.	documentary incompleteness prevents formal retrospective validation.
Akan et al., 2020 [2]	200 children with AD and 90 controls	Hanifin-Rajka had higher sensitivity than UK Working Party (94% versus 72%); UK had higher specificity (92% versus 71%).	The pattern of frequent major criteria favors clinical compatibility with Hanifin-Rajka, but does not allow sensitivity/specificity calculation.
Vakharia et al., 2018 [7]	Review of 212 randomized clinical trials	Hanifin-Rajka was the most used criterion; 37.3% of trials did not specify diagnostic criteria.	The incomplete documentation observed in the local study is consistent with the literature regarding low diagnostic uniformity.
Reynolds et al., 2020 [4]	Review of current diagnostic criteria	Diagnosis remains clinical, centered on pruritus, typical lesions, and atopic history.	Pruritus, typical morphology, and atopic history were among the most documented findings in the local database.
De et al., 2006 [8]	101 pediatric cases and 48 controls	Hanifin-Rajka showed sensitivity of 96% and specificity of 93.75% in a hospital setting.	The predominance of pruritus and typical morphology in the local study is compatible with the good performance of these criteria in hospital settings.
Rudzki et al., 1994 [6]	481 patients with AD	Four major criteria in 72%; more than six minor criteria in 96%.	Minor criteria were much less documented in the local study, suggesting retrospective underreporting.
Shetty et al., 2023 [5]	52 pediatric patients	Pruritus 94.2%; typical morphology/distribution 92.3%; xerosis 86.5%; early onset 80.8%; Dennie-Morgan 76.9%.	Pruritus was similar in the local study (96.6%), but Dennie-Morgan, palmar hyperlinearity, and orbital darkening were much less documented.

Table 3

H&R = Hanifin and Rajka; UKWP = UK Working Party; AD = Atopic Dermatitis.

Figure 1. Bar chart showing the ten most frequently documented diagnostic criteria in 177 medical records. Table 1. Documentation frequency of diagnostic criteria (n=177); NS = Not specified. Table 2. Variables with identical documentation frequencies. Table 3. Comparison with previously published studies; H&R = Hanifin and Rajka; UKWP = UK Working Party.

Conclusions

Major criteria for atopic dermatitis, especially pruritus and typical morphology/distribution, were widely documented in the evaluated medical records. However, the high incompleteness in the documentation of minor criteria limits standardized retrospective interpretation and suggests clinically relevant underreporting. Standardization of dermatologic medical records may improve diagnostic accuracy and strengthen clinical care and research.

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Abstract N°: 4340

New diagnostic criteria and characterization of atopic dermatitis in the elderly

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Introduction

Atopic dermatitis (AD) is the most common inflammatory skin disease, primarily occurring in childhood. Recent research has highlighted that the number of patients with AD in older age is also increasing. However, the clinical picture can be more heterogeneous in elderly populations, and the traditional diagnostic criteria have limited applicability in this age group. Cheng et al. suggested a new diagnostic criteria for AD in Asian children, adults and the elderly based on (i) pruritus; (ii) 'typical morphology and distribution' or 'atypical morphology and distribution with xerosis'; and (iii) a chronic or chronically relapsing course. Our aim was to test this new Chinese diagnostic algorithm in elderly Caucasians with AD and to characterise the skin symptoms of patients with age-related eczema.

Materials and Methods

Patients over 60 years of age who had experienced itchy skin symptoms suspected of eczema, for at least three months were included in the study. After excluding patients with other possible skin conditions (such asscabies, cutaneous T-cell lymphoma, psoriasis) and other types of eczema (such as seborrhoeic dermatitis, contact dermatitis) we declared atopic eczema in the remaining patients. Based on these criteria, 70 patients with atopic eczema over the age of 60 participated in the study. We selected 59 control patients with other skin conditions who were adjusted for age and gender. We evaluated these 129 patients according to Hanifin and Rajka, UK working party and the new Chinese criteria. Xerosis was objectively assessed by TEWL using a Dermalab Combo device. A detailed patient examination was performed to determine the clinical features, localization and severity of skin symptoms, followed by a detailed questionnaire to record the medical history and assess comorbidities. We compared the patient groups identified by the three diagnostic criteria, and we analysed the characteristics of patients identified exclusively using the Chinese criteria. Comparison of two groups was performed by Mann-Whitney test or independent t-test, furthermore, in case of categorical variables Chi^2 or Fisher exact test was used. Sensitivity, specificity, positive predictive value, negative predictive value, and diagnostic accuracy were calculated.

Results

Among elderly eczema patients the sensitivity of Hanifin and Rajka, UK Working Party and the Chinese criteria were 35.7%, 15.7% and 94.3%; the specificity were 98.3%, 98.3% and 96.6%; the negative predictive value was 56.3%, 49.6% and 93.4%, and the positive predictive value was 96.2%, 91.7% and 97.1%, respectively. The Chinese criteria had the highest diagnostic accuracy (95.3%), compared to the Hanifin and Rajka (64.3%) and the UK Working Party (53.5%). 51.4% of AD patients could only be identified by the Chinese criteria. Among these patients, classic AD morphology was significantly less common, while atypical morphological forms (e.g. prurigo-type, nummular eczema and papular lichenoid variants) and atypical localization were more prevalent. Furthermore, asthma was significantly less common in this patient group, while disease severity scores were significantly lower.

Conclusions

The classical Hanifin and Rajka and UK Working Party criteria are primarily applicable to Caucasian pediatric population. In the case of the elderly Caucasian AD population, we were the first to examine the Chinese criteria, demonstrating their higher sensitivity and diagnostic accuracy in this patient group. Patients with AD in the elderly who are identified using these criteria are characterised by atypical morphology and milder forms of the disease.

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Abstract N°: 4357

Safety and Tolerability of Janus Kinase Inhibitors in Atopic Dermatitis: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Introduction

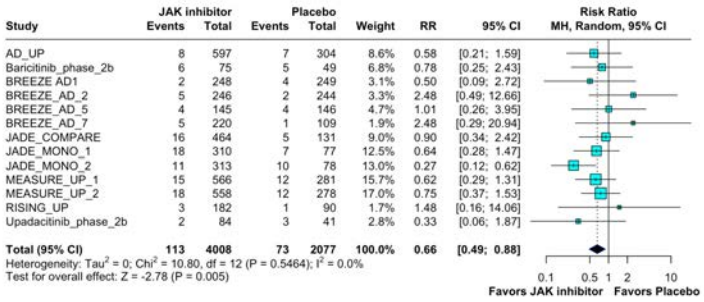
Although Janus kinase (JAK) inhibitors have demonstrated significant efficacy in the treatment of atopic dermatitis (AD), concerns regarding their tolerability and safety persist and continue to influence prescribing practices. While existing studies have primarily focused on overall adverse events and serious safety outcomes, treatment discontinuation due to adverse events remains a clinically relevant but less frequently evaluated measure of tolerability.

Materials and Methods

PubMed, Embase, and Cochrane CENTRAL were systematically searched for randomised controlled trials comparing JAK inhibitors with placebo in atopic dermatitis. A PRISMA-compliant systematic review and meta-analysis was performed, and risk of bias was assessed using the Cochrane Risk of Bias 2 tool. The primary outcome was discontinuation due to adverse events. Secondary outcomes included total adverse events (TAE), serious adverse events (SAE), and serious infections. Risk ratios (RR) with 95% confidence intervals (CI) were pooled using random-effects models. Heterogeneity was evaluated using I^2.

Results

A total of 13 randomised controlled trials involving 6085 patients were included. JAK inhibitor therapy was associated with a significantly lower risk of treatment discontinuation due to adverse events compared with placebo (RR 0.66, 95% CI 0.49–0.88; p=0.005), suggesting favourable tolerability despite increased overall adverse events. Total adverse events occurred more frequently in the JAK inhibitor group (RR 1.14, 95% CI 1.09–1.21; p<0.001), although no significant increase in serious infections was observed (RR 0.79, 95% CI 0.35–1.75; p=0.558). JAK inhibitors were also associated with a lower risk of serious adverse events compared with placebo (RR 0.69, 95% CI 0.49–0.98; p=0.037; I^2=0%). Dose-related subgroup analysis demonstrated a greater magnitude of overall adverse events with higher-dose regimens, suggesting a dose-dependent effect on tolerability.



Forest plot of treatment discontinuation due to adverse events comparing JAK inhibitors with placebo in atopic dermatitis randomised controlled trials. Risk ratios <1 favour JAK inhibitors.

Conclusions

Although JAK inhibitors were associated with increased overall adverse events, they demonstrated favourable short-term tolerability, reflected by lower rates of treatment discontinuation due to adverse events. No increased risk of serious adverse events or serious infections was identified, supporting the short-term safety profile of JAK inhibitors in atopic dermatitis. These findings suggest that increased adverse events associated with JAK inhibitors may not translate into clinically significant rates of treatment discontinuation.

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Abstract N°: 4381

Clinical Characteristics and Biomarkers of Super-Response to Dupilumab in Patients with Refractory Atopic Dermatitis: A Single-Center Retrospective Study

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Introduction
Therapeutic response to dupilumab in patients with refractory moderate-to-severe atopic dermatitis (AD) is highly heterogeneous. This study aimed to identify the clinical characteristics and baseline biomarkers of patients who achieve a super responder (SR) status within 16 weeks, to inform personalized treatment strategies.

Materials and Methods
A single-center retrospective study was conducted, enrolling patients with refractory moderate-to-severe AD who received dupilumab treatment for at least 16 weeks. SR was defined as simultaneously achieving the following at 16 weeks: ① EASI-75, ② a ≥4-point improvement in PP-NRS, and ③ a ≥4-point improvement in DLQI. Baseline demographics, clinical features, and laboratory indicators (total IgE, eosinophil count, LDH, etc.) were compared between the SR and non-SR groups. Logistic regression and linear regression were used to identify independent predictive factors, and a COX predictive model was constructed.

Results
Among the 209 enrolled patients, 115 (55.02%) were identified as SRs, achieving significant clinical improvement within 16 weeks. Univariate analysis revealed no significant differences between SR and non-SR groups in demographics (gender, age, BMI), family history, prior medication history, or lifestyle habits (outdoor activity time, sleep duration, moisturizer use, smoking, alcohol consumption, hair dye history). Biological indicators, including eosinophil count, basophil count, lactate dehydrogenase, and vitamin D levels, before and after treatment also showed no significant differences. The age at first symptom onset (P=0.085) and daily screen time (P=0.070) showed marginally significant trends, suggesting that SR patients may have a later disease onset and longer screen time. The proportion of SRs differed significantly across family income levels (P=0.037), with higher monthly family income potentially serving as a positive predictor for SR, possibly related to treatment frequency and adherence. Bathing duration was significantly different between groups (Z=-2.340, P=0.019), while bathing frequency was not (P=0.663), indicating that "how long one bathes" may be more critical than "how often." Baseline severity scores, including SCORAD, EASI, NRS, DLQI, POEM, ADCT, and BSA, were all significantly higher in the SR group (P<0.05), indicating more severe disease at baseline. Higher baseline NRS and POEM scores were independent positive predictors for becoming an SR (OR: 1.47, 95% CI: 1.19-1.80; OR: 1.11, 95% CI: 1.02-1.21, respectively).

Conclusions
Bathing duration may be a risk factor influencing dupilumab efficacy, while baseline severity scores—particularly NRS, POEM, EASI, and ADCT—are key predictors of a super response in AD, suggesting that a dramatic

improvement in pruritus is the most prominent feature of SR. Early identification of these characteristics can help optimize treatment decisions and manage patient expectations. Conventional short-term serum biomarkers showed limited predictive value, warranting further exploration of their potential long-term clinical utility.

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Abstract N°: 4390

Comparative disproportionality of adverse events across four type 2 inflammation-targeting biologics for atopic dermatitis: a FAERS analysis of dupilumab, tralokinumab, lebrikizumab, and nemolizumab

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Introduction

Type 2 inflammation-targeting biologics are widely utilized in dermatologic conditions. These agents include dupilumab, an IL-4Rα inhibitor; tralokinumab and lebrikizumab, both IL-13 inhibitors that differ in their binding mechanisms; and nemolizumab, which targets IL-31Rα. These biologics have broadened treatment options; however, their switching, sequencing, and mechanism-specific safety differences remain limited, since traditional whole-database FDA Adverse Event Reporting System (FAERS) disproportionality compares one drug against the rest of the database, which includes unrelated drug classes such as oncology, cardiovascular, and psychiatric medications. To improve clinical relevance, this study presents a matched drug-class comparative disproportionality analysis focusing on a shared 10-MedDRA Preferred Terms panel to provide more clinically relevant drug-vs-drug estimates that are often lost in whole-database comparisons.

Materials and Methods

We conducted a retrospective disproportionality analysis of FDA Adverse Event Reporting System (FAERS) quarterly data files from Q1 2024 to 25th of April 2026. Reports listing dupilumab, tralokinumab, lebrikizumab, or nemolizumab as suspect or concomitant drugs were extracted and duplicates removed. A pre-specified panel of 10 MedDRA Preferred Terms, injection site reaction, headache, nasopharyngitis, conjunctivitis, rash pruritic, eczema herpeticum, pemphigoid, rebound atopic dermatitis, psoriasis, and arthralgia, was analyzed. For each drug-event pair, the reporting odds ratio (ROR) with 95% CI and the proportional reporting ratio (PRR) were calculated against the remainder of FAERS (whole-database design). A signal was defined as PRR ≥ 2 with ROR lower 95% CI > 1. Cross-drug differences are descriptive, not direct statistical contrasts.

Results

Conjunctivitis signaled for lebrikizumab (ROR 97.21; PRR 89.96), tralokinumab (ROR 22.96; PRR 22.54), and dupilumab (ROR 17.20; PRR 17.07), with no signal for nemolizumab. Injection site reaction signaled for tralokinumab (ROR 8.95; PRR 8.80), lebrikizumab (ROR 8.04; PRR 7.93), and dupilumab (ROR 5.06; PRR 5.03), with no signal for nemolizumab. Rash pruritic signaled for dupilumab (ROR 7.25; PRR 7.19) and tralokinumab (ROR 2.86; PRR 2.85), with no signal for lebrikizumab or nemolizumab.Eczema herpeticum signaled for nemolizumab (ROR 63.32; PRR 63.19), tralokinumab (ROR 49.80; PRR 49.71), and lebrikizumab (ROR 35.48; PRR 35.43); no significant signal was identified for dupilumab. The tralokinumab and lebrikizumab estimates were based on

limited case counts. Pemphigoid signaled for nemolizumab (ROR 27.96; PRR 27.72), lebrikizumab (ROR 4.11; PRR 4.10), and dupilumab (ROR 2.28; PRR 2.28), with no signal for tralokinumab. Dupilumab additionally demonstrated a rebound atopic dermatitis signal (ROR 6496.33; 95% CI 2700.55–15627.29; PRR 6450.53), nasopharyngitis (ROR 2.54; PRR 2.51), and arthralgia (ROR 3.22; PRR 3.13). Lebrikizumab additionally signaled for psoriasis (ROR 2.30; PRR 2.29). Headache did not signal for any agent.

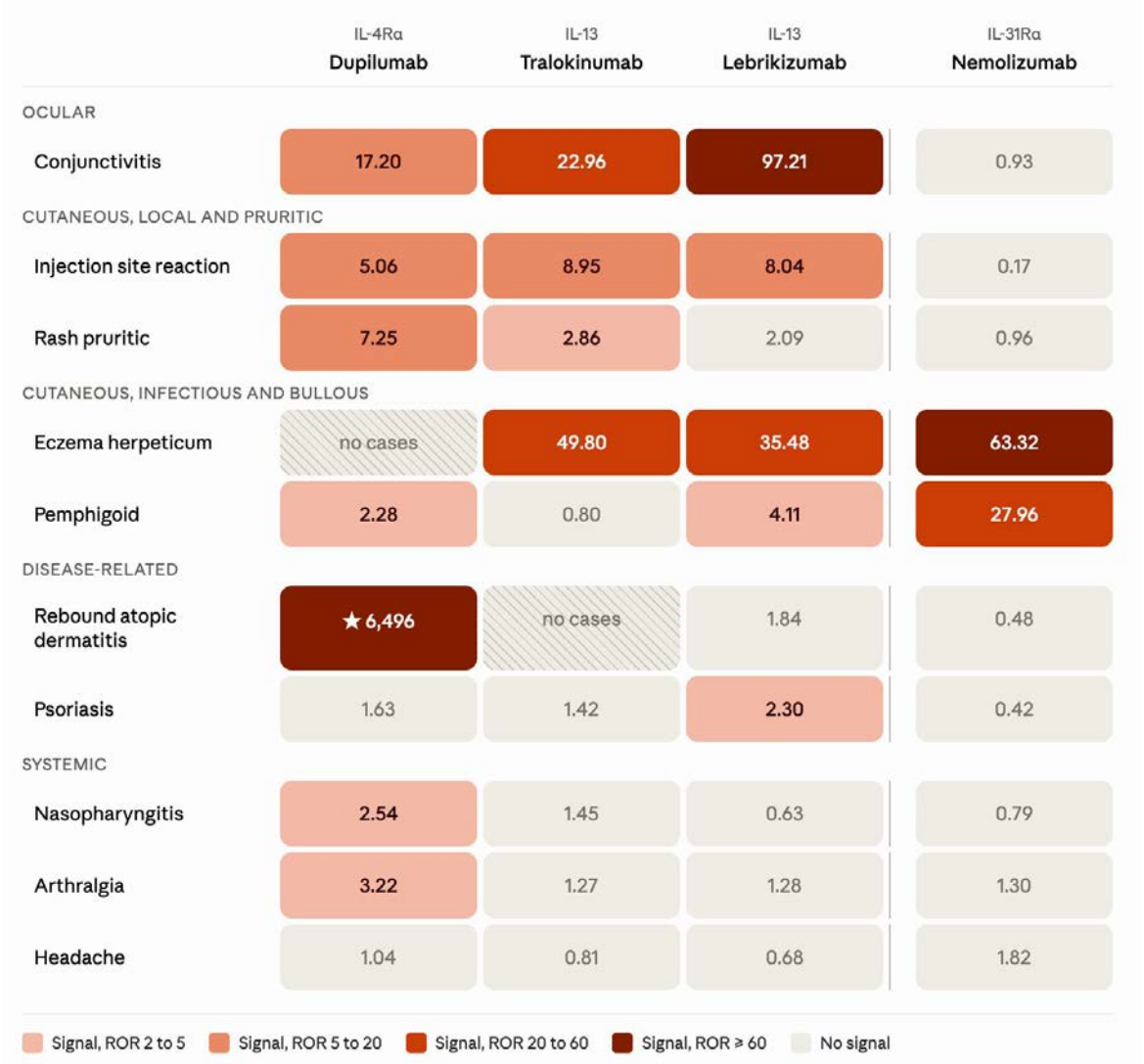

Figure 1. ROR heatmap across four Type 2 cytokine-targeted biologics for 10 MedDRA Preferred Terms, columns ordered by molecular target. Signal is defined as PRR ≥ 2 with ROR lower 95% CI > 1. Hatched cells denote no reported cases; ★ marks an off-scale outlier. FAERS, Q1 2024 to April 2026.

Conclusions

This pharmacovigilance analysis identified adverse event reporting patterns that appeared to track cytokine target rather than individual drug. Ocular and injection-site signals were most prominent among IL-4/13 and IL-13 inhibitors. These signals were not observed with the IL-31Rα-directed agent, while eczema herpeticum was observed across three of four biologics, suggesting a possible class-level association with mucocutaneous viral susceptibility. An unexpected pemphigoid signal was observed with nemolizumab and merits further investigation.These results may help guide biologic selection, switching, and safety monitoring, especially when managing patients with different risk factors. Results should be interpreted in light of FAERS limitations, including differential market tenure across agents, notoriety bias for newer biologics, and the absence of exposure denominators.

EA DV CONGRESS
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Abstract N°: 4393

Differential Adverse Event Patterns of JAK Inhibitors in Alopecia Areata and Atopic Dermatitis: A Retrospective Real World Comparative Study

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Introduction
Janus kinase inhibitors have expanded treatment options in alopecia areata and atopic dermatitis. However, whether adverse event profiles differ according to disease background remains unclear. This distinction may be important because atopic dermatitis is associated with epidermal barrier dysfunction and microbial dysbiosis, whereas alopecia areata primarily involves collapse of hair follicle immune privilege. This study aimed to compare adverse event patterns of systemic JAK inhibitors in alopecia areata and atopic dermatitis patients in routine clinical practice.

Materials and Methods
This study is a retrospective single centre study including alopecia areata and atopic dermatitis patients treated with systemic JAK inhibitors between 01.01.2024 and 01.04.2026. Demographic characteristics, treatment duration, JAK inhibitor, laboratory results, and adverse events were extracted from medical records. Adverse events were categorized as cutaneous infections, non cutaneous infections, acne/acneiform eruption, gastrointestinal complaints, headache, musculoskeletal symptoms, laboratory abnormalities, and serious adverse events. Laboratory abnormalities included lipid elevation, transaminase elevation, cytopenia, and creatine phosphokinase increase. The primary outcome was overall adverse event frequency in alopecia areata versus atopic dermatitis. Logistic regression analysis evaluated whether disease group independently predicted selected adverse events after adjustment for age, sex, treatment duration, and drug type.

Results
A total of 96 patients were included, comprising 48 alopecia areata and 48 atopic dermatitis patients. Median treatment duration was 8.5 months. Overall, at least one adverse event occurred in 41.7% of patients. The overall adverse event rate was significantly higher in atopic dermatitis compared with alopecia areata (52.1% vs 31.3%, p=0.038).

Cutaneous infectious events were more frequent in atopic dermatitis patients (22.9% vs 8.3%, p=0.041), mainly consisting of folliculitis, impetiginization, and localized herpes simplex reactivation. Acne/acneiform eruptions were also more common in atopic dermatitis patients (16.7% vs 6.3%), although the difference was not statistically significant (p=0.11). Rates of non-cutaneous infections were comparable between groups (14.6% vs 10.4%, p=0.52).

Laboratory abnormalities occurred in 27.1% of the cohort, most commonly hyperlipidemia and transient creatine phosphokinase elevation, without significant difference between alopecia areata and atopic dermatitis groups (29.2% vs 25.0%, p=0.64). Headache, gastrointestinal complaints, and musculoskeletal symptoms were infrequent and similarly distributed. No venous thromboembolism, major cardiovascular event, opportunistic infection, or treatment related malignancy was observed.

Multivariable logistic regression demonstrated that atopic dermatitis independently predicted cutaneous infectious adverse events (adjusted odds ratio 2.94, 95% confidence interval 1.12–7.71, p=0.028). Disease type did not independently predict laboratory abnormalities.

Conclusions

JAK inhibitors demonstrated an acceptable safety profile in both alopecia areata and atopic dermatitis in this real world cohort. However, atopic dermatitis patients showed higher rates of cutaneous infectious complications, possibly related to underlying barrier dysfunction and microbial dysbiosis. In contrast, laboratory abnormalities and systemic adverse events were comparable between groups. These findings suggest that disease specific immunity profile and barrier characteristics may influence JAK inhibitor tolerability and adverse event patterns in clinical practice.

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Abstract N°: 4409

Real-world experience of lebrikizumab for atopic dermatitis: A 16-week multicenter retrospective study

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Introduction
Lebrikizumab is a novel IgG4 monoclonal antibody targeting interleukin-13, recently approved for the treatment of moderate-to-severe atopic dermatitis in adults and adolescents. While randomized clinical trials have demonstrated its efficacy and favorable safety profile, real-world evidence remains limited. Herein, we present a 16-week multicenter retrospective review evaluating the effectiveness and safety of lebrikizumab in routine clinical practice.

Materials and Methods
Our retrospective multicenter study in Canada included adult and adolescent patients with atopic dermatitis from 3 institutions who were initiated on subcutaneous lebrikizumab as per standard dosing (500 mg loading doses at weeks 0 and 2, followed by 250 mg every 2 weeks through week 16, then 250 mg every 4 weeks). Three patients with a baseline body surface area (BSA) of 0% were excluded. Effectiveness outcomes were measured at week 16 ± 8. Safety was assessed via treatment-related adverse events.

Results
A total of 30 patients were included. Mean age was 46.2 (range: 15–84) years, with 53.3% (16/30) being male. At week 16 ± 8: 72.4% (21/29) achieved an Investigator Global Assessment score of clear (0) or almost clear (1) (IGA 0/1); 53.3% (16/30), 43.3% (13/30), and 36.7% (11/30) of patients achieved 75%, 90%, and 100% improvements in Eczema Area and Severity Index (EASI) scores from baseline (EASI-75, EASI-90, and EASI-100, respectively); 80.0% (24/30), 80.0% (24/30), 63.3% (19/30), and 53.3% (16/30) reached absolute EASI scores ≤7, ≤5, ≤3, and ≤1. Additionally, DLQI 0/1 was achieved by 45.0% (9/20) at week 16 ± 8.

Among 30 patients treated with lebrikizumab for atopic dermatitis, 3 (10.0%) received concomitant topical

therapy and 3 (10.0%) required concomitant systemic agents (cyclophosphamide, upadacitinib, and abrocitinib) during the treatment period. Over a cumulative follow-up of approximately 22.3 patient-years, no adverse events were reported including no cases of conjunctivitis, injection site reactions, headache, hepatic enzyme abnormalities, major adverse cardiovascular events (MACE), malignancies, serious infections, inflammatory bowel disease, or candidiasis. No patients discontinued lebrikizumab during the study period due to adverse events or lack of efficacy.

Conclusions

Across ADvocate 1 (n = 283), ADvocate 2 (n = 281), and ADhere (n = 145) clinical trials, 33.2% to 43.1%, 52.1% to 69.5%, and 30.6% to 42.9% of lebrikizumab-treated patients achieved IGA 0/1, EASI75, and EASI90, respectively, at week 16. Previously, a UK retrospective study (n = 72) demonstrated EASI75 and EASI90 responses of 56.9% and 27.8%, respectively, at weeks 16–20. Similarly, a Japanese prospective real-world study (n = 126) demonstrated IGA 0/1, EASI75, and EASI90 responses of 33.3%, 57.1%, and 27.3%, respectively, at week 16. In comparison to this existing evidence, our Canadian retrospective study (n = 30) demonstrated superior response rates for IGA 0/1 (72.4%) and EASI90 (43.3%) at week 16 ± 8; furthermore, we observed an absence of conjunctivitis (0% [our study] vs 4.8% to 8.5% [clinical trials] vs 21.4% [ocular events, UK real-world] vs not reported [Japanese real-world]). Overall, we demonstrate the real-world utility of lebrikizumab for atopic dermatitis. Study limitations include its retrospective nature, heterogeneous assessment period, and short follow-up interval.

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Abstract N°: 4416

Ethnic variation in clinical response to an IL-13 Inhibitor for moderate to severe atopic dermatitis: Real-world evidence from an ethnically diverse UK population

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Introduction

Lebrikizumab, a monoclonal antibody targeting IL-13, has demonstrated efficacy in moderate to severe atopic dermatitis in phase 3 clinical trials. However, real-world data evaluating treatment response across different ethnic groups remain limited. Asian and Black individuals represent a substantial proportion of people living with atopic dermatitis (AD) across Europe yet remain significantly underrepresented in pivotal biologic trials, limiting the external validity and generalisability of findings. Real-world datasets that include these groups are essential to understand treatment performance in routine clinical practice. We evaluated ethnic variation in lebrikizumab effectiveness and treatment outcomes in a real-world UK population with high ethnic diversity.

Materials and Methods

Objectives:

To evaluate ethnic variation in real-world effectiveness, safety profile, and treatment persistence of an IL-13 inhibitor in adults with moderate to severe AD from an ethnically diverse UK population.

Methods:

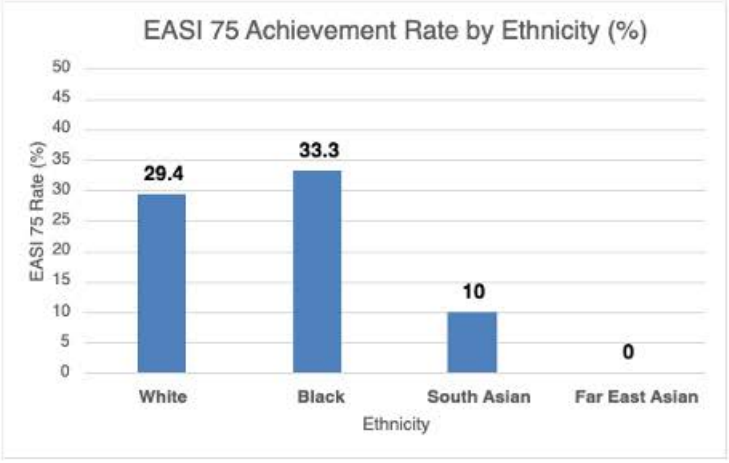
Retrospective analysis of 50 patients with moderate to severe atopic dermatitis treated with lebrikizumab across two UK tertiary dermatology centres. Ethnicity distribution: South Asian 40% (n=20), White 40% (n=20), Black 14% (n=7), Far East Asian (Chinese) 6% (n=3).

Primary outcomes included EASI (Eczema Area and Severity Index), DLQI (Dermatology Life Quality Index), EASI 75 achievement (≥75% reduction from baseline), DLQI MCID (minimally clinically important difference ≥4 points), and treatment switching at Week 24.

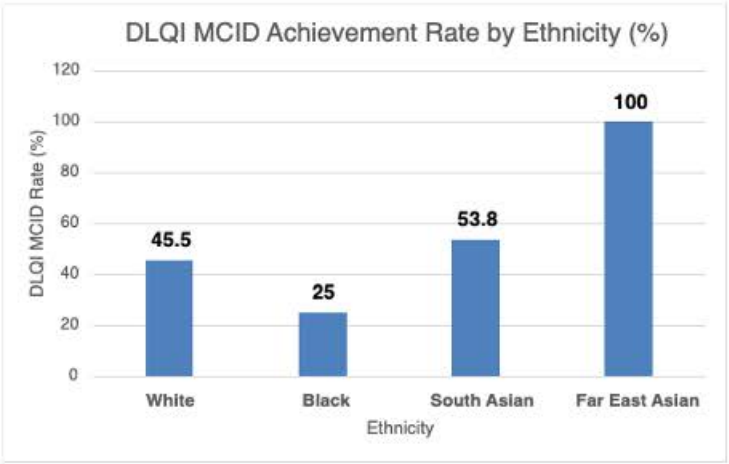
Results

At Week 24, EASI 75 achievement varied substantially by ethnicity: Black 33.3%, White 29.4%, South Asian 10.0%, Far East Asian 0%. South Asian patients demonstrated the lowest EASI 75 rate and highest treatment switch rate (40.0% vs 17.6% White). Mean absolute EASI improvement was greatest in Black patients (15.9 points, 60.4% reduction) compared with White (8.8 points, 41.3%), South Asian (10.0 points, 53.2%), and Far East Asian (-2.0 points, worsening). Paradoxically, Black patients showed DLQI worsening (-3.6 points) despite the greatest EASI improvement, while South Asian patients achieved the highest DLQI MCID rate (53.8%) despite the lowest EASI 75. White patients achieved DLQI MCID in 45.5% and Black patients in 25.0%. Overall, 31.4% achieved EASI 75 and 54.5% achieved DLQI MCID. Adverse event rates also varied by ethnicity: South Asian patients reported the highest rate (45%) and most flare-ups (25%), while Black patients reported no adverse events (0%).

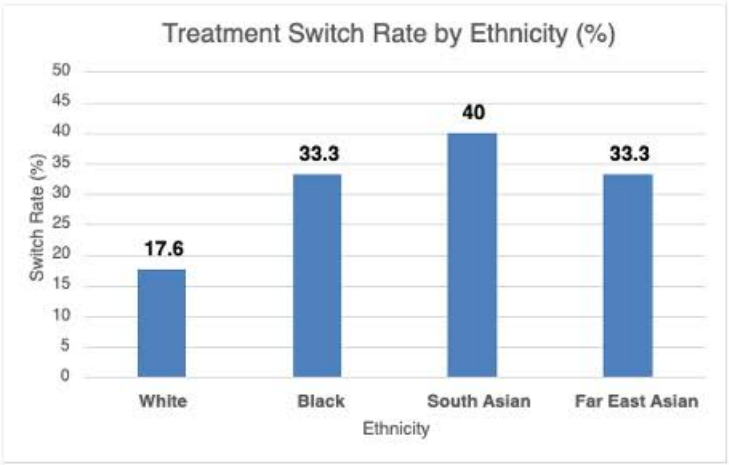
A


EASI 75 Achievement Rate by Ethnicity (%)
EASI 75 Rate (%)
50
45
40
35
30
25
20
15
10
5
0
29.4
33.3
10
0
White
Black
South Asian
Far East Asian
Ethnicity

B


DLQI MCID Achievement Rate by Ethnicity (%)
DLQI MCID Rate (%)
120
100
80
60
40
20
0
45.5
25
53.8
100
White
Black
South Asian
Far East Asian
Ethnicity

C


Treatment Switch Rate by Ethnicity (%)
Switch Rate (%)
50
45
40
35
30
25
20
15
10
5
0
17.6
33.3
40
33.3
White
Black
South Asian
Far East Asian
Ethnicity

D

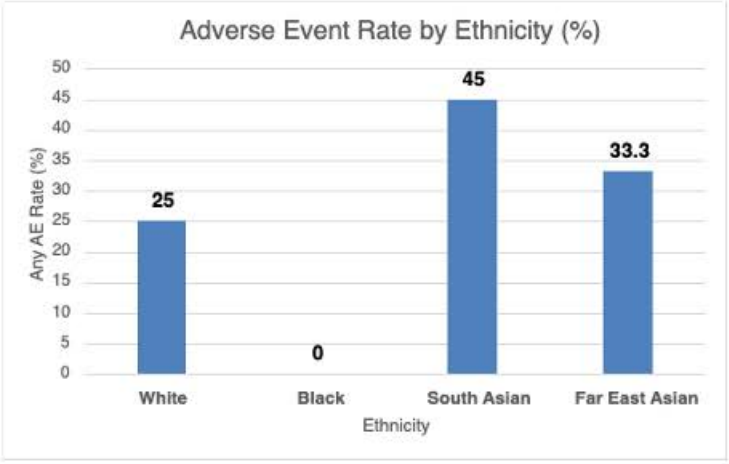

Adverse Event Rate by Ethnicity (%)
Any AE Rate (%)
50
45
40
35
30
25
20
15
10
5
0
25
0
45
33.3
White
Black
South Asian
Far East Asian
Ethnicity

Figure A EASI-75 (≥75% reduction in EASI score from baseline) achievement rate by ethnicity (%), B DLQI MCID (≥4-point reduction in DLQI score) achievement rate by ethnicity (%), C Treatment switch rate by ethnicity (%), D Adverse event rate by ethnicity (%)

Conclusions

This real-world study identified clinically meaningful variation in lebrikizumab response across ethnic groups. South Asian patients demonstrated 3-fold lower EASI 75 rates (10% vs 29%) and 2.3-fold higher treatment switching (40% vs 18%) compared with White patients. The discordance between objective disease severity and patient reported outcomes warrants further investigation and may reflect potential biological, immunological, and socio-cultural contributors to differential treatment responses. These findings have important implications for treatment management and counselling in ethnically diverse populations.

EADV CONGRESS
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Abstract N°: 4424

Longitudinal changes in clinical severity and skin barrier function inpatients with prurigo nodularis treated with dupilumab

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Introduction
Prurigo nodularis is a chronic inflammatory skin disease characterized by intense pruritus, nodular lesions and substantial impairment in quality of life. Dupilumab has shown clinical efficacy in prurigo nodularis, but real-world data on the longitudinal evolution of skin barrier function during treatment remain limited.
So, the objetive of this study was to evaluate changes in clinical severity and skin barrier function over time in patients with prurigo nodularis treated with dupilumab.

Materials and Methods
We conducted a longitudinal observational study including patients with prurigo nodularis treated with dupilumab. Clinical severity was assessed using Investigator Global Assessment (IGA), Dermatology Life Quality Index (DLQI) and body surface area (BSA). Skin barrier parameters were measured in both lesional and non-lesional skin, including transepidermal water loss (TEWL), stratum corneum hydration (SCH), erythema, skin temperature and elasticity parameters R0, R2 and R7. Assessments were performed at baseline and during follow-up visits at week 16, week 24 and 1 year, when available. Paired comparisons versus baseline were performed using the Wilcoxon signed-rank test, including only patients with available paired data for each variable.

Results
Twelve patients were included in the study. A significant improvement in clinical severity was observed during follow-up. Median IGA decreased from 3.0 [3.0–4.0] at baseline to 1.0 [1.0–2.0] at week 16 and 1.0 [0.8–1.2] at week 24 and 0.5 [0.0–1.0] at 1 year ($p<0.05$). BSA also decreased significantly, from 18.5% [12.6–35.1] at baseline to 5.5% [4.6–9.2] at week 16 and 3.2% [1.6–10.8] at week 24, and 0.8% [0.1–1.8] at 1 year ($p<0.05$). DLQI improved descriptively although these changes did not reach statistical significance (8.0 at baseline, 1.0 at week 16 and 0.0 at week 24, and 0.5 at 1 year). Regarding skin barrier function, in lesional skin, SCH increased significantly at week 24, from 23.6 [15.1–34.7] to 41.6 [36.8–46.1], with a median paired change of +10.1 ($p=0.023$). TEWL and erythema in lesional skin showed a decreasing trend, although without statistical significance. No significant longitudinal changes were observed in non-lesional skin.

Conclusions
In this real-world cohort of patients with prurigo nodularis, dupilumab was associated with a significant and sustained improvement in clinical severity. Skin barrier changes were less consistent, although the significant increase in SCH in lesional skin at week 24 suggests partial recovery of stratum corneum hydration. These findings support the clinical effectiveness of dupilumab and suggest that improvement in skin barrier function may occur more slowly than clinical improvement. Larger studies are needed to confirm these exploratory findings.

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Abstract N°: 4439

Real-world experience of abrocitinib for atopic dermatitis: A 16-week multicenter retrospective study

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Introduction
Abrocitinib is an oral, selective Janus kinase 1 (JAK1) inhibitor approved for moderate-to-severe atopic dermatitis in adults and adolescents. While its efficacy and safety have been established in pivotal randomized trials, real-world evidence particularly in patients who have failed prior biologic therapy remains limited. Herein, we provide evidence regarding abrocitinib use in routine clinical practice across two Canadian centers.

Materials and Methods
Our retrospective multicenter study in Canada included adult and adolescent patients with atopic dermatitis from 2 institutions who were initiated on on oral abrocitinib per standard dosing (100 mg or 200 mg once daily). Effectiveness outcomes were measured at week 16 ± 8. Safety was assessed via treatment-related adverse events.

Results
A total of 25 patients were included. Mean age was 46.8 ± 18.5 (range: 19–78) years, with 44.0% (11/25) being male. Prior therapies included topicals (92.0%, 23/25), phototherapy (20.0%, 5/25), nonbiologic systemic immunosuppressants (60.0%, 15/25), and biologic therapy (36.0%, 9/25; dupilumab 28.0%, lebrikizumab 12.0%). At week 16 ± 8: 92.0% (23/25) achieved an Investigator Global Assessment score of clear (0) or almost clear (1) (IGA 0/1); 90.5% (19/21), 85.7% (18/21), and 81.0% (17/21) of patients achieved 75%, 90%, and 100% improvements in Eczema Area and Severity Index (EASI) scores from baseline (EASI75, EASI90, and EASI100, respectively). 95.2% (20/21), 95.2% (20/21), 90.5% (19/21), and 85.7% (18/21) reached absolute EASI scores ≤7, ≤5, ≤3, and ≤1. Body surface area (BSA) ≤1% was achieved by 85.7% (18/21).

Among 25 patients treated with abrocitib for atopic dermatitis, 10 (30.3%) received concomitant topical therapy and none required concomitant systemic agents during the treatment period. Over the cumulative follow-up of

7.4 patient-years, only one treatment-related adverse event occurred, which was nausea/vomiting (4.0%, 1/25). No other adverse events commonly associated with abrocitinib, such as acne, nasopharyngitis, herpes simplex, or headache, were reported. No conjunctivitis, herpes zoster, hepatic abnormalities, major adverse cardiac events, venous thromboembolism, malignancy, or serious infections were observed, and no treatment discontinuations occurred over the study period.

Conclusions

Across the JADE COMPARE (n = 450 [abrocitinib arms combined]) clinical trial, 34.8% to 47.5%, 60.3% to 71.0%, and 41.7% to 54.6% of abrocitinib-treated patients achieved IGA 0/1, EASI75, and EASI90, respectively, at week 16. Previously, an Italian multicenter retrospective study (n = 85) demonstrated IGA 0/1, EASI75, and EASI90 responses of 61.2%, 77.7%, and 49.4%, respectively, at week 16. Similarly, a single-center South Korean retrospective study assessed abrocitinib through week 16 with comparable real-world effectiveness across baseline severity strata. In comparison to this existing evidence, our Canadian retrospective study (n = 25) demonstrated superior response rates for IGA 0/1 (92.0%), EASI75 (90.5%), and EASI90 (85.7%) at week 16 ± 8. Additionally, we observed an absence of conjunctivitis (0% [our study] vs 1.4% to 3.5% [JADE COMPARE abrocitinib arms]) and a single mild treatment-related adverse event (nausea/vomiting, 4.0%), with no herpes zoster, hepatic abnormalities, major adverse cardiac events, venous thromboembolism, or serious infections. Overall, we demonstrate the real-world utility of abrocitinib for atopic dermatitis, including in a cohort that included a substantial proportion of patients with prior biologic exposure (40%). Study limitations include its retrospective nature, heterogeneous assessment period, short follow-up interval, and small sample size.

EADV CONGRESS
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Abstract N°: 4455

Lower Household Income Correlates With Greater Atopic Dermatitis Severity: A Real-World Cross-Sectional Study

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Introduction
Atopic Dermatitis (AD) is a chronic inflammatory skin disease associated with substantial physical, psychosocial, and economic burden. Although advances in systemic therapies have significantly improved disease control in moderate-to-severe AD, access to specialized care and advanced treatments remains heterogeneous, particularly in resource-limited settings. Socioeconomic disparities may influence treatment adherence, continuity of care, and long-term outcomes; however, the relationship between socioeconomic status and AD severity remains incompletely characterized.

Objectives:
To evaluate the association between household income and AD severity and to investigate demographic and clinical variables associated with more severe disease.

Materials and Methods
A retrospective cross-sectional study was conducted at a tertiary referral dermatology center in southern Brazil. Medical records of patients diagnosed with AD between April 2015 and March 2024 according to Hanifin and Rajka criteria were reviewed. Disease severity was assessed using SCORAD, and the highest score recorded during follow-up was considered for analysis. Ninety randomly selected patients were included until 45 mild and 45 moderate-to-severe cases were obtained. Demographic variables, educational level, household income, disease duration, serum IgE levels, and treatment profile were analyzed. Educational level was categorized from 0 to 6 according to degree of formal education. Household income was expressed in Brazilian minimum wages. Distribution normality was assessed using the Shapiro–Wilk test. Comparisons between quantitative and qualitative variables were performed using the Mann–Whitney test, Pearson's chi-square test, Fisher's exact test, and the chi-square test for trend. Correlations between SCORAD and household income, age, educational level, disease duration, and serum IgE levels were analyzed using Spearman's correlation coefficient (rs).

Table 1 – Clinical and Demographic Characteristics (N=90)

Características	Mild (n=45)	Moderate-severe (n=45)	p
Age, year			0,004
average±SD	16,2±11,0	27,1±21,7	
minimum–maximum	1 – 53	4 – 90	
Sex, n (%)			0,049
masculine	19 (42,2)	28 (62,2)	
feminine	26 (57,8)	17 (37,8)	
Race, n (%) #			0,049
white	26 (57,8)	17 (37,8)	
asian	18 (40,0)	9 (20,0)	
mixed	1 (2,2)	14 (31,1)	
black	0 (0,0)	5 (11,1)	
Educational level, n (%)&			0,190
No formal education	6 (13,3)	1 (2,2)	
incomplete elementary education	17 (37,8)	14 (31,1)	
complete elementary education	1 (2,2)	0 (0,0)	
incomplete high school education	3 (6,7)	8 (17,8)	
complete high school education	2 (4,4)	7 (15,6)	
incomplete higher education	10 (22,2)	7 (15,6)	
Complete higher education	6 (13,3)	8 (17,8)	
Household income, n (%)$			0,001
average±SD	11,0±6,4	4,4±2,6	
minimum–maximum	4 – 25	2 – 10	
Disease duration, years			0,015
average±SD	13,4±9,1	19,2±14,7	
minimum–maximum	0,5 – 39	2– 53	
SCORAD *			<0,001
average±SD	15,7±4,3	61,6±20,9	
minimum–maximum	7,45 – 24,4	27,4 – 98,5	
Total IgE			0,014
average±SD	218±213	3288±864	
minimum–maximum	88 – 1349	99– 10000	
Immunosuppressive therapy, n (%)¶			
yes	0 (0,0)	25 (55,5)	<0,001
Biologic therapy, n (%) †			
yes	0 (0,0)	10 (22,2)	<0,001

Race/ethnicity was self-reported according to Brazilian demographic categories.
& Educational level was categorized from 0 to 6 (no formal education=0; incomplete primary education=1; completed primary education=2; incomplete secondary education=3; completed secondary education=4; incomplete higher education=5; completed higher education=6).
$ Household income was expressed in Brazilian minimum wages..
* SCORAD corresponded to the worst score recorded during follow-up.
¶ included methotrexate, cyclosporine, and azathioprine. Immunosuppressive doses of systemic corticosteroids were not considered.
† Dupilumab was the biologic agent used.

Table 1 – Clinical and Demographic Characteristics (N=90)

Results

Ninety patients were included, with a mean age of 21.7 years. Patients with moderate-to-severe AD were significantly older than those with mild disease (27.1 vs 16.2 years; p=0.004) and had longer disease duration (19.2 vs 13.4 years; p=0.015). Moderate-to-severe AD was also associated with substantially higher serum IgE levels (3,288 vs 218 IU/mL; p=0.014). A predominance of female patients was observed in the mild AD group, whereas male patients predominated in the moderate-to-severe group (p=0.049). White patients were more prevalent in the mild group, while non-white patients predominated in moderate-to-severe disease (p=0.049), although no significant correlation between race and SCORAD was identified.

Patients with moderate-to-severe AD presented markedly lower household income compared with patients with mild disease (4.4 vs 11.0 minimum wages; p=0.001). SCORAD demonstrated a moderate inverse correlation with household income (r_s=-0.60; p<0.001), indicating greater disease severity among lower-income patients. Positive correlations were also observed between SCORAD and both disease duration and serum IgE levels. No correlation was identified between SCORAD and educational level.

Regarding treatment profile, no patient with mild AD required immunosuppressive or biologic therapy. In contrast, immunosuppressive agents were used in 55.2% of patients with moderate-to-severe disease, while biologic

therapy was used in 22.2% of cases. Dupilumab was the only biologic agent prescribed in this cohort.

Table 2 – Correlation between SCORAD and selected clinical and demographic characteristics (N=90)

Variáveis	rs	p
Age	0,24	0,034
Race	0,19	0,077
Educational level	0,11	0,273
Household income	-0,60	<0,001
Disease duration	0,22	0,040
IgE	0,30	0,003

SCORAD: SCORing Atopic Dermatitis; rs: Spearman's correlation coefficient; p: statistical significance. Educational level was categorized on a scale from 0 to 6. Household income was expressed in Brazilian minimum wages.

Table 2 – Correlation between SCORAD and selected clinical and demographic characteristics (N=90)

Conclusions

Lower socioeconomic status was significantly associated with increased AD severity in this real-world cohort from a tertiary referral center. These findings suggest that socioeconomic disparities may negatively affect long-term disease control, access to specialized care, and access to advanced therapies in AD. Recognition of socioeconomic vulnerability may therefore be important in the therapeutic planning and longitudinal management of patients with moderate-to-severe disease.

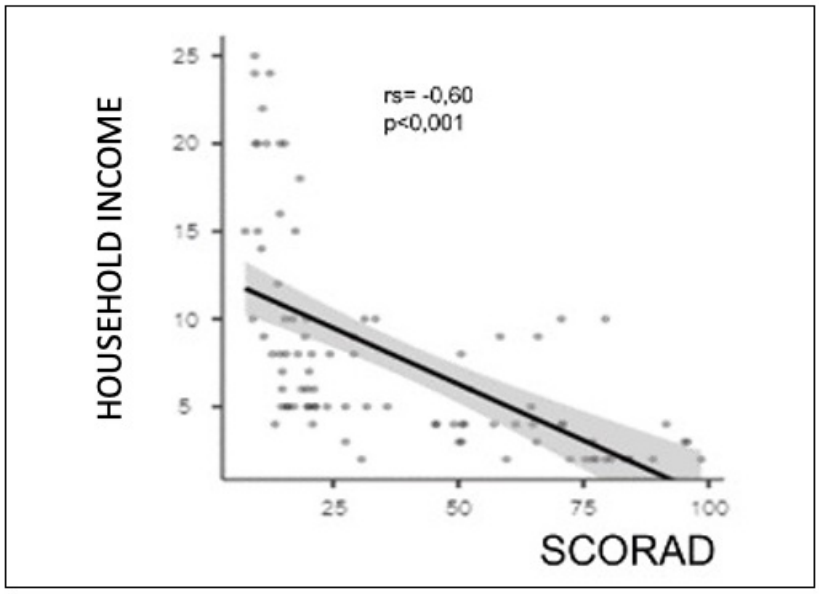

Figure 1. Correlation Between SCORAD and Household Income in Patients With Atopic Dermatitis (N=90)

EADV CONGRESS
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Abstract N°: 4458

JAK1 inhibition with abrocitinib reshapes keratinocyte states and improves epidermal barrier pathology in atopic dermatitis

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Introduction
Atopic dermatitis (AD) is characterized by epidermal barrier dysfunction, immune activation, and microbial dysbiosis. While current therapies primarily target aberrant T-cell responses and cytokine signaling, the contribution of keratinocyte remodeling and epidermal recovery to treatment response remains incompletely understood.

Materials and Methods
In this prospective open-label study, patients with AD received abrocitinib for 12 weeks. Clinical assessments were integrated with barrier physiology, histopathology, microbiome profiling, tape-strip proteomics, and epidermal single-cell transcriptomics.

Results
Abrocitinib induced rapid clinical improvement, with EASI50, EASI75, and EASI90 response rates of 75%, 15%, and 5% at week 2, respectively. Clinical response was accompanied by early restoration of epidermal barrier function, reflected by marked reductions in lesional transepidermal water loss at week 2 (-43.49%, $p < 0.0001$) and week 12 (-51.48%, $p < 0.0001$). Treatment additionally normalized epidermal pathology and attenuated cutaneous dysbiosis, including reductions in total bacterial load and absolute *Staphylococcus aureus* abundance. Single-cell transcriptomics demonstrated extensive remodeling of keratinocyte states, including suppression of stress-associated, interferon-responsive, and hyperproliferative lesional programs alongside restoration of barrier-associated differentiation states. Pseudotime analysis revealed dysregulated keratinocyte differentiation dynamics in lesional AD that progressively shifted toward non-lesional trajectories during treatment. These changes correlated with barrier repair and histopathological recovery. Multiplex ELISA from tape strips further demonstrated rapid reductions in inflammatory stratum corneum biomarkers, including IL-18, IL-8/CXCL8, CXCL10, periostin, fibronectin, and VEGF-A. Key findings were validated using 3D skin models and immunofluorescence analyses

Conclusions
Selective JAK1 inhibition results in coordinated epidermal recovery extending beyond inflammatory suppression. Abrocitinib redirects lesional keratinocytes towards differentiated, barrier-supportive states, supporting re-establishment of epidermal homeostasis at cellular and tissue levels.

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Abstract N°: 4465

TREatment of ATopic eczema registry taskforce in Brazil (TREAT- Brazil): Implementation of a national registry for moderate-to-severe atopic dermatitis.

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Introduction

Atopic dermatitis (AD), an inflammatory skin disorder, affects 15–20% of individuals during their lifetime, with adult prevalence ranging from 1%-10% (1, 2). The TREAT Registry Taskforce is an international registry created to

compile and generate data on the long-term systemic treatments for AD (3). Brazil is a heterogeneous country of continental dimensions, with a diverse, mixed ethnic/racial population. This study describes the implementation framework and emphasizes the unmet needs for a national AD registry. assessing demographic and ethnic diversity, disease severity and burden, response to systemic treatments, and the feasibility of a nationwide registry across all five Brazilian regions (4), thereby characterizing AD patients nationwide.

Materials and Methods

TREAT-Brazil is an ongoing prospective, multicentric, non-interventional registry that aims to enroll patients with moderate-to-severe AD receiving systemic therapy, including phototherapy, and was released in October 2024. 26 academic health centers were selected, representing five different regions of the country, and the project was approved by the Ethics Committee of the Coordinator Unit. Core data include demographic data, disease severity, systemic treatment outcomes, and patient-reported outcomes, obtained through the REDCap platform.

Results

Seventeen of the 26 selected centers launched the data collection. To date, 175 patients have been enrolled. According to age, 119/175 were adults (18–70 years), and 57/175 were children and adolescents (1–17 years). There was a predominance of female patients in both age groups (93/175). Regarding ethnicity/skin color, white individuals comprised 76/175, followed by mixed race (72/175), black (15/175), and yellow (3/175). As for Fitzpatrick skin phototypes, types III (63/175) and IV (46/175) were the most frequent, followed by type II (35/175), type V (24/175), type I (5/175), and type I (2/175). These findings likely reflect the ethnic composition of the Brazilian population, historically influenced by the country's colonization and extensive ethnic admixture, resulting in a predominance of mixed-race and white individuals compared with black individuals in the national population. Regarding educational level, intermediate education was the most common category among adults.

Data obtained from systemic therapies in 118 adults revealed 22.8% on ciclosporin, 31.3% on oral methotrexate, 1.6% on subcutaneous (SC) methotrexate, 23.7% on dupilumab, 5.9% on upadacitinib, 2.5% on abrocitinib, and 5.9% on UVB phototherapy. As for the 57 pediatric patients, data showed 26.3% on ciclosporin, 26.3% on oral methotrexate, 1.7% on subcutaneous (SC) methotrexate, 31.5% on dupilumab, 3.5% on upadacitinib, 1.7% on abrocitinib, and 7.0% on UVB phototherapy. The results of systemic therapy are summarized in Table 1.

Table 1. TREAT-Brazil registry and the use of systemic therapies.

Systemic Therapy/Phototherapy	Adults Total 118 n (%)	Children Total n=57 n (%)
Oral Prednisone	7(5.9)	1(1.7)
Ciclosporin	27(22.8)	15(26.3)
Oral Methotrexate	37(31.3)	15 (26.3)
SC Methotrexate	2(1.6)	1 (1.7)
Dupilumab	28(23.7)	18(31.5)
Abrocitinib	3 (2.5)	1(1.7)
Upadacitinib	7(5.9)	2(3.5)
UVB Phototherapy	7(5.9)	4 (7.0)

Conclusions

TREAT-Brazil is the first Latin American registry of patients with moderate-to-severe atopic dermatitis receiving systemic therapies. Relevant national-level data on demographics, ethnic-racial distribution, access to medication, patient-reported outcomes, and disease management will map regional differences that may influence the choice

of the best therapeutic approach, highlight the heterogeneity of the Brazilian population, and contribute to the global TREAT Task Force.

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Abstract N°: 4484

RECLASSIFYING PLACEBO: A SYSTEMATIC REVIEW AND META-REGRESSION OF PLACEBO RESPONSE MAGNITUDES ACROSS PHASE 3 TRIALS IN PRURIGO NODULARIS AND ATOPIC DERMATITIS

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Introduction

Placebo response rates in dermatology trials have risen dramatically over the past decade, yet their biological meaning remains largely unexplored. Prurigo nodularis (PN) and atopic dermatitis (AD) share chronic itch but differ in dominant pathophysiology: AD is primarily immune-driven (Th2 axis), while PN has prominent neural sensitization components. This review tests the hypothesis that placebo response magnitude reflects underlying disease biology. Specifically, that conditions with greater neural involvement show larger placebo responses, making placebo effect itself a potential surrogate marker for neural versus immune disease drivers.

Materials and Methods

A systematic search of ClinicalTrials.gov, PubMed, and EMBASE (2015–2026) identified 23 phase 3 randomized controlled trials (n=11,247 patients): 12 in AD (dupilumab, tralokinumab, lebrikizumab, nemolizumab) and 11 in PN (nemolizumab, dupilumab, vixarelimab). Placebo-arm response rates for the primary endpoints (IGA 0/1 or WI-NRS ≥4-point improvement) were extracted at weeks 12 and 16. Meta-regression examined associations between placebo response magnitude and baseline serum IgE, eosinophil counts, and trial geographic region. Random-effects models calculated pooled placebo response rates, and heterogeneity was assessed using I^2 statistics.

Results

Pooled placebo response rates were significantly higher in PN than AD at week 12: 31.4% (95% CI 27.1–35.9) for PN versus 18.2% (95% CI 15.3–21.4) for AD ($p<0.001$). This gap persisted at week 16: PN 34.7% (95% CI 29.8–39.9) versus AD 20.1% (95% CI 16.9–23.7, $p<0.001$). Meta-regression revealed that higher baseline eosinophils (≥500/μL) predicted lower placebo response ($\beta = -0.31$, $p=0.008$), while higher baseline itch severity (WI-NRS ≥8) predicted higher placebo response ($\beta = +0.44$, $p=0.002$). Trials conducted in East Asia showed lower placebo responses than North American or European trials (22.3% vs. 31.7%, $p=0.01$). Moderate heterogeneity was observed (I^2=54% for PN, I^2=47% for AD). A proposed neural-immune axis classification based on placebo response threshold (>30% = neural-predominant, <20% = immune-predominant) correctly predicted dominant pathophysiology in 21 of 23 trials (91% accuracy) when compared against biomarker gold standards (serum IgE and eosinophil counts). Placebo response >30% showed 84% sensitivity and 79% specificity for identifying PN over AD.

Conclusions

Placebo response magnitude differs systematically between immune-driven (AD) and neural-driven (PN) conditions, suggesting that placebo effect itself carries biological signal. Higher placebo responses in PN support a greater role for central neural modulation of itch perception. A proposed placebo-response-based classification threshold (30%) may help distinguish neural-predominant from immune-predominant disease drivers in early-phase trials. These findings argue for reclassifying placebo not as noise but as a potential surrogate marker for

underlying pathophysiology.

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Abstract N°: 4557

Efficacy and Safety of Systemic Immunomodulatory Treatments in Moderate to Severe Atopic Dermatitis: A Systematic Review of Randomized Controlled Trials

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Introduction
Atopic dermatitis (AD) is a chronic inflammatory skin disease that can become severe and refractory to topical therapy, often requiring systemic immunomodulatory treatment. Although several systemic agents are used in clinical practice, their comparative efficacy and safety remain uncertain, and treatment recommendations vary across guidelines. This systematic review was conducted to evaluate the available randomized controlled trial (RCT) evidence on systemic therapies for moderate to severe AD and to generate evidence based treatment recommendations.

Materials and Methods
A systematic search of MEDLINE, EMBASE, and CENTRAL databases (up to June 2012) was conducted to identify randomized controlled trials (RCTs) evaluating systemic treatments in moderate to severe atopic dermatitis (AD). The study material comprised published full text RCTs involving patients with moderate-to-severe AD receiving systemic immunomodulatory therapies. Eligible studies were independently screened for inclusion, and data extraction, risk of bias assessment, and evidence grading were performed according to the GRADE approach. Outcomes assessed included clinical severity scores, quality of life measures, symptom control, and adverse events.

Results
A total of 34 RCTs involving 1,653 patients and 12 systemic treatment modalities were included. Cyclosporin A consistently demonstrated the strongest evidence of efficacy, showing significant improvement in clinical severity compared with placebo and other active treatments. Based on moderate to high quality evidence, cyclosporin A was recommended as first line short-term systemic therapy.

Azathioprine showed moderate efficacy and was considered a second-line treatment option. Methotrexate demonstrated comparable efficacy to azathioprine and was recommended as a third line option. Interferon-γ showed potential benefit in selected patients but requires careful monitoring due to limited evidence.

For other systemic therapies including mycophenolate mofetil, systemic corticosteroids, intravenous immunoglobulin, montelukast, thymopentin, M. vaccae, and traditional Chinese herbal medicine, the evidence was inconsistent or insufficient to support routine clinical use.

Conclusions
Among systemic treatments for moderate-to-severe atopic dermatitis, cyclosporine A has the most robust evidence and remains the preferred first-line short-term therapy. Azathioprine and methotrexate represent second and third-line options, respectively. However, the overall evidence base remains limited, emphasising the need for large, well-designed head-to-head trials with standardised outcome measures to guide long term treatment strategies.

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Abstract N°: 4561

Mental Health Correlates in Atopic Eczema and Psoriasis: A Systematic Review of Associated Risk Factors

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Introduction
Atopic eczema and psoriasis are chronic inflammatory skin disorders that affect a significant proportion of adults worldwide. Beyond their physical burden, both conditions are increasingly recognised for their psychological impact, particularly in relation to depression, anxiety, and more severe psychiatric illnesses. Although an association between skin inflammation and mental health disorders has been described in previous research, the specific patient-level and disease-related factors that influence this relationship remain unclear. Understanding these contributors is important for identifying high-risk individuals and improving integrated dermatological and mental health care.

Materials and Methods
A systematic review was conducted to synthesize evidence on factors associated with depression, anxiety, and severe mental illness in adults with atopic eczema or psoriasis.

MEDLINE, EMBASE, and CENTRAL were searched from inception to the latest update, alongside grey literature sources and clinical trial registries to minimize publication bias and improve coverage of unpublished evidence.

Eligible studies included randomized controlled trials, cohort, case–control, and cross-sectional designs in adults (≥18 years), reporting associations between clinical, demographic, or disease-related factors and mental health outcomes.

Study screening, data extraction, and selection were performed independently by reviewers to ensure methodological rigor. Risk of bias was evaluated using the Quality in Prognostic Studies (QUIPS) tool, focusing on selection bias, outcome assessment, confounding, and analytical methods.

Where sufficient homogeneity existed across studies, random-effects meta-analyses were conducted. Otherwise, findings were synthesized narratively, with heterogeneity assessed using standard statistical measures.

Results
A total of 21 studies met inclusion criteria, comprising observational studies and randomized controlled trials.

Atopic Eczema

Evidence from randomized trials suggested that individuals receiving placebo experienced higher levels of depressive and anxiety symptoms compared with those treated with targeted biologic therapies. However, no eligible observational studies were identified for factor-level analysis in eczema populations.

Psoriasis

Observational evidence indicated that several factors were associated with mental health outcomes:

- **Depression:** Female sex and the presence of psoriatic arthritis were consistently associated with higher risk. Disease severity showed inconsistent associations across studies, and most other variables demonstrated weak or inconclusive evidence.
- **Anxiety:** Similar to depression, female sex, more severe disease, and psoriatic arthritis were linked with increased anxiety risk.
- **Severe mental illness:** Evidence was extremely limited, with only a single study addressing schizophrenia-related outcomes.

Randomized trials reinforced the observational findings, showing that effective treatment of psoriasis with biologic agents was associated with lower depression and anxiety scores compared with placebo groups, although follow-up durations were relatively short.

Conclusions

This systematic synthesis demonstrates that depression and anxiety in atopic eczema and psoriasis are linked to a limited but consistent set of factors, particularly female sex and more severe disease phenotypes. Treatment of skin inflammation may offer short-term psychological benefits, but the long-term relationship between disease control and mental health remains uncertain. Future research should prioritize longitudinal studies, standardized outcome measures, and deeper exploration of severe psychiatric comorbidities to better inform clinical screening and intervention strategies.

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Abstract N°: 4564

Gut Microbiome Dysbiosis, Intestinal Parasitism, and Exposome Factors in Adults with Atopic Dermatitis from an Upper-Middle-Income Country

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Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease in which microbial and environmental factors may contribute to immune dysregulation through the gut–skin axis. Although gut microbiome alterations have been associated with AD, population-specific data remain limited. Intestinal eukaryotes may also influence gut microbial ecology and host immune responses, but their relevance in AD is not fully understood. Here we aimed to characterize the gut microbiome in adults with AD and explore its relationship with intestinal parasitism and disease severity.

Materials and Methods

We conducted a cross-sectional analytical study in two medical centers in an upper-middle-income country (ethics approval records 2023054/85 and CEI-000002-139). Adults with AD diagnosed by experienced dermatologists and healthy controls without personal or family history of AD or other inflammatory skin diseases were recruited. Individuals with recent antibiotic or antiparasitic treatment were excluded. AD severity was assessed using EASI. Stool samples underwent conventional parasitological examination, molecular protozoa detection, and gut microbiome profiling using PacBio 16S rRNA sequencing. Alpha diversity was evaluated with Chao1, Shannon, Simpson, and Faith-PD indices, while beta diversity was assessed using unweighted UniFrac distances. Anti-*Strongyloides stercoralis* IgG antibodies were detected using a commercial ELISA kit.

Results

A total of 248 participants were recruited, including 113 AD patients and 135 controls. No significant demographic differences were observed between groups. Based on EASI 35.4% had moderate-to-severe disease. Most patients were receiving topical corticosteroids (81.3%), while 27.4% were under systemic treatment. Gastrointestinal symptoms were more frequent in AD patients (p = 0.015). Anti *S. stercoralis* IgG antibodies were detected in one AD patient and one control.

Stool samples were available from 214 individuals for parasitological and microbiome analyses. Parasitic infection was more frequent among controls (85.96%; p = 0.028). *Blastocystis* was the most frequent parasite detected (82.46%) and showed higher prevalence in controls (p = 0.09), followed by *Endolimax nana* (28.07%; p = 0.17). No helminth infections were identified, and pathogenic protozoa were infrequent in both groups.

Gut microbiome analysis demonstrated significant differences in beta diversity between groups ($p < 0.05$). AD patients showed significantly reduced alpha diversity, richness, and phylogenetic distance (all $p < 0.0001$). Differential taxonomic analysis identified a reorganization of intestinal anaerobic lineages in AD patients. No microbiome differences were observed according to AD severity, based on either EASI or maximum peak pruritus NRS scores.

Additionally, over 50 exposome-related variables were systematically analyzed in the context of intestinal parasitism and gut microbiome composition.

Conclusions

In this cohort, AD was associated with gut dysbiosis independently of disease severity, suggesting that microbiome alterations may occur early in the disease course. The lower frequency of intestinal parasites, particularly *Blastocystis*, among AD patients, together with the observed reorganization of intestinal anaerobic lineages, suggests that alterations of the intestinal ecosystem may contribute to AD-associated dysbiosis.