EA DV CONGRESS
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EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 66

Safety, Pharmacokinetics, Pharmacodynamics, and Efficacy of AK120 in Participants with Moderate to Severe Atopic Dermatitis: Results from a Randomized, Double-blind, Placebo-controlled Phase II Clinical Trial

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Introduction & Objectives:

Interleukin-4 (IL-4) and interleukin-13 (IL-13) are two essential cytokines involved in the Th2-mediated inflammatory response of diseases, such as atopic dermatitis (AD). AK120 is a humanized immunoglobulin G subclass 4 (IgG4) monoclonal antibody (mAb) directed against the IL-4 receptor alpha (IL-4Rα) subunit shared by the IL-4 and IL-13 receptor complexes. The binding of AK120 to IL-4Rα results in inhibition of the signaling of the IL-4 and IL-13 cytokines. This trial was to evaluate the efficacy, pharmacokinetics (PK), pharmacodynamics (PD), and safety of AK120 following multiple subcutaneous (SC) administrations in AD participants.

Materials & Methods:

Participants (male and female) with age ≥ 18 and ≤ 75 years were enrolled. There were 4 parallel dose groups with 160 participants. Eligible participants were randomized in a 1:1:1:1 ratio to receive 1 of 3 dose levels of the active drug AK120 (N=120) or matching placebo (N=40). For group 1 to 3, participants received a SC injection of 150mg, 300mg or 450 mg AK120 every 2 weeks (Q2W); participants in group 4 received placebo Q2W from week 0 to 14, then were randomly assigned in a 1:1 ratio to group 4A (AK120 300mg Q2W) and group 4B (AK120 450mg Q2W) from week 16 (Figure 1).

Results:

Efficacy: The proportion of participants in AK120 treatment groups (150 mg, 300 mg, 450 mg) who achieved EASI75 at week 16 was higher than in the placebo group, with the percentages of 55.0% (22/40), 57.5% (23/40), 56.1% (23/41) and 28.2% (11/39) ($P<0.05$) (Figure 2). The IGA0/1 response rate of each AK120 group at week 16 was 32.5% (13/40), 27.5% (11/40), and 29.3% (12/41), respectively, which was higher than that of the placebo group (10.3%, 4/39). Following one year treatment, the EASI75 and IGA0/1 response rates can be effectively maintained and further improved.

PK&PD: Steady-state concentrations were achieved by Week 12 in each dose of groups. The mean ±SD steady-state trough concentrations at Week 16 were 14.7 μg/mL, 45.2 μg/mL, and 78.8 μg/mL in 150 mg Q2W (300 mg loading dose), 300 mg Q2W (600 mg loading dose), and 450 mg Q2W (Figure 3). Serum TARC/CCL17 can be almost maintained with an over 50 % decrease in all AK120 treatment groups (Figure 4). Serum Ig E decreased over 40% at week 16 in the AK120 300-450 mg Q2W groups (Figure 5).

Safety: A total of 141 (90.4%) participants received AK120 treatment and 27 (69.2%) participants who received the placebo experienced at least one treatment-emergent adverse event (TEAE). The majority of TEAEs were mild and moderate in severity. The incidence of TEAE in AK120 groups was 90.4% for the overall treatment and follow-up period. During the placebo control period, incidence of TEAE was similar between the AK120 groups and the placebo group (71.1% vs. 69.2%). The most common treatment-related adverse events (TRAE) that occurred in the AK120 groups were elevated hyperuricaemia (8.3%, 13/156), upper respiratory tract infections (5.8%, 9/156) and alanine aminotransferase (5.1%, 8/156). There were 9 serious adverse events (SAE) in the trial, and all had improved or recovered. The majority were judged as possibly unrelated to the investigational products by investigators. No death was reported in the trial.

Conclusion:

AK120 ranging from 150 mg to 450 mg administered via SC injection was safe and well tolerated, and showed prefound efficacy in AD participants, which provided sufficient basis for the dose selection in the phase 3 confirmative trial.

Figure 1 Overall Study Design

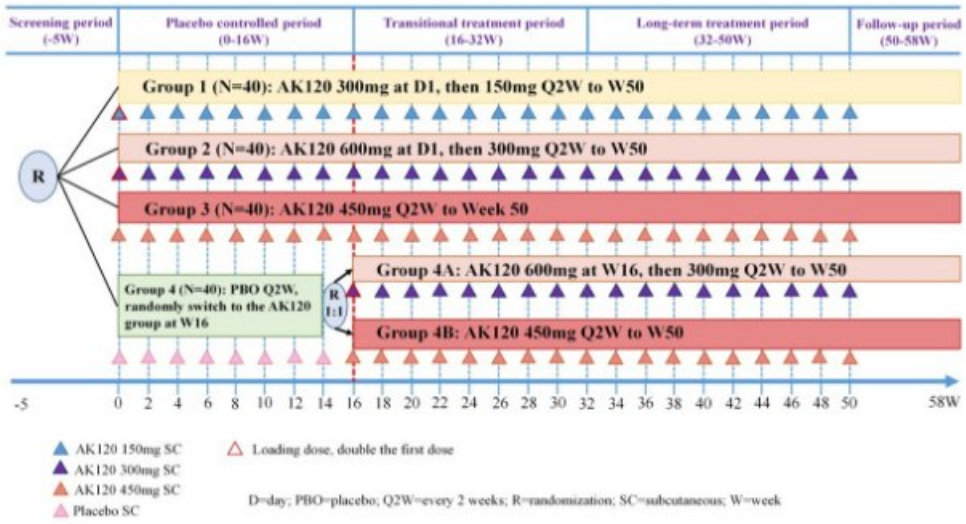


Figure 2 EASI 75 Response at Week 16

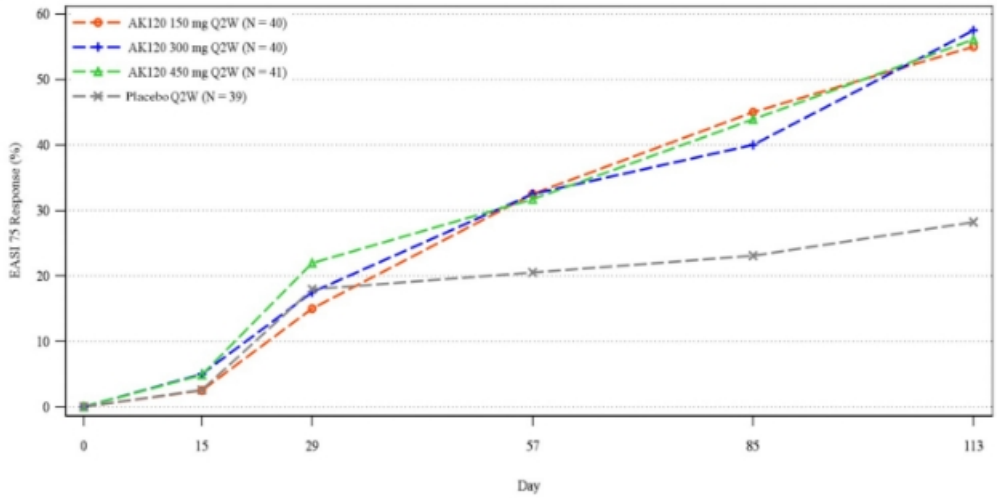
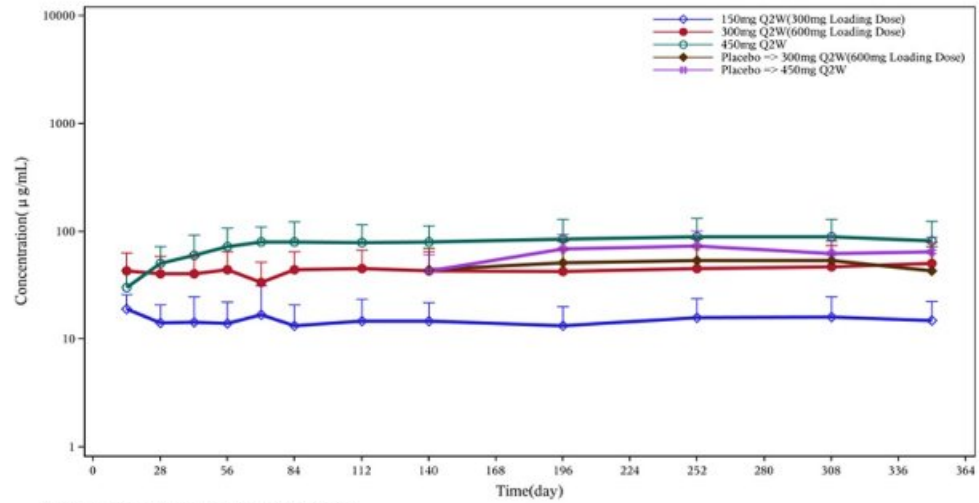
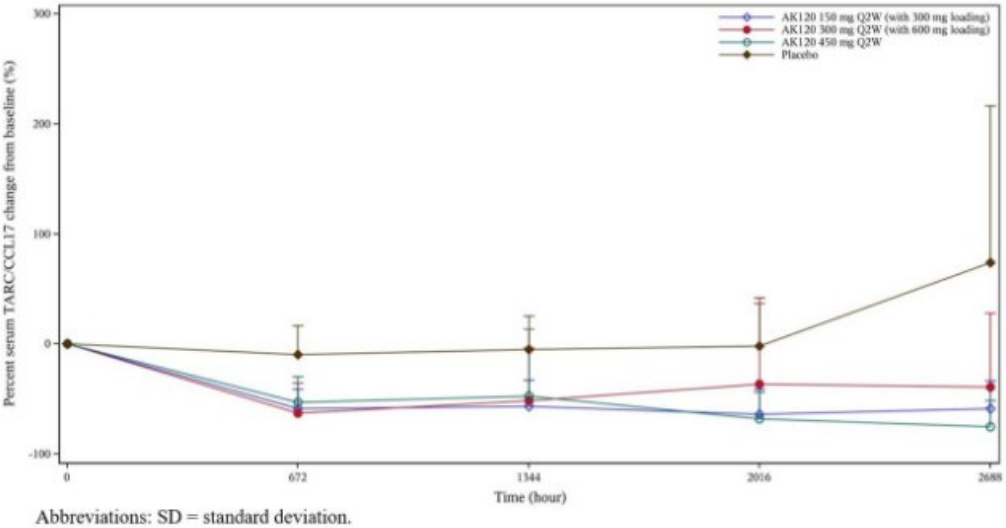


Figure 3 Mean (+SD) Serum Trough Concentration -Time Profiles in AD Patients



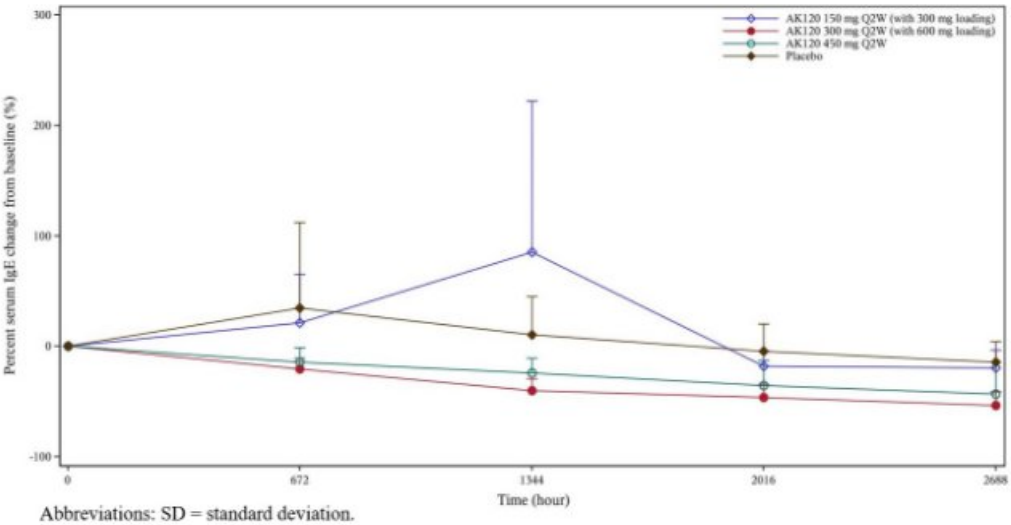
Abbreviations: SD = standard deviation.

Figure 4 Mean (+SD) Serum TARC -Time Profiles



Abbreviations: SD = standard deviation.

Figure 5 Mean (+SD) Serum Ig E -Time Profiles



Abbreviations: SD = standard deviation.



Abstract N°: 91

Effectiveness of Upadacitinib in moderate vs. severe atopic dermatitis: interim results

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Objectives:

Approximately 60% of real-world Upadacitinib patients have moderate atopic dermatitis (AD). However, there is no analysis comparing the effectiveness of Upadacitinib in moderate versus severe AD patients. This analysis aims to compare effectiveness rates in both patient populations.

Methods:

UP-TAINED is an ongoing observational study for atopic dermatitis patients treated with Upadacitinib in Germany. Moderate and severe patients were stratified based on baseline validated Investigator Global Assessment (vIGA), where vIGA = 3 is considered moderate and vIGA = 4 is severe AD. Patient demographics and disease parameters at baseline were analyzed. Treatment outcomes included the Eczema Area and Severity Index (EASI), Worst Pruritus Numeric Rating Scale (WP-NRS), and Dermatology Life Quality Index (DLQI). All patients with at least one follow-up visit were included in this analysis. Results are reported as observed for up to two years of observation.

Results:

A total of 441 patients were included, of which 287 had moderate (vIGA = 3) and 154 had severe AD (vIGA = 4). Despite disease severity being the main factor for dose choice, no difference in prescribed dosage between both severity groups was observed. No statistically significant differences were found in age, gender, disease duration, or BMI categories between the two groups.

The mean EASI at baseline was 18.0 for moderate and 33.3 for severe AD patients. Differences in EASI were present until month 6, after which both groups had comparable mean EASI scores. 61.1% of moderate patients achieved EASI≤3 at month 1 and 77.7% at month 3. EASI≤3 response rates in severe patients were 46.9% and 63.5% at month 1 and 3, respectively. No differences in EASI75/90/100 response rates were observed.

The WP-NRS score was significantly higher at baseline in patients with severe AD (7.8 vs. 6.7 for patients with moderate AD). At month 1, the proportion of patients achieving WP-NRS0/1 was higher in patients with moderate AD. At later follow-up visits, itch response rates were similar.

Mean DLQI scores were 13.3 for moderate and 15.5 for severe AD patients. 60.3% and 78% of the patients with moderate and severe AD, respectively, reported that AD had a very to extremely large impact on their quality of

life (DLQI >10).

Some differences were observed in affected body regions. For example, patients with severe AD more likely had active AD lesions on the feet (48.7% vs. 25.1%), hands (73.4% vs. 58.2%), and genital area (29.9% vs. 16.7%) compared to patients with moderate AD. Although the proportion of patients with facial AD was similar in both groups (76.3% in moderate AD and 79.9% in severe AD), severe AD patients had more moderate-to-severe facial AD (86.2% vs. 66.7%) compared to moderate AD patients.

During up to two-years of follow-up, 725 adverse events (AEs) were reported in 231 (52.4%) patients. The most frequent AEs were dermatitis atopic 92 (20.9%), nasopharyngitis 25(5.7%), and acne 23(5.2%). 18 (4.1%) patients reported serious AE.

Conclusion:

Regardless of investigator-assessed disease severity and other observed differences at baseline response rates were similar in both severity groups after 1 to 3 months of Upadacitinib treatment. This suggests that Upadacitinib is a suitable treatment option for diverse AD patients, aligning with its indication for moderate to severe AD.

This analysis also highlights the significant negative impact on the quality of life among moderate AD patients, emphasizing the need for treatment.



Abstract N°: 294

Patient-reported outcomes evaluations of 12-months tralokinumab treatment in 824 adults with atopic dermatitis: Real-world data from the prospective, non-interventional, international, single-cohort TRACE study

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, burdensome skin disease significantly affecting patients' quality of life (QoL), sleep, and self-confidence. Tralokinumab is a monoclonal antibody targeting interleukin-13 indicated for the treatment of moderate-to-severe AD and was effective and well-tolerated in Phase 3 clinical trials. Here, we present data on the impact of 12-months real-world tralokinumab use on patient-reported outcomes (PROs) including QoL measures.

Materials & Methods:

TRACE is a prospective, non-interventional, international, single-cohort study of adults with AD who were prescribed tralokinumab according to national approved label at treating physician's discretion. Concomitant medications were allowed. Of the enrolled 835 patients (Nov-2021 to Jun-2023), 824 comprised the full analysis set. Assessments included dermatology life quality index (DLQI), peak pruritus numeric rating scale (PP-NRS), sleep-numeric rating scale (Sleep-NRS), atopic dermatitis control tool (ADCT), recap of atopic eczema (RECAP), and/or work productivity and activity impairment questionnaire-general health (WPAI-GH) as per individual clinical practice. Data are presented as observed.

Results:

At baseline, patients were 47.6% female, 52.4% male and 75.7% White, with a mean age of 44.1 years and mean AD duration of 18.8 years. All PRO evaluations showed AD improvement over time (Table 1). The mean DLQI score (0–30; higher score means worse QoL) improved from 12.8 at baseline (n=452) to 7.0 (n=253) and 4.9 (n=192) at months 3 and 12, while the proportion of patients with DLQI ≤5 ('no' to 'small' QoL impairment) increased from 20% at baseline to 68% at month 12. The mean PP-NRS score (0–10; 'no itch' to 'worst itch imaginable') improved from 6.4 at baseline (n=490) to 4.3 (n=267) and 3.3 (n=192) at months 3 and 12, while the proportion of patients with PP-NRS ≤4 increased from 22% at baseline to 70% at month 12. Mean Sleep NRS score (0–10; 'no sleep loss' to 'I did not sleep at all') improved from 5.1 at baseline (n=377) to 2.8 (n=212) and 2.3 (n=149) at

months 3 and 12. Among patients with Sleep NRS ≥2 at baseline, a ≥2 points improvement was achieved by 67% (n=148) and 70% (n=105) of patients at months 3 and 12. AD control improved over time (lower score means better control) from ADCT mean score (0–24) of 13.9 (n=280) at baseline to 7.9 (n=166) and 6.4 (n=115) at months 3 and 12, and from RECAP mean score (0–28) of 16.5 (n=239) at baseline to 10.0 (n=145) and 7.7 (n=93) at months 3 and 12. All health-related work ability measures (WPAI-GH) improved over time (Table 1).

Conclusion:

12-months treatment with tralokinumab in adults with AD in a real-world setting provided early improvements across all endpoints including itch, QoL, sleep, AD control, and health-related work ability.

Table 1 PROs assessments during 12 months of tralokinumab treatment (TRACE study)

	Baseline (N=824)	3 months (N=708)	6 months (N=596)	9 months (N=500)	12 months (N=460)
DLQI[1] score, n Mean (SD)	452 12.8 (7.46)	253 7.0 (5.98)	202 5.8 (5.51)	176 5.3 (5.85)	192 4.9 (4.93)
DLQI[1] ≤5, n Proportion (95% CI)	452 0.20 (0.16; 0.24)	253 0.48 (0.42; 0.54)	202 0.61 (0.54; 0.68)	176 0.69 (0.61; 0.76)	192 0.68 (0.61; 0.75)
PP-NRS[2] score, n Mean (SD)	490 6.4 (2.54)	267 4.3 (2.69)	213 3.5 (2.62)	174 3.3 (2.62)	192 3.3 (2.49)
PP-NRS[2] ≤4, n Proportion (95% CI)	490 0.22 (0.19; 0.26)	267 0.52 (0.46; 0.58)	213 0.69 (0.62; 0.75)	174 0.70 (0.63; 0.77)	192 0.70 (0.63; 0.77)
Sleep-NRS[3] score, n Mean (SD)	377 5.1 (3.15)	212 2.8 (2.77)	156 2.4 (2.66)	140 2.2 (2.60)	149 2.3 (2.81)
Sleep-NRS[3] ≥2-point reduction[4], n Proportion (95% CI)	-	148 0.67 (0.59; 0.74)	109 0.69 (0.59; 0.77)	91 0.75 (0.65; 0.83)	105 0.70 (0.61; 0.79)
ADCT[5], n Mean (SD)	280 13.9 (6.35)	166 7.9 (5.78)	123 7.2 (5.52)	105 6.6 (5.64)	115 6.4 (5.44)
RECAP[6] total score, n Mean (SD)	239 16.5 (7.08)	145 10.0 (6.87)	103 8.9 (6.72)	82 8.2 (6.70)	93 7.7 (6.67)
WPAI-GH[7] summary scores					
Percent of health-related work time missed, n Mean (SD)	152 8.7 (22.33)	89 4.1 (10.77)	75 7.0 (21.48)	63 3.5 (11.41)	75 2.8 (10.22)
Percent of health-related work impairment, n Mean (SD)	150 32.0 (26.60)	91 20.3 (26.48)	71 18.7 (23.66)	62 21.9 (27.27)	75 16.8 (22.73)
Percent of overall health-related work impairment, n Mean (SD)	146 29.4 (24.52)	89 18.6 (23.99)	71 17.1 (20.31)	62 20.2 (25.02)	74 15.4 (21.07)
Percent of health-related activity impairment, n Mean (SD)	248 43.7 (30.82)	159 25.4 (27.51)	117 24.1 (27.83)	102 21.4 (25.33)	111 22.5 (28.84)

824 patients were included in the full analysis set. Percentages are calculated using 'n' as denominator.
ADCT = atopic dermatitis control tool; CI = confidence interval; DLQI = dermatology life quality index; N = number of patients in the analysis set; n = number of patients with available data; NRS = numeric rating scale; PP-NRS = peak pruritus numeric rating scale; PROs = patient-reported outcomes; RECAP = recap of atopic eczema; SD = standard deviation; Sleep-NRS = Sleep-numeric rating scale; WPAI-GH = work productivity and activity impairment questionnaire-general health.
[1] DLQI is a 10-item questionnaire assessing health-related quality of life over the last week in patients with dermatological symptoms (total DLQI score range 0-30; higher score indicating worse quality of life).
[2] PP-NRS is a single-item patient-reported measure for assessing the maximum severity of itch during the previous 24 hours in patients with pruritic skin disorders (range 0-10; higher score indicating worse itch).
[3] Sleep-NRS is a single-item patient-reported measure for assessing the severity of sleep disturbance over the past week in patients (range 0-10; higher score indicating worse sleep).
[4] Among patients with baseline Sleep-NRS ≥2.
[5] ADCT is a validated instrument to assess control of AD. It has 6 items that evaluate AD control over the last week, focusing on symptoms, itching, intensity of bother, sleep disturbances, daily activities, and mood (range 0-24; lower score indicates a better control of AD).
[6] RECAP of AD consists of 7 items that reflect the control of AD. It captures a snapshot of eczema control over the last week from the time of completion. The items focus on the overall individual perception, the symptoms of the skin, flares, sleep, effect on everyday life, emotional impact, and acceptability (range 0-28; lower score indicating a better control of AD).
[7] The WPAI-GH questionnaire is a validated instrument that measures impairment in paid and unpaid work. General health version is used to measure absenteeism [work time missed], presenteeism [impairment at work], work productivity loss and activity impairment during the last 7 days.

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Abstract N°: 370

Lipidomic Analysis of Exosomes Derived from ASC (ASCE) : Insights into Epidermal Barrier Restoration

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Introduction & Objectives:

The lipid-dominant epidermal permeability barrier in the outermost layer of mammalian skin, the stratum corneum, protects cells/tissues from exogenous stressors (pathogens, allergens, chemicals, dryness) and prevents the loss of body fluids. Epidermal permeability barrier defects are associated with several skin diseases, including atopic dermatitis (AD). Adipose-derived stem cell exosomes (ASCE) are recognized for their dual functions in skin regeneration, anti-inflammation, and skin barrier construction. Previous research ASCE's ability to enhance skin barrier integrity is affected by inflammatory conditions like atopic dermatitis by influencing epidermal lipid metabolite production. This study aimed to analyze the lipid metabolite profiles and lipid functions of ASCE.

To understand that ASCEs contain several critical lipid molecules for cellular signaling

To find that ASCEs and donor cells have different profiles of critical lipid molecules that have huge potential in regenerative aesthetics and therapeutics

To understand that a new quality control standard can be set up based on the lipid profiles of exosomes

To find that ASCE-mediated increases in lipid suppress pro-inflammatory cytokine production in an AD-like in vitro model.

Materials & Methods:

ASCEs isolated from the culture media of 4 different GMP-compliant master cell banks of human adipose mesenchymal stem cells. Free fatty acids, glycerides, glycerophospholipid, sphingolipids, sterols, and their total lipid species are quantitated using LC-ESI-MS/MS. Ceramide metabolic enzymes activity assay is quantitated using LC-ESI-MS/MS. Measurement of Th2 inflammatory cytokines' suppression level in mimics atopic dermatitis-like-inflammation in human keratinocytes (AD model-hKC).

Results:

This study compared the lipid composition of ASC-derived exosomes (ASCE) to their donor cells. ASCE exhibited significantly higher levels of ceramide NS, free fatty acid, and sphingomyelin, essential for epidermal structure, while levels of pro-inflammatory lyso-sphingomyelin and lyso-dihydrosphingomyelin were significantly lower. Additionally, ASCE had lower levels of oxidized cholesterol, which is known to contribute to skin inflammation. These findings suggest that ASCE may benefit skin health by strengthening the epidermal barrier and reducing inflammation.

Conclusion:

These results indicated that certain lipid metabolites contained in ASCE in part account for the improvement of epidermal permeability barrier functions compromised by skin diseases, including AD. ASCE application could be an alternative therapeutic strategy for ameliorating atopic dermatitis, and other inflammatory diseases. Furthermore, specific lipids that were not detected in ASCE or their donor cells could be considered as potential

candidate(s) for quality control standards in the GMP production of the therapeutic-level stem cell-derived exosomes.

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Abstract N°: 374

Adipose tissue-derived mesenchymal stem cell-derived exosomes alleviate particulate matter-induced inflammatory response and skin barrier damage in atopic dermatitis-like triple-cell model

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Introduction & Objectives:

Particulate matter (PM) is a mixture of solid and liquid particles in the air. PM has been reported to cause inflammation in various skin diseases. Also recently, PM has been shown to exacerbate atopic dermatitis (AD) by inducing an inflammatory response. Meanwhile, several studies revealed that exosomes derived from adipose tissue-derived mesenchymal stem cells promote wound healing and alleviate inflammation via their regenerative and immunomodulatory capacities. Our study aimed to investigate the effects of human adipose tissue-derived mesenchymal stem cell-derived (ASC-EXOs) in PM-induced AD. An AD-like triple-cell model was established by treating human keratinocytes, dermal fibroblasts, and mast cells with polyinosinic:polycytidylic acid (Poly I:C) and interleukin 1 alpha (IL-1α).

Materials & Methods:

An AD-like triple-cell model was established through Poly I:C and IL-1α treatment of triple-cells model (Keratinocyte, dermal fibroblast, and mast cell). Cells were pretreated with Poly I:C and IL-1α for 24 hours, followed by treatment with ASC-exosomes and PM (25 μg/cm2) for 24 and 48 hours. qPCR was used to analyze the mRNA expression levels of proinflammatory cytokines such as IL-10, IL-6, IL-1β, IL-1α, and skin barrier-related genes loricrin, and filaggrin.

Western blotting was confirmed to evaluate the effect of PM and ASC-exosomes on the protein expression of pro-inflammatory cytokines and a skin barrier protein filaggrin.

The expression of IL-4, IL-1β, and FLG in our AD-like triple-cell model was assayed using immunofluorescence staining analyses.

Results:

The effects of PM and ASC-exosomes on the expression of pro-inflammatory cytokines and skin barrier proteins were examined using quantitative real-time polymerase chain reaction, western blotting, and immunofluorescence. PM increased pro-inflammatory cytokines (IL-6, IL-1β, and IL-1α) and decreased the anti-inflammatory cytokine IL-10, while the mRNA expression of skin barrier proteins (loricrin and filaggrin) decreased. However, when the cells were treated with ASC-exosomes, the PM-induced effects on pro-inflammatory cytokines and skin barrier proteins were reversed.

Conclusion:

ASC-exosomes are expected to present a new paradigm for treating the fundamental causes of AD as a single drug or through combination therapy with existing treatments. ASC-exosomes may, therefore, improve the efficacy of existing therapies against inflammation, skin barrier damage, and itching.

Our results confirm that PM-exacerbated inflammation and skin barrier damage were alleviated by ASC-exosomes using an AD-like triple-cell model. These findings will aid in discovering potential therapeutic targets using ASC-

exosomes in AD; however, further research is needed to elucidate the precise mechanisms of ASC-exosome treatment in AD and to investigate the in vivo effects using animal models and clinical studies.



Abstract N°: 420

Counting the Burden: Atopic Dermatitis and Quality of Life

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, itchy inflammatory disease that significantly impacts quality of life (QoL). It affects various aspects of daily life, including emotional well-being, social interactions, and performance at school or work. Fully understanding this impact is crucial for improving disease management and enhancing the QoL of affected individuals.

Materials & Methods:

In order to assess the impact of AD on the QoL of patients and their families, while exploring the etiological factors likely to modulate this impairment, we conducted a case-control study over a four-month period (September–December 2022). Our sample included 100 patients with the disease and 100 controls. To assess patients' QoL, we used the DLQI questionnaire for patients aged over 15, the CDLQI for patients aged 5 to 15, the IDQOL for children under 5 and the DFI to assess the impact of AD on the QoL of patients' families.

Results:

The median age of patients and controls was 13.5 years, with a female predominance, the sex ratio (F/H) being 1.32. The median age of onset was 5 years. Assessment of QoL revealed significant impairment in AD patients and their families compared with controls. Moderately positive correlations were observed between the CDLQI score and the SCORAD disease severity score ($p=0.004$; $r=0.434$), as well as between the DLQI and SCORAD ($p=0.033$; $r=0.322$), highlighting the increasing impact on QoL as disease severity increases. Similarly, a significant positive correlation was found between DFI and SCORAD ($p<0.001$; $r=0.575$), underlining the fact that the QoL of families of children under the age of 15 is highly disrupted. In addition to the direct relationship between AD severity and its impact on QoL, various other factors were identified, including pruritus intensity, socio economic status, environmental influences, and eczema appearance, extent and topography.

Conclusion:

AD is a disease that has a significant impact not only on patients' QoL, but also on that of their families. The use of specific scales dedicated to measuring QoL is therefore an essential tool for better management of this chronic dermatosis.



Abstract N°: 434

Abrocitinib for Cyclosporine-Resistant Moderate-to-Severe Atopic Dermatitis: A Real-World Case Series

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by pruritus and eczematous lesions. Abrocitinib, a Janus kinase 1 (JAK1) inhibitor, has recently been recently approved for moderate-to-severe AD in adults. This case series evaluates the effectiveness and safety of abrocitinib in patients with moderate-to-severe AD who had inadequate response to cyclosporine and/or required a rapid response. Our objectuives were to evaluate the effectiveness of abrocitinib in the treatment of moderate-to-severe atopic dermatitis in patients with inadequate response to cyclosporine and to assess the safety and tolerability of it.

Materials & Methods: This was a real-world retrospective case series evaluating the use of abrocitinib in patients with moderate-to-severe atopic dermatitis (AD). Patients included had an inadequate response to cyclosporine (3–5 mg/kg body weight) and/or required a faster therapeutic response due to significant life events such as job interviews or marriage.

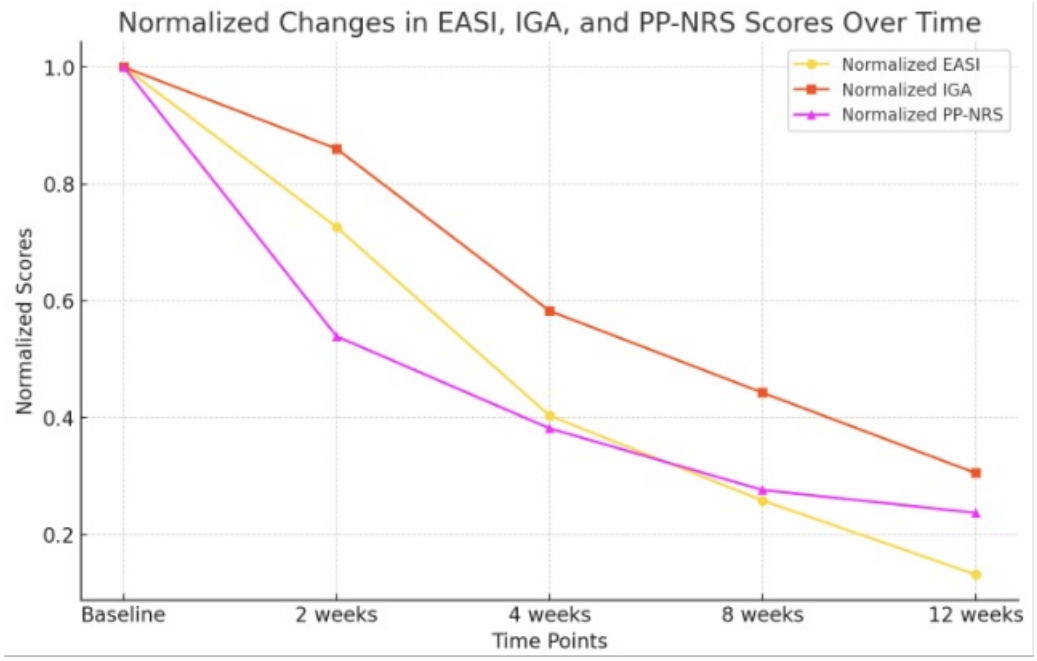
A total of nine patients (five females, four males; mean age: 19.44 ± 7.68 years, range: 10–34 years) with moderate-to-severe AD were treated with abrocitinib. Among them, three were adolescents or children, for whom the drug was used off-label. The mean disease duration was 13.33 ± 8.06 years (range: 6–29 years), and eight patients had a positive family history of AD.

Prior treatments included cyclosporine, methotrexate, and systemic corticosteroids. Abrocitinib was prescribed at a mean dose of 177.77 ± 44.09 mg, with seven patients receiving 200 mg and two receiving 100 mg daily. Treatment effectiveness was assessed at baseline and at weeks 2, 4, 8, and 12 using the Eczema Area and Severity Index (EASI), Investigator's Global Assessment (IGA), and Peak Pruritus Numerical Rating Scale (PP-NRS).

Results: Significant reductions were observed in EASI, IGA, and PP-NRS scores over the 12-week treatment period. Mean EASI score was decreased from 48.22 ± 7.88 at baseline to 35 ± 8.81 at 2 weeks, 19.44 ± 8.29 at 4 weeks, 12.44 ± 6.67 at 8 weeks, and 6.33 ± 3.35 at 12 weeks (Baseline vs. 2 weeks, $P = 0.0003$; Baseline vs. 12 weeks, $P < 0.0001$). Mean IGA score was decreased from 4 ± 0 at baseline to 3.44 ± 0.72 at 2 weeks, 2.33 ± 0.71 at 4 weeks, 1.77 ± 0.44 at 8 weeks, and 1.22 ± 0.44 at 12 weeks (Baseline vs. 4 weeks, $P = 0.001$; Baseline vs. 12 weeks, $P < 0.0001$). Mean PP-NRS score was decreased from 8.44 ± 0.52 at baseline to 4.55 ± 0.88 at 2 weeks, 3.22 ± 0.97 at 4 weeks, 2.33 ± 1.11 at 8 weeks, and 2 ± 0.86 at 12 weeks (Baseline vs. 2 weeks, $P < 0.0001$; Baseline vs. 12 weeks, $P < 0.0001$).

Most patients demonstrated excellent treatment adherence. Some patients required dose adjustments during the study period. One patient experienced mild thrombocytopenia.

Conclusion: Abrocitinib demonstrated rapid and significant improvement in clinical outcomes for patients with moderate-to-severe AD, including those with prior inadequate response to cyclosporine. The treatment was generally well-tolerated. These findings suggest that abrocitinib is an effective therapeutic option for moderate-to-severe AD for Indian patients, particularly in cases requiring a fast response or with prior inadequate response to cyclosporine


Normalized Changes in EASI, IGA, and PP-NRS Scores Over Time
Normalized EASI
Normalized IGA
Normalized PP-NRS
Normalized Scores
1.0
0.8
0.6
0.4
0.2
Baseline
2 weeks
4 weeks
8 weeks
12 weeks
Time Points



Abstract N°: 485

Cumulative Life Course Impairment in Moderate-to-Severe Atopic Dermatitis: A Novel Cross-Sectional Study in Singapore

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Introduction & Objectives:

Atopic dermatitis (AD) significantly impacts patients' quality of life over their lifespan. Traditional measures such as Dermatology Life Quality Index (DLQI) and Patient-Oriented Eczema Measure (POEM) primarily assess short-term effects at a single time point, potentially overlooking cumulative impairment. The novel Cumulative Life Course Impairment (CLCI) model uniquely evaluates both retrospective (CLCI R) and prospective (CLCI P) disease burdens. This study, one of the first globally, aims to extensively assess CLCI in moderate-to-severe AD patients and its association with disease severity and quality-of-life metrics. Understanding the long-term implications of AD through CLCI assessments can significantly enhance patient care and inform targeted interventions.

Materials & Methods:

A cross-sectional study was conducted involving 82 adult patients diagnosed with moderate-to-severe AD. Participants completed CLCI R and CLCI P questionnaires. Clinical assessments included evaluations of disease severity using Eczema Area and Severity Index (EASI) and POEM, quality of life through DLQI and symptom-specific assessments including ITCH and SLEEP scores. Demographic and clinical data, such as age, gender, duration of disease was systematically collected. Statistical analyses include Spearman's correlation coefficients to assess associations, Mann-Whitney U tests for group comparisons, and multiple regression analyses to determine independent predictors of cumulative impairment. Further exploratory subgroup analyses were conducted to assess the potential influence of demographic and psychosocial factors.

Results:

The mean CLCI R score was 29.4 ± 1.88, with no significant difference between moderate and severe AD groups ($p=0.907$), indicating substantial retrospective impairment in both severity groups. However, prospective impairment (CLCI P) scores were significantly higher in severe AD patients (Mean: 28.4 ± 5.50 vs. 15.9 ± 1.96; $p=0.007$), indicating increased anticipated future impairment in more severe disease. Statistically significant correlations were observed between CLCI P and DLQI ($r=0.611$, $p<0.01$) and disease severity ($r=0.489$, $p<0.01$). Multiple regression analysis identified DLQI ($\beta=0.07$ (0.04,0.10), $p<0.001$), CLCI-R ($\beta=0.02$ (0.01,0.03), $p<0.001$), disease duration ≥21 years ($\beta=0.33$ (0.05,0.60), $p=0.019$), and age >34 years ($\beta=-0.38$ (-0.66,-0.10), $p=0.007$) as significant predictors of prospective impairment. Notably, age >34 years exhibited a protective effect against future impairment, possibly due to enhanced coping strategies or better access to resources, warranting further investigation.

Conclusion:

This study highlights significant cumulative impairment in moderate-to-severe AD patients, supporting the novel use of the CLCI model in routine dermatology practice. Implementing CLCI assessments could identify high-risk individuals earlier, enabling personalized care and proactive interventions. Findings encourage integrating AD care into broader chronic disease frameworks, emphasizing early intervention, mental health support and

innovative approaches such as teledermatology. Future research should validate these results longitudinally and explore targeted interventions to reduce cumulative disease burden.

	CLCI (P)	CLCI (R)
DLQI	0.611**	0.247*
ITCH	0.339**	0.063
SLEEP	0.357**	0.232
POEM	0.489**	-
EASI	-	0.082

Table 1 Spearman's correlation coefficients. *p<0.05 ; **p<0.01

Variables	Unadjusted estimate (95% CI)	P value	Adjusted estimate (95% CI)	P value
Age	-0.01 (-0.02, 0.01)	0.261		
Gender (Reference = Female)	0.25 (-0.16, 0.65)	0.231		
Ethnicity (Reference = Chinese)				
Non-Chinese	0.03 (-0.38, 0.45)	0.875		
Housing (Reference = HDB 1-4 RMS)	0.02 (-0.49, 0.53)	0.949		
HDB 5 Rooms/Exec/Condo/Others				
Treatment group (Reference = Jak-inhibitors)		0.6114+		
Biologics	-0.22 (-0.72, 0.27)	0.380		
Traditional immunomodulators	-0.21 (-0.75, 0.33)	0.447		
Tropical	-0.42 (-1.06, 0.22)	0.196		
Topical Vs Systemic (Reference = Topical)				
Systematic	0.27 (-0.28, 0.83)	0.336		
EASI severity (Reference = Moderate)				
Severe	0.85 (0.06, 1.63)	0.035		
POEM Severity (Reference = Moderate)				
Severe	0.74 (0.21, 1.28)	0.006		
DLQI	0.09 (0.06, 0.12)	<.0001	0.07 (0.04, 0.10)	<.0001
CLCIR	0.03 (0.02, 0.04)	<.0001	0.02 (0.01, 0.03)	<.0001
AGE ONSET	-0.02 (-0.03, -0.01)	0.002		
Disease Duration (Reference = < 21years)				
≥ 21 years	0.57 (0.22, 0.93)	0.002	0.33 (0.05, 0.60)	0.0194
Sleep	0.13 (0.05, 0.22)	0.002		
Age (Reference = < 34years)				
≥ 34years	-0.25 (-0.65, 0.14)	0.202	-0.38 (-0.66, -0.10)	0.0077
Itch	0.13 (0.04, 0.21)	0.003		
POEM	0.06 (0.03, 0.08)	<.0001		
EASI	0.03 (0.01, 0.06)	0.009		

Note: + refers to type 3 p value or overall p value.

Table 2 Univariate and multivariable linear regression for CLCI P



Abstract N°: 530

Lebrikizumab provides high levels of effectiveness in patients with moderate-to-severe atopic dermatitis in routine practice: interim analysis of the non-interventional study AD-LIFE

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Introduction & Objectives: Efficacy and safety of lebrikizumab (LEB) for the treatment of moderate-to-severe atopic dermatitis (AD) was demonstrated throughout its extensive clinical development program. However, real-world data on LEB in AD remains scarce. Here, we report interim effectiveness and safety data from the non-interventional study (ADlife).

Materials & Methods: This is an open, prospective, multi-center, observational cohort study to evaluate AD control at week (W) 52. Patients were included if they were ≥18 years old, had moderate-to-severe AD requiring systemic therapy as per label, received LEB treatment according to physician's decision, and provided informed consent. Effectiveness outcomes reported here were percent change from baseline (CFB) of EASI, percentage of patients with EASI50, EASI75, EASI90 and IGA 0/1, percent CFB of 24h-peak pruritus numerical rate scale (peak-pruritus NRS), and percentage of patients with peak-pruritus NRS ≥4-point improvement from baseline (W4 and W16). Safety outcomes reported were adverse drug reactions (ADRs) and serious ADRs. This interim analysis covered patients completing 16W of treatment. Data are reported as observed. T-Test was performed for CFB analyses.

Results: A total of 100 patients were included (8 patients dropped out of the study until W16). Baseline characteristics: mean [SD] age of 41.3 [15.0] years and 57% were female; baseline severity: mean scores of EASI 21.6 [11.5], IGA 3.4 [0.6], peak-pruritus NRS 7.2 [2.1] and DLQI 17.1 [7.2]). The most common atopic comorbidities: 63% of patients presented allergic rhinitis /hay fever, 40% asthma, 27% food allergy and 60% other allergies. Thirty percent (30/100) of patients have been previously treated with advanced systemic treatments (of which 76.7% [23/30] of patients had been pre-treated with dupilumab) and 86% (86/100) with TCS. At baseline/W4/W16, 48/36/26 patients received TCS as concomitant topical prescription. Effectiveness outcomes (W4 and W16): percent CFB of EASI was -53.8% and -70.1% ($p<0.0001$ both); % of patients achieving EASI50: 66.0% and 85.9%; % of patients achieving EASI75: 30.9% and 63.0% and % of patients achieving EASI90: 11.7% and 32.6%, respectively; % of patients with IGA 0/1 was 10.4% and 31.9%; percent CFB of peak-pruritus NRS was -44.0% and -52.5% ($p<0.0001$ both); and 48.9% and 60.5% of patients achieved peak-pruritus NRS ≥4-points improvement from baseline, respectively. In this preliminary analysis, ADRs under lebrikizumab were consistent with those in clinical trials. No new safety signals were observed.

Conclusion: The results of this interim analysis, the first data reporting real-world evidence on LEB for moderate-to-severe AD, demonstrated high levels of effectiveness with relevant improvements of signs and symptoms, seen as early as W4, and a favorable safety profile. These data suggest that efficacy seen in randomized clinical trials

translates well into the real-world setting even with a significant share of patients being pre-treated with advanced systemics and patients suffering from comorbid conditions.



Abstract N°: 953

Optimizing the Management of Atopic Dermatitis with JAK Inhibitors: Real-World Evidence from a 36-week Multicenter Study – Italian Landscape AD

Luigi Gargiulo*[1, 2], Luciano Ibba[1, 2], silvia ferrucci[3], Mariateresa Rossi[4], Simone Ribero[5], Michela Ortoncelli[5], Maddalena Napolitano[6], Elena Pezzolo[7], Piergiorgio Malagoli[8], Antonio Costanzo[1, 2], Alessandra Narcisi[1, 2]

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[2]Humanitas University, Department of Biomedical Sciences, Pieve Emanuele (MI), Italy
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Optimizing the Management of Atopic Dermatitis with JAK Inhibitors: Real-World Evidence from a 36-week Multicenter Study – Italian Landscape AD

Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin condition that often requires personalized treatment strategies. Janus kinase inhibitors (JAKi) represent a novel class of targeted therapies with rapid onset of action and potential to address both objective signs and subjective symptoms of AD. While randomized clinical trials have demonstrated their efficacy, real-world data are essential to better understand their performance in routine clinical practice. This study aimed to evaluate the real-world effectiveness of JAK inhibitors in the treatment of moderate-to-severe AD across a large cohort of Italian patients, using optimal treatment targets recently recommended by Silverberg and colleagues.

Materials & Methods:

This observational, multicenter study involved 30 Italian dermatology centers and included 388 adult patients initiating treatment with a JAK inhibitor. Patients were evaluated at baseline and at Weeks 4, 16, and 36. The primary objective was to assess the proportion of patients achieving the combined endpoint of Eczema Area and Severity Index (EASI) ≤ 3 and itch-Numerical Rating Scale (NRS) 0/1. These targets were selected in accordance with the consensus proposed by *Silverberg et al.,* which emphasizes the need for both objective and patient-reported outcomes to define optimal response in AD. No direct comparisons were made between different JAK inhibitors.

Results:

At baseline, the mean age of participants was 40.1 years (SD 15.9), with 54.6% being male. The mean disease duration was 24.2 years (SD 20.3). Notably, 70.9% of patients were bio-experienced, with dupilumab being the most frequently used prior treatment.

At Week 4, 30.1% of patients achieved the combined endpoint of EASI ≤ 3 and itch-NRS 0/1. This proportion increased to 55.2% at Week 16 and reached 59.2% at Week 36 (Figure 1). These results demonstrate a progressive and sustained clinical response over time. As expected, response rates followed a time-dependent pattern,

reflecting the therapeutic trajectory of JAKi in routine practice. Data for baricitinib at Week 36 were not shown due to very limited sample size.

Conclusion:

This large, real-world study confirms the effectiveness of JAK inhibitors in managing moderate-to-severe atopic dermatitis across a heterogeneous patient population. The proportion of patients achieving optimal disease control increased steadily over time, supporting the role of JAKi as a valuable therapeutic option in daily clinical care. The use of combined, patient-centered treatment targets—aligned with recent international recommendations—offers a practical and meaningful approach to evaluating treatment success. These findings provide real-world support for integrating JAK inhibitors into optimized AD management strategies, while highlighting the need for continued research into long-term outcomes and treatment sequencing.

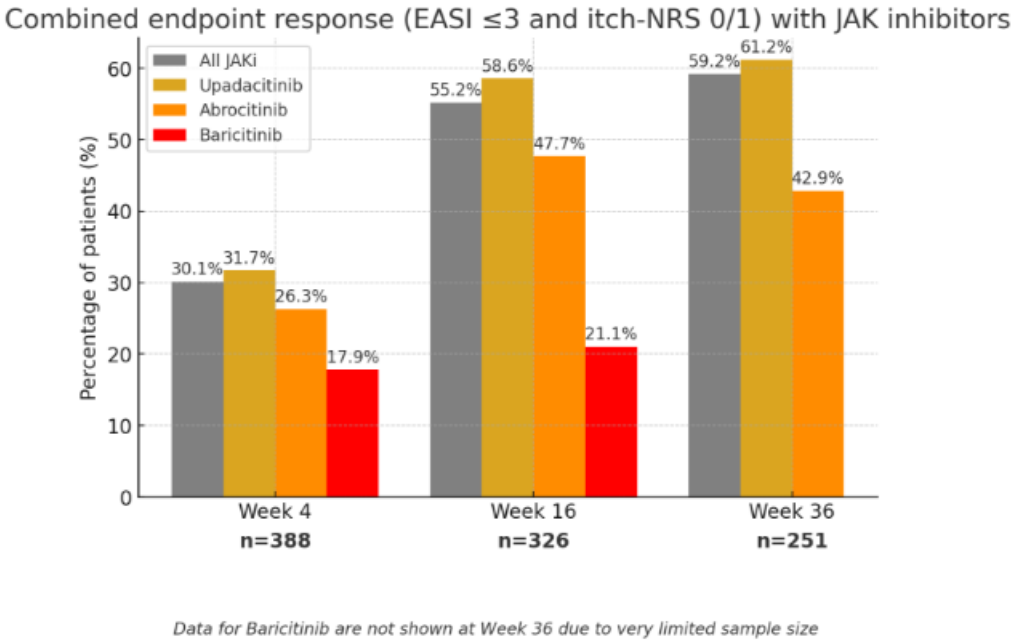


Figure 1. Proportion of patients achieving the combined endpoint response during the 36 weeks of observation.



Abstract N°: 974

When living in the countryside is not that peaceful

Safa Gueroum[1], el fetoiki fatima zahra[1], hali fouzia[1], chiheb soumiya[1]

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Introduction & Objectives:

Compositae dermatitis or specifically parthenium dermatitis is a term commonly used to indicate a specific form of chronic allergic contact dermatitis, called weed dermatitis by many physicians. It is a chronic disorder whose management is extremely difficult, since the allergen avoidance is almost impossible, the topical corticosteroid therapy provides only partial relief and a prolonged systemic corticosteroid therapy has unacceptable side-effects. We report a case of an old farmer with a severe parthenium dermatitis treated with azathioprine.

Materials & Methods:

A 60-year-old male farmer was referred to our hospital due to a rash on his face, hands, and forearms. This rash occurred each spring but had become more frequent and nearly constant in recent years. The patient reported that the itching was significantly impacting his quality of life.

Upon physical examination, we observed erythematous, lichenified plaques with mild scaling on his bilateral upper and lower eyelids, brow bones, and forehead, sparing the nasal bridge and extending to the chin, zygomatic prominence, and nasolabial folds on both sides. Additionally, erythematous patches and scaling were affecting his forearms and hands. The patient appeared depressed.

Results:

We considered a diagnosis of airborne contact dermatitis. The patient underwent patch testing with the European Comprehensive Baseline Series. Results read on day 2 showed a positive reaction to the sesquiterpene lactones mix (+3). He was started on topical corticosteroids, which yielded mild improvement.

Since the patient had no plans to relocate to an urban environment, and given the widespread presence of the allergen and the persistence of flare-ups due to climate change, we decided to initiate a steroid-sparing immunosuppressive treatment with 100 mg of azathioprine per day. This treatment provided significant improvement.

Conclusion:

The Compositae family of plants is extensive, ranging in type from sunflower and chrysanthemum, thistle to ragweed and cocklebur. Its members can cause mechanical, irritant, and allergic contact dermatitis or phototoxic and photoallergic reactions.

The typical clinical picture is that of an elderly male farmer with a chronic, widespread eczematous eruption in exposed areas, reminiscent of airborne contact dermatitis, photocontact dermatitis, or atopic eczema. Involved skin is erythematous, thickened, and often lichenified.

Though it has a very low rate of mortality, the disease usually persists with variable remissions and relapses, causing great distress and morbidity. The management of the dermatitis is very difficult because avoidance of Parthenium is almost impossible owing to its ubiquitous distribution. Treatment is mostly symptomatic and

topical, and systemic corticosteroids are the mainstay of therapy. However, to overcome the side-effects since the disease runs a chronic course with frequent relapses, azathioprine has been extensively studied as a steroid-sparing drugs; it is considered as an effective and safe alternative to corticosteroid therapy in the treatment of chronic Parthenium dermatitis



Abstract N°: 978

Exercise may improve atopic dermatitis by modulating the gut microbiota

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Introduction & Objectives:

Atopic dermatitis (AD), a prevalent chronic inflammatory skin disorder, arises from complex interactions between genetic predisposition, environmental triggers, and immune dysregulation. While epidemiological studies indicate an inverse correlation between moderate-to-vigorous physical activity and AD incidence, the underlying mechanisms remain elusive. This study investigates the therapeutic effects of voluntary exercise on AD-like inflammation in mice and elucidates its gut microbiota-dependent mechanisms.

Materials & Methods:

AD-like inflammation was induced in mice via topical application of the vitamin D3 analog MC903. Mice underwent voluntary wheel running for 4 weeks. To dissect microbiota involvement, a tripartite experimental design was implemented: 1) Gut microbiota depletion via oral broad-spectrum antibiotics; 2) Fecal microbiota transplantation (FMT) from exercised/sedentary donors; 3) Multidimensional assessment including dermatitis severity (SCORAD-like scoring), transepidermal water loss (TEWL), serum IgE quantification, Th2 cytokine profiling (IL-4/IL-13), and histopathological analysis of $CD4^+$ T-cell infiltration.

Results:

Voluntary exercise markedly alleviated AD-like pathology in mice, as evidenced by significant reduction in epidermal hyperplasia, TEWL, and ear swelling. Exercised mice demonstrated suppressed systemic inflammation characterized by decreased serum IgE levels and downregulated cutaneous expression of Th2-associated cytokines (IL-4/IL-13). Furthermore, histopathological analysis revealed substantially diminished $CD4^+$ T-cell infiltration in lesional skin. Importantly, improvement of AD-like inflammation persisted beyond the exercise intervention period.

Notably, sedentary AD mice co-housed with exercised counterparts exhibited parallel improvements in ear swelling and epidermal thickness. Antibiotic-mediated gut microbiota depletion abrogated the therapeutic benefits of exercise, whereas FMT from exercised mice effectively recapitulated the anti-inflammatory phenotype, restoring improvements in TEWL, epidermal architecture, and inflammatory cytokine expression.

Conclusion:

This study demonstrates that voluntary exercise confers durable AD protection through gut microbiota remodeling, potentially via microbiota-immune crosstalk. Our findings validate exercise as a viable adjunct therapy for AD and propose microbiome-targeted strategies as novel therapeutic frontiers.

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Abstract N°: 1042

Joint Pain and Inflammatory Arthropathy After Dupilumab Use in Atopic Dermatitis: A Systematic Review and Meta-Analysis

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[2]National Skin Centre, Singapore, Singapore

Introduction & Objectives:

Dupilumab has emerged as an important treatment for inadequately controlled moderate-to-severe atopic dermatitis (AD). Dupilumab is a human monoclonal antibody which works by inhibiting the interleukin (IL)-4 receptor subunit α. However, adverse events from dupilumab use has been reported, including ocular complications, nasopharyngitis and injection site reactions. Additionally, rarer adverse events like joint pain, alopecia areata, psoriasis, lymphoma, red face, skin peeling have also been reported. Notably, complaints regarding joint pain has prompted the inclusion of arthralgia to the Summary of Product Characteristics of dupilumab. Joint pain included conditions like osteoarthritis, arthralgia, myalgia, musculoskeletal symptoms, back pain, and inflammatory conditions, such as arthritis, enthesitis or enthesopathies, tendinitis or tenosynovitis, rheumatoid arthritis, ankylosing spondylitis, inflammatory joint pain, infrapatellar fat pad inflammation and psoriatic arthritis. In this paper, we reviewed arthritis and inflammatory arthropathy as an adverse effect of dupilumab treatment for AD.

Materials & Methods:

A comprehensive search was performed for randomized controlled trials, observational studies, case series and case reports analysing joint pain prevalence among AD patients treated with dupilumab. This study was performed according to the Preferred Reporting Items for Systematic reviews and Meta-Analyses 2020 checklist and quality was assessed via the Newcastle-Ottawa Quality Assessment Scale (NOS) (Figure 1).

Results:

43 studies were included in the systematic review, and 34 studies (15101 patients) were included for the meta-analysis. In the systematic review, seven case reports and two case series have reported patients with joint pain after dupilumab use, in addition to the 27 cohort studies and 7 RCTs showing reports of joint pain following dupilumab use. Some studies showed investigations being conducted for joint pain, which included elevated inflammatory markers, such as CRP and ESR, ultrasound and MRI confirmed inflammatory arthropathy or enthesitis

Among the 34 studies, the pooled prevalence of joint pain among dupilumab patients was 1.74% (95%CI:1.12–2.68) (Figure 2). Among the eight studies that reported inflammatory arthropathy prevalence among dupilumab patients, the pooled prevalence of inflammatory arthropathy among dupilumab patients was 2.62% (95%CI: 1.44–4.70) (Figure 3). There were 34 cases of arthritis, 79 cases of enthesitis or enthesopathies, 40 cases of tendinitis or tenosynovitis (or 60 were enthesitis or enthesopathies or tendinitis or tenosynovitis), one case of rheumatoid arthritis, one mild ankylosing spondylitis, four cases of inflammatory back pain, one infrapatellar fat pad inflammation and one case of psoriatic arthritis. Some patients had multiple symptoms, such as arthritis and tenosynovitis concurrently. Among the 8 studies with a control group, the overall relative risk of developing joint pain after dupilumab use for AD was not significantly higher at 0.68 (95%CI: 0.29–1.58, p=0.31), compared to the control group (Figure 4).

Conclusion:

Although our findings found that there is insufficient evidence to suggest that dupilumab use was associated with joint pain, the prevalence of joint pain observed among patients treated with dupilumab may warrant a proactive surveillance in clinical practice.

Figure 1: Preferred Reporting Items for Systematic reviews and Meta-Analysis Flow Diagram

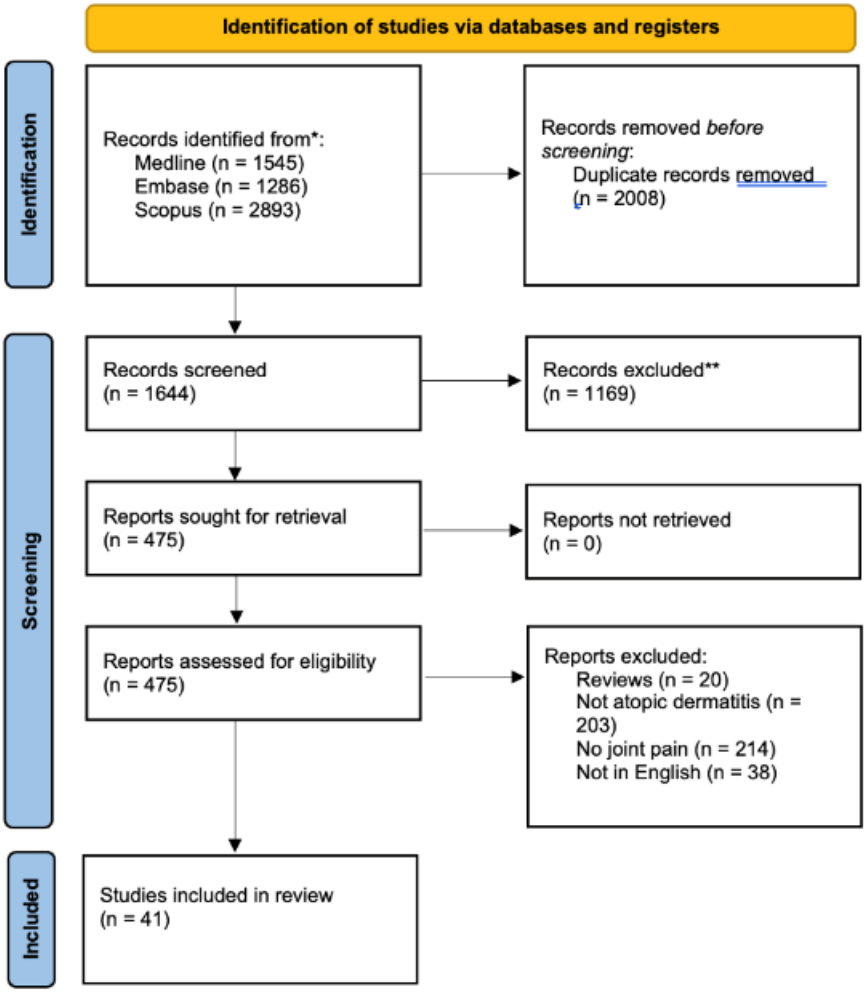


Figure 2: Proportion of Joint Pain

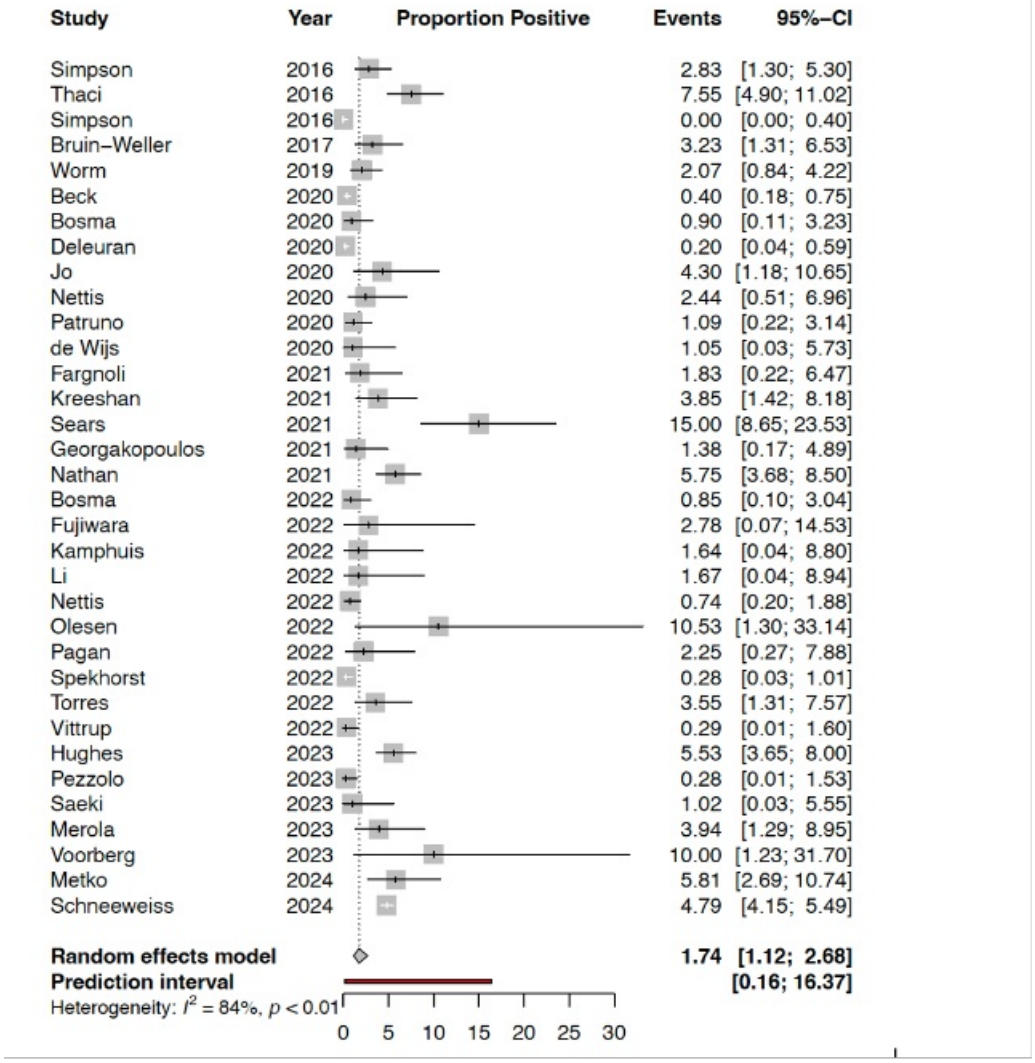


Figure 3: Proportion of Inflammatory Arthropathy

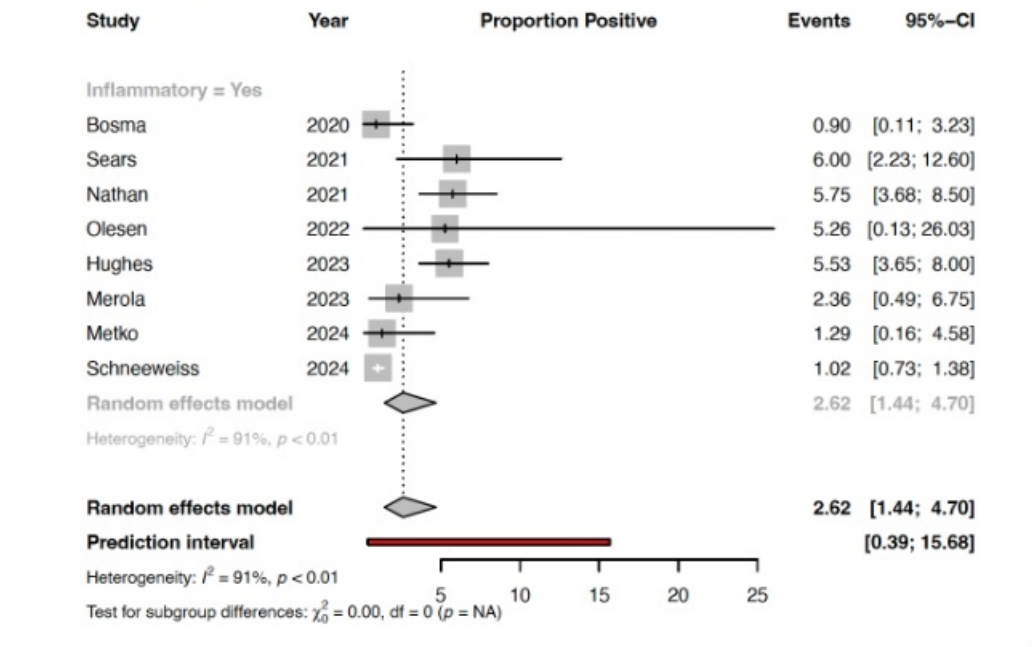
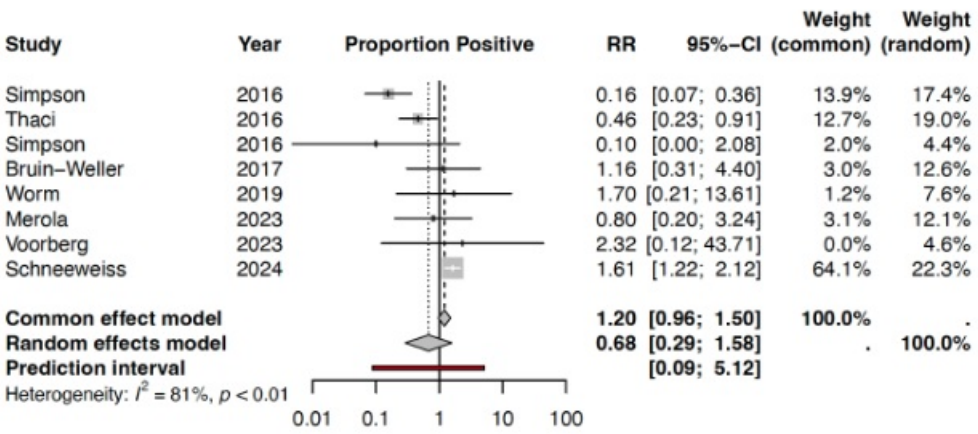


Figure 4: Relative Risk of Joint Pain





Abstract N°: 1045

Repercussions of Atopic Dermatitis on Patients' Quality of Life: An Impact Not to Be Overlooked

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic and recurrent skin condition characterized by skin inflammation, intense pruritus, and an impaired skin barrier. Beyond physical manifestations, AD has profound repercussions on patients' quality of life, affecting their psychological well-being, sleep, and social life. This study aims to evaluate the impact of AD on the quality of life of patients followed in our department.

Materials & Methods:

This is a retrospective descriptive study involving children with atopic dermatitis treated in the dermatology department, conducted between January 2016 and January 2025. Quality of life was assessed using the CHILD-DLQI.

Results:

We included 120 children aged 4 to 16 years with atopic dermatitis (AD). The mean age of patients was 7.4 ± 3.2 years. A slight male predominance was noted (55% boys). The severity of AD varied, with 45% of cases classified as mild, 37% as moderate, and 18% as severe. The impact on quality of life, measured by the CHILD-DLQI score, had a mean of 10.6 ± 4.3, indicating a moderate to severe impact. Regarding score distribution, 5% of children reported no impact, 28% reported a mild impact, 42% a moderate impact, 18% a severe impact, and 7% a very severe impact. Pruritus and skin discomfort were reported by 85% of patients, significantly affecting sleep in 65% of them. Additionally, 50% of children experienced difficulties in engaging in physical activities, 40% suffered psychological repercussions such as frustration or depression, and 30% faced social interaction issues, with cases of isolation reported in 15% of them. Regarding treatment, 70% of children were on topical corticosteroids, while 25% received systemic treatments. A significant improvement in CHILD-DLQI scores was observed in 60% of patients after six months of follow-up. These results highlight the considerable impact of atopic dermatitis on children's quality of life, necessitating a comprehensive therapeutic approach.

Conclusion:

Atopic dermatitis has a significant impact on children's quality of life, affecting not only their physical well-being but also their psychological and social health. The use of tools such as the CHILD-DLQI is essential to assess the extent of this impact and guide therapeutic management in a holistic manner.



Abstract N°: 1183

Effectiveness of tralokinumab and lebrikizumab in Japanese atopic dermatitis patients with persistent head and neck dermatitis after long-term treatment with dupilumab: A single-centerretrospective study

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Introduction & Objectives: Dupilumab, an anti-interleukin (IL)-4Rα antibody, has showed efficacy and effectiveness for moderate-to-severe atopic dermatitis (AD). However, some patients experience persistent lesions on the head and neck despite lesions improving on the limbs and trunk after long-term treatment with dupilumab, which is one of the unmet needs of dupilumab. Although some patients switch to tralokinumab or lebrikizumab (anti-IL-13 antibodies) as a result, evidence showing the effectiveness of these treatments is limited. Herein, we investigated the effectiveness of anti-IL-13 antibodies in patients who switched to one to these IL-13 antibody treatments due to persistent dermatitis in the head and neck after long-term dupilumab treatment.

Materials & Methods: This study included all AD patients who had been treated with dupilumab for more than 1 year at our department and subsequently switched to tralokinumab or lebrikizumab by December 2024 due to persistent facial and neck dermatitis. The total Eczema Area and Severity Index (EASI) and head and neck EASI 3 months after switching to tralokinumab or lebrikizumab were evaluated. Patient data were retrospectively collected from medical records. The patients with insufficient data were excluded. Assessments were conducted by well-trained dermatologists in our department. This study was approved by the Teikyo University Institutional Review Board and was conducted in accordance with the principles of the Declaration of Helsinki. Informed consent was obtained by the opt-out method on the website.

Results: Twelve patients (female, 1; male, 11) were analyzed. The median age of the patients was 43.5 years (1st quartile, 33.25 years; 3rd quartile, 50 years). All patients directly switched from dupilumab to tralokinumab (7 patients) or lebrikizumab (5 patients). All patients except for one showed a decrease in head and neck EASI, with a significant difference from 0.9 (0.55, 1.65) to 0.3 (0.175, 0.9) in total (Wilcoxon matched-pairs signed-rank test, p=0.0088) and from 1.5 (0.9, 2.1) to 0.4 (0.2, 0.9) in patients switching to lebrikizumab (paired t-test, p=0.0224). A numerical difference from 0.8 (0.5, 1.05) to 0.2 (0.15, 0.8) was observed in patients switching to tralokinumab (Wilcoxon matched-pairs signed-rank test, p=0.1563).

Conclusion: Head and neck EASI scores significantly decreased 3 months after switching from dupilumab to tralokinumab or lebrikizumab. Switching to tralokinumab or lebrikizumab could be considered for AD patients with persistent head and neck lesions during dupilumab treatment.



Abstract N°: 1264

Atopic eczema is associated with herpes zoster in adults

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Introduction & Objectives:

Eczema is associated with an altered immune response and a heightened susceptibility to certain infections. Systemic eczema treatments including oral corticosteroids, methotrexate, and more recently JAK inhibitors - a subclass of newly developed small-molecule treatments - have been linked to an increased risk of herpes zoster. However, some limited evidence suggests an independent association between eczema and herpes zoster.

The aim of the present study was to investigate the association between eczema* and herpes zoster in the UK and explore the role of eczema treatments in this relationship.

Materials & Methods:

A matched (on age, sex, clinical practice) cohort study was conducted using routinely collected primary care data from the UK's Clinical Practice Research Datalink Aurum (CPRD) over a period from 1997 to 2023. A total of 2,445,090 adults with incident or prevalent eczema were identified using a previously validated algorithm and compared with 11,636,684 observations from adults without eczema. Cox regression models were used to estimate the univariable and adjusted association between eczema and herpes zoster. Covariates included age at baseline, behavioural factors, and multiple comorbidities. Various definitions of immunosuppressant treatment and oral corticosteroid exposure were employed to examine their influence on the association. To assess the impact of age on effect estimates, an interaction term between eczema and age was incorporated into the analysis.

Results:

Individuals with eczema had an unadjusted hazard ratio of 1.33 for herpes zoster (95%-CI: 1.31–1.34), which decreased to 1.28 (95%-CI: 1.27–1.29) after adjusting for covariates. The risk increased with greater eczema severity (mild: aHR: 1.22 [95%-CI: 1.20-1.23]; moderate: aHR: 1.28 [95%-CI: 1.27-1.30]; severe: aHR: 2.33 [95%-CI: 2.22-2.45]). Adjustments for different definitions of oral corticosteroid exposure led to slight further reductions (aHRs: 1.24 to 1.27 with confidence intervals from 1.23–1.25 and 1.26–1.28, for exposure at baseline and ever-exposure respectively). There was strong evidence for effect modification by age, with younger eczema patients experiencing a comparatively higher relative excess zoster risk (group of 30- to 40-year-olds: aHR 1.51 [95%-CI: 1.47-1.56], followed by 40- to 50-year-olds: aHR 1.42 [95%-CI: 1.39-1.46]).

Conclusion:

Our findings indicate that individuals with eczema have an increased risk of herpes zoster, regardless of comorbidities or oral corticosteroids. With herpes zoster increasingly emerging as a potential adverse effect of newer eczema treatments, recognising this risk is especially important for guiding clinical practice and vaccination

strategies to improve care and prevent herpes zoster in individuals with eczema. Further research is required to investigate the underlying biological mechanisms and to assess additional factors such as vaccinations.



Abstract N°: 1284

Online Education Significantly Improved Dermatologists' Knowledge and Competence in Diagnosing and Managing Chronic Hand Eczema

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Introduction & Objectives:

Chronic hand eczema (CHE) is defined as hand eczema (HE) that lasts for more than three months or relapses twice or more within a year. Key symptoms include itch and pain. CHE can also negatively impact patients' quality of life, psychological well-being, physical functioning, and ability to work.

We assessed whether online accredited education could improve dermatologists' understanding of the impact of CHE, differential diagnosis of CHE and emerging therapies to treat CHE, and could also enhance their confidence in communicating with patients about this condition.

Materials & Methods:

Dermatologists participated in a 30-minute, online video activity entitled 'Managing Chronic Hand Eczema: How Can We Do Better for Our Patients?'. Responses to 3 multiple-choice, knowledge questions and 1 self-efficacy, 5-point Likert scale confidence question were analyzed. Educational effect was assessed using a repeated-pair design, pre-/post-assessment. A paired samples t-test was conducted for significance testing on overall average number of correct responses and for confidence rating. A series of McNemar's tests were conducted at the question level (5% significance level, P <.05). Cohen's d with correction for paired samples estimated the effect size of the education on number of correct responses (<.20 modest, .20-.49 small, .59-.79 moderate, ≥.80 large). The activity launched on 26 September 2024 with data collection through 9 November 2024.

Results:

- Dermatologists (n=68) significantly improved their knowledge of:
  - The mode of action of emerging therapies for CHE (46% correct responses at baseline rising to 71% post-activity; *P* <.001)
  - Differential diagnosis of CHE (63% correct responses at baseline rising to 79% post-activity;*P* <.01)
- Dermatologists (n=68) also demonstrated significant competence gains in:
  - Selecting an appropriate questionnaire to assess the impact of CHE on patients' lives as the basis for patient communication (57% correct responses at baseline rising to 82% post-activity; *P* <.001)
- The average percentage of correct responses increased from 55% at baseline to 77% post-activity (*P* <.001), and there was a large educational impact (Cohen's d=0.84)
- The proportion of dermatologists answering all 3 questions correctly rose from 21% at baseline to 59% post-activity
- After completing the activity, 51% of dermatologists reported improved confidence in communicating with patients about the impact of CHE on their lives, resulting in a notable confidence shift of 51%

Conclusion:

This online activity significantly improved dermatologists' knowledge and competence regarding the impact, diagnosis and management of CHE. Given the evolving treatment landscape for this condition, dermatologists would benefit from additional education to improve their knowledge of recently approved and emerging therapies and translate this knowledge into clinical practice for improved patient outcomes.



Abstract N°: 1285

Online Education Significantly Improved Dermatologists' Knowledge Of The Mode Of Action And Key Clinical Data On Emerging Therapies For Atopic Dermatitis That Target The OX40-OX40 Ligand Pathway.

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Introduction & Objectives:

Moderate to severe atopic dermatitis (AD) is a chronic, heterogeneous condition with unpredictable disease course that requires effective, long-term disease control. Several new therapies have reached the clinic recently with more in the pipeline. Dermatologists need to stay abreast of emerging therapies in order to be fully informed about how the treatment landscape continues to evolve. We assessed whether online accredited education could improve dermatologists' understanding of the mode of action and clinical data on emerging therapies for AD that target the OX40-OX40L pathway.

Materials & Methods:

This online educational video activity entitled 'What's on the horizon in atopic dermatitis? A focus on OX40-OX40 ligand-targeted therapies' was a 30-minute discussion with 3 panelists. Responses to 3 multiple-choice knowledge questions and 1 self-efficacy, 5-point Likert scale confidence question were analyzed. Educational effect was assessed using a repeated-pair design, pre-/post-assessment. A paired samples t-test was conducted for significance testing on overall average number of correct responses and for confidence rating. A series of McNemar's tests were conducted at the question level (5% significance level, P <.05). Cohen's d with correction for paired samples estimated the effect size of the education on number of correct responses (<.20 modest, .20-.49 small, .59-.79 moderate, ≥.80 large). The activity launched 26 June 2024 with data collection through 9 October 2024.

Results:

1,479 dermatologists viewed the education in this time period; 145 completed all pre- and post-assessment questions. The average percentage of correct responses across all questions increased from 31% at baseline to 57% post-activity (*P* <.001), with a large educational impact (Cohen's d=0.94). The proportion of dermatologists answering all 3 questions correctly rose from 2% at baseline to 20% post-activity.

Dermatologists significantly improved their knowledge of survival of pathogenic T cells as a key consequence of OX40-OX40L interaction in the pathogenesis of AD (17% pre- vs 43% post-activity; *P* <.001), the mode of action of amlitelimab and rocatinlimab (21% pre- vs 55% post-activity; *P* <.001) and clinical data for these novel therapies (54% pre- vs 74% post-activity; *P* <.001).

Post activity, 62% of dermatologists reported improved confidence in understanding the role of the OX40-OX40L pathway in AD, resulting in a notable confidence shift of 109%.

Conclusion:

This online activity significantly improved dermatologists' understanding of the role of the OX40-OX40L pathway in the pathogenesis of AD and of emerging biologic therapies targeting this pathway. Although there was significant knowledge improvement for all questions, the post test scores of 43% to 74% indicate that

dermatologists would benefit from additional education to embed their knowledge of emerging biologic therapies targeting this pathway in AD.



Abstract N°: 1321

Unravelling the Mechanism of Action of Rilzabrutinib in Atopic Dermatitis: An Attractive Therapeutic Agent for the Treatment of Itch Related Conditions

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Introduction & Objectives: Rilzabrutinib, a selective oral Bruton's tyrosine kinase (BTK) inhibitor, was investigated in a placebo-controlled phase-2 trial (NCT05018806) in adult patients with moderate-to-severe atopic dermatitis (AD). A rapid improvement in absolute and relative change in weekly average of daily Peak Pruritus Numerical Rating Scale (PP-NRS) was demonstrated with rilzabrutinib.

Materials & Methods: We used a minimally invasive, tape-stripping approach, to evaluate the effect of rilzabrutinib on the cutaneous transcriptomic and proteomic profile of AD patients. We performed transcriptomic and Olink proteomic analysis on tape-strip skin samples from patients with AD (n=27 patients for transcriptomics and n=24 for proteomics) treated with rilzabrutinib 800 mg/d (n=8/5), 1200 mg/d (n=10/10) and placebo (n=2 BID-7 TID/9). Tape-strips were obtained from lesional (LS) and non-lesional (NL) skin at baseline and week 16. Differentially expressed genes and proteins were defined as fold changes (FCH)>1.5/1.3, and p-value<0.05. RNA sequencing (RNA-seq), followed by gene set enrichment analysis, was carried out on the skin tape strips to identify pathways of genes altered with rilzabrutinib.

Results: At week 16, we observed in LS samples downregulation of BTK related pathways, in the 1200mg/d cohort including MHC Class1 presentation, FcgR signaling, FceR signaling, DAP12 interactions, Myd88 deficiency (TLR2/4), Irak4 deficiency (TLR2/4) and G-protein beta signaling. These pathways are associated with B-cell, granulocytes and monocytes activation. In addition, downregulation of several immune related pathways associated with Th1, innate immunity and Th17 as well as various itch-related markers including NGF, serotonin biosynthesis, IL-31, and NMBR pathways in LS skin were seen at week 16 after rilzabrutinib treatment, with a dose effect. Similar downregulation of immune products was also observed in the proteomic data. Unsupervised RNA-seq analysis showed that improvement in the PP-NRS (placebo corrected) was associated with the downregulation of 31 pathways in LS skin, 6 of which are directly related to BTK. This is in line with the proteomics data which indicates that the lesional proteome of patients receiving rilzabrutinib 1200 mg/d showed 100% improvement from baseline towards a non-lesional profile compared to 40% in the placebo respectively (p<0.001), whereas no significant improvement was observed in the 800mg/d group. At baseline, responders showed downregulation in keratinization pathways, increased sensory perception and IL-12 signaling.

Conclusion: These mechanistic insights suggest that rilzabrutinib is an attractive therapeutic agent for the treatment of conditions associated with a high itch burden.



Abstract N°: 1361

Optimising consultations for patients with atopic dermatitis- a clinical controlled trial

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease that requires ongoing self-management. Managing symptoms, treatments, and the psychological and social impact of the disease is part of everyday life for patients with AD. However, self-management can be complex, and patients request support from healthcare professionals (HCPs) with knowledge and experience in AD, preferably the same HCP.

Integrating agenda-setting into consultations using Conversation Cards (CCs) may enhance self-management. A set of CCs has been developed for patients with AD, empowering them to actively contribute to the focus of the consultation and receive tailored support.

The objective of this study was to investigate whether using CCs developed for patients with AD, in combination with a designated contact nurse offering additional self-management support when needed, could positively impact patient well-being and self-management.

Materials & Methods:

The study was designed as a prospective, clinical, non-randomised controlled trial involving 200 patients of all ages with AD. In the intervention group, CCs were used in all consultations, and patients were assigned to two designated contact nurses. One of the contact nurses, alongside a physician, participated in consultations with patients. Patients could contact the nurses between consultations if they needed further support with self-management. The primary outcome was the Well-being Index (WHO-5), and secondary outcomes included measurements of quality of life, symptoms, and collaboration. All participants answered questionnaires at baseline, six months, and 12 months.

Results:

We report the preliminary results from baseline to six months, as 12-month data is not yet available. At 6 months, we have data from n=61 and n=74 in the control and intervention groups, respectively. The median age is 36 years (range: 1-76) in the control group and 27 years (range: 0-76) in the intervention group, with 64% of women in the control group versus 49% in the intervention group.

We find that from baseline to six months, patients in the intervention group have a mean change in the WHO-5 score that is 6.6 points higher than that of the control group (P=0.01). For patients ≥ 15 years, the WHO-5 further increases to 7.37 points (P=0.03). Additionally, patients ≥ 15 years have a higher mean increase in the collaboration score of 6.13 points (P=0.00). In measuring quality of life, we found an improvement of 2.47 points (P=0.02) in patients < 15 years.

Conclusion:

We find that using CCs in consultation, while simultaneously adding two designated contact nurses whom

patients will meet in every consultation and who can provide extra self-management support if needed, affects patients' feelings of well-being, as well as their feelings of collaboration with HCPs, particularly those ≥ 15 years of age. For patients < 15 years, the intervention positively affects their quality of life measurements.



Abstract N°: 1367

Preferences for therapy and treatment outcomes in atopic dermatitis: A systematic review

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Introduction & Objectives:

The preferences and treatment goals of AD patients, caregivers, and healthcare providers have been a research area of increasing interest. Several different new treatments for atopic dermatitis (AD) have been approved in recent years, but the potential influence of industry funding on published patient, caregiver, and healthcare provider preferences remains uncertain. This systematic review aimed to investigate if patient, caregiver, and healthcare provider preferences in relation to different properties of therapies and treatment outcomes of AD might be subject to funding bias.

Materials & Methods:

This descriptive systematic review was performed following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Guidelines (PRISMA). PubMed and EMBASE were searched. Studies were included if they presented data on therapy and/or treatment outcome preferences of AD patients, caregivers, and/or healthcare providers. The risk of bias of each study was assessed by using the Newcastle-Ottawa-Scale (NOS) and identifying funding sources of the included studies. Treatments developed and supported by pharma-sponsors were assessed to identify if review findings favored certain therapies, advocated by sponsors.

Results:

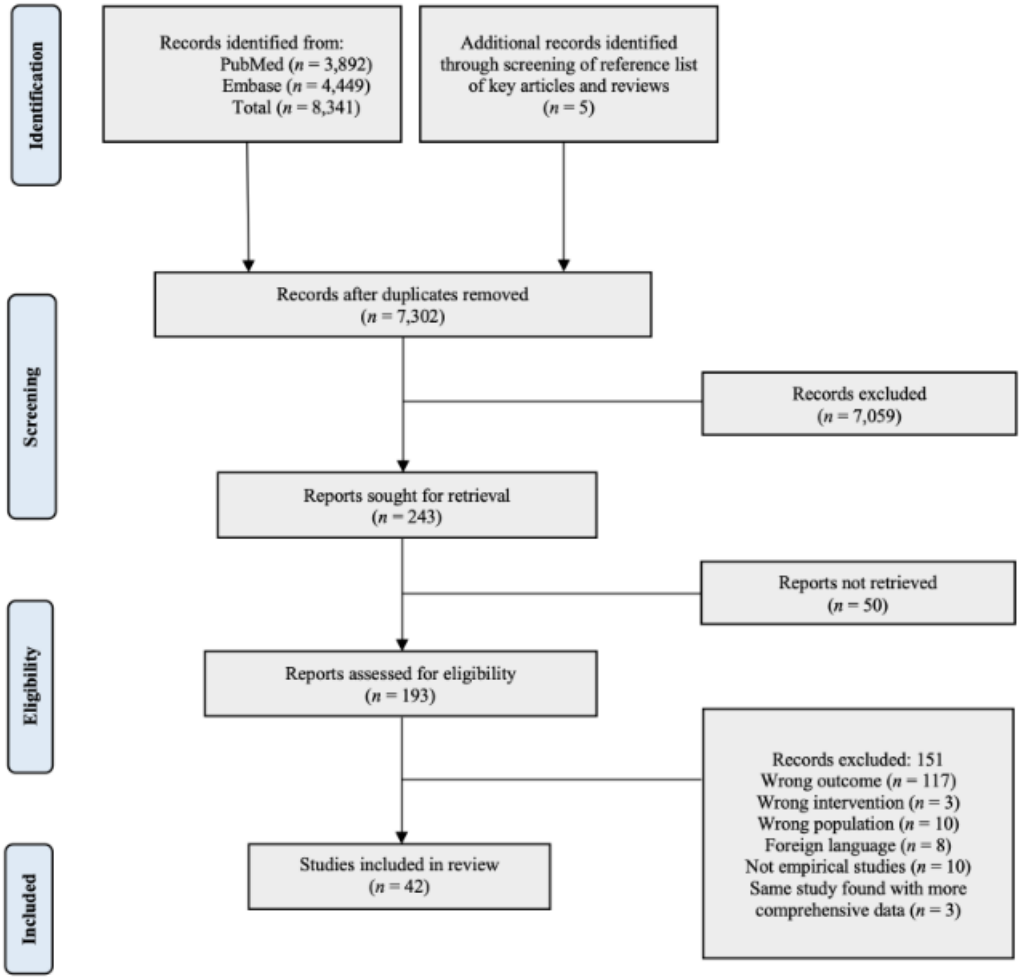
A total of 8,346 studies were identified, and 42 were included for data analysis (participants, 19,839; females, 62.2%). Nineteen and twenty-three studies were pharma-sponsored and non-pharma-sponsored, respectively. The pharma-sponsored studies were of recent dates, had larger patient populations, and included discrete choice experiments (DCE). Three studies used validated surveys to investigate treatment preferences. Efficacy, especially itch relief, was preferred by patients, caregivers, and healthcare providers, and most studies supporting this finding were pharma-sponsored. Moreover, patients were willing to deprioritize safety to achieve other treatment goals in many pharma-sponsored studies. Studies funded by Janus kinase inhibitors (JAKi) producing companies showed that patients preferred treatment by oral route rather than injection despite increased administration frequency. Studies evaluating preferred characteristics of topical treatment were often non-pharma-sponsored.

Conclusion:

The findings of this study indicate that preference research might be biased. Therefore, healthcare providers should be careful when using preference research to guide decision-making. More independent research is needed, and surveys should be standardized and validated before use to provide a more complex view of research regarding preferences and treatment goals, ensuring that findings are impartial to the researchers' affiliations and

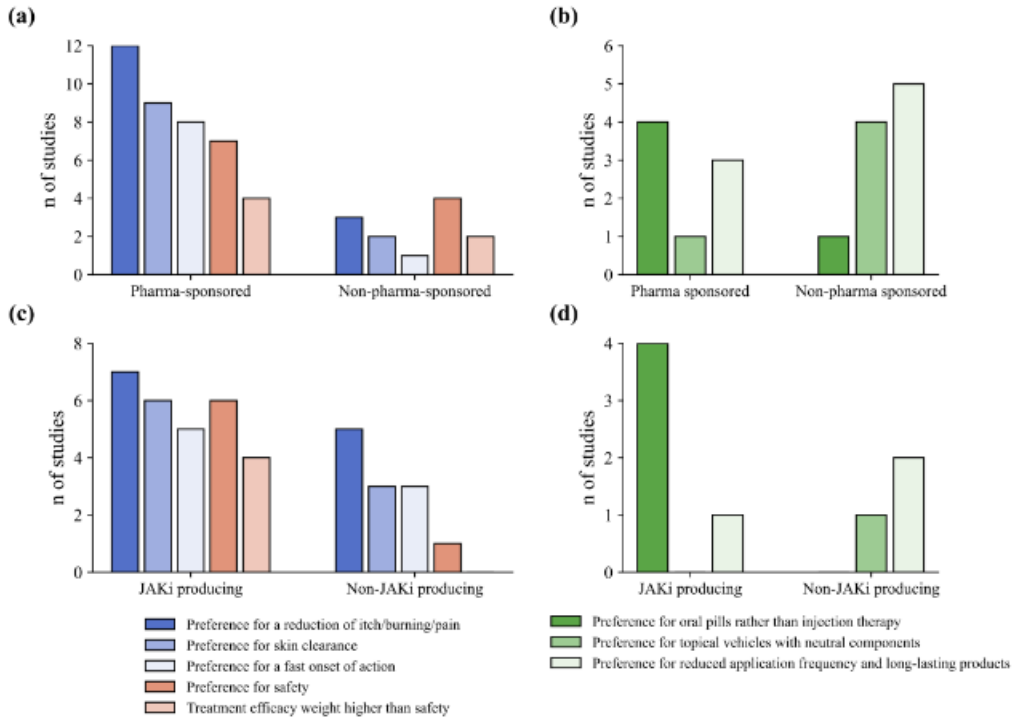
the populations studied.

Figure 1.



PRISMA flow diagram.

Figure 2.



a. Preferences regarding efficacy and safety categorized into pharma-sponsored and non-pharma-sponsored studies. (b) Preferences regarding efficacy and safety categorized into the number of pharma-sponsored studies being JAKi producing and non-JAKi producing. (c) Preferences regarding administration of treatments categorized into pharma-sponsored and non-pharma-sponsored studies. (d) Preferences regarding administration of treatments categorized into the number of pharma-sponsored studies being JAKi producing and non-JAKi producing.



Abstract N°: 1415

Zabalafin Hydrogel, A Novel Safe and Effective Topical Botanical Drug That Comprehensively Addresses The Four Demons of Atopic Dermatitis

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Introduction & Objectives:

The role of S. aureus in the etiology and exacerbation of atopic dermatitis (AD) is now well-characterized and recognized as one of the targets necessary for a comprehensive therapeutic approach. The ideal AD treatment should target the four “demons” of AD, namely inflammation, xerosis, pruritus, and colonization/infection with S. aureus. The continuum of multifactorial AD triggers (S. aureus, immunological, genetic, and environmental) cannot be satisfactorily resolved by the current single target/single therapeutic agents. These agents also have problems with adverse events and patient tolerability. A critical unmet need exists for a topical drug that provides comprehensive management of the four AD demons, including the progression of S. aureus from colonization to pathogenic colonization to infection, that is safe and effective for all ages. Zabalafin is a first-in-class, anti-pruritic, anti-inflammatory, anti-xerotic and S. aureus modulating complex single source topical botanical drug containing multiple compounds with multiple mechanisms of action, enabling the targeting of the four AD demons, with a low-risk side-effect profile.

Materials & Methods:

A recent Phase 2a trial assessed the safety and efficacy of 9.5% zabalafin hydrogel BID in mild/moderate AD that was colonized but not yet at infection stage, ie, the standard AD population (Cohort A double-blind ages 2-66) or in mild/moderate AD with AD at the infection stage (Cohort B open-label ages 3-63).

Results:

In Cohort A, zabalafin BID (n=19) was significantly better than vehicle (n=21) after 4 weeks (IGA 1-point decrease; p<.002) with no safety concerns. In Cohort B, 11 patients completed 8-weeks and 8 completed 12-weeks. Clinically relevant NRS reduction >4 occurred in 13/19 (68%) at EOT. Clinically relevant QoL improvement (POEM) of >6 occurred in 18/19 (95%) patients with EASI50 n=14, 74%; EASI75 n= 7, 37%; EASI100 n= 2, 10%. IGA clear/almost clear and >2 improvement were achieved in 4/8 (50%) at 12 weeks. For patients with S. aureus infection, 16/19 (84%) infections were cleared (bacteriology confirmation) and 6/6 (100%) with MRSA were cleared. SIRS showed an overall decrease and correlated with bacterial clearance. In support of safety, only 1 AE occurred for study drug (mild transient stinging with no interruption in treatment). Efficacy was demonstrated for all endpoints regardless of initial infection status, as evidenced by improvement in pruritus NRS, POEM QoL, IGA, EASI, S. aureus clearance, and SIRS.

Conclusion:

These findings demonstrate the potential for zabalafin as a singular comprehensive topical approach for AD management that targets the four demons of AD.



Abstract N°: 1440

A Novel Topical JAK1 Inhibitor for Atopic Dermatitis: Safety and Early Efficacy of IN-115314

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A Novel Topical JAK1 Inhibitor for Atopic Dermatitis: Safety and Early Efficacy of IN-115314

Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by pruritus and recurrent eczematous lesions. Dysregulation of the JAK/STAT signaling pathway, particularly JAK1, plays a central role in mediating type 2 cytokines such as IL-4, IL-13, IL-22, and IL-31, which contribute to the pathogenesis of AD. IN-115314 is a novel topical selective JAK1 inhibitor, exhibiting 10–36-fold higher selectivity for JAK1 over other JAK family kinases in vitro. This first-in-human clinical study aimed to evaluate the safety, pharmacokinetics (PK) including systemic absorption, and preliminary efficacy of IN-115314 ointment in healthy subjects and patients with AD.

Materials & Methods:

The study included both healthy subjects and patients with mild to moderate atopic dermatitis. In the healthy cohort, a single-dose application of 0.3% and 0.5% IN-115314 ointment was administered in groups of four participants (3 active:1 placebo) per concentration, whereas the 1%, 3%, and 5% formulations were evaluated in groups of eight participants (6 active:2 placebo) per concentration. For multiple-dose administration, 1%, 3%, or 5% ointment was applied twice daily for 14 days in groups of eight participants (6 active:2 placebo) per dose. In the patient cohort, individuals with 3–30% body surface area (BSA) involvement and mild to moderate AD (EASI score < 23) received either 1% or 3% IN-115314 ointment, or pimecrolimus cream, applied twice daily for 28 days, with twelve participants (8 active:4 comparator) in each group. PK endpoints included Cmax, AUC, Tmax, and t1/2. Efficacy assessments included changes from baseline in the Eczema Area and Severity Index (EASI), Investigator's Global Assessment (IGA), and Dermatology Life Quality Index (DLQI). Safety was evaluated throughout the study, including assessments of both systemic and local adverse events (AEs).

Results:

Minimal systemic absorption was observed in both cohorts. In healthy subjects, plasma concentrations were mostly below the limit of quantification (LLOQ) even at the 5% group. In AD patients, steady-state plasma concentrations above the LLOQ were observed in only 2 of 8 participants in the 1% group and 5 of 8 participants in 3% group. Statistically significant improvements were noted in EASI, IGA, and DLQI scores from baseline ($p<0.05$), as well as in the pruritus numeric rating scale (NRS), indicating a rapid reduction in itch. The incidence of AEs was low, with no clinically significant systemic AEs reported. Local application site reacions were mild and

comparable to those observed with the placebo or comparator (pimecrolimus) treatment.

Conclusion:

IN-115314 showed favorable safety, low systemic exposure, and early signs of clinical efficacy when applied topically to both healthy individuals and patients with AD. These findings support its further development as a topical selective JAK1 inhibitor for the treatment of atopic dermatitis.



Abstract N°: 1455

Clinical trial exit interviews in patients with moderate to severe Chronic Hand Eczema: evaluation of treatment experiences with delgocitinib cream 20 mg/g in the phase 3 DELTA 1 trial

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Introduction & Objectives: Clinical trial exit interviews can provide valuable insight into patients' experiences and highlight the treatment benefits that are most meaningful to them. In the phase 3 DELTA 1 (NCT04871711) trial, significantly more patients with moderate to severe Chronic Hand Eczema (CHE) treated with the topical pan-JAK inhibitor delgocitinib cream 20 mg/g vs cream vehicle achieved the primary endpoint of Investigator's Global Assessment for CHE treatment success (IGA-CHE TS, defined as IGA-CHE score of 0/1 [clear/almost clear] with a ≥2-step improvement from baseline) at Week 16. Here, we summarise patient-reported treatment experiences in DELTA 1 and how they compare to achievement of IGA-CHE TS.

Materials & Methods: In DELTA 1, adults with moderate to severe CHE received delgocitinib cream or cream vehicle twice daily for 16 weeks. In this post hoc analysis, patients who completed treatment with delgocitinib cream were invited for a 1-hour telephone/video call. Participants who were fluent in English and provided written consent were asked to describe changes (improvement, worsening or minimal change) in signs/symptoms of CHE and to discuss impact on health-related quality of life (HRQoL). Verbatim interview transcripts were analysed using AI software (ATLASti.com).

Results: The 23 participants (male, n=9; female, n=14) who completed exit interviews had baseline characteristics consistent with the total population of DELTA 1. The majority of interview participants who discussed each individual key skin-related sign/symptom of CHE at Week 16 reported improvements in cracked skin (n=14/19), pain (n=15/20), redness (n=12/13), dryness (n=10/13), itch (n=10/14), and flaking (n=11/12). The majority felt 'satisfied' or 'very satisfied' with these sign/symptom improvements (n=13/23) and reported a positive impact on their HRQoL across multiple domains, including activities of daily living (n=12/22), emotional wellbeing (n=15/21), physical functioning (n=10/15), and social functioning (n=9/15). Although only 4 of 23 interview participants achieved IGA-CHE TS, all the participants not meeting IGA-CHE TS still reported improvement in at least one sign/symptom (n=19/19) with the majority reporting a positive impact on at least one HRQoL domain (n=15/19). These results highlight that IGA-CHE TS is a high threshold for defining treatment success and may not identify all participants with positive response to delgocitinib cream. Notably, no participants who did achieve IGA-CHE TS reported worsening in any signs/symptoms or HRQoL domains.

Conclusion: This analysis of exit interviews shows that delgocitinib cream 20 mg/g provides meaningful improvement in signs/symptoms and HRQoL in patients with moderate to severe CHE, including a majority of participants who did not meet IGA-CHE TS at Week 16 still reporting satisfaction and treatment benefits across all relevant symptoms and signs of CHE.



Abstract N°: 1458

Improving paediatric experience in connection with injection treatment to Atopic dermatitis

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Introduction & Objectives:

More and younger children with atopic eczema need injection treatment. This places different demands on us. It can be challenging for both the family and us as staff.

Medical procedures can induce pain and anxiety in children, potentially leading to long-term psychological effects, including fear of future treatment, needle anxiety and reduced engagement in healthcare. This study presents a structured, ethically sound approach to injection procedures ensuring that no child undergoes an injection without proper local anesthesia, in accordance with national and international ethical guidelines.

Materials & Methods:

A structured protocol was implemented, emphasizing patient/ families-centered care. Key components included:

• Plan A: Pre-procedure counseling between nurse, child, and parents to assess prior experiences and discuss pain management preferences.

• Five mandatory principles: application of topical anesthetic cream, use of sucrose solution or breastfeeding for infants, proper patient positioning, age-appropriate distraction techniques, and effective communication strategies.

• Plan B: Referral to the pediatric department for nitrous oxide sedation when necessary.

Results:

The implementation of these principles improved the pediatric experience during injection treatments. Children demonstrated reduced anxiety, improved pain management, and increased cooperation. The occurrence of unintentional restraint decreased, mitigating procedure-related trauma.

Conclusion:

A structured, child-centered approach to pediatric injection procedures enhances both ethical and clinical outcomes. By integrating pain management strategies and communication techniques, children receiving injections for atopic dermatitis experienced a less distressing, more positive healthcare encounter. This model aligns with ethical mandates prioritizing child welfare, setting a standard for best practices in dermatological care.



Abstract N°: 1541

Improvement of atopic dermatitis-like symptoms in a murine model via the chromogranin A-derived peptide catestatin

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Introduction & Objectives:

Atopic dermatitis (AD), a prevalent chronic inflammatory skin disorder, is characterized by compromised skin barrier and heightened immune responses. The study investigates the therapeutic efficacy of catestatin (CST), a chromogranin A-derived antimicrobial peptide, in mitigating AD-like symptoms.

Materials & Methods:

Utilizing both keratinocyte cultures and a C57BL/6 mouse model, we examined CST's impact on skin barrier proteins, tight junction (TJ) integrity, inflammatory cytokines, and AD-like symptoms.

Results:

CST administration led to a significant upregulation of skin barrier proteins and improved TJ function, counteracting the negative effects of Th2 cytokines on these parameters. In a 2,4-dinitrochlorobenzene-induced AD mouse model, CST treatment markedly reduced AD-like symptoms, including ear thickness, transepidermal water loss, and scratching behavior, and normalized barrier protein expression and TJ barrier function. Furthermore, CST was found to interact with the Notch1 receptor, activating the Notch1/PKC pathway, which may underlie its skin barrier-enhancing properties.

Conclusion:

Collectively, these findings suggest CST as a promising therapeutic agent for AD, capable of enhancing skin barrier function, modulating immune responses, and targeting the Notch1/PKC pathway, offering a novel approach to AD treatment focusing on barrier restoration and immune modulation.

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EUROPEAN ACADEMY OF DERMATOLOGY & VENEREOLOGY

Abstract N°: 1547

A cross sectional study of Clinico-Demographic Patterns and Characteristics of Adult Atopic Dermatitis in skin of colour

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Introduction & objectives:

Atopic Dermatitis(AD) is not limited to childhood; many patients first experience symptoms in adulthood, and a significant portion of childhood cases persist into adulthood. This study characterises adult atopic dermatitis in the Indian population, addressing the scarcity of specific data. The aim of the present study was to study the clinicodemographic patterns and characteristics of adult patients having AD.

Materials & methods:

This cross-sectional observational study recruited adult AD patients aged 18 and above, diagnosed using the Hanifin and Rajka criteria. This study investigated the clinico-demographic features of adult AD, with a focus on disease onset, prevalence, minor clinical features, site involvement, morphological patterns, seasonal variation, and gender differences.

Results:

We enrolled 150 patients (76 males, 74 females). The median age of onset of AD was 22 years (IQR: 12.25 to 34), with 68% (102) having disease onset in adulthood. The median duration of illness was 7.5 years (IQR: 4–15.75 years).

The median IgE, AEC, and SCORAD values were 1010 IU (IQR: 213.25–3192.00), 0.33 (IQR: 0.20–0.60), and 30 (IQR: 22–40.88), respectively.

Disease commonly began in the head and neck (32%) and upper limb flexors (25.33%). Flexor involvement (elbow: 63.3%, popliteal fossa: 52%) and extensor patterns (elbow: 54.7%, knee: 26.7%) were noted, along with nasal sparing (43.33%).

Morphologies included papular (40.7%), follicular (40%), nummular (34.7%), lichenification (38.6%), and prurigo (20.7%), with prurigo more common in older age groups ($p = 0.041$).

Two-thirds of cases had adult-onset AD; one-third had childhood-onset persisting/recurring in adulthood. Prevalence was equal among genders, peaking in the 18–30 age group (46.7%) and lowest in the 61–70 years group (6%).

Elevated IgE levels (84%) indicated extrinsic AD; 31.7% had elevated AEC.

Key features included xerosis (96.7%), keratosis pilaris (80%), intolerance to wool/solvents (76%), and seasonal triggers (winter: 35.3%, summer: 30.7%). Family history of atopy was found in 51%, with allergic rhinitis (79.3%) as the most common comorbidity.

Childhood-onset disease persisting into adulthood was associated with more itching when sweating (83.8% vs 36.4%, $p = 0.007$), cheilitis (81.1% vs 52%, $p = 0.008$), perifollicular accentuation (83.8% vs 58.8%, $p = 0.020$),

orbital darkening (81.1% vs 58.8%, p = 0.044), and Dennie–Morgan folds (73% vs 44.1%, p = 0.010).

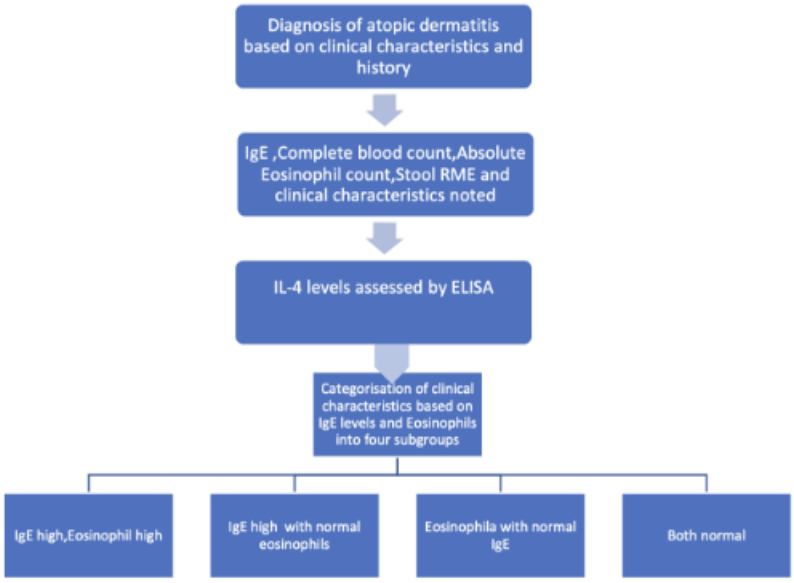
Males showed more severe disease (23.6% vs 9.5%, p = 0.026), involving the head and neck (86.8% vs 73%, p = 0.034) and extensors (63.2% vs 45.9%, p = 0.034), as well as early-onset disease (15.8% vs 5.4%, p = 0.039).

Females had higher rates of non-specific hand/foot dermatitis (86.8% vs 73%, p = 0.034) and prurigo (25.5% vs 10.8%, p = 0.103).

Conclusion:

Adult atopic dermatitis (ad) demonstrates significant clinical and demographic heterogeneity, distinct patterns of involvement, such as flexor/extensor distribution, site-specific morphologies, and gender-based differences, were identified, emphasizing the need for personalized management.

Study Design:



Basic Details	Median (IQR) || Min-Max OR N (%)
Current age (Years)	32.00 (22.25-43.75) || 18.00 - 70.00
Current age	
• 18-30 Years • 31-40 Years • 41-50 Years • 51-60 Years • 61-70 Years	• 70 (46.7%) • 33 (22.0%) • 21 (14.0%) • 17 (11.3%) • 9 (6.0%)
Gender	
• Male • Female	• 76 (50.7%) • 74 (49.3%)
Age at Onset (Years)	22.00 (12.25-34.00) || 0.10 - 62.00
Total Duration of Illness (Years)	7.50 (4.00-15.75) || 0.50 - 41.00
pattern/mode of onset of AD	
• Adult Onset • Childhood Onset with Persistence in adulthood • Onset in childhood followed by Remission and then recurrence in Adulthood	• 102 (68.0%) • 37 (24.7%) • 11 (7.3%)
SCORAD	30.00 (22.00-40.88) || 6.00 - 75.80
SCORAD Category	
• Mild • Moderate • Severe	• 48 (32.2%) • 77 (51.7%) • 24 (16.1%)
Absolute Eosinophil Count (10^3 cells/ul)	0.33 (0.20-0.60) || 0.00 - 1.83
Serum IgE (IU/ml)	1010.00 (213.25-3192.00) || 10.00 - 38220.00



Abstract N°: 1550

Correlation between clinical characteristics and lab parameters in a cohort of adult patients having atopic dermatitis

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Introduction & Objectives:

AD is not limited to childhood; many patients first experience symptoms in adulthood, and aA significant portion of childhood cases persist into adulthood. This study characterises adult atopic dermatitis in the Indian population, addressing the scarcity of specific data.The aim of the present study was to correlate the clinical characteristics of adult patients having AD with their IgE, eosinophil and IL-4 levels.

Materials & Methods:

This cross-sectional observational study recruited adult AD patients aged 18 and above, diagnosed using the Hanifin and Rajka criteria. We divided the patients into four groups (Both high, both low, eosinophilia with normal IgE, IgE high with normal eosinophils) and compared the clinicodemographic data amongst these groups.

Results:

We enrolled 150 patients (76 males,74 females). The median age of onset of AD was 22 (IQR: 12.25 to 34) years with 68% (102) having disease onset in adulthood, the median duration of illness being 7.5 years (IQR:4-15.75 years).

The median IgE, AEC and SCORAD values were 1010 IU (213.25-3192.00), 0.33(IQR:0.20-0.60) and 30(IQR:22-40.88) respectively. Among the 150 participants, 28.7% had elevated IgE and AEC (group A), 14.0% had normal IgE and AEC (group B), 2.0% had elevated AEC only (group C), and 55.3% had elevated IgE only (group D).

Group A showed a higher prevalence of atopy (88.4% vs 57.1%, p=0.040), asthma(23.3% vs 0%, p=0.045), eczema deterioration from environmental factors(88.4% vs 42.9%, p=0.001), Dennie-Morgan fold(62.8% vs p=0.016), lower back(72.1% vs 38.1%, p=0.030), knee involvement(41.9% vs 9.5%, p=0.013) compared to group B.

Group B had more hand eczema(47.6% vs 14% vs 14.5%, p=0.006) compared to groups A and D. Group C had more asthma cases than group B(33.3% vs 0%, p=0.045). Group D exhibited more Dennie-Morgan fold than group B(53% vs 28.6%, p=0.016). Groups A and D shared similar features, differing mainly in antecubital fossa as site of onset(42.9% vs 16.2%, p=0.010) and nasal sparing(76.7% vs 33.7%, p=0.028), more common in group A.

Disease severity varied significantly: group A had the highest SCORAD (median 34, 67.4% moderate cases), group B had the lowest SCORAD (median 24.85, 52.4% mild cases), and group D had 45.7% moderate cases.

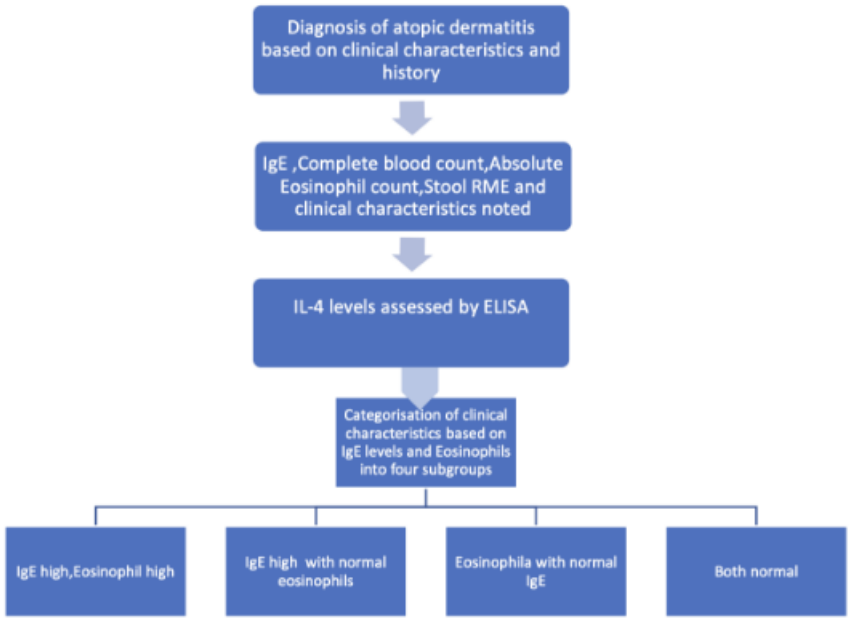
Serum IL-4 levels were elevated in cases (median 81.9) compared to controls (median 69.78), with no subgroup differences.

Conclusion:

Overall, this study contributes to our understanding of various endotypes and phenotypes of adult AD based on age-appropriate IgE levels and eosinophil levels. The findings highlight the clinical differences, disease course, and

associated factors between these subtypes, which can aid in personalised care for individuals with AD.

Study Design:



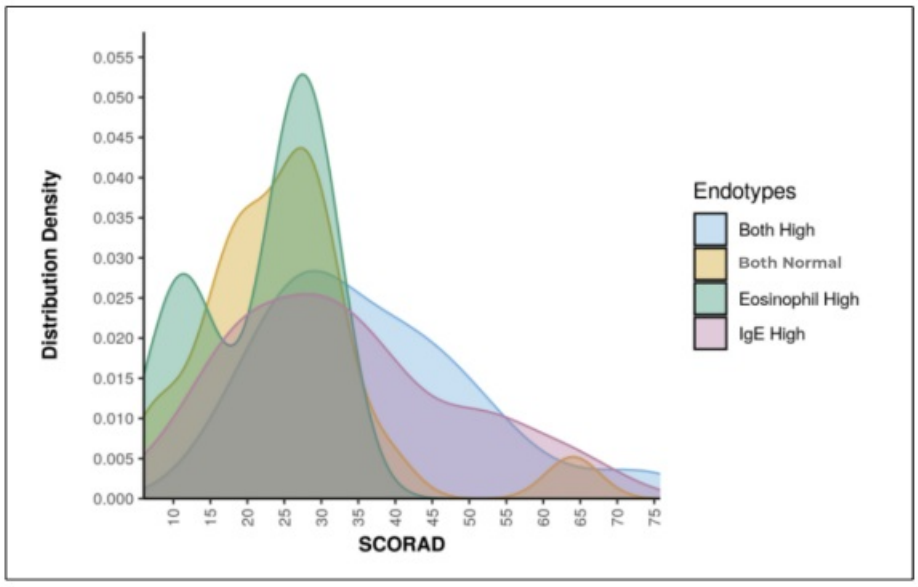


Figure 74:The density plot above depicts the distribution of SCORAD in the 4 different groups of the variable Endotypes with X axis depicting the SCORAD and Y axis depicting the distribution density.



Abstract N°: 1597

Assessing Physician and Patient-Reported Clinical and Humanistic Disease Burden Among White Patients with Atopic Dermatitis and Those From Other Races/Ethnicities in the United States

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Introduction & Objectives: The objective was to compare clinical burden, treatment satisfaction, quality of life (QoL), impairment of daily work/activities across White patients with AD and those of Other Races/Ethnicities (ORE).

Materials & Methods: Data were from the Adelphi AD Disease Specific Programme™, a cross-sectional survey with retrospective data collection of physicians and their adult AD patients with history of moderate-to-severe disease in the US (August 2022–March 2023).

Results: 215 patients were included; 37 (17%) ORE, 178 (83%) White; mean age [SD] ORE 34.1 [12.6] years, White 40.4 [15.6] (p=0.022). Though sex, disease duration, and physician reported severity (IGA, BSA) were similar across cohorts, significant differences were seen between DLQI scores of ORE and White patients (8.2 [7.4], 3.5 [4.7]; p<0.001), POEM (9.2 [6.5], 5.5 [5.3]; p<0.001), EQ-5D-5L (0.814 [0.257], 0.917 [0.137]; p<0.001), overall mean percent work impairment due to AD (27.7% [30.0], 13.7% [16.3]; p=0.003) and percent activity impairment (25.1% [22.0], 16.3% [15.7]; p=0.005), respectively.

Significantly more ORE than White patients suffered from negative self-opinion (56%, 22%; p<0.001), anxiety (47%, 22%; p=0.002) and self-consciousness due to AD 'all the time'/'sometimes' (62%, 33%; p<0.001).

Non-systemic, systemic and Advanced Therapy (biologic/Oral JAK-I) use similar across cohorts. Significantly less physician-stated satisfaction with disease control in ORE than White patients (65%, 82%; p=0.015). ORE patients stated less satisfaction than White (47%, 84%; p<0.001).

Conclusion: Though similar in demographics, severity and treatment use, ORE patients experience greater impact on QoL, work productivity, negative self-image, mental health, potentially leading to lower patient/physician-reported satisfaction with disease control.

Presented at American Academy of Dermatology - 83rd Annual Meeting; Florida, USA; 7-11 March, 2025.



Abstract N°: 1599

Raising the Bar of Efficacy in Atopic Dermatitis: Lebrikizumab Maintains Depth of Response Over 3 Years in Week 16 Responders

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Introduction & Objectives: In prior analyses of the phase 3 monotherapy trials, ADvocate1, ADvocate2, and the long-term extension study ADjoin (NCT04392154), many patients treated with lebrikizumab maintained a deep response (defined by total skin clearance and minimal itch) up to 2 years.1 Here, we report sustained depth of response and maintenance in patient-assessed severity with lebrikizumab treatment up to 3 years (1 year in ADvocate1 and -2 and 2 years in ADjoin).

Materials & Methods: Lebrikizumab responders at Week 16 (achieved ≥75% improvement in Eczema Area and Severity Index [EASI 75] or Investigator's Global Assessment [IGA] of 0/1 without rescue therapy) who completed ADvocate1 and ADvocate2 (1 full year) and enrolled in ADjoin, received lebrikizumab 250 mg every 2 or 4 weeks (Q2W or Q4W) for an additional 2 years. Deep response was assessed using IGA 0 (clear skin), EASI 90, EASI 100 (≥90% or 100% EASI improvement), and Patient-Oriented Eczema Measure (POEM) of 0/1 (clear/almost clear skin). POEM measures patient-reported symptoms including itch, skin dryness, and sleep disturbance over the previous week. Analyses were descriptive using as-observed data.

Results: At Week 100 of ADjoin (3 years of lebrikizumab treatment), IGA 0 was reported for 63.4% [26/41] of patients receiving lebrikizumab Q2W; 50.0% [25/50] receiving lebrikizumab Q4W. EASI 90/EASI 100 was reported for 79.4% [50/63]/49.2% [31/63] of patients receiving lebrikizumab Q2W; 86.8% [59/68]/50.0% [34/68] receiving lebrikizumab Q4W. POEM 0/1 was reported for 24.0% [12/50] of patients receiving lebrikizumab Q2W; 32.7% [18/55] receiving lebrikizumab Q4W.

Conclusion: A large percentage of Week 16 lebrikizumab responders maintained total or near total skin clearance through 3 years of lebrikizumab treatment.

Reference:

1. Simpson E, Biedermann T, Kircik L, et al. Raising the bar of efficacy in atopic dermatitis: lebrikizumab maintains depth of response over 2 years. *Br J Dermatol*. 2024;191(Suppl_2) doi:10.1093/bjd/ljae266.082

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Abstract N°: 1603

Individual Clinical Response Trajectories to Lebrikizumab in Atopic Dermatitis: A Cluster Analysis

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Introduction & Objectives: The study aimed to assess individual patient experiences to lebrikizumab using data from the ADvocate1 and ADvocate2 monotherapy trials, to better determine the variety and breadth of clinical responses, and to better inform real-world experience. A cluster analysis was conducted to identify response patterns in patients with moderate-to-severe atopic dermatitis over the first 16 weeks of lebrikizumab treatment in the ADvocate1 and ADvocate2 monotherapy trials

Materials & Methods: Per-protocol response criteria can have limited ability to inform patient–healthcare provider dialogue** as** individual patient experiences may vary in the same responder population. This analysis aimed to assess individual patient trajectories of response to lebrikizumab using data from the ADvocate monotherapy trials.

Results: This analysis included patients with moderate-to-severe atopic dermatitis treated with 250-mg lebrikizumab every 2 weeks from the pooled ADvocate1 and ADvocate2 trials (modified intention-to-treat populations) during the induction period (weeks 0-16). A machine learning growth mixture model (GMM) was used to cluster patients by longitudinal trajectory of percent change in the Eczema Area and Severity Index (EASI). Proportions and rates of patients achieving EASI thresholds were evaluated.

The GMM clustered patient response trajectories (N=564) into 2 groups. Cluster 1 (EASI responders) comprised 85% of patients (n=477), and on average achieved an EASI50 response at week 4 and with a continued response trajectory beyond EASI75. Cluster 2 (EASI nonresponders) comprised 15% of patients (n=87), with a mean EASI reduction of 24% at week 16. A GMM on Cluster 1 identified 3 subclusters (Clusters 1A/1B/1C), which varied by depth of and time to response and represented 38%, 32%, and 15% of patients, respectively. Patients in Clusters 1A, 1B, and 1C achieved mean EASI reductions of 93%, 84%, and 67%, respectively, at week 16. All clusters, including nonresponders in Cluster 2, had notable improvements in itch and quality of life.

Conclusion: This analysis identified distinct EASI response patterns to lebrikizumab, which may help guide patient and healthcare provider expectations.

Presented at American Academy of Dermatology - 83rd Annual Meeting; Florida, USA; 7-11 March, 2025.



Abstract N°: 1644

Patient perspectives in moderate-to-severe chronic hand eczema: Understanding patient experience and factors influencing treatment preference through in-depth qualitative patient interviews in the US

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Introduction & Objectives:

Chronic hand eczema (CHE) is a form of eczema disease affecting the hands and wrists characterized by dry skin, itch, pain, redness, cracking, flaking, blistering, and in some cases, bleeding, persisting for ≥ 3 months or recurring at least twice within 1 year. Due to its chronic nature, CHE can have a profound impact on patients' lives and daily activities. Currently, there are few approved treatment options for CHE globally, but several products are being investigated in clinical trials and sometimes used off-label with varied effectiveness, safety, and modes of administration. A better understanding of patient preferences and factors influencing treatment choices in this population is thus required. This qualitative study evaluated treatment attributes important to adult patients with moderate-to-severe CHE providing a basis to inform the design of a discrete choice experiment (DCE) survey.

Materials & Methods:

Semi-structured one-on-one qualitative interviews were conducted in adults (≥18 years) with moderate-to-severe CHE recruited via a panel of geographically and demographically diverse individuals in the US. Eligible participants self-reported (1) having CHE, and (2) inadequate response to prior topical corticosteroids or prior/current use of systemic therapy or phototherapy for CHE. Participants were asked about their general treatment experience, and factors of importance when choosing to start their current or most recent treatment. Additionally, participants rated the importance of 16 attributes related to treatment effectiveness, safety, and logistical considerations (1 to 5 scale, with 5 being the most important).

Results:

Interviews were conducted with 15 patients (mean age 44.5 years; 67% female; 53% White; 87% employed; 73% diagnosed > 5 years ago) across various CHE subtypes (multiple subtypes: 60%; atopic only: 33%; other: 7%). At the time of the interviews, 67% were treated with topical corticosteroids, 33% with injectables, and 27% with oral treatments, while phototherapy was least common (7%). Most participants reported their treatment helped manage symptoms and alleviate flare-ups, though they expressed a lack of complete skin clearance. Most participants found the frequency of treatment dosing schedules to be manageable and convenient.

When rating the importance of treatment attributes, effectiveness was consistently considered a key factor in treatment decisions, with itch relief, skin appearance, duration of symptom improvement, and pain ranked among the most important. Among effectiveness attributes, speed of onset was ranked lowest in importance. Safety concerns, including risk of infections, malignancies, major cardiovascular events, were also key considerations. Treatment logistics, including monitoring, costs, mode (whether topical, oral, or injectable) and frequency of

administration, were ranked as less important.

Conclusion:

Qualitative interviews highlighted effectiveness being a key driver of patient treatment preferences, followed by safety considerations (risk of infection, malignancies, and major cardiovascular events). These findings provide a basis for the design of a DCE study to quantify the relative importance of treatment attributes in moderate-to-severe CHE.

Table 1. Attribute ratings

Attribute	Overall	
	Mean	Rank
Effectiveness attributes		
Itch reduction	4.7	**1**
Improvement in skin's appearance	4.6	**2**
Sustained effectiveness	4.2	**5**
Pain reduction	4.0	**7**
Onset of action	3.8	**8**
Safety attributes		
Risk of serious respiratory tract infection	4.5	**3**
Risk of infection (other than serious respiratory tract infections)	4.3	**4**
Risk of malignancies	4.1	**6**
Risk of major cardiovascular events	3.8	**8**
Risk of thromboembolic event	3.6	10
Risk of muscle or joint pain	3.5	11
Risk of eye disorders	3.4	12
Risk of edema	3.3	13
Logistical attributes		
Monitoring requirements	3.3	13
Cost of treatment	3.3	13
Mode and frequency of administration of the treatment	3.1	16

Note:
Attributes with the highest ranking are bolded.

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Abstract N°: 1685

A 1% Colloidal Oat Balm was More Effective than a Standard Lotion in Protecting and Moisturizing the Skin Barrier in an Ex Vivo and Clinical Model

Alana Levine*[1], Rachel Junod[1]

[1]Kenvue Brands, LLC, Summit, United States

Introduction & Objectives:

The stratum corneum of infant skin is thinner and loses moisture quicker than adult skin, while the pH buffering capacity of the skin is still developing. If their moisture barrier is not maintained, an infant's skin can become vulnerable to external allergens penetrating the stratum corneum, which can increase the risk of sensitization and subsequent development of atopic disease. One way of fortifying the skin barrier is by using an appropriate moisturizing emollient. Moisturizers come in many different forms with various benefits and ingredients. Past research has shown a thick, emollient rich balm with colloidal oat helps hydrate the skin barrier. Few studies have evaluated whether this formulation can fortify the skin barrier by forming a protective barrier on baby's skin to help seal in moisture and reduce allergen penetration. A 1% colloidal oat balm (COB) was hypothesized to show superior efficacy compared to a standard lotion (SL) in improving skin parameters including pH, hydration, barrier function, and visual dryness in two different study designs.

Materials & Methods:

In Study A, an ex vivo model with adult skin (age 40) that underwent tape stripping to mimic infant skin evaluated a COB, a SL, and petrolatum for efficacy in preventing penetration of soy peptide (SP) and house dust mite allergen (HDM).

Study B was a 48-hour moisturization clinical study was conducted on females with dry skin (n=58, ages 18-65 years old) to compare the efficacy of the COD to the SL and a cream. Instrumental measurements of skin capacitance, conductance (hydration), trans-epidermal water loss (TEWL), and clinical grading evaluations of visual dryness and tactile surface roughness were assessed over the course of 48 hours after a single application of product.

Results:

The SL allowed a statistically significantly greater amount of SP ($p<0.05$) (Fig1) and HDM ($p<0.001$) (Fig2) to penetrate the stratum corneum compared to the COB. When analyzing skin samples treated without the SP or HDM, the COB exhibited the most substantial reduction in skin surface pH, compared to the SL (Fig3).

There was a statistically significant improvement in skin hydration for all formulations; however, the COB showed the greatest improvement. When compared to the SL and cream, the COB had statically significant improvement in moisturization of 4x more and up to 2x more moisturizing respectively.

All formulas showed statistically significant improvement in trans-epidermal water loss with the COB having a greater improvement compared to the SL. This indicated the COB had better and long-lasting improvement in skin barrier function. The COB also had statistically significant improvement in visual dryness when compared to the SL at 1 hr and in surface roughness, respectively. This confirms the COB formula acts as a protective layer fortifying the skin barrier by reducing trans-epidermal water loss and minimizes dry-skin related symptoms such as visual dryness and surface roughness.

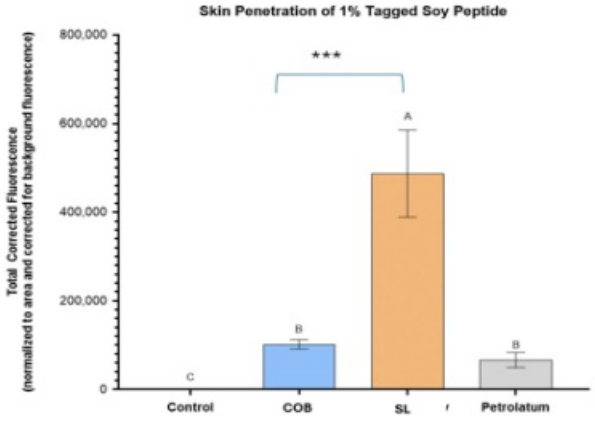


Figure 1: Total corrected fluorescence calculated from fluorescence microscopy images of skin samples treated for 16 hours with COB, SL and Petrolatum containing 1% of tagged soy peptides compared to untreated skin sample (control) after 16 hours of incubation in Franz diffusion cells. Total intensity normalized to the area and corrected for any background fluorescence using formula TCF = Integrated density – (area of ROI x Mean Background Intensity), where the values were obtained from ImageJ analysis of each fluorescence image. The bar graph is representative of mean TCF from 6 images ± SEM. One-way ANOVA statistical analyses with Tukey's Post hoc test were conducted using GraphPad PRISM; treatments not connected by the same letter are statistically different ($p<0.001$)

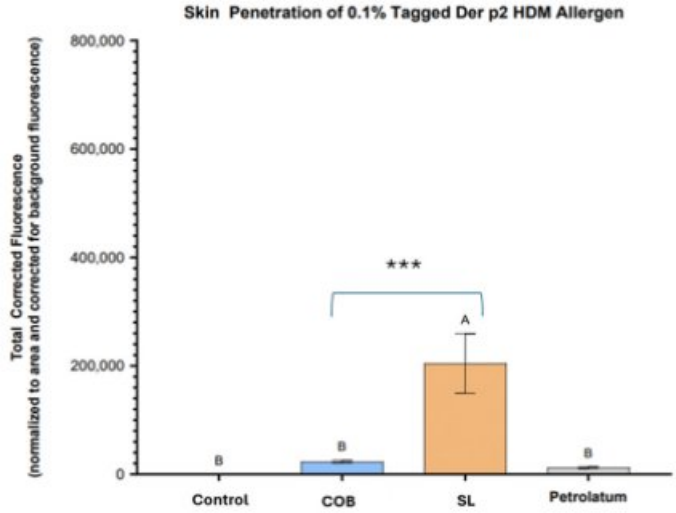


Figure 2 Total corrected fluorescence calculated from fluorescence microscopy images of skin samples treated for 16 hours with COB, SL and Petrolatum containing 0.1% of tagged der p2 allergen compared to untreated skin sample (control) after 16 hours of incubation in Franz diffusion cells. Total intensity normalized to the area and corrected for any background fluorescence using formula TCF = Integrated density – (area of ROI x Mean Background Intensity), where the values were obtained from ImageJ analysis of each fluorescence image. The bar graph is representative of mean TCF from 6 images ± SEM. One-way ANOVA statistical analyses with Tukey's Post hoc test were conducted using GraphPad PRISM; treatments not connected by the same letter are statistically different

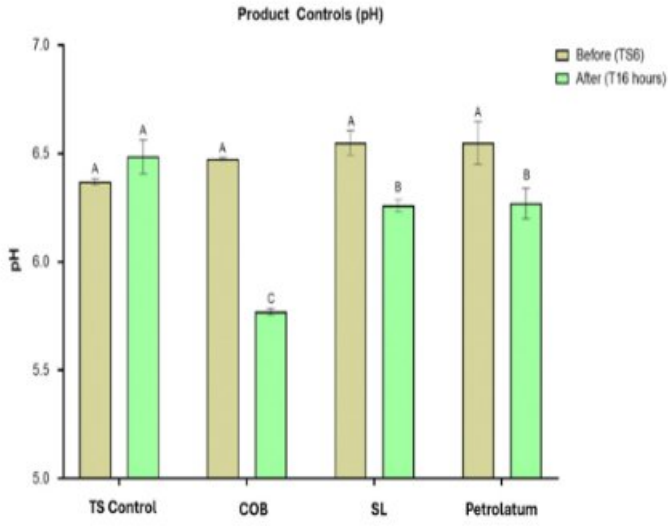


Figure 3 pH measurement at the skin surface obtained before treatment (T0) and after incubation with treatment for 16 hours (T16) with no SP or HDM

Conclusion:

The findings of both studies demonstrate novel multifunction benefits of a COB, especially when compared to a SL, resulting in an elevated class of complex emollients for newborns and infants.



Abstract N°: 1800

Is Juvenile Plantar Dermatosis Associated with Atopy - a Systematic Review and Meta-Analysis

Israel Khanimov[1], Maya Engler Markowitz[1], Igor Snast[1], Yehonatan Noyman[1], Assi Levi[1], Daniel Mimouni[1], Shany Sherman[1]

[1]Rabin Medical Center, Petah Tikva, Israel

Is Juvenile Plantar Dermatosis Associated with Atopy - a Systematic Review and Meta-Analysis

Introduction & Objectives:

Juvenile plantar dermatosis (JPD) is a challenging dermatological condition, clinically characterized by erythematous patches exhibiting a characteristic shiny or glazed appearance, affecting the weight-bearing surfaces of the feet. This condition may manifest with pruritus, tenderness, and discomfort. The precise pathophysiology of JPD remains unclear. While studies have investigated a potential association between JPD and atopy, current evidence remains inconclusive. Therefore, this study aims to perform a systematic review and meta-analysis to further elucidate the association between JPD and atopy, especially in light of the estimated prevalence of personal and familial atopy in the general population—10–30% and 20–40%, respectively.

Materials & Methods:

A systematic review was conducted. The literature search across PubMed, Google Scholar, ScienceDirect, CENTRAL and ClinicalTrials.gov, covering all records from database inception to January 1, 2025. Random-effects model meta-analysis was performed to quantify the pooled proportion (with 95% confidence interval) of patients with atopic background among those diagnosed with JPD. Subgroup analyses were conducted to assess the proportion of personal and familial atopic background. Heterogeneity was assessed using the I^2 statistic.

Results:

Among 958 citations identified from database searching, 25 studies with a total of 1220 subjects were included. Among the 915 participants for whom sex was recorded, 488 (53%) were male. The disease typically manifested between the ages of 5 and 9 years, with a duration ranging from 3 to 10 years. In the majority of patients, the dermatosis symmetrically affected the weight-bearing zones of both plantar surfaces, specifically the distal soles and the plantar aspects of the toes, with sparing of the interdigital spaces.

The pooled proportion of personal atopic background among patients with JPD was 0.29 (22 studies; 95% CI 0.20-0.39, I^2=93.9%), meaning that 1 in 3.4 patients with JPD had personal atopic background. The pooled proportion of atopy among patients with JPD or their relatives (first-degree or distant) was 0.50 (25 studies; 95% CI 0.39-0.60, I^2=95.8%), and in patients with JPD or first-degree relatives was 0.47 (16 studies; 95% CI 0.35-0.60, I^2=98.2%). Data on IgE levels were available for a total of 77 patients across 5 studies. Of these patients, 10 (13%) had elevated IgE levels. Alternative diagnoses of allergic contact dermatitis and fungal infection were less likely as patch tests yielded negative or non-relevant results and mycological tests were negative (17 studies).

Conclusion:

The findings of this systematic review and meta-analysis provide evidence supporting a positive association between JPD and both personal and family history of atopy. These results may contribute to a better understanding of the underlying pathophysiology of this condition.

Figure 1: Forest plot of prevalence of personal atopic background among patients with JPD

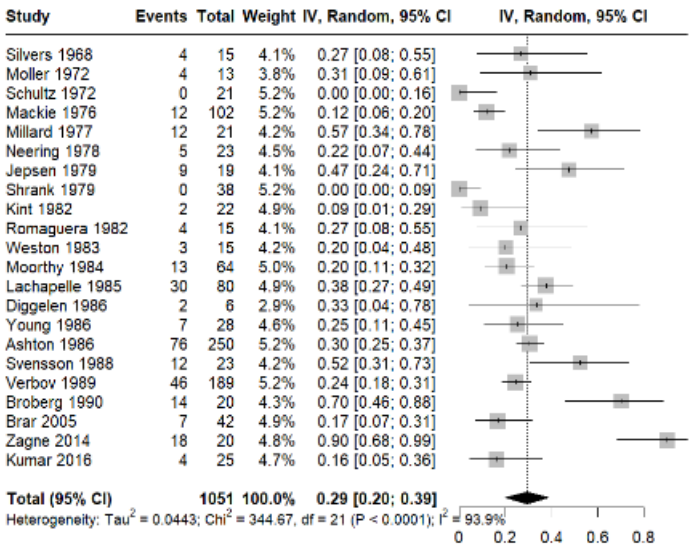


Figure 2: Forest plot of prevalence of atopy among patients with JPD or their relatives (first-degree or distant)

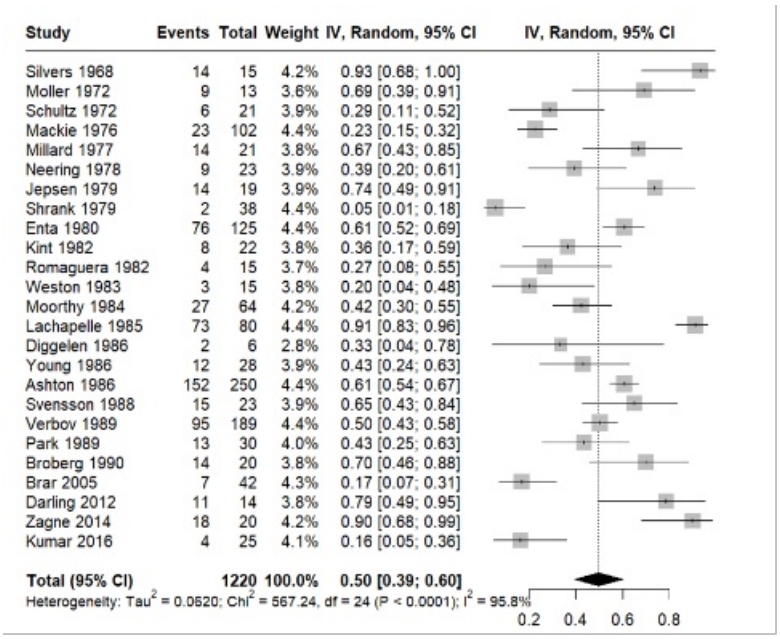
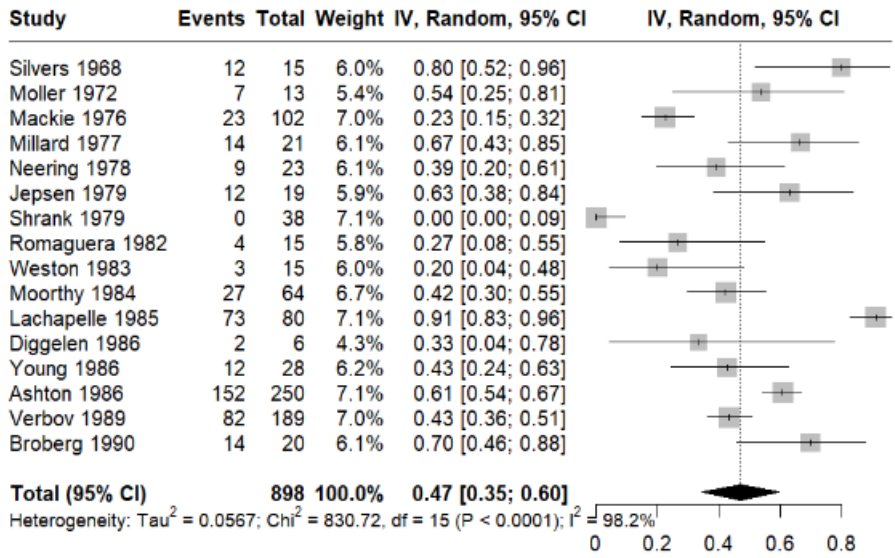


Figure 3: Forest plot of prevalence of atopy among patients with JPD or first-degree relatives



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Abstract N°: 1852

Dupilumab's Impact on Sleep Disruptions in Atopic Dermatitis: A Systematic Review and Meta-Analysis

Dea Metko[1], Shanti Mehta[2], Grace Xiong[1], Eric McMullen[3], Vincent Piguet[3, 4]

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[2]Temerty Faculty of Medicine, University of Toronto, Toronto, Canada
[3]Division of Dermatology, Department of Medicine, Temerty Faculty of Medicine, Toronto, Canada
[4]Division of Dermatology, Women's College Hospital, Toronto, Canada

Introduction & Objectives:

Atopic dermatitis (AD) is a common chronic and relapsing inflammatory condition, for which patients rank pruritus and sleep impairment as the two most impactful factors in disease-related quality of life. In AD, scratching is a well-recognized reason for sleep disturbance, however, other theories including dysregulated IL-4 and higher morning serum IL-31 are correlated with poor sleep efficacy. Non-restorative sleep is in part a consequence of the pruritus in AD. Dupilumab, a monoclonal antibody targeting the IL-4 and IL-13 signalling pathways, has demonstrated efficacy and safety in managing AD. This systematic review and meta-analysis aims to examine efficacy of dupilumab for improving sleep quality in individuals with AD.

Materials & Methods:

A systematic review and meta-analysis was conducted per PRISMA guidelines and registered in PROSPERO. Statistical analysis was conducted to examine the impact of dupilumab on the Sleep Disturbance Numerical Rating Scale (NRS), Pruritus NRS, and Dermatology Life Quality Index (DLQI) in patients with AD. A random-effects model was used to calculate the pooled mean differences (MDs) with corresponding 95% confidence intervals (CIs), with an I^2 statistic $\geq$ 50% indicating significant heterogeneity.

Results:

Fifteen studies were identified and comprised ten retrospective cohorts, four prospective observational studies, and one randomized controlled trial (RCT). Twelve studies qualified for quantitative synthesis based on outcome homogeneity, 10/12 investigated dupilumab in 300 mg biweekly doses, and 2/12 with varied dosages. The cohort of 2,522 patients had a mean age of 30.2 years, and a mean AD duration of 22.1 years. The mean baseline eczema area and severity index (EASI) score was 27.5.

Overall, patients' Sleep Disturbance NRS decreased by 5.1687 (95% CI: 5.8580, 4.4795, p>0.0001) points on average after dupilumab therapy. In the pediatric subgroup analyses, dupilumab had a slightly higher impact on reducing NRS sleep scores than the adult group, with pooled MDs of 5.5128 (95% CI: 6.6281, 4.3975, p>0.001) and 4.8122 (95% CI: 6.4384, 3.1859, p>0.001) respectively. The difference between subgroups was not statistically significant (p=0.3239), dupilumab may be comparably effective in both populations. Dupilumab was also effective at reducing itch, with an average decrease in Pruritus NRS scores of 5.1824 (95% CI: 5.6666, 4.6983, p>0.0001), and improving quality of life, with an average DLQI score improvement of 12.3497 (95% CI: 14.6855, 10.0139, p>0.0001)

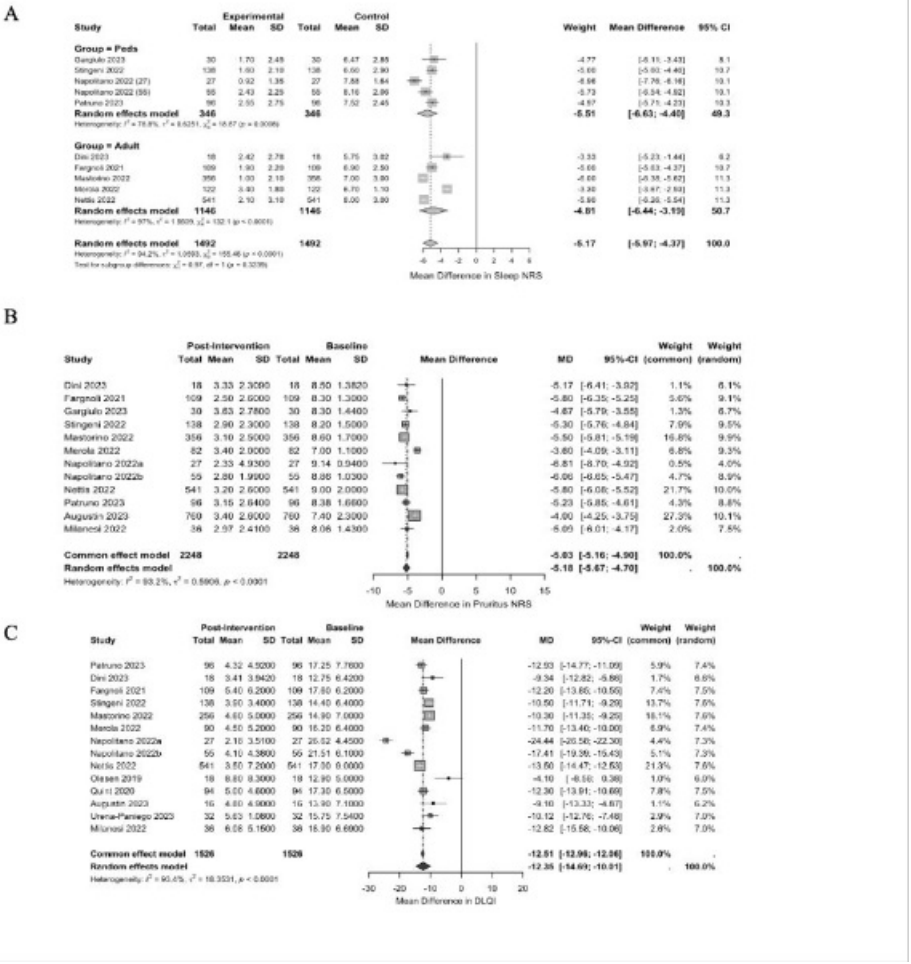
Conclusion:

We highlight the efficacy of dupilumab in improving Sleep Disturbance NRS, indirectly by managing AD related pruritus. Improvements were observed in pediatric and adult populations, suggesting that dupilumab is effective

for sleep related outcomes irrespective of age. Impaired sleep due to AD can be a significant contributor to the overall disease burden, with strong associations to chronic fatigue and insomnia, which serve as predictors of poorer overall outcomes.

Limitations of the present study include its small sample size. Future research should ensure rigorous outcome reporting to further investigate the role of dysregulated cytokines in sleep-related outcomes, including sleep scores, quality, and duration. Further exploration is required to determine which demographic of patients with AD is most likely to report improvement in sleep disturbances from dupilumab use.

Figure 1: Forest Plots of Mean Differences for Sleep Disturbance NRS (A), Pruritus NRS (B), and DLQI (C)





Abstract N°: 1856

Clinical Efficacy, Safety Profile, and Systemic Exposure of Benvitimod Cream 1% Twice-Daily in Pediatric Atopic Dermatitis: Results from a Phase 3 Trial in China

Quanzhong Liu*[1], Genhui Chen[2]

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[2]Thederma Shanghai ltd., Shanghai , China

Introduction & Objectives:

Atopic dermatitis (AD) is a prevalent chronic inflammatory skin disease in children. This study evaluates the efficacy, safety, and systemic exposure of benvitimod (BEN) 1%, an aryl hydrocarbon receptor modulator, in pediatric patients with moderate-to-severe AD. As the first Phase 3 trial in China focusing on BEN for pediatric AD, this study addresses critical gaps in efficacy and safety data for this population.

Materials & Methods:

This multicenter, randomized, double-blind, vehicle-controlled Phase 3 trial (CTR20231413) enrolled participants aged 2 years and older. Participants were randomized 2:1 to receive benvitimod cream 1% or vehicle twice daily for 8 weeks. The pediatric subset (aged 2–17 years) met the Hanifin-Rajka criteria (disease duration ≥6 months in adolescents [12-17 years], ≥3 months in children [2-11 years]); a baseline Investigator's Global Assessment (IGA) score of ≥3; and an affected body surface area (BSA) of 5–35%. Clinical efficacy endpoints included the percentage of participants achieving a 75% reduction in the Eczema Area and Severity Index (EASI75 response rate) and the percentage of participants achieving an IGA score of 0 or 1 with at least a 2-point reduction from baseline (IGA response rate) at Day 56. Safety assessments included treatment-emergent adverse events (TEAEs), and systemic exposure was evaluated through plasma concentrations after 56 days of treatment.

Results:

A total of 142 patients aged 2–17 years were randomized. At Week 8, both the primary and key secondary efficacy endpoints were met with statistical significance in the benvitimod groups versus vehicle: EASI75 response rates were 69.2% vs 31.0% (P<0.001); IGA response rates were 61.5% vs 28.6% (P<0.001). Notably, the treatment effect was particularly pronounced in children aged 7–11 years, with EASI75 response rates of 83.9% vs 19.2% and IGA response rates of 73.3% vs 23.1%. Further age-stratified efficacy data are presented in the table below.

Age Group	2-6		7-11		12-17	
	BEN Group	Placebo Group	BEN Group	Placebo Group	BEN Group	Placebo Group
N	38	18	35	17	23	11
EASI75 Response Rate	58.9%	42.8%	83.9%	19.2%	63.9%	30.0%
IGA Response Rate	57.4%	33.5%	73.3%	23.1%	50.3%	29.1%

TEAEs were predominantly mild to moderate, with incidence rates comparable between the benvitimod group and vehicle group. The incidence of TEAEs across age subgroups was consistent with the overall population, with no significant increase observed.

Systemic exposure (n=10; age distribution: 4 [2-6 years], 5 [7-11 years], 1 [12-17 years]) showed all plasma

concentrations below lower limit of quantification (<0.1 ng/mL), indicating minimal systemic absorption.

Conclusion:

This Phase 3 trial demonstrates that benvitimod cream 1% twice-daily is an effective and well-tolerated treatment for pediatric patients (2–17 years) with moderate-to-severe AD. Significant improvements in EASI75 and IGA response rates were observed, particularly in children aged 7–11 years. The favorable safety profile, with mostly mild or moderate TEAEs and minimal systemic exposure, supports its use as a promising topical therapy for pediatric AD.



Abstract N°: 1880

Atopic Dermatitis with Prurigo Nodularis-like Lesions: Effective Response to Dupilumab in a Pediatric Patient

Isabel Gainza Apraiz[1], Nekane Martínez Peña[1], Leopoldo Fernandez Domper[2], Laura Blanch Rius[1], Marc Juliá-Manresa[1], Rosa María Izu Belloso[1]

[1]Basurto University Hospital, Dermatology, Bilbao, Spain
[2]Mendaro Hospital, Dermatology, Mendaro, Spain

Introduction & Objectives:

Prurigo nodularis (PN) is a chronic inflammatory disease of heterogeneous etiology, primarily affecting middle-aged adults, though it is not uncommon in children. It often arises in the context of atopic dermatitis (AD) or its comorbidities. It is characterized by highly pruritic lesions and chronic scratching. Treatment is largely unsatisfactory in most cases despite multiple therapeutic approaches. In recent years, Dupilumab has become available for the treatment of PN in adults, marking the first drug specifically approved for this condition.

Materials & Methods:

Case report and literature review.

Results:

We present a 9-year-old female patient with a history of AD, asthma, allergic rhinoconjunctivitis, allergies to dust mites, pollen, dog and cat epithelium, and multiple food allergies. Additionally, she had obesity under endocrinological management and an anxiety syndrome undergoing psychological treatment. The patient had mild AD from the first year of life, which was controlled with topical treatments. Over the past year, she developed papulo-nodular, hyperkeratotic, highly pruritic lesions affecting the back of her arms and hands, as well as the anterior aspect of her legs. Based on these findings, the patient was diagnosed with PN in the context of AD. Treatment included potent corticosteroids under occlusion, oral antihistamines, oral corticosteroids, and narrow band UVB, with no improvement in neither pruritus nor the skin lesions. Eventually, Dupilumab treatment was initiated, resulting in a rapid improvement in both lesions and pruritus, which persisted at 24 weeks follow-up without any side effect.

Conclusion:

Dupilumab represents a new effective and safe treatment for atopic dermatitis, and in our experience for atopic dermatitis with a prurigo nodularis phenotype in children, as demonstrated in the case of this patient.



Abstract N°: 1911

Online case-based education improved dermatologists' knowledge, competence and confidence in diagnosing patients with chronic hand eczema.

Elaine Bell[1], Marinella Calle[1], Ana Giménez-Arnau[2]

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[2]SKiN Hospital del Mar Research Institute, Universität Pompeu Fabra, Barcelona, Spain

Introduction & Objectives:

Chronic hand eczema (CHE) is a challenging condition to recognize and accurately diagnose. We assessed whether online education could improve dermatologists' knowledge, competence and confidence in diagnosing patients with this condition.

Materials & Methods:

Dermatologists participated in an online text-based Test and Teach activity entitled 'Can you diagnose and manage these patients with itchy and painful hands and wrists?' The activity featured two patient cases with questions that "tested" knowledge and discussion of the main "teaching" points. Educational effect was assessed using a repeated-pair design, pre-/post-assessment. A paired samples t-test was conducted for significance testing on overall average number of correct responses and for confidence rating, and a McNemar's test was conducted at the question level (5% significance level, P <.05). Cohen's d with correction for paired samples estimated the effect size of the education on number of correct responses (<.20 modest, .20-.49 small, .59-.79 moderate, ≥.80 large). Data were collected from 23 July to 19 September 2024.

Results:

- 1,237 dermatologists took the activity in the defined time period, and of these, 122 completed both pre and post questions
- Overall, this educational activity significantly improved dermatologists' knowledge and competence in the diagnosis of CHE (54% average correct answers pre-activity, 92% post-activity; *P* <.001) and had a large educational impact (Cohen's d=1.51)
- Dermatologists (n=122) showed significant gains in knowledge regarding:
  - The role of validated patient-reported outcome measures when CHE is suspected (20% correct answer pre-activity, 83% post-activity; *P* < .001)
- Dermatologists (n=122) also showed significant gains in competence regarding:
  - Differential diagnosis of CHE (61% correct answer pre-activity, 96% post-activity;*P* < .001)
  - The position of epicutaneous patch testing in the diagnostic pathway (80% correct answer pre-activity, 98% post-activity; *P* < .001)
- The percentage of dermatologists answering all 3 questions correctly rose from 8% at baseline to 80% post-activity
- 34% of dermatologists reported a measurable increase in confidence in diagnosing & managing patients with CHE, with an average confidence shift (for those who increased confidence) of 38%

Conclusion:

This interactive 'test then teach' activity was highly successful in educating dermatologists about recognizing the

signs of CHE & making a differential diagnosis. Dermatologists would likely benefit from further education to reinforce and embed their knowledge and competence, and to support confidence in early diagnosis of CHE in order to initiate effective therapies in a timely manner.



Abstract N°: 1913

Chronic Hand Eczema in France: Expert Insights

Bruno Halioua[1], Florence TETART[2], Camille Leleu[3], Ziad Reguiai[4], Laurent Misery[5], Françoise Giordano[6], Annick Barbaud[7], Marie-Noëlle Crepy*[8]

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[2]Centre Hospitalier Universitaire de Rouen, Service de Dermatologie, Rouen, France
[3]Centre Hospitalier Universitaire de Dijon, Service de Dermatologie, Dijon, France
[4]Polyclinique Courlancy-Bezannes, Service de Dermatologie, Reims, France
[5]Centre Hospitalier Universitaire de Brest, Service de Dermatologie, Brest, France
[6]Centre Hospitalier Universitaire de Toulouse, Service de Dermatologie, Toulouse, France
[7]Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, AP-HP. Sorbonne Université, Hôpital Tenon, Service de Dermatologie et d'Allergologie, Paris, France
[8]Hôpital Hôtel-Dieu, Centre de Pathologies Professionnelles et Environnementales, AP-HP, Paris, France

Introduction & Objectives:

Chronic hand eczema (CHE) is a persistent inflammatory skin disease that significantly impairs patients' quality of life, particularly among individuals in high-risk occupations. Often historically misdiagnosed as atopic dermatitis, CHE has long been subject to inconsistent and suboptimal management strategies. Recent advances in our understanding of its epidemiology, socio-economic burden, and pathophysiology have highlighted the urgent need for more targeted and effective treatment approaches.

This expert panel of French dermatologists and allergologists sought to review and update key clinical aspects of CHE and develop a practical treatment algorithm for daily clinical use in France, rooted in both current evidence and real-world practice.

Materials & Methods:

Over a six-month period, including a virtual meeting held in October 2024, a panel of seven French dermatologists and allergologists engaged in structured discussions to explore the multifaceted nature of CHE. The goal was to consolidate current evidence and clinical experience in order to develop a therapeutic algorithm adapted to real-life dermatological practice in France.

Results:

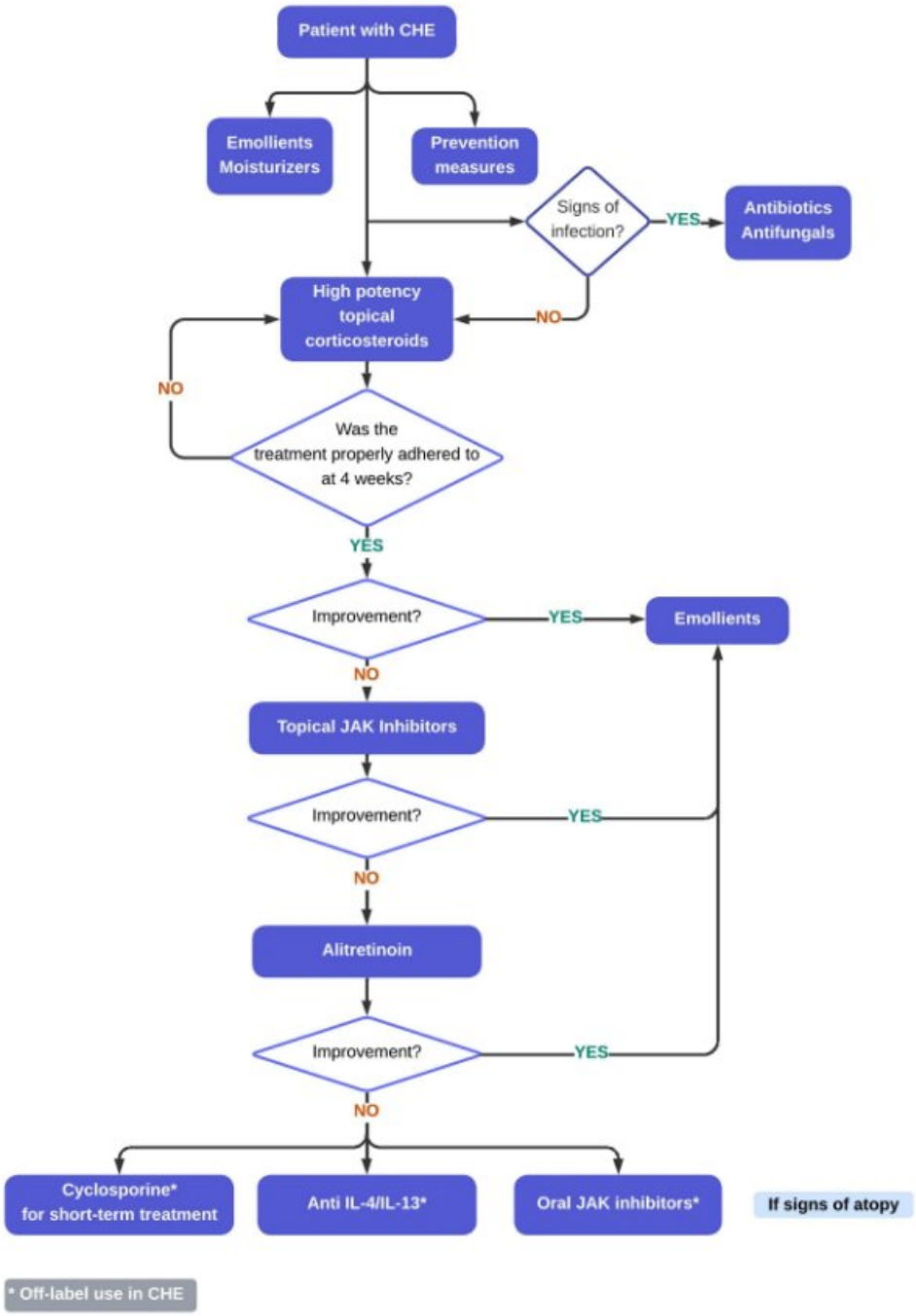
The expert panel conducted an in-depth review of the latest data on CHE, reaffirming the disease's complex etiology, high prevalence in occupational settings, and considerable psychosocial and economic burden. An agreement was reached on updated diagnostic criteria, emphasizing the importance of thorough clinical evaluation, occupational history, and appropriate use of skin and patch testing. Subtypes such as irritant, allergic, atopic, and protein contact dermatitis were discussed, with particular attention to overlapping forms and diagnostic challenges in clinical practice.

Treatment pathways were critically appraised, distinguishing between approved and off-label therapies currently available in France. The panel highlighted the emerging role of new targeted therapies, in managing moderate-to-severe CHE. Preventive strategies, including patient education on irritant and allergen avoidance, were also emphasized.

The result of these discussions was the development of a stepwise, pragmatic therapeutic algorithm tailored to daily dermatological practice in France. This algorithm integrates disease severity, clinical phenotype, patient response, current treatment options, and therapies that are soon to be available, and reflects both current evidence and expert opinion.

Conclusion:

This expert opinion not only provides a practical treatment algorithm but also reinforces the need for earlier recognition, multidisciplinary collaboration, and improved care strategies for CHE in everyday clinical practice.



EA DV CONGRESS
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Abstract N°: 1987

Toward improvement of global patient and caregiver education in atopic dermatitis: results of an international community survey

Kristen Willard*[1], Špela Novak[1], Peter Lio[2], Mark Luttmann[1], Gretchen McCreary[1], Ghulam Mustafa[3], Ruth Tal-Singer[1]

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[2]Northwestern Feinberg School of Medicine, Chicago, United States
[3]Nishtar Medical University, Multan, Pakistan

Introduction & Objectives:

Patient education in atopic dermatitis (AD) has been shown to improve medication adherence, severity of disease, and quality of life.1 One goal of our international survey was to determine the educational needs and support needed as treatments and outcomes continue to evolve. Global perspectives were gathered patients and caregivers residing in the US, Europe, Japan and the Gulf region.

Materials & Methods:

A cross-sectional anonymous survey was conducted online in the winter of 2024/5 and analyzed using the Survey Monkey platform. Ethics exemption in the US was from BRANY IRB. Consented 1103 eligible respondents included individuals aged ≥18 reporting a diagnosis of AD (68%) or being a caregiver of children aged 6-12 with AD (32%) residing in the US (56%), France (13%), Germany (12%), UAE (8%), and Saudi Arabia (5%) and Japan (6%).

Results:

A total of 66% of patients and caregivers said they/the child had been diagnosed with AD within the last five years. 75% had symptoms at least once a month, with 50% reporting daily to weekly symptoms (Figure, A). When asked about managing their symptoms, 46% reported finding it difficult or very difficult (Figure, B). Respondents both spent considerable time thinking about their AD (62% reporting constantly or regular thoughts) and were clearly impacted by their AD, citing anxiety (46%), fatigue (31%), getting a good sleep (29%), depression (28%), and ability to work (27%) as considerations.

It was positive to see that 61% of respondents found it easy or very easy to find information on AD; however, other responses indicate interest in improving AD educational content. 46% of respondents would find it beneficial to have a list of questions to use when talking to their healthcare team; in addition, 42% want to know more about AD triggers, 40% a way to communicate to their doctor the impact of AD on daily life and mental wellbeing; 39% seek information on what to bring to doctor's appointments and 39% want more information on the causes of AD.

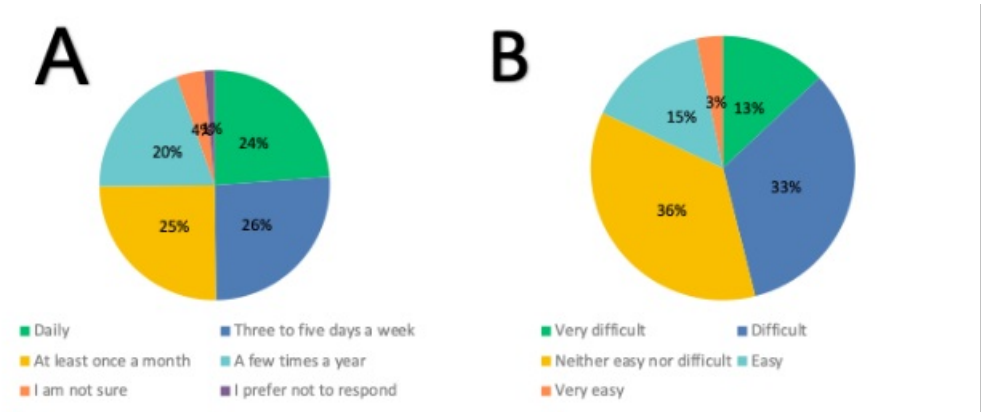
With respect to new medications, more than 50% of patients and caregivers wish to understand safety and duration of treatment information (both >50%). Similarly, respondents prioritize education on the mechanism of action (54%) and safety and side effects (53%) as the most important factors in determining if they would try a new AD drug.

Conclusion:

Patient and caregiver education in AD is essential for improving disease management and often-compromised

quality of life. While access to disease information in participants was is reasonably high, there is a clear opportunity to refine content and provide actionable, patient-centered tools. Empowering patients and caregivers with evidence-based, practical education — especially tools that facilitate doctor-patient communication at visits, treatment options, and coping with emotional health and quality of life impacts — could enhance adherence, reduce disease burden, and foster better health outcomes globally.

The survey was funded by GAAPP, supported by an educational grant from Sanofi.



1. Wilken B, Zaman M, Asai Y. Patient education in atopic dermatitis: a scoping review. *Allergy Asthma Clin Immunol.* 2023;19(1):89. Published 2023 Oct 13. doi:10.1186/s13223-023-00844-w

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Abstract N°: 2007

Local Tolerability of Benvitimod Cream 1% Twice Daily in Adults and Children with Atopic Dermatitis: Results from a Phase 3 Randomized Trial

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Introduction & Objectives:

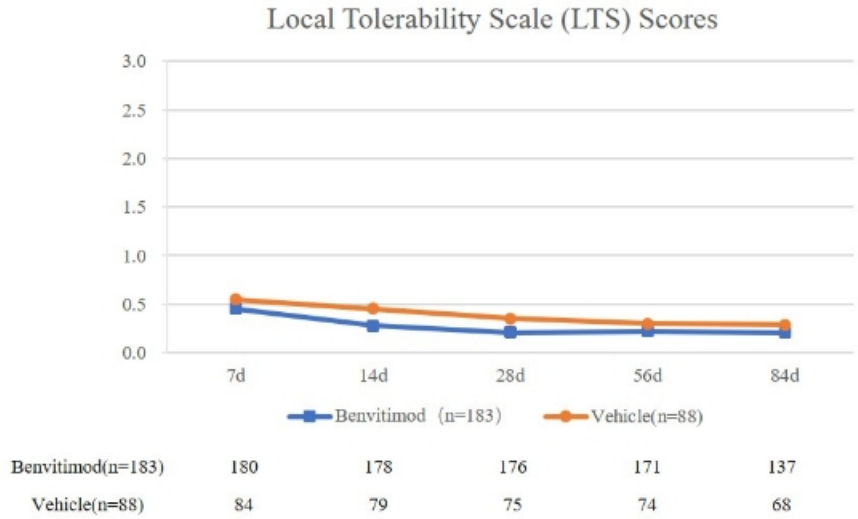
Benvitimod cream 1% twice-daily demonstrated significant efficacy in patients down to age 2 years with atopic dermatitis (AD) in a phase 3 trial. Here, we report local tolerability outcomes.

Materials & Methods:

In this trial, patients were randomized to receive either benvitimod cream or vehicle cream twice daily for 8 weeks. Local tolerability was assessed using the Local Tolerability Scale (LTS), which measures the frequency and severity of local irritation symptoms, including burning/stinging, itching, and erythema. The LTS ranges from 0 (none) to 3 (severe).

Results:

A total of 272 patients were randomized, with over 50% being pediatric participants. The highest LTS scores were recorded on Day 7 of treatment, after which scores decreased. On Day 7, the mean LTS scores for the treatment and control groups were 0.45 ± 0.714 and 0.55 ± 0.803, respectively. On Day 7, 15 participants (8.3%) in the treatment group had an LTS score of 2, 1 participant (0.6%) had a score of 2.5, and 2 participants (1.1%) had a score of 3. In the control group, 11 participants (13.1%) had an LTS score of 2, none had a score of 2.5, and 2 participants (2.4%) had a score of 3. Median LTS scores for both groups remained at 0 on Days 7, 14, 28, 56, and 84. Overall, LTS scores were comparable between the treatment and control groups, indicating good local tolerability.



Conclusion:

Benvitimod cream demonstrated excellent local tolerability from the first application through Week 8, including in sensitive skin areas. These findings support its use in the management of atopic dermatitis in both adults and children.



Abstract N°: 2040

Incorporating the QALYs of Comorbidities into Cost-Utility Analysis of Atopic Dermatitis

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Incorporating the QALYs of Comorbidities into Cost-Utility Analysis of Atopic Dermatitis

Introduction & Objectives:

Comorbidities significantly impact patients' health and economic burden. Certain diseases and their comorbidities share similar pathogenesis, enabling some treatments to address multiple conditions simultaneously. However, conventional quality-adjusted life-year (QALY) assessments focus on single indications, often derived from clinical trials with limited comorbidity representation, thus underestimating broader therapeutic benefits.

Atopic dermatitis (AD) exemplifies this challenge due to its heterogeneous comorbidities. AD has some associated atopic comorbidities, which are demonstrated to related to the atopic march. Some monoclonal antibodies can bring benefits to these kind diseases at the same time. Another major category of AD comorbidities shares a similar pathogenesis with autoimmune diseases. Janus Kinase (JAK) inhibitors show good efficacy in these diseases.

This study introduces total QALY (T-QALY) to capture a drug's cumulative effectiveness across multiple indications, using AD as a case study. We compare the T-QALY of dupilumab and upadacitinib to provide a comprehensive value assessment for AD patients with comorbidities.

Materials & Methods:

According to indications of dupilumab and upadacitinib and the accessibility of data, ten comorbidities were included in this case study for either dupilumab or upadacitinib, specifically allergic rhinitis, asthma, chronic rhinosinusitis with nasal polyps, alopecia areata, eosinophilic esophagitis, rheumatoid arthritis, ulcerative colitis, Crohn's disease, psoriatic arthritis, and ankylosing spondylitis. We extracted QALYs of drugs for different diseases from previous cost-effectiveness analyses. T-QALY was calculated by the QALY for AD, the QALYs for comorbidities, and the prevalences of comorbidities among AD patients. Cost data were sourced from published literature and Chinese clinical guidelines. The incremental cost-effectiveness ratio (ICER) was calculated using T-QALYs and costs, then compared to the willingness-to-pay (WTP) threshold.

Results:

The T-QALY of dupilumab was calculated to be higher than that of upadacitinib, at 16.73 and 14.19, respectively. The ICER for dupilumab versus upadacitinib was ¥52,482 in China. At the China's 2024 GDP per capita threshold, dupilumab exhibited an 87.53% probability of cost-effectiveness. This probability increased with higher WTP thresholds, reinforcing dupilumab's economic advantage.

Conclusion:

This study proposes a T-QALY model to evaluate treatment efficacy across syndemics, using AD as an example. Dupilumab demonstrates cost-effectiveness compared to upadacitinib when accounting for comorbidities' QALYs.

The T-QALY model supports personalized treatment selection for AD patients with diverse comorbidities. Future applications could involve stratifying patients by comorbidity profiles, enabling physicians to leverage T-QALY for tailored clinical decision-making across various therapeutic areas.



Abstract N°: 2044

Dupilumab Treatment Significantly Reduces Age-Associated Total IgE Levels in Young Children With Atopic Dermatitis

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[2]Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, United States
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[6]University of California San Diego, San Diego, United States
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[9]Oregon Health & Science University, Portland, United States
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[11]Medical Dermatology Associates of Chicago, Chicago, United States
[12]Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing, China
[13]Sanofi Cambridge, Cambridge, United States
[14]Regeneron Pharmaceuticals, Inc., Tarrytown, United States

Introduction & Objective: Most patients with moderate-to-severe atopic dermatitis (AD) have elevated levels of total IgE, an allergen sensitization marker that contributes to the pathophysiology of other atopic conditions such as food allergies and asthma. In AD, IgE sensitization is associated with increased severity and flares, and also has been associated with atopic comorbidity development, especially in young children (atopic march). The aim of this analysis is to report total IgE level differences at study baseline and after dupilumab treatment in different age cohorts of 0.5 to <6-year-old children with moderate-to-severe AD.

Materials & Methods: In** LIBERTY AD PRESCHOOL (NCT03346434), children with moderate-to-severe AD aged <6 years received dupilumab or placebo, both with topical corticosteroids (TCS), for 16 weeks. Baseline and Week 16 total IgE levels are reported, stratified by age cohort: 0.5 to <2 years, ≥2 to <4 years, and ≥4 to <6 years. A mixed-effect model for repeated measures was used to compare the IgE ratio and IgE difference between Week 16 and baseline in dupilumab and placebo groups.

Results: At baseline, mean IgE levels (kU/L) showed age-cohort–dependent increase in both dupilumab (n = 71) and placebo (n = 69) treatment arms: 0.5 to <2 years, 3,481.8 and 636.3; ≥2 to <4 years, 5,736.4 and 5,066.7; ≥4 to <6 years, 10,046.0 and 9,044.9, respectively. At Week 16, dupilumab + TCS vs placebo + TCS significantly reduced IgE levels in children aged 0.5 to <2 years (275.9 vs 918.0), and in those aged ≥2 to <4 years (1,233.3 vs 4,960.0), and ≥4 to <6 years (3,932.8 vs 9,510.4). Overall, in young children, mean IgE levels were significantly reduced by 70% in those treated with dupilumab + TCS ($P < 0.001$), while in those treated with placebo + TCS, IgE levels increased by 30% ($P = 0.03$).

Conclusion: IgE levels increased with age in young children with moderate-to-severe AD managed with placebo + TCS. In contrast, dupilumab + TCS treatment significantly decreased IgE levels and curbed IgE level increases in all tested age cohorts. Given that total IgE progressively increases with increasing age in young children, early

intervention with dupilumab to reduce IgE levels in children with moderate-to-severe AD may contribute to lowering the risk of developing atopic comorbidities.



Abstract N°: 2062

Comparative real-world analysis of national variations in advanced systemic therapy initiation in atopic dermatitis across the UK

Piru Pathmarajah*[1], Sarah Elyoussfi[2], Nora Makary[3], Lowri Edwards[2], Zhi Lim[4], Dalia Eid[5], Vijaytha Muralidharan[5], Puo Nen Lim[6], Wei Chern Gavin Fong[7], Erma Qazi[8], Kit Gallagher[9], Maria-Angeliki Gkini[4], Antoaneta Grunova[1]

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[2]Salford Royal NHS Trust , Manchester, United Kingdom
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[4]Barts Health NHS Trust, London, United Kingdom
[5]Aneurin Bevan University Health Board, Newport, United Kingdom
[6]NHS Greater Glasgow and Clyde, Glasgow, United Kingdom
[7]Nottingham University Hospitals NHS Trust, Nottingham, United Kingdom
[8]University Hospitals Birmingham NHS Trust, Solihull, United Kingdom
[9]University of Oxford, Oxford, United Kingdom

Introduction & Objectives:

Advanced systemic therapies, including biologic drugs and Janus kinase inhibitors, have revolutionized atopic dermatitis management. The National Institue for Health and Care Excellence (NICE) has published their guidance on atopic dermatitis, yet there seems to be national variations how patients access advanced systemic therapies. This work focuses on describing and comparing traditional immunosupressant (IS) and advanced systemtic therapies prescribing practice and potential delay of advanced systemic therapy inititiation between district general hospitals versus specialist centres for patients with atopic dermatitis (AD) in the UK.

Materials & Methods:

This was a retrospective, multi-site study across 7 centres in the UK. Clinical records were reviewed from November 2024 and the following data were recorded: demographic data, number and type of immunosuppressant, choice of advanced systemic therapy, timeline of switching from immunosuppressant to advanced systemic therapy and factors for delay in switching. A psoriasis cohort group has been included for comparison to characterise the potential delay in switching to an advanced systemic therapy. Descriptive statistics and relevant statistical models were used. A p-value <0.05 was deemed statistically significant.

Results:

This study included 350 patients from 7 different centres (4 district general hospitals where AD patients are seen in general dermatology clinics and 3 specialist centres with a dedicated AD clinic often having resources and protocols optimized for AD management) across the UK. The mean age was 43.9 years (median age 42 years, interquartile range 22 years). This study included 56.2% male and 44.6% White patients. There was no significant difference between age and gender distributions between the district general hospitals and the specialist centres. A range of different immunosuppressants were used: methotrexate, ciclosporin and phototherapy (in decreasing order of frequency) for both AD and psoriasis (Figure 1). Patients with AD spent half as long on immunosuppressants than patients with psoriasis (2.54 years vs 5.02 years) (Figure 1). There were significant differences in side effects experienced on the different immunosuppressants (Table 2). Specialist centres experienced significantly shorter delays in switching patients from immunosuppressants to advanced systemic

therapy (1.9 months, compared to 3.7 months in district general hospitals, p-value =0.0027) (Figure 3). Homecare (a service where medicines can be directly delivered to the patient's home address or care homes) was the most common reason for this delay which was significantly longer and more frequent for district general hospitals.

Conclusion:

Patients with AD at specialist centres experience a shorter delay before being initiated on an advanced systemic therapy (1.9 months vs 3.7 months). Specialist centres also have significantly fewer homecare delays. This study provides real life data demonstrating that in general, access and initiation of advanced systemic therapy differs across the UK and is quicker in dedicated AD clinics where patient flow is more coordinated through regular multidisciplinary team meetings and efficient setup of home care services which can impact treatment goal and patient satisfaction.

Figure 1:

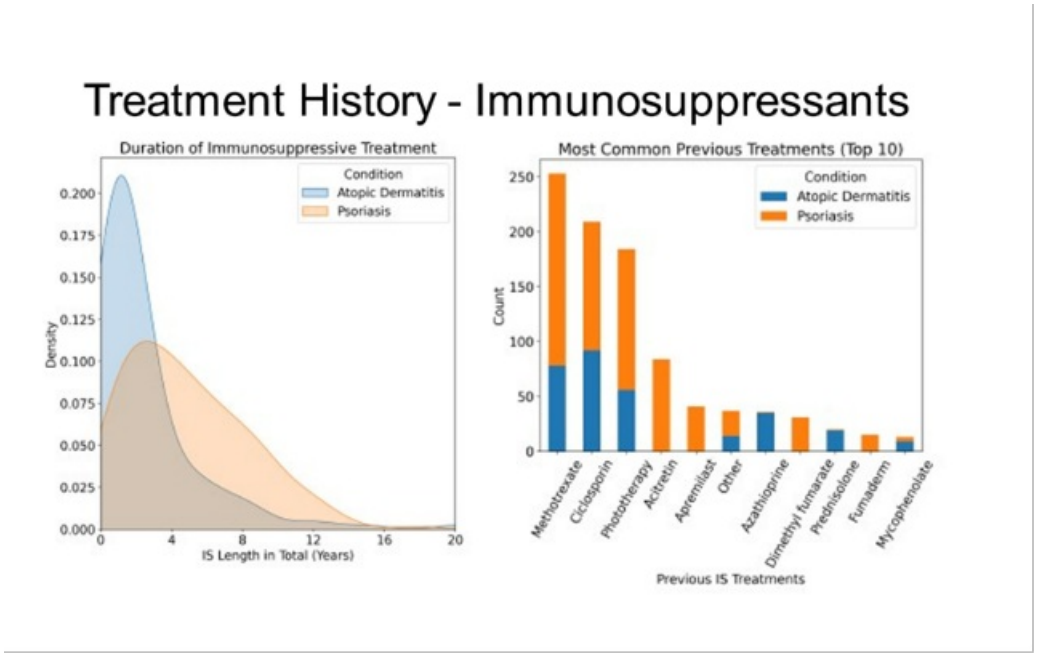


Figure 2:

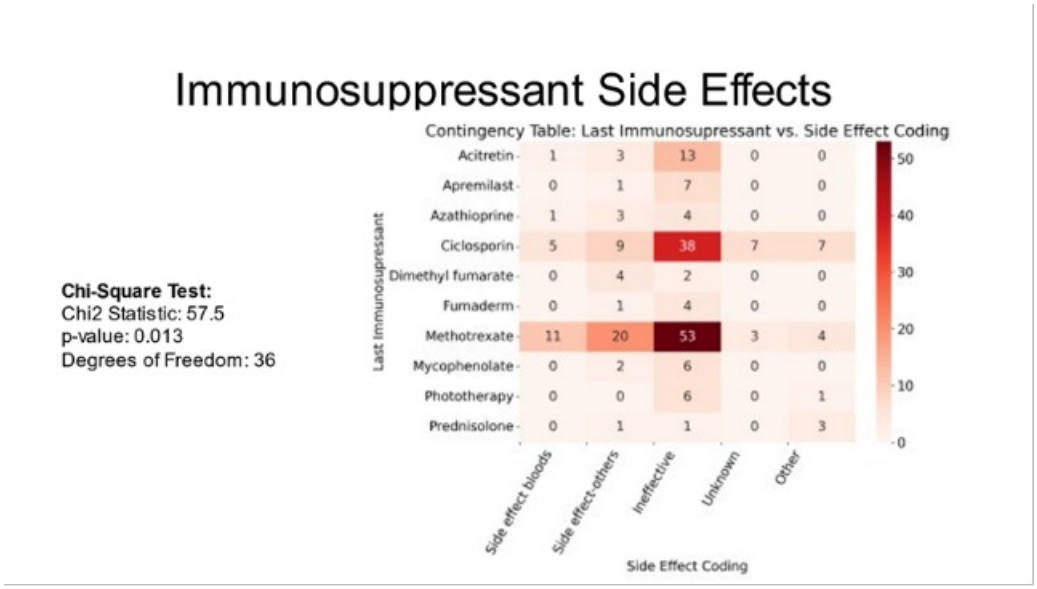
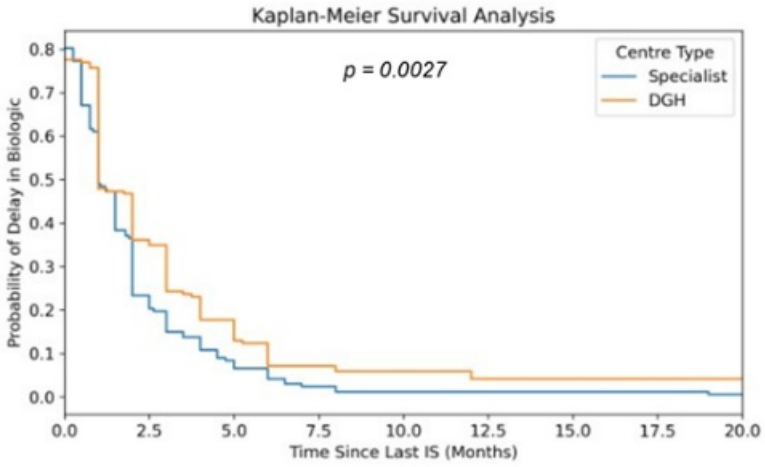


Figure 3:

Survival Analysis – Treatment Delay





Abstract N°: 2084

Adverse health outcomes of atopic eczema: a comprehensive evidence resource using UK electronic health records data

Julian Matthewman*[1], Anna Schultze[1], Krishnan Bhaskaran[1], Spiros Denaxas[2], Amanda Roberts[1], Kathryn Mansfield[3], Sinead Maire Langan[1]

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[2]University College London, London, United Kingdom
[3]University of Lincoln, Lincoln, United Kingdom

Introduction & Objectives:

Atopic eczema is related to adverse health outcomes. Existing work has largely focused on associations with individual outcomes, with limited work looking more comprehensively at multiple outcomes. Here, we produced a comprehensive atlas of results on how eczema is associated with thousands of diseases assessing the full health spectrum.

Materials & Methods:

We harnessed UK hospital admissions data to systematically assess associations with all 2,056 category-level ICD-10 (International Classification of Diseases) morbidity codes (e.g., "J45 Asthma", "K58 Irritable bowel syndrome"), recorded in any diagnostic position. We identified over 3 million people with eczema from primary care records (Clinical Practice Research Datalink), matched (age, sex, general practice) to over 14 million comparators without eczema. We followed participants for up to 25 years using their hospital records. By mapping ICD-10 codes to Global Burden of disease (GBD) categories and phecodes, we utilised additional strategies to define diagnoses. We performed multiple different types of analyses on different cohorts.

Results:

We produced results from 60,000 statistical models, and created a dashbaord to explore these. Some of the most relevant results are: 1. Strong associaitons in all cohorts and analyses with eye outcomes including the rarer and more serious complicaitons of cataracts and keratoconus. 2. An increased risk of Crohn's disease emerged as the strongest signal that would not typically be seen as part of the complications of atopic eczema and is markedly stronger than for Ulcerative colitis. 3. Reassuringly, for people who had eczema in childhood, compared to outcomes informing atopic eczema diagnosis (e.g., asthma, allergy, skin infections, conjunctivitis) any increase in risk in other organ systems was much smaller.

Conclusion:

In conclusion, our results give the first comprehensive overview of excess hospital diagnoses in eczema and provide a resource for generating and testing individual association hypotheses.

We highlight ophthalmologic outcomes, for which there has previously been a research gap with few studies available, as key complications of eczema. Considering the emergence of novel treatments for eczema that have themselves been linked to ophthalmic complications it is especially important to consider these. For Crohn's disease, the evidence is amassing from other studies including from large routinely collected data, birth cohorts and Mendelian randomisation studies, but here, for the first time, we demonstrate this increased risk in the context of all hospital-recorded diagnoses.

Together with our recently published large-scale work investigating eczema outcomes in primary care (doi: 10.1038/s41467-024-54035-1) the evidence on eczema outcomes has received a considerable update, with implications for guidelines and future research, e.g., studies on adverse effects of new medicines.



Abstract N°: 2110

Use of Dupilumab in Patients with Severe Atopic Dermatitis and History of Liver Transplantation: Report of Two Cases.

Marina Gagliardi*[1], María Walker[1], Carla Castro[1]

[1]Austral University Hospital, Dermatology, Pilar Centro, Argentina

Introduction & Objectives:

Severe atopic dermatitis (AD) in liver transplant recipients presents a major therapeutic challenge, as standard systemic treatments are often contraindicated due to immunosuppression and hepatic dysfunction. The objective of this report is to highlight the effectiveness and safety of Dupilumab in treating severe AD in this unique patient population through two illustrative clinical cases.

Materials & Methods:

Two liver-transplanted patients with severe, treatment-refractory AD were evaluated. Both were under chronic immunosuppressive therapy and had extensive disease not controlled with conventional treatments. Clinical scores including EASI, SCORAD, IGA, Pruritus and Sleep NRS, DLQI, and BSA were recorded before and during treatment with Dupilumab.

Results:

- Case 1: A 27-year-old male with a history of two liver transplants presented with widespread lichenified eczema, bacterial superinfections, and severe pruritus. Initial scores: EASI 30.3, SCORAD 53, IGA 4, Pruritus NRS 10, Sleep NRS 8, DLQI 12. After 5 weeks of Dupilumab, there was a marked improvement: EASI 5.2, Pruritus NRS 2, Sleep NRS 0, DLQI 1.
- Case 2: A 20-year-old female developed severe AD after liver transplantation for autoimmune hepatitis. Baseline: EASI 48.9, SCORAD 87.58, IGA 4, Pruritus/Sleep NRS 10, DLQI 19, BSA 92.9%. Under Dupilumab, the disease significantly improved: EASI 1, SCORAD 7.6, NRS 0, BSA 3%.

Conclusion:

Dupilumab demonstrated a favorable safety profile and remarkable clinical efficacy in liver transplant recipients with severe AD, offering a promising alternative when conventional therapies are contraindicated. Its mechanism, independent of hepatic metabolism and targeting the Th2 axis, makes it especially suitable in this context. A multidisciplinary approach was key to successful treatment implementation.



Abstract N°: 2142

Tolerance, efficacy, and quality of life of a dermocosmetic in subjects with atopic dermatitis and skin disorders associated with dryness in South Africa

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Introduction & Objectives:

Patients with dermatological conditions like atopic dermatitis (AD), eczema, senile xerosis, psoriasis, and severe xerosis often experience dry skin symptoms, including pruritus, pain, and discomfort. Regular use of emollients play a pivotal role in restoring the skin barrier leading to improved dryness and skin discomfort. This study assessed the local tolerance and efficacy of an 'emollient plus' dermocosmetic (DC), which contains ingredients including Aqua Posae Filiformis (APF), microresyl, shea butter, and niacinamide, on the symptoms and quality of life (QOL) in subjects with AD and other dermatologic conditions with skin dryness.

Materials & Methods:

This was an open-label, observational study conducted over 2 months to assess the effect of a DC in subjects above 16 years of age with AD and other skin diseases with dryness across different skin phototypes. The participants were prescribed the emollient plus DC for once- or twice-daily application. A dermatologist assessment was conducted at week 8 on key metrics, including skin dryness, disease severity, pruritus, sleep quality, and daily discomfort. Response to treatment was defined as at least one severity grade decrease on a five-point scale.

The QOL was assessed using DLQI. To evaluate patient satisfaction, tolerance, and cosmetic acceptability, dermatologist assessments, and patient self-assessments were conducted.

Results:

This study included 198 participants, the majority of whom were female (99.4%) (mean age ± SD: 31.5 ± 10.6 years). Most patients suffered from severe xerosis (67.4%) and AD (7.7%) and patients with senile xerosis (1.1%) and psoriasis (0.6%) were included. The subjects had phototypes II-VI, of which phototype V (48.9%) was the main phototype observed. Most of the participants applied the emollient (63.5%) twice a day.

After 8 weeks of emollient use, there was a statistically significant improvement ($p<0.001$) in efficacy based on evaluation by dermatologists compared to baseline for the parameters. Specifically, 93.3% of patients with at least mild intensity at inclusion observed an improvement of at least one grade in their disease severity. Similarly, for 94.6% and 92.4% of patients with skin dryness and pruritus, an improvement was observed in at least one grade, respectively. For 95.5% of patients, there was an improvement in inflammatory lesions of at least one grade. Regarding daily discomfort and quality of sleep, 98.1% and 95.0% of patients exhibited improvement in at least one grade. Finally, after 8 weeks of use of the DC, the mean intensity of dryness and desquamation were reduced by at least 91.2%.

A significant improvement was found in the mean intensities of parameters including skin pain (95.3%), burning sensation (92.5%), tingling sensation (92.7%), numbness sensation (88.0%), itching sensation (94.1%), and sleep quality (96.1%).

The QOL significantly ($p<0.001$) improved with a mean burden reduction of 96.8%, changing on average from moderate to no impact. Overall tolerance was rated excellent by 97.0% of patients and 99.0% of investigators.

Conclusion:

The study demonstrates that a specifically formulated emollient plus DC had an improvement in the symptoms of AD and other dermatologic conditions associated with skin dryness and severe xerosis across ages and phototypes. Quality of life had remarkably improved and the DC was very well tolerated.



Abstract N°: 2180

Assessing the impact of Atopic Dermatitis on Quality of Life using DLQI: A Real world cross sectional study from India

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Introduction & Objectives:

Atopic dermatitis (AD) is the most prevalent chronic inflammatory skin disease globally, exerting a substantial burden not only on patients but also on caregivers and families. Quantifying this impact is essential for guiding clinical management and optimizing support strategies. The Dermatology Life Quality Index (DLQI) is the most widely used instrument to assess quality of life (QoL) in AD patients. This study aimed to examine gender-based differences in QoL domains, stratify findings by disease severity, and evaluate the association between socio-economic status (SES) and DLQI scores.

Materials & Methods:

A cross-sectional study was conducted between November 2024 and March 2025 involving consecutive clinically diagnosed AD patients attending outpatient department from 25 centres across India with Independent Ethics committee approval. Disease severity was stratified by DLQI total score into mild (0–5), moderate (6–10), and severe (>11) categories. Gender differences across six QoL domains—Symptoms, Daily Activities, Leisure, Work/School, Personal Relationships, and Treatment—were analysed using unpaired t-tests. Differences in DLQI scores across socioeconomic status (SES) groups (Low, Middle, High) were assessed using one-way ANOVA with Tukey's post hoc analysis.

Results:

A total of 660 AD patients were included in the study, of which 320 (48.5%) were female and 340 (51.5%) were male. The mean age was 27.9 ± 14.7 years, with a mean disease duration of 3.5 ± 4.2 years. The average DLQI score was 10.8 ± 6.7. No significant gender differences were found across QoL domains or total DLQI scores in the overall population ($p > 0.05$). However, among patients with severe disease (DLQI >11), males reported significantly greater impairment only in the Leisure domain ($t = 2.09$, $p = 0.038$). SES was significantly associated with DLQI scores ($F = 10.86$, $p < 0.0001$), with patients in the low SES group reporting greater QoL impairment compared to those in the medium and high SES groups. No significant difference was observed between medium and high SES groups ($p = 0.263$).

Conclusion:

QoL outcomes in adults with AD were influenced by socio-economic status and, in severe cases, by gender. Lower SES was associated with greater overall impairment, and male patients with severe disease report higher disruption in leisure activities. These findings highlight the need for tailored interventions targeting patients with severe disease and socio-economic vulnerability.

Table 1: **Comparison of DLQI Scores on the Basis of Severity in male and female in 6 Domains**

Parameter	t-statistic	p-value	t-statistic	p-value	t-statistic	p-value
Severity of DLQI Score	(0-5)	(6-10)	(>11)			
Symptoms	-1.20	0.23	-0.64	0.52	0.24	0.81
Daily Activities	-0.57	0.57	-1.59	0.11	0.00	1.00
Leisure	0.43	0.67	0.59	0.55	2.09	**0.04**
Work	1.00	0.32	0.88	0.38	0.82	0.41
Personal Relation	-0.01	0.99	0.92	0.36	-0.16	0.87
Treatment	-1.26	0.21	1.11	0.27	-1.20	0.23
Total	-0.75	0.45	0.53	0.60	0.52	0.60

Table 2: **Comparison of total DLQI by Socio-economic status**

**	n	Mean	SD	Mean ± SD	95% CI lower	95% CI upper
Low	162	12.73	7.36	12.73 ± 7.36	11.59	13.88
Medium	326	10.46	6.66	10.46 ± 6.66	9.73	11.18
High	172	9.49	5.58	9.49 ± 5.58	8.65	10.33

Table 3: **Analysis of DLQI in different SES groups**

Group 1	Group 2	Mean Difference	p-value	95% CI Lower	95% CI Upper
High	Low	3.246	<0.001	1.554	4.938
High	Medium	0.969	0.263	-0.488	2.425
Low	Medium	-2.278	0.001	-3.763	-0.792



Abstract N°: 2184

Antipruritic Efficacy of Azathioprine in Patients with Atopic Dermatitis

Yingyu Ding[1], kochergin nikolay[1], Kristina Myzina[1]

[1]Sechenov University, dermatology, moscow

Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by relapsing episodes of eczematous lesions and persistent pruritus. Its development is driven by a multifactorial interplay of genetic susceptibility, impairment of the epidermal barrier, immune system dysregulation, and environmental influences. The global prevalence of AD is estimated at 15–20% in children and around 10% in adults.

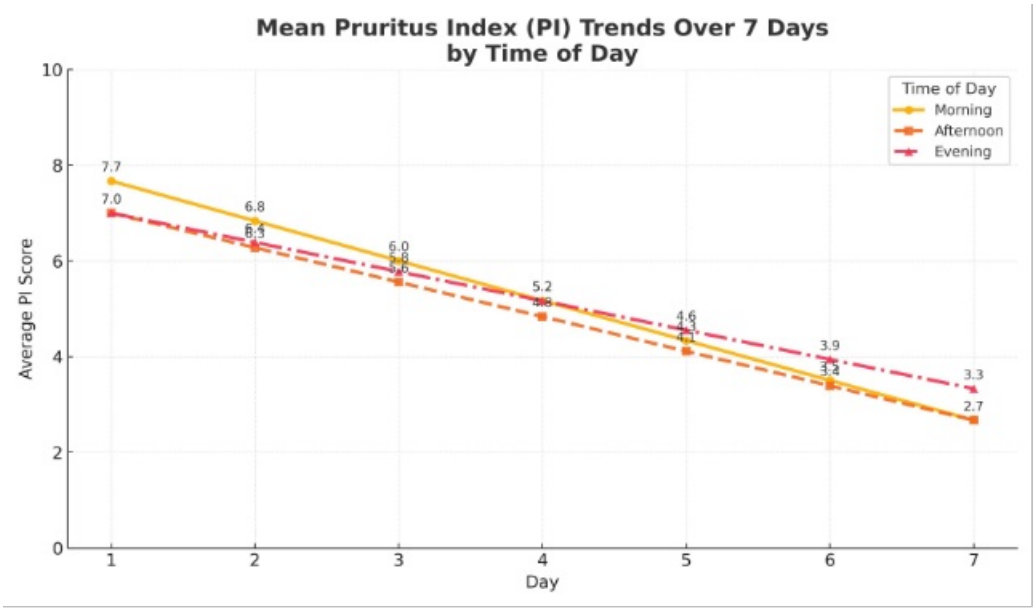
Effective management of AD requires a comprehensive strategy that includes routine skin care, topical anti-inflammatory agents, and, in more severe or refractory cases, systemic immunosuppressants such as cyclosporine A, methotrexate, and azathioprine. Although azathioprine is commonly employed in clinical practice, its specific role in mitigating AD-associated pruritus remains inadequately defined.

This study aimed to evaluate the antipruritic efficacy of azathioprine in patients with moderate-to-severe AD, utilizing the Pruritus Index (PI) as a standardized quantitative measurement.

Materials & Methods: We collected data from five patients diagnosed with moderate to severe atopic dermatitis, including four males and one females aged 18 to 29 years. All patients met established diagnostic criteria for atopic dermatitis and presented with persistent, treatment-resistant pruritus. Each patient received systemic therapy with oral azathioprine at a dosage of 50 mg twice daily for seven consecutive days.

Throughout the study period, pruritus intensity was assessed using the Pruritus Index (PI) on a 0–10 scale, recorded three times daily (morning, afternoon, evening). In addition, all patients underwent laboratory evaluations, including complete blood count (CBC), serum biochemistry.

Results: During the 7-day azathioprine therapy, significant reductions in pruritus severity were observed across all time intervals. Morning PI scores decreased from an average of 7.67 to 2.67 (65.2% reduction), afternoon scores from 7.00 to 2.67 (61.9% reduction), and evening scores from 7.00 to 3.33 (52.4% reduction).



Conclusion: Azathioprine provided rapid and significant relief of refractory pruritus in moderate-to-severe AD, demonstrating both antipruritic and immunomodulatory effects. These results support its potential role in combination regimens for immune-mediated dermatoses. However, patient-specific considerations and regular monitoring remain essential to ensure safety and maximize therapeutic benefit.



Abstract N°: 2196

Effectiveness and Safety of individual dosing alternatives of Upadacitinib in atopic dermatitis real-world population

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Objectives:

In clinical trials, Upadacitinib's efficacy was assessed separately for two doses (15 and 30mg daily). Real-world data comparing the effectiveness and safety of different dosing regimens (15mg, 30mg, flexible) are lacking. This analysis compares these dosing schemes.

Methods:

The analysis included patients with 6 months of follow-up and full documentation of Upadacitinib dosage at each visit, as well as those who discontinued within the first 6 months. Results are reported as observed. Patients were stratified into three groups based on their 6-month dosing: always 15mg, always 30mg, and flexible dosing for those with at least one dose change.

Results:

A total of 361 patients were analyzed, with 81 patients on a constant 15mg dose, 199 consistently on 30mg, and 81 in the flexible dosing group (12 started with 15mg, 69 with 30mg). Reason and type of Upadacitinib medication change is shown in Table 1.

The always 30mg group had more men (62.3% vs. 43.2%) and longer disease duration (25.9 vs. 22.2 years) than the 15mg group. At baseline, patients in the always 30mg group had a numerically higher mean Eczema Area and Severity Index (EASI) 23.5 vs. 21.6 (always 15mg) and 19.5 (flexible dosing). At 1 month, mean EASI was 4.5 for both constant dosing groups and 2.8 for the flexible dosing group. Similar tendencies were observed at month 3. At month 1, 70.9% of the flexible dosing group achieved EASI $\leq$ 3, compared to 57.7% and 58.6% for the always 15 mg and 30 mg groups, respectively. At month 3, this trend continued with 70.3% and 71.0% in the always 15 mg and 30 mg groups, respectively, versus 86.7% in the flexible dosing group.

Baseline mean Dermatology Life Quality Index (DLQI) was significantly higher in patients constantly receiving the 30mg dose 14.8 vs. 13.0 (always 15mg) vs. 12.6 (flexible dosing). At month 1, 44.9% of the patients in the flexible dosing group achieved DLQI 0/1, compared to 32.8% and 32.2% in the always 15 mg and always 30 mg groups, respectively. At month 3, DLQI 0/1 rates were 43.9%, 40.1%, and 47.9% for the always 15 mg, always 30 mg, and

flexible dosing groups, respectively.

No significant differences in itch were noted across groups at baseline (WP-NRS ~7). WP-NRS0/1 responses at month 1 were similar (~50%) across all dosing schemes. However, by months 3 and 6, the flexible dosing group showed a numerically higher WP-NRS0/1 rate, though not statistically significant.

386 adverse events (AEs) were reported in total. The most frequent AEs were dermatitis atopic, acne, and nasopharyngitis. At least one AE was reported in 32 (39.5%), 90 (45.2%), and 49 (60.5%) patients in the 15mg, 30mg and flexible dosing group, respectively. No serious AE was reported in the 15mg group, whereas 5 (2.5%) and 2 (2.5%) patients reported serious AE in the 30mg and flexible dosing groups, respectively.

Conclusion:

There was a tendency towards higher disease burden in patients treated with the higher dose. Patients in the flexible dosing group had slightly higher response rates at month 1, the rapid response led in 68% of the patients to a dose reduction within the first 6 months of treatment. By comparing response rates across all groups, this analysis confirms the effectiveness of Upadacitinib across different dose regimens in a real-world setting. The reported safety aligns with the known safety profile of Upadacitinib and supports the current evidence. This is the first data to show the effectiveness of Upadacitinib in real-world stratified by dose and including a flexible dosing regimen.

Table 1: Type of and Reason for Upadacitinib Medication Change

Patients starting with Upadacitinib 30mg		
Type / Reason for dose change	**n = 69**	**100%**
Dose reduction due to good treatment response	47	68.12%
Dose reduction due to adverse event	10	14.49%
Dose reduction due to patient's wish	5	7.25%
Flexible Dosing (multiple dose changes)	3	4.35%
Treatment break	2	2.90%
Treatment discontinuation	2	2.90%

Patients starting with Upadacitinib 15mg		
Reason/ Type for dose increase /change	**n = 12**	**100%**
Dose increase to achieve higher treatment goals	10	83.33%
Treatment break	2	16.67%



Abstract N°: 2224

Outcomes Following Discontinuation of Systemic Immunomodulatory Therapies in Adults with Atopic Dermatitis: A Systematic Review

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Introduction & Objectives:

The widespread adoption of highly effective systemic immunomodulatory therapies such as biologics and small molecule Janus Kinase (JAK) inhibitors has transformed the therapeutic landscape for atopic dermatitis (AD). As more patients achieve clear or nearly clear skin, there is growing interest in whether disease control can be maintained after discontinuing systemic immunomodulatory therapy. This question is especially important given concerns surrounding the long-term use of these agents, including financial burden, risk of opportunistic infections and implications for family planning.

Aim: To evaluate disease-related outcomes in adults with AD following discontinuation of systemic immunomodulatory monotherapy, with a focus on maintenance of disease control.

Materials & Methods:

A systematic search was conducted across four databases (Medline, Embase, Web of Science and Cochrane Library) from database inception to 8th January 2025. Eligible studies included randomised controlled trials (RCTs) and cohort studies reporting outcomes after discontinuation of targeted or conventional systemic immunomodulatory monotherapy in adults with AD who had achieved disease control. Two reviewers independently screened records and extracted data. Study quality was assessed using the Cochrane Risk of Bias tool for RCTs and the Newcastle-Ottawa Scale for observational studies. Data extracted included participant baseline characteristics, maintenance of disease control, and outcomes on relapse and retreatment.

Results:

Nine studies (2,558 participants) met the inclusion criteria, including 8 RCTs and one cohort. Six studies examined biologic agents (amlitelimab, dupilumab (2 studies), tralokinumab, rezpegaldesleukin, rocatinlimab) and three evaluated JAK inhibitors (baricitinib, abrocitinib, upadacitinib). No eligible studies were identified for conventional systemic immunomodulatory therapies. Amlitelimab, rocatinlimab and rezpegaldesleukin are investigational and not currently approved for AD treatment. Overall risk of bias was generally low.

Across studies, there was considerable heterogeneity in definitions of disease control, treatment duration (12 - 52 weeks), and follow-up duration post-discontinuation (4 - 72 weeks). This limited direct comparisons and precluded meta-analysis. Higher proportions of participants maintained EASI-75 responses post-discontinuation with investigational agents: rezpegaldesleukin (71.4% at 36 weeks), rocatinlimab (73–96% at 20 weeks), and amlitelimab (61.6% at 28 weeks). In contrast, a lower proportion of participants were able to maintain responses with approved biologics: dupilumab (30.4% at 36 weeks) and tralokinumab (26.4% at 36 weeks). Rapid loss of EASI-75 was observed with JAK inhibitors after discontinuation: baricitinib (45.2% at 16 weeks), abrocitinib (42.3% at 4 weeks), and upadacitinib (~20% at 72 weeks).

Conclusion:

Emerging evidence suggests that sustaining disease control following discontinuation of systemic immunomodulatory therapy is possible in some adults with AD. Differences in outcomes between therapies may reflect variations in drug mechanisms or study design. To confidently identify individuals who may benefit from treatment discontinuation, further studies are required with harmonised outcomes (e.g. definition of disease control used) and standardised treatment and follow-up durations.



Abstract N°: 2238

Effectiveness and safety of age-based dosing of abrocitinib in children and adolescents with moderate to severe atopic dermatitis: a two-center, prospective real-world study in China

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Background: Abrocitinib have been approved for patients with moderate to severe atopic dermatitis (AD), but its effectiveness and safety in adolescents, especially children is not established in both clinical trial and real-world studies.

Objective: We aimed to analyze real-world data of abrocitinib in the treatment of children and adolescents.

Methods: We prospectively enrolled children and adolescents with moderate to severe AD from two centers, who were stratified based on age groups (< 6 years, 6-11 years, 12-17 years) and treated with oral abrocitinib at dosages of 25, 50, or 100 mg daily accordingly. The study assessed various parameters, including the eczema area and severity index (EASI), scoring of atopic dermatitis (SCORAD), investigator's global assessment (IGA), numerical rating scale (NRS)-itch, sleep-loss scores, children dermatology quality of life index (CDLQI)/DLQI, and safety at baseline and at weeks 2, 4, and 12 of treatment.

Results: This study included 28 children and adolescents with moderate to severe AD (4 patients aged <6 years, 9 aged 6-11 years, and 15 aged 12-17 years). All patients combined exhibited a rapid and significant improvement in the clinical signs and symptoms of AD following the initial follow-up visit. By week 12, EASI-50, EASI-75 and EASI-90 responses were achieved by 100%, 60.7% and 25.0% of all patients combined, respectively. 57.2% of all patients combined achieved IGA 0/1, and 85.7% had a reduction in NRS-itch score of at least 4 points. The sleep-loss score and CDLQI/DLQI score were reduced by 78.8% and 78.5% of all patients combined, respectively. Similar trends in the data were observed across various age groups, including patients aged < 6 years, 6-11 years, and 12-17 years. Two adolescents (7.1%) experienced mild adverse events, including Kaposi's varicelliform eruption and nausea, with no occurrence of serious adverse events throughout the treatment period.

Conclusions: The real-world application of age-based dosing of abrocitinib revealed favorable efficacy and well-tolerated safety profiles in treating moderate to severe AD among children and adolescents.



Abstract N°: 2239

Facial Redness Associated with Therapy: A case series

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Introduction & Objectives:

Facial redness (FR) has recently been recognized in patients with atopic dermatitis (AD) treated with biologics and immunemodulators, particularly dupilumab. The pathogenesis remains unclear. This case series aims to explore the causes of FR in patients treated with different therapeutic agents.

Materials & Methods:

A retrospective observational study was conducted involving 10 patients with AD receiving biologics or immunemodulators who developed FR. Data were collected from electronic medical records, including patient demographics, treatment history, comorbidities, time to onset of FR, and serum IgE levels (total and *Malassezia*-specific). Statistical analysis was performed using JAMOVI, R, Excel, and STATA.

Results:

Of the 10 patients, 3 (30%) experienced FR with multiple therapeutic agents. The majority of cases were associated with dupilumab and tralokinumab, while abrocitinib and upadacitinib were linked to isolated occurrences. The time to FR onset varied widely (0.42–35 weeks). Malassezia-specific IgE was elevated in 5 patients (50%), most of whom responded to antifungal therapy. Statistical analysis showed no significant association between treatment type and FR onset ($p > 0.05$).

Conclusion:

This case series broadens the understanding of FR, indicating that it can occur with various therapeutic agents beyond dupilumab. The findings suggest multiple contributing factors, including Malassezia hypersensitivity and treatment site failure. Further studies are needed to clarify the pathogenesis and guide management strategies.



Abstract N°: 2240

Integrated assessment of clinical, pathomorphological and microbiological parameters in atopic dermatitis for the development of a digital severity scoring system

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease with increasing incidence in dry, hot climate regions. This study aimed to assess the correlation between clinical severity, histopathological features, and microbial colonization in AD, and to develop a digital diagnostic system. Objectives included: (1) evaluating phenotypes and histological changes in patients with varying AD severity; (2) analyzing skin and gut microbiota, focusing on Staphylococcus aureus and Candida spp.; (3) integrating findings into a digital diagnostic tool.

Materials & Methods:

The study involved 355 patients aged 1–62 years. Severity was assessed using SCORAD and DISHS. Lesional skin and stool samples were analyzed microbiologically. PCR was used for S. aureus genotyping (MRSA vs. MSSA). Skin biopsies (n=48) were examined histologically. Statistical analysis used Student's t-test and Pearson correlation. A mobile application for AD severity scoring was developed, combining clinical, microbiological, and histological inputs.

Results:

Mild, moderate, and severe AD were observed in 17.2%, 39.7%, and 43.1% of patients, respectively. Histological changes included spongiosis in mild cases and pronounced acanthosis, fibrosis, and parakeratosis in severe cases. S. aureus was detected in 94.7% of skin samples; MRSA strains were found in 45.6%, more frequently in children (up to 61.1%). Candida spp. (C. krusei 38.8%, C. albicans 27.3%) were prevalent in stool. Severity correlated with S. aureus colonization and histological chronicity ($r \approx +0.8$, $p<0.05$), while Candida colonization inversely correlated with S. aureus presence.

Conclusion:

Clinical AD severity strongly correlates with histopathology and microbial dysbiosis. High MRSA and Candida prevalence reflects microbial contribution to disease chronicity. The digital scoring tool offers accurate, integrated assessment and treatment guidance, especially valuable in climate-stressed regions. This approach supports personalized AD care and future microbiota-targeted therapies.



Abstract N°: 2242

AtopicHealth3 - Quality of care for atopic dermatitis 2024/2025 in Germany: Interim analysis of quality indicators

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Introduction & Objectives:

AtopicHealth2 was the second national care study conducted between 2017-2019 with patients with atopic dermatitis (AD) in dermatological care. Compared to AtopicHealth1 from 2010, there was no improvement in the care situation. Therapeutic innovations are now available and the AtopicHealth3 study aims to investigate whether the care situation has changed.

Materials & Methods:

The Germany-wide multicentre cross-sectional study 'AtopicHealth3' records clinical data, the severity of AD (SCORAD), quality of life impairment (DLQI), therapies, preventive behaviour and patient-defined treatment benefit (PBI). One focus is on the patient's perspective. The care situation is assessed on the basis of previously defined quality indicators. The inclusion of 1,000 patients with AD is planned.

Results:

Since May 2024, 107 dermatological practices and outpatient clinics throughout Germany have been recruited and by mid-March 2025, 300 fully completed, valid questionnaire sets from 35 dermatological practices were returned to the study centre, on which the present analysis is based. Of the 300 patients, 58% described themselves as female, 41.7% as male and 0.3% as diverse. The mean age was 43 years. The mean SCORAD (scale from 0=minimal to 103=maximal severity of AD) was 34.9±21.3, lower than the SCORAD of AtopicHealth2 (45.4±20.6) and AtopicHealth1 (42.3±18.6). The mean DLQI (scale from 0=minimum to 30=maximum impairment of dermatology-related quality of life) was 7.2±6.4 compared to 8.5±6.5 in the two previous studies. The proportion of patients with high severity (SCORAD>50) was 26.6% compared to 41.6% in AtopicHealth2 and 32.2% in AtopicHealth1. The mean PBI (0=no benefit to 4=maximum patient-defined treatment benefit) was 2.6±1.2 compared to 2.2±1.1 in AtopicHealth2 and 2.4±1.1 in AtopicHealth1.

Conclusion:

Compared to the AtopicHealth studies 2010 and 2017-19, outcome indicators show an improved quality of care for patients with atopic dermatitis in Germany. As this is a small sample, it remains to be seen whether this result will be confirmed in the overall evaluation.

The study received financial support from Sanofi.



Abstract N°: 2253

Effectiveness of Tralokinumab Across Atopic Dermatitis Phenotypes

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Introduction & Objectives:

Tralokinumab, a fully human monoclonal antibody targeting IL-13, has shown efficacy and safety in clinical trials

and real-life studies for atopic dermatitis (AD). However, data on its effectiveness across AD phenotypes are limited.

Materials & Methods:

A multicentric study evaluated tralokinumab's efficacy over 52 weeks in 416 severe AD patients. EASI (Eczema Area and Severity Index), P-NRS (Pruritus Numerical Rating Scale), DLQI (Dermatology Life Quality Index), and ADCT (Atopic Dermatitis Control Tool) were recorded up to 52 weeks of treatment.

Results:

The EASI, P-NRS, DLQI, and ADCT trends across phenotypes showed significant improvement in all phenotype subgroups. By week 16, classical and generalized lichenoid phenotypes showed the highest EASI improvements compared to the generalized flammatory (75.0 vs. 45.5 [$p < 0.001$] and 79.3 vs. 45.5 [$p < 0.001$]), with most achieving EASI-75 ($p < 0.001$, $\chi 2 = 25.96$). By week 24, generalized lichenoid reached 100% EASI improvement, significantly outperforming other phenotypes. The highest EASI-75 rates were seen in classical, eneralized lichenoid, and portrait/head and neck phenotypes ($p = 0.016$, $\chi 2 = 13.85$). No significant differences were observed at weeks 32, 40, or 52.

Conclusion:

Our results suggest that tralokinumab's durability and tolerability are consistent across the various phenotypes. The classical and generalized lichenoid were the fastest phenotypes to improve. However, given the uneven distribution of phenotypes and the gradual reduction in patient numbers over time, larger prospective studies are essential to confirm the observed trends.

This is an encore



Abstract N°: 2264

Efficacy and Safety of Abrocitinib in Elderly with Atopic Dermatitis: A Prospective Study

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Background: Atopic dermatitis (AD) in the elderly has received widespread attention as a new clinical subtype of AD. Treatment for moderate-to-severe AD requires systemic drugs, and their use may be challenging in elderly due to complex comorbidities and progressive deterioration body functions. The efficacy and safety of abrocitinib for the treatment of AD in the elderly has not been demonstrated in clinical trials and real-world studies.

Objectives: We aimed to assess the efficacy and safety of abrocitinib monotherapy in elderly with moderate-to-severe atopic dermatitis from baseline to 12 weeks.

Methods: A study was conducted at Guangzhou Dermatology Hospital from March 2023 to January 2024. Patients aged 60 years and older with moderate-to-severe AD were treated with abrocitinib 100 mg/d, Patients' scores of SCORing Atopic Dermatitis (SCORAD), Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA), Dermatology Life Quality Index (DLQI), Patient-Oriented Eczema Measure (POEM), Atopic Dermatitis Control Tool (ADCT) and Peak Pruritus Numerical Rating Scale (PP-NRS) changes were recorded at weeks 2, 4, 8, 10, and 12 of treatment to assess clinical efficacy, and blood counts, immunoglobulin E (IgE), hepatic and renal function, D-dimer, lipids, and cardiac enzyme levels were monitored at weeks 0 and 12 of treatment.

Results: A total of 15 patients were included, of which 12 patients (80%) completed the study with a mean age of (70 ± 8.22) years. From baseline to week 12, the differences in patients' SCORAD, EASI, IGA, DLQI, POEM, ADCT, and PP-NRS scores showed statistical significance at different time points (all $P < 0.05$). By the 12th week, all 12 patients reached SCORAD50, 66.7% (8 patients) reached SCORAD75, and 16.7% (2 patients) reached SCORAD90. Additionally, all 12 patients attained EASI50, 66.7% (8 patients) attained EASI75, and 25% (3 patients) attained EASI90. 41.7% (5 patients) of patients reached IGA0/1, 83.3% (10 patients) attained PP-NRS ≤4, and all 12 patients accomplished DLQI ≤5, POEM ≤7, and ADCT ≤7. The absolute value of eosinophils, percentage of eosinophils, and IgE decreased significantly compared with the baseline values in the 12th week, all of which were statistically different (all $P < 0.05$). One case each of abnormal AST, D-dimer and cardiac enzyme indices were observed, which decreased to normal range upon follow-up review. No gastrointestinal reaction or infection was noted.

Conclusion: In the 12-week study, abrocitinib was an effective and safe medication for the treatment of patients 60 years of age and older with moderate-to-severe atopic dermatitis.

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Abstract N°: 2282

Atopic dermatitis increases risk for multimorbidity with unique orofacial and cardiometabolic signatures

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Introduction & Objectives:

Atopic dermatitis (AD) has been proposed as a systemic disease due to underlying systemic inflammation and a range of reported comorbidities, not only limited to other atopic diseases. Thus, this study aimed to examine the associations between AD and (non-atopic) multimorbidity in a population-based cohort from the Northern Netherlands, considering disease severity and age. Further we sought to identify whether there are AD-specific multimorbidity patterns among participants with non-atopic multimorbidity.

Methods:

We assessed lifetime prevalence of 52 diseases, from 15 domains, combining data from questionnaires, validated medication records and clinical assessments within the Lifelines Cohort. AD presence was assessed as self-reported, physician-diagnosed AD over lifetime and disease severity was evaluated using the Patient Oriented Eczema Measure. Multimorbidity was defined as lifetime presence of at least two diseases within an individual, excluding AD, with non-atopic multimorbidity disregarding asthma, rhinitis and food allergy. A composite morbidity score (cMS) indicated the degree of (non-atopic) multimorbidity. We analysed associations of AD and AD severity with multimorbidity and the cMS using binary and multinomial logistic regression, adjusting for age and sex. Another model additionally adjusted for socioeconomic and lifestyle factors. Patterns of non-atopic multimorbidity based on 14 non-atopic domains were explored using Latent Class Analysis (LCA).

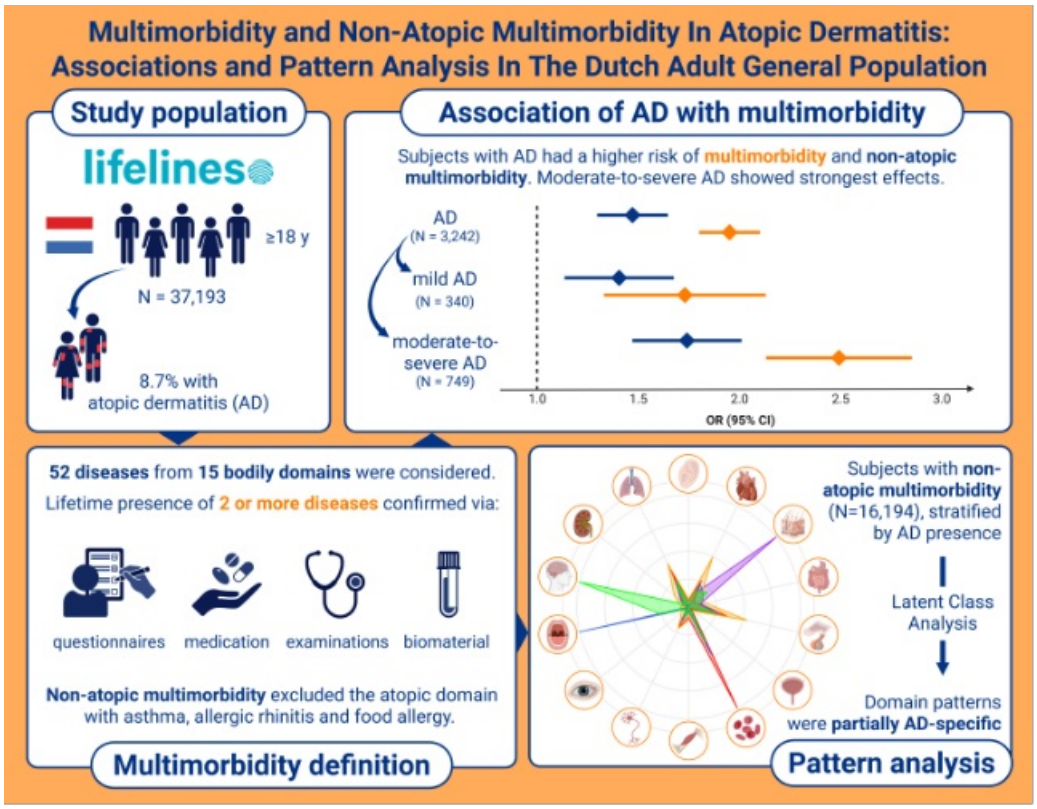
Results:

Among 37,193 participants, 8.7% had AD. Prevalence of (non-atopic) multimorbidity was higher in participants with AD, compared to those without AD, increasing with AD severity. The most affected domains in the AD group were *hematologic* (aneamia) with 25.5% and *respiratory* (chonic obstructive pulmunary disease [COPD]) with 21.2%, both significantly more prevalent than in those without AD. The risk for non-atopic multimorbidity was 47% higher in participants with AD compared to those without, and increased with more severe disease (Figure). The association strengthened with higher degrees of non-atopic multimorbidity, reaching 2.09-fold for ≥5 diseases. Associations between AD and outcomes which considered the atopic diseases were even stronger. Further adjustments for socioeconomic and lifestyle factors corroborated most results, especially for moderate-to-severe AD. Lastly, we identified five distinct multimorbidity classes in participants with AD, of which two classes differed compared to those without AD. We found the presence of an *orofacial* class (periodontitis) and unique distribution of a composite class characterised by *cardiovascular* (heart failure, atrial fibrillation), *endocrinologic* (hypercholestorolemia, thyroid disease, diabetes) and *respiratory* (COPD) involvement in those with AD.

Conclusion:

Participants with AD, especially moderate-to-severe cases, were at higher risk for both multimorbidity and non-atopic multimorbidity. Additonally, we identified partially AD-specific patterns of multimorbidity, suggesting differences regarding orofacial disease and a metabolic syndrome-like class. Our results highlight the importance

of screening for comorbidities alongside their risk factors and interdesciplinary approaches in the treatment of patients with atopic dermatitis. Whether our findings result from the underlying systemic inflammation in AD, needs further investigation.





Abstract N°: 2327

Real-world Effectiveness by Body Regions and Safety of Upadacitinib in Canadian Adult Patients With Atopic Dermatitis who Were Inadequate Responders or Intolerant to Dupilumab: Results From the CAN UpTIMISE Study

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Introduction & Objectives:

The superiority of once daily orally administered upadacitinib (UPA), a selective Janus kinase 1 inhibitor, over biweekly and subcutaneously administered dupilumab (DUPI), an IL-4Ra inhibitor, was demonstrated in adult and adolescent patients with moderate-to-severe atopic dermatitis (AD) in international randomized controlled trials (RCTs). The benefits of switching DUPI-treated patients with AD to UPA has also been demonstrated via open-label and extension studies. The CAN UpTIMISE study sought to prospectively assess the real-world effectiveness of daily UPA 15 mg (UPA15) and 30 mg (UPA30) in patients with AD who were inadequate responders to DUPI or discontinued DUPI due to safety/tolerability reasons. The current analyses report the effectiveness of UPA switch in terms of severity and extent of skin clearance across different body regions.

Materials & Methods:

CAN UpTIMISE (NCT05394792) was a Canadian observational study of adult patients treated with DUPI for ≥16 weeks as previous line of systemic therapy for moderate-to-severe AD and for whom the decision to change treatment to UPA had been made, in accordance with the local label and prior to enrolment in the study. Effectiveness was assessed over 4 months using scores for validated Investigator Global Assessment for AD (vIGA-AD), facial IGA, Eczema Area and Severity Index (EASI) and localized EASI by body regions, body surface area (BSA), and Dermatology Life Quality Index (DLQI). Results are presented using descriptive statistics.

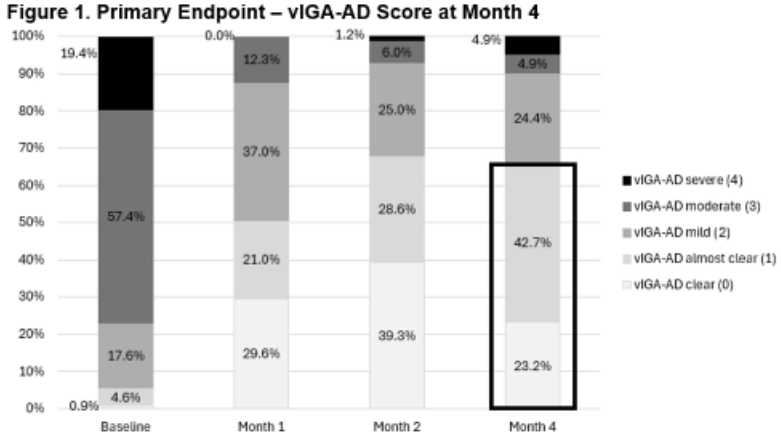
Results:

A total of 108 patients (n=44 [UPA15]; n=64 [UPA30]) were included in the analysis (mean age: 42.9 years [SD 16.7]; male gender: 55.6%; race: mainly White [61.1%] or Asian [33.3%]). Most patients (83.3%) discontinued DUPI due to suboptimal disease control per investigator's judgment, while 16.7% of patients discontinued due to safety/tolerability reasons. Mean and median exposure to DUPI prior to enrolment were 577 and 309 days, respectively. At baseline, 94.4% of patients had vIGA-AD scores ≥ 2 (mild through severe). As a primary endpoint, 65.9% (95% CI: 55.1 – 75.2%) of patients achieved vIGA-AD 0/1 at Month 4 with either UPA dose (Figure 1). From baseline to Month 4, there were notable increases in the proportion of patients with facial IGA score of 0/1 (from 23.1% to 77.5%) or 0 (from 12.0% to 52.5%), with most improvements seen as early as Month 1 post-UPA initiation (Table 1). Throughout the study period, rapid and generally sustained improvements were observed in the global EASI score (percent change from baseline [%CFB]: 73.1%), localized EASI scores (head and neck [68.6%], trunk [80.1%], upper limbs [74.3%], and lower limbs [81.8%]), and BSA (67.5%), with 39.2% of the patients with baseline BSA > 2% achieving BSA ≤ 2% at Month 4. These clinical improvements were accompanied by similarly rapid and generally sustained reductions in the impact of AD on quality of life (DLQI). UPA was well-tolerated, and its safety profile aligned with findings from RCTs.

Conclusion:

The CAN UpTIMISE study shows that UPA is effective and well-tolerated in AD patients who either did not respond adequately to DUPI or discontinued DUPI due to safety or tolerability concerns. The switch to UPA treatment resulted in significant improvements in the severity and extent of skin disease across body areas, including the face. Improvements in quality of life were seen as early as Month 1 and generally sustained by Month 4. No new safety signals were reported.

Figure 1. Primary Endpoint – vIGA-AD Score at Month 4



vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis.
Black box is indicative of the study primary endpoint.
Observed values are presented. Sensitivity analyses comparing imputation methods with data as observed indicated overall alignment between both statistical approaches. Imputation methods applied were pre-specified as follows: missing data without intercurrent events (dose change/discontinuation) were imputed using the multiple imputation method, missing data with intercurrent event due to lack of efficacy/intolerability were imputed using the non-responder imputation method, and missing data with intercurrent events due to another reason were imputed using the last on-treatment post-baseline value.

Table 1. Effectiveness of UPA in Patients with Inadequate Response or Intolerance to Dupilumab

Endpoints % (95% CI)	All patients N = 108[a] Month 1	Month 2	Month 4
Facial IGA[b]			
Facial IGA score 0/1	74.1% (63.6, 82.4)	76.5% (66.2, 84.4)	77.5% (67.2, 85.3)
Facial IGA score 0	53.1% (42.3, 63.6)	60.5% (49.6, 70.4)	52.5% (41.7, 63.1)
EASI (whole body)			
Percent CFB	-75.2% (-86.0, -64.5)	-81.9% (-88.8, -75.0)	-73.1% (-83.3, -63.0)
EASI (localized: head and neck)			
Percent CFB	-74.9% (-84.9, -64.8)	-77.2% (-86.4, -67.9)	-68.6% (-82.6, -54.5)
EASI (localized: trunk, including genitals)			
Percent CFB	-84.3% (-90.4, -78.2)	-85.9% (-92.8,-78.9)	-80.1% (-90.2, -70.0)
EASI (localized: upper limbs)			
Percent CFB	-74.9% (-83.2, -66.6)	-82.0% (-89.0, -75.1)	-74.3% (-88.6, -59.9)
EASI (localized: lower limbs, including buttocks)			
Percent CFB	-80.7% (-88.0, -73.5)	-86.5% (-93.9,-79.1)	-81.8% (-92.0, -71.6)
BSA (%)			
Percent CFB[c]	-63.4% (-81.4, -45.5)	-76.6% (-84.3, -68.8)	-67.5% (-81.2, -53.8)
BSA ≤ 2%[d]	47.1% (35.9, 58.7)	40.3% (29.7, 51.8)	39.2% (28.9, 50.6)
DLQI			
Percent CFB	-65.0% (-74.9, -55.2)	-59.3% (-75.8, -42.7)	-55.7% (-66.7, -44.6)

BSA, body surface area; CFB, change from baseline; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; UPA, upadacitinib.

Observed values are presented. When available, similar results were obtained when missing data were imputed as described for the primary endpoint.

[a] N = 108 represents the number of patients at baseline, but may not represent observed cases for each endpoint/time point.

[b] At baseline, 23.1% patients had facial IGA score of 0/1; while 12.0% patients had facial IGA score of 0.

[c] For reference, baseline mean (SD) BSA was 21.4% (21.6) and baseline median (min, max) was 13.0 (0.0, 96.0).

[d] In patients with BSA >2% at baseline.



Abstract N°: 2499

Tralokinumab for Cronic Hand Eczema: 52-week experience and flexible dosing outcomes

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Introduction & Objectives:

Chronic hand eczema (CHE) remains a therapeutic challenge, especially in patients with disease refractory to topical treatment and without clearly defined atopic phenotypes. While systemic therapies often involve off-label use and carry significant safety concerns, emerging biologics targeting Th2 inflammation have shown promise. Tralokinumab, a monoclonal antibody against IL-13, has demonstrated efficacy in atopic dermatitis but its long-term effect in CHE is not well established. Our objective was to evaluate the 52-week response to Tralokinumab in patients with severe CHE and assess outcomes following dose deintensification.

Materials & Methods:

We conducted an observational study including 16 patients with severe or very severe chronic hand eczema refractory to topical therapy. All patients were treated with subcutaneous Tralokinumab at an initial dose of 600 mg followed by 300 mg weekly. Disease severity was measured using the Hand Eczema Severity Index (HECSI). Patients achieving sustained clinical response were evaluated for dose deintensification to 300 mg every 4 or 6 weeks.

Results:

By week 52, all 16 patients had achieved HECSI-75, with 13 (81.3%) reaching HECSI-90 and 8 (50%) achieving complete clearance (HECSI-100). Nine patients underwent dose deintensification: six to 300 mg every 4 weeks, and three to every 6 weeks. All maintained their clinical responses without relapse during follow-up. No significant adverse events were observed.

Conclusion:

Tralokinumab demonstrates sustained efficacy in chronic hand eczema up to week 52, including in patients with non-atopic and hyperkeratotic phenotypes. Dose deintensification appears feasible in responders, maintaining disease control with reduced treatment burden. These findings support the potential role of Tralokinumab as a long-term therapeutic option in refractory CHE.



Abstract N°: 2503

Lebrikizumab: A New Effective Alternative for the Treatment of Severe Atopic Dermatitis in Patients Resistant to Previous Therapies

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Introduction & Objectives: Atopic dermatitis (AD) is a highly heterogeneous inflammatory skin disorder. It affects approximately 2-10% of adults. Improved understanding of AD pathogenesis has enabled the development of new therapeutic targets in recent decades.

Lebrikizumab is a humanized monoclonal antibody that selectively binds to IL-13, preventing the heterodimerization of subunits IL-4Rα and IL-13Rα1 of Type 2 receptor and its subsequent signaling.

Materials & Methods: A retrospective, descriptive, and observational study was conducted to evaluate the effectiveness of lebrikizumab in the AD patients treated to date in our service. Four adult patients with severe atopic dermatitis treated with lebrikizumab from December 2024 to the present were included.

Patients were administered lebrikizumab following SPC (subcutaneously, starting with loading dose of 500 mg at weeks 0 and 2, followed by 250 mg every two weeks until week 16, then 250 mg monthly).

Results: Three of the patients were women with a mean age of 19 (range 17 to 23). Among the comorbidities, one patient had rhinitis and another had blepharoconjunctivitis. All patients had previously been treated with cyclosporine; one patient had also failed tralokinumab, and another had failed multiple systemic treatments (azathioprine, ustekinumab, upadacitinib, dupilumab, and tralokinumab). The baseline EASI and IGA average scores of the patients were 39 and 4, respectively. All patients achieved EASI < 6 and IGA = 1 after an average of 10 weeks of treatment. The therapeutic response was rapid in all cases, showing improvement between weeks 1 and 3. Two patients reported a sensation of dry eye without signs of conjunctivitis. No serious adverse effects have been identified to date.

Discussion: Severe forms of AD requiring systemic treatment have a significant impact on patients' quality of life, affecting their daily activities and social relationships. This justifies the need for developing new effective drugs for its treatment. Lebrikizumab has shown that patients who respond at week 16 subsequently present a sustained response, improving pruritus, sleep quality, and overall quality of life.

Conclusion: We present four cases of patients with severe AD successfully treated with lebrikizumab. Lebrikizumab has proven to be a rapid and effective drug and, therefore, positions itself as an alternative for the treatment of moderate-to-severe AD, even in patients who have previously failed other biological treatments.



Abstract N°: 2540

Efficacy and Safety of Benvitimod in Patients with Moderate-to-Severe Chronic Hand Eczema: A Prospective, Single-Center, Parallel-Group, Open-Label Randomized Trial

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Introduction & Objectives: Topical corticosteroids are the first-line treatment for chronic hand eczema (CHE). However, data from randomized trials supporting their use are limited. Topical benvitimod is a potential alternative for long-term maintenance. To evaluate the efficacy and safety of benvitimod cream compared to halometasone in the treatment of moderate-to-severe CHE.

Materials & Methods: A prospective, single-center, parallel-group, open-label randomized trial was conducted, involving 64 patients with moderate-to-severe CHE. Patients were randomly assigned to either the benvitimod group (n=32, 1% benvitimod cream twice daily for 8 weeks) or the halometasone group (n=32, halometasone cream twice daily for 8 weeks). The primary endpoint was the proportion of patients achieving “treatment success” at week 12. Secondary endpoints included changes from baseline to week 12 of the Hand Eczema Severity Index (HECSI), Patient Global Assessment (PaGA), Dermatology Life Quality Index (DLQI), and Quality of Life in Hand Eczema Questionnaire (QOLHEQ). The relapse rate and dverse events were also recorded.

Results: A total of 30 patients in the benvitimod group and 29 patients in the halometasone group completed the trial. At week 12, the treatment success rate was 26.7% (8/30) in the benvitimod group and 24.1% (7/29) in the halometasone group ($p = 0.824$). Both groups showed significant reductions in HECSI, PaGA, DLQI, and QOLHEQ scores from baseline to week 12 ($p < 0.05$), but there were no statistically significant differences in the changes between the two groups. Among patients achieving treatment success, 25.0% (2/8) patients in benvitimod group and 57.1% (4/7) patients in halometasone group relapsed at week 24 ($p=0.315$). The main adverse events associated with benvitimod were skin pigmentation, pruritus, and skin dryness, none of which led to treatment discontinuation.

Conclusion: The efficacy of benvitimod in treating moderate-to-severe CHE is comparable to that of halometasone, with a favorable safety and low recurrence rate.



Abstract N°: 2545

Achieving minimal disease activity with Upadacitinib for moderate-to-severe atopic dermatitis: a 3-year real-world study

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Achieving minimal disease activity with Upadacitinib for moderate-to-severe atopic dermatitis: a 3-year real-world study

Introduction & Objectives:

Minimal Disease Activity (MDA) is an emerging treatment goal in atopic dermatitis (AD), representing a state of optimal disease control with minimal symptoms. Despite its relevance, MDA remains underexplored in real-world settings. To assess the achievement of MDA in patients with moderate-to-severe AD treated with upadacitinib over three years and identify predictive factors.

Materials & Methods:

This retrospective study included all patients treated with upadacitinib at the Dermatology Clinic of the University of Turin between December 2020 and December 2024. MDA was defined as the simultaneous achievement of EASI-90 (≥90% improvement in Eczema Area and Severity Index) and P-NRS (Pruritus Numerical Rating Scale) ≤ 1. Effectiveness was assessed at 28, 52, 104, and 156 weeks.

Results:

At 28 weeks, 50.0% of patients achieved MDA, with sustained results over three years. Female sex was significantly associated with MDA achievement (OR 4.14, p = 0.034), while other factors showed no significant correlation.

Conclusion:

Upadacitinib effectively achieves and maintains MDA in moderate-to-severe AD over three years. Female sex was a positive predictor of MDA. Further studies are warranted to confirm these findings.



Abstract N°: 2599

Skin Allergy Research Society and Society for Eczema Studies Joint Task Force Guidelines of Care for Management of Atopic Dermatitis for Adult, Children and Special Population in India: An Evidence-Based Review and an Expert Consensus

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease with significant morbidity. Recognizing the need for region-specific guidance, the Skin Allergy Research Society (SAS) and Society for Eczema Studies (SES) have collaborated to develop updated, evidence-based guidelines tailored to the Indian context. These guidelines address AD management across all age groups and special populations while considering local epidemiology, healthcare infrastructure, and treatment accessibility.

Materials & Methods:

A structured Delphi consensus process was conducted among 23 dermatology experts over three months through virtual and in-person meetings. Literature from MEDLINE, Cochrane, Google Scholar, and other sources was systematically reviewed, and the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) approach was used to assess evidence quality. Clinical recommendations were refined through

multiple voting rounds, leading to consensus statements. Recommendations are based on an extensive literature review up to December 2024.

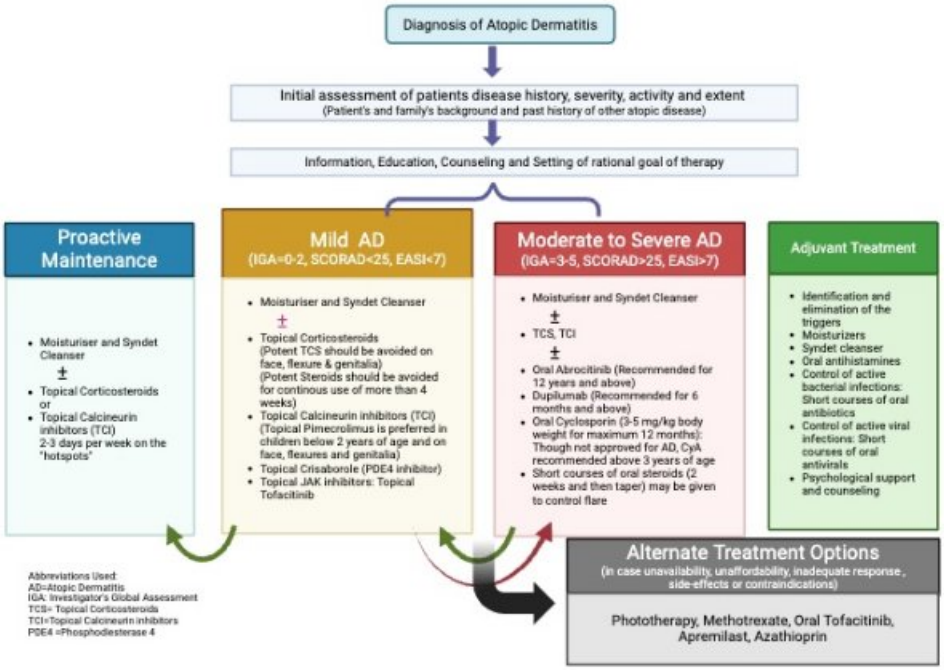
Results:

This document updates the 2019 Skin Allergy Society guidelines, reinforcing global recommendations while allowing local adaptability. These guidelines provide updated recommendations for topical, systemic, phototherapy, and biologic therapies in AD. Key advancements include the introduction of topical crisaborole and JAK inhibitors for mild to moderate AD, along with a focus on emerging systemic therapies, such as biologics and systemic JAK inhibitors.

In the Indian context, the guidelines define the roles of dupilumab and abrocitinib while also addressing the off-label use of tofacitinib and baricitinib in resource-limited settings. Specific recommendations are provided for children, elderly patients, and pregnant women, emphasizing safety considerations for systemic and biologic therapies.

Conclusion:

These guidelines align with global AD management while incorporating India-specific adaptations based on epidemiology, accessibility, and affordability. They serve as a key reference for dermatologists, pediatricians, and general practitioners in India and other resource-limited settings. Though tailored for India, they are also relevant to dermatologists in developing countries, guiding treatment selection based on disease patterns, environmental factors, and medication availability.





Abstract N°: 2635

Calcineurin inhibitors compared to corticosteroids for atopic dermatitis treatment in children: a systematic review and meta-analysis

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Introduction & Objectives: Atopic dermatitis (AD) is the most common inflammatory skin disorder in the developed world. While current treatments for AD primarily focus on anti-inflammatory therapy using topical corticosteroids (TCS), topical calcineurin inhibitors (TCIs) present a promising steroid-sparing alternative. In light of this, we conducted an updated meta-analysis comparing TCIs and TCS in the pediatric population.

Materials & Methods: We searched the PubMed, Embase, and Cochrane databases up to December 2024 for studies comparing topical calcineurin inhibitors (TCIs) such as pimecrolimus, tacrolimus, or cyclosporine with topical corticosteroids (TCS) in children and adolescents with atopic dermatitis (AD). The studies included outcomes measured by the Eczema Area and Severity Index (EASI) or the modified EASI (mEASI), the Investigator Global Assessment (IGA), and reported side effects. We calculated risk ratios (RRs) for binary outcomes and mean differences (MDs) for continuous outcomes, along with 95% confidence intervals (CIs). The heterogeneity of the studies was assessed using I^2 statistics.

Results: 12 studies comprising 2,583 patients were included, of whom 1,405 (54.39%) underwent TCI treatment. The results were similar between groups regarding EASI (MD -0.45 points; 95% CI -1.07, 0.17; I2 = 0; p = 0.154) and mEASI (MD 0.32 points; 95% CI -0.71, I2 = 75.3; p = 0.54) and IGA scored as clear/improvement (RR 1.14; 95% CI 0.53, 2.46; I2 93.3; p = 0.734). Concerning side effects, the burning sensation was more common in the intervention group (RR 3.20; 95% CI 1.91, 5.35; I2 = 56.4; p < 0.001).

Conclusion: In our analysis, TCIs demonstrated similar effectiveness to TCS in children with atopic dermatitis (AD). For patients unable to use TCS, TCIs can serve as a suitable alternative in the search for steroid-sparing or alternative therapies. However, it is important to consider the higher risk of side effects when weighing the benefits and risks of these two.



Abstract N°: 2648

Development and characterization of IAR129, a novel bispecific antibody co-blocking IL-4Ra and OX40L for atopic dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) has been characterized as a type 2 dominant inflammation. Recent data indicate that additional proinflammatory pathways can play a role besides the core Th2 response. Current targeted therapies focus on type 2 immunity, primarily the IL-4/IL-13 pathway, and have achieved good clinical response in AD patients. Nevertheless, there is still room to improve the depth, width and duration of response. OX40L is an emerging target with a key upstream function in priming, differentiation and memory response of T cells including Th2 and the other subsets. OX40 and OX40L antagonist antibodies are in active clinical development, and the OX40L antibody, amlitelimab, has demonstrated promising response with inhibition of Th2, Th1 and Th17/22 cytokines. Here, we report a novel, half-life extended bispecific antibody, IAR129, that simultaneously blocks both IL-4Ra and OX40L. It aims at suppressing both the core type 2 cytokines and the OX40L pathway for effective and durable response in patients with type 2 dominant as well as a more mixed cytokine profile. We examine IAR129 for its *in vitro* and *in vivo* activity, developability and PK/PD in NHP.

Materials & Methods:

The *in vitro* blocking activity of each arm was assessed by IL-4 and IL-13 blockade respectively in TF-1 cell proliferation assay, as well as suppression of IL-2 release in activated primary human T cells. To evaluate the combinatorial effect of the bsAb, an *in vitro* allogeneic mixed lymphocyte reaction (MLR) assay of DC-T cell coculture was performed with PBMC from different donors. Additionally, we established mouse models of IL13-induced airway inflammation and TSLP-induced atopic dermatitis to evaluate the *in vivo* activity of IAR129. PK profile was evaluated in cynomolgus monkeys via single-dose intravenous administration at 10 mg/kg. Developability tests were performed according to industrial standards for biologics.

Results:

IAR129 strongly inhibited IL-4, IL-13 and OX40L signaling comparable to benchmarks dupilumab (anti-IL4R) or amlitelimab (anti-OX40L). In human DC-T cell coculture assay, IAR129 robustly suppressed both IL-5 and IL-13 production, better than dupilimab and amlitelimab alone. Furthermore, IAR129 effectively alleviated airway inflammation and atopic dermatitis in mice. In cynomolgus monkeys, IAR129 exhibited favorable PK profile with a clearance of 0.43 mL/h/kg and a half-life of 377 hours. Importantly, IgE was reduced in these monkeys for over 40 days after a single injection. Besides, IAR129 had favorable developability with a viscosity of 6.15 cp at 150 mg/mL formulation, making it possible for high concentration formulation and subcutaneous administration.

Conclusion:

IAR129 is a first-in class IL4R and OX40L bispecific antibody with half life extension. It potently blocks IL-4, IL-13 and OX40L *in vitro* comparable to dupilumab and amlitelimab. It shows combinatorial activity superior to single blockade in DC-T coculture, and is highly effective in suppressing both airway inflammation and atopic dermatitis in mice. It has good PK profile and durable PD response in monkeys. The favorable developability profile enables

high concentration formulation and subcutaneous administration.

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Abstract N°: 2657

Efficacy and safety of a topical cream containing Lignosus rhinocerus in mild-to-moderate atopic dermatitis: a 6-week split-site pilot study

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Introduction & Objectives:

Lignosus rhinocerus (*L. rhinocerus*), commonly known as the tiger milk mushroom, is a wild edible mushroom indigenous to the jungles of Asia, including Malaysia. It was successfully cultivated in 2009, which subsequently spurred extensive research into its therapeutic applications. Previous studies have successfully highlighted the anti-inflammatory and immunomodulatory properties of *L. rhinocerus*, including downregulation of the Th2 pathway which is crucial in the development of atopic dermatitis. Due to its anti-inflammatory, immunomodulatory, antifungal and antibacterial properties, we investigated the use of *L.rhinocerus* as a steroid-sparing topical treatment option for atopic dermatitis (AD).

Materials & Methods:

A six-week, randomized, split-site study involving 22 patients aged 12 years and above evaluated the efficacy and safety of a topical cream containing *L. rhinocerus* as a treatment for mild-to-moderate AD compared to hydrocortisone 1% cream. Site-specific disease severity was assessed using the Peak Pruritus Numerical Rating Scale (PNRS) and the Atopic Dermatitis Severity Index (ADSI). The occurrence of any adverse events (AEs) was recorded.

Results:

The study cream containing *L. rhinocerus* showed a significant improvement in site-specific disease severity (mean ADSI 4.4 at baseline to 2.1 at Week 6, p=0.010) and pruritus (mean PNRS 2.2 at baseline to 1.1 at Week 6, p=0.018) at the end of the study. These results at 6 weeks were comparable to the hydrocortisone 1% cream arm with reduction in mean ADSI from 4.3 at baseline to 1.9 (p=0.010) and mean PNRS from 2.3 to 0.8 (p=0.002). No adverse effects were reported.

Conclusion:

L. rhinocerus is a steroid-sparing topical agent with potential utility in the treatment armamentarium for adults and adolescents with AD, especially for areas of thinner skin or body folds, where the risk of adverse events of topical corticosteroids may be more pronounced.

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Abstract N°: 2662

Inhibition of indoleamine 2,3-dioxygenase 1 alleviates atopic dermatitis-like symptoms

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Inhibition of indoleamine 2,3-dioxygenase 1 alleviates atopic dermatitis-like symptoms

Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by immune dysregulation and skin barrier dysfunction. The tryptophan metabolism, primarily through the tryptophan-indoleamine 2,3-dioxygenase 1 (IDO1)-kynurenine pathway, plays a key role in immune regulation and inflammation; however, its involvement in AD pathogenesis remains unclear. This study investigated the therapeutic effects of PF-06840003 (PF), a selective inhibitor for IDO1, in AD models.

Materials & Methods:

Human primary keratinocytes were stimulated with PF (100 ~ 400 μM) in the presence or absence of interleukin (IL)-4/IL-13 and the mRNA expression of inflammatory cytokines and chemokines was analyzed using real-time PCR. *In vivo*, an MC903-induced AD-like mice were administered with PF (5 ~ 15 mg/kg) or vehicle. Disease severity was evaluated by ear thickness, scratching behavior, and transepidermal water loss (TEWL). Skin biopsies were analyzed for inflammatory cytokines and skin barrier-related genes. Histological assessments included hematoxylin and eosin (H&E) staining for epidermal thickness and toluidine blue staining for mast cell infiltration.

Results:

In vitro studies revealed that PF dose-dependently suppressed the mRNA expression of *IL1α*, *IL6*, *IL8*, *CCL2*, and *CCL3* in human keratinocytes stimulated with IL-4/IL-13 cocktail. Moreover, *in vivo*, PF alleviated AD-like symptoms in mice, significantly reducing skin inflammation, ear thickness, scratching bouts, and TEWL in a dose-dependent manner. Meanwhile, PF suppressed the mRNA expression of *Tnf*, *Il4*, and *Il13*, and upregulated skin barrier-related genes such as *Tjp1* and *Cldn1* in AD skin lesion. Histologically, H&E staining and toluidine blue staining showed a significant decrease in epidermal thickness and mast cell infiltration, respectively, in PF-treated groups compared to the counterpart.

Conclusion:

PF exhibited potent anti-inflammatory and skin barrier-protective effects in both *in vitro* and *in vivo* models of AD, suggesting that IDO1 inhibition and regulation of tryptophan metabolism as a promising therapeutic strategy for skin inflammation such as AD.



Abstract N°: 2668

Emollients containing urea and/or propylene glycol as humectant have varying effects on the skin barrier of patients with atopic dermatitis, while all remain gentle on the skin microbiome

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Introduction & Objectives: The imparied skin barrier plays a pivotal role in the pathogenesis of Atopic Dermatitis (AD), and the most common symptoms are itch and dry skin. Regular emollient application is the mainstay of xerosis management. While almost any emollient can improve skin dryness, their long term effect on the skin barrier vary, with some even shown to impair the barrier. Therefore, it's crucial to assess the effect of an emollient on the skin barrier before recommending it to a patient with AD, who needs daily moisturization.

Recently, there has been growing interest in how emollients affect the resident skin microbiome. Propylene glycol has some antimicrobial effect, and concerns regarding potential negative effects that preservatives in skincare can have on the skin microbes have been raised. Therefore, it is becoming increasingly important to consider the impact of emollients on the skin microbiome. The aim of the study was to compare the barrier-strengthening properties of a new emollient, containing 5% urea and 20% propylene glycol (test emollient), to 1) a propylene glycol containing emollient 2) an emollient containing urea and 3) no treatment. The impact of these emollients on the skin microbiome was also analysed.

Materials & Methods: A double-blind prospective within-subject multilateral randomized controlled study in adults with a personal history of AD. Enrolled participants were instructed to treat the lower or upper parts of the lower volar forearms (i.e. 4 treatment areas, includes no treatment control, randomized allocation) with the 3 products twice daily. After 4 weeks of treatment, all 4 areas were challenged with the irritant 1 % sodium lauryl sulphate (SLS). The primary outcome was skin sensitivity to the irritant. In addition, a skin swab from each treatment area (and untreated skin) of each participant was collected and sent for skin microbiome analysis using 16S rDNA sequencing.

Results: 43 patients completed treatment with no major protocol deviations and were included in the analysis. The primary objective was achieved; the test emollient was shown to be superior to no treatment and to the emollient containing propylene glycol in reducing TEWL, indicating that the skin barrier became stronger and more resilient after treatment. The skin barrier strengthening effect was equal to that of the urea emollient. The skin also became less red following application of skin irritant on areas treated with the new emollient compared to untreated skin.

Skin swabs collected from each treatment area were analyzed for positive or negative impact of the skin emollients on the resident microbiome. No significant changes were observed in the microbiome after treatment of any of the emollients, indicating that the emollients in this study are gentle to the microbiome. The study treatments were all well tolerated.

Conclusions: Treatment for 4 weeks with the test emollient containing urea and propylene glycol showed significant protection from SLS-induced skin irritation, resulting from a more resilient skin barrier. In contrast, the protection provided by the emollient containing only propylene glycol was no different from untreated skin, which highlights that not all emollients have positive influence on the skin barrier function. By helping to correct a major

pathophysiological process in AD, the test emollient has the potential to improve the long-term control of this condition without disrupting the resident microbiome.



Abstract N°: 2691

Early Super-Responder to Lebrikizumab in Moderate-to-Severe Atopic Dermatitis: A Real-World Clinical Case

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Introduction & Objectives: We present the case of a 23-year-old male with long-standing moderate-to-severe atopic dermatitis (AD) and insufficient response to prior systemic therapies, who showed rapid improvement after starting lebrikizumab. By week 4, he met criteria for both super-responder (Spanish Delphi consensus) and Minimal Disease Activity (MDA; Silverberg et al.). This case emphasizes lebrikizumab's potential as a fast-acting option for refractory AD.

Materials & Methods: The patient had perinatal-onset AD with comorbid allergic rhinitis and seasonal asthma. Prior therapies included high-potency topical corticosteroids, calcineurin inhibitors, short systemic corticosteroids, subcutaneous methotrexate (15 mg/week), and cyclosporine (4 mg/kg/day), which lost efficacy after 8 months. Due to poor control, lebrikizumab was initiated per approved regimen: 500 mg SC at weeks 0 and 2, then 250 mg every two weeks to week 16, followed by 250 mg every 4 weeks. At baseline, he had involvement of the face (frontal region, upper eyelids), antecubital folds, dorsal/lumbar areas, and feet dorsum. EASI: 22.81; IGA: 3; PP-NRS: 8 (pruritus), 7 (sleep disturbance).

Results: At week 4, he showed marked improvement—particularly in the face and back—with IGA 1, EASI 1.41, PP-NRS 3 (pruritus), and 2 (sleep). Response was maintained without rescue therapy or adverse events. Lebrikizumab, a high-affinity IgG4 monoclonal antibody, targets IL-13, a key cytokine in type 2 inflammation, blocking IL-13Rα1/IL-4Rα signaling without affecting IL-13Rα2. Phase 3 ADvocate 1 and 2 trials demonstrated efficacy as monotherapy by week 16 (EASI-75 >50%) with sustained results and favorable safety. The "super-responder" phenotype, per Liñán-Barroso et al., describes rapid (≤4 weeks), sustained improvement and QoL gains. Silverberg et al. proposed MDA targets (EASI <5, pruritus/sleep ≤3) for individualized treatment goals.

By week 4, our patient had EASI <2, pruritus reduced from 8 to 3, sleep from 7 to 2, and IGA 1—meeting both definitions. Rapid facial and dorsal lesion resolution was especially meaningful psychosocially. These outcomes align with ADvocate and TREBLE trial findings showing early pruritus (week 2) and EASI (week 4) improvements. Chovatiya et al. showed that over 85% of patients on tralokinumab reached H&N-EASI ≤1 at week 152, correlating with reduced discomfort and embarrassment from facial AD. Similarly, early frontal and eyelid lesion clearance in our patient was highly impactful, reinforcing anti–IL-13 agents' role in systemic control and hard-to-treat regions like the face and neck.

Conclusion: Lebrikizumab is a safe, effective therapy for moderate-to-severe AD, offering rapid symptom relief and potential for deep, sustained responses. This case illustrates how even treatment-refractory patients can achieve early super-responder and MDA status, supporting the clinical value of lebrikizumab.



Abstract N°: 2722

Delgocitinib cream is well tolerated in Chronic Hand Eczema: DELTA 1 and 2 pooled analysis

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Introduction & Objectives: In adults with moderate to severe Chronic Hand Eczema (CHE), delgocitinib cream, a topical pan-Janus kinase (JAK) inhibitor, demonstrated significant improvement in primary and all secondary efficacy endpoints and was well tolerated in DELTA-1 (NCT04871711) and DELTA-2 (NCT04872101) with a safety profile comparable to cream vehicle. The objective of this pooled *post hoc* analysis of DELTA-1/-2 was to further analyse the tolerability of delgocitinib cream to help clinicians communicate expectations to their patients by exploring the relationship between tolerability and CHE.

Materials & Methods: Adults with moderate to severe CHE, who were treated with delgocitinib cream 20 mg/g (N=638) or cream vehicle (N=321) twice daily for 16 weeks, were included. Patients and investigators provided local tolerability assessments up to Week (W)16. Patients reported worst stinging/burning experienced over the last week in association with trial drug application (severity grade: 0-3). Investigators evaluated the skin of patients for signs of possible local reactions to trial drug. Tolerability was also examined in relation to baseline Hand Eczema Symptom Diary (HESD) cracking subscore (weekly average; 0-3; 4-6; ≥7) or baseline Hand Eczema Severity Index (HECSI) fissure subscore (0-2; 3-4; ≥5).

Results: Most patients experienced no to mild local symptoms at any timepoint from W1-16 ([W1/4/16] delgocitinib: 79.7/87.7/97.6%; cream vehicle: 71.5/77.7/97.7%). The proportion of patients with severe symptoms was low, with symptoms quickly resolving from W1-16 ([W1/4/16] delgocitinib: 5.0/2.5/0.2%; cream vehicle: 12.3/5.5/0.0%). Few (0.5% [3/638]) delgocitinib-treated patients discontinued due to adverse events related to treatment. According to the investigator assessment, almost all patients had no suspected local skin reactions related to trial treatment during W1-16 ([W1(n/N)/16(n/N)] delgocitinib: 99.8% [620/621]/100% [596/596]; cream vehicle: 98.4% [302/307]/100% [263/263]). Similar results were seen for patients who terminated early (delgocitinib/cream vehicle: 97.1% [34/35]/90.2% [37/41]). Any stinging/burning sensations reported by delgocitinib-treated patients were likely related to underlying disease, particularly cracking or fissures. Patients with higher cracking or fissures scores tended to report more symptoms versus those with lower scores. From W1-16, mild to severe symptoms decreased in all observed categories for baseline HESD cracking ([W1/4/16] scores 0-3: 41.6/35.7/5.9%; 4-6: 44.8/33.6/11.1%; ≥7: 56.6/47.5/7.2%) and baseline HECSI fissure scoring ([W1/4/16] subscores 0-2: 51.6/36.1/8.1%; 3-4: 48.8/39.9/7.1%; ≥5: 61.1/47.3/10.8%). Overall, few patients reported local skin infections of the hands or wrists, with similar rates observed between the treatment groups ([number of events/R] delgocitinib: 5/2.5; cream vehicle: 3/3.2).

Conclusion: In DELTA-1/-2, most delgocitinib-treated patients reported no or mild symptoms, e.g., stinging/burning, with symptoms quickly resolving/improving through W16. Although infrequent, it is important

to inform and educate clinicians about possible symptoms in patients with CHE, to maximize treatment compliance and appropriately manage expectations.



Abstract N°: 2730

Delgocitinib cream provides early and meaningful responses in adults with moderate to severe Chronic Hand Eczema: a pooled analysis of the phase 3 DELTA-1 and DELTA-2 trials

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Introduction & Objectives: The topical Janus kinase (JAK) inhibitor, delgocitinib cream, was well tolerated and significantly improved all efficacy endpoints in moderate to severe Chronic Hand Eczema (CHE) in 2 phase 3 trials (DELTA-1/2). The primary endpoint was Week (W)16 Investigator's Global Assessment for CHE (IGA-CHE) score of 0/1 (clear/almost clear skin), with ≥2-step improvement from baseline. The newly redefined and stringent 'almost clear' category in the IGA-CHE scale does not fully capture the full range of responses to delgocitinib. Here we investigate other measures of clinical response, and treatment kinetics, to help clinicians contextualize and explain potential benefits of delgocitinib to patients with CHE.

Materials & Methods: Patient-reported outcome measures (PROMs), including Hand Eczema Symptom Diary (HESD)-itch, HESD-pain, Dermatology Life Quality Index (DLQI), and Hand Eczema Impact Scale (HEIS), were assessed in pooled DELTA-1/2 patients treated with twice-daily delgocitinib (N=639) or cream vehicle (N=321) through Week (W)16, according to baseline primary aetiological and morphological CHE subtype.

Results: Responder rates for ≥4-point improvement in HESD-itch/HESD-pain/DLQI at W16 were greater with delgocitinib than cream vehicle across all CHE subtypes. For example, in vesicular CHE, 53.0%/57.0%/72.9% of patients treated with delgocitinib achieved these clinically meaningful improvements versus 21.6%/28.1%/47.1% with cream vehicle. Significantly greater response in each of these endpoints was achieved with delgocitinib versus cream vehicle ($P<0.05$) within 4 weeks for all subtypes, and as early W1 for DLQI (for ICD/AD/vesicular). Similar response time was observed for HEIS, with clinically meaningful responses from W2. Greater improvements from baseline in absolute HESD-itch/HESD-pain were seen with delgocitinib versus cream vehicle ($P<0.05$) for all subtypes by Day 10, and as early as Day 1.

Conclusion: Delgocitinib demonstrated clinically meaningful improvements at W16 in itch, pain, and quality of life in adults across all major subtypes of moderate to severe CHE. These improvements were statistically significant with delgocitinib versus cream vehicle as early as W1, demonstrating the rapid efficacy of delgocitinib across subtypes.

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Abstract N°: 2738

Delgocitinib cream 20 mg/g in Chronic Hand Eczema patients with skin fissures: efficacy, safety, and pharmacokinetics

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Introduction & Objectives: Patients with CHE often have skin fissures, which are typically painful and difficult to treat. When treating fissures with topical therapies, the systemic exposure and safety, alongside efficacy, are of high importance due in part to the damaged skin barrier. Here, we examined efficacy, safety, and PK of delgocitinib cream in patients with fissures from two phase 3 trials.

Materials & Methods: Adults with moderate to severe CHE receiving twice-daily delgocitinib cream 20 mg/g or cream vehicle for 16 weeks in DELTA-1 (NCT04871711) or DELTA-2 (NCT04872101) were analyzed. Efficacy was based on the HECSI fissure score, defined as sum of fissure severity scores across five hand regions (range: 0-15). Responder rates for HECSI fissure 0 or 0/1 (clear/mild in a single region) and AE rates were assessed. Plasma concentrations of delgocitinib (DELTA-2) were compared with PK data from a phase 1 trial (NCT05050279) of healthy adults receiving oral delgocitinib 1.5mg and IC50 values from in vitro spiking of whole blood from healthy adults.

Results: At baseline, patients in the delgocitinib cream group with fissures (HECSI fissure >0, n=586) had a mean fissure score of 4.9 (SD=2.7) and showed greater disease severity vs patients without fissures (HECSI fissure 0, n=52) (mean HECSI, 73.6 vs 43.3). From Weeks 2-16, more patients receiving delgocitinib cream vs cream vehicle achieved HESCI fissure 0 (Week 16: 40.8% vs 18.3%, P<0.001) or 0/1 (Week 16: 55.3% vs 29.7%, P<0.001). Median percent improvement in HECSI fissure score was greater from Weeks 1-16 in patients receiving delgocitinib cream vs cream vehicle (Week 16: 72.7% vs 33.3%, P<0.001). No meaningful differences in safety were observed between delgocitinib cream-treated patients with vs without fissures at baseline (overall AEs, 45.6% vs 46.2%; severe AEs, 2.0% vs 5.8%). Delgocitinib geometric mean plasma concentrations (ng/mL) among patients with fissures at baseline (n=284) were minimal and decreased from Week 1 (0.23) and Week 4 (0.21) to Week 16 (0.12). These plasma concentrations were substantially lower compared with oral delgocitinib 1.5mg (7.22 ng/mL) and whole blood IC50 (24 ng/mL).

Conclusion: Delgocitinib cream demonstrated efficacy, leading to complete resolution of fissures in 40% of patients, and a comparable safety profile in patients with/without fissures. Additionally, systemic exposure of delgocitinib cream was negligible in patients with fissures at baseline.



Abstract N°: 2749

PKM2 is a promising novel target in atopic dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) is a complex, chronic inflammatory, non-contagious skin disease with high unmet need and no curative treatment options. Pyruvate kinase M2 (PKM2) is a key enzyme in the central metabolic pathway of glycolysis and is specifically upregulated in inflammatory tissues. Here we describe PKM2 as a novel target in AD and demonstrate efficacy of novel PKM2 modulators in several mouse models of inflammatory skin disease: KLH-induced delayed-type hypersensitivity (DTH), 2,4 dinitrofluorobenzene (DNFB) and oxazolone induced contact dermatitis models. A PKM2 modulator has recently entered into a clinical trial for AD.

Materials & Methods:

PKM2 expression was studied in human healthy skin and AD skin using immunohistochemistry and RNA sequencing. The *in vitro* pharmacology of PKM2 modulators was studied using biochemical assays and pyruvate kinase activity in human CD4+ T cells. The *in vivo* pharmacology of PKM2 modulators was determined in 3 murine models. DNFB or oxazolone were used to induce contact dermatitis and KLH was used to induce DTH. Efficacy was measured using ear thickness, excoriations, ear RNA sequencing or ear Luminex (IL-1β, IL-4, IL-6, IL-13, IFNγ, IL-17a, IL-31).

Results:

PKM2 was overexpressed in the immune cell infiltrate and in keratinocytes in severe lesional atopic dermatitis compared to healthy skin. Similarly, PKM gene expression was elevated in AD biopsies, notably in chronic lesions. As a potential AD therapeutic, novel, small molecule PKM2 modulators were shown to potently activate human and mouse PKM2 enzymes. Pyruvate kinase activity was also observed in lysates from human CD4+ T cells pre-treated with these compounds. In the DNFB model, PKM2 modulators resulted in a significant decrease in ear thickness, a surrogate for inflammation, and were accompanied by decreases in ear IL-13, IL-17A and IL-6 and decreases in chemokine gene expression. Similarly, there was a decrease in IL-31, a cytokine associated with itch. PKM2 modulation also normalised expression of genes required for barrier function, including filaggrin, loricrin and involucrin. A decrease in ear thickness was also observed in the oxazolone model, accompanied by a decrease in skin excoriations, consistent with itch reduction. Similarly, PKM2 modulators decreased ear thickness in the KLH model.

Conclusion:

PKM2 modulation offers an oral, targeted, disease-modifying anti-inflammatory approach, targeting a critical enzyme that regulates cell metabolism. The proposed mechanism of action is believed to have targeted effects at sites of inflammation, enabling a differentiated safety profile. The studies show that a novel PKM2 modulator inhibits both inflammation and itch, whilst promoting skin barrier repair. This modulator has recently entered clinical trials in healthy volunteers and patients with moderate to severe AD. This PKM2 modulator could address

the major unmet needs of AD as a safe oral, convenient and effective therapy where there are limited treatment options under the current standard of care.

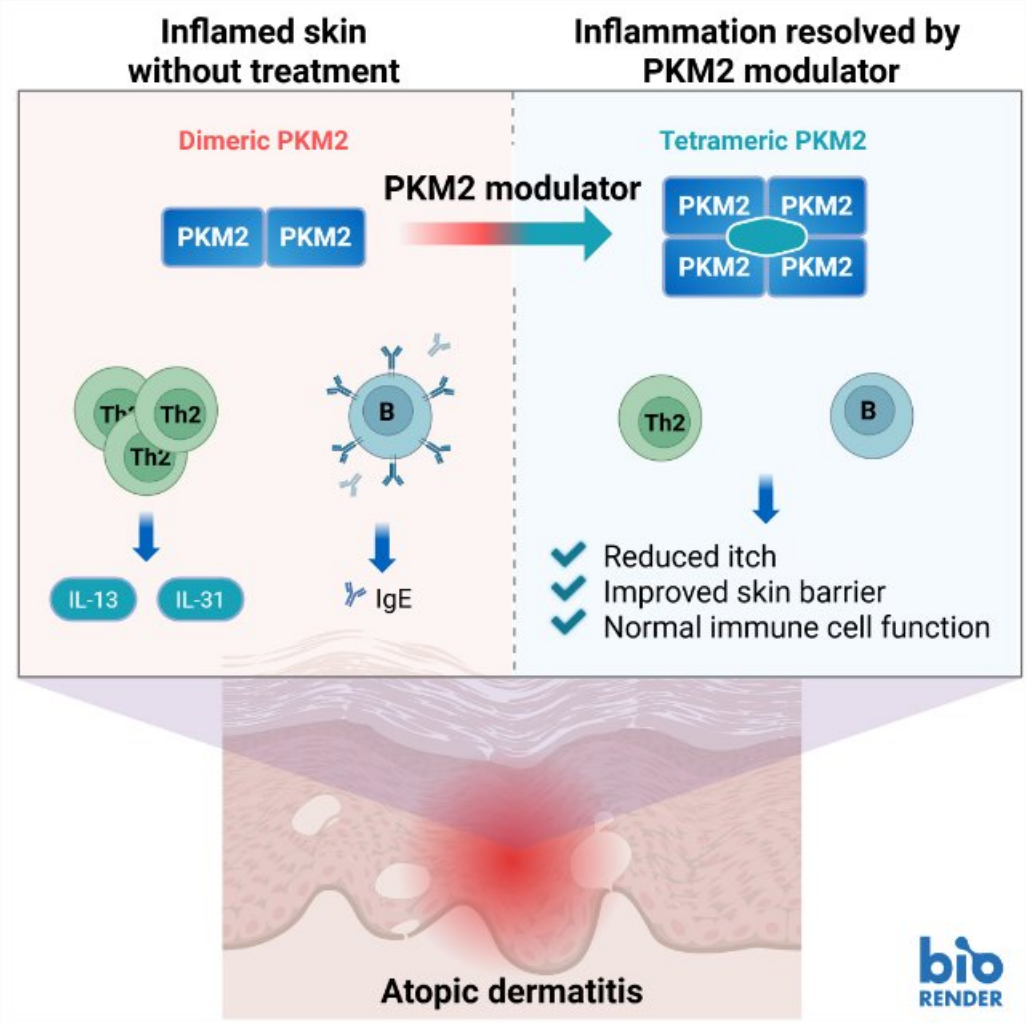


Figure – Resolution of inflammation in atopic dermatitis with a PKM2 modulator



Abstract N°: 2764

Drug Survival in Atopic Dermatitis: Comparison of Biologics and JAK inhibitors in the BioDay Registry

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Introduction & Objectives:

With the expansion of targeted systemic drugs for atopic dermatitis (AD), comparative data on effectiveness and tolerability are needed. This study aimed to (i) compare the 2-year drug survival (DS) of biologics and Janus kinase inhibitors (JAKi) and identify associated predictors and (ii) evaluate the impact of the introduction of new targeted therapies on dupilumab DS.

Materials & Methods:

This multicenter, prospective cohort study included adult AD patients treated with biologics (dupilumab, tralokinumab) or JAKi (abrocitinib, baricitinib, upadacitinib) between Jan 2021 - Oct 2024 from the BioDay registry. Dupilumab TEs from Oct 2017 - Oct 2024 were included in the secondary analysis. Subgroup analyses included biologic-/JAKi-naïve and -experienced patients. Uni- and multivariable Cox regression models corrected for within-subject correlation were used to compare DS and identify potential predictors per discontinuation reason and treatment type.*

Results:

1583 treatment episodes (TEs) were included: 865 dupilumab, 227 tralokinumab, 144 abrocitinib, 106 baricitinib,

241 upadacitinib. The 2-year overall DS rates were 75.9% for dupilumab, 48.4% for tralokinumab, 27.1% for abrocitinib, 28.9% for baricitinib, and 51.7% for upadacitinib, and were mostly associated with ineffectiveness (n=260, 16.4%). Multivariable analyses found superior overall DS for dupilumab compared to tralokinumab (HR 2.4, 95% CI 1.8-3.2, p<.0001), abrocitinib (HR 3.3, 95% CI 2.4-4.4, p<.0001), baricitinib (HR 5.0, 95% CI 3.6-7.1, p<.0001), and upadacitinib (HR 2.2, 95% CI 1.6-2.9, p<.0001). Analyses in naïve and experienced patients found similar superior dupilumab DS, though differences were less pronounced. Dupilumab DS decreased after the introduction of new therapies in 2021 (HR 2.0, 95% CI 1.4-2.5, p<.0001). Predictors for discontinuation due to ineffectiveness in the total cohort were use of ≥2 prior conventional immunosuppressants (HR 1.3, 95% CI 1.1-1.5, p=.0007) and higher Numeric Rating Scale (NRS) itch score at baseline (HR 1.2, 95% CI 1.1-1.4, p=.003). Age (HR 1.4, 95% CI 1.1-1.7, p=.004) and pulmonary disease (HR 1.5, 95% CI 1.1-2.1, p=.02) were predictors for discontinuation due to adverse effects. Higher NRS itch scores at baseline (HR 1.4, 95% CI 1.1-1.7, p=.002) and concomitant immunosuppressant use at baseline (HR 1.9, 95% CI 1.3-2.6, p=.0001) were predictors for higher discontinuation rates of dupilumab, and older age for lower discontinuation rates of baricitinib (HR 0.5, 95% CI 0.3-0.8, p=.002).

Conclusion:

In this prospective, multicenter cohort, dupilumab had the highest overall DS, followed by upadacitinib, tralokinumab, and abrocitinib, with baricitinib showing the lowest DS rates. Ineffectiveness was the main reason for treatment discontinuation across all therapies. Dupilumab consistently showed superior DS in both naïve and experienced subgroups. Several predictors for DS per discontinuation reason and treatment type were identified. Dupilumab DS declined following the introduction of new targeted systemic therapies, indicating that the expanding treatment landscape influences treatment persistence with established therapies. These comparative DS rates and predictors can support patients and physicians in expectation management and enhance shared decision-making.

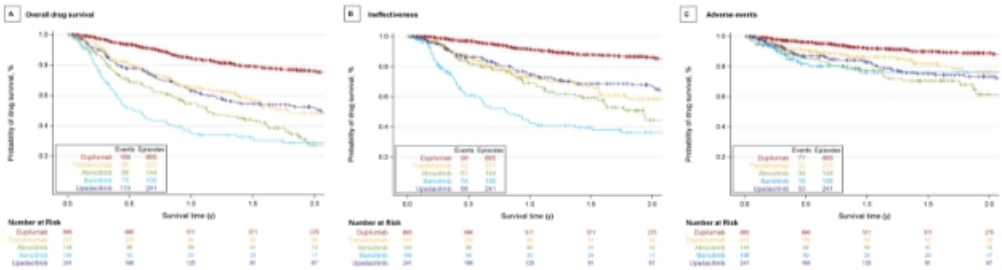


Figure 1. Overall drug survival of the total cohort and survival stratified by reason for discontinuation.



Abstract N°: 2785

Delgocitinib cream formulation development for Chronic Hand Eczema (CHE): insights from patient preference and skin penetration studies

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Introduction & Objectives: Chronic Hand Eczema (CHE) is an inflammatory skin disease associated with significant physical and psychosocial burdens and limited approved treatment options. Delgocitinib cream 20 mg/g (2%) is a non-steroidal topical pan-Janus kinase (JAK) inhibitor formulated for application on hands and does not contain parabens, perfumes, or penetration enhancers. It was well tolerated with minimal systemic exposure and has demonstrated efficacy versus cream vehicle in adults with moderate to severe CHE in DELTA 1 (NCT04871711) and DELTA 2 (NCT04872101). To support the initial development of the delgocitinib cream formulation, two studies assessed (1) patients' preference for formulation and (2) delgocitinib skin penetration.

Materials & Methods: The Patient Preference Market Research Study (PPMRS) was conducted as 'Hall test-style' group sessions with patients with CHE, in which five early formulation options (no active substance) were tested simultaneously (3 light creams, 1 lipid cream, and 1 ointment). Formulation characteristics of consistency/feel, application, and appearance were tested. Skin penetration was assessed in an *in vivo* dermal Open Flow Microperfusion study (OFM) in pigs. Four probes at each of two application sites were inserted within the dermis of two pigs. A single dose of delgocitinib cream formulation was applied to the skin surface (10 mg/cm2) of the application sites and OFM samples were collected in 3-hour intervals for 12 hours.

Results: In the PPMRS, 74 adults with CHE were included, of those 54% were female and 79% were 18-54 years. Overall, 49% of the patients had been diagnosed with CHE for ≥15 years (23% for 10-14 years), with 77% reporting CHE impacted their lives to a "moderate" or "very large" extent. The treatment features being considered most important by patients were quick absorption (58%), not being sticky (43%), and not being greasy (42%). One of the light cream samples performed the best according to perception of consistency/feel (62%), application (77%), and appearance (69%), and was the most preferred product overall among the 5 samples. Based on these results, this formulation was selected to further guide development of delgocitinib cream. Demographic factors, e.g., age, disease history, spot/whole hand application, and impact on quality of life, did not influence product preference. In the OFM, it was shown that delgocitinib distributed into the dermis. The mean (standard deviation) OFM concentration based on the area under the curve (AUC) over the 12 hours sampling time was 121 (102) nM.

Conclusion: Delgocitinib cream is well-suited to patients with CHE, as it was developed based on preferences of patients with CHE and was shown to deliver the active substance to the site of inflammation within the dermis. The cream was developed without skin penetration enhancers which may contribute to the negligible systemic exposure seen in later clinical delgocitinib studies.



Abstract N°: 2787

Delgocitinib cream leads to significant improvements across all Chronic Hand Eczema signs and region HECSI subscores in the phase 3 DELTA-1 and DELTA -2 trials

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Introduction & Objectives: In the phase 3 DELTA-1 (NCT04871711) and DELTA-2 (NCT04872101) trials, delgocitinib cream 20 mg/g, a topical Janus kinase inhibitor, demonstrated statistically significant improvement in all primary and secondary efficacy endpoints and was well-tolerated in patients with moderate to severe Chronic Hand Eczema (CHE). Here we investigate the impact of delgocitinib cream on Hand Eczema Severity Index (HECSI) subscores, and to use changes in HECSI score to assess the proportion of patients achieving clear or almost clear skin.

Materials & Methods: This pooled *post hoc* analysis of DELTA-1 and DELTA-2 included 639 adults treated with delgocitinib cream 20 mg/g and 321 with cream vehicle twice daily for 16 weeks. Times to reach 75% improvement on the HECSI (HECSI-75) and HECSI score of ≤16 (clear/almost clear), and HECSI sign and hand region subscores were measured.

Results: By Week 16, 67.7% of delgocitinib-treated patients achieved HECSI-75 at least once (cream vehicle: 37.1%; P<0.0001 vs. cream vehicle) and 69.5% achieved HECSI measure of clear/almost clear skin at least once (cream vehicle: 43.5%; P<0.0001 vs. cream vehicle), whereas 42.8% of delgocitinib-treated patients achieved Investigator's Global Assessment for CHE (IGA-CHE) score of 0 or 1 (clear/almost clear; cream vehicle: 18.7%) when measuring skin clearance with the IGA-CHE scale. At Week 16, delgocitinib cream treatment improved median HECSI sign subscores from baseline versus cream vehicle (erythema [55.6% vs. 14.3%], fissures [72.7% vs. 33.3%], infiltration/papulation [66.7% vs. 16.7%], oedema [83.3% vs. 36.4%], scaling [50.0% vs. 20.0%], and vesicles [100% vs. 50.0%]; all P<0.0001 vs. cream vehicle). Median improvements were observed in all affected areas of the hand (region subscore [delgocitinib cream vs. cream vehicle]: back of hand [100% vs. 50.0%], fingers excluding tips [77.5% vs. 25.0%], fingertip [78.7% vs. 33.3%], palm of hand [75.0% vs. 33.3%], and wrists [100% vs. 54.5%]; all P<0.0001 vs. cream vehicle).

Conclusion: Delgocitinib cream 20 mg/g was a well-tolerated topical treatment that led to improvements across the key clinical signs of CHE and all affected areas of the hand, throughout the 16-week trials. More than 2 out of 3 delgocitinib-treated patients achieved clear or almost clear skin as measured by change from baseline in HECSI score. Statistically significant improvements with delgocitinib cream 20 mg/g over cream vehicle were seen across

all signs of CHE (including erythema, scaling, vesicles, and fissures) and all regions of the hand and wrist up to Week 16.



Abstract N°: 2803

Caregiver-Reported Outcomes From the Phase 3 INTEGUMENT-PED Trial of Children Aged 2–5 Years With Atopic Dermatitis and Treated With Roflumilast Cream 0.05%

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Introduction & Objectives: Poorly controlled AD may impact the whole family. Roflumilast cream 0.15% and 0.05% have demonstrated efficacy, safety, and tolerability, compared with vehicle, in patients aged ≥6 years and aged 2–5 years with atopic dermatitis (AD) in the INTEGUMENT-1/2 and INTEGUMENT-PED phase 3 trials, respectively. Poorly controlled AD may impact the whole family. The objectives of this analysis of patients in INTEGUMENT-PED/NCT04845620 were to evaluate symptom and health-related quality-of-life changes with roflumilast versus vehicle.

Materials & Methods: Eligible patients were aged 2–5 years with mild to moderate AD. Roflumilast cream 0.05% or vehicle cream was applied once daily by a caregiver for 4 weeks. The primary endpoint was Validated Investigator Global Assessment for AD (vIGA-AD) success (clear/almost clear [0/1] plus ≥2-grade improvement from baseline) at week 4. Worst Itch-Numeric Rating Score (WI-NRS) success (≥4-point improvement in patients with baseline score ≥4), SCORing AD (SCORAD), Patient-Oriented Eczema Measure (POEM), Children's Dermatology Life Quality Index (CDLQI; aged ≥4 years), Infant DLQI (IDLQI; aged <4 years), and the Dermatitis Family Impact questionnaire (DFI) were used to evaluate PROs, as reported by caregivers.

Results: There were 652 patients randomized into roflumilast cream 0.05% (n=437) and vehicle cream (n=215) treatment groups. After 4 weeks, vIGA-AD success was achieved by significantly greater proportions of patients who received roflumilast versus vehicle (25.4% vs 10.7%; $P<0.0001$). Significantly greater proportions ($P<0.0002$) also achieved WI-NRS success with roflumilast (35.3% [97.5% CI, 29.7–41.4]) versus vehicle (18.0% [12.0–26.1]). Least-squares mean (LSM) improvement in SCORAD from baseline to week 4 was significantly greater for the roflumilast versus vehicle group overall (19.30 vs 12.30; $P<0.0001$) and for individual components of pruritus (3.11 vs 1.85; $P<0.0001$), sleep loss (2.05 vs 1.29; $P=0.0005$), and dryness (0.59 vs 0.43; $P=0.0061$). Significant improvements (all $P<0.05$) with roflumilast versus vehicle occurred for POEM overall (7.5 vs 3.7) and individual component scores (itching, 1.30 vs 0.73; sleep, 1.01 vs 0.60; skin bleeding, 0.91 vs 0.55; skin weeping/oozing, 0.40 vs 0.25; skin cracking, 1.35 vs 0.60; skin flaking, 1.19 vs 0.54; dryness/roughness, 1.47 vs 0.60). After 4 weeks, roflumilast improved quality of life measures significantly more than vehicle (each LSM change from baseline), including CDLQI (5.2 vs 3.2; $P=0.0031$), IDLQI (4.2 vs 2.1; $P<0.0001$), and DFI (4.2 vs 2.9; $P=0.0015$).* Safety and application-site tolerability profiles of roflumilast cream 0.05% were favorable.

Conclusion: Once-daily roflumilast cream 0.05% significantly improved AD as measured by multiple PROs,

compared with vehicle cream, after 4 weeks of treatment in patients aged 2–5 years with AD. Outcomes were consistent with those reported for patients aged ≥6 years with AD.



Abstract N°: 2806

Dupilumab treatment is not associated with changes in lymphoma risk in atopic dermatitis and other type 2 inflammatory diseases: Data from a large-scale retrospective cohort study

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Introduction & Objectives:

The association between atopic dermatitis (AD) and lymphoma risk remains inconclusive. Dupilumab, approved for moderate to severe AD, has been linked to an increased lymphoma risk, raising significant concerns. Clarify the association between AD and lymphoma risk and extend to non-dermatological type 2 inflammatory diseases (T2IDs). Assess the impact of dupilumab on lymphoma risk in AD and non-dermatological T2IDs.

Materials & Methods:

Retrospective cohort study using TriNetX database. Propensity-score-matching allowed for better comparability, and sensitivity analyses ensured robustness.

Results:

Among 801,508 cases and controls, AD was associated with an increased risk of lymphoma, e.g., cutaneous T-cell lymphoma (CTCL) and non-Hodgkin lymphoma (NHL). In over 14.4 million cases and controls, non-dermatological T2IDs also conferred an increased lymphoma risk. In the comparison of AD patients treated with dupilumab versus other systemic treatments (n=7,840 per group), dupilumab exposure did not alter the risk for lymphomas but tended towards reduced risks. This decreased risk associations were most evident in non-dermatological T2IDs (n=16,908 per group).

Conclusion:

T2IDs, including AD are associated with a significantly increased risk for lymphoma. Treatment with dupilumab partially ameliorates this risk association, especially for NHL.

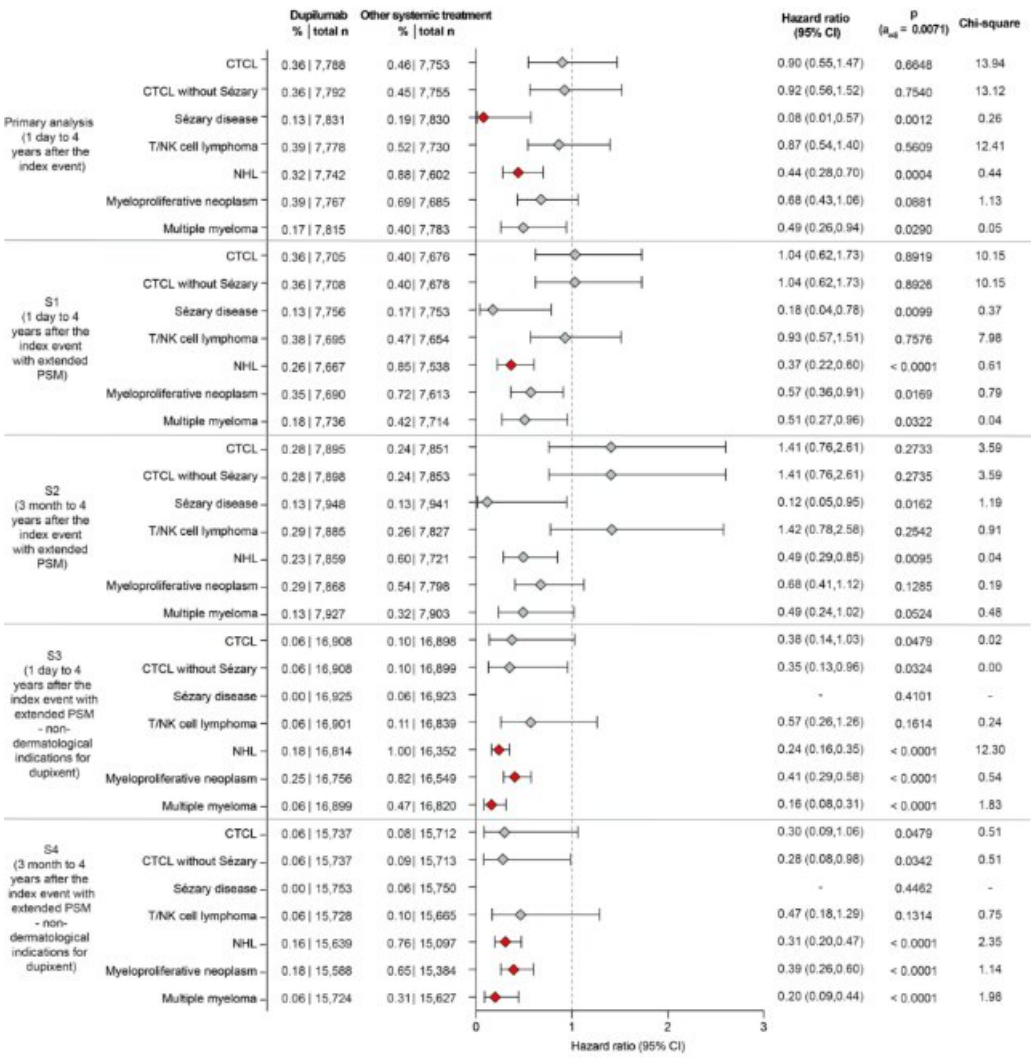


Figure. Forest plot of lymphoma risks in patients with AD or T2IDs (and the corresponding controls) treated with either dupilumab or alternative systemic drugs. The forest plots display the hazard ratios (HR) with 95% confidence intervals (CI) for the risk of the indicated lymphomas. Dupilumab treatment does not increase lymphoma risk, but is rather associated with reductions in lymphoma risks, e.g., non-Hodgkin lymphoma. The boxes correspond to the HR, while error bars represent the 95% CI. More details are shown in the supplement full dataset for figure 4. Confidence intervals are shown at the 95% level for interpretability. However, statistical significance was assessed using a Bonferroni-adjusted threshold of a=0.0071, and readers are advised to interpret confidence intervals in conjunction with adjusted p-values.



Abstract N°: 2841

Scars of Life: Unraveling Skin Pain in Atopic Dermatitis – Prevalence, Severity, and Psychosocial Burden

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Introduction & Objectives:

Skin pain is an increasingly recognized symptom in atopic dermatitis (AD), contributing to patient discomfort and reduced quality of life. Despite its importance, the nature and prevalence of skin pain in AD remain poorly understood. This study aimed to assess the frequency, severity, and psychosocial impact of skin pain in a large, diverse population of AD patients, as part of the "Scars of Life" initiative, which seeks to build an international

database evaluating the burden of AD.

Materials & Methods:

This project is part of the Scars of Life initiative, dedicated to skin diseases, to examine and celebrate life journeys related to dermatoses. A cross-sectional observational study was conducted between June and September 2024, involving 21,687 adults from 27 countries across 5 continents. Participants were selected using the quota method to ensure representativeness. They self-reported a clinical diagnosis of AD, its age of onset (childhood, adolescence, or adulthood), and severity via the POEM score. Four groups were defined: AD with an onset in childhood, adolescence, adulthood, and a control group without skin conditions. Skin pain prevalence and its psychological impact (via ABS-A5 and PUSH-D scores) were analyzed, with statistical significance assessed ($p<0.05$).

Results:

Of the 15,223 patients with AD, 20.2% reported skin pain, compared to 4.4% in the control group ($p<0.001$). Skin pain was more frequent in women (57.3% vs. 42.7% in men, $p<0.007$) and increased with AD severity: 9.5% in mild, 27.3% in moderate, and 45.0% in severe cases ($p<0.001$). Patients with childhood-onset AD reported the highest prevalence (27.9%) compared to adolescence (18.3%) or adulthood (18.5%) onset ($p<0.001$). Multivariate analysis identified male gender, childhood onset, and burning sensations as key predictors of skin pain ($p<0.05$). Psychosocial burden was significantly higher in those with pain, with ABS-A5 scores of 27.5 vs. 12.7 and PUSH-D scores of 30.7 vs. 15.1 ($p<0.001$).

Conclusion:

This survey confirms skin pain as a critical factor in AD, strongly associated with disease severity and early onset, particularly in childhood. The elevated psychosocial burden and burning sensations highlight the need for multidisciplinary management, combining dermatological and psychological approaches. Surprisingly, pruritus did not differ between groups with and without pain, contrasting with prior published data. These findings emphasize the importance of addressing skin pain associated with AD to improve patient outcomes and quality of life.



Abstract N°: 2849

Patient reported outcome measures and symptom improvements across subtypes of Chronic Hand Eczema: outcomes from the Phase 3 DELTA-1 and DELTA-2 trials

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Introduction & Objectives: In the Phase 3 studies DELTA-1/2 (NCT04871711/NCT04872101), twice-daily delgocitinib cream 20 mg/g, a topical pan-JAK inhibitor, demonstrated efficacy versus cream vehicle in adults with major aetiological (irritant contact/allergic contact/atopic dermatitis [ICD/ACD/AD]) and morphological (hyperkeratotic/vesicular) subtypes of moderate to severe Chronic Hand Eczema (CHE).

Materials & Methods: Patient-reported outcome measures (PROMs), including Hand Eczema Symptom Diary (HESD)-itch, HESD-pain, Dermatology Life Quality Index (DLQI), and Hand Eczema Impact Scale (HEIS), were assessed in pooled DELTA-1/2 patients treated with twice-daily delgocitinib (N=639) or cream vehicle (N=321) through Week (W)16, according to baseline primary aetiological and morphological CHE subtype.

Results: Responder rates for ≥4-point improvement in HESD-itch/HESD-pain/DLQI at W16 were greater with delgocitinib than cream vehicle across all CHE subtypes. For example, in vesicular CHE, 53.0%/57.0%/72.9% of patients treated with delgocitinib achieved these clinically meaningful improvements versus 21.6%/28.1%/47.1% with cream vehicle. Significantly greater response in each of these endpoints was achieved with delgocitinib versus cream vehicle ($P<0.05$) within 4 weeks for all subtypes, and as early W1 for DLQI (for ICD/AD/vesicular). Similar response time was observed for HEIS, with clinically meaningful responses from W2. Greater improvements from baseline in absolute HESD-itch/HESD-pain were seen with delgocitinib versus cream vehicle ($P<0.05$) for all subtypes by Day 10, and as early as Day 1.

Conclusion: Delgocitinib demonstrated clinically meaningful improvements at W16 in itch, pain, and quality of life in adults across all major subtypes of moderate to severe CHE. These improvements were statistically significant with delgocitinib versus cream vehicle as early as W1, demonstrating the rapid efficacy of delgocitinib across subtypes.

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Abstract N°: 2855

"Super-response" following treatment with delgocitinib cream 20 mg/g in a subgroup of patients with moderate to severe Chronic Hand Eczema

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Introduction & Objectives: In the DELTA-1 (NCT04871711) and DELTA-2 (NCT04872101) phase 3 trials, delgocitinib cream 20 mg/g demonstrated significant improvement in all efficacy endpoints in adults with moderate to severe CHE. Here we investigate the depth and consistency of treatment response in patients treated with delgocitinib cream 20 mg/g for 16 weeks in DELTA-1 and DELTA-2 and the maintenance of treatment response after up to 36 weeks off treatment in the DELTA-3 extension trial (NCT04949841) among patients initially treated for 16 weeks.

Materials & Methods: In the DELTA-1 and DELTA-2 phase 3 trials, adults with moderate to severe CHE received twice daily delgocitinib cream (n=636) or cream vehicle (n=319) for 16 weeks optionally followed by a 36-week extension trial. Outcomes assessed included HESD itch or pain scores, DLQI, HECSI, and IGA-CHE.

Results: At Week 16, more patients receiving delgocitinib cream vs cream vehicle achieved HESD itch 0/1 (30.0% vs 9.4%), HESD pain 0/1 (35.2% vs 16.0%), or DLQI 0/1 (33.3% vs 13.9%). In delgocitinib cream-treated patients, 48.0% achieved at least 1 "0/1" outcome (vs 23.8% with cream vehicle) and 19.2% achieved all 3 outcomes (vs 5.4% with cream vehicle).

Greater percentages of patients receiving delgocitinib cream vs cream vehicle consistently (at Weeks 4, 8, 12, and 16) achieved ≥4-point reduction from baseline in HESD itch (24.1% vs 6.6%) or pain (25.0% vs 9.0%) or ≥75% improvement in HECSI (27.3% vs 8.1%). Among patients receiving delgocitinib cream who achieved IGA-CHE 0 at Week 16, 32.9% and 15.7% maintained IGA-CHE 0 after 8 and 16 weeks off treatment, respectively.

Conclusion: Delgocitinib cream 20 mg/g provided a "super-response" in a subgroup of patients exhibiting deep and consistent treatment responses, equivalent to little-to-no itch, pain, or negative impact on quality of life and/or consistent improvement in disease extent/severity. One-third of IGA-CHE 0 responders exhibited prolonged treatment response after 8 weeks off treatment.



Abstract N°: 2864

Interim safety results of amlitelimab (anti-OX40 ligand antibody) in participants with moderate-to-severe atopic dermatitis from the RIVER-AD phase 2/3 ongoing open-label study

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Introduction & Objectives: Amlitelimab (SAR445229, KY1005) is a fully human, nondepleting, anti-OX40 Ligand monoclonal antibody. The efficacy and safety of amlitelimab administered subcutaneously every 4 weeks (Q4W) in adults with moderate-to-severe atopic dermatitis (AD) was previously demonstrated in the STREAM-AD phase 2b trial (NCT05131477). At Week 24 of STREAM-AD, clinical responders (defined as achieving at least a 75% improvement in the Eczema Area and Severity Index [EASI-75] and/or an Investigator Global Assessment score of 0 or 1 [IGA 0/1]) were rerandomized to either continue or withdraw from amlitelimab for an additional 28 weeks. The majority of participants maintained durable responses at Week 52 (Part 2) on and off amlitelimab treatment. Participants in the STREAM-AD trial were eligible to enter the RIVER-AD open-label long-term extension study if they met one of the following criteria: 1) did not achieve clinical responses by week 24; 2) lost clinical responses (<EASI-50) during part 2; or 3) completed part 2 and experienced AD worsening during or after the safety follow-up. Additionaly, participants with moderate-to-severe AD from other amlitelimab AD clinical trials were eligible to enter RIVER-AD. Here, interim safety results from RIVER-AD are reported for participants who previously had been enrolled in STREAM-AD, with an interim data cutoff date of 20 February 2024.

Materials & Methods: RIVER-AD (NCT05492578) is an ongoing phase 2/3, open-label, 332-week extension study evaluating the long-term safety and efficacy of amlitelimab. The use of topical corticosteroids/calcineurin inhibitors is permitted. Based on the cut-off date (20 February 2024), this interim safety analysis includes only participants from STREAM-AD who had entered RIVER-AD and received amlitelimab 250 mg Q4W. Data are presented as number of patients with ≥1 event per 100 patient-years at risk (nP/100 PYR). PYR is calculated as the time from first dosing of amlitelimab to the initial occurrence of an event or end of follow-up/data cutoff for those without any event.

Results: This interim safety analysis included 249 participants with a cumulative exposure of 185.7 patient-years. The median treatment duration was 282.0 days (range: 28-548 days), with the following distribution: >0 - ≤20 weeks, 20.9%; >20 - ≤40 weeks, 28.9%; >40 - ≤60 weeks, 36.1%; >60 - ≤80 weeks, 14.1%. At data cutoff, the exposure-adjusted incidence of treatment-emergent adverse events (TEAEs) was 143.1 nP/100 PYR in the safety population, with 144 (57.8%) participants reported to have ≥1 TEAE. The most commonly reported TEAEs (occurring in ≥5% of participants) were nasopharyngitis (16.7 nP/100 PYR), worsening of AD (15.1 nP/100 PYR), and upper respiratory tract infection (10.6 nP/100 PYR). Treatment-emergent serious adverse events and TEAEs leading to treatment discontinuation each occurred in 4 (1.6%) participants (2.2 nP/100 PYR). Adverse events of special interest occurred in 6 (2.4%) participants (3.4 nP/100 PYR). No deaths occurred.

Conclusion: In this RIVER-AD phase 2/3 interim safety analysis of adult participants with moderate-to-severe AD originally from the phase 2b STREAM-AD trial, amlitelimab 250 mg Q4W demonstrated an acceptable safety profile generally consistent with what was previously reported in STREAM-AD.

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Abstract N°: 2868

Erythrodermic atopic dermatitis successfully treated with combination of upadacitinib and dupilumab

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, inflammatory, pruritic skin disease commonly affecting children and adults with personal or family history of atopy. Although sensitization to environmental or food allergens is clearly associated with AD, in most patients it seems to be a contributory factor and not a causative agent. Erythrodermic AD is a severe clinical subtype, characterized by marked erythema, severe pruritus, and scaling of extensively affected skin (≥90% body surface area). A high risk of infection accompanies erythrodermic AD because inflammation, fissuring, and excoriation increase susceptibility to bacteria and other microbes.

A healthy 15-year-old male presented with six-month history of erythroderma with AD background. Patient initially received topical and systemic steroids, following ciclosporin up to 5 mg/kg/day with modest improvement in erythrodermic AD. Few courses of systemic antibiotics were completed for septicaemia.

Materials & Methods:

Extensive workup for lymphoma was performed. Blood tests were in normal range, apart from total IgE >2000 IU, and increased specific IgE to pollens and cat dander. Repeated skin biopsies confirmed AD. Extensive lymphadenopathy required lymph node biopsies that were in line with dermatopathic lymphadenopathy. *CARD14* variant was not found.**

Results:

Oral JAK inhibitor upadacitinib 15 mg OD was introduced with improvement in AD. Ten days into treatment, patient became erythrodermic with Staphylococcus aureus positive skin swabs. Intravenous antibiotics improved skin and upadacitinib was increased to 30 mg OD. Four weeks into treatment, erythroderma persisted and treatment was stopped. Dupilumab 300 mg SC every other week was commenced immediately, with no improvement in erythroderma after 8 weeks of treatment. Upon receiving repeated skin and lymph node biopsy results confirming AD, the combination of dupilumab and upadacitinib 15 mg OD resulted in EASI-75 eight weeks into treatment. Patient continued combined therapy over the last 18 months with complete resolution of AD (EASI-100).

Conclusion:

Erythrodermic AD requires extensive workup with repeated skin biopsies to exclude cutaneous lymphoma and other causes of erythroderma. Our patient had suffered a severe attack of AD in his teen years. Shared decision-making, his optimism and parents' support, along with multidisciplinary team support, resulted in timely and aggressive treatment that brought this story to a happy ending.



Abstract N°: 2872

Short- and Long-Term Effectiveness of Upadacitinib in Treatment-Naïve Patients with Atopic Dermatitis: A Multicenter Cohort Study Across 16 Hospitals in the Community of Madrid.

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Introduction & Objectives:

The approval of upadacitinib for the treatment of atopic dermatitis in patients aged 12 years and older reflects the efficacy and safety demonstrated in clinical trials. An increasing number of real-world studies support this evidence, although most focus on short-term outcomes and do not specifically address subgroups such as patients who are naïve to other advanced therapies.

Materials & Methods:

We conducted a study involving patients treated with upadacitinib across 16 hospitals in the Community of Madrid, aiming to evaluate its short- and long-term safety and effectiveness. The study included patients with atopic dermatitis who had not previously received any of the recently approved advanced systemic therapies for the disease (biologics or other JAK inhibitors). This is an ambispective cohort study with up to 52 weeks of follow-up, including patients who initiated treatment in real-life clinical practice between December 2022 and October 2024.

Results:

A total of 125 patients were included. Most patients showed marked clinical improvement as early as week 4,

which was maintained through week 52 of follow-up. The mean EASI score decreased to 5.09 at week 4 (N=117), 4.76 at week 16 (N=113), and 4.92 at week 52 (N=71). At week 16, 73% of patients achieved EASI75 and 48% achieved EASI90. By week 52, 75% had reached EASI75 and 53% had reached EASI90. At week 16, 65% of patients achieved an IGA score of 0 or 1, increasing to 69% by week 52 (Fig. 3). Pruritus, measured using the NRS, decreased to a mean of 2.24 at week 4 (N=111), 2.39 at week 16 (N=113), and 2.69 at week 52 (N=68). A pruritus score of 0 or 1 was achieved by 45% of patients at week 4 and by 44% at week 52. Quality of life, measured through the DLQI, also showed significant improvement throughout the treatment period. Aquí tienes la frase traducida y adaptada al estilo científico en inglés: A total of 35.24% of patients achieved both a pruritus NRS score of 0 or 1 and EASI90 at week 16. Regarding safety, a total of 108 adverse events were reported in 71 patients (56.8%), the majority of which were mild and did not require treatment modification.

A total of 24 treatment discontinuations were recorded, most of which occurred after week 24. Seven were due to adverse events, ten due to loss of efficacy (one primary and nine secondary failures), three due to well-controlled atopic dermatitis, and three due to poor adherence.

Conclusion:

The data obtained in our cohort are consistent with those reported in clinical trials and support findings from other real-world studies. These results confirm the high effectiveness and favorable safety profile of upadacitinib in patients who were naïve to other advanced therapies



Abstract N°: 2907

TRIV-509, a dual inhibitor of KLK5 and KLK7, normalizes epidermal hyper-proliferation, improves barrier integrity and reduces secretion of inflammatory cytokines in atopic dermatitis skin explants

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Introduction & Objectives: Atopic dermatitis (AD) results from a combination of barrier impairment, pruritus, and inflammation. Approved biologics such as dupilumab, lebrikizumab, and tralokinumab directly target the IL-4/IL-13 inflammatory pathway. However, only ~20-40% of patients achieve an Investigator's Global Assessment (IGA) score of 0 or 1 after 16 weeks of these treatments. Novel therapeutics that directly target all three components of AD pathology are needed. We have developed a dual-targeting monoclonal antibody, TRIV-509, that selectively and potently inhibits kallikreins (KLK) 5 and 7. KLK5 and KLK7, members of a serine protease family, directly contribute to barrier dysfunction (including corneodesmosome degradation), pruritus (through a KLK7-dependent pathway), and inflammation (via KLK5-PAR2 signaling). In normal skin, KLK5 and KLK7 activity is limited to the top layers of the epidermis to enable natural desquamation. In AD, KLK5 and KLK7 activity and expression is higher and penetrate deeper into the epidermis, resulting in cleavage of structural barrier proteins (e.g., DSG1) and impaired structural barrier integrity.

Materials & Methods: To further understand the mechanisms of KLK5 and KLK7, biopsies were collected from lesional and peri-lesional skin from patients with a clinical diagnosis of AD (IGA ^{3} 2). Biopsies were then cultured with TRIV-509 or control IgG for 72 hours. The biopsies were processed for histology/protein analysis, and supernatant was collected for cytokine analysis.

Results: TRIV-509 significantly reduced epidermal hyperplasia and parakeratosis in active AD skin from all three patients. Furthermore, TRIV-509 rapidly normalized hyperproliferation, resulting in significant reduction (~80%) of Ki-67+ cells compared to control IgG. Additionally, TRIV-509 increased the number of desmoglein 1 (DSG1) positive cells and filaggrin (FLG) expression in the granular layers of the epidermis. Finally, TRIV-509 reduced the secretion of Th1/Th2/Th17-related cytokines.

Conclusion: Inhibition of KLK5 and KLK7 ameliorates the AD epidermal phenotype in *ex vivo* explant cultures by normalizing epidermal keratinocyte proliferation, improving barrier integrity, and reducing secretion of AD-associated cytokines. These data support therapeutic rationale for KLK5 and KLK7 inhibition and ongoing clinical development of TRIV-509 in AD.



Abstract N°: 2970

Clinical overlap between Psoriasis, Atopic Dermatitis and Prurigo Nodularis. A rare phenotipic presentation

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Introduction & Objectives: Psoriasis, (Pso) atopic dermatitis (AD), and prurigo nodularis (PN) are common T-cell–mediated inflammatory skin disorders that can be treated with targeted cytokine inhibitors or broader immunomodulatory agents. We report a case highlighting the clinical and histopathological overlap of these conditions in a male patient with longstanding disease's history. **Materials & Methods:** A 43-year-old male with a 20-year history of generalized plaque psoriasis accompanied by a long history of Atopia, consistent on large, oozing, and crusted patches predominantly in flexural areas. Initial assessments using Hanifin and Rajka's criteria showed an AD with SCORAD 80 and a PASI 20 score. The patient had notable comorbidities, including smoking, a sedentary lifestyle, and a BMI of 35. He was started on methotrexate 20 mg weekly with folic acid 5 mg supplementation to assess both features.As well as dietary and exercise assessment, and avoid smoking recommendation. After one month, he experienced a flare-up with extensive erythematous, scaly plaques involving the genitalia, face, trunk, arms, and legs, raising his PASI score to 90. During the initial laboratory test latent tuberculosis infection was diagnosed based on a 20 mm PPD, and isoniazid was initiated for six months. Due to severe psoriasis, guselkumab 100 mg every 8 weeks was introduced, yielding a PASI 90 improvement within the first 6 months. However, the patient later developed deeply infiltrated dermal nodules on the extensor surfaces of the forearms, thighs, back, and groin, accompanied by intense pruritus. The biopsy showed Prurigo Nodularis (PN). Therapy was adjusted to include fexofenadine 180 mg daily, methotrexate 20 mg weekly, and continued guselkumab. Despite this drug regime, he experienced disease progression. At the one-year mark, guselkumab was discontinued due to lack of efficacy, and treatment was switched to ixekizumab 80mg monthly. This regimen achieved PASI 100 and SCORAD 10, right after induction period ended, indicating marked improvement in psoriasis and moderate response in PN and AD. After 3 months on ixekizumab ,he developed complications, including acute myocardial infartation (AMI), recurrent dental and urinary tract infections, which precluded further therapies combination. Seven months later he continues improving psoriasis with ixekizumab reaching PASI 100 for the last 3 months and currently regression of the nodules (PN) on both forearms and muscles. **Conclusion:** The Flip Flop phenomenon was described between psoriasis and atopic dermatitis. This case shows how prurigo nodularis and AD can both be also part of the phenomenon. It underscores the importance of careful clinical evaluation, individualized treatment strategies, and vigilance for systemic complications, especially in patients receiving long-term target therapy.



Abstract N°: 2977

Real-world effectiveness and safety of every-four-week lebrikizumab maintenance dosing from Week 4 following two loading doses in Japanese patients with atopic dermatitis

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Introduction & Objectives: Lebrikizumab, an anti-interleukin (IL)-13 antibody, has shown efficacy in clinical trials for patients with moderate-to-severe atopic dermatitis (AD), with dosing every two weeks (q2w) or every four weeks (q4w). In Japan, lebrikizumab was approved for AD in May 2024, with an initial loading dose of 500 mg administered at Weeks 0 and 2, followed by a maintenance dose of 250 mg q2w starting at Week 4. Depending on the patient's condition, a q4w maintenance regimen beginning at Week 4 is also permitted. Given the small differences in efficacy between q2w and q4w observed in clinical trials and the benefits of reduced dosing frequency, q4w dosing from Week 4 onward could be a viable alternative. However, to date, no data have been reported regarding the effectiveness of this regimen. In our department, most patients received lebrikizumab q4w from Week 4 following the two initial loading doses. This study aims to evaluate the real-world effectiveness and safety of lebrikizumab with the q4w regimen from Week 4 onward in AD patients.

Materials & Methods: Patients with AD who initiated lebrikizumab treatment at our department between May 2024 and January 2025 were retrospectively included in this study. Effectiveness, safety, and laboratory findings were assessed over a 3-month period.

Results: A total of 36 patients were included in the analysis. The mean age of patients without prior exposure to systemic therapy (naïve group, n=15) was 35.9 ± 3.76 years, while that of patients with it (switch group, n=21) was 38.4 ± 3.36 years. Prior treatments in the switch group included dupilumab (n=16), tralokinumab (n=2), baricitinib (n=3), and upadacitinib (n=6), with some overlap. At baseline, the mean values for the naïve and switch groups were as follows, respectively: total Eczema Area and Severity Index (EASI), 23.8 ± 2.95 / 18.2 ± 3.07; head/neck EASI, 2.49 ± 0.36 / 1.78 ± 0.36; affected body surface area (BSA), 46.4 ± 5.43% / 37.0 ± 4.84%; visual analogue scale (VAS) for pruritus, 65.3 ± 7.39 / 45.5 ± 6.58; Dermatology Life Quality Index (DLQI), 12.9 ± 1.94 / 9.15 ± 1.60; Patient-Oriented Eczema Measure (POEM), 17.8 ± 1.45 / 6.58 ± 1.23; lactate dehydrogenase (LDH), 267 ± 36.2 / 228 ± 19.3 U/L; thymus and activation-regulated chemokine (TARC), 2778 ± 972 / 4751 ± 2746 pg/mL; and IgE, 14,725 ± 7618 / 10,330 ± 5930 IU/mL. All patients except two received lebrikizumab q4w from Week 4 following the two initial loading doses at Weeks 0 and 2. After 3 months of treatment, the naïve group demonstrated significant improvements in all outcomes except for IgE, with mean reductions of: IGA, 55.6% ($p < 0.0001$); total EASI, 83.5% ($p = 0.0002$); head/neck EASI, 81.7% ($p = 0.0003$); BSA, 84.9% ($p = 0.0007$); VAS for pruritus, 70.0% ($p = 0.0054$); DLQI, 77.7% ($p < 0.0001$); POEM, 58.1% ($p = 0.0025$); LDH, 36.2% ($p = 0.0302$); TARC, 70.2% ($p = 0.00453$); and IgE, 46.4% ($p = 0.5256$). The switch group showed statistically significant improvements only in IGA (33.3% reduction, $p = 0.0165$) and total EASI (54.7% reduction, $p = 0.0179$). Regarding safety, conjunctivitis was observed in 8 patients. Anaphylaxis, psoriasis-like eruptions, AD exacerbation, and injection site reactions were each observed in one patient and led to treatment discontinuation.

Conclusion: This real-world study demonstrates that lebrikizumab administered q4w from Week 4 following two loading doses is an effective and generally well-tolerated treatment option for AD patients.



Abstract N°: 2989

Efficacy and Safety of Janus Kinase Inhibitors for Chronic Hand Eczema: A Systematic Review of Randomized Controlled Trials

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Introduction & Objectives: Chronic hand eczema (CHE) is a recalcitrant skin condition often linked to filaggrin gene mutations and immune dysregulation involving both Type 1 and Type 2 pathways, with JAK/STAT signaling playing a key role in the immune alterations and skin barrier disruption. It typically persists for at least 3 months or recurs at least twice within 1 year. Recent studies show that CHE involves mixed Type 1/Type 2 pathway activation and immune dysregulation, with JAK/STAT signaling contributing to barrier damage. Treatment options are multiple and have more recently included topical and systemic Janus kinase inhibitors (JAKi) as a notable object of studies. This study aims to assess their effectiveness and potential adverse effects in CHE.

Materials & Methods: We conducted a systematic review on the efficacy of JAK inhibitors for hand eczema, searching PubMed, Embase, Cochrane Library, and Scopus for randomized controlled trials (RCTs) published up to March 28, 2025. Study selection and data extraction followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) and Cochrane recommendations.

Results: Five studies were included, comprising six RCTs and 1,260 participants, evaluating delgocitinib, gusacitinib, and ruxolitinib. Delgocitinib 20 mg demonstrated consistent improvements in Investigator's Global Assessment for Chronic Hand Eczema (IGA-CHE) response. In the DELTA 1 and DELTA 2 trials, responses rose from 15.4% at Week 4 to 22.8% at Week 8, with a slight decline by Week 16. Smaller studies supported these findings, with one reporting a response rate of 45.8% at Week 8 versus 13.3% for placebo. Another reported improvement from 24.5% to 37.7% between Weeks 8 and 16, with placebo groups maintaining low responses. Topical ruxolitinib 1.5% showed a progressive increase in IGA response, reaching 53.3% by Week 16 in a limited sample. Gusacitinib showed significant early efficacy based on the Physician's Global Assessment (PGA). At Week 2, 12.5% (80 mg) and 12.1% (40 mg) had clear or almost clear hands, compared to 0% in placebo. By Week 16, responses increased to 31.3% (80 mg) and 21.2% (40 mg) versus 6.3% with placebo. Regarding safety, gusacitinib 80 mg was associated with the highest frequency of adverse events (AEs), particularly infections, gastrointestinal, and nervous system disorders. Delgocitinib had a moderate AE profile, with nasopharyngitis and infections and infestations being the most reported. Serious AEs were rare across all studies. Ruxolitinib safety data were limited due to small sample size, though one serious AE was reported.

Conclusion: This systematic review underscores the potential of topical and systemic JAKi in management of CHE. Oral delgocitinib demonstrated sustained, consistent IGA-CHE improvements across multiple timepoints, while topical ruxolitinib also exhibited a progressive therapeutic response. Gusacitinib showed early and lasting efficacy based on PGA, with notable clinical responses as early as Week 2. The overall safety profile of JAKi was favorable, with serious adverse events infrequent. However, gusacitinib 80 mg was linked to a higher incidence of AEs, whereas delgocitinib showed a more moderate and manageable profile. These findings support the effectiveness

and safety of both topical and systemic JAKi in CHE, though further studies are needed to confirm efficacy, refine dosing, and assess long-term safety.



Abstract N°: 3066

Assessing the impact of Atopic Dermatitis on Quality of Life using DLQI: A Real world cross sectional study from India

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Introduction & Objectives:

Atopic dermatitis (AD) is the most prevalent chronic inflammatory skin disease globally, exerting a substantial burden not only on patients but also on caregivers and families. Quantifying this impact is essential for guiding clinical management and optimizing support strategies. The Dermatology Life Quality Index (DLQI) is the most widely used instrument to assess quality of life (QoL) in AD patients. This study aimed to examine gender-based differences in QoL domains, stratify findings by disease severity, and evaluate the association between socio-economic status (SES) and DLQI scores.

Materials & Methods:

A cross-sectional study was conducted between November 2024 and March 2025 involving consecutive clinically diagnosed AD patients attending outpatient department from 110 centres across India with Independent Ethics committee approval. Disease severity was stratified by DLQI total score into mild (0–5), moderate (6–10), and severe (>11) categories. Gender differences across six QoL domains—Symptoms, Daily Activities, Leisure, Work/School, Personal Relationships, and Treatment—were analysed using unpaired t-tests. Differences in DLQI scores across socioeconomic status (SES) groups (Low, Middle, High) were assessed using one-way ANOVA with Tukey's post hoc analysis.

Results:

A total of 660 AD patients were included in the study, of which 320 (48.5%) were female and 340 (51.5%) were male. The mean age was 27.9 ± 14.7 years, with a mean disease duration of 3.5 ± 4.2 years. The average DLQI score was 10.8 ± 6.7. No significant gender differences were found across QoL domains or total DLQI scores in the overall population ($p > 0.05$). However, among patients with severe disease (DLQI >11), males reported significantly greater impairment only in the Leisure domain ($t = 2.09$, $p = 0.038$). SES was significantly associated with DLQI scores ($F = 10.86$, $p < 0.0001$), with patients in the low SES group reporting greater QoL impairment compared to those in the medium and high SES groups. No significant difference was observed between medium and high SES groups ($p = 0.263$).

Conclusion:

QoL outcomes in adults with AD were influenced by socio-economic status and, in severe cases, by gender. Lower SES was associated with greater overall impairment, and male patients with severe disease report higher disruption in leisure activities. These findings highlight the need for tailored interventions targeting patients with severe disease and socio-economic vulnerability.

Table 1: **Comparison of DLQI Scores on the Basis of Severity in male and female in 6 Domains**

Parameter	t-statistic	p-value	t-statistic	p-value	t-statistic	p-value
Severity of DLQI Score	(0-5)	(6-10)	(>11)			
Symptoms	-1.20	0.23	-0.64	0.52	0.24	0.81
Daily Activities	-0.57	0.57	-1.59	0.11	0.00	1.00
Leisure	0.43	0.67	0.59	0.55	2.09	**0.04**
Work	1.00	0.32	0.88	0.38	0.82	0.41
Personal Relation	-0.01	0.99	0.92	0.36	-0.16	0.87
Treatment	-1.26	0.21	1.11	0.27	-1.20	0.23
Total	-0.75	0.45	0.53	0.60	0.52	0.60

Table 2: **Comparison of total DLQI by Socio-economic status**

**	n	Mean	SD	Mean ± SD	95% CI lower	95% CI upper
Low	162	12.73	7.36	12.73 ± 7.36	11.59	13.88
Medium	326	10.46	6.66	10.46 ± 6.66	9.73	11.18
High	172	9.49	5.58	9.49 ± 5.58	8.65	10.33

Table 3: **Analysis of DLQI in different SES groups**

Group 1	Group 2	Mean Difference	p-value	95% CI Lower	95% CI Upper
High	Low	3.246	<0.001	1.554	4.938
High	Medium	0.969	0.263	-0.488	2.425
Low	Medium	-2.278	0.001	-3.763	-0.792



Abstract N°: 3134

Bruton's Tyrosine Kinase Inhibitor Attenuates Skin Lesions in an Atopic Dermatitis Mouse Model by Suppressing Th2 Inflammation and Enhancing Skin Barrier Function

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Introduction & Objectives:

Bruton's tyrosine kinase (BTK) is a key mediator of B cell receptor signaling and an established therapeutic target in autoimmune diseases. Covalent BTK inhibitors (BTKis), such as remibrutinib, have demonstrated clinical efficacy in conditions like chronic spontaneous urticaria. Beyond B cells, BTK also participates in T cell receptor signaling, suggesting broader immunomodulatory potential. Atopic dermatitis (AD) is primarily driven by Th2-mediated inflammation, but the therapeutic potential of BTK inhibition in AD remains underexplored. This study investigates the efficacy and underlying mechanisms of BTKi treatment in a murine model of AD.

Materials & Methods:

Bruton's tyrosine kinase (BTK) is a key mediator of B cell receptor signaling and an established therapeutic target in autoimmune diseases. Covalent BTK inhibitors (BTKis), such as remibrutinib, have demonstrated clinical efficacy in conditions like chronic spontaneous urticaria. Beyond B cells, BTK also participates in T cell receptor signaling, suggesting broader immunomodulatory potential. Atopic dermatitis (AD) is primarily driven by Th2-mediated inflammation, but the therapeutic potential of BTK inhibition in AD remains underexplored. This study investigates the efficacy and underlying mechanisms of BTKi treatment in a murine model of AD.

Results:

Remibrutinib treatment significantly ameliorated AD-like skin lesions and reduced scratching behavior compared to untreated controls. Histologically, it diminished MC903-induced hyperkeratosis, inflammatory cell infiltration, and mast cell degranulation. RNA-seq analysis revealed that remibrutinib suppressed Th2-, Th17-, and Treg-related pathways while restoring expression of skin barrier-related genes.

Conclusion:

Remibrutinib alleviates clinical and histological features of AD by inhibiting mast cell activation, downregulating pro-inflammatory cytokines, and enhancing skin barrier function. These findings support the potential of BTK inhibition as a novel therapeutic strategy for atopic dermatitis.



Abstract N°: 3185

Real-world effectiveness and safety of upadacitinib for atopic dermatitis between dupilumab-experienced and dupilumab-naïve patients

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Introduction & Objectives: Upadacitinib, a selective Janus kinase inhibitor (JAK)1 inhibitor, has demonstrated a favourable aggregate response benefit in skin clearance and itch reduction over dupilumab as demonstrated in the Heads Up, phase 3 study. It has also been reported to improve outcomes in patients with previous dupilumab use, in the open-label extension of the same study. Real-world data on patients with atopic dermatitis needing to switch from dupilumab to upadacitinib treatment are currently limited. Therefore, the aim of this study was to summarize our centre's experience and compare the outcomes of upadacitinib in dupilumab-experienced and dupilumab-naïve patients.

Materials & Methods: We retrospectively included all patients treated with upadacitinib at our centre and further analysed their corresponding data based on previous dupilumab exposure. 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), scoring atopic dermatitis (SCORAD), dermatology life quality index (DLQI) and the worst pruritus numerical scale score (WP-NRS). Drug-related adverse events (AEs) were assessed and documented.

Results: In total, 36 patients (10 dupilumab-experienced, 26 dupilumab-naïve) were identified and included. Regarding those that had previously discontinued dupilumab, nine patients had discontinued due to inadequate disease management (non-achieving or maintaining EASI75 or according to patient preference due to severely impacted quality of life) and one patient due to AEs (conjunctivitis). EASI75/90/100 were achieved by 70/50/10% of the dupilumab-experienced patients after 4 weeks of treatment and by 87.5/ 87.5/62.5 after 16 weeks. In the dupilumab-naïve cohort, EASI75/90/100 were achieved by 88.5/53.8/23.1% after 4 weeks and by 100/100/55% after 16 weeks. At weeks 48, complete skin clearance was achieved by all five (100%) dupilumab-exposed patients. Eight (72.7%) of the dupilumab-naïve patients had a clear skin at week 48. For both groups, all patients that reached week 96 had achieved EASI100 along with the other clinical endpoints. Concerning safety, two (20%) of the dupilumab-exposed patients experienced AEs, one hepatic enzyme abnormalities, and the other, who discontinued medication after one-month, recurrent urinary tract infections. Among the dupilumab naïve patients, four (15.4%) suffered from AEs, two from hepatic enzyme abnormalities with one discontinuing medication, one had anaemia with a significant reduction in the haemoglobin and haematocrit counts and one from recurrent respiratory infections, both leading to upadacitinib discontinuation.

Conclusion: This study confirmed the clinical effectiveness and good safety profile of upadacitinib treatment in both dupilumab-experienced and dupilumab-naive patients with atopic dermatitis in a real-world setting. Further research is warranted with larger studies, prospective in design, to evaluate the long-term effectiveness and safety of upadacitinib in real-world settings.

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Abstract N°: 3191

Real-world treatment patterns and effectiveness of abrocitinib in atopic dermatitis: Interim results on Abrocitinib Chinese rEgistry on AD (AHEAD)

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease marked by pruritis and polymorphic rashes, significantly impacting patients' quality of life. Abrocitinib, a Janus kinase (JAK) inhibitor, has shown great efficacy in moderate-to-severe AD in clinical trials. However, real-world data on its use among Chinese AD patients is lacking. The Abrocitinib Chinese Registry on AD (AHEAD) is an ongoing prospective, multicenter registry including AD patients from 42 sites in China. Here we conducted the 2nd interim analysis of AHEAD data, describing the treatment patterns and effectiveness of Abrocitinib in Chinese AD patients.

Materials & Methods: Patients were eligible if they were ≥18 years old, Abrocitinib-naïve, or had discontinued Abrocitinib for >30 days at enrollment. The index date was the first prescription date of Abrocitinib during the study. Data were collected during routine clinical visits at week 2, 4, 12, 24, and 52, including demographic characteristics, Abrocitinib treatment patterns, and AD clinical outcomes. The AD Clinical outcomes included AD flare-ups, Investigator's Global Assessment (IGA), Eczema Area and Severity Index (EASI), Peak Pruritus Numerical Rating Scale (PP-NRS), and other patient- or physician-reported outcomes.

Results: From 18 Oct 2023 to 10 Feb 2025, a total of 1117 AD patients were enrolled with a mean (SD) follow-up of 178.4 (117.3) days. The mean (SD) age of all participants was 42.9 (16.4), and 47.4% were female. In all 1104 patients with records of medication history, 187 (16.9%) had received at least one form of systemic treatment, among whom, 66 (35.3%) received traditional treatments, 78 (41.7%) received biologics, and 64 (34.2%) received small molecule JAK inhibitors. 982 (89.4%) of patients started with 100mg daily Abrocitinib, while 117 took 200mg daily. 37.9% of patients underwent Abrocitinib dose adjustment. Among them, 39.0% decreased the dose, 12.7%

increased the dose, and 62.7% discontinued Abrocitinib treatment (patients who experienced multiple dose adjustments could be included in more than one category). As of the cutoff date, 1031 (93.6%) of patients had good adherence (proportion of days covered [PDC] ≥ 0.8) to Abrocitinib. 47(18.1%) of patients who discontinued Abrocitinib experienced AD flare-ups during their follow-up, with a mean (SD) time-to-flare-up of 30.9 (35.8) days. 47.2% and 69.2% of patients achieved IGA success at weeks 24 and 52, respectively. EASI-90 response rates increased from 9.8% at week 2 to 44.0% at week 24 and 57.7% at week 52. EASI-75 response rates also increased from 23.4% at week 2 to 67.6% at week 24 and 76.9% at week 52. PP-NRS 4 achievement rates rose from 56.6% at week 2 to 66.2% at week 4, and remained stable until week 52. (Figure 1) Changes in IGA, EASI, PP-NRS, and other AD clinical outcomes from baseline during the follow-up were presented in Table 1. Patients on Abrocitinib 200mg daily showed numerically more changes from baseline in EASI and PP-NRS throughout the 12-week follow-up. (Figure 2)

Conclusion: This interim analysis demonstrated that Abrocitinib consistently improved AD clinical outcomes over a one-year follow-up. Patients receiving dose of 200mg daily showed numerically more improvement from baseline in EASI and PP-NRS than those on 100mg since week 2.

Pfizer's funding support to this study as well as the development of this abstract.

		Baseline	Week 2	Week 4	Week 12	Week 24	Week 52
IGA	N	1079	836	757	555	343	52
	Mean (SD)	3.0 (0.6)	2.2 (0.9)	1.8 (0.9)	1.7 (0.9)	1.5 (0.9)	0.9 (1.0)
	Change from baseline, Mean (SD)	-	-0.8 (0.9)	-1.2 (0.9)	-1.4 (1.0)	-1.6 (1.0)	-2.1 (1.0)
EASI	N	1078	836	758	555	343	52
	Mean (SD)	13.7 (12.1)	7.1 (7.6)	4.9 (6.1)	3.8 (4.9)	3.0 (5.2)	1.8 (3.0)
	Change from baseline, Mean (SD)	-	-6.6 (9.2)	-8.7 (9.5)	-10.2 (10.5)	-10.7 (10.1)	-10.1 (9.1)
PP-NRS	N	1094	848	779	567	343	53
	Mean (SD)	6.7 (2.4)	3.1 (2.4)	2.7 (2.3)	2.7 (2.3)	2.6 (2.3)	2.3 (2.1)
	Change from baseline, Mean (SD)	-	-3.6 (3.0)	-4.0 (2.9)	-4.1 (3.1)	-4.4 (3.0)	-4.7 (3.0)
SCORAD	N	1076	835	757	553	342	52
	Mean (SD)	49.9 (16.5)	29.6 (15.4)	23.5 (13.9)	20.6 (14.5)	18.3 (14.6)	13.0 (12.4)
	Change from baseline, Mean (SD)	-	-20.7 (15.7)	-26.3 (16.5)	-29.6 (18.0)	-31.6 (18.6)	-34.4 (17.9)
POEM	N	1094	846	779	567	343	53
	Mean (SD)	15.8 (7.0)	7.8 (6.2)	6.1 (5.6)	5.9 (5.7)	6.1 (5.6)	5.0 (4.5)
	Change from baseline, Mean (SD)	-	-8.1 (7.0)	-10.1 (7.4)	-10.2 (7.9)	-10.2 (8.1)	-10.3 (7.6)
ADCT	N	1095	846	779	567	343	53
	Mean (SD)	13.8 (5.5)	6.5 (4.8)	5.2 (4.4)	5.2 (4.4)	4.9 (4.5)	4.3 (3.4)
	Change from baseline, Mean (SD)	-	-7.5 (5.8)	-8.9 (6.0)	-9.1 (6.6)	-9.3 (6.5)	-9.1 (5.3)
DLQI	N	1094	846	779	567	343	53
	Mean (SD)	11.9 (7.4)	6.6 (6.0)	5.4 (5.6)	5.0 (5.5)	4.8 (5.7)	4.0 (4.1)
	Change from baseline, Mean (SD)	-	-5.7 (6.4)	-7.0 (6.8)	-7.9 (7.6)	-8.1 (7.7)	-6.9 (5.3)
PtGA	N	1094	845	779	567	343	53
	Mean (SD)	3.3 (0.5)	2.6 (0.8)	2.3 (0.9)	2.2 (0.9)	2.1 (1.0)	1.8 (1.0)
	Change from baseline, Mean (SD)	-	-0.7 (0.9)	-1.0 (1.0)	-1.1 (1.1)	-1.2 (1.1)	-1.3 (1.1)
EQ-5D-5L index score	N	1094	846	779	567	343	53
	Mean (SD)	0.83 (0.20)	0.92 (0.14)	0.93 (0.14)	0.93 (0.12)	0.94 (0.11)	0.96 (0.07)
	Change from baseline, Mean (SD)	-	0.09 (0.17)	0.10 (0.18)	0.12 (0.20)	0.12 (0.21)	0.10 (0.19)

Table 1 AD clinical outcomes in patients receiving abrocitinib at baseline and during follow-up

Abbreviations: IGA, Investigator's Global Assessment; EASI, Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numerical Rating Scale; SCORAD, Scoring Atopic Dermatitis, POEM, Patient-Oriented Eczema Measure, ADCT, Atopic Dermatitis Control Tool, DLQI, Dermatology Life Quality Index; EQ-5D-5L, EuroQol 5-Dimension 5-Level Questionnaire; PtGA, Patient global assessment.

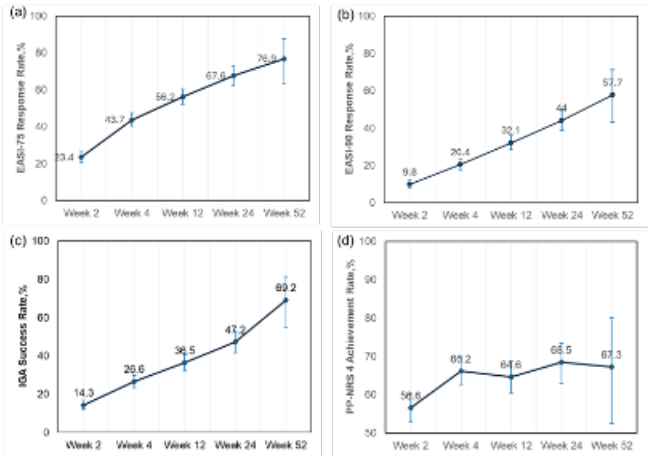


Figure 1 AD clinical outcomes from week 2 to week 52. (a) EASI-75 Response Rate; (b) EASI-90 Response Rate; (c) IGA Success Rate; (d) PP-NRS 4 Achievement Rate

EASI-75: Achievement of a 75% improvement in the Eczema Area and Severity Index score from baseline
EASI-90: Achievement of a 90% improvement in the Eczema Area and Severity Index score from baseline
IGA Success: Achievement of Investigator's Global Assessment score of 0 [clear] or 1 [almost clear] with a ≥ 2 grade improvement from baseline, targeting patients whose IGA baseline score is ≥ 2
PP-NRS 4: Achievement of ≥ 4-point improvement of Peak Pruritus Numerical Rating Scale score

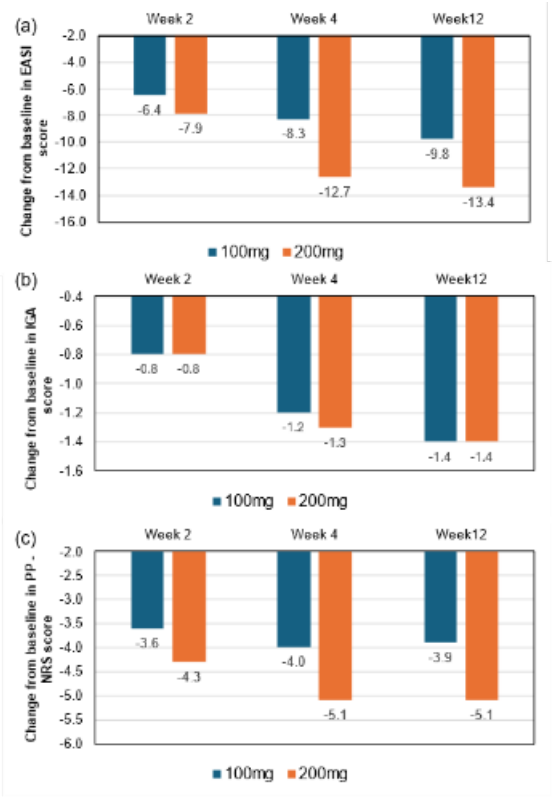


Figure 2. Changes in AD clinical outcomes from baseline to week 12. (a) EASI score; (b) EASI-90 Response Rate; (c) IGA score; (d) PP-NRS score

Abbreviations: IGA, Investigator's Global Assessment; EASI, Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numerical Rating Scale



Abstract N°: 3206

Number needed to treat and associated costs per additional responder of biologic therapies in adult patients with moderate to severe atopic dermatitis

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Introduction & Objectives:

Dupilumab, tralokinumab and lebrikizumab are the currently approved biologic therapies for patients with moderate-to-severe atopic dermatitis (AD) ineligible or with an inadequate response to topical therapies in the United States (US). The current analysis compared the number needed-to-treat (NNT) and the costs per additional responder (CPR) in adult patients with moderate-to-severe AD treated with these biologic therapies, from a US payer perspective.

Materials & Methods:

Based on comparative efficacy data from Silverberg et al. (2021) and from Guyot et al (2024) on systemic AD therapies, an Excel model was developed to estimate the NNT and incremental CPR. The model compared dupilumab, tralokinumab, and lebrikizumab in combination with topical therapy over a 16-week treatment period. Response to treatment was defined as a 75% reduction from the baseline in Eczema Area and Severity Index (EASI-75) at Week 16. NNT was calculated as the inverse of the absolute risk reduction versus standard of care for each biologic. Current US list prices based on RED BOOK (IBM Micromedex, 2024) were used for the drugs. Sensitivity analyses were done based on the drug price variation for tralokinumab and lebrikizumab.

Results:

The NNT to achieve one additional responder was lower with dupilumab versus tralokinumab (3 versus 4) and lebrikizumab (3 versus 6), respectively, considering EASI-75 as the response measure. The CPR to achieve EASI-75 was higher for tralokinumab ($69.1K versus $51.3K) and lebrikizumab ($210.0K versus $51.3K) versus dupilumab. These results were consistent in the sensitivity analyses.

Conclusion:

Dupilumab demonstrated a lower NNT and approximately 1.5- and 4-times lower CPR, compared to tralokinumab and lebrikizumab, respectively. Dupilumab appears to have considerable economic benefits in the management of moderate-to-severe AD over other biologics.



Abstract N°: 3286

Long-term efficacy with tralokinumab in patients with moderate-to-severe atopic dermatitis: final results from the 5-year ECZTEND study

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Introduction & Objectives: To ensure minimal residual disease and to prevent relapses, recently published consensus-based recommendations have defined long-term treatment targets for atopic dermatitis (AD) [1]. Tralokinumab, a fully human monoclonal antibody that specifically neutralizes interleukin-13, is approved for the treatment of moderate-to-severe AD in adults and adolescents in multiple countries. ECZTEND (NCT03587805) was a 5-year, open-label extension study that investigated the long-term safety and efficacy of tralokinumab. Here, the objectives were to determine the proportion of tralokinumab-treated patients with moderate-to-severe AD who achieved long-term treatment targets and maintained stable disease control, with no or minimal fluctuations, during and up to 5 years of treatment in ECZTEND.

Materials & Methods: The ECZTEND study assessed tralokinumab 300 mg every other week with optional topical corticosteroids in patients (≥12 years) with moderate-to-severe AD who completed any of 9 parent trials. Efficacy endpoints analyzed included the proportion of patients meeting recommended skin response targets (EASI-75, EASI ≤7, EASI-90, and EASI ≤3) at Week 248 and the proportion of patients maintaining response with no or minimal disease fluctuations (at ≥80% of days after first endpoint achievement up to end of treatment).

Results: A total of 1647 patients were enrolled in ECZTEND. At Week 248, EASI-75 and EASI ≤7 (95% confidence interval) were observed in 92.9% (85.3-96.7) and 95.2% (88.4-98.1) of patients, respectively; EASI-90 and EASI ≤3 were detected in 81.0% (71.3-87.9) and 83.3% (73.9-89.8) of patients, respectively. Proportions of patients who maintained EASI-75 and EASI-90 with no or minimal fluctuations were 75.1% (72.9-77.2) and 54.7% (52.0-57.3), respectively.**

Conclusion: Optimal skin responses (EASI-90; EASI ≤3) occurred in more than 80% of patients treated with tralokinumab 300 mg every other week for up to 5 years, with a large proportion maintaining stable response with no or minimal disease fluctuations (at ≥80% of days after first endpoint achievement up to end of treatment).

References:

\1. Silverberg J et al. J Eur Acad Dermatol Venereol. 2024;38:2139–2148.

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Abstract N°: 3315

Mechanisms of blood-brain barrier disruption and central nervous system inflammation in calcipotriol-induced atopic dermatitis mice

Zhiyan Zhang[1], Siming Yang*[1], jie yang[1], Yunda Guo[1], minglu xiao[1], tong peng[1]

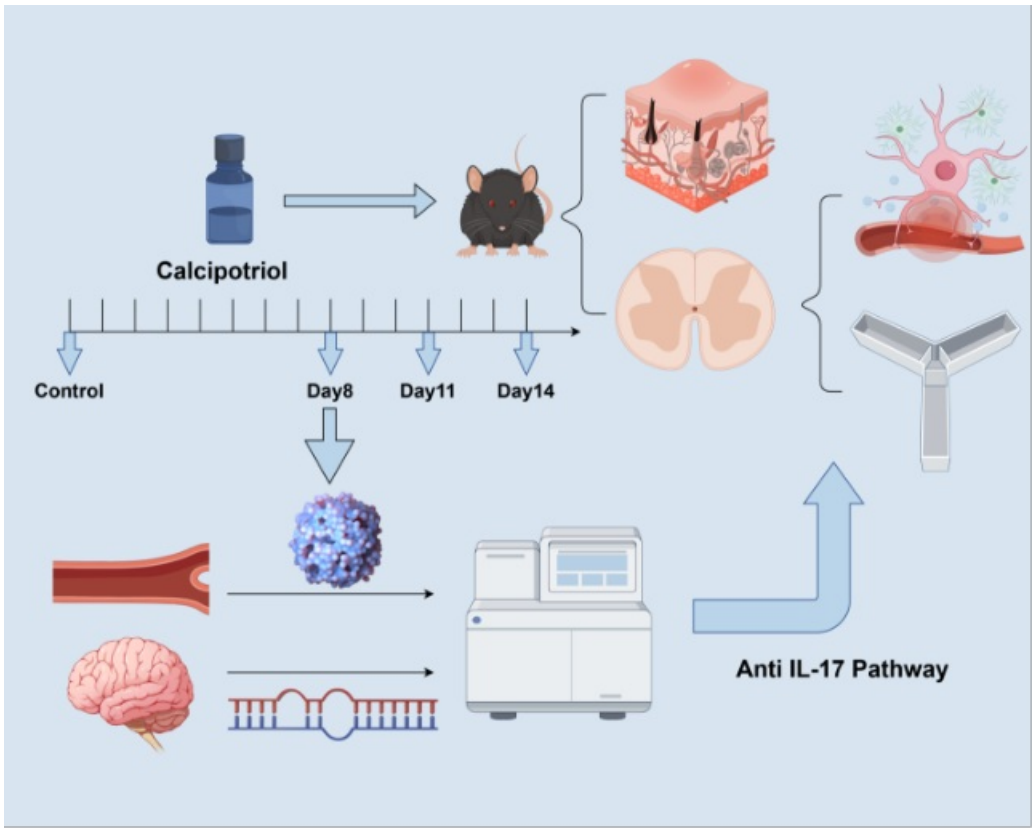
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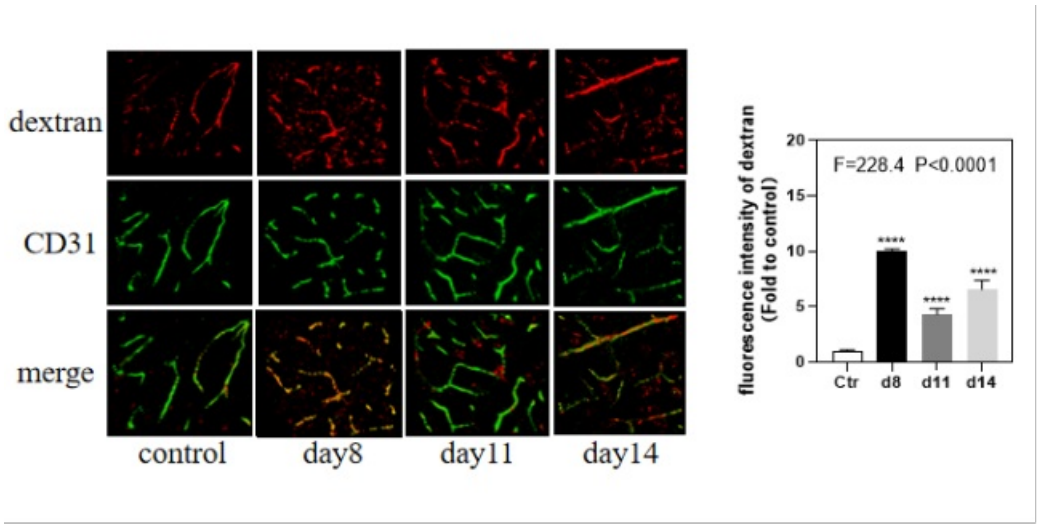
Introduction & Objectives: Atopic dermatitis（AD） and its central nervous system complications are a significant concern for many patients in clinical practice, but the specific connections and mechanisms remain unclear.We aim to investigate whether there is a destruction of the blood-brain barrier when the skin lesions occur simultaneously and whether there are inflammatory changes in the central nervous system, as well as the mechanisms that produce these changes.

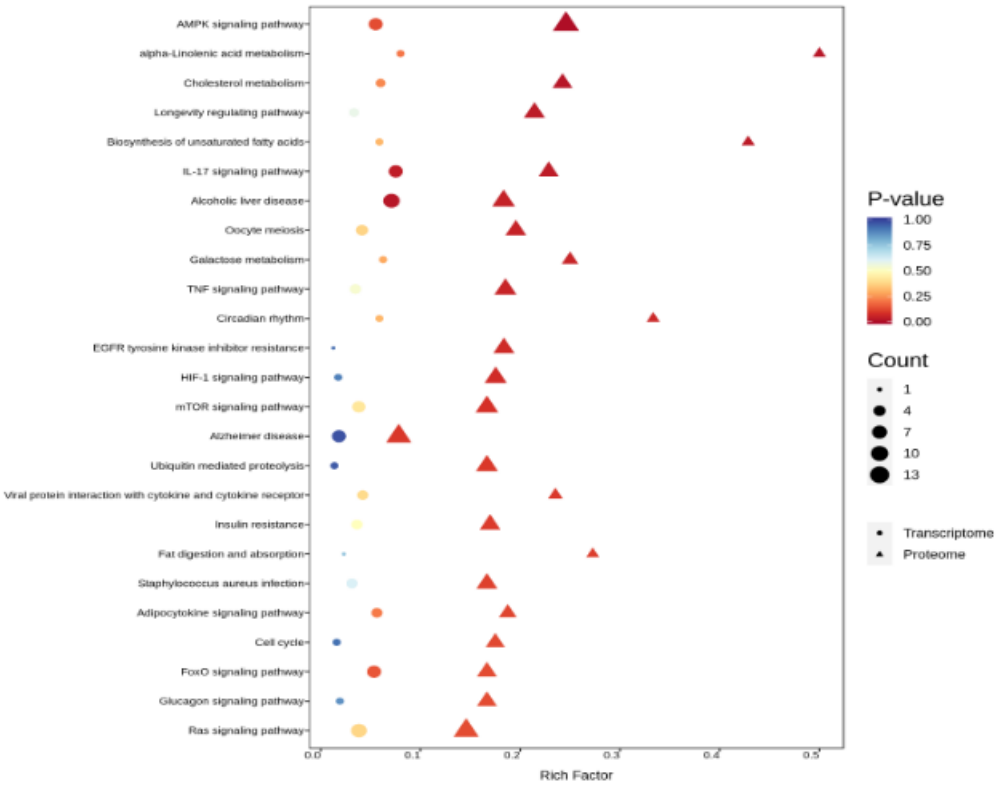
Materials & Methods: Continuous application of calcipotriol solution (2 nmol/L) on the back of C57/BL6 mice induces AD. Skin paraffin sections are stained with HE and Masson to observe pathological changes. The open field test, Y-maze test, and tail suspension test are used to assess behavioral changes in mice. After intravenous injection of Dextran dye, brain frozen sections are observed under laser confocal microscopy to assess changes in blood-brain barrier permeability. After Iba-1 staining of mouse brain frozen sections, microglial activation is observed under laser confocal microscopy. GFAP staining of brain paraffin sections is used to observe astrocyte activation. Transmission electron microscopy is used to observe changes in vesicular transport in brain vascular endothelial cells. Western blot analysis is conducted to observe changes in tight junction proteins of the blood-brain barrier. ELISA experiments validate changes in inflammatory factors in serum. High-performance liquid chromatography is used to measure the concentration of calcipotriol in mouse blood. A combined analysis of blood proteomics and brain transcriptomics is performed to screen pathways that may lead to central nervous system complications in AD mice.

Results: When mice were continuously administered calcipotriol for 8 days, both macroscopic and pathological changes resembling AD were observed, with significant behavioral abnormalities ($P<0.05$), marked leakage of the blood-brain barrier ($P<0.001$), and full activation of microglia and astrocytes indicating the occurrence of neuroinflammation ($P<0.05$). Additionally, there was an increase in vesicular transport in brain endothelial cells, and tight junction proteins were significantly disrupted ($P<0.05$). Calcipotriol was not detected in the blood of the mice. The IL-17 pathway showed significant differences in blood proteomics and brain transcriptomics ($P<0.05$). After intervention with an IL17A inhibitor, the skin lesions in the mice showed some improvement, with a significant reduction in blood-brain barrier leakage and alleviation of neuroinflammation.

Conclusion: In the AD mouse model induced by calcipotriol, there was a disruption of the blood-brain barrier and inflammation of central nervous. During the process of central nervous lesions, the IL-17 pathway played an important role, providing novel insights for the diagnosis and treatment of patients with AD accompanied by central nervous complications in clinical practice.


Calcipotriol
Control
Day8
Day11
Day14
Anti IL-17 Pathway


dextran
CD31
merge
control
day8
day11
day14
fluorescence intensity of dextran (Fold to control)
F=228.4 P<0.0001
Ctr
d8
d11
d14


AMPK signaling pathway
alpha-Linolenic acid metabolism
Cholesterol metabolism
Longevity regulating pathway
Biosynthesis of unsaturated fatty acids
IL-17 signaling pathway
Alcoholic liver disease
Oocyte meiosis
Galactose metabolism
TNF signaling pathway
Circadian rhythm
EGFR tyrosine kinase inhibitor resistance
HIF-1 signaling pathway
mTOR signaling pathway
Alzheimer disease
Ubiquitin mediated proteolysis
Viral protein interaction with cytokine and cytokine receptor
Insulin resistance
Fat digestion and absorption
Staphylococcus aureus infection
Adipocytokine signaling pathway
Cell cycle
FoxO signaling pathway
Glucagon signaling pathway
Ras signaling pathway
0.0
0.1
0.2
0.3
0.4
0.5
Rich Factor
P-value
1.00
0.75
0.50
0.25
0.00
Count
1
4
7
10
13
Transcriptome
Proteome



Abstract N°: 3323

Durable maintenance of EASI-90 with amlitelimab in adults with moderate-to-severe atopic dermatitis: 52-week results from the STREAM-AD phase 2b trial

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Introduction & Objectives: Amlitelimab (SAR445229, KY1005) is a fully human, anti-OX40 Ligand (OX40L) monoclonal antibody. In the STREAM-AD phase 2b trial (NCT05131477), the primary endpoint was met at Week 16, with a significant decrease in Eczema Area and Severity Index (EASI) percentage change with amlitelimab versus placebo. Amlitelimab demonstrated clinically meaningful improvements in atopic dermatitis (AD) lesions and pruritus compared with placebo-treated participants up to Week 24 in Part 1, including the proportion of patients achieving ≥90% improvement of EASI (EASI-90). In clinical responders, defined as participants achieving EASI-75 and/or Investigators Global Assessment (IGA) 0/1 at Week 24, durability of response (EASI-75 and IGA 0/1) was observed through Week 52 (Part 2), with improvements maintained while participants were either on- or off-amlitelimab. Here, the proportion of clinical responders achieving and maintaining EASI-90 with amlitelimab in Part 2 of the STREAM-AD trial is reported.

Materials & Methods: STREAM-AD was a 52-week, randomised, double-blinded, placebo-controlled trial, consisting of a 24-week treatment period (Part 1) and a 28-week maintenance/withdrawal period (Part 2). Adults with moderate-to-severe AD (N=390) were randomised 1:1:1:1:1 to receive subcutaneous amlitelimab every 4 weeks (Q4W; 250 mg + 500-mg loading dose [LD], n=77; 250 mg, n=78; 125 mg, n=77; or 62.5 mg, n=79) or placebo Q4W (n=79) in Part 1. In Part 2, clinical responders (N=190) were re-randomised 3:1 to withdraw from amlitelimab or continue their pre-Week 24 dose (250 mg with 500-mg loading dose, n=34 [treatment withdrawal]/n=13 [continuing]; 250 mg, n=28/n=12; 125 mg, n=33/n=12; 62.5 mg, n=35/n=7; placebo responders continuing placebo, n=16) for 28 weeks. Among overall clinical responders (participants achieving EASI-75 and/or IGA 0/1 at Week 24), the proportion of patients who achieved EASI-90 at Week 24 and maintained it at Week 52 following continuation or withdrawal from amlitelimab during Part 2 (post hoc) was evaluated. Participants using rescue medications in Part 2 or with missing data were imputed as non-responders.

Results: Among overall amlitelimab-treated clinical responders, 62.6% achieved EASI-90 at Week 24. Among these Week 24 EASI-90 responders, 61.3% of participants who continued amlitelimab during Part 2 maintained EASI-90 at Week 52. Of the Week 24 EASI-90 responders who withdrew from amlitelimab for 28 weeks, 59.0% maintained EASI-90 at Week 52.

Conclusion: The results demonstrate that a high proportion of clinical responders achieved EASI-90 response at Week 24. The majority maintained EASI-90 response with continued amlitelimab treatment at Week 52. Notably,

EASI-90 was also maintained at Week 52 after 28 weeks of withdrawal from amlitelimab by the majority of Week 24 EASI-90 responders. Taken together, these data further demonstrate that targeting the OX40L/OX40 pathway via amlitelimab may lead to durable disease control, even while off-amlitelimab, in patients with moderate-to-severe AD. Ongoing phase 3 trials will further evaluate the effect of continued amlitelimab treatment or withdrawal over longer observational periods.



Abstract N°: 3353

Atopic Eruption of Pregnancy: insights from our experience

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Introduction & Objectives:

Atopic eruption of pregnancy (AEP) is a condition that includes atopic dermatitis that either worsens or begins during pregnancy, as well as prurigo of pregnancy and pruritic folliculitis of pregnancy. It was reclassified in 2006 by Ambros-Rudolph et al., who proposed grouping these entities under the umbrella of AEP based on their shared clinical features and a possible association with atopy.

AEP most commonly begins in the first trimester, and approximately 20% of patients have a prior history of atopy. Clinically, it presents in one-third of patients as an eczematous eruption (AEP type E) and in another third as a papular eruption (AEP type P). Lesions may appear anywhere on the body, including the palms and soles. Diagnosis is generally clinical, and treatment is symptomatic, involving oral antihistamines and topical or oral corticosteroids. This condition poses no maternal or fetal risk, unlike other pregnancy dermatoses that do, such as gestational pemphigoid and intrahepatic cholestasis of pregnancy.

The objective of this study is to describe the characteristics of patients diagnosed with AEP at the Pregnancy Dermatoses Unit of the Austral University Hospital.

Materials & Methods:

We conducted an observational study including patients treated at the Pregnancy Dermatoses Unit of the Austral University Hospital with a diagnosis of AEP. Data collected included maternal age, gestational age at diagnosis, number of previous pregnancies and deliveries, type of AEP (E or P), history of atopy, need for skin biopsy for histopathological analysis, and treatment administered.

Results:

A total of 30 patients were included in the study, with a mean age of 31.7 years. The average gestational age at diagnosis was 24.6 weeks, ranging from 9 to 39 weeks. Three patients were diagnosed during the immediate postpartum period (within 30 days after delivery). A third of the patients were primiparous, and all pregnancies involved a single fetus. Regarding the type of AEP, 50% presented with an eczematous eruption (type E) and 50% with a papular eruption (type P). Only three patients reported a personal history of atopy. In two cases, a skin biopsy was performed for histopathological diagnosis. All patients were treated with topical corticosteroids, combined with oral antihistamines in most cases. In six patients (20%), oral corticosteroids were necessary to control the symptoms.

Conclusion:

In our population, AEP presented with most of the characteristics described in the literature, although with some differences. The average gestational age at diagnosis was slightly later, although the majority of cases still occurred during the first trimester. Half of the patients presented with type P AEP, whereas the literature usually describes this presentation in only a third of cases.

We emphasize the importance of recognizing the different types of specific dermatoses of pregnancy to achieve

early diagnosis and assess their potential maternal or fetal risks.



Abstract N°: 3368

German AD-Best TREAT Registry

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by severe pruritus and skin inflammation, leading to significant psychosocial burden and a substantial reduction in quality of life. The development of new treatment options has improved the management of AD, however, these therapies require real-world evaluation to assess their benefits, risks, and specific treatment profiles.

Materials & Methods:

ADBest-TREAT is a digital, web-based, large-scale, non-interventional, observational registry designed to collect real-world data on systemic AD therapies from dermatological practices in Germany. Developed in cooperation with dermatology, biostatistics, and IT experts, as well as patients, ADBest-TREAT aims to enroll 5000 AD patients over five years, with a possible extension to ten years. The registry collects data on the effectiveness, patient-reported outcomes, treatment patterns, and safety of systemic AD therapies, including biologics and Janus kinase inhibitors (JAKi). Additionally, it supports predictive model development and guideline optimization. The data presented were collected from enrollment visits between January 2023 and March 2025 at the IVDP of the University Medical Center Hamburg-Eppendorf as well as the dermatology practices “Dr. Dirk Maaßen” in Maxdorf and “am Löwenmarkt” in Stuttgart.

Results:

Between 2023 and 2025, **175** patients were enrolled in ADBest-TREAT, 53,14**%** (n=93) female and 46,86% (n=82) male. **86,86%** (n=152) of patients received systemic treatment. The most commonly prescribed systemic therapy was **Dupixent** (n=77), followed by **Lebrikizumab** (n=26), **Tralokinumab** (n=22), **Abrocitinib** (n=13), Upadacitinib (n=10), **Baricitinib** (n=3), and others (n=2). In total, **66,86%** (n=117) of patients received topical treatment, with **45,71%** (n=80) treated with tacrolimus, **38,86%** (n=68) with pimecrolimus, and **12,57%** (n=22) with topical steroids.

Conclusion:

ADBest-TREAT provides an efficient platform for large-scale data collection, offering valuable insights into the real-world management of AD in Germany. With the anticipated inclusion of additional centers in the coming years, its capacity to generate comprehensive real-world evidence is expected to further expand.



Abstract N°: 3380

Ruxolitinib Cream Demonstrated Long-Term Disease Control With Time Off Treatment in Children With Atopic Dermatitis

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Introduction & Objectives: Ruxolitinib cream demonstrated efficacy and was well tolerated in children aged 2–11 years with atopic dermatitis (AD) in the phase 3 TRuE-AD3 study (NCT04921969). Here, we evaluated long-term disease control and time off treatment among patients initially randomized to ruxolitinib cream who applied ≥1 dose in the long-term safety (LTS) period of TRuE-AD3 (0.75%/1.5% ruxolitinib cream, n=119/114).

Materials & Methods: In TRuE-AD3, children with mild to moderate AD (Investigator's Global Assessment [IGA] score of 2/3 and 3%–20% affected body surface area [BSA]) were randomized (2:2:1) to twice-daily ruxolitinib cream (0.75% or 1.5%) or vehicle for 8 weeks. At Week 8, patients remained on ruxolitinib cream, and patients in the vehicle group were rerandomized to either strength of ruxolitinib cream for 44 weeks of as-needed treatment (LTS period).

Results: Disease control was evident with mean affected BSA reduced from baseline (0.75%/1.5% ruxolitinib cream, 9.9%/11.1%) to Week 52 (2.0%/1.9%). Clear (IGA 0) or almost clear (IGA 1) skin was achieved at least once in the LTS period by 80.7% and 91.2% of patients who applied 0.75% and 1.5% ruxolitinib cream, respectively. Patients in the 0.75% and 1.5% ruxolitinib cream groups achieved IGA 0/1 for a mean of 60.0% and 69.0% of all visits in the LTS period, respectively, among those with ≥2 visits from Weeks 12–52 (n=101 and n=106). The median (range) number of days with no treatment due to lesion clearance in the LTS period was 136.0 (8–296) and 151.0 (2–296) days in the 0.75% and 1.5% ruxolitinib cream groups, respectively; patients spent 50.4% and 50.2% of the LTS period (median cumulative percentage) off treatment due to lesion clearance. Ruxolitinib cream was well tolerated, with no serious treatment-related adverse events over 52 weeks.

Conclusion: Children aged 2–11 years with mild to moderate AD achieved long-term disease control with as-needed ruxolitinib cream monotherapy. Clear or almost clear skin was maintained for the majority of the as-needed treatment period, with substantial time off treatment due to lesion clearance.



Abstract N°: 3512

successful treatment 'dupilumab induced exacerbation of atopic dermatitis' with upadacitinib

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Introduction & Objectives: Atopic dermatitis (AD) is a common chronic inflammatory disease that is characterized by severe itching and recurrent eczematous lesions. Many immunological components, including IL-4, IL-5, IL-13, IL-31, IL-33, TSLP, contribute to its complicated pathogenesis. Dupilumab is a monoclonal antibody that inhibits interleukin-4 (IL-4) and IL-13 signaling. Although it's effectiveness has been shown in AD, several adverse effects reported after dupilumab therapy; including local injection site reactions, conjunctivitis, headache, nasopharyngitis, face and neck rash, psoriatic dermatitis, lichenoid eruption and exacerbation of AD. Upadacitinib is an oral Janus kinase (JAK) inhibitor, modulates different combinations of kinases than dupilumab, addressing a wider range of proinflammatory mediators associated with AD.

Materials & Methods: Here we present a 85-year-old male patient who has diagnosed as atopic dermatitis with diffuse itchy rash on his body and by histopathological examination. One month after initiation of dupilumab therapy exacerbation of the rash and itch were observed. Thereupon, dupilumab therapy was discontinued and the patient was started on narrowband UVB, topical steroids and mouisturizers. Histopathological examination revealed spongiosis, compact hyperkeratosis, widespread parakeratosis, silent psoriasiform hyperplasia. According to histopathological examination exacerbation of the dermatitis was considered. Since he was 85 years old, upadacitinib 15 mg/day has been started and the patient's complaints significantly improved after one month.

Results: While biologics are largely effective and safe, some patients develop paradoxical reactions, defined as the development of inflammatory manifestations in patients treated with biologics for immune-mediated inflammatory diseases. Exacerbation of facial, head and neck dermatitis after dupilumab has been described in the literature. The cause of eczematous dermatitis after initiation of dupilumab might be an immune shift from Th2- to Th1- and/or Th17-mediated auto-inflammatory processes. By selectively inhibiting JAK1, upadacitinib abrogates the signaling of a wider range of proinflammatory mediators, including IL-4, IL-13, IL-22, IL-31, IFN-γ, and TSLP. Therefore, upadacitinib has emerged as an effective option when eczematous lesions appear following dupilumab. The simultaneous inhibition of multiple pathways may contribute to the efficacy of upadacitinib. Since the patient was 85 years old lower dose of upadacitinib was started. Although no side effects were observed during the first month, long-term monitoring of JAK inhibitors is necessary due to possible side effects in elderly patients.

Conclusion: In conclusion, the exacerbation of AD following dupilumab were effectively managed with upadacitinib, highlighting the use of JAK inhibitors as a possible treatment of paradoxical reactions after dupilumab for atopic dermatitis.



Abstract N°: 3575

Real-world utilization and minimal disease activity achievement with upadacitinib in atopic dermatitis: interim analysis of the multicenter China P24-965 study

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Introduction & Objectives:

Upadacitinib (UPA) is an oral selective JAK inhibitor, approved for the treatment of patients with moderate to severe atopic dermatitis (AD). Real-world data on safety and efficacy of UPA are limited, especially in China. The minimal disease activity (MDA) concept from the AHEAD consensus recommendations is gradually adopted; MDA combines treat-to-target principles with patient / clinician shared decision-making principles. P24-965 study aims to characterize the real-world utilization patterns and effectiveness of UPA via achievement of MDA in adults and adolescents AD patients in clinical practice in China.

Materials & Methods:

P24-965 is an ongoing, observational, prospective study to assess the use of UPA in clinical practice among 1000 patients in 40 AD centers in China for 1 years. Adults and adolescents initially treated with UPA for AD are being enrolled. Primary outcomes included UPA utilization patterns, and important secondary outcomes included Eczema Area and Severity Index (EASI), Peak Pruritus Numeric Rating Scale (PP-NRS), while moderate and optimal targets per AHEAD consensus recommendations were regarded as exploratory outcomes. This interim analysis (data cutoff 14th Feb, 2025) reports baseline data and 3-month UPA utilization patterns and effectiveness data among patients who were enrolled at least 3 months by the data cutoff date or discontinued from the study.

Results:

304 patients were included in this interim analysis, of whom 61 (20.1%) were adolescent; the mean EASI was 20±12; the mean PP-NRS was 6±2. 5.6% patients had prior conventional systemic treatments, 1.0% had dupilumab and 0.3% had systemic JAK inhibitors other than UPA (Table 1).

The most common reasons for starting on UPA were 88.8% inadequate response and 0.7% intolerability to prior treatment; 297 (97.7%) patients started on UPA 15 mg. 282 (92.8%) remained on UPA at month 3. 3 (1.0%) patients received dose escalation of UPA within 3 months all for inadequate disease control, and 21 patients received dose tapering within which due to remission or disease stabilization (95.2%), and adverse events (4.8%) .

In month 3, EASI 75 or EASI <=7 was achieved in 84.7% patients, and EASI 90 or EASI <=3 in 39.8% patients. PP-NRS improvement >=4 was in 72.4% patients with baseline PP-NRS >=4, and PP-NRS 0/1 was 54.3% patients (Figure 1). As for selection of treatment outcomes for assessment, 78.3% dermatologists chose EASI as clinical

report outcome (ClinRO), and 54.3% chose SCORD and 43.1% chose IGA with BSA. 90.8% chose PP-NRS as patient report outcome (PRO) via share decision making with patients, and 74.0% chose POEM, 43.4% chose sleep NRS, 31.3% chose Hospital Anxiety and Depression Scale (HADS), 25.7% chose pain NRS and 43.4% chose DLQI (cDLQI for 12 to 17-year-old patients). 54.3% patients achieved moderate target in month 3, and 34.1 achieved optimal target.

The AE with reasonable possibility of being drug related, AE leading to discontinuation of study drug and SAE were low in this analysis (Table 2). Death was not observed.

Conclusion:

The results of this analysis indicate that UPA treatment can feasibly achieve moderate and high treatment clinical and patients targets in real-world settings in China AD patients, where most AD patients remained adhered to UPA after 3 months of initiation. Safety profile is consistent with the known safety profile of UPA with no new signals identified.

Table 1. Baseline Demographic and Disease Characteristics

Characteristic	Value
Age, median (IQR) years	31.0 (19.5-46.0)
12-17 years, n (%)	61 (20.1)
>=18 years, n (%)	243 (79.9)
Male, n (%)	157 (51.6)
BMI, median (IQR) kg/m^2	23.40 (21.20-25.40)
Healthcare insurance status, n (%)	
National Healthcare Insurance	288 (95.0)
Commercial Insurance	20 (6.6)
No Healthcare Insurance	13 (4.3)
Duration of AD symptoms, median (range) years	0 (0-36)
vIGA-AD, n (%)	
Moderate (3)	108(35.8)
Severe (4)	14(4.6)
EASI, mean (SD)	20 (12)
SCORAD, mean (SD)	57 (15)
PP-NRS, mean (SD)	6 (2)
POEM, mean (SD)	15 (7)
Sleep-NRS, mean (SD)	5 (3)
HADS-A, mean (SD)	7 (4)
HADS-D, mean (SD)	5 (3)
Pain-NRS, mean (SD)	4 (3)
(c)DLQI, mean (SD)[a]	13 (7)
Concomitant medication	
Topical treatments[b]	152 (50.0)
Conventional systemic treatments[c]	17 (5.6)
Dupilumab	3 (1.0)
Other JAK inhibitors[d]	1 (0.3)
AD-related treatment changes rationale	
Inadequate response	270 (88.8)
Intolerability	2 (0.7)
Other[e]	37 (12.2)

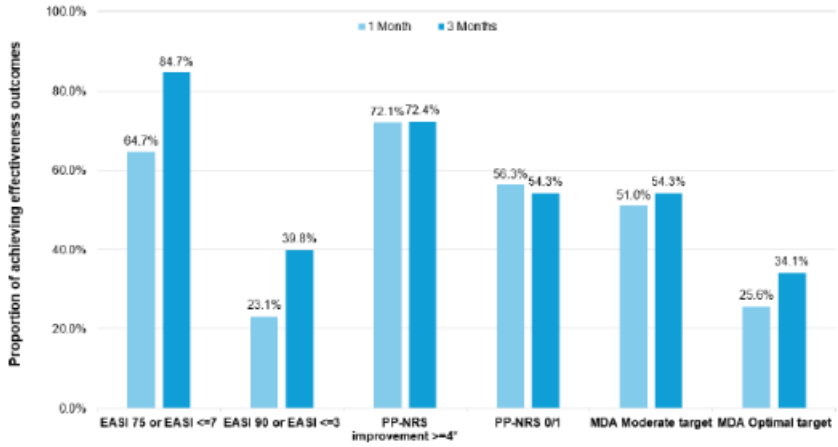
SD, standard deviation; BMI, body mass index; AD, atopic dermatitis; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; EASI, Eczema Area and Severity Index; SCORAD, Scoring Atopic Dermatitis; PP-NRS, Peak Pruritus Numeric Rating Scale; POEM, Patient Oriented Eczema Measurement; NRS, Numeric Rating Scale; DLQI, Dermatology Life Quality Index; ADCT, Atopic Dermatitis Control Tool.
[a]For patients from 12-16 years of age, cDLQI will be used. [b]Topical treatments include topical corticosteroids and topical calcineurin inhibitors. [c]Conventional systemic treatments include corticosteroids, cyclosporin A, tripterygium glycosides. [d]Include abrocitinib.

Table 2. Treatment-Emergent Adverse Events at Month 3

Events (E/100PY)	N=304, PYs=74.91
Any AE	70 (93.5)
SAE	1 (1.3)*
AE with reasonable possibility of being drug related	27 (36.0)
AE leading to discontinuation of study drug	11 (14.7)
AE leading to death	0

AE, Adverse Event; SAE, Serious Adverse Event. *Patients had paroxysmal atrial fibrillation onset after 48 days initialization of UPA, the patients is still on UPA without discontinuation.

Figure 1. Effectiveness of UPA at Month 1 and Month 3



EASI, Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numeric Rating Scale; MDA, Minimal Disease Activity
*For those participants with baseline PP-NRS >=4.
MDA moderate / optimal target is defined as achieving every moderate / optimal target through patient/clinician shared decision-making principles at baseline, of which the criteria are defined in AHEAD consensus recommendations[2].



Abstract N°: 3614

Age-Stratified Dose Optimization Of Lumbricus Rubellus Extract: A Translational Approach To Il-5 Reduction And Symptom Remission In Atopic Dermatitis

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Introduction & Objectives: The age-stratified optimal dose of *Lumbricus rubellus* extract for AD treatment remains unexplored. This study aims to establish a dose-response relationship across age groups. To analyze the efficacy of age-adjusted doses (250–2000 mg/day) in reducing IL-5 and AD symptoms.

Materials & Methods: A controlled pretest-posttest study included 30 mild AD patients. Doses were age-adjusted: adults (2000 mg/day), children aged 3–12 years (500 mg/day), and 1–3 years (250 mg/day). IL-5 levels were measured via ELISA, and symptom severity was assessed using the SCORAD index.

Results: The highest IL-5 reduction was observed in adults (37.37 pg/mL; $p < 0.001$), with a 45% improvement in SCORAD scores ($p < 0.05$). Pediatric groups showed 22% (3–12 years) and 15% (1–3 years) IL-5 reduction. No severe adverse effects were reported.

Conclusion: *Lumbricus rubellus* extract exhibits dose-dependent efficacy in IL-5 reduction and symptom remission, supporting age-tailored therapy. Multi-center validation is recommended.



Abstract N°: 3625

Blood Biomarkers as Predictors of Treatment Response to Biological Agents in Prurigo Nodularis: A Single-Center Retrospective Analysis

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Introduction & Objectives:

Prurigo nodularis (PN) is a chronic, intensely pruritic skin condition that significantly impairs quality of life. Biological agents, including dupilumab and nemolizumab, have shown efficacy in treating PN, but predictive biomarkers for treatment response remain poorly characterized. This study aimed to identify blood biomarkers that might predict treatment response to these biologics.

Materials & Methods:

We retrospectively analyzed 28 patients with PN who visited our dermatology department between April 1, 2024, and September 30, 2024, and received either dupilumab (n=13) or nemolizumab (n=19). Visual Analog Scale (VAS) for pruritus and Investigator's Global Assessment for Prurigo Nodularis (IGA-PN) were evaluated before treatment and at 4, 12, and 24 weeks after treatment initiation. Treatment response was defined as ≥50% reduction in VAS at 12 weeks. Blood parameters including IgE, TARC, and eosinophil percentage were analyzed using various cutoff values to determine optimal thresholds for predicting treatment response.

Results:

In the dupilumab group, patients with IgE ≥500 IU/mL showed higher response rates (66.7%) compared to those with IgE <500 IU/mL (16.7%). Patients with TARC ≥1000 pg/mL demonstrated a 100% response rate to dupilumab, while those with TARC <1000 pg/mL had only a 12.5% response rate. For nemolizumab, patients with IgE ≥200 IU/mL showed an 85.7% response rate compared to 44.4% in those with IgE <200 IU/mL. Similarly, patients with eosinophils ≥5% showed a substantially higher response rate to nemolizumab (88.9%) compared to those with eosinophils <5% (37.5%). Combined biomarker analysis revealed that patients with both elevated IgE and TARC levels appeared to show optimal response to both biologics. The presence of comorbid atopic dermatitis did not seem to significantly affect nemolizumab efficacy, whereas dupilumab appeared potentially more effective in patients without atopic dermatitis.

Conclusion:

Our preliminary findings suggest that blood biomarkers may help predict treatment response to biological agents in patients with PN. IgE ≥500 IU/mL and TARC ≥1000 pg/mL might be considered as predictive biomarkers for dupilumab response, while IgE ≥200 IU/mL and eosinophils ≥5% may predict nemolizumab response. Patients with both elevated IgE and TARC levels might benefit from either biologic. These potential biomarker-based selection criteria could contribute to more personalized treatment approaches for PN. However, the small sample size limits definitive conclusions, and larger prospective studies are needed to validate these findings.



Abstract N°: 3637

Effectiveness and safety of 12-months tralokinumab treatment in 824 adults with atopic dermatitis: Final real-world data from the prospective, non-interventional, international, single-cohort TRACE study

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, burdensome skin disease affecting various body areas, associated with negative impact on patients' quality of life and sleep. Tralokinumab is a monoclonal antibody targeting interleukin-13, indicated for the treatment of moderate-to-severe AD and was effective and well-tolerated in Phase 3 clinical trials. This study assesses the real-world effectiveness and safety of 12-months tralokinumab treatment in patients with AD.

Materials & Methods:

TRACE is a prospective, non-interventional, international, multi-center, single-cohort study of adults with AD, who were prescribed tralokinumab according to national approved label at treating physician's discretion; concomitant medications were allowed. Of the 835 patients enrolled (Nov-2021 to Jun-2023), 824 comprised the full analysis set and 825 the safety analysis set. Assessments included AD localization and overall AD disease severity scores, i.e., investigator global assessment (IGA) and/or eczema area and severity index (EASI), as per individual clinical practice, as well as adverse events (AE) reporting. Data are presented as observed.

Results:

At baseline, patients were 47.6% female, 52.4% male and 75.7% White, with a mean age of 44.1 years and mean AD duration of 18.8 years. Treatment with tralokinumab reduced AD severity across all endpoints (Table 1). Of those with data, the proportion of patients with clear or almost clear skin (IGA 0/1) increased from 2% at baseline (n=780) to 39% (n=632) and 66% (n=400) at months 3 and 12. Among patients with baseline IGA ≥2, 46% (n=608) at month 3 and 71% (n=383) at month 12 had a ≥2-point IGA improvement. The proportion of patients with severe disease (IGA 4) decreased markedly from 34.1% at baseline (281/823) to 4.0% (27/674) and 1.9% (8/420) at months 3 and 12. Mean EASI scores improved from 20.1 (n=640) at baseline to 6.6 (n=517) and 2.9 (n=355) at months 3 and 12. The proportion of patients with EASI ≤7 (no or mild eczema) increased dramatically from 14% (n=640) at baseline to 71% (n=517) and 89% (n=355) at months 3 and 12. Treatment with tralokinumab was generally well-tolerated and no new safety signals were identified. AEs were mostly non-serious and of mild or moderate severity. The well-known adverse drug reactions 'conjunctivitis' and 'injection site reaction' were the most frequent AEs (all non-serious) and reported in <5% of patients (Table 2).

Conclusion:

12-months tralokinumab treatment in adults with AD in a real-world setting decreased AD severity across all endpoints with no new safety signals identified.

Table 1 Investigator-assessed AD disease outcomes during 12 months of tralokinumab treatment (TRACE study)

Endpoints	Baseline (N=824)	3 months (N=708)	6 months (N=596)	9 months (N=500)	12 months (N=460)
IGA 0/1, n2	780	632	522	427	400
Proportion (95% CI)	0.02 (0.01; 0.03)	0.39 (0.35; 0.43)	0.55 (0.51; 0.60)	0.61 (0.56; 0.65)	0.66 (0.61; 0.71)
IGA 4 (severe disease), n1/n2 (%)	281 / 823 (34.1%)	27 / 674 (4.0%)	12 / 548 (2.2%)	15 / 449 (3.3%)	8 / 420 (1.9%)
IGA ≥2-point improvement[1], n2	-	608	497	411	383
Proportion (95% CI)		0.46 (0.42; 050)	0.62 (0.57; 0.66)	0.66 (0.61; 0.71)	0.71 (0.66; 0.76)
EASI, n2	640	517	434	360	355
Mean (SD)	20.1 (11.06)	6.6 (7.47)	4.8 (6.59)	4.1 (5.97)	2.9 (4.78)
EASI ≤7, n2	640	517	434	360	355
Proportion (95% CI)	0.14 (0.11; 0.17)	0.71 (0.66; 0.74)	0.81 (0.77; 0.84)	0.82 (0.78; 0.86)	0.89 (0.85; 0.92)

824 patients were included in the full analysis set. Percentages are calculated using 'n2' as denominator.
[1] Among patients with baseline IGA score ≥2.
AD = atopic dermatitis; CI = confidence interval; EASI = eczema area and severity index (clinician-rated scoring system that grades the area and severity of eczema across 4 body regions [total range: 0–72; higher score indicating worse disease]); IGA = investigator global assessment (clinician-rated 5-point scoring system for global AD disease severity ranging from 0 [clear] to 4 [severe]); IGA 0/1 = clear (IGA score 0) or almost clear (IGA score 1); N = number of patients in the analysis set; n1 = number of patients achieving endpoint; n2 = number of patients with available data; SD = standard deviation.

Table 2 Adverse events reporting during 12-months tralokinumab treatment (TRACE study)

Safety analysis set	Tralokinumab N=825
Patients with at least 1 AE, n (%) E	232 (28.1%) 454
Mild, n (%)	158 (19.2%)
Moderate, n (%)	98 (11.9%)
Severe, n (%)	23 (2.8%)
Related to tralokinumab, n (%)	132 (16.0%)
Patients with at least 1 SAE, n (%)	19 (2.3%)
Most frequent (in ≥2% of patients) AEs	
Conjunctivitis*, n (%) E	36 (4.4%) 40
Injection site reaction*, n (%) E	19 (2.3%) 21

825 patients were included in the safety analysis set.
AE = adverse event; E = number of events; N = number of patients in safety analysis set; n = number of patients with event, SAE = serious adverse event.
*All were non-serious and mild or moderate in severity. The majority was assessed as related to tralokinumab.



Abstract N°: 3677

Unveiling the Burden and Impact of Flare in Patients With Moderate-to-severe Atopic Dermatitis: Results From the Adelphi Real World Disease Specific Program in Europe

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Introduction & Objectives:

To describe the characteristics, burden and impact of flares in patients with moderate-to-severe AD from both the physician and patient perspective in Europe.

Materials & Methods:

This was a cross-sectional survey of physicians and their adult patients with moderate-to-severe AD in France, Germany and United Kingdom using data from the Adelphi MG Disease Specific Programme™ conducted between Sept 2022 and July 2023. Patients were classified as either currently flaring or not based on physician's assessment. Baseline demographics; frequency, duration and severity of flares; associated signs, symptoms and impacts; and patient-reported outcome measures were summarised using descriptive statistical analyses.

Results:

A total of 278 physicians completed patient record forms for 707 patients (mean age: 35.7 years; 52% male; 87% white; mean disease duration: 7.5 years). Based on physician report 42% of patients were currently experiencing flare with majority of current flares classified as moderate (74%) or severe (23%). Most patients and physicians reported ≥2 flares experienced by patients in the past year (70% [96/138] and 62% [280/455]; mean number of flares: 3.6 and 2.2, respectively). The most common signs and symptoms experienced in ≥80% patients during current flare episode as reported by both physicians and patients were itching, skin pain, scratching, dry skin, scaling/scaly skin, with cracking/raw areas and sleep disturbance ≥80% reported by patients only. The mean scores of EuroQol 5-Dimension Visual-analog scale, Dermatology Life-Quality-Index and Patient-oriented Eczema-Measure in currently flaring were 70.4, 9.8 and 13.7 and in non-flaring were 74.3, 5.6 and 11.8, respectively.

Conclusion:

The burden of flare and patient and physician perception of flare identified in this research highlights the importance of defining patient-centered measures of flare and developing new therapies to better address flares in patients with AD.



Abstract N°: 3690

Design and Rationale of ARMADA-AD Disease Registry: An International, Prospective, Observational Registry to Characterize Unmet Needs and Evaluate Real-World Effectiveness and Safety of Systemic Therapies in Adults and Adolescents with Atopic Dermatitis

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Introduction & Objectives:

Despite recent advances in the management of atopic dermatitis (AD), patients continue to face significant burden and diminished quality of life1. Real-world studies are essential to understand patient needs and evaluate long-term effectiveness and safety of current therapies. Here, we present the design of ARMADA-AD disease registry that aims to collect real-world data to characterize unmet needs in AD, patient journey, and long-term outcomes of various AD treatment options.

Materials & Methods:

ARMADA-AD, a global, multicenter, longitudinal, prospective, observational, real-world study, plans to recruit atleast 1000 patients aged ≥12 years with confirmed diagnosis of AD and follow them for 5 years. Patients initiating or switching a systemic therapy for AD (including, but not limited to biologics, oral JAKi, and immunosuppressive/immunomodulatory therapies) will be included. Patients concurrently participating in interventional clinical trials will be excluded. Primary objectives are to comprehensively document patients' unmet needs, describe patient characteristics and treatment patterns, and characterize real-world safety, effectiveness, and patient satisfaction with systemic treatment options for AD. Key secondary objectives include evaluation of longitudinal course of AD and selected atopic and non-atopic comorbidities, long-term safety and effectiveness of systemic AD therapies, impact of AD treatment across relevant sub-groups, general healthcare practices, and comprehensive patient experiences.

Results:

ARMADA-AD is expected to begin enrollment in H1 2025.

Conclusion:

Data collected from the ARMADA-AD registry will address existing gaps and serve as a valuable resource to further our understanding of unmet needs and burden of AD, and real-world safety and effectiveness of systemic therapies, compared to other registries.



Abstract N°: 3709

Biomarkers associated with therapeutic response and adverse reactions in atopic dermatitis patients: A systematic review

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, inflammatory cutaneous disease characterised by intense itch, affecting approximately 20% of children and up to 10% of adults. BIOmarkers in Atopic Dermatitis and Psoriasis (BIOMAP) is a large European consortium that aims to improve precision medicine and availability of individualised AD treatment by identifying key predictive biomarkers for AD treatment response and treatment-related adverse events (AEs), disease trajectory, and comorbidity development. Our systematic review aims to identify biomarkers with clinical significance for predicting response to systemic therapies and treatment-related AEs for patients with moderate-to-severe AD.

Materials & Methods:

A systematic search was conducted across the electronic databases Embase and MEDLINE from database inception to September 2024. All records were independently screened for inclusion by four authors at both the title/abstract and full-text screening stages. Articles were included if they were randomised clinical trials, cohort studies, or case-control studies and included relevant outcome data for investigating associations between biomarkers and therapeutic response and adverse reactions. Data extraction was performed by the same three authors. All discrepancies or conflicts at any stage were resolved through adjudication and by a senior reviewer.

Results:

We identified 32 papers addressing the association between biomarkers and treatment response, and 12 evaluating the association between biomarkers and adverse events. Most studies investigated the association between biomarkers and dupilumab, and studies reporting associations between biomarkers and AEs were limited to dupilumab-related conjunctivitis and ocular surface disease (OSD). Interestingly, few studies evaluated the relationship between biomarkers and conventional systemic treatments. Our findings are heterogeneous, stemming from large variance in included study methodologies, such as follow-up biomarker collection times, treatments assessed, and the definition of elevated biomarker levels, and therefore meta-analysis was not possible. The primary findings on treatment response include four studies reporting a significant association between high

baseline total eosinophil count and poorer response to dupilumab, and five studies that identified an association between high baseline LDH levels and poorer treatment response to dupilumab. The most frequently studied AE was OSD, in particular conjunctivitis. There was an association between inflammatory markers such as high baseline IgE, TARC, and TEC, and the development of OSD.

Conclusion

Predicting therapeutic responses and identifying patients at risk of developing AEs will be increasingly important with an expanding range of treatment options for AD. Finding robust predictive biomarkers for AD, however, is complicated by its clinical heterogeneity and multifactorial aetiology. Collaborative projects, such as BIOMAP, hold great potential to advance precision medicine and enhancing individualised care.



Abstract N°: 3716

Outcomes Following Discontinuation of Systemic Immunomodulatory Therapies in Adults with Atopic Dermatitis: A Systematic Review

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Introduction & Objectives:

The widespread adoption of highly effective systemic immunomodulatory therapies such as biologics and small molecule Janus Kinase (JAK) inhibitors has transformed the therapeutic landscape for atopic dermatitis (AD). As more patients achieve clear or nearly clear skin, there is growing interest in whether disease control can be maintained after discontinuing systemic immunomodulatory therapy. This question is especially important given concerns surrounding the long-term use of these agents, including financial burden, risk of opportunistic infections and implications for family planning.

Aim: To evaluate disease-related outcomes in adults with AD following discontinuation of systemic immunomodulatory monotherapy, with a focus on maintenance of disease control.

Materials & Methods:

A systematic search was conducted across four databases (Medline, Embase, Web of Science and Cochrane Library) from database inception to 8th January 2025. Eligible studies included randomised controlled trials (RCTs) and cohort studies reporting outcomes after discontinuation of targeted or conventional systemic immunomodulatory monotherapy in adults with AD who had achieved disease control. Two reviewers independently screened records and extracted data. Study quality was assessed using the Cochrane Risk of Bias tool for RCTs and the Newcastle-Ottawa Scale for observational studies. Data extracted included participant baseline characteristics, maintenance of disease control, and outcomes on relapse and retreatment.

Results:

Nine studies (2,558 participants) met the inclusion criteria, including 8 RCTs and one cohort. Six studies examined biologic agents (amlitelimab, dupilumab (2 studies), tralokinumab, rezpegaldesleukin, rocatinlimab) and three evaluated JAK inhibitors (baricitinib, abrocitinib, upadacitinib). No eligible studies were identified for conventional systemic immunomodulatory therapies. Amlitelimab, rocatinlimab and rezpegaldesleukin are investigational and not currently approved for AD treatment. Overall risk of bias was generally low.

Across studies, there was considerable heterogeneity in definitions of disease control, treatment duration (12 - 52 weeks), and follow-up duration post-discontinuation (4 - 72 weeks). This limited direct comparisons and precluded meta-analysis. Higher proportions of participants maintained EASI-75 responses post-discontinuation with investigational agents: rezpegaldesleukin (71.4% at 36 weeks), rocatinlimab (73–96% at 20 weeks), and amlitelimab (61.6% at 28 weeks). In contrast, a lower proportion of participants were able to maintain responses with approved biologics: dupilumab (30.4% at 36 weeks) and tralokinumab (26.4% at 36 weeks). Rapid loss of EASI-75 was observed with JAK inhibitors after discontinuation: baricitinib (45.2% at 16 weeks), abrocitinib (42.3% at 4 weeks), and upadacitinib (~20% at 72 weeks).

Conclusion:

Emerging evidence suggests that sustaining disease control following discontinuation of systemic immunomodulatory therapy is possible in some adults with AD. Differences in outcomes between therapies may reflect variations in drug mechanisms or study design. To confidently identify individuals who may benefit from treatment discontinuation, further studies are required with harmonised outcomes (e.g. definition of disease control used) and standardised treatment and follow-up durations.



Abstract N°: 3787

Dupilumab Induced Musculoskeletal Symptoms: A Case Series and Description of Clinical Features

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Introduction & Objectives:

Dupilumab is a humanised monoclonal antibody that binds to the interleukin-4 receptor, causing a blockade of the IL-4 and IL-13 pathways which are critical in the pathophysiology of atopic dermatitis (AD). As we increase our use of dupilumab to treat moderate-to-severe AD, we notice a growing number of patients presenting with musculoskeletal symptoms.

Materials & Methods:

We describe five patients presenting with musculoskeletal symptoms, their treatment outcomes and our proposed approach in management.

Results:

A 24-year-old Chinese male presents with mild arthralgias of the neck, bilateral fingers, wrists, and ankle joints 2 years after starting dupilumab. The pain is worse on motion, while weight-bearing, and in the morning. Rheumatology concluded that symptoms were not secondary to inflammatory arthritis. Dupilumab at 300 mg every 4 weeks relieves symptoms, while more frequent injections induce recurrence. Both his eczema and joint symptoms were quiescent on a 4-weekly regimen.

A 66-year-old Indian female presents with mild joint pains affecting the left index finger and left thumb 1 month after initiation of dupilumab. There is no early morning stiffness or swelling. Reducing dosage to 300 mg every 3 weeks resolved her musculoskeletal symptoms, and she elected to continue dupilumab at this dose.

A 36-year-old Caucasian female presents with right shoulder pain 3 months after starting dupilumab, progressing to the left shoulder, right hip, and right knee. Orthopaedic surgery diagnosed right supraspinatus full-thickness tear, left supraspinatus partial tear, and right patellar tendinitis. Rheumatology excluded inflammatory enthesopathy. A trial of dupilumab discontinuation did not abate her symptoms and caused her eczema to flare. She opted to continue dupilumab every 2 weeks while continuing orthopaedic treatment.

A 46-year-old Chinese male presents with mild bilateral ankle and elbow stiffness 4 months after starting dupilumab, worse in the morning and at rest. Inflammatory markers, rheumatoid factor, and ankle radiography were normal. A trial of dupilumab on a 5-weekly regimen failed to relieve his musculoskeletal symptoms but remained efficacious for eczema control.

A 67-year-old Chinese male presents with right shoulder arthralgia 5 months after starting dupilumab. There is no association with motion or early morning stiffness. He is currently trialled on a reduced regimen of 300 mg every 4 weeks.

Conclusion:

In this case series, musculoskeletal symptoms on dupilumab were mild, non-specific

and do not meet rheumatologic diagnostic criteria for inflammatory arthritis. However, a suggestive timeline, dose-response relationship, and lack of alternative aetiologies should raise clinical suspicion. The latency after dupilumab initiation is variable, ranging from 1 month to 2 years. As symptoms are often non-debilitating, we suggest a trial of dupilumab at a reduced frequency for these patients, which may result in acceptable control of musculoskeletal symptoms, but at increased risk of flaring eczema. Discontinuation is usually unnecessary. Shared decision making between clinicians and patients remains paramount in ensuring optimal patient outcomes.



Abstract N°: 3827

Characterization of underdiagnosed atopic dermatitis in colombian school-age children

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin condition. It develops mainly in infancy and childhood, reaching 20% of these ages globally. Misdiagnosis or delayed treatment could negatively affect both the physical and mental health of the child. The aim of this study is to characterize the behavior of AD in an underserved school population in Colombia.

Materials & Methods:

Cross-sectional study conducted between March 2023 and November 2024 in students under 18 years of age with AD, evaluated in free medical brigades carried out in Colombia. Sociodemographic variables, age at lesion onset, age at diagnosis, time of lesion duration and disease severity were included using SCORAD, DLQI and POEM. Data were expressed in absolute and relative frequencies.

Results:

Of 222 patients, 56.8% were female; 47.7% (n=106) were between 6 and 11 years old. Most patients did not know their socioeconomic level (39.6%), 35.6% were from low strata.

According to SCORAD, the majority had mild AD (49.5%). Of the patients with severe and moderate disease, 64.7% and 61.5% were female, respectively. Of those with severe AD, 41.2% belonged to low socioeconomic level. POEM results showed that 31.1% had mild dermatitis; women were the 78.6% and 67.4% in the category of very severe and severe disease, respectively.

Regarding DLQI, 35.1% showed mild impairment of quality of life. Women had severe and moderate impairment in 75.0% and 63.3%, respectively.

Most lesions appeared under 6 years of age (42.8%). Regarding the time of lesions onset, 34.2% of the population had had them for more than 5 years. At the time of assessment, 26.1% of patients had no diagnosis.

It is worth mentioning that nearly half of the patients had not been evaluated by general physicians (43.2%) or dermatologists (53.6%) for AD.

Conclusion:

We found that, in contrast to what has been reported, the prevalence in our population was slightly higher in women. As in the literature, our sample presented the same behavior with respect to the age of onset of the lesions and the degree of severity according to the three scales applied. However, women showed a considerably higher frequency of severe disease with respect to the scales employed. This makes it necessary to consider greater attention to this population at the time of diagnosis, and to propose studies to explain the causal factors that help to prevent the progression of the disease and to individualize treatment.

We identified a non-negligible number of patients who had a delay in diagnosis, highlighting that there is still a

need for improvement strategies for the identification of AD.

Regarding socioeconomic status, our population showed a higher prevalence of lower socioeconomic strata, different from the findings of other authors. We consider that this occurred because most of the people who attended the screening sessions belonged to these strata, in addition, they could present barriers in access to health care and the disease is being underdiagnosed in this population.

Although AD is a common and often mild condition, it can be difficult to manage. To better address this condition, parents, caregivers and school teachers should be educated about the identification and natural history of the disease, as well as general measures that can be taken to control and prevent the intrinsic complications of AD.



Abstract N°: 3847

Frequency of ADHD in school population with atopic dermatitis in Colombia

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease with a high prevalence in children. The presence of behavioral disorders such as attention deficit hyperactivity disorder (ADHD) has been described in patients with AD. In our country there are no published studies in this regard, so this study aims to describe the frequency of ADHD in school-aged population with AD in Colombia

Materials & Methods:

A cross-sectional study was conducted between March and November 2024 among school-aged children under 18 years from different departments in Colombia (Cundinamarca, Bolívar, Risaralda). Sociodemographic variables, severity of AD measured by the SCORAD index, and the ADHD Rating Scale-IV were included. Patients were categorized into three groups according to ADHD Rating Scale-IV: absence of hyperactivity (0-17 points), some traits of hyperactivity (18-36 points), and marked hyperactivity (37-54 points). The variables were expressed in absolute and relative frequencies. Data were obtained from medical records from patients who assisted the screening sessions in the places mentioned above.

Results:

Of 32 patients, 56.3% were male. Regarding age ranges, 50.0% were patients aged between 6 and 11 years (n=16), 40.6% were adolescents (n=13), and 9.4% (n=3) were under 6 years of age.

Regarding the scores of ADHD Rating Scale-IV, 68.7% (n=22) exhibited absence of hyperactivity, while 31.3% (n=10) displayed some traits of hyperactivity. No patient showed marked hyperactivity.

SCORAD was obtained for 19 patients, of whom 7 (36.8%) had severe AD, 7 (36.8%) had moderate AD, and 5 (26.3%) had mild AD. Among patients with severe and moderate AD, 5 (71.4%) scored for absence of hyperactivity in each case. Finally, of those with mild AD, 3 (60.0%) had an absence of hyperactivity and 2 (40.0%) exhibited some traits of hyperactivity.

Conclusion:

Consistent with previous research, AD was slightly more prevalent in males. However, this study found a higher frequency of AD in children aged 6 to 11 years, which contrasts with other reports that usually identify the 2 to 5 year age group as the most affected.

Despite the small sample size and the absence of patients with marked hyperactivity, the study suggests that a significant percentage of individuals present hyperactivity traits. Difficulties in data collection and the study's preliminary condition affected the number of patients assessed with the SCORAD. The severity of AD in our sample differed from previous descriptions, with more moderate and severe cases found. No differences were noted in ADHD symptoms based on AD severity.

The results highlight a comorbidity that affects quality of life and psychosocial development, and emphasizing the need for the application of effective and context-specific assessment tools.

In conclusion, AD impacts beyond the skin, so an interdisciplinary approach is required to identify and treat conditions such as ADHD to mitigate its consequences. As this is a preliminary study, it may not have captured enough ADHD cases, being the first study of its kind in Colombia focused directly on patients with AD.



Abstract N°: 3856

Cardiovascular disease risk among patients with atopic dermatitis: A case-control study

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease with a rising incidence. Systemic inflammation has been associated with an increased risk of cardiovascular disease (CVD). Other dermatological conditions, such as psoriasis and hidradenitis suppurativa, have been linked to a higher CVD risk; however, evidence regarding this association in AD remains controversial. The aim of this study was to assess CVD risk in adults with AD.

Materials & Methods: A cross-sectional study was conducted including adults with AD and healthy controls. Clinical interviews were used to collect sociodemographic data and lifestyle factors (diet, physical activity). Anthropometric parameters (BMI, waist circumference) were measured through physical examination. Hemodynamic parameters (blood pressure (BP), pulse wave velocity (PWV), cardiac output (CU)) were assessed using the IEM Mobil-O-Graph device and I3 software. Analytical parameters (cholesterol, triglycerides, glucose) were analyzed following standard hospital protocols.

Results: A total of 100 participants were included: 50 AD patients (mean age 38.3 ± 15.3 years, 48% (24/50) female) and 50 healthy controls (mean age 38.3 ± 15.2 years, 48% (24/50) female), with no significant differences in sociodemographic characteristics between groups.

Patients with AD had a higher BMI (27.2 ± 5.8 vs. 24.6 ± 2.9, p=0.006) and a larger waist circumference, especially in women (88.6 ± 13.9 vs. 79.3 ± 10.7, p=0.01), with a trend in men (96.1 ± 15.6 vs. 89.4 ± 8.8, p=0.06). AD patients also exhibited poorer lifestyle habits, with lower adherence to the mediterranean diet (7.9 ± 2.0 vs. 10.0 ± 1.4, p<0.001) and higher levels of sedentary behavior (443.2 ± 144.0 vs. 381.6 ± 140.2, p=0.03).

Regarding metabolic and cardiovascular parameters, AD patients showed higher glucose (86.5 ± 18.9 vs. 79.9 ± 8.6, p=0.03) and triglyceride levels (99.1 ± 64.3 vs. 77.7 ± 31.2, p=0.04). They also had higher systolic BP (SBP) (132.3 ± 18.5 vs. 118.6 ± 12.4, p<0.001), diastolic BP (DBP) (81.0 ± 12.3 vs. 72.7 ± 10.1, p=0.004), mean arterial pressure (103.7 ± 14.7 vs. 93.6 ± 9.5, p=0.001), pulse pressure (52.2 ± 14.3 vs. 46.2 ± 12.8, p=0.03), CU (4.8 ± 0.7 vs. 4,52 ± 0.7, p=0.04), central PWV was also higher in AD patients, with a trend approaching statistical significance (6.7 ± 1.7 vs. 6.1 ± 1.5, p=0.08).

Conclusion: Adults with AD might exhibit a higher CVD risk profile, including increased BMI, central adiposity, poorer dietary habits, and greater sedentary behavior. Additionally, they demonstrated elevated glucose, triglycerides, and blood pressure. These findings highlight the importance of cardiovascular risk assessment and lifestyle interventions in AD patients to mitigate potential long-term complications.

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Abstract N°: 3923

Effectiveness and Achievement of Minimal Disease Activity with Upadacitinib in Adults and Adolescents With Atopic Dermatitis: 12-Month Interim Analysis of the Real-World Multicountry AD-VISE Study

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Introduction & Objectives: Upadacitinib (UPA), an oral selective Janus kinase (JAK) inhibitor administered once daily, is approved for the treatment of moderate-to-severe atopic dermatitis (AD) in adolescents and adults. While multiple clinical studies have demonstrated the efficacy and safety of UPA, real-world evidence is needed on the achievement of optimal treatment targets. Here we assess the effectiveness and the achievement of minimal disease activity (MDA)1 in a real-world population of patients with AD and up to a year of exposure to UPA.

Materials & Methods: AD-VISE is an ongoing observational, prospective, multi-country 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 ≥12 months before data cutoff date or had discontinued the study. Outcome measures included validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) 0/1 (primary), Eczema Area and Severity Index (EASI), Worst Pruritus Numeric Rating Scale (WP-NRS), Dermatology Life Quality Index (DLQI), Patient Oriented Eczema Measurement (POEM), and Atopic Dermatitis Control Tool (ADCT), per clinically relevant response thresholds. Achievement of minimal disease activity (MDA)1 was defined as the simultaneous achievement of EASI ≤3 and WP-NRS 0/1. Results are reported using non-responder imputation with multiple imputation.

Results: A total of 856 patients were included in this analysis with 465 patients initially receiving UPA 15 mg and 391 receiving UPA 30 mg. Most patients were adults 91.2% (n=781) and 43.9%(n=376) were female. The most common countries of residence were Canada (26.2%; n=224), Spain (9.9%; n=85), and Greece (8.2%; n=70). The most common reason for initiating UPA 15 mg was in attempt to use the lowest possible effective dose (43.1%; n=160) while patients mostly initiated UPA 30 due to high disease burden-severity of skin (39.1%; n=129). Mean (SD) UPA exposure was 439.9 (±217.61) days and 13.2% (n=113) discontinued the study. Beginning at 2 months, most patients (53.0%) achieved vIGA 0/1, increasing to 54.8% at 12 months. Similarly, many patients achieved EASI 90 (48.4%), EASI ≤3 (58.6%), and WP-NRS 0/1 (39.2%) at 2 months, with similar rates at 12 months 54.5%, 64.2%, and 32.4% for EASI 90, EASI ≤3, and WP-NRS 0/1, respectively **(Figure 1)**. Importantly, MDA (EASI ≤3 + WP-NRS 0/1) was achieved by 31.1% of patients at 2 months and 28.7% at 12 months **(Figure 1)**. Clinically meaningful improvements and minimal disease burden thresholds in other patient-reported outcomes measures (DLQI, POEM, and ADCT) at 2 months reported similar results or slight declines at 12 months (**Table 2**).

Conclusion: Consistent with findings from AD clinical trials, results of this interim real-world analysis suggest that most patients with AD achieved clear/almost clear skin and clinically meaningful itch improvement by 2 months of UPA initiation, with generally similar results after 12 months of treatment. Additionally, about 30% of patients receiving UPA achieved MDA after up to 12 months of treatment.

Table 1. Baseline Demographic and Disease Characteristics by Starting Dose of Upadacitinib

Characteristic	UPA 15 mg (N=465)	UPA 30 mg (N=391)
Age, mean (SD) years	36.9 (18.8)	36.2 (13.4)
<18 years, n (%)	68 (14.6)	7 (1.8)
18 to <65 years, n (%)	348 (74.8)	374 (95.6)
≥65 years, n (%)	49 (10.5)	10 (2.6)
Female, n (%)	217 (46.7)	159 (40.7)
Duration of AD symptoms, years		
Mean (SD)	23.0 (15.3)	26.4 (15.0)
Median (range)	20.0 (2, 74)	26.0 (2, 75)
Disease-related comorbidities, n		
Asthma	116 (24.9)	138 (35.3)
Allergic rhinitis	150 (32.3)	133 (34.0)
Food allergies	41 (8.8)	36 (9.2)
Eosinophilic esophagitis	1 (0.2)	0 (0.0)
AD location, n (%)		
Face	336 (73.4)	268 (69.4)
Neck	337 (73.6)	264 (68.4)
Scalp	195 (42.6)	138 (35.8)
Arm	414 (90.4)	349 (90.4)
Hand	344 (75.1)	256 (66.3)
Leg	403 (88.0)	341 (88.3)
Foot	235 (51.3)	173 (44.8)
Anterior trunk	353 (77.1)	306 (79.3)
Posterior trunk	346 (75.5)	295 (76.4)
Genitalia	104 (22.7)	81 (21.0)
Body surface area, %, mean (SD)	35.52 (23.4)	38.79 (23.5)
Prurigo nodules, n (%)	57 (12.3)	63 (16.1)
Prior dupilumab use, n (%)	81 (17.4)	74 (18.9)
vIGA-AD, n (%)		
Moderate (3)	228 (49.8)	178 (46.0)
Severe (4)	192 (41.9)	189 (48.8)
EASI, mean (SD)	21.81 (11.9)	22.82 (11.7)
WP-NRS, mean (SD)	7.1 (2.30)	7.1 (2.23)
POEM, mean (SD)	17.9 (6.7)	19.0 (6.4)
ADCT, mean (SD)	15.20 (5.8)	15.13 (5.8)
DLQI,[a] mean (SD)	14.2 (7.2)	14.9 (7.1)

Percentages are calculated based on non-missing values.

[a]DLQI was assessed in patients aged ≥16 years.

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; POEM, Patient Oriented Eczema Measurement; UPA, upadacitinib; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numeric Rating Scale.

Table 2. Effectiveness Outcomes at Months 2, 6, and 12 of Treatment with Upadacitinib in Adolescent and Adult Patients With AD

Endpoint, n (%) [95% CI]	N	Any UPA Month 2	Any UPA Month 6	Any UPA Month 12
WP-NRS ≥4-point reduction from baseline[a]	568	380 (66.9) [62.8, 70.9]	357 (62.8) [58.5,	337 (59.4) [55.0,
DLQI[b] 0/1	595	210 (35.4) [31.2, 39.6]	217 (36.4) [32.0,	197 (33.1) [28.8,
DLQI[b] ≥4-point reduction from baseline[a]	550	442 (80.3) [76.6, 84.0]	460 (83.6) [80.0,	436 (79.2) [75.3,
POEM ≤2	625	209 (33.4) [29.6, 37.3]	223 (35.7) [31.5,	163 (26.0) [22.3,
POEM ≥4-point reduction from baseline[a]	610	517 (84.7) [81.7, 87.8]	501 (82.2) [78.8,	464 (76.0) [72.2,
ADCT <7	625	443 (70.8) [67.1, 74.5]	434 (69.4) [65.5,	404 (64.6) [60.4,
ADCT ≥5-point reduction from baseline[c]	590	472 (80.0) [76.5, 83.4]	465 (78.8) [75.2,	437 (74.0) [70.1,

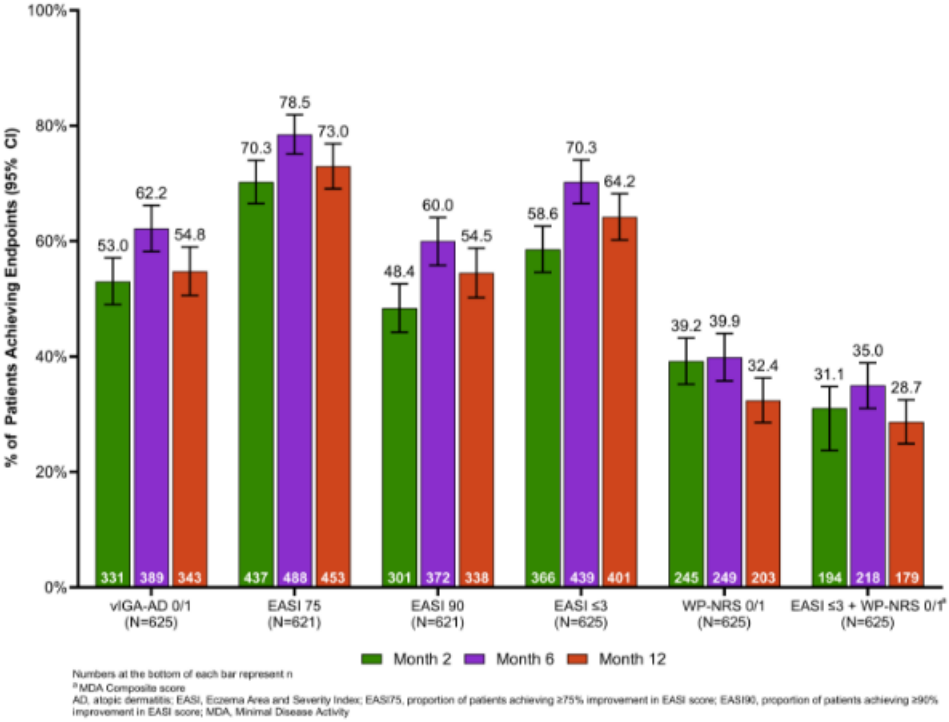
[a]Baseline score ≥4

[b]DLQI was assessed in patients aged ≥16 years

[c]Baseline score ≥5

AD, atopic dermatitis; ADCT, Atopic Dermatitis Control Tool; DLQI, Dermatology Life Quality Index; POEM, Patient Oriented Eczema Measurement; UPA, upadacitinib; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; WP-NRS, Worst Pruritus Numeric Rating Scale

Figure 1. Effectiveness of UPA on Outcomes at Months 2, 6, and 12 of Treatment in Adolescent and Adult Patients With AD



Numbers at the bottom of each bar represent n

[a]MDA Composite score

AD, atopic dermatitis; EASI, Eczema Area and Severity Index; EASI75, proportion of patients achieving ≥75% improvement in EASI score; EASI90, proportion of patients achieving ≥90% improvement in EASI score; MDA, Minimal Disease Activity



Abstract N°: 3961

Real-World Dupilumab Use in Chinese Infants, Children and Adolescents with Atopic Dermatitis: Patient Characteristics and 24-Week Outcomes in the ADOPED-STAD Study

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Introduction & Objectives: Systemic treatment options for paediatric patients with atopic dermatitis (AD), particularly infants, are limited. While topical corticosteroids (TCS) are the primary treatment for these patients, long-term TCS use is associated with adverse effects. Dupilumab is currently approved for moderate-to-severe AD in patients aged ≥6 months in China, where real-world data in paediatric patients remain scarce. The aim of this interim analysis of the ADOPED-STAD study was to evaluate patient profiles in infants, children and adolescents with AD receiving dupilumab, as well as treatment effectiveness and safety outcomes at Week 24 (W24).

Materials & Methods: The ongoing, prospective, observational ADOPED-STAD study is enrolling patients with AD aged ≥6 months to <18 years who were prescribed dupilumab from 15 clinical sites. This analysis included baseline (BL) data collected within 30 days before dupilumab initiation (disease severity, atopic comorbidities, concomitant AD treatment) from patients who were enrolled from 28 Sep 2022 to the data cut-off date (31 Aug 2024). Effectiveness outcomes at W24 included Eczema Area and Severity Index (EASI)-75, absolute changes in body surface area (BSA), pruritus- and sleep disturbance-Numerical Rating Scale (p-NRS and sd-NRS) and Children's Dermatology Life Quality Index (CDLQI). Changes in concomitant AD treatments and safety outcomes were also assessed.

Results: At the data cut-off, 580 patients with AD had been screened, 563 were enrolled (75 [13.3%] aged ≥6 months to <6 years, 366 [65.0%] aged ≥6 to <12 years and 122 [21.7%] aged ≥12 to <18 years). At BL, EASI scores and affected BSA were lower in the ≥6 months to <6 years group than in older patients, but p-NRS, sd-NRS and CDLQI scores were higher (Table 1). The most common atopic comorbidities were food allergy (26.7%) and

allergic rhinitis (25.3%) in patients aged ≥6 months to <6 years, and allergic rhinitis in those aged ≥6 to <12 years or ≥12 to <18 years (52.5% and 73.0%). At W24, the proportion of patients achieving EASI-75 was 75.6% across all patients. Absolute mean reductions from BL to W24 were observed in BSA (−27.5%), p-NRS (−4.5), sd-NRS (−3.8) and CDLQI (−7.0) scores, with similar trends across age groups (Table 2). The proportion of patients receiving TCS and topical antimicrobials was also reduced from BL (69.1% and 31.1%) to W24 (43.9% and 21.0%), with similar reductions observed across all age groups (Table 2). Adverse events (AEs) occurred in 196/563 patients (34.8%); 14 (2.5%) had serious AEs, none of which were considered related to dupilumab.

Conclusion: In this real-world population of patients aged ≥6 months to <18 years with AD receiving dupilumab in China, younger patients had less severe disease, but poorer patient-reported outcomes. Dupilumab was effective across all age subgroups at W24 of treatment and had no new safety concerns. Use of TCS and topical antimicrobials decreased during dupilumab treatment.

Table 1. Patient baseline and disease characteristics overall and by age subgroup

Characteristic	All patients n=563	≥6 months to <6 years n=75	≥6 to <12 years n=366	≥12 to <18 years n=122
Age, years	8.5 ± 3.5	3.1 ± 1.4	7.9 ± 1.7	13.5 ± 1.4
Male sex, n (%)	302 (53.6)	43 (57.3)	192 (52.5)	67 (54.9)
AD duration, median (IQR), months	20.6 (0.7, 51.7)	6.5 (0.1, 21.6)	22.6 (1.0, 54.1)	25.0 (1.1, 96.1)
Other atopic comorbidities,[a] n (%)	413 (73.4)	40 (53.3)	269 (73.5)	104 (85.2)
Common atopic comorbidities,[b] n (%)				
Allergic rhinitis	300 (53.3)	19 (25.3)	192 (52.5)	89 (73.0)
Food allergy	150 (26.6)	20 (26.7)	99 (27.0)	31 (25.4)
Urticaria	60 (10.7)	9 (12.0)	30 (8.2)	21 (17.2)
Conjunctivitis allergic	59 (10.5)	3 (4.0)	38 (10.4)	18 (14.8)
Asthma	45 (8.0)	4 (5.3)	20 (5.5)	21 (17.2)
EASI score	17.7 ± 10.8	12.0 ± 8.0	18.3 ± 10.6	19.5 ± 11.9
BSA, %	35.4 ± 19.4	25.1 ± 15.7	36.8 ± 19.0	37.4 ± 20.5
p-NRS score	7.0 ± 2.1	7.5 ± 1.6	7.0 ± 2.1	6.5 ± 2.3
sd-NRS score	5.5 ± 2.7	6.4 ± 1.9	5.6 ± 2.8	4.7 ± 2.7
CDLQI score[c]	n=506	n=40	n=359	n=107
	12.2 ± 6.2	14.6 ± 6.6	12.2 ± 6.0	11.3 ± 6.2
Concomitant treatment at BL, n (%)				
Topical treatment	431 (76.6)	52 (69.3)	289 (79.0)	90 (73.8)
Corticosteroids	389 (69.1)	48 (64.0)	264 (72.1)	77 (63.1)
Antimicrobials	175 (31.1)	21 (28.0)	118 (32.2)	36 (29.5)
Calcineurin inhibitors	118 (21.0)	17 (22.7)	79 (21.6)	22 (18.0)
PDE-4 inhibitors	105 (18.7)	7 (9.3)	77 (21.0)	21 (17.2)
Other	83 (14.7)	12 (16.0)	52 (14.2)	19 (15.6)
Systemic treatment	218 (38.7)	18 (24.0)	151 (41.3)	49 (40.2)
Antihistamines	211 (37.5)	17 (22.7)	148 (40.4)	46 (37.7)
Corticosteroids	5 (0.9)	2 (2.7)	3 (0.8)	0
Biological therapy	1 (0.2)	0	1 (0.3)	0
JAK inhibitors	1 (0.2)	0	0	1 (0.8)
Other	38 (6.7)	5 (6.7)	22 (6.0)	11 (9.0)

Data are presented as mean ± SD, unless stated otherwise; all data are reported as observed, with missing data excluded.

[a]At least one other atopic comorbidity.

[b]Other atopic comorbidities occurring in ≥ 10% of patients in any age group.

[c]Assessed in patients aged ≥ 4 to <16 years.

AD, atopic dermatitis; BL, baseline; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; JAK, Janus kinase; IQR, interquartile range; PDE-4, phosphodiesterase-4; p-NRS, pruritus-Numerical Rating Scale; SD, standard deviation; sd-NRS, sleep disturbance-Numerical Rating Scale; W, week.

Table 2. Week 24 outcomes overall and by age subgroup

Outcome	All patients	≥6 months to <6 years	≥6 to <12 years	≥ 12 to <18 years
EASI-75, n (%)	n=308	n=20	n=225	n=63
	233 (75.6)	14 (70.0)	172 (76.4)	47 (74.6)
Change from BL in BSA, %	n=308	n=20	n=225	n=63
	−27.5 ± 18.1	−12.2 ± 10.4	−28.3 ± 18.0	−29.5 ± 18.3
Change from BL in p-NRS score	n=343	n=44	n=231	n=68
	−4.5 ± 2.9	−4.4 ± 2.7	−4.7 ± 2.8	−3.9 ± 3.2
Change from BL in sd-NRS score	n=347	n=45	n=233	n=69
	−3.8 ± 3.0	−3.8 ± 2.6	−4.0 ± 3.0	−2.9 ± 2.9
Change from BL in CDLQI score[a]	n=283	n=21	n=214	n=48
	−7.0 ± 6.3	−8.2 ± 6.2	−7.3 ± 6.4	−5.5 ± 5.7
Concomitant treatment at W24, n (%)	n=563	n=75	n=366	n=122
Topical treatment	275 (48.8)	15 (20.0)	203 (55.5)	57 (46.7)
Corticosteroids	247 (43.9)	14 (18.7)	183 (50.0)	50 (41.0)
Antimicrobials	118 (21.0)	4 (5.3)	91 (24.9)	23 (18.9)
Calcineurin inhibitors	98 (17.4)	8 (10.7)	71 (19.4)	19 (15.6)
PDE-4 inhibitors	111 (19.7)	4 (5.3)	90 (24.6)	17 (13.9)
Other	56 (9.9)	1 (1.3)	40 (10.9)	15 (12.3)
Systemic treatment	144 (25.6)	7 (9.3)	108 (29.5)	29 (23.8)
Antihistamines	136 (24.2)	7 (9.3)	102 (27.9)	27 (22.1)
Corticosteroids	2 (0.4)	0	2 (0.5)	0
Biological therapy	1 (0.2)	0	1 (0.3)	0
JAK inhibitors	4 (0.7)	0	2 (0.5)	2 (1.6)
Other	29 (5.2)	3 (4.0)	18 (4.9)	8 (6.6)

Data are presented as mean ± SD, unless stated otherwise; all data are reported as observed, with missing data excluded.

[a]Assessed in patients aged ≥ 4 to <16 years.

BL, baseline; BSA, body surface area; CDLQI, Children's Dermatology Life Quality Index; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; JAK, Janus kinase; PDE-4, phosphodiesterase-4; p-NRS, pruritus-Numerical Rating Scale; sd-NRS, sleep disturbance-Numerical Rating Scale; W, week.



Abstract N°: 4007

A Multicenter, Randomized, Double-Blind, Placebo-Controlled Phase 2b Part 1 Study of a Topical GPCR19 Agonist in Patients with Mild-to-Moderate Atopic Dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disorder characterized by eczematous lesions and intense pruritus. Despite available therapies, there remains an unmet need for safe and effective topical treatments. The NLRP3 inflammasome has been identified as a key driver of inflammation in AD. Taurodeoxycholate (TDCA), a selective agonist of G protein–coupled receptor 19 (GPCR19), has demonstrated anti-inflammatory effects in preclinical AD models by inhibiting both the priming (cAMP–PKA–NF-κB) and activation (P2X7R–NLRP3) phases of inflammasome signaling. These effects were abolished in GPCR19-KO mice, underscoring the essential role of GPCR19 in mediating TDCA's mechanism of action. Based on these findings, we conducted a multicenter, randomized, double-blind, placebo-controlled Phase 2b trial to assess the clinical potential of NuGel, a topical TDCA formulation, in patients with mild-to-moderate AD. This report presents findings from Part 1, a dose-escalation cohort (n = 33) designed to evaluate the safety, tolerability, and preliminary efficacy of NuGel and to inform dose selection for Part 2.

Materials & Methods:

33 adult patients with mild-to-moderate AD were randomized to receive one of four NuGel concentrations (0.5%, 1%, 2%, or 4%) or placebo, applied topically twice daily for 8 weeks. Efficacy was assessed at baseline and Weeks 2, 4, and 8 using the Eczema Area and Severity Index (EASI), Investigator's Global Assessment (IGA), pruritus Numeric Rating Scale (NRS), Dermatology Life Quality Index (DLQI), and Patient-Oriented Eczema Measure (POEM). Safety assessments included treatment-emergent adverse events (TEAEs), adverse drug reactions (ADRs), serious adverse events (SAEs), serious ADRs (SADRs), and TEAEs leading to treatment discontinuation, study withdrawal, or death.

Results:

NuGel demonstrated robust clinical responses by Week 8, with EASI score reductions of –78.6%, –73.6%, and –70.4% in the 0.5%, 1%, and 2% groups, respectively, compared with –42.5% in the placebo group and –12.8% in the 4% group. In line with these results, EASI-50 was achieved in 80%, 100%, and 83.3% of patients in the 0.5%, 1%, and 2% groups, respectively, compared with 44% in the placebo group and 25% in the 4% group. IGA-TS was achieved by 50% of patients in the 2% group, 33.3% in the 1% group, 20% in the 0.5% group, 11.1% in the placebo group, and none in the 4% group.

Patient-reported outcomes, including itch NRS, DLQI, and POEM, improved across all groups except 4%. The 1% and 2% NuGel groups demonstrated the greatest reduction in pruritus and the most notable shifts toward

improved quality of life and milder symptom categories by Week 8.

No major safety concerns were identified during the 8-week treatment period. ADRs occurred in two placebo patients and in one patient each in the 0.5%, 1%, and 4% groups. No SAEs, SADRs, or treatment discontinuations were reported.

Conclusion:

In this Phase 2b Part 1 study, NuGel was well tolerated and demonstrated consistent improvements across multiple clinician- and patient-reported outcomes in adults with mild-to-moderate AD. Notably, dose-dependent improvements were observed in IGA-TS, a primary endpoint commonly used in Phase 3 trials, supporting the potential for future clinical success. These findings highlight the clinical potential of NuGel and support the selection of the 1% and 2% concentrations for further evaluation in the ongoing Phase 2b Part 2 expansion cohort.

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Abstract N°: 4050

Real-World Outcomes of Treat-to-Target (T2T) Strategy in Atopic Dermatitis Management

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Introduction & Objectives:

The treat-to-target (T2T) approach has been widely implemented in the management of chronic diseases. Atopic dermatitis (AD) is characterized by chronic inflammation of the skin, T2T consensus and shared decision-making Combining treat-to-target principles has been proposed by international experts. However, there is lack of study to compare the real-world data with the proposed consensus. By utilizing real-world data, our objective was to compare the proportion of patients achieving goals according to the consensuses to provide the evident based insights of the real-world effectiveness of the T2T consensus.

Materials & Methods:

We systematically collected data from atopic dermatitis (AD) patients attending outpatient clinics in our department. Treatment regimens were determined by dermatologists in accordance with established guidelines and the treat-to-target (T2T) approach. Baseline assessments and follow-ups at 2, 4, 8, and 16 weeks included the Patient Global Impression of Severity 5-point scale (PGIS-5), SCORing Atopic Dermatitis (SCORAD), weekly average of peak daily pruritus numerical rating scale (PP-NRS), Patient-Oriented Eczema Measure (POEM), and Dermatology Life Quality Index (DLQI). Treatment targets were categorized as acceptable or optimal. Acceptable targets included PGIS-5 reduction ≥1, EASI 50, SCORAD 50, pp.NRS reduction ≥3, DLQI reduction ≥4, and POEM reduction ≥4. Optimal targets were defined as PGIS-5 ≤2, EASI 75, EASI ≤7, EASI 75 or ≤7, SCORAD 75, SCORAD ≤24, SCORAD 75 or ≤24, pp.NRS ≤4, DLQI ≤5, and POEM ≤7.

Results:

A total of 61 patients were enrolled. Along the time, at 2, 4, 8, and 16 weeks respectively, the proportion of patients achieving PGIS-5 reduction ≥1 was 55.74%, 80.33%, 85.25%, and 93.55%. EASI 50 was reached by 24.59%, 32.79%, 60.66%, and 80.65%, and SCORAD 50 by 26.23%, 37.70%, 62.30%, and 80.65%. pp.NRS reduction ≥3 was observed in 42.62%, 50.82%, 65.57%, and 96.77%, DLQI reduction ≥4 in 29.51%, 50.82%, 59.02%, and 77.42%, and POEM reduction ≥4 in 54.10%, 75.41%, 83.61%, and 87.10%. For optimal targets, PGIS-5 ≤2 was achieved by 52.46%, 86.89%, 91.80%, and 87.10%; EASI 75 by 13.11%, 19.67%, 36.07%, and 70.97%; EASI ≤7 by 57.38%, 73.77%, 80.33%, and 93.55%. SCORAD 75 was met by 13.11%, 19.67%, 34.43%, and 70.97%, and SCORAD ≤24 by 26.23%, 40.98%, 65.57%, and 74.19%. pp.NRS ≤4 was achieved by 57.38%, 67.21%, 81.97%, and 90.32%; DLQI ≤5 by 26.23%, 32.79%, 59.02%, and 80.65%; and POEM ≤7 by 24.59%, 27.87%, 55.74%, and 87.10%.

Conclusion:

This study elucidates a real-world implementation of the treat-to-target (T2T) approach and lays the groundwork for refining the T2T framework.



Abstract N°: 4057

Prediction of dupilumab-associated ocular surface disease in atopic dermatitis: a model for clinical practice

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Introduction & Objectives:

Dupilumab-associated ocular surface disease (DAOSD) is a frequently reported side effect in dupilumab-treated atopic dermatitis (AD) patients. As the number of treatment options for moderate-to-severe AD increases, early identification of patients at high risk for DAOSD could support clinical decision-making. This study aims to develop a clinical prediction model based on a prospective real-world cohort to assess the risk of DAOSD in dupilumab-treated patients with moderate-to-severe AD.

Materials & Methods:

This prospective study included moderate-to-severe AD patients between February 2020 and January 2025. Patients were examined by an ophthalmologist and a dermatologist before and during dupilumab treatment (at baseline, week 4, and week 28). Additional ophthalmological examinations were performed if indicated. DAOSD was assessed by using the Utrecht Ophthalmic Inflammatory and Allergic disease (UTOPIA) score, and was defined as an increase of ≥ 3 points in UTOPIA score from baseline. Potential predictive factors were selected based on previous literature, such as baseline AD severity, eyelid eczema, and seasonal allergic conjunctivitis. Logistic regression with Firth's correction was used to identify predictive factors for the development of DAOSD. C-statistics were used for the initial evaluation of the prediction model.

Results:

A total of 150 patients (median age 40.1 years [IQR 27.3-52.9], 52.7% male) with a median baseline Eczema Area and Severity Index of 13.9 (IQR 9.8-20.9) were included. Eyelid eczema was reported in 68.0% (102/150) of patients in the past year. Self-reported seasonal allergic conjunctivitis was present in 75.3% (113/150) of patients, and a history of non-allergic ocular disease was reported in 9.3% (14/150) of patients. At baseline, 60.0% (90/150) of patients reported ocular symptoms. Ophthalmologically confirmed DAOSD was identified in 32.7% (49/150) of patients. The c-statistic of the initial model was 0.68, indicating moderate discriminative ability. Further results of the clinical prediction model, including patient characteristics, dermatological characteristics, ophthalmological history, and ocular symptoms, are currently pending.

Conclusion:

DAOSD was identified in 32.7% of the dupilumab-treated AD patients. The initial prediction model demonstrated a moderate ability to discriminate between patients who will and will not develop DAOSD. As the model includes only clinical predictors, it is highly applicable in dermatological practice to identify patients at risk of DAOSD. The prediction model could support decision-making between different therapies and enable timely referral to an ophthalmologist. The clinical prediction model is currently being further developed, final results will follow.



Abstract N°: 4087

Activation of LIGHT/HVEM Signaling in CD4+ T cells Redounds to Aggregation of Atopic Dermatitis

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease with CD4+ T cells. LIGHT-HVEM pathway signaling has been identified as a costimulatory signal for T cells, yet if the LIGHT signaling of CD4+ T cells contributes to AD is still unknown. The aim is to identify the correlation and mechanism of LIGHT-HVEM pathway in AD.

Materials & Methods: To elucidate the underlying mechanisms that how the LIGHT signaling contributes to AD. We analyzed to identify the expression of LIGHT and HVEM in AD lesions by the spatial and single-cell transcriptomics data and immunofluorescence microscopy. The severity of lesions and subtypes of CD4+ T cells were analyzed to explore the effects of activating and inhibiting LIGHT/HVEM signaling on AD using exogenous LIGHT, HVEM antibody and CD4+ T cells-specific HVEM-deficient mice. The levels of T cells to proliferate, differentiate, and secrete cytokines in vitro were measured by flow cytometry to explore the regulatory effects of LIGHT/HVEM on CD4+ T cells.

Results: We showed that LIGHT/HVEM was markedly expressed in CD4+ T cells in AD patients than healthy control. LIGHT/HVEM activation aggravated MC903-induced AD-like dermatitis and enhanced Th2-mediated immune response. CD4+ T cells-specific HVEM-deficient didn't alleviate the overall severity of AD but hinder the Th2 expansion in AD. LIGHT/HVEM promoted the proliferation, differentiation and cytokine production of CD4+ T cells but has no effects on directing the polarization of CD4+ T cells in vitro.

Conclusion: Our study revealed that LIGHT/HVEM signaling in CD4+ T cells could exacerbate AD by promoting the proliferation, differentiation and cytokine production of Th2 cells and thus enhancing type 2 immune response. It may a potential target for the therapy of AD.



Abstract N°: 4090

Herpes Zoster Occurrence in Atopic Dermatitis Patients Treated with JAK Inhibitors – A Systematic Review

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Introduction & Objectives

Atopic dermatitis (AD) is a chronic inflammatory skin disorder that significantly diminishes quality of life. In recent years, Janus kinase (JAK) inhibitors have emerged as a novel and effective treatment option for moderate-to-severe AD, offering rapid symptom relief and the convenience of oral administration. Despite their promising efficacy, concerns have been raised regarding the safety profile of these agents, particularly in relation to viral reactivation. Among the most commonly reported infectious complications in clinical trials is herpes zoster (HZ), caused by the reactivation of latent varicella zoster virus (VZV). This review aims to evaluate current evidence on the association between the use of JAK inhibitors in AD and the risk of herpes zoster development.

Materials & Methods

A systematic search of the PubMed database was conducted to explore the relationship between JAK inhibitors and herpes zoster in the treatment of atopic dermatitis. The search spanned from the inception of the database until March 2025, adhering to PRISMA guidelines and utilizing EMTREE and MeSH strategies. Eight key studies published between 2021 and 2025 were identified and included in the analysis.

Results

The analyzed literature indicates a moderately elevated risk of herpes zoster among AD patients treated with JAK inhibitors compared to those receiving placebo or other systemic therapies. The incidence of HZ varied based on factors such as the specific JAK inhibitor used, treatment duration, patient age, and presence of comorbidities. While most reported cases of HZ were mild to moderate and resolved with antiviral therapy, some instances necessitated temporary discontinuation of JAK inhibitor therapy. Proposed mechanisms for viral reactivation include the suppression of interferon signaling pathways and natural killer (NK) cell function, both of which are critical for maintaining control over latent viral infections.

Conclusion:

JAK inhibitors represent a significant advancement in the treatment of atopic dermatitis. However, clinicians should remain vigilant regarding the potential for herpes zoster reactivation. Risk mitigation strategies, such as pre-treatment screening, patient education, and consideration of varicella zoster vaccination—particularly for older adults and immunocompromised individuals—may enhance the overall safety of these therapies. Continued pharmacovigilance and real-world evidence are essential to further clarify the risk profile and optimize clinical outcomes for patients receiving JAK inhibitors.



Abstract N°: 4108

A Pilot Study to Establish an Ovalbumin-induced Atopic Dermatitis Chronic Recurrence Mouse Model

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Introduction & Objectives: Atopic dermatitis (AD) is a common, chronic and relapsing inflammatory skin disease. To date, the mechanisms of chronic recurrence in AD are less understood. We aimed to establish an animal model to demonstrate AD recurrent inflammatory process effectively.

Materials & Methods: Here, six-week-old female C57 mice were randomly divided into five groups (control group, acute group, regression group, relapse group and restimulation group; n = 6) and underwent induction of AD-like dermatitis by Epicutaneous (EC) sensitized ovalbumin (OVA) after repeated tape-stripping. Gross phenotype, histopathological manifestations, serum total immunoglobulin E (IgE) level and skin lesion resident memory T cell (TRM) subsets infiltration were performed and analyzed.

Results: The results showed that the OVA-induced AD-like lesions in the relapse group and restimulation group exhibited highest disease severity, epidermal thickness and serum IgE. Furthermore, we found the predominance of CD4+TRM cells in the basal layer of the epidermis and the follicular root sheaths of AD lesions, with CD4+TRM expansion upon OVA re-exposure.

Conclusion: Collectively, our data demonstrate that this chronic relapsing AD mouse model renders it very attractive to study AD pathogenesis and sustained immunologic abnormalities involved in AD development, maintenance and recurrence. Furthermore, this model might be useful for preclinical studies aiming at unraveling new therapeutic strategies to treat AD.



Abstract N°: 4130

Baseline Demographics, Disease Severity, Treatment Patterns and Effectiveness in Moderate-to-Severe Atopic Dermatitis Patients Grouped by Systemic Treatment Initiation: An Analysis of the ChinaSTAD Registry Study

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Introduction & Objectives:

Atopic dermatitis (AD) is the most common chronic type 2 inflammatory skin disease, with a lifetime prevalence of up to 20% and significant quality-of-life impact. This subgroup analysis, based on the ongoing ChinaSTAD Registry Study (NCT05023668), a prospective observational study, focused on describing baseline disease severity and quality of life, healthcare economic burden and treatment patterns in moderate-to-severe AD patients and the effectiveness in systemic treatment patients.

Materials & Methods:

Patients aged ≥12 years with moderate-to-severe AD (SCORing AD [SCORAD] ≥25, Investigator Global Assessment ≥3, or Eczema Area and Severity Index ≥24) not controlled by topical therapy were included. In this analysis, patients who were on systemic therapy at baseline were excluded, defined as systemic corticosteroids, biologics, immunosuppressants, and JAK inhibitors. Disease severity and patient-reported outcomes were assessed at baseline using SCORAD, Peak Pruritus Numerical Rating Scale (PP-NRS), Patient-Oriented Eczema Measure (POEM), Dermatitis Life Quality Index (DLQI) or children's DLQI (cDLQI), and Atopic Dermatitis Control Test (ADCT). Patients who initiated systemic therapy at baseline were grouped as systemic group (SG), others as non-systemic group (NSG). Descriptive statistics are used to summarize baseline values.

Results:

A total of 7,490 patients were enrolled across 84 sites from July 2021 to June 2023, with 6,392 patients without systemic therapy history included in this analysis (1,930 in SG and 4,442 in NSG). The mean (SD) age was 45.6 (21.4) years in SG and 41.3 (20.1) years in NSG, with males accounting for 58.4% and 56.1%, respectively (Table 1).

At baseline, the mean SCORAD score for assessing AD severity was 55.7 (16.3) in the SG and 52.8 (16.1) in the NSG. The PP-NRS scores were 7.3 (2.2) and 6.9 (2.3), respectively (Table 2). Additionally, 90.9% of patients in the SG and 88.0% in the NSG had an ADCT score ≥7. All the scores gradually declined during the 4-month follow-up of the SG cohort. For disease-related healthcare economic burden, the average cost per outpatient visits the year before enrollment (CNY) was numerically higher in SG 987.5 (1,906.9) vs NSG 495.3 (1,031.5). In the SG, 49.3% of patients treated with topical corticosteroids, and 43.4% with antihistamines. In the NSG, the most treatments were topical corticosteroids (62.1%) and antihistamines (62.6%) (Table 1). In systemic therapy initiated at baseline, the most common was dupilumab (69.8%), JAK inhibitor (15.1%) (Table 3).

Conclusion:

This analysis of ChinaSTAD demonstrated that the disease burden in both groups was high, with a substantial proportion of patients still experiencing poor disease control and non-systemic treated patients still mainly used topical corticosteroids and antihistamines. Among patients on systemic therapy at baseline, dupilumab was the most commonly used systemic treatment in real-life clinical practice.

Table 1. Baseline Demographics, Economic Burden and Treatment Patterns at Systemic Group and Non-Systemic Group.

Baseline Characteristics	Systemic Group	Non-Systemic Group
Demographic characteristics	n=1930	n=4442
Age (years), Mean(SD)	45.6(21.4)	41.3(20.1)
Gender, n(%)		
Male	1127(58.4%)	2493(56.1%)
Female	803(41.6%)	1949(43.9%)
BMI (kg/m^2), Mean(SD)	22.9(3.4)	22.9(3.5)
Ethnicity, n(%)		
Han	1870(96.9%)	4291(96.6%)
Others	60(3.1%)	151(3.4%)
Place of residence, n(%)		
Urban	1749(90.6%)	3934(88.6%)
Rural	181(9.4%)	508(11.4%)
Diagnostic criteria, n(%)	n=1930	n=4442
Zhang's criteria	1548(80.2%)	3119(70.2%)
Williams criteria	382(19.8%)	1323(29.8%)
Disease-related healthcare economic burden in the previous year, Mean (SD)	n=1925	n=4383
Average cost per hospitalization (CNY)	559.5(2225.5)	679.7(2962.1)
Average cost per outpatient visit (CNY)	987.5(1906.9)	495.3(1031.5)
Other AD-related expenses (e.g., skincare products, etc.) (CNY)	522.6(4830.2)	427.6(1989.5)
Number of days missed from school or work due to atopic dermatitis (days)	1.6(8.3)	1.6(9.9)
Baseline Medication, n(%)	n=1930	n=4137
Topical therapy		
Moisturising emollients	479(24.8%)	1406(31.7%)
Anti-inflammatory agents		
topical corticosteroids	951(49.3%)	2760(62.1%)
topical calcineurin inhibitors	231(12.0%)	711(16.0%)
Ultraviolet phototherapy	9(0.5%)	37(0.8%)
Traditional Chinese medicine		
Tripterygium wilfordii	48(2.5%)	132(3.0%)
Others	220(11.4%)	876(19.7%)
Other therapies		
Antihistamines	837(43.4%)	2779(62.6%)
Glycyrrhizin compound	134(6.9%)	606(13.6%)
Topical antimicrobials	89(4.6%)	276(6.2%)
Systemic anti-infective drugs	42(2.2%)	120(2.7%)
Zinc oxide preparations	11(0.6%)	70(1.6%)
Sodium thiosulfate	5(0.3%)	55(1.2%)
Others	277(14.4%)	861(19.4%)

Table 2. Baseline Disease Severity and Quality of Life at Systemic Group and Non-Systemic Group.

Scales	Systemic Group		Non-Systemic Group	
	n	Mean (SD)/ n(%)	n	Mean (SD)/ n(%)
SCORAD	1930	55.7(16.3)	4442	52.8(16.1)
PP-NRS	1930	7.3(2.2)	4442	6.9(2.3)
POEM	1930	16.5(6.9)	4442	15.8(6.8)
DLQI	1800	11.6(7.0)	4098	11.2(6.9)
cDLQI	130	12.2(6.6)	344	9.6(6.0)
ADCT				
≥7 points	1755	90.9%	3910	88.0%
<7 points	175	9.1%	532	12.0%

Score range: SCORAD, 0 to 103; PP-NRS, 0 to 10; POEM, 0 to 28; DLQI and cDLQI, 0 to 30; ADCT, 0 to 24.

Table 3, Systemic Treatment Patterns Initiated at Baseline (n=1930).

Systemic Treatment	Systemic Group, n (%)
Dupilumab	1348(69.8%)
Janus kinase inhibitors	292(15.1%)
Systemic corticosteroids	136(7.0%)
Cyclosporine	19(1.0%)
Methotrexate	10(0.5%)
Omalizumab	5(0.3%)
Mycophenolate mofetil	1(0.1%)

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Abstract N°: 4157

Effect of tralokinumab on QoL in atopic patients with head and neck involvement

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Introduction & Objectives:

AD (atopic dermatitis) is a chronic inflammatory skin disease that can affect multiple body areas, with H&N (head and neck) AD having been observed in up to 72% of patients with moderate-to-severe AD in real-world populations. Due in part to its high visibility, patients with H&N AD greatly value treatments that provide complete/almost complete skin clearance. H&N AD is incredibly challenging to treat compared with AD involvement in other body regions, and notably one recent real-world study observed that 68% of patients still displayed H&N AD after 2 years of treatment with dupilumab. Tralokinumab is a high-affinity monoclonal antibody that targets explicitly IL-13 and is approved for the treatment of moderate-to-severe AD. So far, data reporting on the effectiveness of anti-IL on different body site involvement are scant. The different distribution can impact the perception of the body and affect daily social life. We aim to describe the effectiveness of tralokinumab in the H&N region.

Materials & Methods:

This is a prospective, non-interventional study on patients receiving tralokinumab. The objective was to evaluate effectiveness on H&N involvement in patients with AD in a real-world clinical practice setting. Patients were followed until week 52. Primary and secondary endpoints were assessed at W0, and then W16, 32, and 52. The primary endpoint was **H&N EASI (eczema area severity index)** reduction from baseline to week 16 (reaching EASI75). Secondary endpoints include Dermatology Life Quality index analysis, total EASI reduction analysis, the correlation between DLQI values and H&N EASI values, NRSp (numerical rating scale pruritus) trend, and reduction of at least 4 points of NRSp, change of World Health Organization Quality of Life brief version questionnaire, Anxiety Brief Symptom Inventory – 18, and Depression Patient Health Questionnaire-9 from baseline to W16, 32, and 52.

Results:

Of 100 AD patients, 89.9% showed H&N involvement. Total EASI fell from 24.3 at baseline to 5.1 at one year of treatment, similarly, H&N EASI fell from 2.44 to 1.21. At 16 weeks 20.3% of patients reached EASI 75, H&N EASI75 was reached by 55.1% of patients, and progressive improvement was observed at the following time points. DLQI dropped from 12 to 6.6 at the same time points, NRSp from 8.3 to 3.8. Two-thirds of patients experienced a reduction of at least 4 points in NRSp after 52W of treatment. Impact on QoL was higher for H&N patients with higher DLQI values at every time point, with significant differences in the comparison of the absence of H&N involvement at 16W (7.1 vs 2.3 $p=0.041$). Mean H&N values strength correlates with mean DLQI values with a significant correlation with Pearson correlation's test ($p<0.05$) at each time point. Progressive reductions were shown by the BSI-18 test and PhQ9 test with values ranging from 6 to 3, and 6.3 to 0, respectively, at baseline and one year of treatment. Progressive improvement in two domains of WHOQoL-BREF was observed during the observation (physical health, and psychological health), with stable results for social relationships and environment domains.

Conclusion:

Tralokinumab showed effectiveness in the reduction of H&N and Total EASI at 52W, and in the QoL improvement in the domain of depression and anxiety. Higher proportion of patients achieved H/N EASI75 as compared to Total EASI75 at W16. The involvement of the Head and Neck correlates with higher QoL impact according to DLQI.

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Abstract N°: 4185

Upadacitinib in daily practice for the treatment of atopic dermatitis in adolescents: a case series from the BioDay registry

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Introduction & Objectives:

Upadacitinib has been approved for the treatment of moderate-to-severe atopic dermatitis (AD) in both adult and adolescent patients. Effectiveness and safety are demonstrated in clinical trials. However, data on the effectiveness and safety of upadacitinib in adolescent patients with AD in daily practice is limited. Therefore, we prospectively evaluated the effectiveness and safety of upadacitinib in daily practice in adolescents with moderate-to-severe AD.

Materials & Methods:

Adolescent AD patients from the BioDay registry who were treated with upadacitinib 15mg once daily between November 2021 and February 2025 were evaluated at the start of upadacitinib treatment (baseline) and after 4, 8, 16, and 28 weeks of treatment. Effectiveness was assessed by using the Eczema Area and Severity Index (EASI) and the Investigator Global Assessment (IGA). Patient-reported outcome measures (PROMs) included the Numeric Rating Scale (NRS) of the average weekly pruritus and the presence of sleep disturbance. Adverse events (AE)s were evaluated at each visit.

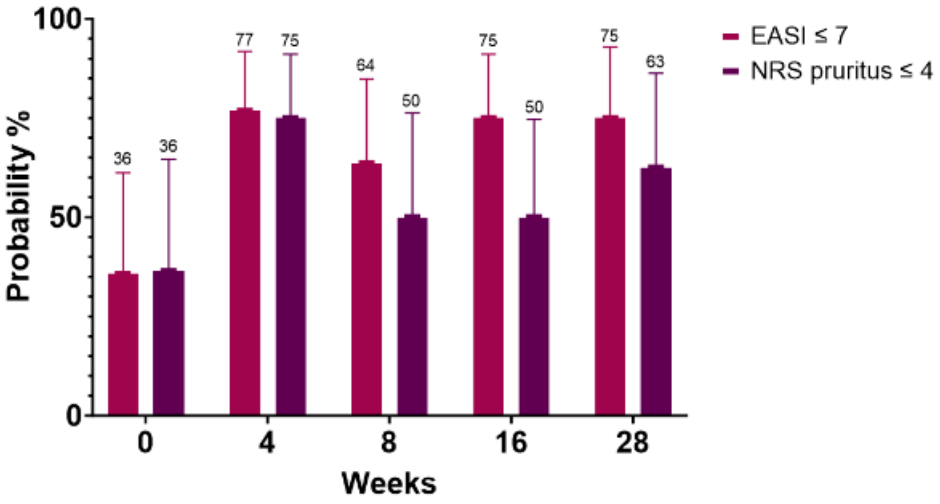
Results:

A total of 15 adolescent AD patients were included, of whom 73.3% had previously used dupilumab and 53.3% conventional immunosuppressive therapy. The mean EASI score significantly decreased from 13.4 (95% CI 8.5 – 18.3) to 7.8 (95% CI 2.4 – 13.3) after 28 weeks (P=.002). Similarly, the mean NRS pruritus significantly decreased from 6.5 (95% CI 4.9 – 8.2) to 4.8 (95% CI 3.0 – 6.6) after 28 weeks of treatment (P=.003). At week 16, the probability of achieving EASI ≤7 and NRS pruritus ≤4 was 75.0% (95% CI 46.8 – 91.1) and 50.0% (95% CI 25.4 – 74.6), respectively. In total, 31 AEs were reported in 10 patients (66.7%), with the most frequent being skin infections (19.4%), acne (9.7%) and headache (9.7%). Five patients (33.3%) discontinued treatment: 2 (13.3%) due to ineffectiveness, 2 (13.3%) due to side effects, and 1 (6.7%) due to needle phobia, making laboratory monitoring impossible.

Conclusion:

Upadacitinib is an effective and relatively safe treatment for moderate-to-severe AD in adolescents. However, 33.3% discontinued treatment due to ineffectiveness, side effects or laboratory monitoring problems. Future studies are needed to confirm the effectiveness and safety of upadacitinib in adolescents in a daily practice setting.

Figure 1. Secondary effectiveness outcomes of 28-weeks upadacitinib treatment. Probability % of achieving EASI ≤7 or NRS pruritus ≤4. EASI: Eczema Area and Severity Index; NRS: Numeric Rating Scale


100
50
0
Probability %
36
36
77
75
64
50
75
50
75
63
0
4
8
16
28
Weeks
EASI ≤ 7
NRS pruritus ≤ 4



Abstract N°: 4207

Efficacy and Drug Survival of Tralokinumab in Severe Atopic Dermatitis: A Two-Year Multicenter Study

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Introduction & Objectives:

Tralokinumab, an anti-interleukin-13 monoclonal antibody, has demonstrated efficacy in the treatment of atopic dermatitis (AD) in both clinical trials and real-world settings. However, limited data exist on the long-term use of tralokinumab in real-world settings.

A multicentric Italian study, evaluating tralokinumab's drug survival (DS) and efficacy up to 24 months of treatment among 471 patients with severe AD was conducted.

Materials & Methods:

The study enrolled 471 patients with severe AD receiving tralokinumab across fifteen tertiary centers in Italy. Clinical scores such as Eczema area and Severity Index (EASI) and Pruritus Numerical Rating Scale (P-NRS) were recorded. Drug survival (DS) was analyzed using unadjusted Kaplan-Meier survival curves to estimate the risk and time to discontinuation, while log-rank test was applied to assessed differences in drug survival across baseline clinical characteristic.

Results:

The entire study population consisted of 471 patients. Patients naïve to biologics or JAK-inhibitors (Group A) accounted for 355, while 116 patients (Group B) had been previously treated with these treatments. At the data lock, 373 were still undergoing treatment, 15 were lost to follow-up, and 83 discontinued tralokinumab. The reasons for discontinuation included adverse events (AEs) in 12 patients, inefficacy in 59, and other reasons in 12. Overall DS rates were 81.5% and 70.5% at 12 and 24 months respectively. When considering discontinuation due to inefficacy, although not statistically significant, a difference was observed between group A and B. Statistically significant differences between the two groups were observed at month (T) 4 ($p=0.028$), T8 ($p=0.028$), T10 ($p=0.005$) and T12 ($p=0.007$), with Group B showing slower clinical improvement. Similar trends were seen for the endpoint EASI-50/EASI-75/EASI-90/EASI-100 at T4 ($p=0.019$, $\chi^2=0.152$) and T10 ($p=0.017$, $\chi^2=10.096$).

Conclusion:

Tralokinumab showed a good drug retention rate and a significant clinical improvement, with patients with a history of previous use of dupilumab or JAK-inhibitors showing a slower improvement.

This is an encore



Abstract N°: 4215

Successful tapering of dupilumab in pediatric patients with atopic dermatitis: daily practice results from the BioDay registry

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Introduction & Objectives:

Dupilumab is approved for the treatment of moderate-to-severe atopic dermatitis (AD) in children aged ≥6 months and has been shown to be a safe and effective treatment option in both clinical trials and daily practice studies. In adult patients, it was previously shown that dupilumab could be successfully tapered while maintaining disease control. However, there is a lack of data on tapering of dupilumab in the pediatric population. Therefore, this study aims to evaluate the successful tapering of dupilumab in a pediatric population in daily practice.

Materials & Methods:

This prospective multicenter study included pediatric patients (<18 years), participating in the BioDay Registry, who were treated with dupilumab between April 2018 and February 2025. Tapering was defined as interval prolongation of dupilumab standard label dose, according to age and weight, in case of ≥52 weeks persistent controlled AD [Eczema Area and Severity Index (EASI) ≤7 for ≥6 months]. The percentage of (successful) tapering over time and the mean EASI and Numeric Rating Scale (NRS) pruritus over time after initiating tapering were assessed.

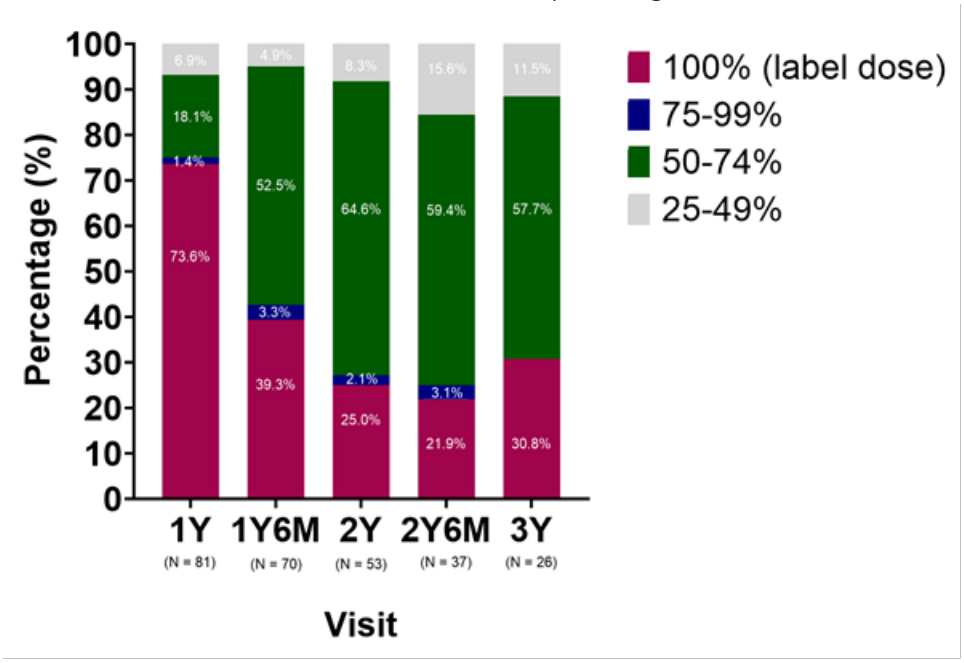
Results:

A total of 316 pediatric patients were included, of whom 183 were eligible for tapering. The mean age was 11.6 (standard deviation (SD) ±4.4) years and 53.3% were male. A total of 81 patients prolonged their dupilumab interval [mean EASI 1.6 (95% CI 1.2-2.0); NRS pruritus 2.5 (95% CI 2.1-2.9); at tapering baseline], of which 91.4% was successful. Reasons for tapering were controlled disease only (79.0%), controlled disease with administration problems (12.4%), and controlled disease with side effects (8.6%). More than half of the patients (57.7%) who initiated tapering remained on a dose of 50-74% of the label dose after 3 years of dupilumab treatment. After initiating tapering, the EASI score and NRS itch remained low, with the highest estimated mean values being 3.8 (95% CI 3.2-4.3) and 4.0 (95% CI 3.5-4.5), respectively, after 24 months of tapering.

Conclusion:

This study shows that dupilumab could be successfully tapered in 91.4% of pediatric patients with AD who attempted tapering, while maintaining disease control. The majority of the patients who initiated tapering remained on a dose of 50-74% of the label dose.

Figure 1. Overview of monthly dupilumab dose per visit for the cohort of patients who initiated tapering; 100%, label dose; 75-99%, 50-74%, 25-49% and 0-24% percentage of label dose. Abbreviations: M, month; Y, year.





Abstract N°: 4265

Efficacy and Safety of OX40-Receptor Targeting With Rocatinlimab in Moderate-to-Severe Atopic Dermatitis: Results From the Phase 3 ROCKET-Ignite Trial

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Introduction & Objectives:

OX40 receptor (OX40R) is transiently expressed on activated effector and memory T cells and plays a key role in atopic dermatitis pathogenesis by driving T-cell imbalance and amplifying the proinflammatory activity of OX40R+ pathogenic T cells. Rocatinlimab (ROCA; AMG 451/KHK4083), a first-in-class T-cell–rebalancing therapy, inhibits and reduces pathogenic T cells by targeting OX40R. The global phase 3 ROCKET program is evaluating the efficacy and safety of ROCA in moderate-to-severe atopic dermatitis (AD) in adults and adolescents. ROCKET-Horizon (NCT05651711) previously reported ROCA 300 mg Q4W monotherapy significantly improved signs and symptoms of AD in adults vs PBO by specifically reducing OX40R+ pathogenic T cells. We report the results of ROCA monotherapy in ROCKET-Ignite (NCT05398445).

Materials & Methods:

760 adults ≥18yrs with AD were randomized 3:2:2 to subcutaneous ROCA 300 mg, ROCA 150 mg, or PBO Q4W (plus Wk-2 loading dose) for 24 wks. Co-primary endpoints were ≥ 75% reduction in EASI from baseline (EASI 75) and vIGA-AD™ 0/1 with ≥ 2-point baseline reduction at Wk 24. Rescue therapy (RT) was permitted from study Day 1. Efficacy was analyzed using all randomized patients; (Full Analysis Set), with RT users considered nonresponders in the primary analysis; a prespecified sensitivity analysis was conducted regardless of RT use (All Data analysis). Missing data were imputed using non-responder imputation for both analyses. Safety analyses included all patients receiving ≥ 1 study drug dose.

Results:

Demographics were well balanced among a diverse global population (Table 1). Of the study population, 59%

previously used systemic therapy for AD; 21% had used a biologic or systemic JAK inhibitor. RT use was lower for ROCA vs PBO through Wk 24 (any RT, 28% vs 53%; topical RT, 26% vs 43%; systemic RT, 2% vs 10%). Both ROCA arms demonstrated statistical significance vs PBO for the co-primary endpoints at Wk 24. EASI 75 response rates were 42.3% (ROCA 300 mg) and 36.3% (ROCA 150 mg) vs 12.8% (PBO; $P < 0.001$, both ROCA arms); vIGA-AD 0/1 response rates were 23.6% (ROCA 300 mg) and 19.1% (ROCA 150 mg) vs 8.7% (PBO; $P < 0.001$, ROCA 300 mg vs PBO; $P = 0.002$, ROCA 150 mg vs PBO). The All Data analysis regardless of RT demonstrated greater improvement for ROCA vs PBO (EASI 75, 54.3% [ROCA 300 mg] and 49.3% [ROCA 150 mg] vs 20.1% [PBO; $P < 0.001$, both ROCA arms]; vIGA-AD 0/1, 27% [ROCA 300 mg] and 22.8% [ROCA 150 mg] vs 11.9% [PBO; $P < 0.001$, ROCA 300 mg; $P < 0.01$, ROCA 150 mg]). ROCA met all key secondary endpoints (primary and All Data analyses) including EASI 90 and ≥ 4-point reduction in weekly average of daily worst pruritus NRS at Wk 24. Efficacy in both ROCA arms was continuing to increase at Wk 24. TEAEs were balanced between treatment arms: 69.3%, 70.6%, and 69.3% for ROCA 300 mg, ROCA 150 mg, and PBO, respectively. SAE rates for ROCA were comparable to PBO (ROCA 300 mg, 4.6%; ROCA 150 mg, 2.8%; PBO, 5.5%). Infection rate did not increase for ROCA vs PBO (ROCA 300 mg, 38.3%; ROCA 150 mg, 38.8%; PBO, 40.8%).

Conclusion:

ROCKET-Ignite met its co-primary endpoints in a diverse treatment-experienced AD patient population. ROCA significantly improved AD clinical signs and symptoms with even greater efficacy observed in the All Data analyses regardless of RT and no indication of efficacy plateau at Wk 24 and was generally well tolerated. Along with the previously reported ROCKET-Horizon study, data from ROCKET-Ignite confirm the efficacy of ROCA monotherapy in adults with AD.

Table 1. ROCKET-Ignite Study Population Demographics and Disease Characteristics (Full Analysis Set)

	ROCA 300 mg (N = 326)	ROCA 150 mg (N = 215)	PBO (N = 219)	Total (N = 760)
Population demographics				
Age, yr, mean ± SD	38.5 ± 15.4	36.6 ± 13.9	37.1 ± 14.0	37.6 ± 14.6
Female, n (%)	132 (40.5)	84 (39.1)	97 (44.3)	313 (41.2)
Hispanic/Latino, n (%)	41 (12.6)	23 (10.7)	22 (10.0)	86 (11.3)
Race, n (%)				
White	196 (60.1)	127 (59.1)	128 (58.4)	451 (59.3)
Asian	113 (34.7)	70 (32.6)	73 (33.3)	256 (33.7)
Black	12 (3.7)	11 (5.1)	10 (4.6)	33 (4.3)
Other*	5 (1.5)	7 (3.3)	8 (3.7)	20 (2.6)
Region, n (%)				
Europe	131 (40.2)	89 (41.4)	92 (42.0)	312 (41.1)
Asia	93 (28.5)	60 (27.9)	64 (29.2)	217 (28.6)
North America	77 (23.6)	53 (24.7)	47 (21.5)	177 (23.3)
Latin America	25 (7.7)	13 (6.0)	16 (7.3)	54 (7.1)
Disease characteristics				
vIGA-AD™ score†, n (%)				
Moderate (score = 3)	206 (63.2)	137 (63.7)	143 (65.3)	486 (63.9)
Severe (score = 4)	119 (36.5)	78 (36.3)	76 (34.7)	273 (35.9)
EASI total score (0–72)†, mean ± SD	29.2 ± 11.4	29.3 ± 11.0	28.1 ± 10.1	28.9 ± 10.9
Moderate (score ≤ 21), n (%)	98 (30.1)	56 (26.0)	69 (31.5)	223 (29.3)
Severe/Very severe (score > 21), n (%)	227 (69.6)	159 (74.0)	150 (68.5)	536 (70.5)
BSA of AD involvement (0%–100%)†, mean ± SD	44.7 ± 22.3	45.0 ± 21.2	42.1 ± 19.6	44.0 ± 21.2
Prior use of systemic therapy, n (%)	183 (56.1)	129 (60.0)	136 (62.1)	448 (58.9)
Prior use of biologics or systemic JAK inhibitors, n (%)	69 (21.2)	40 (18.6)	48 (21.9)	157 (20.7)

*Includes American Indian or Alaska Native, Native Hawaiian or other Pacific Islander, multiple, and other.
†Baseline vIGA-AD score, EASI, and BSA were assessed after the first dose on Day 1 and considered missing for one patient randomized to ROCA 300 mg within the moderate stratum.
AD, atopic dermatitis; BSA, body surface area; EASI, Eczema Area and Severity Index; PBO, placebo; ROCA, rocatinlimab; SD, standard deviation; vIGA-AD™, validated Investigator Global Assessment for AD; yr, year.



Abstract N°: 4440

Abrocitinib and quality-of-life in severe atopic dermatitis: beyond clinical outcomes

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic skin condition that significantly impacts patients' quality-of-life (QoL). It can be severe enough to require systemic treatments, including JAK inhibitors. Abrocitinib, a JAK1-selective inhibitor, has demonstrated significant improvement of AD severity; nevertheless, there is less information regarding its impact on patients' QoL in a real-world setting.** This study aimed to describe the clinical and sociodemographic characteristics of patients treated with abrocitinib for the first time and to assess its effectiveness in improving their QoL.

Materials & Methods: A prospective observational study was conducted, including patients with severe AD starting abrocitinib treatment for the first time. Disease severity was evaluated using the Eczema Area Severity Index (EASI) and the SCORing Atopic Dermatitis (SCORAD) score. Symptom intensity was measured with the Worst Pruritus Numerical Rating Scale (WP-NRS) and the Sleep Disturbances Numerical Rating Scale (SD-NRS). QoL was assessed through five instruments: the Atopic Dermatitis Control Tool (ADCT), Dermatology Life Quality Index (DLQI), Patient-Oriented Eczema Measure (POEM), Skindex mini, and the World Health Organization Quality of Life (WHOQOL) questionnaire. All assessments were conducted at baseline and after 16 weeks of treatment

Results: Fourteen patients participated, with a mean age of 33.93 years (SD 14.32), being men 71.4% of them. At baseline, the mean scores for disease severity and symptoms were as follows: EASI 21.90 (SD 3.43), SCORAD 51.74 (SD 12.40), WP-NRS 7.21 (SD 2.67), and SD-NRS 4.29 (SD 3.65). Baseline quality-of-life scores were as follows: ADCT 10.70 (5.66), DLQI 9.20 (5.98), POEM 15.30 (7.20), Skindex mini 9.30 (5.50), and WHOQOL 57.33 (20.62). After 16 weeks of treatment with abrocitinib, all patients improved disease severity, WP-NRS and SD-NRS. Moreover, QoL scores significantly improved to the following: ADCT (-4.1, $p = 0.03$), DLQI (-4.4, $p = 0.04$), POEM (-6.3, $p = 0.02$), and Skindex mini (-3.5, $p = 0.05$). WHOQOL also improved (+9.78), but did not reach statistical significance ($p = 0.85$).

Conclusion: Abrocitinib appears to be effective both improving AD severity and patients' QoL.



Abstract N°: 4478

Facial Discoid Dermatosis: A Rare and Recalcitrant Facial Dermatosis—A Case Series

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Facial Discoid Dermatosis: A Rare and Recalcitrant Facial Dermatosis—A Case Series

Introduction & Objectives:

Facial discoid dermatosis (FDD) is an uncommon and underrecognized dermatological condition characterized by persistent, psoriasiform plaques localized to the face. Due to its clinical resemblance to various dermatoses such as psoriasis, seborrheic dermatitis, and discoid lupus erythematosus, FDD poses significant diagnostic and therapeutic challenges. Although its nosological position remains debated, some findings suggest a possible overlap with pityriasis rubra pilaris (PRP). In this case series, we aim to share the clinical and histopathological features of two patients with chronic, treatment-resistant facial plaques diagnosed as FDD, and to contribute to the growing recognition of this distinct entity.

Materials & Methods:

Two adult patients, a 45-year-old female and a 38-year-old male, presented with slowly progressive, well-demarcated, orange-pink discoid plaques on the face, persisting over several years. Detailed clinical evaluations were performed, including dermoscopic assessment, laboratory workup to exclude infectious, autoimmune, and granulomatous conditions, and histopathological examination through punch biopsies. Previous treatment regimens and their outcomes were reviewed.

Results:

In both patients, clinical presentations were limited to the facial region and involved symmetrical, scaly plaques over the cheeks, forehead, and chin. Both reported minimal pruritus and denied photosensitivity or systemic symptoms. Dermoscopy revealed mild scaling and dotted vessels. Histopathological examination revealed psoriasiform epidermal hyperplasia, focal parakeratosis, follicular plugging, and superficial perivascular lymphocytic infiltrates. Additional findings included mild spongiosis, telangiectatic vessels, mucin deposition, and in one case, the presence of fibroblastic giant cells. Despite multiple courses of topical corticosteroids, calcineurin inhibitors, retinoids, antimicrobials, and pulsed-dye laser therapy, therapeutic responses remained limited and transient. The chronicity, clinicopathologic correlation, and exclusion of other dermatoses supported the diagnosis of FDD.

Conclusion:

FDD should be considered in patients with chronic, treatment-refractory facial plaques showing histological features that overlap with psoriasiform dermatoses but lack systemic involvement. Although histopathology is often non-specific, it remains essential for excluding mimickers such as tinea faciei, cutaneous lupus, or parapsoriasis. FDD is notably resistant to conventional therapies, though emerging evidence suggests some benefit from topical retinoids and biologics in selected cases. Increased clinical recognition and further

documentation through case-based observations are needed to refine diagnostic criteria and establish effective treatment strategies for this persistent and cosmetically distressing condition.



Abstract N°: 4530

Eczema herpeticum in an atopic dermatitis patient treated with JAK1 inhibitor and UVB phototherapy: a case report

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin condition frequently treated with topical agents, phototherapy, and systemic immunomodulators. With the increasing use of Janus kinase (JAK) inhibitors, particularly abrocitinib, understanding their safety profiles is critical. Eczema herpeticum (EH), a disseminated herpes simplex virus (HSV) infection often due to HSV-1, is a rare but serious complication in AD patients. This case aims to highlight the potential synergistic risk of developing EH when narrowband UVB (NBUVB) phototherapy is combined with systemic JAK inhibition.

Materials & Methods:

A case of a 32-year-old Filipino-Middle Eastern male with chronic AD since childhood is presented. Previously maintained on topical corticosteroids and moisturizers, the patient developed worsening flares and was started on NBUVB phototherapy and oral abrocitinib.

Results:

Over the course of ten NBUVB sessions and concurrent abrocitinib at 200 mg every other day, the patient developed worsening pruritus, hyperpigmented lichenified plaques, and weight loss. A day prior to admission, he developed vesicles on the axillae and trunk, followed by fever (40.1°C) and chills. He was admitted as a case of EH. Empiric oral antivirals and antibiotics were given. The patient improved significantly and was discharged after 8 days. Follow-up two weeks post-discharge showed marked resolution of lesions and absence of systemic symptoms.

Conclusion:

This case underscores the potential additive immunosuppressive effect of combining JAK1 inhibitors and NBUVB phototherapy in AD patients, which may predispose them to viral complications such as EH. While both modalities are effective individually, their simultaneous use warrants caution. Clinicians must maintain vigilance for cutaneous infections and adopt a multidisciplinary approach to manage immunomodulatory treatments in atopic patients. Further studies are needed to evaluate the safety of combining phototherapy with JAK inhibitors in real-world settings.

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Abstract N°: 4552

Achieving Optimal Treatment Targets for Skin Clearance and Itch Relief in Older Adults (≥65 Years) with Moderate-to-Severe Atopic Dermatitis Treated with Upadacitinib Monotherapy: 140-Week Outcomes from Integrated Phase 3 Measure Up 1 and 2 Studies

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Introduction & Objectives: Atopic dermatitis (AD) can be burdensome in older adults due to age-related skin barrier dysfunction and immunological shifts. This study used an integrated analysis from the Measure Up 1 and Measure Up 2 Phase 3 clinical trials to assess the efficacy and safety of upadacitinib monotherapy at the approved dose of 15 mg once daily in patients aged ≥65 years with moderate-to-severe AD.

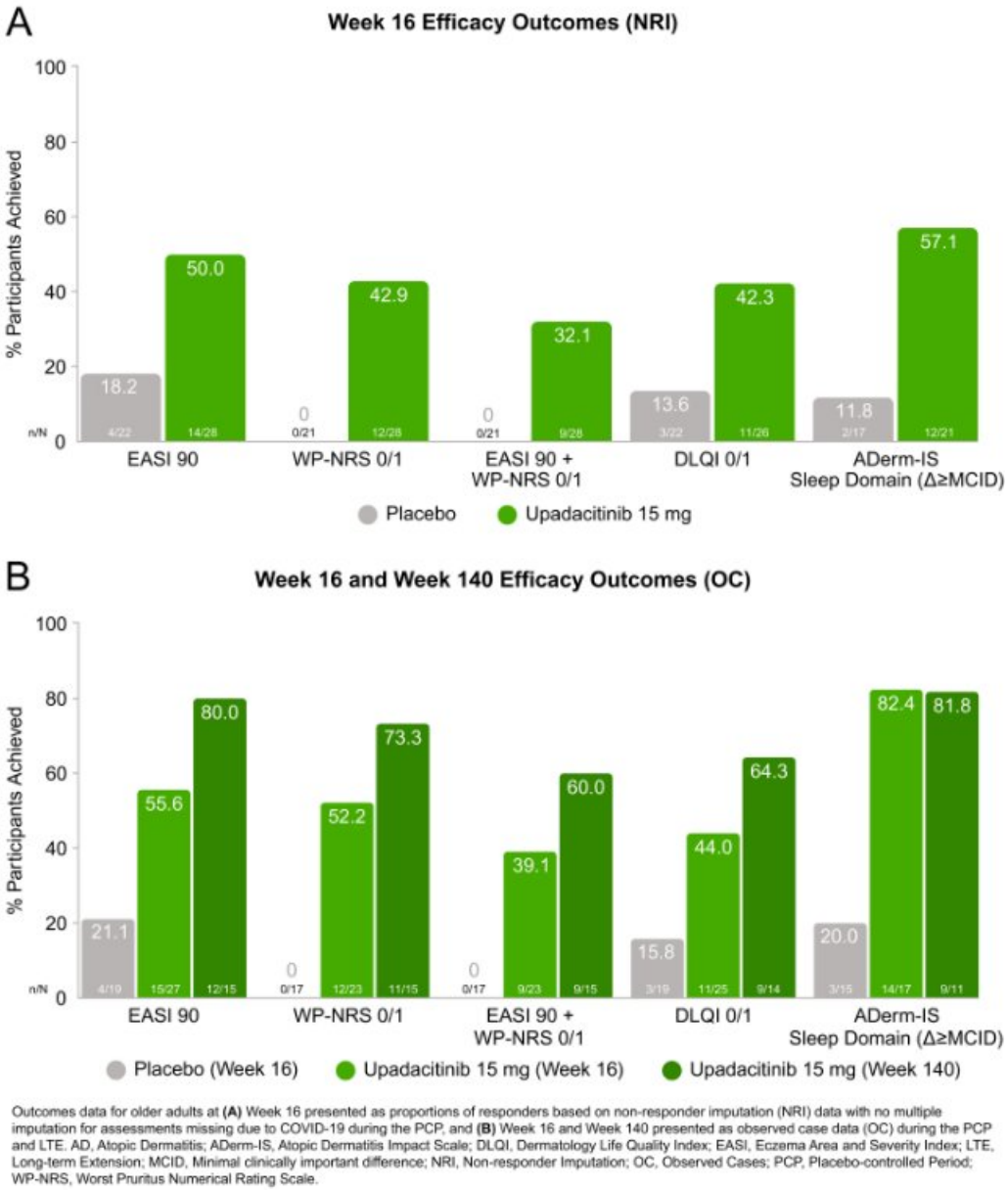
Materials & Methods: Trial design for Measure Up 1 (NCT03569293) and Measure Up 2 (NCT03607422) have been previously described. This post-hoc integrated analysis included patients aged ≥65 years randomized to double blinded daily oral upadacitinib 15 mg or placebo for 16 weeks, who then completed a blinded long-term extension period through Week 140 with 15 mg daily upadacitinib. The study assessed the achievement of optimal treatment targets as outlined by Aiming High in Eczema/Atopic Dermatitis (AHEAD) recommendations. Optimal targets included clinician-reported outcomes, such as clear or almost clear skin (≥90% Eczema Area and Severity Index improvement; EASI 90), and patient-reported outcomes, such as little-to-no itch (Worst Pruritus Numeric Rating Scale of 0 or 1; WP-NRS 0/1) and no impact of AD on quality of life (Dermatology Life Quality Index of 0 or 1; DLQI 0/1). Achievement of Minimal Disease Activity (defined as simultaneous achievement of both EASI 90 & WP-NRS 0/1; MDA) and clinically meaningful improvement in AD-related sleep disturbance (≥12-point improvement on Atopic Dermatitis Impact Scale Sleep domain score; ΔADerm-IS Sleep≥12) were also assessed. Response rates were based on non-responder imputation (NRI) during the PCP (through Week 16) and observed cases (OC) for the extension period (through Week 140). Adverse events of special interest (AESIs) were assessed through Week 16 and long-term (up to Week 140).

Results: At Week 16, upadacitinib-treated patients (n=28) achieved optimal outcomes for skin clearance (50.0% achieved EASI 90) and itch relief (42.9% achieved WP-NRS 0/1), as well as MDA (32.1% achieved simultaneous EASI 90 and WP-NRS 0/1) (Figure). Additionally, 42.3% reported DLQI 0/1, and 57.1% experienced ΔADerm-IS Sleep≥12. At Week 16, no placebo-assigned patients (n=22) achieved WP-NRS 0/1 or MDA (Figure); 18.2% achieved EASI 90, 13.6% reported DLQI 0/1, and 11.8% experienced ΔADerm-IS Sleep≥12. Most upadacitinib-

treated patients achieved target outcomes at Week 140 (n=15) (Figure): 80.0% EASI 90, 73.3% WP-NRS 0/1, 60.0% EASI 90 & WP-NRS 0/1, 64.3% DLQI 0/1, and 81.8% ΔADerm-IS Sleep≥12. Exposure-adjusted rates for the following AESIs remained low through Week 140 (n=38; 88.3 patient-years [PY]): serious infections (1.1 events per 100 PY [E/100PY]), herpes zoster (4.5E/100PY), malignancy excluding non-melanoma skin cancer (1.1 incidents per 100 patient-years [n/100PY]), and major adverse cardiovascular events (3.5n/100PY), with no opportunistic infections, gastrointestinal perforations, or thromboembolic events reported. None of these AESIs were reported at Week 16.

Conclusion: Older adults aged ≥65 years treated with oral upadacitinib 15 mg once daily achieved optimal skin clearance and itch relief, along with meaningful improvements in quality of life and sleep. Most maintained higher response rates through Week 140. Upadacitinib was well tolerated, with no new important safety concerns identified, underscoring its utility as a treatment option for moderate-to-severe atopic dermatitis in this population.

Figure. Achievement of optimal clinician-reported and patient-reported outcomes through 140 weeks of treatment with upadacitinib for older adults with moderate-to-severe AD



Outcomes data for older adults at **(A)** Week 16 presented as proportions of responders based on non-responder imputation (NRI) data with no multiple imputation for assessments missing due to COVID-19 during the PCP, and **(B)** Week 16 and Week 140 presented as observed case data (OC) during the PCP and LTE. AD, Atopic Dermatitis; ADerm-IS, Atopic Dermatitis Impact Scale; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; LTE, Long-term Extension; MCID, Minimal clinically important difference; NRI, Non-responder Imputation; OC, Observed Cases; PCP, Placebo-controlled Period; WP-NRS, Worst Pruritus Numerical Rating Scale.



Abstract N°: 4586

Demographic and clinical characteristics of atopic patients who have been lost to follow-up after initiation of systemic treatment, data from the OMCCI real-life study

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Introduction & Objectives:

Studies into the effectiveness of the various therapeutic treatments for atopic dermatitis (AD) focus primarily on analysing their results, their maintenance over time and their side-effects. Few studies have focused on identifying patients for whom treatment has been initiated but who do not take it.

Materials & Methods:

We analysed the demographic, social and clinical characteristics and feelings of patients lost to hyper-early diagnosis (PPHP), defined as those included at the screening visit and not seen again at the 6- and 12-month visits, and compared them with the compliant population (PO) who were still taking their treatment at the M24 visit. These data corresponded to those available during a standard outpatient dermatology consultation and not to a research protocol.

Results:

The number of PPHPs (patients previously hospitalized for atopic dermatitis) was 28 out of a total population of 679, representing 4.1%.

Socio-demographic data revealed no statistically significant differences between groups in terms of age, sex, age group, family situation, number of household members, highest qualification obtained, type of occupation, or type of social insurance.

Regarding disease activity, 36% of PPHPs had an EASI score <7, compared to 13% of POs (patients only treated as outpatients); 52% had an EASI score between 7 and 21, versus 50.5% of POs; and 12% had an EASI score >21, compared to 36.3% of POs.

The mean age at disease onset in the PPHP group was 10 ± 20.6 years, with a median of 1 year, compared to 14.7 ± 20 years and a median of 5 years in the PO group.

Satisfaction with the therapeutic solution for atopic dermatitis was reported as positive by 82.1% of PPHPs, versus 14.2% of POs ($p < 0.001$). In contrast, discomfort due to atopic dermatitis was more frequently reported among POs (92.6% very or fairly discomforting) compared to 82.1% in the PPHP group.

No significant differences were found between the groups in terms of disease duration, number of hospitalizations in the past six months, affected anatomical sites, disease progression during that period, DLQI or SF-12 quality of life scores, work absenteeism, or self-reported treatment adherence.

The primary management failure rate of 4.1% is a notable finding. Based on data available in routine outpatient

practice, patients with early-onset AD (typically in infancy) and an EASI score <7 represent a distinct subgroup with better tolerance to atopic dermatitis compared to those managed exclusively as outpatients.

Conclusion:

AD is a disease that can occur at any age. Clearly, some patients may develop resilience and less adherence to treatment. This makes them less receptive to medical treatment. It is very likely that the repeated failures of the therapeutic promises that have marked out their pathway explain this non-adherence. Holistic treatment with psychological follow-up would certainly optimise their therapeutic management.

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Abstract N°: 4727

Efficacy and safety of stapokibart in adolescents with moderate-to-severe atopic dermatitis: a multicenter, randomized, double-blind, placebo-controlled phase 3 trial

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Efficacy and safety of stapokibart in adolescents with moderate-to-severe atopic dermatitis: a multicenter, randomized, double-blind, placebo-controlled phase 3 trial

Introduction & Objectives: Adolescents with moderate-to-severe atopic dermatitis (AD) have significant disease burdens, with limited treatment options available. Stapokibart, a novel humanized monoclonal antibody targeting IL-4Rα, has been approved for the treatment of adults with moderate-to-severe AD in China. A multicenter, randomized, double-blind, placebo-controlled phase 3 trial (NCT06277765) was designed to evaluate the efficacy and safety of stapokibart in the adolescents with moderate-to-severe AD.

Materials & Methods: Eligible patients (aged ≥12 to <18 years) were randomly assigned (2:1) to stapokibart 300 mg group (n=120; loading dose, 600 mg) or placebo group (n=60) during an 18-week treatment period. Patients with baseline weight ≥60 kg received subcutaneous stapokibart (n=54) or placebo (n=26) every two weeks, while those weighting 30 to <60 kg received treatment every three weeks (n=66 and n=34, respectively). Coprimary endpoints were the proportions of patients achieving ≥75% improvement from baseline in Eczema Area and Severity Index (EASI-75) and an Investigator's Global Assessment (IGA) score of 0/1 with ≥2-point reduction from baseline (IGA response) at week 18. Safety was also evaluated.

Results: Between March 21, 2024, and September 25, 2024, of 198 screened patients, 180 were enrolled (mean [SD] age, 14.5 [1.8] years; 98 [54.4%] female), with 178 (98.9%) completing treatment. Patients' demographics and baseline characteristics were well-balanced between groups. At baseline, the mean EASI scores were 25.2 in the stapokibart group and 23.4 in the placebo group, and the proportions of patients with IGA score of 3 were 55.8% and 55.0%, respectively. Stapokibart achieved both coprimary endpoints at week 18. 73.9% of stapokibart-treated patients achieved EASI-75 versus 43.3% in the placebo group (P<0.0001); IGA response rates were 57.1% and 25.0% (P<0.0001), respectively (Figure 1). Significant improvement was observed for the least-square mean percent change from baseline in weekly average of daily Peak Pruritus Numerical Rating Scale score at week 18 (-49.5% vs. -25.3%; P<0.0001). Stapokibart also significantly improved patients' quality of life. The incidence of treatment-emergent adverse events (TEAEs) was comparable between groups (62.5% vs. 61.7%), with most events being mild to moderate in severity (Table 1). The most common TEAE of infections and infestation was upper respiratory tract infection. No conjunctivitis occurred throughout the study.

Conclusion: Stapokibart demonstrated significant efficacy and a favorable safety profile in adolescents with moderate-to-severe AD.

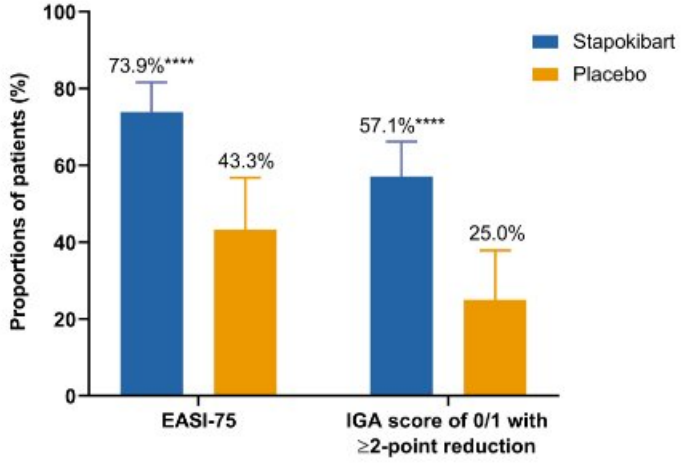


Figure 1. Proportions of patients achieving coprimary endpoints at week 18.
****, p<0.0001 versus placebo. Error bars indicated 95% confidence interval.

Table 1. Safety assessment

	Stapokibart n = 120	**Stapokibart n = 120**
Any TEAEs	75 (62.5)	37 (61.7)
Mild	61 (50.8)	31 (51.7)
Moderate	24 (20.0)	12 (20.0)
Severe	1 (0.8)	0
Drug-related TEAEs	26 (21.7)	18 (30.0)
Mild	24 (20.0)	15 (25.0)
Moderate	2 (1.7)	5 (8.3)
Severe	0	0
Any serious adverse events	1 (0.8)	0
TEAEs leading to treatment discontinuation	0	0
TEAEs leading to death	0	0
Most common TEAEs (SOC/PT) [a]		
Infections and infestation	43 (35.8)	19 (31.7)
Upper respiratory tract infection	33 (27.5)	11 (18.3)
Folliculitis	1 (0.8)	2 (3.3)
Skin infection	0	3 (5.0)
Hordeolum	0	2 (3.3)

Data are denoted as n (%). Safety set (SS) is used for safety analysis.
[a] TEAEs occurred in ≥3% of patients in any treatment group, according to Medical Dictionary for Regulatory Activities v26.1.
PT, Preferred Term; SOC, system organ class.



Abstract N°: 4753

Assessing atopic dermatitis control in Chinese patients: validation of the Chinese version of Recap of atopic eczema questionnaire (RECAP) and an investigation into its interpretability

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Introduction & Objectives:

The Recap of atopic eczema questionnaire (RECAP) is recommended by Harmonizing Outcome Measure Eczema (HOME) for assessing eczema control. However, the lack of a validated Chinese version limits its applicability in clinical and research settings. Therefore, this study aimed to evaluate the measurement properties of the Chinese versions of RECAP, including its construct validity, reliability, responsiveness, and interpretability.

Materials & Methods:

A prospective study was conducted at a Chinese tertiary hospital, enrolling adults diagnosed with atopic dermatitis (AD) based on the UK Working Party criteria, between April and November 2024. Participants completed RECAP, and reference instruments at three time points: baseline, 1-3 days later, and 4-6 weeks later. The reference instruments included the Atopic Dermatitis Control Tool (ADCT), Patient-Oriented Eczema Measure (POEM), Dermatology Life Quality Index (DLQI), Numerical Rating Scale (NRS) for peak itch, and anchor measures, namely the Patient's Global Assessment (PtGA) of AD control and the Global Rating of Change (GRC) scale. Clinical disease severity was assessed by dermatologists using the Eczema Area and Severity Index (EASI), and the Investigator Global Assessment-AD (IGA). Construct validity was evaluated through hypotheses testing, while reliability was assessed using the standard error of measurement (SEMagreement) and intraclass correlation coefficient (ICCagreement). To enhance interpretability, disease control bandings for RECAP scores were proposed. Change-score interpretability was examined using the smallest detectable change (SDC) and minimally important change (MIC). The MIC values were estimated through receiver operating characteristics (ROC) analysis and predictive modelling.

Results:

A total of 153 adults (mean age 28.4 years, 51.0% male) were included in baseline analyses, with follow-up rates of 97.4% at T1 and 96.7% at T2. Of the predefined hypotheses, 57.1% (single-score) and 71.4% (change-score) were confirmed, indicating moderate validity. RECAP scores effectively distinguished between patients with different AD severities and quality-of-life impairments, demonstrating strong known-groups validity. The SEMagreement was 1.99 points, and the ICCagreement was 0.96 [95% confidence interval (CI) 0.92-0.98], indicating excellent test-retest reliability. Proposed RECAP bandings were: 0-2 (completely controlled); 3-10 (mostly controlled); 11-12 (moderately controlled); 13-18 (a little controlled); 19-28 (not at all controlled). A binary cutoff of ^{3}11 points identified patients with uncontrolled AD. The MIC was 3.5 based on the ROC method and 0.6 after adjustment using predictive modelling. No floor or ceiling effects were observed.

Conclusion:

The Chinese version of RECAP is a valid, reliable, and responsive tool for assessing disease control in Chinese AD patients. A binary cutoff of ^{3}11 points identifies uncontrolled AD, while an improvement of ^{3}6 points represents a clinically meaningful change. With the newly established population-specific thresholds, the validated Chinese RECAP could serve as a robust tool for evaluating eczema control in both clinical practice and research settings.



Abstract N°: 4754

Lebrikizumab in Atopic Dermatitis: Real-World Clinical Experience in Our Center

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Introduction & Objectives: ** Atopic dermatitis (AD) is a chronic inflammatory skin disease that significantly impacts sleep and quality of life, especially in moderate to severe cases. In the past year, new therapeutic options have been approved to improve and control this condition, including lebrikizumab. Lebrikizumab is an IgG4 monoclonal antibody that binds with high affinity to interleukin-13 (IL-13) and selectively inhibits its signaling through the IL-4 receptor alpha (IL-4Rα)/IL-13 receptor alpha 1 (IL-13Rα1) heterodimer, thus blocking the downstream effects of IL-13 binding and markedly reducing the inflammation involved in the pathogenesis of the disease, leading to significant symptomatic improvement.

Materials & Methods: We conducted a prospective observational study including 12 patients with moderate-to-severe atopic dermatitis treated with lebrikizumab in our center. We assessed their clinical response at weeks 4, 12, and 24 by evaluating EASI, BSA, IGA, and NRS itch scores.

Results: ** Twelve patients initiated treatment with lebrikizumab for moderate-to-severe AD in our department; 9 (75%) were women and 3 (25%) were men, with a mean age of 33.08 years (SD 9.27) and an average disease duration of 7.16 years (SD 6.74). All patients (100%) exhibited the classic phenotype. Facial and cervical involvement predominated in 9 (75%) patients, and 7 (58.3%) had hand involvement. Three (25%) were active smokers, and 9 (71.42%) were non-smokers.

Regarding comorbidities, 6 (50%) had bronchial asthma, 4 (33.33%) allergic rhinitis, 5 (41.67%) food allergy, 2 (16.67%) allergic conjunctivitis, and none had nasal polyposis or eosinophilic esophagitis.

In terms of prior treatments, 50% had received systemic corticosteroids, 100% cyclosporine, 16.67% phototherapy, and none methotrexate. Additionally, 1 (8.33%) had been treated with the biologic dupilumab, 2 (16.67%) with tralokinumab, and 6 (50%) with JAK inhibitors: upadacitinib (25%), abrocitinib (16.67%), and baricitinib (8.33%).

Baseline mean scores were: EASI 20.88 (SD 6.43), IGA 3.5 (SD 0.52), BSA 23.92 (SD 13.83), and NRS itch 7.5 (SD 2.11). At week 4, data from 8 patients showed mean EASI 9.66 (SD 5.41), IGA 2.25 (SD 0.89), BSA 16.13 (SD 11.49), and NRS itch 4.75 (SD 2.82). Only 1 (8.33%) required concomitant oral immunosuppressive therapy. At week 12, data from 7 patients showed mean EASI 2.36 (SD 2.73), IGA 1 (SD 0.58), BSA 5.14 (SD 3.93), and NRS itch 1.86 (SD 2.85). At week 24, data from 3 patients showed mean EASI 0.97 (SD 1.67), IGA 0.33 (SD 0.58), BSA 5 (SD 7.81), and NRS itch 0.33 (SD 0.58).

Only one patient (8.33%) reported an adverse event—ocular involvement in the form of conjunctivitis. No patient required discontinuation of treatment during the study period.

Conclusion:

Lebrikizumab has demonstrated efficacy in the treatment of moderate-to-severe atopic dermatitis in patients who did not respond to other biologics such as dupilumab or JAK inhibitors including baricitinib and upadacitinib. It was associated with early symptom improvement and reduced need for adjunctive systemic immunosuppressive therapy.



Abstract N°: 4770

Epidermal IL18 and IL22RA1 Co-expression Reflects Hyperplasia and Barrier Dysfunction in AD

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Introduction & Objectives:

Atopic dermatitis (AD) is a complex chronic skin condition characterized by persistent itching, skin barrier dysfunction, and inflammation dominated by Th2 cells, with contributions from Th1 and Th22 cells. While Th2 targeting therapies have improved patient outcomes, many still experience uncontrolled symptoms or side effects, highlighting the need for therapies with different modes of action. This study (NCT04295824) explores the role of interleukin-18 (IL-18) and interleukin-22 receptor subunit alpha 1 (IL-22RA1), in AD pathophysiology. IL-22RA1, involved in epidermal regeneration, defense, and inflammation, is expressed only by epithelial cells, while IL-18, a pro-inflammatory cytokine that can promote Th2 cytokine production, is expressed by both epithelial and immune cells. IL-22 can induce IL-18 expression in keratinocytes. Investigational therapies directed against IL-18 and IL-22RA1 are in development for the treatment of AD, however, clinical effects relating to co-expression of IL-18 and IL-22 pathways are poorly understood.

Materials & Methods:

Skin biopsies were collected from lesional and non-lesional cubital fossae in 42 AD patients with varying severity (11 unaffected, 39 mild, 14 moderate and 20 severe) and 30 healthy controls. *In-situ* hybridization detected *IL18* and *IL22RA1* mRNA, while immunohistochemistry quantified epidermal thickness, cytokeratin-16 (CK16), and filaggrin. Carboxylate functional groups, were quantified with FTIR and trans-epidermal water loss (TEWL) was measured to assess barrier function. The local clinical severity of each lesion was graded using an adapted EASI-based scoring system.

Results:

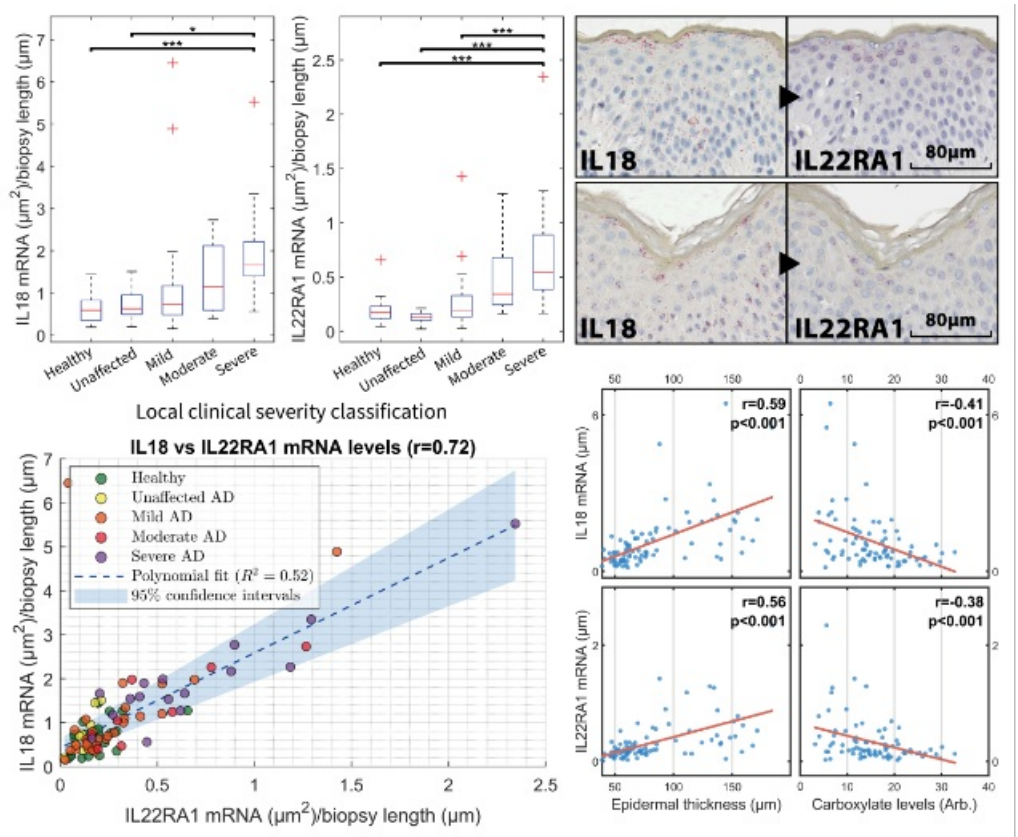
Both *IL18* and *IL22RA1* mRNA were elevated in severe AD lesions compared to healthy controls. Expression was co-localized within the epidermis, and mRNA levels were significantly correlated (r=0.72). *IL18* and *IL22RA1* expression was, respectively, positively associated with clinical signs of both acute (erythema: r=0.35 and 0.43; papulation: r=0.36 and 0.44) and chronic (lichenification: r=0.25 and 0.38; xerosis: r=0.43 and 0.50) AD, with a consistently higher correlation for *IL22RA1*. Xerosis showed the strongest association, supporting its potential role as a clinical proxy for cytokine-driven barrier disruption.

Prominent hyperplasia and barrier disruption were present in lesional skin compared to healthy skin, evidenced by rising mean epidermal thickness (60.7 to 97.9µm) and TEWL (12.9 to 30.2g/m2/h). For both *IL18* and *IL22RA1*

respectively, epidermal thickness (r=0.59, 0.56) and CK16 (r=0.40, 0.38) were correlated, suggesting both play a role in the progression of hyperplasia. In terms of barrier function, TEWL (r=0.46, 0.49) was positively associated, while filaggrin relative to epidermal area (r=-0.44, -0.34) was inversely related. To further evidence this, carboxylate groups, found in components of filaggrin breakdown, were depleted (r=-0.41, -0.38).

Conclusion:

IL18 and *IL22RA1* mRNA expression was concertedly linked to clinical severity, epidermal hyperplasia, and barrier dysfunction in AD, highlighting that both are promising targets in AD. Co-expression of *IL18* and *IL22RA1* in keratinocytes suggests that inhibition of IL-22RA1 would likely affect IL-22 induced *IL18* expression in keratinocytes. Results from clinical trials targeting IL-18 and IL-22RA1 will increase the understanding of this co-expression and whether it translates to clinical effects.



Top left) Expression of IL18 and IL22RA1 as a function of the local clinical severity of each biopsy. Top right) Apparent co-localisation of IL18 and IL22RA1 mRNA was observed in the epidermis. Bottom left) Co-expression of IL18 and IL22RA1. Bottom right) Correlation matrix showing IL18 and IL22RA1 vs epidermal thickness and skin carboxylate levels as measured with FTIR.



Abstract N°: 4802

Basophil Modification in Atopic Dermatitis: Differential Effects of Dupilumab and Abrocitinib on Phenotypic and Functional Responses

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, pruritic inflammatory skin disease that significantly reduces quality of life. Basophils are increasingly recognized as key contributors to AD pathogenesis, driving itch flares and amplifying type 2 inflammation. Although dupilumab, an IL-4 receptor α antagonist, and abrocitinib, a selective JAK1 inhibitor, are approved treatments for AD, their specific effects on basophil phenotype and function remain unclear. This study investigates how these therapies modulate basophil activity in the context of AD, aiming to clarify their immunomodulatory roles and potential implications for disease management.

Materials & Methods:

This single-center, prospective observational cohort study enrolled 113 participants—24 healthy controls (HCs) and 89 patients with atopic dermatitis (AD). Among the AD group, 52 received systemic therapy (25 with dupilumab, 27 with abrocitinib). Clinical severity was measured using the Eczema Area and Severity Index (EASI) and Peak Pruritus Numeric Rating Scale (PP-NRS). Longitudinal blood samples were collected at baseline and after 3 months of treatment. Flow cytometry was used to analyze basophil surface markers (FcεRIα, MRGPRX2, CD63, CD203c, CCR3, CXCR4) in both HCs and AD patients. Purified basophils were also stimulated in vitro with fMLP and anti-IgE to assess functional responses.

Results:

In patients with AD, basophils showed marked alterations in both phenotype and function, which were differentially modulated by dupilumab and abrocitinib. Compared to HCs, AD patients exhibited increased basophil infiltration in skin tissue and elevated peripheral blood basophil counts. Flow cytometry revealed significantly higher expression of FcεRIα, MRGPRX2, and CD63 on circulating basophils in AD patients versus HCs ($p < 0.01$). Upon fMLP or anti-IgE stimulation, purified basophils from AD patients displayed enhanced MRGPRX2 expression relative to HCs. Both dupilumab and abrocitinib achieved significant clinical improvement, with reductions in EASI and NRS scores. However, they exerted distinct effects on basophil markers. Dupilumab treatment led to significant downregulation of MRGPRX2 ($p < 0.01$), alongside upregulation of CD63 ($p < 0.1$), CD203c ($p < 0.05$), and CCR3 ($p < 0.05$). In contrast, abrocitinib selectively reduced CD203c expression ($p < 0.05$). Functionally, anti-IgE–induced MRGPRX2 activation remained intact after dupilumab treatment, while fMLP failed to induce MRGPRX2 upregulation following treatment with either drug.

Conclusion:

Basophils in AD exhibit distinct phenotypic and functional changes that are differentially modulated by dupilumab and abrocitinib. Basophils may serve not only as biomarkers of disease activity and treatment response but also as potential targets for tailored therapeutic strategies in AD.



Abstract N°: 4806

Successful Treatment of Refractory Chronic Hand Eczema with Iontophoresis of Exosome from Adipose Tissue-Derived Mesenchymal Stem Cells

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Introduction & Objectives:

Exosomes are recognized as the key component that regulates MSCs' paracrine effect. A previous study showed that ASC-exosomes reduce atopic dermatitis symptoms in animal models by decreasing systemic inflammation. ASC-exosomes improve epidermal permeability barrier functions by significant increase in ceramides and a reduction in immune responses. Also, notably, ASC-exosomes delivered immediate clinical improvements in DFR, a result not typically seen with other treatment approaches . These findings suggest that ASC-exosomes can be a promising treatment option for CHE, which is unresponsive to conventional modalities such as topical steroids. CHE is characterized by recurrent itching and painful erythematous papules and vesicles followed by lichenification, scaling, hyperkeratinizing, and skin fissuring. This condition is sometimes debilitating and refractory to treatment. We report one case of refractory CHE managed successfully with iontophoresis of ASC-exosomes.

Materials & Methods:

A 24-year-old male presented to our clinic with severe hand dermatitis. Itchy, small erythematous plaques initially presented on the dorsal part of both hands, which had been developing for 3 years. Since then, the lesion had gradually spread and lichenified, and painful skin fissures had appeared. The patient had been treated with various steroid ointments, oral steroids, oral antihistamines, and emollients.

ASC-Exosomes were prepared, and 1.5 mL of ASC-exosome solution (ExoCoBio Inc., Republic of Korea) was applied to each hand. For enhancing the delivery of ASC-exosome, we used an iontophoresis machine (Ionzyme) at 50mA. We treated the patient twice a week with 3 days interval.

Results:

No recurrence was detected at a subsequent 6-month follow-up examination. These findings suggest that ASC-exosomes can be a promising treatment option for CHE, which is unresponsive to conventional modalities such as topical steroids. This condition is sometimes debilitating and refractory to treatment. We report one case of refractory CHE managed successfully with iontophoresis of ASC-exosomes.

Conclusion:

This case report highlights the successful treatment of chronic hand eczema (CHE) refractory to conventional therapies using iontophoretic delivery of ASC-exosomes. The patient experienced significant clinical improvement without adverse effects, indicating that ASC-exosomes, when combined with iontophoresis, may offer a novel, safe, and effective therapeutic approach for recalcitrant CHE. Given the encouraging outcome observed in this single case, further large-scale, controlled clinical studies are warranted to validate the therapeutic potential and establish standardized protocols for ASC-exosome-based treatments in chronic inflammatory skin diseases.



Abstract N°: 4854

Prevalence and Risk Factors of Insomnia in Atopic Dermatitis Without Pruritus: Insights from the Scars of Life Study

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Introduction & Objectives:

Atopic dermatitis (AD) is a common chronic inflammatory skin condition linked to sleep disturbances (SD) in 47–80% of children and 33–90% of adults. While pruritus is widely seen as the main cause of SD, studies show that

42.3% of patients with cutaneous disorders, including AD, report SD, with factors like burning sensations or skin pain also predictive. No prior research has specifically examined SD in AD patients without pruritus, particularly sleep-onset insomnia (difficulty falling asleep) and sleep-maintenance insomnia (nighttime awakenings). This study aims to address this gap by assessing the prevalence and risk factors of SD in adults with AD without pruritus, using a large international cohort.

Materials & Methods:

As part of the "Scars of Life" initiative, a cross-sectional observational study was conducted from June to September 2024, involving 30,801 adults from 27 countries across five continents. A representative sample was selected using the quota method. Participants, aged 18 and older, completed an online questionnaire on sociodemographic data, AD confirmed by a healthcare professional, absence of pruritus, and skin pain experiences. AD severity was assessed with the POEM score. SD was evaluated via questions on sleep-onset insomnia ("$>$20 min to fall asleep") and sleep-maintenance insomnia ("difficulty falling back asleep after waking"). When both types are present, we refer to a mixed situation. The analysis compared 5,267 AD patients without pruritus to 5,394 controls without skin disease.

Results:

AD patients without pruritus showed a significantly higher SD prevalence (OR = 2.04) than controls, with 55.3% reporting sleep-onset insomnia (vs 39.2%) and 58.3% sleep-maintenance insomnia (vs 44%). SD patterns varied with AD severity: isolated insomnia decreased with severity (e.g., 21.2% mild to 15.9% severe for sleep-onset), while mixed insomnia rose (51.7% mild to 74.5% severe). Overall SD prevalence increased with severity of AD: 63.3% (mild), 83.5% (moderate), 85.2% (severe). Adjusted odds ratios confirmed higher risk with severity: OR = 2.94 (moderate) and OR = 3.33 (severe). Risk factors included age $<$40, female gender, and BMI $>$30, especially for mixed insomnia.

Conclusion:

These findings reveal that SD persists in AD patients without pruritus and correlates with disease severity, suggesting mechanisms beyond itching, such as transepidermal water loss, proinflammatory cytokines (IL-6, IL-31), or psychological stress. As the first study to analyze insomnia subtypes in this context, it highlights the need for early SD detection and tailored interventions, particularly for young adults and at-risk groups (obese, females). It calls for further research into cytokines and melatonin's roles in AD-related SD.



Abstract N°: 4878

emerging role of apremilast in hand dermatoses

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Introduction & Objectives:

Chronic hand dermatoses involves different dermatoses affecting hands like hand eczema and palmoplantar psoriasis. These conditions are notoriously challenging to treat, particularly when resistant to conventional topical therapies. The functional and psychosocial burden of hand involvement is disproportionately high, often necessitating systemic intervention. However, treatment options that are both effective and well-tolerated remain limited . The objective of study is to highlight the pharmacological profile, mechanism of action, and emerging clinical role of Apremilast in the management of chronic, treatment-refractory hand dermatoses.

Materials & Methods:

Apremilast, an oral phosphodiesterase-4 (PDE4) inhibitor, modulates inflammatory pathways by decreasing the production of pro-inflammatory cytokines such as TNF-α, IL-17, and IL-23. Here , we will be presenting 10 resistant cases of hand dermatoses treated with oral apremilast (dose given according to recommendations),topical steroids and preventive measures .The patients were followed at 1 and 3 weeks and also monitor improvement in different scores like hand eczema clinical severity index(HECSI) , visual analogue scale (VAS) score for pruritus & quality of life in hand eczema questionnre(QOCHEQ)

Results:

It offers many advantages over traditional immunosuppressants: oral administration, minimal monitoring requirements, and a favourable safety profile. Clinical improvement is often noted by 1-4 weeks, with benefits in both disease severity and quality of life.

Conclusion:

Apremilast represents a valuable systemic option for chronic hand dermatoses, especially in cases where localized disease is unresponsive to topical therapy and where biologics may not be appropriate. Further clinical trials are warranted to strengthen its evidence base in this niche which is an impactful area of dermatology.



Abstract N°: 4886

Advanced systemic therapies for atopic dermatitis: real-world comparison of clinical and analytical outcomes between biologics and JAK inhibitors after 12 months in a reference hospital in Spain.

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Introduction & Objectives:

Atopic Dermatitis (AD) is a chronic inflammatory skin disorder characterized by intense pruritus and eczematous lesions. Advanced systemic therapies, including biologic drugs and JAK inhibitors (JAKi), have revolutionized AD management by specifically targeting immune pathways involved in its pathogenesis. However, real-world comparative analyses of these therapies remain limited. Given the rapid expansion of available treatment options, their high costs, and the ongoing challenges in clinical practice, robust real-world data are urgently needed to support clinical decision-making and optimize treatment outcomes. This study aims to evaluate and compare the clinical efficacy, safety profiles, and analytical impacts—including variables related to cardiovascular risk—of biologic therapies versus JAK inhibitors in patients with AD after 12 months of continuous treatment at a tertiary referral hospital in Spain

Materials & Methods:

We conducted an observational, analytical, ambispective study including patients diagnosed with AD who initiated advanced systemic treatments between 2019 and 2024 at a tertiary referral hospital in Spain. Patients were divided into two groups: those treated with biologic therapies (Group 1) and those receiving JAK inhibitors (Group 2). Baseline demographic, anthropometric, clinical, and laboratory data were collected, along with efficacy and safety outcomes over a 12-month follow-up period. Descriptive and inferential statistical analyses were performed to compare the two groups. Measures of central tendency were expressed as mean (± standard deviation) and, when relevant, minimum and maximum values were also provided. Statistical significance was set at $p < 0.05$. All analyses were carried out using SPSS v.24 (SPSS Inc., Chicago, IL, USA).

Results:

A total of 202 patients with AD were included and analyzed based on sociodemographic characteristics, body measurements, disease history, and both clinical and analytical treatment outcomes over 12 months of follow-up. Among them, 134 (66.34%) were treated with biologic agents (dupilumab, tralokinumab, lebrikizumab), while 68 (33.66%) received JAK inhibitors (upadacitinib, abrocitinib, baricitinib). Statistically significant differences were observed between groups regarding baseline disease severity—greater in the biologics group (higher EASI and BSA scores, $p < 0.01$). These differences influenced initial treatment responses, which favored JAK inhibitors at earlier time points but equalized by week 52. Prior exposure to advanced therapies differed, with a higher proportion of treatment-naïve patients in the biologics group ($p = 0.0001$). Distinct safety profiles were observed, with adverse events consistent with those previously reported in clinical trials. Biologics were associated with a higher frequency—though not statistically significant—of disease phenotype shift ($p = 0.0818$). Analytical parameters, including lipid profiles and inflammatory markers, were also compared.

Conclusion:

These findings provide valuable real-world insights into the comparative performance of advanced systemic therapies for AD in a tertiary referral center. Such evidence is essential to complement data from clinical trials and to support clinicians in making informed decisions when selecting among available treatment options.



Abstract N°: 4914

Effectiveness and safety of lebrikizumab after switching from dupilumab in adult patients with moderate-to-severe atopic dermatitis involving the head and neck area

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Introduction & Objectives:

Atopic Dermatitis (AD) is a chronic inflammatory skin disease, often localized to the head and neck (H&N) area. These specific body regions can respond differently to topical or systemic therapy. Lebrikizumab (LEB) is a monoclonal antibody that binds to interleukin (IL)-13 with high affinity, blocking its effects. It has demonstrated clinical efficacy and safety in both adults and adolescents. A 16-week treatment with LEB significantly improved the Eczema Area and Severity Index (EASI) (H&N) in patients with moderate-to-severe AD, as shown in three randomized, placebo-controlled phase 3 trials. Herein, we report a sub-analysis of a retrospective, multicenter cohort study conducted across 29 Italian tertiary referral centers.

Materials & Methods:

This cohort includes 78 adult AD patients that underwent LEB 250mg every 2 weeks (LEBQ2W) monotherapy, with a 500 mg loading dose at baseline and week 2. They have been observed for 16 weeks. This sub-analysis includes 19 patients with AD involving the H&N area and previously treated with dupilumab. Switching to LEB was due to lost of efficacy (n=9), lack of efficacy (n=3), adverse events (4 due to conjunctivitis) and patient decision (n=3). Characteristics at baseline: mean age was 33.8 years old, EASI 22.3 and EASI H&N was 4.3. In addition, during the anamnesis 10 patients reported 1 or more comorbidities: asthma (n=6) and allergic rhinitis (n=7).

Results:

By week 4, among the 15 patients available for evaluation, the mean total EASI score had decreased to 10.2, and the H&N EASI score had declined to 1.7, representing a 60.5% improvement in the H&N region. At week 16, among the 11 patients still under evaluation, the mean total EASI score had further decreased to 2.8, while the H&N EASI score dropped to 0.8, corresponding to an overall improvement of 81.4% in the affected area. No adverse events were reported during the treatment period.

Conclusion:

This cohort of patients treated with lebrikizumab contributes to the growing body of evidence supporting its efficacy and safety in the AD management. The rapid onset of action, combined with sustained clinical improvement, highlights its therapeutic potential even in challenging cases involving the H&N region and in patients previously exposed to biologic therapies. Further research is needed to investigate the variability in clinical responses and to elucidate the underlying mechanisms driving these differences, with the ultimate goal of developing personalized treatment strategies.



Abstract N°: 4935

Real-world utilization and minimal disease activity achievement with upadacitinib in atopic dermatitis: interim analysis of the multicenter China P24-965 study

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Introduction & Objectives:

Upadacitinib (UPA) is an oral selective JAK inhibitor, approved for the treatment of patients with moderate to severe atopic dermatitis (AD). Real-world data on safety and efficacy of UPA are limited, especially in China. The minimal disease activity (MDA) concept from the AHEAD consensus recommendations is gradually adopted; MDA combines treat-to-target principles with patient / clinician shared decision-making principles. P24-965 study aims to characterize the real-world utilization patterns and effectiveness of UPA via achievement of MDA in adults and adolescents AD patients in clinical practice in China.

Materials & Methods:

P24-965 is an ongoing, observational, prospective study to assess the use of UPA in clinical practice among 1000 patients in 40 AD centers in China for 1 years. Adults and adolescents initially treated with UPA for AD are being enrolled. Primary outcomes included UPA utilization patterns, and important secondary outcomes included Eczema Area and Severity Index (EASI), Peak Pruritus Numeric Rating Scale (PP-NRS), while moderate and optimal targets per AHEAD consensus recommendations were regarded as exploratory outcomes. This interim analysis (data cutoff 14th Feb, 2025) reports baseline data and 3-month UPA utilization patterns and effectiveness data among patients who were enrolled at least 3 months by the data cutoff date or discontinued from the study.

Results:

304 patients were included in this interim analysis, of whom 61 (20.1%) were adolescent; the mean EASI was 20±12; the mean PP-NRS was 6±2. 5.6% patients had prior conventional systemic treatments, 1.0% had dupilumab and 0.3% had systemic JAK inhibitors other than UPA (Table 1).

The most common reasons for starting on UPA were 88.8% inadequate response and 0.7% intolerability to prior treatment; 297 (97.7%) patients started on UPA 15 mg. 282 (92.8%) remained on UPA at month 3. 3 (1.0%) patients received dose escalation of UPA within 3 months all for inadequate disease control, and 21 patients received dose tapering within which due to remission or disease stabilization (95.2%), and adverse events (4.8%) .

In month 3, EASI 75 or EASI <=7 was achieved in 84.7% patients, and EASI 90 or EASI <=3 in 39.8% patients. PP-NRS improvement >=4 was in 72.4% patients with baseline PP-NRS >=4, and PP-NRS 0/1 was 54.3% patients (Figure 1). As for selection of treatment outcomes for assessment, 78.3% dermatologists chose EASI as clinical

report outcome (ClinRO), and 54.3% chose SCORD and 43.1% chose IGA with BSA. 90.8% chose PP-NRS as patient report outcome (PRO) via share decision making with patients, and 74.0% chose POEM, 43.4% chose sleep NRS, 31.3% chose Hospital Anxiety and Depression Scale (HADS), 25.7% chose pain NRS and 43.4% chose DLQI (cDLQI for 12 to 17-year-old patients). 54.3% patients achieved moderate target in month 3, and 34.1 achieved optimal target.

The AE with reasonable possibility of being drug related, AE leading to discontinuation of study drug and SAE were low in this analysis (Table 2). Death was not observed.

Conclusion:

The results of this analysis indicate that UPA treatment can feasibly achieve moderate and high treatment clinical and patients targets in real-world settings in China AD patients, where most AD patients remained adhered to UPA after 3 months of initiation. Safety profile is consistent with the known safety profile of UPA with no new signals identified.

Table 1. Baseline Demographic and Disease Characteristics

Characteristic	Value
Age, median (IQR) years	31.0 (19.5-46.0)
12-17 years, n (%)	61 (20.1)
>=18 years, n (%)	243 (79.9)
Male, n (%)	157 (51.6)
BMI, median (IQR) kg/m^2	23.40 (21.20-25.40)
Healthcare insurance status, n (%)	
National Healthcare Insurance	288 (95.0)
Commercial Insurance	20 (6.6)
No Healthcare Insurance	13 (4.3)
Duration of AD symptoms, median (range) years	0 (0-36)
vIGA-AD, n (%)	
Moderate (3)	108(35.8)
Severe (4)	14(4.6)
EASI, mean (SD)	20 (12)
SCORAD, mean (SD)	57 (15)
PP-NRS, mean (SD)	6 (2)
POEM, mean (SD)	15 (7)
Sleep-NRS, mean (SD)	5 (3)
HADS-A, mean (SD)	7 (4)
HADS-D, mean (SD)	5 (3)
Pain-NRS, mean (SD)	4 (3)
(c)DLQI, mean (SD)[a]	13 (7)
Concomitant medication	
Topical treatments[b]	152 (50.0)
Conventional systemic treatments[c]	17 (5.6)
Dupilumab	3 (1.0)
Other JAK inhibitors[d]	1 (0.3)
AD-related treatment changes rationale	
Inadequate response	270 (88.8)
Intolerability	2 (0.7)
Other[e]	37 (12.2)

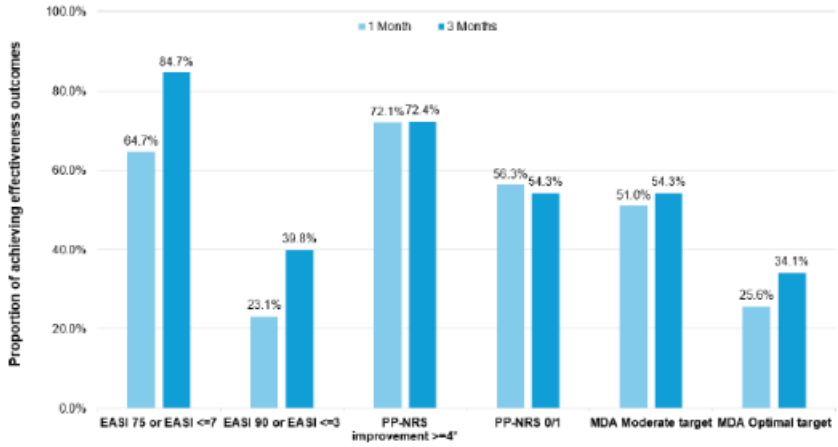
SD, standard deviation; BMI, body mass index; AD, atopic dermatitis; vIGA-AD, validated Investigator Global Assessment for Atopic Dermatitis; EASI, Eczema Area and Severity Index; SCORAD, Scoring Atopic Dermatitis; PP-NRS, Peak Pruritus Numeric Rating Scale; POEM, Patient Oriented Eczema Measurement; NRS, Numeric Rating Scale; DLQI, Dermatology Life Quality Index; ADCT, Atopic Dermatitis Control Tool.
[a]For patients from 12-16 years of age, cDLQI will be used. [b]Topical treatments include topical corticosteroids and topical calcineurin inhibitors. [c]Conventional systemic treatments include corticosteroids, cyclosporin A, tripterygium glycosides. [d]Include abrocitinib.

Table 2. Treatment-Emergent Adverse Events at Month 3

Events (E/100PY)	N=304, PYs=74.91
Any AE	70 (93.5)
SAE	1 (1.3)*
AE with reasonable possibility of being drug related	27 (36.0)
AE leading to discontinuation of study drug	11 (14.7)
AE leading to death	0

AE, Adverse Event; SAE, Serious Adverse Event. *Patients had paroxysmal atrial fibrillation onset after 48 days initialization of UPA, the patients is still on UPA without discontinuation.

Figure 1. Effectiveness of UPA at Month 1 and Month 3



EASI, Eczema Area and Severity Index; PP-NRS, Peak Pruritus Numeric Rating Scale; MDA, Minimal Disease Activity
*For those participants with baseline PP-NRS >=4.
MDA moderate / optimal target is defined as achieving every moderate / optimal target through patient/clinician shared decision-making principles at baseline, of which the criteria are defined in AHEAD consensus recommendations[2].



Abstract N°: 5018

Recalcitrant Atopic Dermatitis: Switch from Tralokinumab to Lebrikizumab

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Introduction: Atopic dermatitis (AD) is a chronic inflammatory disease primarily mediated by the Th2 immune pathway, in which interleukin 13 (IL-13) plays a key role in its pathophysiology. Monoclonal antibodies that selectively target this cytokine, such as lebrikizumab and tralokinumab, have emerged as targeted therapeutic options. Although both share the same molecular target, they present different mechanisms of action, which may influence clinical response.

Case Report: We present the case of a 17-year-old female, with no relevant medical history, diagnosed with atopic dermatitis for over five years. The patient had shown resistance to multiple topical treatments (corticosteroids, calcineurin inhibitors, antibiotics) and systemic therapies (cyclosporine).

Due to poor disease control, and with baseline scores of EASI 21, IGA 4, sleep NRS 5, itch NRS 7, and DLQI 9, standard-dose tralokinumab was initiated in June 2024, along with a gradual tapering of cyclosporine. After five months, primary therapeutic failure was observed, with less than 25% improvement in EASI. Consequently, treatment was switched to lebrikizumab in January 2025, administered following SmPC (subcutaneously, starting with dose of 500 mg at weeks 0 and 2, followed by 250 mg every two weeks until week 16, then 250 mg monthly).

At 6 weeks, a marked clinical improvement was observed, with an EASI of 6,2. Other outcome measures also improved significantly: IGA 1, sleep NRS 0, itch NRS 3, and DLQI 1.

Discussion: Lebrikizumab is a humanized monoclonal antibody (IgG4) that binds with high affinity to IL-13 and selectively inhibits its signaling through the blockage of the heterodimerization of subunits IL-4Rα and IL-13Rα1 of Type 2 receptor. Its binding epitope of IL-13 differs from 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. Its differential mechanism of action together with its high affinity binding to IL-13 may explain its efficacy in patients who do not respond to other IL-13 inhibitors.

Recently, Hagino et al. published the first case series involving 13 patients who switched from tralokinumab to lebrikizumab, observing a favorable clinical response at weeks 4, 12, and 16.

Conclusion: We present a case of recalcitrant atopic dermatitis with a rapid and well-tolerated clinical response to lebrikizumab after switching from tralokinumab. This case supports the use of lebrikizumab as an effective alternative in selected patients.



Abstract N°: 5054

Genetically proxied inhibition of lipid pathways and risk of atopic dermatitis: a multi-ancestry Mendelian randomisation study

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Introduction & Objectives:

Cholesterol-lowering therapies have been associated with the risk of atopic dermatitis (AD) in observational studies, but their causal role across different ancestries remains unclear. This study aimed to evaluate the impact of genetically proxied inhibition of lipid-lowering targets; HMG-CoA reductase (HMGCR), Niemann-Pick C1-Like 1 (NPC1L1), Proprotein convertase subtilisin/kexin type 9 (PCSK9), and Cholesteryl ester transfer protein (CETP) on the risk of AD across European (EUR), East Asian (EAS), and African (AFR) populations.

Materials & Methods:

We applied drug-target Mendelian Randomisation (MR) approach using single nucleotide polymorphisms (SNPs) within or near the *HMGCR*, *NPC1L1*, *PCSK9*, and *CETP* genes to proxy the therapeutic perturbation of each lipid lowering drug/class: statins, ezetimibe, PCSK9, and CETP inhibitors respectively. Genetic association data for AD were obtained from 60,653 cases and 804,329 controls of EUR ancestry, supplemented by data from FinnGen (31,245/432,874), EAS (2,385/209,651), and AFR (7,063/15,879) populations. Genetic variants strongly associated with cholesterol traits were obtained from the Global Lipid Genetics Consortium which includes data from 1,320,016 individuals of EUR, 146,492 of EAS, and 99,432 of admixed AFR ancestry. Fixed-effect inverse-variance weighted analysis was used to estimate the effect for each drug-target then pooled across ancestries. We applied colocalisation analysis to test for genetic confounding by linkage disequlibrium (LD) and examined potential pleiotropy using MR-Egger.

Results:

Genetically proxied HMGCR inhibition was not associated with AD risk across ancestries. NPC1L1 inhibition was associated with increased AD risk in EUR (OR=1.32; 95%CI=1.02–1.70 per SD reduction in total cholesterol), but reduced AD risk in AFR population (OR=0.18; 95%CI=0.05–0.65 per SD LDL reduction). PCSK9 inhibition lowered AD risk in EUR (OR=0.91; 95%CI=0.85–0.97 per SD LDL reduction), while increased risk was observed among EAS population (OR=1.38; 95%CI=0.78-2.42) though not statistically significant. CETP inhibition was associated with low risk of AD in EUR and AFR individuals through reduction in LDL (OR=0.62; 95%CI=0.46-0.84) and non-HDL (OR=0.84; 95%CI=0.75-0.94), however, total cholesterol reduction via CETP inhibition was associated with a fourfold increased AD risk in AFR population (OR=4.63; 95%CI=2.31–9.30). Colocalisation analyses suggested no evidence of genetic confounding by LD in the AFR ancestry, however, other analyses were underpowered. There was no statistical evidence of horizontal pleiotropy.

Conclusion:

Genetic proxies for cholesterol pathway inhibition suggest ancestry-specific association with AD. Genetically predicted cholesterol reduction via NPC1L1 inhibition was associated with an increased risk of AD in EUR population, but a decreased risk in AFR population. PCSK9** inhibition was associated with reduced AD risk among EUR. CETP inhibition, although protective in some contexts, was associated with an increased AD risk in AFR ancestry group. These findings underscore the need for further investigation through triangulation with clinical trial data or real-world evidence to better understand ancestry-specific effects and their implications.



Abstract N°: 5070

PKM2 is a promising novel target in atopic dermatitis

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PKM2 is a promising novel target in atopic dermatitis

Introduction & Objectives:

Atopic dermatitis (AD) is a complex, chronic inflammatory, non-contagious skin disease with high unmet need and no curative treatment options. Pyruvate kinase M2 (PKM2) is a key enzyme in the central metabolic pathway of glycolysis and is specifically upregulated in inflammatory tissues. Here we describe PKM2 as a novel target in AD and demonstrate efficacy of novel PKM2 modulators in several mouse models of inflammatory skin disease: KLH-induced delayed-type hypersensitivity (DTH), 2,4 dinitrofluorobenzene (DNFB) and oxazolone induced contact dermatitis models. A PKM2 modulator has recently entered into a clinical trial for AD.

Materials & Methods:

PKM2 expression was studied in human healthy skin and AD skin using immunohistochemistry and RNA sequencing. The *in vitro* pharmacology of PKM2 modulators was studied using biochemical assays and pyruvate kinase activity in human CD4+ T cells. The *in vivo* pharmacology of PKM2 modulators was determined in 3 murine models. DNFB or oxazolone were used to induce contact dermatitis and KLH was used to induce DTH. Efficacy was measured using ear thickness, excoriations, ear RNA sequencing or ear Luminex (IL-1β, IL-4, IL-6, IL-13, IFNγ, IL-17a, IL-31).

Results:

PKM2 was overexpressed in the immune cell infiltrate and in keratinocytes in severe lesional atopic dermatitis compared to healthy skin. Similarly, PKM gene expression was elevated in AD biopsies, notably in chronic lesions. As a potential AD therapeutic, novel, small molecule PKM2 modulators were shown to potently activate human and mouse PKM2 enzymes. Pyruvate kinase activity was also observed in lysates from human CD4+ T cells pre-treated with these compounds. In the DNFB model, PKM2 modulators resulted in a significant decrease in ear thickness, a surrogate for inflammation, and were accompanied by decreases in ear IL-13, IL-17A and IL-6 and decreases in chemokine gene expression. Similarly, there was a decrease in IL-31, a cytokine associated with itch. PKM2 modulation also normalised expression of genes required for barrier function, including filaggrin, loricrin and involucrin. A decrease in ear thickness was also observed in the oxazolone model, accompanied by a decrease in skin excoriations, consistent with itch reduction. Similarly, PKM2 modulators decreased ear thickness in the KLH model.

Conclusion:

PKM2 modulation offers an oral, targeted, disease-modifying anti-inflammatory approach, targeting a critical enzyme that regulates cell metabolism. The proposed mechanism of action is believed to have targeted effects at sites of inflammation, enabling a differentiated safety profile. The studies show that a novel PKM2 modulator

inhibits both inflammation and itch, whilst promoting skin barrier repair. This modulator has recently entered clinical trials in healthy volunteers and patients with moderate to severe AD. This PKM2 modulator could address the major unmet needs of AD as a safe oral, convenient and effective therapy where there are limited treatment options under the current standard of care.

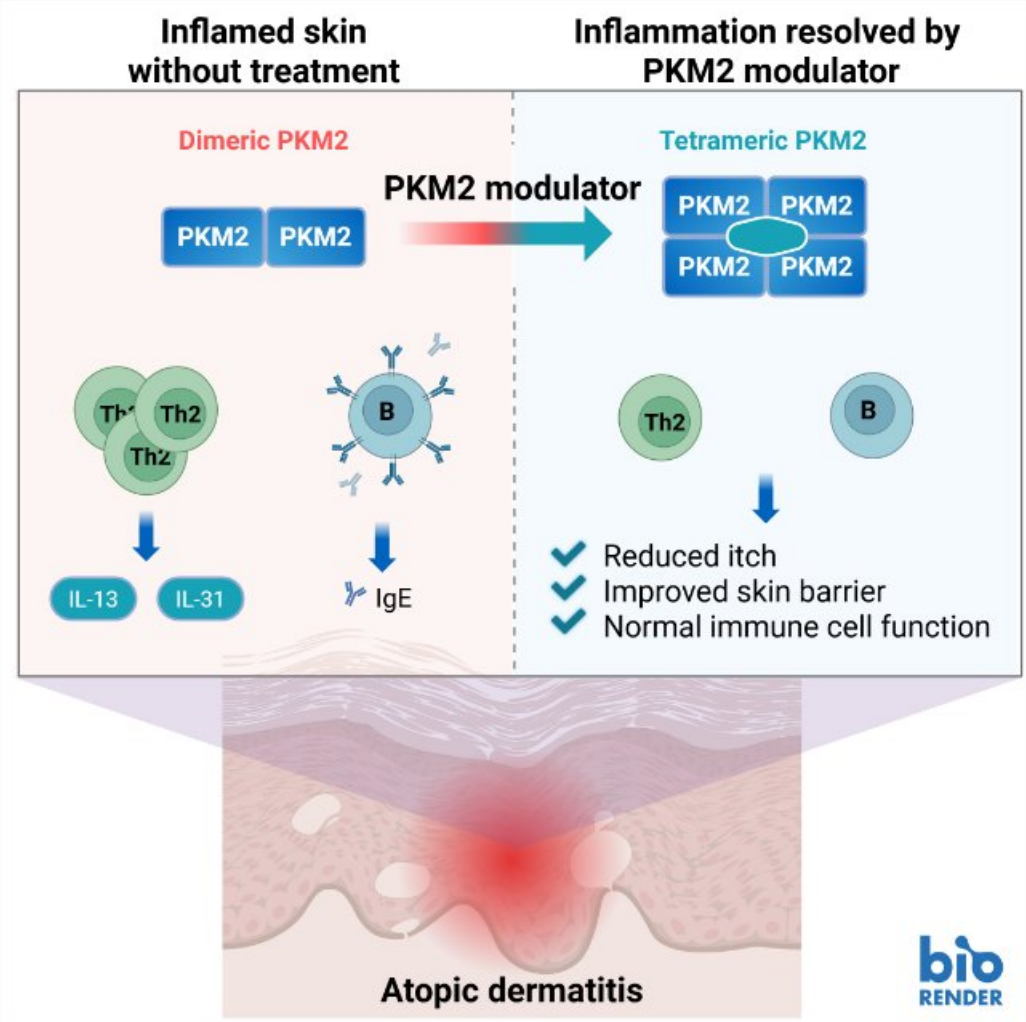


Figure – Resolution of inflammation in atopic dermatitis with a PKM2 modulator



Abstract N°: 5133

Serine determines tissue targeted efficacy of PKM2 modulators in atopic dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) is a complex, chronic inflammatory, non-contagious skin disease with high unmet need and no curative treatment options. Elevation of serine synthesis enzymes and transporters have previously been described in psoriatic tissues, presenting a potential metabolic vulnerability for therapeutic intervention (Cappello et al., 2022). This study demonstrates that serine is also limiting in AD skin, accompanied by elevation of serine synthesis enzymes and transporters. Furthermore, Th2 cells and IgE-expressing B cells play a crucial role in the pathogenesis of AD and these cell types require serine for proliferation and inflammatory responses (D'Avola et al., 2022; Ma et al., 2017). This study describes a novel therapeutic approach to exploit serine limitation in inflammatory tissues by small molecule modulation of a key glycolytic enzyme, pyruvate kinase M2 (PKM2), resulting in anti-inflammatory activity in human Th2 cells and IgE-expressing B cells.

Materials & Methods:

Gene expression and metabolite profiles were studied in human skin from AD patients and human cells using RNA sequencing and metabolomics, respectively. Human Th2 and B cell assays were performed in RPMI media containing 100 µM serine or 10 µM serine. Proliferation and expression of cell surface markers, CD20, CD27 and CD38 were assessed using flow cytometry. Release of IL-13, IL-31, IgG or IgE were measured using Homogeneous Time Resolved Fluorescence (HTRF) or Meso Scale Diagnostics (MSD) assays. The *in vivo* pharmacology of PKM2 modulators was determined in the 2,4 dinitrofluorobenzene (DNFB) contact dermatitis model.

Results:

Differentially regulated metabolites and metabolic genes were characterised in AD skin, healthy skin, DNFB skin and human CD4 T cells. Serine was decreased in AD skin compared to healthy, with a corresponding increase in serine synthesis enzymes and transporters. When Th2 cells were cultured in serine limited conditions, a PKM2 modulator inhibited Th2 cell proliferation and release of IL-13 and IL-31. Similarly, when B cells were cultured in serine limited conditions, PKM2 modulation inhibited release of IgE or IgG. These anti-inflammatory effects of PKM2 modulation were caused by channeling of the glycolytic intermediate, 3-phosphoglycerate towards pyruvate production, reducing carbon flux through serine biosynthesis.

Conclusion:

Serine limitation in AD is characterised by by high expression of serine biosynthesis genes and transporters. This presents a potential metabolic vulnerability for therapeutic intervention with a novel PKM2 modulator that inhibits Th2 and IgE-releasing B cells in serine limited conditions. The tissue-targeted efficacy of PKM2 modulation at AD inflammatory sites enables a differentiated safety profile. This oral PKM2 modulator has recently entered clinical trials in healthy volunteers and patients with moderate to severe AD. It could address the major unmet needs of AD as a safe, convenient and effective therapy where there are limited treatment options under the current

standard of care.

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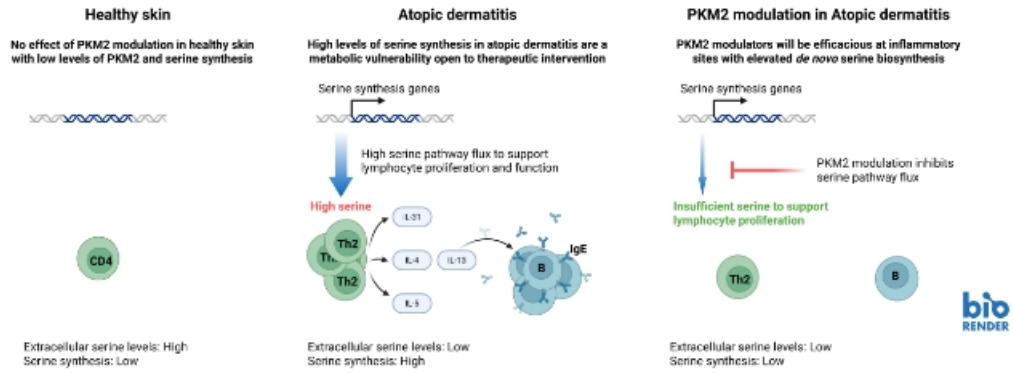


Figure - Serine determines tissue targeted efficacy of PKM2 modulators in atopic dermatitis

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Abstract N°: 5206

Prevalence of Sleep Disorders In Patients with Atopic Dermatitis at Cu Chi Regional General Hospital

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Introduction & Objectives:

Atopic dermatitis is a common chronic skin condition characterized by persistent itching and frequent relapses, significantly affecting patients' quality of life. One often-overlooked issue in this population is sleep disturbance, which can exacerbate dermatological symptoms and negatively impact mental health. This study aims to determine the prevalence of sleep disorders (SD) among patients with atopic dermatitis (AD) and to describe related clinical features at Cu Chi Regional General Hospital in 2024.

Materials & Methods:

A descriptive cross-sectional study was conducted on 100 adult AD patients at the Dermatology Clinic of Cu Chi Regional General Hospital from May to August 2024. Data were collected via structured interviews and questionnaires. The SCORAD index was used to assess AD severity, and the Pittsburgh Sleep Quality Index (PSQI) was employed to evaluate sleep quality.

Results:

The prevalence of sleep disorders among AD patients was 42%, with most patients experiencing moderate to severe sleep disturbances (Table 1). A significant association was found between PSQI scores and clinical parameters, including SCORAD severity (Table 2) and itch intensity (5-D itch scale) (Table 3). Sleep disturbance was closely linked to pruritus and nocturnal discomfort.

Conclusion:

Sleep disorders are common in patients with atopic dermatitis and are significantly associated with pruritus severity and disease extent. Early identification and integrated management of sleep disturbances should be considered in the holistic care of AD patients.

Severity of sleep disturbances according to the PSQI score	N (%)
None	26
Mild	32
Moderate	26
Severe	16

Table 1. Severity of sleep disturbances in patients with atopic dermatitis according to the PSQI score

	OR	95% CI	p
SCORAD (per 1-point increase)	1.075	1.026 - 1.126	0.002

Table 2. The correlation between SCORAD score and sleep disturbance according to PSQI

Severity of atopic dermatitis according to SCORAD	Sleep disturbance according to PSQI	p
	Yes (74)	No (26)
Mild (10)	N	4
	%	5.4
Moderate (68)	N	51
	%	68.9
Severe (22)	N	19
	%	25.7

Table 3. The association between atopic dermatitis severity according to SCORAD and sleep disturbance according to PSQI

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Abstract N°: 5331

Potent and Selective Oral STAT6 Degrader, KT-621, Inhibits IL-4 and IL-13 Functions in Human Cells and Blocks Th2 Inflammation In Vivo in Multiple Preclinical Models of Th2 Diseases

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Introduction & Objectives:

STAT6 is an essential transcription factor in the IL-4/IL-13 signaling pathways and the central driver of Th2 inflammation in allergic diseases. Multiple gain of function mutations of STAT6 have been identified to cause severe atopic/allergic diseases in humans. Dupilumab, an injectable monoclonal antibody that blocks IL-4/IL-13 signaling, is an approved therapy for multiple atopic/allergic diseases therefore targeting STAT6 in these diseases is supported by both human genetics and dupilumab's clinical activity. STAT6 functions through protein-protein and protein-DNA interactions. It has been challenging to selectively and potently inhibit STAT6 with traditional small molecule inhibitors. However, STAT6 is well suited for a novel targeted protein degradation approach, where a single binding event is sufficient to drive degradation of the protein and fully block its functions.

Materials & Methods:

We have developed a highly potent, selective, orally administered heterobifunctional degrader of STAT6, KT-621, and assessed functions in disease-relevant human primary immune and tissue cells *in vitro*. KT-621 was assessed *in vivo* across multiple preclinical species for STAT6 degradation. We compared the efficacy of KT-621 to dupilumab *in vivo* in an MC903 induced atopic dermatitis model and a HDM induced asthma model in the IL-4/IL-4RA humanized mice with a prophylactic regimen. Additionally, we tested KT-621 in an HDM-induced asthma model with a treatment regimen where the disease was established prior to KT-621 treatment.

Results:

KT-621 potently and selectively degraded STAT6 in various disease relevant human primary cells including lymphocytes, myeloid cells, epithelial cells, smooth muscle cells, and vascular endothelial cells. As a result of STAT6 degradation, KT-621 fully blocked various IL-4/IL-13 functions in these cells with low picomolar potencies comparable or numerically superior to dupilumab and did not degrade or inhibit any other STAT transcription factors or other proteins. In addition, KT-621 showed potent STAT6 degradation and IL-4/IL-13 functional inhibition in human whole blood. At low oral doses, KT-621 demonstrated deep *in vivo* STAT6 degradation, suppressed Th2 biomarkers, and was well-tolerated in multiple preclinical studies. In the MC903-induced atopic dermatitis mouse model, orally administered KT-621 demonstrated robust degradation of STAT6 *in vivo* and marked reduction of total serum IgE comparable to the activity of an IL-4Rα saturating dose of dupilumab. In the HDM induced asthma model, orally administered KT-621 demonstrated similar robust degradation and reduced all cytokine, cell infiltration, and disease severity readouts in the lung and bronchoalveolar lavage fluid comparable or superior to the IL-4Rα saturating dose of dupilumab. Furthermore, in the HDM-induced asthma model with a treatment regimen, KT-621 administered orally after disease establishment not only fully prevented disease progression with continuous HDM stimulation but also reversed pre-established disease.

Conclusion:

STAT6 degradation is a potential novel oral approach for blocking the IL-4/IL-13 pathways. These data

demonstrate the potential of KT-621, the first STAT6-targeted medicine in clinical development, for the treatment of atopic dermatitis and other allergic diseases with best-in-pathway potential given its biologics-like activity profile and oral bioavailability.



Abstract N°: 5343

Burden of Chronic Hand Eczema (CHE) in France Using the French Nationwide Claims Database

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Introduction & Objectives:

CHE is a dermatological disease that significantly impacts patients' quality of life and professional activity. Despite its high prevalence, data on its economic impact remain limited. The main objective was to assess the economic impact of CHE using the French Nationwide claims database (SNDS). One of the secondary objectives was to delve deeper into the patient care pathway, focusing on the use of medications for anxiety, depression, and sleep disorders. A post-hoc analysis explored the use of topical corticosteroids (TCS).

Materials & Methods:

Observational cohort study of CHE patients identified using the SNDS between 2017 and 2021, which included two groups: i) Alitretinoin CHE group: patients with at least one alitretinoin dispensing (first dispensing as index date); ii) Algorithm-based CHE group: patients identified using an algorithm combining sick leave in high-risk professions (medical sector; butchery, food industry and catering; print shop; hair and beauty care; traditional and industrial bakeries; construction/building; cleaning activity; maintenance and repair of motor vehicles), and concomitant dispensing of potent TCS, ciclosporin, topical tacrolimus, antihistamines, oral alitretinoin, or methotrexate (first sick leave as index date). Each group was matched (1:4) with controls from the general population on age, sex, and city, after assigning the same calendar index date as the matched case. Cost analysis from the payer perspective (including consultations, drug dispensation, sick leave, hospitalizations, thermal therapy, phototherapy sessions) compared the healthcare expenditures between cases and controls using univariate analysis of variance (ANOVA).

Results:

A total of 23,906 CHE patients (11,150 Alitretinoin CHE and 12,756 Algorithm CHE) were matched with 88,358 controls and followed for mean periods of 3.7 and 3.6 years, respectively.

In each group, 51% were men, with a mean age of 45 years at the index date.

General practitioners were the primary healthcare professionals involved in the patient care pathway, with CHE patients consulting them on average 7 times per year versus 4 times for the control group. Specialist visits were rare. A similar pattern was noted in Alitretinoin CHE patients.

During the follow-up period, mean total annual cost was 2 times higher in CHE patients than in controls (3878€ vs. 1879€, $p<0.0001$). After the exclusion of sick leave, which was one criterion used to define CHE patients in the algorithm, it remained almost 2 times higher. Individual expenditures were also significantly higher in CHE patients ($p<0.0001$), with drug dispensing costs 3 times higher (989€ vs. 330€) and consultation costs doubled (189€ vs. 98€).

CHE patients had an average sick leave duration of 37 days per year, controls 11 days, and 13 days for Alitretinoin CHE patients specifically. In CHE patients, there was a higher frequency of anxiety and depression medication dispensing versus controls (48% vs. 33%). This was also observed for sleep disorders medications, though to a lesser extent (14% vs. 9%). 91% of CHE patients underwent at least 3 treatment cycles with potent or very potent TCS, each cycle averaging 48 days.

Conclusion:

This study highlights the CHE burden with a significant extra cost and impact on patients' professional activity and mental health. Moreover, these results demonstrate the need for alternatives to repeated, prolonged use of TCS in CHE and for the adoption of holistic treatment approaches.



Abstract N°: 5373

Flex-Up Study: Evidence of Residual Inflammation Persists in Patients Who Do Not Achieve or Maintain a High Treatment Target in Atopic Dermatitis

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by eczematous lesions and intense pruritus. Upadacitinib (UPA), a selective oral Janus kinase inhibitor, has shown efficacy in treating moderate-to-severe AD, with both the 15mg and 30mg doses being approved for use. The phase 3b/4 Flex Up study is designed to address a critical evidence gap to provide descriptive data on the efficacy and safety of dose escalation and dose reduction based on patients' achievement of an optimal clinical target. To gain a mechanistic understanding of how dose escalation and dose reduction can drive achievement and maintenance of high treatment targets, serum disease biomarkers and circulating absolute eosinophil counts (AEC) were assessed.

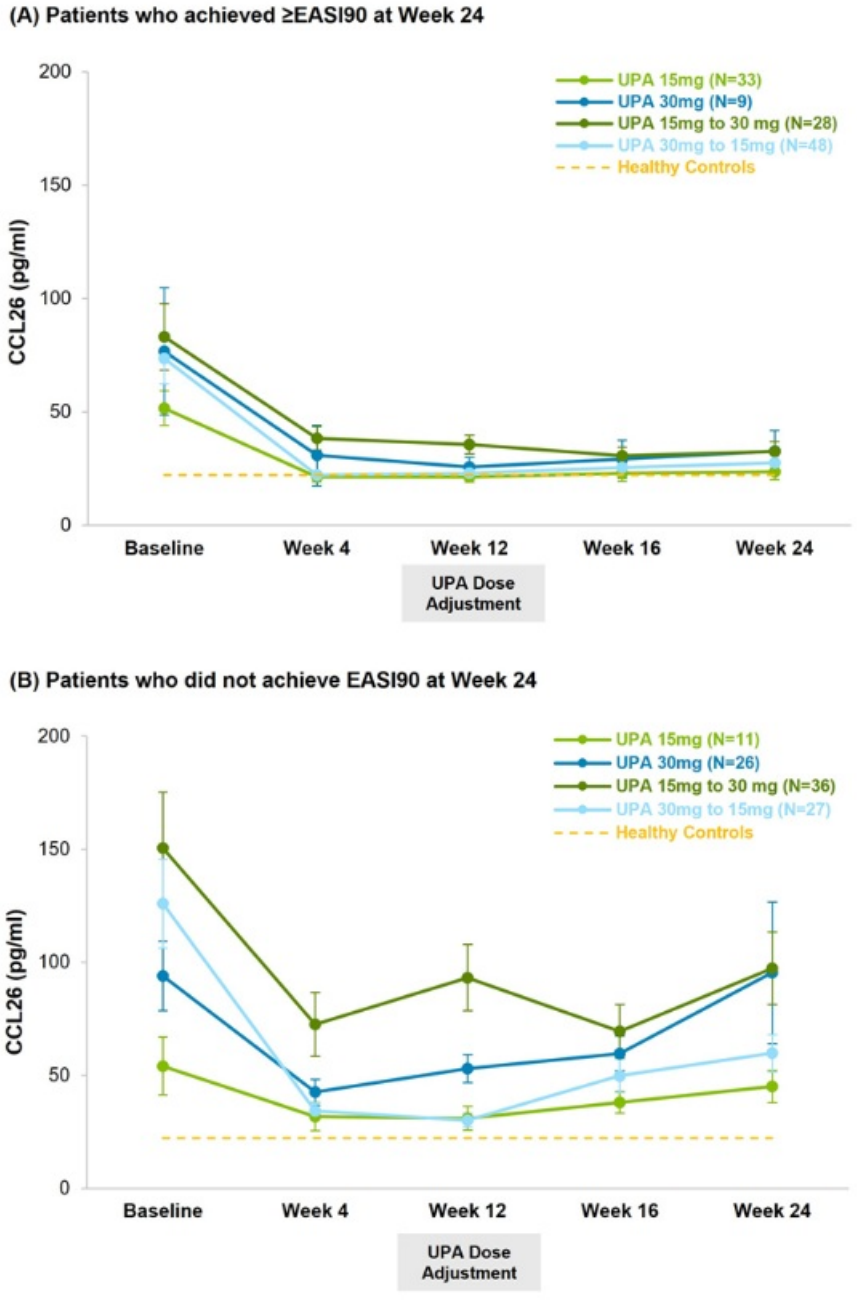
Materials & Methods: Patients were randomized 1:1 to receive UPA 15mg or UPA 30mg daily, during a 12-week double-blind period, followed by an additional 12 week single-blind period. At Week 12, UPA 15mg patients who did not achieve an ≥90% improvement in Eczema Area and Severity Index score (EASI90) were dose-escalated to UPA 30mg, while those achieving EASI90 continued on UPA 15mg. Patients in the UPA 30mg group continued on UPA 30mg if they did not achieve EASI90 or were dose-reduced to UPA 15mg if ≥EASI90 was achieved. Disease-associated inflammatory proteins (CCL17, CCL18, CCL22, CCL26, IL-22, BD2) and circulating AEC were analyzed using samples collected from baseline through Week 24.

Results: Samples from 230 of the 461 patients in the Flex Up study were utilized for biomarker analysis (UPA 15, N=112; UPA 30, N=118) and plotted against biomarker data from healthy controls (healthy control serum samples purchased from Discovery Life Sciences). Demographics were consistent between the current biomarker cohort and the clinical study cohort. At Week 24, patients achieving EASI90 demonstrated a decrease in inflammatory proteins to healthy control levels, whereas levels remained elevated compared to healthy controls in patients who did not achieve EASI90. At week 12, patients dose escalated from UPA 15mg to UPA 30mg had higher baseline inflammatory protein levels compared to those achieving ≥EASI90 without escalation. Similarly, patients dose reduced from UPA 30mg to UPA 15mg that failed to maintain an EASI90 response at Week 24 also had elevated baseline inflammatory protein levels. Patients achieving ≥EASI90 had reductions in AEC approaching healthy control levels after treatment, while AEC remained elevated in patients who did not achieve EASI90 at Week 24. There was an association between all baseline inflammatory protein biomarker values and baseline EASI scores, and between inflammatory protein biomarker values and EASI scores at Week 24.

Conclusion: The analysis of disease-associated biomarkers provides a mechanistic rationale for why some patients with moderate-to-severe AD require UPA 30mg to achieve and sustain high treatment targets such as EASI90. Patients not achieving EASI90 at Week 24 exhibited signs of persistent inflammation, regardless of their starting

dose or dose adjustments made at Week 12. Patients with higher baseline inflammatory protein levels may particularly benefit from a UPA 30mg to achieve and sustain an EASI90 response, suggesting that a 30mg dose may be necessary for optimal efficacy in these individuals. Combined with clinical efficacy results, these data provide evidence to guide clinical practice in personalization of moderate-to-severe AD management.

Figure 1. (A) Patients who achieved ≥EASI90 had reductions in disease-associated biomarkers approaching healthy control levels, while (B) patients who did not achieve EASI90 at Week 24 had evidence of persistent inflammation regardless of starting dose or dose adjustment at Week 12.





Abstract N°: 5385

Efficacy of Upadacitinib vs Dupilumab Treatment for Moderate to Severe Atopic Dermatitis: Analysis of Time Spent in Response State from the Level Up Study

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Introduction & Objectives: Atopic dermatitis (AD) is chronic, inflammatory skin disease characterized by intense pruritus and skin lesions. Time spent with symptoms of AD can be debilitating, resulting in negative impacts on quality of life. Upadacitinib (UPA), a selective oral Janus kinase (JAK) inhibitor, and dupilumab (DUPI), a monoclonal antibody targeting interleukin-4Rα, are both treatments approved for patients with moderate-to-severe AD. Results from a phase 3b/4 trial (Level Up NCT05601882) indicated that UPA was superior to DUPI in simultaneously achieving the stringent endpoints of Eczema Area and Severity Index (EASI) improvement of ≥90% from baseline (EASI 90) and a Worst Pruritus Numerical Rating Scale score of 0/1 (WP-NRS 0/1) at Week 16. In this post-hoc analysis, we analyzed the median time (days) spent in response states based on EASI 90 and/or WP-NRS 0/1 in patients either receiving UPA or DUPI over a 16-week period.

Materials & Methods: The Level Up study was a phase 3b/4 head-to-head global, randomized, open-label, efficacy assessor blinded, multicenter study comparing UPA vs DUPI in adolescents and adults with moderate-to-severe AD. Patients were randomized to UPA 15 mg or DUPI per its label for 16 weeks of treatment. Patients on UPA 15 mg were dose-escalated to 30 mg starting at Week 4 if they had a <EASI 50 response, or a <4-point WP-NRS improvement from baseline. Patients taking UPA 15 mg who did not achieve EASI 75 starting at Week 8 similarly had their dose increased to 30 mg. Starting at Week 4, rescue with topical therapy was optional and per investigator's discretion if protocol criteria were met. The current analyses assessed the number and proportion of days patients spent with clear or nearly-clear skin (EASI 90) and/or no/minimal itch (WP-NRS 0/1), with comparisons made at the median (50th percentile) and upper quartile (75th percentile). Missing data at study visits were imputed using non-responder imputation with multiple imputation.

Results: Participants included 458 patients receiving UPA and 462 receiving DUPI. Cumulatively over a course of 16 weeks, patients taking UPA vs DUPI spent a greater number of days at EASI 90 and WP-NRS 0/1. Over 16 weeks (112 days), 1 in 2 patients (ie, median or 50th-percentile) spent at least 28.0 days at EASI 90 with UPA vs 0 days with DUPI, while 1 in 4 patients spent at least 64.4 days with UPA vs 25.7 days with DUPI. For days at WP-NRS 0/1 with UPA vs DUPI, 1 in 2 patients spent at least 11.3 vs 0.4 days with no/minimal itch respectively; and 1 in 4

patients (ie, upper quartile or 75th-percentile) spent at least 57.2 vs 17.0 days with UPA vs DUPI, respectively. Similar patterns were observed in the number of days simultaneously achieving both EASI 90 and WP-NRS 0/1, as well the proportion of days spent in these responses.

Conclusion: Treatment of moderate-to-severe AD with UPA per label resulted in a greater number or proportion of days spent with EASI 90 and/or WP-NRS 0/1 compared with DUPI over 16 weeks. These results highlight differences in lived day-to-day skin disease and itch symptom burden over the course of treatment and can be used to inform shared decision-making discussions between patients and physicians.

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Abstract N°: 5416

Real-World EASI Component Outcomes in Children Receiving Systemic Therapies for up to 4 Years (PEDISTAD Study)

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Introduction & Objectives: Long-term dupilumab treatment in children and infants with moderate-to-severe atopic dermatitis (AD) has shown sustained efficacy in the reduction of signs and symptoms. Here, we report the long-term effect of systemic treatments on the Eczema Area and Severity Index (EASI) individual components.

Materials & Methods: PEDISTAD (NCT03687359) is an ongoing, international, longitudinal, observational 10-year registry study in children <12 years at enrolment with moderate-to-severe AD. In this 4-year interim analysis, the long-term effect of dupilumab, methotrexate, and cyclosporine on mean head and neck, trunk, lower extremities, and upper extremities EASI component scores at therapy start and last observation are reported. Safety (exposure-adjusted adverse event rates per 100 patient-years) and cumulative discontinuation rates were also evaluated. All analyses are descriptive.

Results: Over a 4-year period, 254, 136, and 145 patients received dupilumab, methotrexate, and cyclosporine, respectively. The mean (standard error [SE]) treatment duration for patients receiving dupilumab, methotrexate, and cyclosporine was 27.3 (0.9), 28.1 (1.6), and 19.5 (1.4) months. The first and last observation mean (SE) scores for patients receiving dupilumab, methotrexate, and cyclosporine for the head and neck component were 2.0 (0.1) and 0.6 (0.1), 2.0 (0.2) and 0.7 (0.1), 2.3 (0.2) and 1.5 (0.2), respectively; for the trunk component were 4.6 (0.3) and 1.1 (0.2), 4.1 (0.3) and 1.9 (0.3), 4.7 (0.3) and 3.5 (0.4), respectively; for the lower extremities component were 8.2 (0.4) and 2.2 (0.2), 7.2 (0.5) and 3.9 (0.4), 7.9 (0.5) and 5.5 (0.5), respectively; and for the upper extremities component were 4.5 (0.2) and 1.3 (0.1), 3.9 (0.2) and 2.0 (0.2), 4.2 (0.2) and 2.9 (0.3), respectively. The exposure-adjusted adverse event rates per 100 patient-years for patients receiving dupilumab, methotrexate, and cyclosporine were 29.2, 31.2, and 40.9, respectively. The respective discontinuation rates were 14.9%, 45.7%, and 63.7%.

Conclusion: Patients who received dupilumab had a numerically greater improvement in EASI component scores, lower exposure-adjusted adverse event rates, and lower discontinuation rates compared with patients who

received methotrexate or cyclosporine.

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Abstract N°: 5449

Matching-Adjusted Indirect Comparison of the Efficacy at week 12 of Delgocitinib and topical PUVA in the treatment of Severe Chronic Hand Eczema

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Introduction & Objectives:

Chronic Hand Eczema (CHE) is a persistent, inflammatory skin disease affecting the hands and wrists, characterised by key symptoms of itch and pain, together with signs such as erythema, scaling, fissures and vesiculation. Current therapies, including topical corticosteroids, phototherapy (including psoralen ultraviolet A [PUVA]), and alitretinoin (approved for severe CHE in Europe, Canada, Israel and South Korea), may be hindered by side effects and poor patient adherence. Delgocitinib, a topical pan-JAK inhibitor cream approved in the EU, UK, Switzerland, and UAE for moderate to severe CHE (Anzupgo cream 20mg/g LEO Pharma A/S 2%), offers an alternative treatment option which has demonstrated significant efficacy in the Phase 3 DELTA FORCE trial versus oral alitretinoin for the treatment of severe CHE (ClinicalTrial.gov ID NCT05259722).

There are currently no head-to-head trials comparing topical delgocitinib to PUVA. However, recent efficacy data from the Phase 3 ALPHA trial (ISRCTN ID 80206075), which evaluated PUVA versus alitretinoin in combination with as required topical corticosteroids (TCS), enabled a matching-adjusted indirect comparison (MAIC) to assess the efficacy of delgocitinib cream alone versus PUVA ± TCS in treating severe CHE.

Materials & Methods:

An anchored MAIC was conducted to indirectly compare delgocitinib to PUVA ± TCS using individual patient data (IPD) from the DELTA FORCE trial and aggregate data from the ALPHA trial, via their common alitretinoin "anchor" comparator.

IPD from DELTA FORCE were reweighted to match the following ALPHA trial baseline characteristics: sex, race (white: yes/no), mean age and mean HECSI at baseline. For the analysis of DLQI, patients were also matched on mean DLQI at baseline. After matching, outcomes assessed at week 12 included PGA/IGA-CHE score of 0/1, HECSI change from baseline (CFB), and DLQI CFB. The primary outcome assumed equivalence between the PGA used in the ALPHA trial and IGA-CHE in the DELTA Force trial to allow comparative analysis of delgocitinib versus PUVA ±

TCS.

Results:

Across all assessed endpoints at week 12, delgocitinib demonstrated greater efficacy than PUVA ± TCS. Patients treated with delgocitinib were statistically significantly more likely to achieve a PGA/IGA-CHE score of 0/1 compared to those treated with PUVA ± TCS (odds ratio [OR] = 2.5; 95% confidence interval [CI]: 1.3, 4.9; p = 0.009). Patients treated with delgocitinib experienced a statistically significantly greater reduction in HECSI score CFB at week 12 compared to those treated with PUVA ± TCS (Difference [Diff] = -13.4; 95% CI: - 24.3, -2.4; p = 0.017). Similarly, delgocitinib led to a significantly greater reduction in DLQI score from baseline to week 12 compared to PUVA ± TCS (Diff = -2.3; 95% CI: -4.1, -0.6; p= 0.008).

Conclusion:

The results of this MAIC analysis demonstrate that treatment with delgocitinib significantly improves both clinical and quality-of-life outcomes compared to PUVA plus as required TCS in severe CHE at week 12, including PGA/IGA-CHE, HECSI, and DLQI. These findings support delgocitinib as a highly efficacious and accessible alternative to PUVA ± TCS for managing severe CHE. As a topical treatment, delgocitinib also offers a more convenient alternative to PUVA based treatment, reducing the need for frequent clinic visits, alongside offering a favourable tolerability and safety profile.



Abstract N°: 5451

Sustained Improvement in Atopic Dermatitis Disease Control and Treatment Satisfaction With Dupilumab in Clinical Practice: 6-Year Follow-up Results From the RELIEVE-AD Study

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Introduction & Objectives:

In the RELIEVE-AD study, adults with moderate-to-severe atopic dermatitis (AD) initiated dupilumab in real-world clinical practice. Previous analyses showed that most dupilumab-treated patients reported controlled disease and high treatment satisfaction, which were maintained for up to 5 years. Here, we report 6-year disease control and treatment satisfaction from RELIEVE-AD.

Materials & 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, and 72. 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"). 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. Only patients who responded to at least one of the Month 33 or Month 48 surveys were contacted for the Month 72 survey.

Results:

Of the 469 patients at baseline who responded at Month 33 and/or Month 48, 298 patients completed the Month 72 survey. Mean age at baseline was 46.2 years and 61.7% were female patients. The mean total ADCT score was significantly lower ($P < 0.001$) at all post-treatment initiation time points, decreasing from 15.8 at baseline to 3.7 at Month 72. Controlled disease (ADCT <7) was reported by 5.9% of patients at baseline, increasing to 61.0% at Month 1 and maintained throughout the study period, then further increasing up to 82.6% at Month 72 ($P < 0.001$ 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 58.7% at Month 72 ($P < 0.001$ for all time points vs baseline). Patient satisfaction with current AD treatments improved over time, with 84.2% reporting being "extremely/very/somewhat satisfied" at Month 72 vs 17.8% at baseline. Subgroup analysis in patients remaining on dupilumab at Month 72 (n = 210) showed that they reported higher controlled disease (90%) and treatment satisfaction (95.2% being "extremely/very/somewhat satisfied").

Conclusion:

Most of the adult patients (>80%) with moderate-to-severe AD treated with dupilumab, who remained in this long-term study, reported controlled disease and remained satisfied with their treatment 6 years after dupilumab initiation in real-world clinical practice.



Abstract N°: 5452

Impact of Dupilumab on Mental and Emotional Well-Being in Patients With Moderate-to-Severe Atopic Dermatitis

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Introduction & Objective:

Atopic dermatitis (AD) is a chronic systemic disease that has a negative impact on mental health in children, adolescents, and adults, which can lead to cumulative life course impairment (CLCI), the persistent and accumulating disease burden over time that leads to irreversible negative effects in various domains of patient life. There are limited data examining the extent that AD affects patients' CLCI and how treatment may affect the lives of these patients. Here, we report the impact of AD and dupilumab treatment on mental and emotional well-being.

Materials & Methods:

Adult patients with moderate-to-severe AD enrolled in RELIEVE-AD (a prospective, long-term survey study) who completed the Year 6 survey, were invited to participate in qualitative one-on-one interviews lasting up to 60 minutes. The semi-structured interview consisted of questions focusing on different domains of life before and after initiating dupilumab. Content analysis using ATLAS.ti was conducted to analyze the qualitative data obtained from the interviews.

Results:

50 patients participated in the interview study. The mean age was 26.3 years at the time of AD diagnosis and 45.4 years at the time of dupilumab initiation, and 31 (62.0%) were female participants. Here we report data on the psychological impact of AD, focused on mental and emotional well-being, and changes after initiating dupilumab treatment. All participants discussed the negative impact of AD on mental and emotional well-being. Participants reported poor self-image (78%), being stressed/worried (76%), poor concentration (58%), shame/embarrassment (56%), and experiencing stigma/discrimination (52%) due to AD. Participants also experienced hopelessness (46%), frustration (40%), depression (40%), exhaustion/fatigue (40%), anxiety (34%), unhappiness (34%), and were irritable with others (12%) due to their AD. After initiating dupilumab treatment, participants reported less stress/worry (78%), increased happiness (66%), improved self-image (66%), improved concentration (42%), less anxiety (32%), and less shame/embarrassment (22%). Participants also reported feeling relief (18%), decreased depression (18%), increased hope (16%), less stigma/discrimination (14%), less frustration (12%), and less exhaustion/fatigue (10%), following dupilumab treatment. A majority of the participants (76%) reported that areas of their life might have been different if they had started dupilumab treatment earlier, with 40% highlighting the impact on their mental health.

Conclusion:

Participants reported substantial mental and emotional burden due to uncontrolled moderate-to-severe AD. Following dupilumab treatment, the majority of participants reported improvements in their mental and emotional well-being. Early use of effective treatment for AD not only can improve patients' psychosocial well-being but also likely can help minimize irreversible life course impairment due to AD.



Abstract N°: 5460

Systemic Treatment Outcomes for Pediatric Atopic Dermatitis in Minority Groups: PEDISTAD 4-Year Results

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Introduction & Objectives: The prevalence of atopic dermatitis (AD), a chronic inflammatory skin condition, is higher in individuals from ethnic/racial minority groups compared with individuals of European ancestry. Additionally, there is variation in the clinical features of AD, and in the AD risk loci depending on the ethnicity of the individual. Despite this, most research focuses on European populations. This analysis aims to report the effect of systemic therapies on clinician-reported outcomes in pediatric patients with AD from ethnic/racial minority groups.

Materials & Methods: PEDISTAD (NCT03687359) is an ongoing, global, 10-year, observational registry that enrolled children younger than 12 years. This interim 4-year analysis reports the effect of dupilumab, methotrexate, and cyclosporine on Eczema Area and Severity Index (EASI) scores and percentage affected body surface area (BSA). Discontinuation rates and safety were also evaluated. Outcomes for American or Alaskan Native, Asian, Black or African American, and multiracial patients were pooled and reported descriptively.

Results: Of the 181 patients from ethnic/racial minority groups, 102 were Asian, 51 were Black or African American, 19 were multiracial, and 9 were American Indian or Alaska Native. Of these 181 patients, 91 received dupilumab, 35 received methotrexate, and 55 received cyclosporine. The mean (SE) treatment duration for patients receiving dupilumab, methotrexate, or cyclosporine were 26.0 (1.3) months, 21.6 (3.0) months, and 16.3 (2.1) months respectively. Clinician-reported outcomes (mean change ± SE) from treatment start to last observation for patients who received dupilumab, methotrexate, or cyclosporine were: EASI scores (−13.6 ± 1.1, −8.2 ± 1.8, −9.2 ± 1.5) and BSA (−20.0 ± 2.9, −16.2 ± 3.6, −16.5 ± 2.8). The 4-year cumulative discontinuation rates for patients receiving dupilumab, methotrexate, or cyclosporine were 14.3%, 42.9%, and 65.5% respectively. Dupilumab safety was consistent with the known dupilumab safety profile.

Conclusion: Pediatric patients with AD from ethnic/racial minority groups receiving dupilumab had numerically greater improvement in AD signs and lower discontinuation rates compared with patients receiving methotrexate or cyclosporine.

Acknowledgments and funding sources

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Abstract N°: 5462

Long-term Dupilumab Treatment Resulted in Consistent Anatomic Regions Improvements in Pediatric Patients with Severe Atopic Dermatitis

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Introduction & Objectives:

Increased disease severity is correlated with decreased quality of life for young children with atopic dermatitis (AD) and their caregivers.** Reductions in disease extent and severity as measured by the Eczema Area and Severity Index (EASI) have been reported in children with severe AD treated with dupilumab for up to 2 years. We assessed changes in AD severity in separate anatomical regions and safety in children aged 6 months to 11 years with severe AD treated with dupilumab for up to 3 years**.**

Materials & Methods:

Children aged 6 months to 5 years with moderate-to-severe AD and 6 to 11 years with severe AD, who had previously participated in dupilumab studies (NCT03346434, NCT03345914) were eligible to enroll in an open-label extension (OLE) study (PED-OLE, NCT02612454). Dupilumab dosing was based on age and body weight: 6 months to 5 years, 200 mg (5 to <15 kg) or 300 mg (15 to <30 kg) every 4 weeks; 6 to 11 years, 200 mg (<60 kg) or 300 mg (≥60 kg) every 2 weeks. Topical AD treatments were allowed. Improvements in EASI scores at Week 152 (mean, 75% and 90% improvements [EASI-75, EASI-90]) across 4 anatomical regions (head/neck – H/N, trunk – T, upper extremities – UE, lower extremities – LE), and safety were evaluated in patients with severe AD, defined as an Investigator's Global Assessment score of 4 at PED-OLE baseline. Data are reported as observed.

Results:

A total of 50 (6mo–5years) and 75 patients (6–11years) had severe AD at PED-OLE baseline. Of children aged 6 months to 5 years with severe AD (n = 50), 11 completed the 5-year study, 23 are ongoing, and 16 discontinued the study (0 due to treatment-emergent adverse events [TEAEs], 2 due to lack of efficacy). Of children aged 6 to 11 years with severe AD (n = 75), 29 completed the 5-year study, 13 are ongoing, and 33 discontinued the study (1 due to TEAEs, 1 due to lack of efficacy).** Mean (SD) treatment exposure was 124.17 weeks (48.567) for children aged 6 months to 5 years (n = 50) and 115.98 weeks (48.504) for children aged 6 to 11 years (n = 75). In children aged 6 months to 5 years, from PED-OLE baseline to Week 152, mean EASI scores improved from 6.0 to

0.5 (H/N), 8.0 to 1.3 (T), 8.3 to 1.5 (UE), and 13.0 to 2.5 (LE). At Week 152, EASI-75 was achieved in most patients across anatomical regions (H/N, 80.6%; T, 77.4%; UE, 71.0%; LE, 67.7%). High-threshold improvements, as measured by EASI-90, were observed in H/N (64.5% of patients), T (64.5%), UE (35.5%), and LE (32.3%). In children aged 6 to 11 years, from PED-OLE baseline to Week 152, mean EASI scores improved from 4.3 to 0.3 (H/N), 10.1 to 0.6 (T), 8.8 to 1.2 (UE), and 16.5 to 2.3 (LE). At Week 152, EASI-75 was achieved in most patients regardless of anatomical region (H/N, 90.2%; T, 94.1%; UE, 80.4%; LE, 80.4%). High-threshold improvements (EASI-90) were observed in H/N (72.5% of patients), T (84.3%), UE (60.8%), and LE (58.8%). TEAEs were reported in 86.0% (6mo–5yrs) and 89.3% (6–11yrs) of patients; serious TEAEs occurred in 6 (12.0%) and 13 (17.3%) patients, respectively. One patient in each group discontinued treatment due to TEAEs. One drug-related serious TEAE occurred in the 6-11 group, resolved/resulted in recovery and did not result in permanent discontinuation of the study drug.

Conclusion:

Dupilumab treatment for up to 3 years demonstrated sustained efficacy across all anatomic regions in children aged 6 months to11 years with severe AD, with safety consistent with the known safety profile of dupilumab.



Abstract N°: 5470

Growth Improvement in Children 6 to 11 Years Old with Severe Atopic Dermatitis Treated with Dupilumab Irrespective of TCS Use

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Introduction & Objectives:

Children with atopic dermatitis (AD) have risk factors for impaired growth, lower bone mineral density, and increased fractures, including chronic itch-triggered sleep disturbance, chronic inflammation, and potential effects of prolonged exposure to corticosteroids. The impact of topical corticosteroids (TCS) on stature in children with AD is incompletely understood. Here, we assess the impact of TCS use on growth in children 6 to 11 years old treated with dupilumab vs placebo.

Materials & Methods:

Children 6 to11 years old with severe AD were enrolled in the phase 3, 16-week, placebo-controlled LIBERTY AD PEDS trial (NCT03345914). The proportion of patients below the 30th height percentiles at baseline with a ≥ 5-percentile change from baseline in height at Week 16 of dupilumab treatment vs placebo (N = 114) was previously reported. TCS use was standardized in this trial. Cumulative TCS use, and TCS- and inhaled corticosteroid (ICS)-free days were recorded over the 16-week treatment period. Multiple logistic regression models were conducted, and the response variable was defined as achieving a ≥ 5-percentile increase in height from baseline to Week 16 in a subset of patients below the 30th baseline height percentile. Covariates were cumulative TCS dose and medication-free days from baseline (TCS alone and TCS + ICS).

Results:

While TCS use was standardized in the trial, patients treated with dupilumab (n = 181) used TCS less frequently than those receiving placebo (n = 123; 219.11 grams [standard deviation: 305.40] vs 292.48 grams [287.36], and they had more TCS-free days (21.42 [24.95] vs 12.17 [20.37]) and more TCS + ICS-free days (17.60 [24.72] vs 9.10 [16.17]). In the unadjusted model (n = 114, of which 45 received placebo + TCS and 69 dupilumab + TCS), the odds ratio (OR) for dupilumab vs placebo was 3.74 (P = 0.01), indicating that patients in the treatment group were 3.7 times more likely to achieve a ≥ 5-percentile height increase vs those in the placebo group. The cumulative dose covariate-adjusted model demonstrated a significant impact of dupilumab treatment with an OR of 4.21 (P =

0.01). In both the medication-free days covariate- adjusted models, a significant impact of dupilumab treatment was observed with an OR of 4.11 (*P* = 0.01; TCS medication-free days) and 3.63 (*P* = 0.02; number of TCS- + ICS-free days).

Conclusion:

TCS use and the number of medication-free days appear to be independent of the effect of 16 weeks of dupilumab treatment on increased growth in children 6 to 11 years compared to placebo. These results suggest that the reduction of TCS use in patients treated with dupilumab may not be contributing to increased growth observed or that any potential negative effects of TCS use on growth could be counteracted by dupilumab.



Abstract N°: 5475

Chronic Hand Eczema has a Profound Impact on Daily Life, Social Interactions and Emotional Wellbeing: Results from a Global Patient Survey

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Introduction & Objectives:

Chronic Hand Eczema (CHE) is a frequent inflammatory skin disease with pain and pruritus, and clinical signs (e.g., erythema, scaling, lichenification, hyperkeratosis, vesicles, oedema, and fissures), carrying significant occupational, functional, social, and psychological burden. Despite available treatments, unmet needs remain for tailored management strategies. To better understand the impact of the disease, we surveyed CHE patients on multiple aspects of their daily lives, with an emphasis on areas not routinely addressed during dermatology consultations. The objective of this study was to quantify, from the patients' perspective, the experiences and behaviors influenced by CHE, addressing functional and social abilities, including work life, personal relationships, and emotional wellbeing.

Materials & Methods:

An international general population-based quantitative online survey was conducted among 192 CHE patients throughout Europe (N=67; France, Germany, Italy and Spain), the United-Kingdom (N=28), North America (N= 47; Canada, the United States) and Asia (N=50; China, Japan). Adult patients currently receiving treatment for moderate to severe CHE, either ongoing at inclusion or documented as prior medical history were recruited. Patients were asked to rate on a Likert scale, ranging from 1 (completely disagree) to 7 (completely agree), their level of agreement with statements related to life activities and mental wellbeing (11 categories). The percentage of patients who strongly agreed, pooling ratings 5 to 7, are presented.

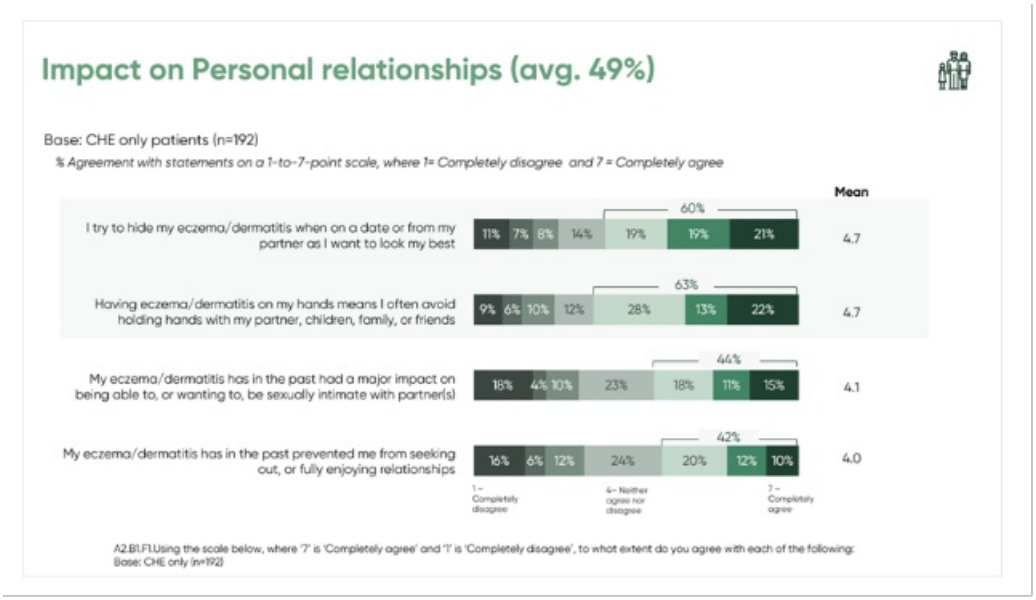
Results:

Nearly half of CHE patients felt they were a burden to their families, struggling with household chores (45%) or childcare responsibilities (47%). Of note, CHE also influenced patients' work lives, with 52% avoiding certain occupations and 50% needing to take time off. Among manual workers, 42% reported frequent painful lesions, compared to 22% of office workers. Overall, pain was often underreported with the majority (58%) of CHE patients downplaying their pain, likely underestimating its impact on their life choices. Importantly, 80% of CHE patients wished the disease was not on visible parts of their skin, 60% attempted to conceal their condition, even from partners. Additionally, patients reported that their condition greatly affected personal relationships (49%) and socializing (51%), possibly linked with how negatively they felt others perceived their condition (56%). Indeed, 63% often avoided holding hands with their partners, family or friends, 51% felt that their condition kept them from socializing as much as they would like, and 46% declared feeling lonely. As a result, half of CHE patients (55%) reported that their emotional wellbeing was deeply affected.

Conclusion:

These findings emphasize that CHE profoundly impacts multiple aspects of patients' lives, including their work,

social interactions, and personal relationships, leading to significant emotional distress. Our study highlights key areas to address routinely in clinical practice, such as the less visible signs of the disease, including pain and mental health. This research supports dermatologists in making informed therapeutic decisions, emphasizing timely interventions to improve care and quality of life for CHE patients. Given the significant personal, work, and societal burdens, patients should seek prompt medical care, as effective management is crucial to mitigating the disease's impact.



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Abstract N°: 5492

Development and Utility Investigation of Educational Artificial Intelligence (AI) Software for Atopic Dermatitis Severity Assessment

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Introduction & Objectives:

Atopic dermatitis (AD) is characterized by chronic eczematous skin lesions and pruritus accompanied by repeated exacerbation and remission. Since disease manifestations are highly variable, precise assessment of severity of AD lesions is crucial for appropriate treatment. The Eczema Area and Severity Index (EASI) is a globally-used assessment tool for objectively evaluating the severity of AD across the entire body. Scores are calculated from the percentage of skin affected by eczema and the severity of the four clinical features of AD (erythema, papule/edema, abrasion, and lichenification) for the four regions of the head and neck, upper limbs, trunk, and lower limbs, and are presented as a composite score from 0 to 72. One disadvantage of EASI in real-world settings is the possibility of the inter-rater variability of results. Therefore, the amount of experience and training of the rater in visually assessing AD is considered to be an important variable factor. Recent advancements in artificial intelligence (AI) technology have facilitated the extraction of feature quantities from complex image data, thereby enabling more precise predictions. This study aimed to develop AI software for educational purposes to determine the severity of four clinical features of AD (erythema, papule/edema, abrasion, and lichenification), and to further evaluate its diagnostic accuracy. We employed this technology to assess skin images for disease severity in AD patients. The AI tool demonstrated an accuracy that was comparable to, or even surpassed, that of medical specialists.

Materials & Methods:

This was a multicenter, non-interventional, prospective, observational study in patients with AD conducted in Japan. Patients 18 years or older, who had been or who were diagnosed with AD by a dermatologist and had given written informed consent prior to participation, were included in the study. Up to four skin images were collected for each participant. ConvNeXt, a Convolutional Neural Network (CNN) model incorporating Vision Transformer technology, was used in the development of the AI tool to simultaneously output continuous values for the severity of four symptoms. The model was trained to minimize the prediction error for the severity of each symptom based on a single image input. Using five-fold cross-validation, all obtained samples were used for evaluation. The data were divided into training, validation, and test sets on a patient basis. Test Time Augmentation was employed during evaluation. Receiver Operating Characteristic (ROC) curves were plotted based on the severity prediction scores for each symptom and the correct labels for each endpoint (≥1, ≥2, ≥3).

Results:

A total of 3,679 images from 1,016 individuals collected from 16 sites in Japan were analyzed by the AI tool. The area under the curve (AUC), sensitivity, and specificity for severity ≥2 are shown in the table.

	AUC	95% CL		Sensitivity	Specificity	FPR	FNR	PPV	NPV
		Lower	Upper						
Erythema	0.860	0.845	0.875	81.83	76.44	23.56	18.17	44.44	94.81
Papule/Edema	0.825	0.809	0.840	74.49	75.92	24.08	25.51	49.70	90.31
Abrasion	0.850	0.831	0.869	87.32	67.53	32.47	12.68	25.65	97.65
Lichenification	0.834	0.819	0.849	75.80	75.86	24.14	24.20	46.02	92.03

CL, Confidence Limits; *FPR*, False Positive Rate; *FNR*, False Negative Rate; *PPV*, Positive Predictive Value; *NPV*, Negative Predictive Value

Conclusion:

The CNN-based AI software developed in this study demonstrated an AUC exceeding 0.8 for each of the four clinical features required for the calculation of the EASI score, where the severity level was evaluated at 2 or higher. The AI software has promising potential to contribute to the education of severity diagnostic capability of the EASI score and may enable more precise and objective evaluations of AD disease severity.



Abstract N°: 5493

Real-world experience with lebrikizumab in moderate-to-severe atopic dermatitis: a case series of eight patients from Hospital Universitario Miguel Servet"

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Introduction & Objectives:

Lebrikizumab, a monoclonal antibody targeting IL-13, has shown efficacy in clinical trials for the treatment of moderate-to-severe atopic dermatitis. We present a series of 8 patients treated with Lebrikizumab in real-life clinical practice at our hospital, aiming to describe their clinical profiles, treatment efficacy, and safety outcomes.

Materials & Methods:

Clinical data were retrospectively collected from 8 patients with moderate-to-severe atopic dermatitis who initiated treatment with Lebrikizumab between [November/2024] and [March/2025] at the Hospital Universitario Miguel Servet. Data included demographics, comorbidities, prior treatments, clinical response (EASI, DLQI, NRS pruritus), and adverse events, assessed during follow-up.

Results:

A total of 8 patients (3 women, 5 men; mean age 42.0 years) were included. Atopic comorbidities were present in 4 patients (44%). All patients had previously received topical treatments. Regarding systemic therapies, prior treatments included ciclosporin (5, 55.6%), dupilumab (5, 55.6%), tralokinumab (3, 33.3%), abrocitinib (2, 22.2%), and upadacitinib (2, 22.2%). Clinical outcomes at week 16 are under analysis. No serious adverse events or treatment discontinuations were reported at the time of writing.

Conclusion:

Lebrikizumab appears to be an effective and well-tolerated treatment option in our real-world cohort of patients with moderate-to-severe atopic dermatitis. These preliminary results are consistent with those observed in clinical trials.



Abstract N°: 5494

Effectiveness, Patient-reported Outcomes, and Safety of Upadacitinib in Canadian Adult Patients With Atopic Dermatitis who Were Inadequate Responders or Intolerant to Dupilumab: Results from the CAN UpTIMISE Study

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Introduction & Objectives:

Open-label studies have shown that switching to upadacitinib (UPA), a once-daily oral Janus kinase 1 selective inhibitor, can improve clinical outcomes in patients with atopic dermatitis (AD) who were previously treated with or inadequately responded to dupilumab (DUPI), a commonly prescribed, biweekly and subcutaneously injected IL-4Rα inhibitor. The CAN UpTIMISE study assessed the real-world effectiveness of daily UPA 15 mg and 30 mg in patients with AD who were inadequate responders to DUPI or discontinued DUPI due to safety/tolerability reasons. To report the effectiveness of UPA switch from DUPI through selected patient-reported outcomes of disease activity/severity, treatment satisfaction, and patient preference.

Materials & Methods:

The CAN UpTIMISE (NCT05394792) study was a Canadian, multicentre, observational study in adult patients with

moderate-to-severe AD who had been treated with DUPI for ≥16 weeks as a prior line of systemic therapy. The decision to switch to UPA was made before study entry, and per the product label. Effectiveness was measured over 4 months with the validated Investigator Global Assessment for AD (vIGA-AD; primary outcome), Eczema Area and Severity Index (EASI), Worst Pruritus Numerical Rating Scale (WP-NRS), Patient Oriented Eczema Measurement (POEM), Patient Global Impression of change (PGI-C), severity (PGI-S), and treatment (PGI-T), and modified Oral versus Injectable Questionnaire scores. Results are presented using descriptive statistics.

Results:

Overall, 108 patients[b] were included in the analysis, of which 59.3% initiated UPA 30 mg. The mean patient age was 42.9 years (SD 16.7), with the majority of patients being male (55.6%) and White (61.1%) or Asian (33.3%). Most patients (83.3%) discontinued DUPI due to suboptimal disease control, while 16.7% stopped DUPI because of safety/tolerability concerns. At baseline, only 5.6% of patients had a vIGA-AD score of 0/1. As a primary endpoint, 65.9% (95% CI: 55.1% – 75.2%) of patients achieved vIGA-AD 0/1 at Month 4, with either UPA dose. At Month 4, 76.8%/54.9%/23.2% of patients achieved EASI 75/90/100, respectively. Between baseline and Month 4, the proportion of patients experiencing little to no itch (WP-NRS 0/1) increased from 6.8% to 46.7%. Improvements in POEM scores were also observed, with 77.3% of patients achieving a reduction of ≥4 points from baseline and 34.3% achieving a POEM score ≤2 at Month 4, in patients with baseline POEM >4 and >2, respectively. Most of the improvements seen with UPA were observed as early as Month 1 and were generally maintained at Month 4. By the end of the study, 75.7% of patients scored the change in disease activity as 'very much/much improved' (PGI-C), 54.7% scored their disease severity as 'absent/minimal' (PGI-S), and 60.0% were 'extremely/very satisfied' with the treatment (PGI-T). Most patients preferred an oral vs injectable AD treatment, both at baseline and Month 4. UPA was well-tolerated, and its safety profile was consistent with observations made across RCTs.

Conclusion:

The CAN UpTIMISE study demonstrates that UPA is effective and well-tolerated in AD patients who were inadequate responders to DUPI or discontinued DUPI due to safety/tolerability reasons. Most patients rapidly achieved clear/almost clear skin and clinically meaningful improvements across patient-reported outcomes, disease activity/severity, and treatment satisfaction assessments, with no new safety signals reported.

Table. Effectiveness of UPA in Patients with Inadequate Response or Intolerance to Dupilumab

	All patients N = 108[a]			
Endpoints	**Baseline**	**Month 1**	**Month 2**	**Month 4**
EASI, % (95%CI)				
EASI 75	-	62.5% (51.5, 72.3)	75.9% (65.5, 84.0)	76.8% (66.6, 84.6)
EASI 90	-	47.5% (36.9, 58.3)	58.2% (47.2, 68.5)	54.9% (44.1, 65.2)
EASI 100	-	28.8% (20.0, 39.5)	36.7% (26.9, 47.7)	23.2% (15.4, 33.4)
WP-NRS, %				
Minimal/no itch (0-1)	6.8%	56.6%	57.7%	46.7%
Mild itch (2-3)	20.4%	25.0%	25.6%	32.0%
Moderate (4-6)	30.1%	14.5%	12.8%)	12.0%
Severe (7-10)	42.7%	3.9%	3.8%	9.3%
POEM, % (95%CI)				
Reduction ≥ 4 points[b]	-	86.2% (75.7, 92.5)	89.4% (79.7, 94.8)	77.3% (65.8, 85.7)
POEM ≤ 2[c]	-	38.6% (28.0, 50.3)	36.6% (26.4, 48.2)	34.3% (24.2, 46.0)
PGI-C, % (95%CI)				
Very/much improved	-	71.1% (60.0, 80.0)	70.1% (59.2, 79.2)	75.7% (64.8, 84.0)
PGI-S, % (95%CI)				
Absent/minimal	11.7% (6.8, 19.3)	50.0% (39.0, 61.0)	60.3% (49.2, 70.4)	54.7% (43.4, 65.4)
PGI-T, % (95%CI)				
Extremely/very satisfied	19.6% (13.1, 28.4)	60.5% (49.3, 70.8)	55.1% (44.1, 65.7)	60.0% (48.7, 70.3)
Oral vs injectable, %				
Injectable treatment	6.0%	-	-	9.3%
Oral therapy	70.0%	-	-	70.7%
No preference	24.0%	-	-	20.0%

EASI XX, Improvement of XX% in Eczema Area and Severity Index from baseline; PGI-C/S/T, Patient Global Impression of change/severity/treatment; POEM, Patient Oriented Eczema Measurement; UPA, upadacitinib; WP-NRS, Worst Pruritus Numeric Rating Scale.
[a] N = 108 represents the number of patients at baseline, but may not represent observed cases for each endpoint/time point.
[b] 4 points reduction from baseline in patients with POEM > 4 at baseline.
[c] Absolute score ≤ 2 in patients with POEM > 2 at baseline.



Abstract N°: 5518

Study on Relapse of Dupilumab in the Treatment of Atopic Dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD), a chronic relapsing inflammatory skin disease driven by Th2-type immunity, exhibits marked heterogeneity in relapse mechanisms across individuals. While dupilumab—a monoclonal antibody targeting IL-4Rα—effectively alleviates AD symptoms by blocking IL-4/IL-13 signaling, relapse occurs in approximately 30% of patients in real-world clinical practice, with risk factors remaining poorly characterized. The objective of this study is to identify factors which contribute to relapse in dupilumab-treated moderate-to-severe AD.

Materials & Methods:

This prospective study enrolled a cohort of 164 patients with moderate-to-severe AD, defined by Scoring Atopic Dermatitis (SCORAD) index ≥25 and diagnosed according to Hanifin & Rajka criteria. Data on demographic characteristics, personal/family medical history, lifestyle, dupilumab treatment pattern, as well as patient-reported relapse events and their associated triggers were collected via structured questionnaires. Disease severity was evaluated using standardized clinical metrics, including SCORAD, Excema Area and Severity Index (EASI), Numerical Rating Scale (NRS), and Atopic Dermatitis Control Tool (ADCT) . Cox proportional hazards models were used to identify relapse risk factors, while the cumulative recurrence risk and gender-stratified analyeses were applied to evaluate cumulative relapse risk.

Results:

Among the 164 patients, 53 patients (32.32%) remained relapse-free, while relapse occurred in 45 patients (27.44%) within 1-month post-treatment, 11 patients (6.71%) between 1-3 months, 39 patients (23.78%) at 3 to 6 months, and 16 patients (9.76%) beyond 6 months. Multivariate Cox analysis identified age stratification (HR=1.28, 95%CI:1.02–1.60), pet ownership (HR=2.84, 95%CI:1.15–7.01), and asthma history (HR=1.82, 95%CI:1.00–3.31) as independent risk factors ($P<0.05$ for all) for relapse. Notably, the relapse group exhibited a higher proportion of early EASI50 responders at week 2 compared to the non-relapse group (50.00% vs. 23.08%, $P = 0.024$). In contrast, the non-relapse group demonstrated superior long-term efficacy outcomes at weeks 12–16, with significantly higher response rates for both SCORAD50 (75.00% vs. 26.09%) and EASI75 (66.67% vs. 26.09%) ($P < 0.05$ for both). Patient-reported relapse triggers predominantly include climate (42.70%) and sweating (29.88%).

Conclusion:

This study reveals a distinct efficacy pattern in dupilumab-treated AD, where rapid initial improvement does not guarantee sustained remission. Age, pet exposure, and asthma history independently elevate relapse risk, highlighting the need for personalized maintenance strategies in high-risk subgroups. Results from this study suggest that mitigation of environmental triggers and management of comorbidity may be critical for relapse prevention. Overall, these findings underscore the importance of regular follow-ups and tailored interventions to achieve long-term outcomes in AD management.



Abstract N°: 5535

Patient reported outcomes in lebrikizumab treated patients with moderate-to-severe atopic dermatitis in a real-world-setting: interim analysis of the non-interventional study AD-LIFE

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Introduction & Objectives: Efficacy and safety of lebrikizumab (LEB) for the treatment of moderate-to-severe atopic dermatitis (AD) was demonstrated throughout the extensive clinical development program. Moreover, patient-reported outcomes (PROs) have also been collected and have provided valuable insights in the randomized controlled trials. Real-world data on LEB in AD remains scarce as of today. Here, we report interim PROs data and safety from the non-interventional study (ADlife).

Materials & Methods: This is an open, prospective, multi-center, observational, cohort study to evaluate AD control under LEB at week (W) 52. Patients were included if they were ≥18 years old, had moderate-to-severe AD requiring systemic therapy, received LEB treatment as per label according to physician´s decision, and provided informed consent. PRO reported measures included: percent (%) change from baseline (CFB) of Dermatology Life Quality Index (DLQI), % of patients with DLQI ≤5%, % of patients with DLQI 0/1, CFB of Patient-Oriented Eczema Measure (POEM), % of patients with POEM ≥4-points improvement from baseline, % CFB of Sleep-Loss Scale (sleep-loss), and % of patients with sleep-loss ≥1-point improvement from baseline (W16). Safety outcomes reported were adverse drug reactions (ADRs) and serious ADRs. This interim analysis covered patients completing 16W of treatment. Data are reported as observed. T-Test was performed for CFB analyses.

Results: A total of 100 patients were included (8 patients dropped out of the study until W16). Baseline characteristics: mean (SD) age of 41.3 (15.0) years and 57% were female; baseline severity: mean (SD) scores of EASI 21.6 (11.5), IGA 3.4 (0.6), 24h-peak pruritus NRS 7.2 (2.1) and DLQI 17.1 (7.2), POEM 19.8 (6.1) and sleep-loss 2.1 (1.1). The most common atopic comorbidities: 63% of patients presented rhinitis allergic/hay fever, 40% asthma, 27% food allergy and 60% other allergies. Thirty percent (30/100) of patients have been previously treated with advanced systemic treatments (of which 76.7% [23/30] of patients had been pre-treated with dupilumab) and 86% (86/100) with TCS. At baseline/W4/W16, 48/36/26 patients received TCS as concomitant topical prescription. PRO data (W16): percent CFB of DLQI was -66.0% ($p<0.0001$), 58.5% of patients had DLQI ≤5, 31.7% of patients achieved DLQI 0/1, percent CFB of POEM was -50.0% ($p<0.0001$), 76.8% of patients reported POEM ≥4-points improvement from baseline, percent CFB of sleep-loss was -53.1% ($p<0.0001$), and 71.6% of patients presented sleep-loss ≥1-point improvement from baseline. In this preliminary analysis, ADRs under lebrikizumab were consistent with those in clinical trials. No new safety signals were observed.

Conclusion: These findings provide reassurance on the clinical benefits of lebrikizumab to patients in a real-world setting in a population suffering from several comorbidities and with patients priorly treated with other advanced systemics.



Abstract N°: 5537

Absolute EASI response achieved with lebrikizumab up to 2 years in patients with moderate-to-severe atopic dermatitis (ADvocate1&2 to ADjoin)

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Introduction & Objectives: Lebrikizumab (LEB) is a monoclonal antibody that binds with high-affinity to IL-13, blocking its downstream effects. Results of LEB efficacy based upon absolute EASI scores (range 0-72 [clear-maximum severity]), considered clinically relevant as they indicate remaining disease regardless of baseline severity, have been reported before up to 52 weeks (W) of treatment.1 Here, we present the proportion of W16 per-protocol responders from the ADvocate1 and ADvocate2 studies who achieved absolute EASI scores of ≤7, ≤5, ≤3 and ≤1 up to 2 years of continuous LEB treatment in the ADjoin long-term extension (LTE) study (NCT04392154).

Materials & Methods: ADvocate1&ADvocate2 were two identically designed, randomized, placebo-controlled, LEB monotherapy Phase 3 trials in adult (≥18 years) and adolescents (12 to <18 years, ≥ 40 kg) with moderate-to-severe AD. Patients were randomized 2:1 to receive LEB 250 mg every 2 weeks (Q2W) (loading dose of 500 mg given at baseline and W2) or placebo Q2W until W16 (Induction period). After W16, LEB Q2W patients who met response-criteria (EASI75 or IGA0/1 with ≥2-point improvement without rescue medication) were rerandomized 2:2:1 (LEB 250 mg Q2W : LEB 250 mg Q4W : PBO [LEB-withdrawal]). Patients who completed W52 (Maintenance period) were enrolled in the ADjoin-LTE (W54-W152), continuing the same dose regimen, except patients in the LEB-withdrawal group which were offered LEB 250 mg Q2W, but were not included in the analysis population. This analysis assessed the proportion (%) of W16 per-protocol responders who achieved absolute EASI scores of ≤7, ≤5, ≤3, and ≤1 up to 2 years of treatment (W104). Topical corticosteroids were allowed at the ADjoin. Data were reported as observed using all collected data regardless of rescue medication use.

Results: 291 patients (ADvocate1&2) achieved EASI75 or IGA0/1 at W16, were rerandomized, and entered in the maintenance-period until W52. Of these, 82 (LEB Q2W) and 99 (LEB Q4W) entered in the ADjoin-LTE. Out of LEB W16 per-protocol responders who entered in the ADjoin-LTE, after 2 years of continuous LEB treatment (LEB Q4W and LEB Q2W), 96.4% and 92.8% of patients reported EASI ≤7, 91.6% and 88.4% of patients reported EASI ≤5, 85.5% and 82.6% of patients achieved EASI ≤3 and 66.3% and 60.9% of patients reported EASI ≤1, respectively.

Less than 13% of patients received concomitant topical therapy through 104 weeks of lebrikizumab treatment.

Conclusion: The proportion of LEB W16 responders who entered in the ADjoin-LTE reporting EASI ≤7 (mild disease) and ≤5 remained sustained after 2 years of continuous treatment, while the proportion of patients reporting more stringent endpoints like EASI ≤3 (optimal target) and EASI ≤1 (clear/almost clear skin) continued to increase over time up to 2 years, with most patients not using concomitant topical therapy. This data supports the long-term sustained disease control with LEB.

References: 1. Thaçi D, et at. EADV Congress; Amsterdam, Netherlands; September 25–28, 2024. Poster presentation (P-0682).



Abstract N°: 5541

Lebrikizumab showed improvements in skin signs, itch and sleep measured by POEM after 3 years of treatment (ADvocate1&2 to ADjoin)

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Introduction & Objectives: Lebrikizumab (LEB) is a monoclonal antibody that binds with high-affinity to IL-13 thereby blocking its downstream effects. Here, we analyze the results of skin signs, itch and sleep assessed by the Patient Oriented Eczema Measure (POEM) in moderate-to-severe AD patients treated with LEB from the ADvocate1 and ADvocate2 induction period who responded to treatment at week (W)16 and continued into the ADjoin long-term extension (LTE) study (NCT04392154) with up to 3 years of continuous LEB treatment.

Materials & Methods: ADvocate1 and ADvocate2 were two identically designed, randomized, placebo-controlled, LEB monotherapy Phase 3 trials in adult (≥18 years) and adolescents (12 to <18 years, ≥ 40 kg) with moderate-to-severe AD. Patients were randomized 2:1 to receive LEB 250 mg every 2W (Q2W) (loading dose of 500 mg given at baseline and W2) or placebo Q2W until W16 (Induction period). After W16, LEB Q2W patients who met response-criteria (EASI75 or IGA0/1 with ≥2-point improvement, without rescue medication) were rerandomized 2:2:1 (LEB 250 mg Q2W; LEB 250 mg Q4W; PBO [LEB-withdrawal]). Patients who completed W52 (Maintenance period) were offered to be enrolled in the ADjoin-LTE (W54-W152) study, taking the same dose regimen assigned during the Maintenance period, except patients in the LEB-withdrawal group which were offered LEB 250 mg Q2W, but were not included in the analysis population. POEM is a patient-reported measurement of signs (skin appearance) and symptoms (itch and sleep) of AD, where a score of 0–2 indicates clear/almost clear, 3–7 mild, 8–16 moderate, 17–24 severe, and 25-28 very severe eczema. The following outcomes were assessed as observed: POEM mean total score, proportion of patients with POEM ≤7 (among patients with POEM >7 at ADvocate1&2 studies baseline), proportion of patients with POEM ≥4-point improvement (among patients with POEM ≥4-points at ADvocate1&2 studies baseline), and proportions of patients according to POEM individual items of itching and sleep disturbance.

Results: 291 patients (ADvocate1&2) were responders at W16, and were rerandomized, and entered the maintenance-period until W52. Of these, 99 (LEB Q4W) and 82 (LEB Q2W) entered into the ADjoin-LTE (mean POEM at baseline of 20.1 and 21.0, respectively). In W16 LEB-responders, POEM mean values were sustained and further improved up to 3 years of continuous treatment with similar values between LEB Q4W and LEB Q2W (mean POEM of 7.7 and 8.6 at W16 and 5.3 and 5.5 after 3 years, respectively). Likewise, the proportion of patients achieving POEM ≥4-points improvement/POEM ≤7 at W16 also were sustained and further increased up to 3 years (92.7% and 98.0% / 69.1% and 77.6%) for both Q4W and Q2W respectively. A total (LEB Q4W and LEB Q2W) of 34.5% and 38.0% of patients reported no days of itching and 85.5% and 74.0% reported no days of sleep disturbance at 3 years, respectively.

Conclusion: LEB improved patient-reported skin signs and symptoms in adult and adolescent patients with moderate-to-severe AD, measured by total POEM scores during the long-term extension study up to 3 years. In W16 LEB-responders, POEM score improvement were sustained and further increased up to 3 years of continuous treatment. Similar results were observed with both treatment arms. Improvements were also observed at 3 years in the POEM individual itching and sleep disturbances scores.

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Abstract N°: 5544

Lebrikizumab provides skin clearance and itch relief at week 16 and week 52: pooled results from 2 phase 3 studies ADvocate1 and ADvocate2

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Introduction & Objectives: Lebrikizumab (LEB) is a novel, high-affinity monoclonal antibody targeting interleukin-13 for moderate-to-severe atopic dermatitis (AD). Improvements in both skin severity and itch are important as they translate into substantial improvements in patient-reported AD outcomes1. Here, we analyze the composite skin clearance and itch relief with LEB at week (W) 16 and W52 from pooled ADvocate1 (ADv1) and ADv2 (NCT04146363 & NCT04178967) clinical trials.

Materials & Methods: ADv1&ADv2 were two identically designed, randomized, placebo-controlled, LEB monotherapy Phase 3 trials in adult (≥18 years) and adolescents (12 to <18 years, ≥ 40 kg) with moderate-to-severe AD. Patients were randomized 2:1 to receive LEB 250 mg every 2 weeks (Q2W) (loading dose of 500 mg given at baseline and W2) or placebo Q2W until W16 (Induction period). Responders were defined as patients achieving EASI75 or IGA 0/1 with ≥2-point improvement from baseline (without rescue medication) at W16. W16 LEB responders were re-randomized 2:2:1 (LEB 250 mg every 4 weeks [Q4W], LEB 250 mg Q2W or placebo [PBO-LEB withdrawal]) for 36W additional (Maintenance Primary population, MPP) (topical rescue medication was permitted). This post-hoc analysis reports the proportion of patients achieving the following composite scores: EASI75 AND pruritus NRS ≥4-point improvement, EASI90 AND pruritus NRS ≥4-point improvement, and EASI ≤7 AND pruritus NRS ≥4-point improvement at W16 and W52, respectively. The pooled Intention-to-Treat (ITT; all randomized patients) population for ADv1 and the modified ITT (mITT) population for ADv2 for W16 and the pooled modified MPP (mMPP) for W52 were used. Analyses were performed at W16 and W52 (on W16 LEB responders). Missing data due to lack of efficacy or data after rescue medication usage were imputed as non-responder imputation. Other missing data were imputed using multiple imputation.

Results: At W16, 31.9% of LEB Q2W treated patients vs 5.2% of PBO patients achieved EASI75 AND pruritus NRS ≥4-point improvement, 22.1% vs 2.8% achieved EASI90 AND pruritus NRS ≥4-point improvement and 32.1% vs 5.8% achieved EASI ≤7 AND pruritus NRS ≥4-point improvement, respectively ($p<0.0001$, all cases). Significant results in all composite scores were already reported at W4. At W52 (LEB Q4W, LEB Q2W, PBO-LEB withdrawal), 52.1%, 54.3% and 45.2% of patients achieved EASI75 AND pruritus NRS ≥4-point improvement, 41.7%, 45.0% and 31.3% of patients achieved EASI90 AND pruritus NRS ≥4-point improvement, and 53.2%, 52.0% and 46.0% achieved EASI ≤7 AND pruritus NRS ≥4-point improvement, respectively.

Conclusion: LEB Q2W provides significant higher rates of composite skin clearance and itch relief at W16 vs PBO

as early as W4. From the W16 LEB responders, high rates of composite skin clearance and itch relief are observed at W52 in both maintenance dosing regimens (LEB Q4W and Q2W).

References:

1. Silverberg et al. J Dermatolog Treat 2024; 35(1):2428729.



Abstract N°: 5549

Safety profile of lebrikizumab in adults and adolescents with moderate-to-severe atopic dermatitis: SmPC integrated safety data

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Introduction & Objectives: Lebrikizumab (LEB) is a novel, high-affinity monoclonal antibody that selectively binds to IL-13. LEB safety data have been reported in individual trial disclosures and multiple long-term integrated analyses. LEB does not require laboratory monitoring, has no expected drug–drug interactions and has no significant hepatic metabolism or renal elimination. Here, we present the integrated safety data reported in LEB' SmPC (cut-off date: 6th June 2022).

Materials & Methods: LEB's SmPC safety section includes integrated data from the following 8 studies: LEB monotherapy and LEB + topical corticosteroids (TCS) studies (ADvocate1&ADvocate2, [NCT04146363&NCT04178967], KGAF [NCT03443024], ADhere [NCT04250337], ADjoin [NCT04392154], ADore [NCT04250350], ARBAN [NCT02465606], and TREBLE [NCT02340234]). Study size-adjusted percentages were calculated for the pooled placebo (PBO)-controlled analysis of the monotherapy (ADvocate1, ADvocate2, and KGAF) and TCS combination therapy (ADhere) studies (induction period: W0-16), for the maintenance period (ADvocate1&ADvocate2) (W16-52), and for all LEB studies. For adverse events (AEs) analyzed as a cluster, searches of the following MedDRA preferred terms were conducted: conjunctivitis (conjunctivitis and conjunctivitis bacterial), keratitis (keratitis; allergic keratitis; ulcerative keratitis; vernal keratoconjunctivitis; and atopic keratoconjunctivitis), and injection site reactions (injection site-related: pain, erythema, reaction, discomfort, dermatitis, pruritus, swelling, and rash).

Results: From W0-16 (783 patients treated with LEB 250 mg Q2W±TCS and 404 patients with PBO±TCS), AEs occurring in ≥1% of patients are described in the Table, being all non-serious and most of them mild or moderate in severity. Most injection site reactions and all conjunctivitis and dry eye events were mild or moderate in severity and the majority did not lead to treatment discontinuation. Herpes zoster, eosinophilia, blepharitis and keratitis AEs occurred in <1% of patients, these events being non-serious, mild or moderate in severity, and most of them not leading to discontinuation (only keratitis led to discontinuation in n=2 [0.3%] patients). From W16-52 / For all LEB studies (118 patients LEB 250 mg Q4W±TCS ADvocate1&ADvocate2 / 1720 patients treated with at least one dose of LEB, respectively), the conjunctivitis incidence rate did not increase over time (n=6, 5.0% LEB 250 mg Q4W±TCS ADvocate1&ADvocate2, and n=12, 0.7% across all LEB studies, respectively).

Table

Patients with ≥1 adverse event, n (%)	**Lebrikizumab vs placebo-controlled dataseta**
	Lebrikizumab 250 mg Q2W±TCSb (N=783)
Conjunctivitisc	54 (6.9)
Conjunctivitis allergic	14 (1.8)
Injection site reactions	20 (2.6)
Dry eye	11 (1.4)

a Integrated analysis of ADvocate1, ADvocate2, KGAF and ADhere (Weeks 0-16); b Lebrikizumab 500 mg at Week 0 and Week 2, followed by 250 mg Q2W; cIncludes preferred terms of conjunctivitis and conjunctivitis bacterial.

Conclusions: LEB safety reported in the SmPC is consistent with the large body of evidence on LEB safety. LEB has a positive benefit-risk in adults and adolescent patients with moderate to severe AD, with most AE being mild or moderate in severity and few leading to treatment discontinuation. The incidence of conjunctivitis did not increase with longer exposure to LEB.



Abstract N°: 5551

Impact of lebrikizumab in combination with topical corticosteroids in the psychological well-being and depression suspicion in patients with moderate-to-severe atopic dermatitis: a randomized phase 3 clinical study (ADvantage)

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Introduction & Objectives: Patients with moderate-to-severe atopic dermatitis (AD) might show a significant impairment of their psychological well-being. Lebrikizumab (LEB) is a high-affinity monoclonal antibody targeting interleukin-13 indicated for moderate-to-severe AD. The objective was to assess the effect of LEB combined with topical corticosteroids (TCS) on psychological well-being calculated by thresholds of response, and depression suspicion, in patients with moderate-to-severe AD included in the ADvantage study.

Materials & Methods: Eligible patients were adults and adolescents (≥12 to <18 years) with moderate-to-severe AD who were inadequately controlled with or ineligible for ciclosporin A (CsA). Patients were randomized 2:1 to LEB 250 mg or placebo (PBO) every two weeks (Q2W). After a 16-week (W), randomized, double-blind, PBO-controlled, induction period, all patients received LEB 250 mg Q2W during an open-label 36-W maintenance period. All patients received concomitant mid-potency TCS through W16; from W16 to W52, TCS use was at investigator discretion. Well-being was assessed at baseline, W16 and W52 through the 5-item WHO Well-being Index (WHO-5; range 0-100, 100=maximal well-being; mean WHO-5 score in the general population of the countries participating in the ADvantage study was calculated to be 64.7; when WHO-5 is used for the screening of depressive symptoms, a cutoff score of ≤50 is used [20-50 mild and ≤28 moderate-to-severe depressive symptoms], with depression suspicion defined as answering 0 or 1 to any of the 5 items, and/or total score <52). Analyses were performed in the full analysis set. Missing data was not imputed, an observed cases approach was used.

Results: 331 patients were randomized (220 LEB+TCS, 111 PBO+TCS; 12% adolescents). In adults/adolescents, mean WHO-5 score increased from 41.0/43.0 and 39.6/45.8 at baseline to 60.9/65.0 and 51.3/58.3 at W16 in the LEB+TCS and PBO+TCS arms, respectively. At W52, mean WHO-5 score was 66.2/64.7 and 66.1/74.4 for LEB+TCS/LEB±TCS and PBO+TCS/LEB±TCS arms, respectively. At baseline, 31.4% and 36.5% of patients in the LEB+TCS (n=204) and PBO+TCS (n=96) arms, respectively, had a WHO-5 score≤28 and the percentages

decreased to 8.2% and 16.5% at W16 (with 75.8% and 58.8% of patients having a WHO-5 score>50 at W16, respectively). At W52, 81.1% and 81.0% of patients in the LEB+TCS/LEB±TCS (n=164) and PBO+TCS/LEB±TCS (n=79) arms had a WHO-5 score>50. Similar trends were observed for subgroups of adults and adolescents. At baseline, 29.9% and 21.9% of patients in the LEB+TCS (n=204) and PBO+TCS (n=96) arms, respectively, did not show depression suspicion and the percentages increased to 70.0% and 52.6% at W16. At W52, 76.8% and 77.2% of patients in the LEB+TCS/LEB±TCS (n=164) and PBO+TCS/LEB±TCS (n=79) arms did not have depression suspicion.

Conclusion: At baseline, patients included in the ADvantage study showed a significant impairment of their psychological well-being, with one third of them reporting WHO-5 scores compatible with moderate-to-severe depressive symptoms. In only 16 weeks of treatment, lebrikizumab improved the psychological well-being of both adults and adolescents, achieving a well-being status similar to the general population, which was maintained or improved after 52 weeks.



Abstract N°: 5575

Correlation Between Atopic Dermatitis and Head-and-Neck Skin Lesions: A Recent Frontier Review

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disorder, which profoundly impacts patients' quality of life. AD patients may develop head-and-neck dermatitis (HND), a distinct clinical subtype of AD characterized by erythematous, desquamative lesions localized on the head and neck region. Furthermore, AD patients are at increased risk of developing comorbid head-and-neck dermatoses, including systemic lupus erythematosus (SLE)-specific facial lesions, rosacea, and perioral dermatitis. However, the association between AD and head-and-neck skin lesions remains incompletely understood. Therefore, we aim to conduct a systematic review to enable better understanding of their association.

Materials & Methods:

A comprehensive literature search was conducted using PubMed, Web of Science databases up to February 2025, targeting studies on the clinical manifestations, diagnosis and treatment, and research progress of AD, HND as well as AD comorbidity. The search terms included atopic dermatitis, head-and-neck dermatitis, and comorbidities.

Results:

The systematic review of selected articles revealed that AD patients had a significantly higher prevalence of autoimmune comorbidities, including SLE and psoriasis, compared to non-AD controls. Additionally, they exhibited greater susceptibility to inflammatory dermatoses (acne, rosacea, contact dermatitis), which was associated with impaired epidermal barrier function. Among AD patients receiving topical therapies, there was a higher prevalence of HND, with clinical features indicative of synergistic effects between epidermal barrier dysfunction and IL-4/IL-13 pathway activation. Although topical corticosteroids provided initial symptom relief, a substantial proportion of HND cases developed treatment-related adverse effects in facial regions. These findings underscore the critical need to concurrently target inflammation and maintain epidermal barrier integrity in AD management.

Conclusion:

This study demonstrates a potential association between AD and HND, as well as AD comorbidities, which is mediated by epidermal barrier dysfunction and potentially exacerbated by topical therapies. However, further studies are needed to fully elucidate the pathophysiological relationship linking with AD, its therapeutic interventions, and the development of both head-and-neck skin lesions and other comorbidities.

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Abstract N°: 5585

TGM3 in Atopic Dermatitis Pathogenesis: A Preliminary Study on the Proliferation, Apoptosis and Inflammation of HaCaT Cells Mediated by TGM3

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease, with autoimmunity present in 18%–91.4% of patients. Elevated immunoglobulin E (IgE) targeting keratinocytes (KC)-derived self-antigens contributes to AD pathogenesis. Transglutaminase 3 (TGM3), an epidermis-specific enzyme, has been shown to induce elevation of specific IgE (sIgE-TGM3) in AD patient sera that positively correlates with skin lesion severity. However, whether TGM3 modulates KC activity to promote AD pathogenesis remains to be investigated. By using HaCaT cell as a keratinocyte model, this study investigates TGM3-mediated effects on HaCaT cell proliferation, apoptosis, transcriptions and inflammatory responses. The effect of TGM3 on skin barrier function was also investigated.

Materials & Methods:

TGM3 knockdown (TGM3KD) and overexpression (TGM3OE) HaCaT models were constructed via small interfering RNA technique (siRNA) and plasmid transfection, respectively, with controls including siRNA negative control group (Ctrl siRNA group) and empty vector group. Ultramicroscopic structural changes of KCs upon alterations of TGM3 expression were analyzed by transmission electron microscopy (TEM). Proliferation and apoptosis were measured via CCK-8 and flow cytometry. qPCR quantified mRNA levels of barrier proteins (FLG, LOR, IVL) and cytokines (TNF-α, IL-4, IL-13, IL-31, IL-33, ST2, IL-17, IL-22, IL-25, TSLP). Next-generation RNA Sequencing identified the major inflammatory pathways affecting HaCaT cells, with western blot (WB) validating the changes key proteins' level.

Results:

TEM revealed normal ultrastructure in blank group, mild damage in empty vector controls, and pronounced disruption in Ctrl siRNA, TGM3KD and TGM3OE groups. Compared to the blank group, significant proliferation reduction occurred in Ctrl-siRNA, TGM3KD, empty vector and TGM3OE group, with no apoptosis differences observed among the five groups. TGM3 modulation did not alter barrier proteins FLG/LOR/ IVL mRNA levels. TGM3 knockdown decreased IL-33, IL-25 and IL-17 mRNA levels (TGM3KD vs. Ctrl siRNA group, $P = 0.0186, 0.0054$ and $P < 0.0001$), while TGM3 overexpression upregulated their levels (TGM3OE group vs. empty vector group, $P = 0.0324$, 0.0062 and < 0.0001). After the stimulation of TGM3 protein for 48h, mRNA expressions of IL-33, ST2, IL-31 and TSLP in HaCaT cells were significantly increased compared with the blank group ($P = 0.0027, 0.0003, 0.0001$ and 0.0015). PI3K-Akt pathway was activated in TGM3 overexpression (TGM3OE group vs. empty vector group, $P = 0.0260$).

Conclusion:

TGM3 dysregulation induced structural and proliferative alterations in HaCaT cells, independent of apoptotic regulation or barrier protein expression. TGM3 overexpression promoted inflammation through upregulation of pro-inflammatory cytokines (IL-17, IL-25, IL-33, TSLP) and activation of the PI3K-Akt pathway. Despite further studies are required, preliminary findings from this study reveal the potential mechanistic roles of TGM3 in AD pathogenesis: 1) compromising keratinocyte structural integrity and growth dynamics, and 2) promoting

inflammatory responses through cytokine dysregulation.



Abstract N°: 5593

Pooled Safety Analysis of Nemolizumab in moderate-to-severe atopic dermatitis: Results from two phase 3 trials

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Introduction & Objectives: Atopic dermatitis (AD) is a heterogeneous disease with significant unmet medical need, particularly for patients with moderate-to-severe disease. Understanding the safety profile of new treatments is crucial, & pooling data from 2 pivotal trials provides better overview of nemolizumab safety profile. Pruritus was reported as the most burdensome symptom of AD & should be a primary treatment goal for these patients. Nemolizumab uniquely inhibits the IL-31-signalling pathway targeting all pillars of AD: itch, inflammation & epidermal dysregulation. In two large-scale phase 3 randomised controlled trials (ARCADIA 1&2), nemolizumab demonstrated fast & safe improvement in key signs & symptoms of AD. This abstract reports the pooled safety data from these two trials.

Materials & Methods: A pooled analysis was conducted on two phase 3 pivotal trials involving ≥12-year-old patients with moderate-to-severe AD (16 week initial treatment period & 32 week maintenance period). Patients were randomized (2:1) to receive either nemolizumab 30 mg (60 mg at baseline) or placebo, administered subcutaneously every 4 weeks (Q4W) in combination with topical corticosteroids (TCS) of medium/low potency and/or topical calcineurin inhibitors (TCI) for 16 weeks. During 32-week maintenance period clinical responders (Investigator's Global Assessment score 0/1 [clear/almost-clear] or ≥75% improvement in the Eczema Area & Severity Index) to nemolizumab at week 16 were re-randomized (1:1:1) to receive nemolizumab 30 mg Q4W, nemolizumab 30 mg Q8W, or placebo (nemolizumab withdrawal) Q4W subcutaneously in combination with TCS and/or TCI. The incidence & severity of treatment-emergent adverse events (TEAEs), including adverse events of special interest (AESI) & serious adverse events (SAEs) were reported.

Results: A 16-week post-hoc pooled analysis showed that the proportion of patients with ≥1%TEAE was similar between the nemolizumab & placebo groups (23.2% vs 17.6%). In both groups the most common TEAE (incidence ≥5%) was AD (nemolizumab: 9.9% vs placebo: 8.4%). During the 32-week maintenance period the most common TEAEs (incidence ≥5%) were nasopharyngitis (nemolizumab Q4W: 8.2%, nemolizumab Q8W: 4.8%, nemolizumab withdrawal: 7.1%), COVID-19 (nemolizumab Q4W: 7.6%, nemolizumab Q8W: 7.8%, nemolizumab withdrawal: 11.3%) & AD (nemolizumab Q4W: 7.6%, nemolizumab Q8W: 6.6%, nemolizumab withdrawal: 10.7%). Most TEAEs were non-serious & mild/moderate in intensity. AESI (injection-related reactions, asthma, infections, & peripheral/facial oedema) occurred at similar rates across the treatment arms. AESI in the field of AD during 32 week maintenance period were conjunctivitis allergic (nemolizumab Q4W: 1.2%, nemolizumab Q8W: 0.6%,

nemolizumab withdrawal: 0.6%) & infective conjunctivitis (nemolizumab Q4W: 0%, nemolizumab Q8W: 0.6%, nemolizumab withdrawal: 0%). No fatal SAE were reported in both the initial & the maintenance periods. The pooled safety data from the maintenance period up to week 48, reported at the 2024 American Academy of Dermatology Annual meeting, showed that the safety profile of nemolizumab remained consistent with that during the initial treatment period.

Conclusion: The pooled safety analysis demonstrates that targeting the IL-31 pathway with nemolizumab has acceptable safety profile at 16 & 48 weeks. The low incidence of conjunctivitis & herpes zoster further supports the safety of nemolizumab in long-term use.



Abstract N°: 5603

Initial Real-World Clinical Practice Experiences with Lebrikizumab in the Management of Severe Atopic Dermatitis

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory disease affecting 3% of the population, with a significant psychosocial impact. The therapeutic ladder includes topical treatments, phototherapy, and systemic immunomodulators. In Spain, cyclosporine is the first-line treatment for moderate-to-severe AD; however, the risk of nephrotoxicity limits its long-term use, often necessitating a switch to safer and more effective agents (biologics/JAK inhibitors). Lebrikizumab is a recently approved anti-IL-13 biologic indicated for moderate-to-severe AD in patients aged 12 years and older. We present three cases treated with lebrikizumab in our department, providing one of the first real-world clinical experiences in Catalonia.

Results:

A 44-year-old male, smoker, with a 20-year history of atopic dermatitis previously treated with topical therapies, cyclosporine, and methotrexate. He presented after a 5-year lapse in follow-up with eczematous lesions, some exhibiting prurigo nodularis–like features, and an EASI score of 45 (BSA 36%, IGA 4, PP-NRS 9, SCORAD 67.6). After 7 weeks of treatment with lebrikizumab, he showed marked clinical improvement, with a reduction in EASI to 11 (BSA 25%, IGA 2, PP-NRS 4, SCORAD 43.9).

A 21-year-old female from Senegal, with a 4-year history of atopic dermatitis previously treated with UVB phototherapy and cyclosporine, showing a partial response. Baseline EASI was 22 (BSA 20%, IGA 3, PP-NRS 8, SCORAD 48.2). After 8 weeks of treatment with lebrikizumab (in combination with low-dose cyclosporine), EASI was reduced to 5 (BSA 12%, IGA 1, PP-NRS 4, SCORAD 31.5).

A 58-year-old female, with no significant medical history, diagnosed with atopic dermatitis since childhood. She has received multiple treatments, including cyclosporine, methotrexate, dupilumab, abrocitinib, and upadacitinib. Treatment with lebrikizumab was initiated in combination with oral prednisone 30 mg. Baseline assessment: EASI 28, BSA 28%, IGA 3, PP-NRS 7, SCORAD 56%. Follow-up evaluation pending.

Conclusion:

Lebrikizumab has demonstrated efficacy over placebo in clinical trials, achieving EASI-75 in up to 58.8% of cases at week 16 (and up to 69.5% when combined with topical corticosteroids). It shows a favorable safety profile, with the most common adverse events being conjunctivitis (6.9%), injection site reactions (2.6%), and eosinophilia (0.4%). In the cases presented, lebrikizumab induced a rapid response, with a mean EASI improvement of 76% at 7–8 weeks, good tolerability, and no notable adverse effects. Further studies are needed to assess its long-term efficacy and safety in larger cohorts and real-world settings.

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Sleep disturbance is twice as prevalent in children and adolescents with atopic dermatitis: A population-based cohort study in English primary care

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Introduction & Objectives: Young people with atopic dermatitis (AD) often experience delayed sleep onset and may wake during the night, reducing both sleep duration and quality. This can impact their quality of life, and affect other family members. Although AD is common in childhood and sleep disturbance has widespread effects, population-based research is limited. Existing studies have focused on selected groups, which do not represent the full spectrum of paediatric patients with AD. Therefore, this study aimed to estimate the burden of sleep disturbance in children and adolescents with AD, using a nationally representative primary care database in England, and to identify those groups most at risk.

Materials & Methods: The population comprised all eligible children and adolescents (aged between 2-<18 years years) registered among 1720 general practices in England contributing data to Clinical Practice Research Datalink (CPRD) Aurum database of routinely collected medical records (March 1, 2003 - March 1, 2023), with linkage to Office for National Statistics (ONS) mortality data and Index of Multiple Deprivation. Individuals with active AD were identified using a previously validated algorithm, requiring at least one AD-specific Read or SNOMED code in addition to two AD treatment codes within 365 days of each other. Cases with active AD were matched with up to four unaffected controls on sex, age (categorical), ethnicity, deprivation score and geographical region, with matching on nearest neighbour for age and duration of practice registration. The outcome was any sleep disturbance recorded in primary care, identified through Read and SNOMED codes. Association between AD and sleep disturbance was evaluated using Cox regression, adjusting for age, sex, deprivation score and ethnicity. Patients were followed until the earliest occurrence of a recorded sleep disturbance, study end, deregistration, or death. Subgroup analysis included sex, age, socioeconomic deprivation, and ethnicity.

Results: 823,860 active AD cases were identified and matched evenly to 3,187,462 unaffected controls across age, sex, socioeconomic deprivation and ethnicity (Table 1). Median follow up time was 5.20 years (Inter quartile range [IQR] 2.35, 9.29] for cases with active AD and 3.50 years (IQR 1.28, 7.57) for controls. New onset sleep disturbance was recorded in 53205 (6.5%) patients with active AD and 81940 (2.6%) controls. Cases with active AD were identified to have a higher risk of sleep disturbance (adjusted hazard ratio [aHR] 2.05, 95% Confidence Interval [CI] 2.03-2.07) compared to controls. Adolescents (12 -<18 years) had the highest risk of sleep disturbance compared to children (2 -<12 years) (aHR 2.30, 95%CI 2.20, 2.39). There were marked differences across ethnic groups, with the highest risk reported in individuals of South Asian ethnicity (aHR 2.50, 95%CI 2.42, 2.59) and the lowest in those of white ethnicity (aHR 1.94, 95%CI 1.91, 1.96). The risk of AD-associated sleep disturbance was similar across sexes and deprivation groups (aHR range 1.96 – 2.11).

Conclusion: A substantial number of children and adolescents with AD experience sleep disturbance, with rates twice as high as those in unaffected controls. AD related sleep disturbances were highest in adolescents and those from ethnic groups other than white. These findings underscore the importance of recognizing the impact of sleep disturbance in paediatric AD patients for optimal patient management and AD treatment.

Table 1: Demographic characteristics of cases and matched population-based controls

	Active AD cases	Unaffected controls
n	823,860	3,187,462
Follow-up, median (IQR)	5.20 (2.4, 9.3)	3.50 (1.3, 7.6)
Age, date median (IQR)	3.0 (1.0, 7.0)	3.0 (2.0, 7.0)
Age group (%)		
2-4 years	518,008 (62.9)	1,998,139 (62.7)
5-11 years	202,969 (24.6)	800,450 (25.1)
12-<18 years	102,883 (12.5)	388,873 (12.2)
Sex		
Female (%)	398,797 (48.4)	1,540,375 (48.3)
Male (%)	425,063 (51.6)	1,647,087 (51.7)
Index of Multiple Deprivation quintile (%)		
1 (least deprived)	155,586 (18.9)	601,875 (18.9)
2	147,043 (17.8)	570,124 (17.9)
3	148,263 (18.0)	573,284 (18.0)
4	176,710 (21.4)	683,342 (21.4)
5 (most deprived)	195,661 (23.7)	756,774 (23.7)
Missing	597 (0.1)	2,063 (0.1)
Ethnicity (%)		
Black	53,593 (6.5)	206,639 (6.5)
Chinese	5,310 (0.6)	19,219 (0.6)
Mixed	36,670 (4.5)	142,663 (4.5)
Other	9,047 (1.1)	34,305 (1.1)
South Asian	91,327 (11.1)	352,980 (11.1)
White	428,531 (52.0)	1,670,567 (52.4)
Missing	199,382 (24.2)	761,089 (23.9)

IQR; Inter quartile range



Abstract N°: 5669

Application of real-world effectiveness outcomes of upadacitinib for atopic dermatitis to Canadian treat-to-target criteria: a retrospective multicenter analysis of week 16±8 data

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Introduction & Objectives:

While randomized controlled trials have investigated the efficacy of upadacitinib for atopic dermatitis (AD), real-world data remains limited. We conducted a retrospective multicenter study of upadacitinib for AD as per the Canadian target-to-treat (T2T) criteria as outlined by Yeung et al (2023).

Materials & Methods:

Our retrospective multicenter study included adult and adolescent patients with atopic dermatitis from three Canadian institutions who initiated treatment with upadacitinib. The primary outcome was achievement of T2T metrics as per week 12-16 goals, which included achievement of one clinician-reported outcome (Eczema Area and Severity Index [EASI] improvement of ≥-50% [EASI50] or Investigator Global Assessment [IGA] score ≤2) and achievement of one ; patient-reported outcome (reduction in Worst Pruritus Numeric Rating Scale [WP-NRS] ≥3, reduction in Dermatology Life Quality Index [DLQI] ≥4, or reduction in Patient Oriented Eczema Measure [POEM] ≥3). A nonresponder imputation (NRI) analysis was used to account for missing data. Safety was assessed via incidence of adverse events (AEs).

Results:

This analysis included a total of 222 patients. The mean age was 45 (range: 12-79) years, with 49.1% (109/222) being male. At weeks 16±8: T2T metrics were achieved by 79.7% (177/222) of patients in total. Clinician-reported T2T outcomes (EASI50 and/or IGA ≤2) were achieved by 91.4% (203/222) of patients, while patient-reported T2T outcomes (WP-NRS improvement ≥3, DLQI improvement ≥4, or POEM improvement ≥3) were achieved by 80.6% (179/222).

In total, 40 treatment-emergent adverse events (TEAEs) occurred (18%, 40/222). The most common AEs were elevated creatine kinase (2.7%, 6/222), elevated triglycerides (2.3%, 5/222), acne (1.4%, 3/222), folliculitis (1.4%, 3/222), herpes simplex (1.4%, 3/222), and myalgia/arthragia (1.4%, 3/222). Six treatment discontinuations (2.7%) were noted (AEs; myalgia/arthralgia [n=2], new-onset lung malignancy [n=1], uveitis [n=1], and venous thromboembolism [n=1]). No serious infections, hypersensitivity reactions, major adverse cardiac events, or hepatic abnormalities were observed during the treatment period analyzed.

Conclusion:

Our real-world effectiveness outcomes indicate that the majority of patients with AD achieve both clinician- and patient-reported Canadian T2T goals at weeks 16±8 with upadacitinib treatment. Study limitations include its

retrospective nature and a lack of real-world documentation of POEM scores.



Abstract N°: 5676

Patients who do not Flare During Maintenance Treatment With Dupilumab Monotherapy for 1 Year Have Lower Baseline CCL17/TARC Regardless of Dose Regimen

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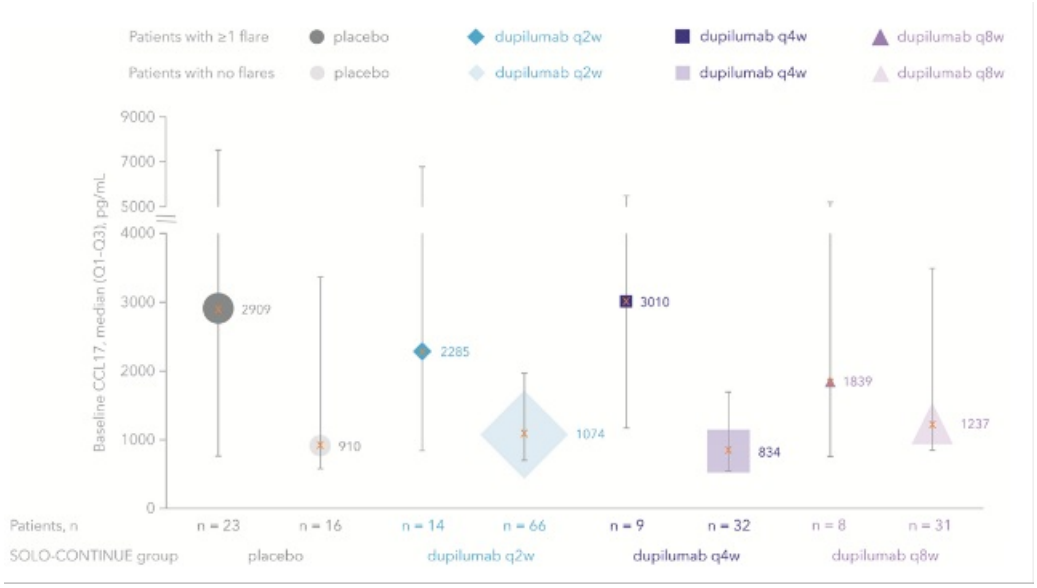
Introduction & Objectives: Absence of flares (worsening of disease requiring escalation of treatment) in patients with atopic dermatitis (AD) is a top priority for patients and physicians. Serum CCL17/TARC is a type 2 biomarker that reflects AD severity. We report the association between baseline serum CCL17 levels and subsequent flares in patients with AD treated with dupilumab monotherapy for 1 year across multiple dose regimens or those rerandomized to placebo for 9 months following 16 weeks of dupilumab every 2 weeks (q2w).

Materials & Methods: In this post hoc analysis, adults with moderate-to-severe AD who received dupilumab 300 mg q2w in the LIBERTY AD SOLO 1/2 trials (NCT02277743/NCT02277769) and achieved an optimal response of Investigator's Global Assessment 0/1 and/or ≥75% reduction from baseline in Eczema Area and Severity Index at Week 16, without occurrence of flare (n = 199/428), were rerandomized in SOLO-CONTINUE (NCT02395133) for an additional 36 weeks to dupilumab 300 mg monotherapy (q2w [n = 80], every 4 weeks [q4w, n = 41], every 8 weeks [q8w, n = 39]) or placebo (n = 39). This analysis reports median baseline serum CCL17 levels prior to initiating dupilumab treatment in SOLO 1/2. Data are presented as observed for patients who experienced ≥1 flare or no flares during SOLO-CONTINUE.

Results: Median baseline CCL17 levels were 1.5–3.6 times greater in patients who subsequently experienced ≥1 flare during the maintenance phase vs patients who experienced no flares, regardless of maintenance regimen (Figure). Safety was consistent with the known dupilumab safety profile.

Conclusion: In this analysis, baseline serum CCL17 level was a robust predictive biomarker of flares in patients with AD.

Figure. Baseline serum CCL17 levels in patients who experienced ≥1 flare vs no flares during SOLO-CONTINUE per maintenance regimen



Symbol sizes per group are proportionate to patient number. Orange X and numerical value represent median value per group.



Abstract N°: 5707

Healthcare Service Utilization and Medication Use in 128,239 Pediatric Patients with Atopic Dermatitis- Insights From a Cross-Sectional Case-Control Study in Israel

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Introduction & Objective:

Atopic dermatitis (AD) is a chronic inflammatory skin disease, affecting both children and adult patients, causing a substantial physiological, mental and social burden. Treatment for AD includes topical treatments such as corticosteroids, calcineurin inhibitors, and phosphodiesterase-4 inhibitors, as well as systemic treatments like immune-modulating agents and biologics. The introduction of biologics and Janus-kinase (JAK) inhibitors has been a milestone in AD treatment options, for both adult and pediatric patients. Past research has suggested an increase in healthcare service uptake among adults, due to the introduction of biologics and JAK inhibitors. Understanding healthcare service utilization and medication use in children with AD is needed to ensure the effective integration of these treatments into clinical practice. This study aims to investigate healthcare service utilization and medication use in children with AD during 2024.

Results:

The study included 128,239 children with AD and 128,239 matched controls. The mean age of children with AD was 9.7 years; 18% of the participants were 0-4 years old, 30.4% were 5-9 years old, 30.1% were 10-14 years old and 21.6% were 15-18 years old. 47.4% of patients were female. Children with AD had increased health care utilization compared to control group, with higher rates of visits to pediatricians, general practitioners (GPs), and dermatologists. 144 children (0.11%) with AD were treated by immunosuppressive drugs as compared to 78 (0.06%) of the control group (OR 1.8, 95% CI 1.4- 2.4, p-value <0.001). 410 children (0.32%) were treated with biologic drugs as compared to 12 (0.01%) of the control group (OR 34.3, 95% CI 19.3- 60.9, p-value <0.001). 34 children (0.03%) were treated with JAK inhibitors as compared to 2 children (0.002%) of the control group (OR 17, 95% CI 4.1- 70.8, p-value <0.001). 11,062 children (8.6%) were treated with systemic corticosteroids as compared to 8,300 (6.5%) in the control group (OR 1.4, 95% CI 1.3- 1.4, p-value <0.001).

Conclusion:

During the year 2024, a higher utilization of health care services (e.g. pediatricians, GPs and dermatologists' visits) was observed in pediatric patients with AD compared to the control group. As only a small number of children with AD received immunosuppressants, biologic treatments and JAK inhibitors, we suggest that the use of systemic medications should be considered in pediatric patients with moderate to severe AD.

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Abstract N°: 5729

Impact of a Novel Topical Cream on Facial Skin Temperature and Redness Appearance Following Infrared Irradiation: A Split-Face Clinical Study

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Introduction & Objectives:

Elevated skin temperature can be a significant factor in various inflammatory skin conditions, including eczema, rosacea, and contact dermatitis, as well as a common consequence of exposure to environmental stressors like sun, wind, and extreme temperatures. This heightened temperature can contribute to discomfort and redness. While long-term management of these conditions requires addressing underlying causes, providing temporary relief from heat-induced discomfort is a crucial aspect of patient care and overall skin comfort1,2. This study investigates the efficacy of a fresh, lightweight, oil-in-water facial skincare product containing skin soothing ingredients such as colloidal oatmeal, bisabolol, and panthenol in reducing skin temperature and reducing temperature related erythema upon application.

Materials & Methods:

This single-center, evaluator-blinded, split-face, randomized, controlled clinical trial enrolled 25 women aged 18-60 with at least half of the panel with self-reported sensitive skin. Following a baseline assessment of facial skin temperature using infrared thermography (IRT) and redness appearance captured using VISIA-CR imaging (Canfield, Parsippany, NJ, USA), subjects underwent controlled IR irradiation (PHILIPS InfraCare 3000 series infrared physiotherapy lamps, Koninklijke Philips N.V., Amsterdam, Netherlands) to elevate skin surface temperature to 42 ± 2°C. Subsequently, the topical cream was applied to one randomized half of the face, while the other half served as an untreated control. IRT and VISIA-CR imaging were repeated immediately post-IR irradiation and post-product application. Skin temperature data from 30 locations on each side of the face were analyzed. Imaging analysis of redness using a* value was analyzed using the VISIA-CR captured images.

Results:

IR irradiation significantly increased bilateral facial skin temperature, maintaining a ≤1°C inter-side difference ($p>0.05$). Topical cream application immediately reduced both temperature and redness (a* value) compared to both post-irradiation and untreated control sides ($p<0.001$).

Conclusion:

This oil-in-water cream, formulated with colloidal oatmeal, bisabolol, and panthenol, effectively and rapidly reduced both skin temperature and redness following IR-induced heat. These findings suggest that this topical cream may offer valuable relief from heat-induced skin discomfort associated with various factors, including post-aesthetic procedures, and has the potential to be a beneficial adjunct in managing inflammatory skin conditions and sensitivity exacerbated by elevated skin temperature.

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Abstract N°: 5812

Efficacy and safety of JAK inhibitors in patients aged >60 years with moderate-to-severe atopic dermatitis: a 52-week multicenter, real-life study - IL AD (Italian Landscape Atopic Dermatitis)

Luca Potestio[1], Cataldo Patruno[2], Alessandra Narcisi[3], Antonio Costanzo[3, 4], Luciano Ibba[3, 4], Luigi Gargiulo[3, 4], Piergiorgio Malagoli[5], Michela Ortoncelli[6], Simone Ribero[6], Luca Mastorino[6], Francesco Leo[6], Silvia Mariel Ferrucci[7], Luisa Angileri[7], Francesca Barei[7], Luca Stingeni[8], Katharina Hansel[8], Claudio Sciarrone[9], Giampiero Girolomoni[10], Martina Maurelli[10], Caterina Foti[11], Benedetta Tirone[11], Anna Balato[12], Maria Esposito[13], Giovanni Paolino[14], Santo Raffaele Mercuri[14], Elena Pezzolo[15], Paola Savoia[16], Claudio Brescia[1], Maddalena Napolitano[1]

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Introduction & Objectives:

The prevalence of atopic dermatitis (AD) in elderly patients is increasing. However, its management remains challenging due to atypical clinical phenotypes, treatment resistance, and comorbidities. Janus kinase (JAK) inhibitors, abrocitinib, baricitinib, and upadacitinib, have emerged as promising therapeutic options. Nevertheless, evidence in elderly populations is scarce due to their underrepresentation in clinical trials and safety concerns. This multicenter, real-life study aimed to evaluate the efficacy and safety of JAK inhibitors in patients aged ≥60 years with moderate-to-severe AD.

Materials & Methods:

A 52-week, multicenter, real-life study was performed enrolling patients aged ≥60 years affected by moderate-to-severe AD undergoing treatment with JAK inhibitors for at least 16 weeks across 16 dermatological centers in Italy. Disease severity was assessed at baseline, week (W)4, 16, 24, and 52 using the Eczema Area and Severity Index (EASI), Dermatology Life Quality Index (DLQI), and Pruritus-Numerical Rating Scale (P-NRS). Adverse events (AEs) were recorded at each follow-up.

Results: Seventy-two patients (mean age 68.83 ± 6.95 years; 50% male) were included [abrocitinib: n=13 (18.06%); baricitinib: n=6 (8.33%); upadacitinib: n=53 (73.61%)]. All completed W16 follow-up, with 33 (45.83%) and 26 (36.11%) patients available at W24 and W52, respectively. Baseline scores were: EASI 21.22 ± 10.38, DLQI 18.21 ± 7.33, and P-NRS 7.84 ± 1.94. Statistically significant improvements were observed from W4 onwards (W52: EASI 0.81 ± 1.27; DLQI 0.31 ± 0.63; P-NRS 0.42 ± 1.03; $p<0.0001$ for all). No treatment discontinuations or dose adjustments due to AEs were reported. No significant efficacy or safety differences were observed among treatment groups.

Conclusion: JAK inhibitors demonstrated significant efficacy and an acceptable safety profile in elderly patients with moderate-to-severe AD. These findings support their use as a valuable therapeutic option in selected elderly individuals, particularly when other systemic treatments are contraindicated or ineffective.



Abstract N°: 5820

Efficacy and safety of dupilumab in a case series of transplanted patients with severe atopic dermatitis. Shared experience from several hospitals in Spain.

Raquel Dominguez-Lopez*[1], Mónica Munera Campos[2], Francisco Navarro Triviño[3], Trinidad Montero Vilchez[4], Constanza Riquelme Mc Loughlin[5], Rubén Barros Tornay[6], Enrique Gómez de la Fuente[7]

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Introduction & Objectives:

New therapies represent a significant advance in the management of atopic dermatitis (AD). Dupilumab, a monoclonal antibody targeting IL-4 and IL-13 signaling, was the first approved targeted therapy for AD, inhibiting Th2-mediated inflammation

However, data on its safety and efficacy in immunosuppressed patients, especially solid organ transplant recipients, remain limited. We present a multicenter case series of transplanted patients with AD treated with dupilumab along with a literature review.

Materials & Methods:

We conducted a retrospective, multicenter case series through an email-based survey of dermatologists from the GEIDAC (Spanish Group for Research on Contact Dermatitis and Cutaneous Allergy). Voluntarily reported cases were analyzed descriptively, without a standardized protocol.

Results:

Nine patients (8 men, 1 woman) with a median age of 35 years were included. Eight of them had undergone kidney transplantation and 1 heart transplantation. All were on immunosuppressive therapy to prevent rejection. Patients exhibited widespread eczematous and intensely pruritic lesions involving nearly the entire body. Three patients had been diagnosed with AD during childhood, and six during adulthood. Elevated baseline serum IgE levels were observed in three cases.

Prior therapies included topical corticosteroids (all), systemic steroids, calcineurin inhibitors, or phototherapy.

Baseline scores were recorded before starting treatment, with mean values of EASI 30, pruritus NRS 9, sleep NRS 8, and DLQI 20.

Treatment with dupilumab was well tolerated. Only one patient developed mild conjunctivitis and facial dermatitis, managed with topical treatment. Clinical response was excellent in most patients, with significant lesion clearance. One case was discontinued due to lack of efficacy. Those who did not achieve EASI 0 and IGA 0 still showed significant improvement, reaching EASI 75 and IGA 1. None showed deterioration of renal function or transplant-related complications.

Conclusion:

Our findings align with previously reported cases (n=15), showing consistent efficacy and safety of dupilumab in transplant recipients, regardless of the age, organ transplanted, its duration or immunosuppressive regimen. No graft rejection occurred, nor was adjustment of immunosuppressive treatment required.

These results support the hypothesis that dupilumab can be safely used in patients with maintained immunosuppression.

From an immunological perspective, preferential inhibition of the Th1 pathway induced by post-transplant immunosuppression may promote a shift towards the Th2 pathway, contributing to the development or exacerbation of AD.

By specifically blocking the Th2 pathway, dupilumab could partially restore this immunological balance and offer a safe and effective treatment for patients with AD and post-transplant immunosuppression.

Patients	Sex	Age	Organ transplant	Age at transplantation	Inmunosupressive tratment	Basal EASI	Basal pruritus NRS	Basal sleep NRS	Outcome of AD with Dupilumab	Follow-up	Adverse events
Patient 1	M	51	Renal	2000	Tacrolimus	28	9	6	No improvement	6 months	None
Patient 2	M	49	Renal	2020	Tacrolimus and Everolimus	50	10	8	Significat improvement	2 years	None
Patient 3	M	20	Renal	2021	Tacrolimus, MMF and Prednisone	24,8	7	5	Significat improvement	4 months	None
Patient 4	M	33	Renal	2008	Tacrolimus and MMF	35	10	9	Complete clearance	2 years	None
Patient 5	M	17	Heart	2009	Tacrolimus and Prednisone	21	8	8	Complete clearance	2 years	None
Patient 6	F	21	Renal	2010	Tacrolimus, MMF and Prednisone	29,61	-	-	Significat improvement	6 months	Conjuctivitis and redness
Patient 7	M	35	Renal	2021	Tacrolimus and MMF	29,6	10	10	Significat improvement	6 months	None
Patient 8	M	46	Renal	2000	Tacrolimus and MMF	21	9	8	Complete clearance	4 months	None
Patient 9	M	71	Renal	DC (2003) and DV 2009	Tacrolimus and Prednisone	29	9	8	Complete clearance	6 months	None

F: Female, M: Male, MMF: Mycophenolate mofetil

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Abstract N°: 5850

Global Trends and Modifiable Risk Factors for Atopic Dermatitis Incidence: Insights from GBD 2021

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Introduction & Objectives:

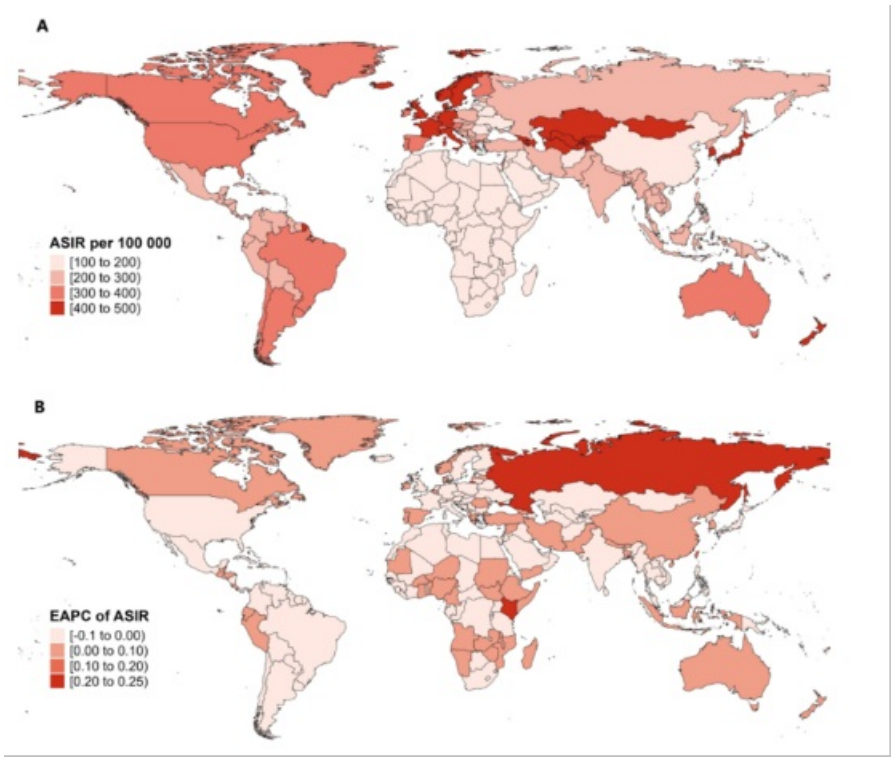
Global patterns in atopic dermatitis (AD) incidence and their associations with modifiable risk factors remain unclear. This study aims to analyze global trends in AD incidence and identify associated socioeconomic, environmental, and lifestyle factors contributing to its global disparities and epidemics.

Materials & Methods:

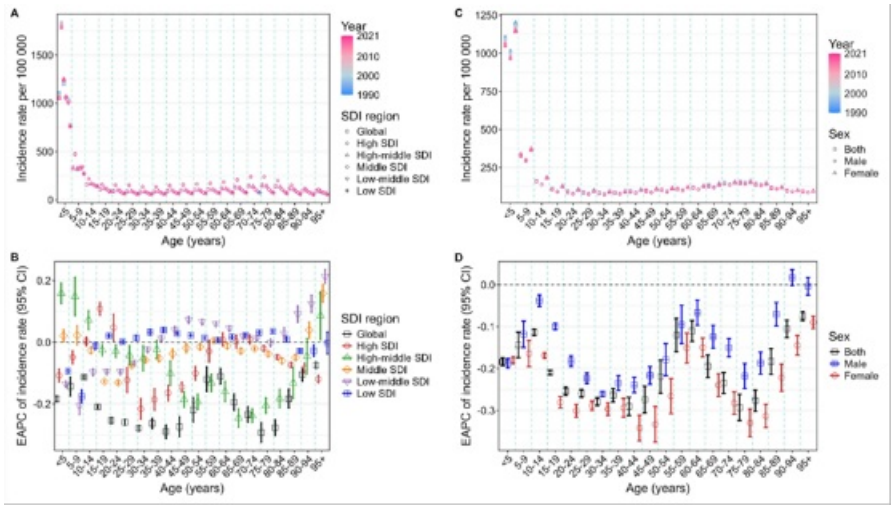
Data on AD in 204 countries and territories from1990 to 2021 were extracted from the Global Burden of Diseases (GBD) Study 2021. Age-standardized incidence rate (ASIR) were calculated by sex and region. We used restricted cubic splines to analyzed the relationship between the ASIR and socioeconomic and modifiable risk factors which were measured by summary exposure values (SEVs), including high body mass index (BMI), physical inactivity, air pollution, and poor dietary habits.

Results:

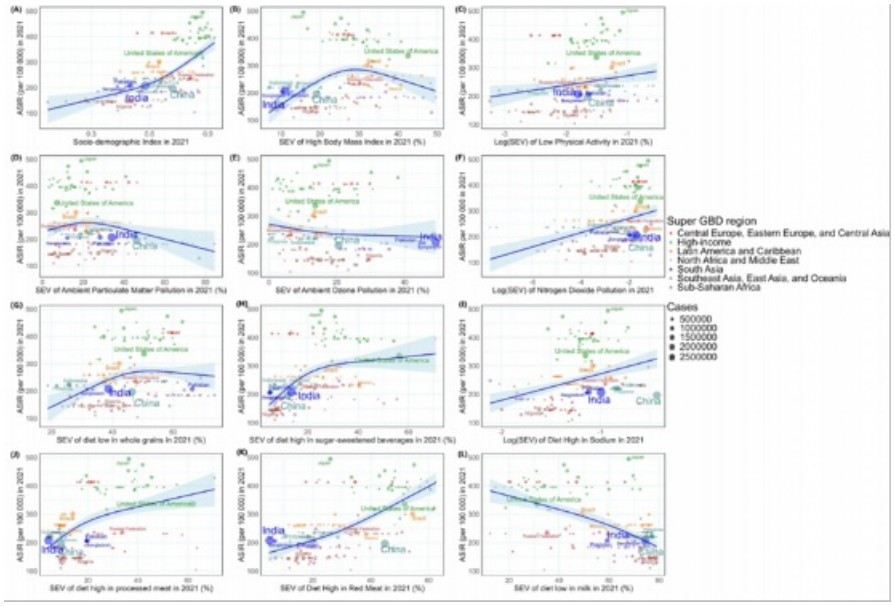
In 2021, 16.0 million new cases of AD were recorded globally, with the highest ASIRs in High-income Asia Pacific (474.8 per 100,000 population) and Western Europe (421.7 per 100,000 population) geographically and higher ASIRs in women. Socioeconomic development showed a strongly positive correlation with AD incidence (TABLE 1; FIG 1).



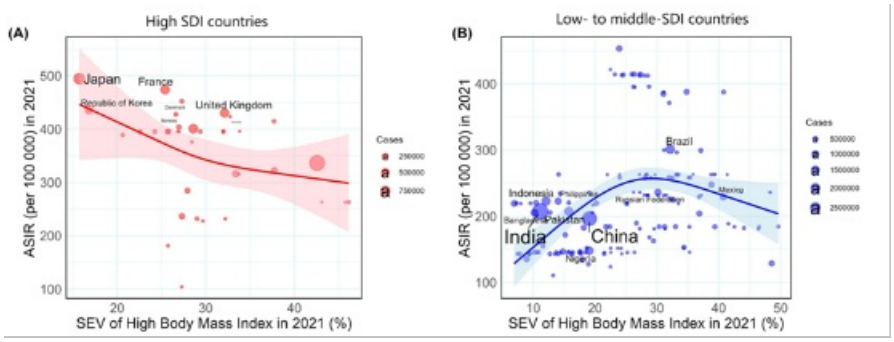
The age distribution showed two major peaks: < 5 years and 75-79 years, with a “W” pattern in ASIR across the lifespan. Among children (0-19 years), high-SDI regions had a higher EAPC, while lower SDI regions showed higher EAPCs in older age groups (FIG 2).



Among modifiable risk factors, high BMI, low physical activity, and nitrogen dioxide pollution performed positive associations with AD risk. Diets rich in sugar-sweetened beverages, processed meat, and sodium and diet low in whole grains further increased risk (FIG 3).



When countries were categorized into high-SDI and low- to middle-SDI groups, we observed that the positive correlation between BMI and incidence was more stable in low- to middle-income countries (FIG 4).



Conclusion:

Global disparities in AD incidence trends are closely linked to socioeconomic development and modifiable risk factors, including obesity, air pollution, and unhealthy diets. Addressing these factors may help mitigate the global

burden of AD, particularly in industrialized and rapidly developing regions. Addressing these factors through targeted public health policies is essential to mitigating the global burden of AD, particularly in industrialized and rapidly developing regions.



Abstract N°: 5865

An integrative framework for polygenic prediction of atopic dermatitis in UK Biobank

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Introduction & Objectives: Polygenic risk scores (PRS) offer valuable insights into the genetic architecture of complex diseases such as atopic dermatitis (AD), but their predictive utility remains limited. Integrating gene expression data into PRS construction may improve prediction accuracy and deepen understanding of disease biology.

Materials & Methods: In this study, we developed polygenic transcriptome risk scores (PTRSs) derived from AD-enriched tissues and evaluated their performance against traditional PRS models and a baseline risk model incorporating eosinophil and lymphocyte counts in the prediction of AD. We conducted transcriptome-wide association studies (TWAS) using the PrediXcan framework to construct tissue-specific PTRSs. Risk score performance was assessed in 256888 Europeans (10,816 cases) and validated in an independent cohort of 64152 Europeans (2669 cases) from the UK Biobank.

Results: We observed a modest correlation between PRS and PTRS, exerting independent effects on AD risk. While PRS demonstrated superior predictive performance compared to single-tissue PTRSs, combining both models significantly enhanced prediction accuracy, yielding a c-statistic of 0.646 (95% confidence intervals: 0.634–0.656). Notably, tissue-specific PTRSs revealed stronger associations with baseline risk factors, where Eppstein-Bar virus (EBV)-transformed lymphocytes and unexposed skin PTRSs tissues reported positive associations with lymphocyte counts.

Conclusion: To our knowledge, this is the first attempt to compute PRSs in UK Biobank for AD, further enhancing clinical risk factors and a novel approach for transcriptome-based risk scores. Our integrative approach underscores the value of incorporating biological information like tissue-specific gene expression to refine polygenic prediction models and elucidate the complex genetic architecture of AD.



Abstract N°: 5953

Efficacy and safety of lebrikizumab in combination with topical corticosteroids for moderate-to-severe atopic dermatitis: A systematic review and meta-analysis of randomized controlled trials

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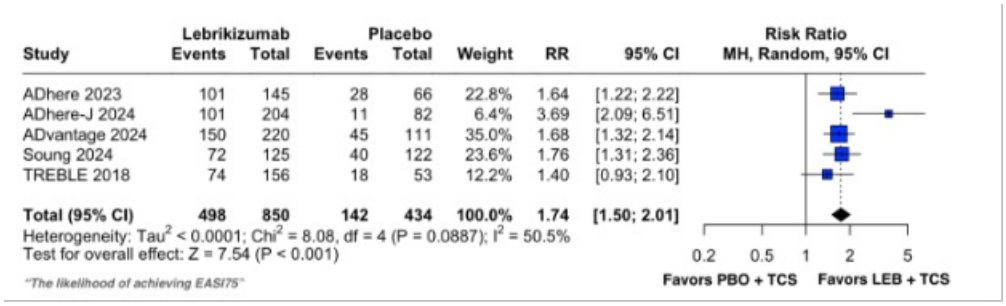
Introduction & Objectives: Atopic dermatitis (AD) is a chronic skin inflammation influenced by genetic, immunological, and environmental factors. While topical corticosteroids (TCS) are the primary treatment, long-term use can cause side effects. Lebrikizumab, an anti-IL-13 therapy, has shown promising results as monotherapy. This meta-analysis evaluates the real-world efficacy and safety of combining lebrikizumab with TCS for AD.

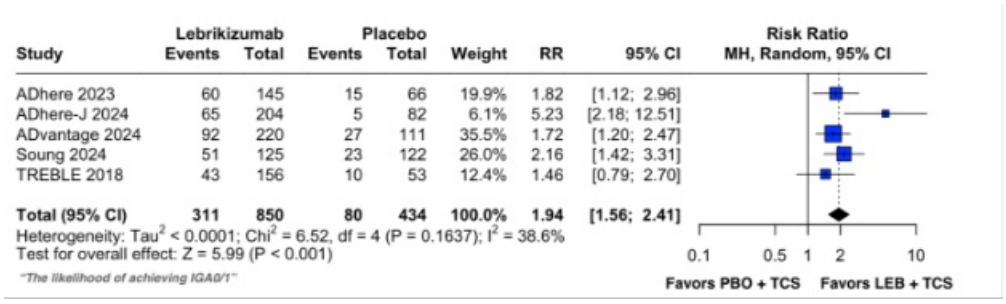
Materials & Methods: This systematic review and meta-analysis, registered in PROSPERO (CRD420251017921), followed the Cochrane and PRISMA guidelines. We searched PubMed, Embase, and Cochrane for randomized controlled trials (RCTs) comparing lebrikizumab with TCS to placebo with TCS in moderate-to-severe AD. Primary endpoints: Investigators' Global Assessment (IGA) 0/1, Eczema Area and Severity Index (EASI)75, and ≥1 treatment-emergent adverse event (TEAE). Secondary endpoints: a 4-point improvement in pruritus numerical rating scale (NRS), mean change in NRS, patient-oriented eczema measure (POEM) scores, and sleep-loss scale. A Der Simonian-Laird random-effects model was used in RStudio.

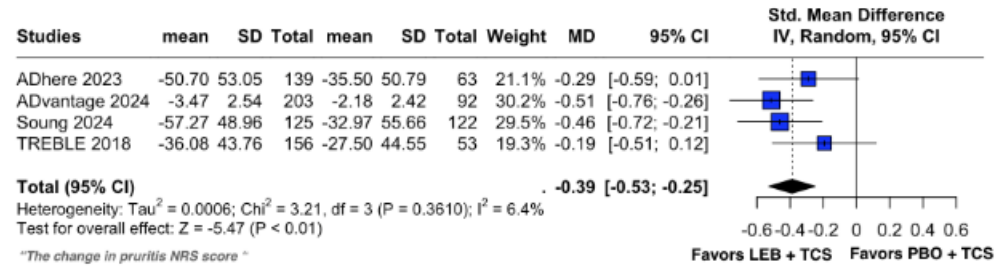
Results: We included 1284 patients from 5 RCTs. Lebrikizumab with TCS group significantly improved the likelihood of achieving EASI75 compared to placebo with TCS group (RR 1.74; 95% CI 1.50-2.01; $p<0.001$; $I^2=50.5\%$). It also increased the probability of IGA0/1 (RR 1.94; 95% CI 1.56-2.41; $p<0.001$; $I^2=38.6\%$) and a 4-point improvement in pruritus NRS (TCS (RR 1.68; 95% CI 1.36-2.06; $p<0.001$; I2=41.0%). Lebrikizumab with TCS showed greater improvement in pruritus NRS (SMD -0.39; 95% CI -0.53 - -0.25; $I^2=6.4\%$), POEM (SMD -5.10; 95% CI -7.06 - -3.14; $I^2=71.0\%$), and sleep-loss scale (SMD -0.41; 95% CI -0.61 - -0.20; $I^2=51.5\%$). No significant difference in TEAEs was observed (RR 1.09; 95% CI 0.96-1.23; $I^2=0.0\%$). Leave-one-out analysis identified ADhere-J as the main source of heterogeneity. Subgroup analysis for EASI75, IGA0/1, and TEAEs showed no significant difference by dosage regimen, indicating the need for further trials.

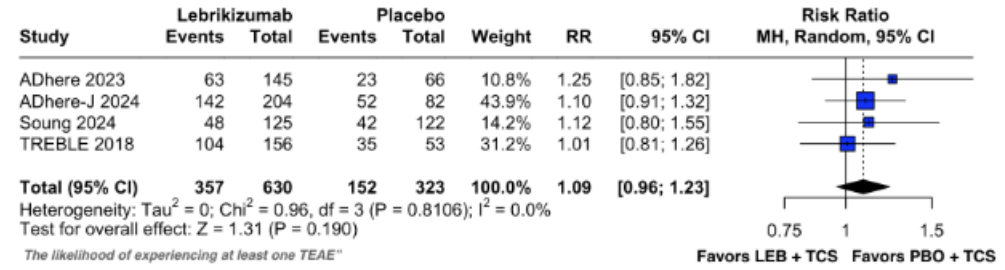
Conclusion: This meta-analysis suggests that lebrikizumab with TCS does significantly improve moderate-to-severe AD, without a significant increase in adverse events.

Study	Follow-up (weeks)	No. of patients, n	Male, n (%)	Adolescents, n (%)	Age (years), mean ± SD	BSA (%), mean ± SD	IGA4 (severe), n (%)	EASI, mean ± SD	SCORAD mean ± SD	Lebrikizumab regimen	TCS administration
ADhere 2023	16	211	108 (51.18)	46 (21.8)	37 ± 19.25	39.71 ± 21.53	65 (30.8)	27.29 ± 10.93	NR	At baseline and week 2: loading dose of 500 mg Followed by 250 mg Q2W	Patients were allowed to taper or stop low to mid-potency TCS use as needed, and TCS treatment could be resumed at the patients' discretion.
ADhere-J 2024	68	286	196 (68.53)	18 (6.29)	35.95 ± 12.57	59.37 ± 18.95	92 (32.16)	33.11 ± 12.02	63.33 ± 13.18	At baseline and week 2: loading dose of 500 mg Followed by 250 mg Q4W or Q2W	All patients initiated mid-potency TCS and low-potency TCS ≥ 7 days before baseline Intermittent high-potency TCS was permitted.
TREBLE 2018	20	209	136 (65)	0(0)	36.15 ± 12.65	26.43 ± 16.73	47 (22.4)	25.33 ± 11.10	58.84 ± 13.12	125 mg single dose 250 mg single dose 125 mg Q4W for 12 weeks	A 2-week mid-potency TCS run-in period before the 12-week treatment period Patients could apply TCS as needed.
ADvantage 2024	16	331	175 (52.9)	40 (11.8)	33.8 ± 14.96	NR	NR	NR	NR	At baseline and week 2: loading dose of 500 mg Followed by 250 mg Q2W	TCS was given for 16 weeks
Soung 2024	16	247	111 (44)	0(0)	35.39 ± 10.90	NR	65 (26.3)	26.96 ±13.10	NR	At baseline and week 2: loading dose of 500 mg Followed by 250 mg Q2W	Low to mid-potency topical corticosteroids (TCS) were allowed from baseline for AD symptoms. Patients could receive TCS if their AD symptoms worsened intolerably.











Abstract N°: 5979

Sustained and rapid efficacy of abrocitinib in atopic dermatitis: A multicenter real-world study with 48-Week follow-up

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease with a significant impact on quality of life. Abrocitinib, an oral selective JAK1 inhibitor, has shown efficacy in clinical trials; however, real-world data with long-term follow-up remain limited. So, the objective of this study was to assess the real-world effectiveness and safety of abrocitinib in patients with moderate-to-severe AD over a 48-week treatment period.

Materials & Methods:

This is a multicenter, observational, retrospective study including AD patients ≥ 12 years with moderate-to-severe AD starting abrocitinib for the first time. Sociodemographic and clinical outcomes were assessed at baseline and at weeks 4, 16, 24, and 48. Primary endpoints included changes in Eczema Area and Severity Index (EASI), SCORing Atopic Dermatitis (SCORAD), Investigator's Global Assessment (IGA), Body Surface Area (BSA), and peak pruritus Numerical Rating Scale (NRS).

Results:

A total of 49 patients with AD were included, being 69.4% (34/49) male with a mean age of 35.25 years (SD 14.32). Comorbidities of the patients involved asthma 49.0% (24/49), allergic rhinitis 40.8% (20/49) and conjunctivitis 40.8% (20/49). Prior treatments included ciclosporin 93.9% (46/49), methotrexate 22.4% (11/49), phototherapy 20.4% (10/49), dupilumab 28.6% (14/49), tralokinumab 26.5% (13/49), upadacitinib 16.3% (8/49), and baricitinib 6.1% (3/49). Some special locations affected were face/neck 69.4% (34/49), gluteal region 26.5% (13/49), genital area 16.3% (8/49), and hands 57.1% (28/49). At baseline, most patients suffered a severe disease reflected in a mean EASI of 25.39 (SD 8.94), SCORAD 53.97 (SD 12.39), IGA 3.58 (SD 0.57), BSA 34.3%, and pruritus NRS 7.53 (SD 2.29). A progressive and clinically meaningful improvement was observed over time as evidenced by changes in EASI scores (7.79 W4, 6.17 W16, 0.82 W24, 5.37 W48; $p<0,05$), IGA (1.51 W4, 1.03 W16, 0.42 W24, 1.11 W48; $p<0,05$); SCORAD (2.29 W4, 23.06 W16, 9.33 W24, 19.47 W48; $p<0,05$), BSA (12.6% W4, 7.71% W16, 1.72% W24, 5.6% W48; $p<0.05$) and NRS for pruritus (3.09 W4, 3.6 W16, 1.38 W24, 3.5 W48; $p<0.05$).

Conclusion:

Abrocitinib demonstrated rapid and sustained efficacy in the treatment of atopic dermatitis in a real-world, multicenter cohort, with meaningful clinical improvements evident by week 4 and largely maintained through week 48.

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Abstract N°: 6052

Increased Risk of Migraine in Patients with Atopic Dermatitis: A Population-Based Cohort Study Using the TriNetX US Collaborative Network

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Introduction & Objectives:

Atopic dermatitis (AD), a chronic inflammatory skin disease, has been increasingly associated with systemic comorbidities, including neurological disorders. This study aimed to investigate the risk of developing migraine in patients with AD using a large real-world dataset.

Materials & Methods:

We conducted a retrospective cohort study using the TriNetX US Collaborative Network, comprising electronic health records from over 70 million patients. Individuals with a diagnosis of AD were identified and compared to non-AD controls using multiple analytic models. Propensity score matching was employed to control for potential confounders, including age, sex, race, BMI, socioeconomic and psychosocial health risks, healthcare utilization, comorbidities (hypertension, hyperlipidemia, diabetes mellitus), and comedications (acetaminophen and non-steroidal anti-inflammatory drugs). Various sensitivity analyses were performed to assess the robustness of the association, including adjustments for different matching covariates, wash-out periods, follow-up durations, and AD case definitions based on claims algorithms and treatment regimens.

Results:

AD patients exhibited a consistently elevated risk of developing migraine across all models. In crude models, the hazard ratio (HR) for migraine was 1.946 (95% CI: 1.906–1.988), increasing to 2.040 (95% CI: 1.967–2.116) after adjusting for age and sex. With stricter wash-out periods of 24 and 36 months, the HRs were 2.097 (95% CI: 2.008–2.190) and 2.123 (95% CI: 2.028–2.222), respectively. When varying the follow-up time to 5 and 15 years, the HRs remained elevated at 2.087 (95% CI: 1.986–2.193) and 1.996 (95% CI: 1.920–2.074), respectively. Alternative AD definitions using more stringent diagnostic and treatment criteria also demonstrated increased migraine risks, with HRs of 2.014 (95% CI: 1.770–2.292) and 2.253 (95% CI: 2.142–2.370).

Conclusion:

Patients with atopic dermatitis have a significantly increased risk of developing migraine. These findings highlight the need for comprehensive care and interdisciplinary management strategies in patients with AD to address potential neurological comorbidities.

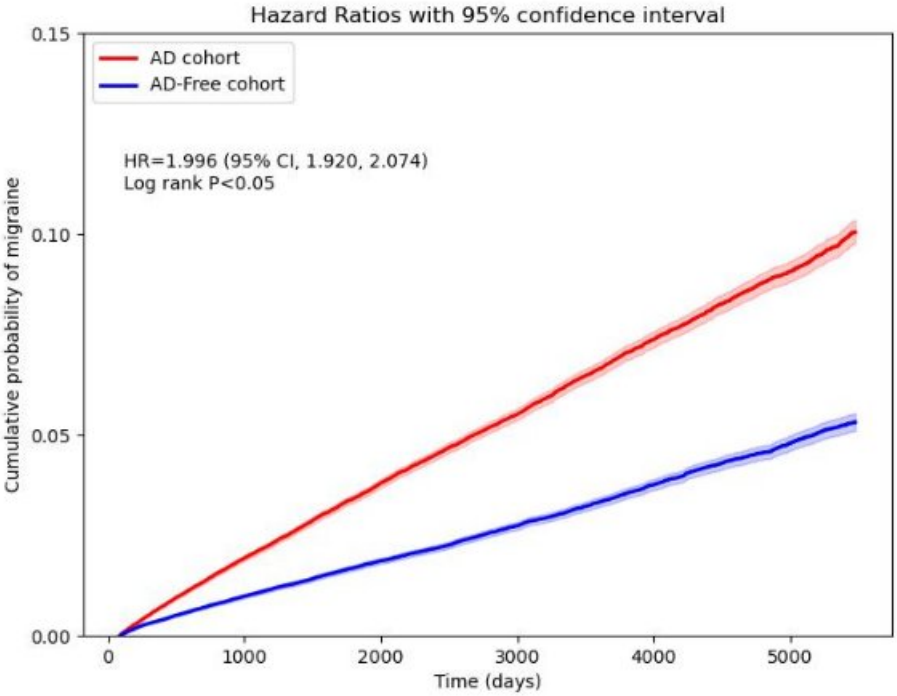


Figure 1. Cumulative probability of migraine risk in AD patients and non-AD controls



Abstract N°: 6111

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

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Introduction & Objectives:

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. We sought to conduct an interim analysis of the ATTRACT registry, for patients enrolled between June 19, 2024, and October 31, 2024, with a data cut-off on November 30, 2024.

Materials & Methods:

This prospective, multicenter study is conducted across 8 medical centers in Taiwan. It enrolled patients aged ≥12 years with moderate-to-severe AD newly prescribed abrocitinib. Data on demographics, clinical features, treatment history, and physician/patient-reported outcomes are collected. Adverse events were also recorded at each participating site through standard AE reporting procedures as the evaluation of safety is not a primary objective of this registry. Recruitment started in June 2024, and data collection will continue for a minimum of 12 months and up to 24-month observation period per participant.

Results:

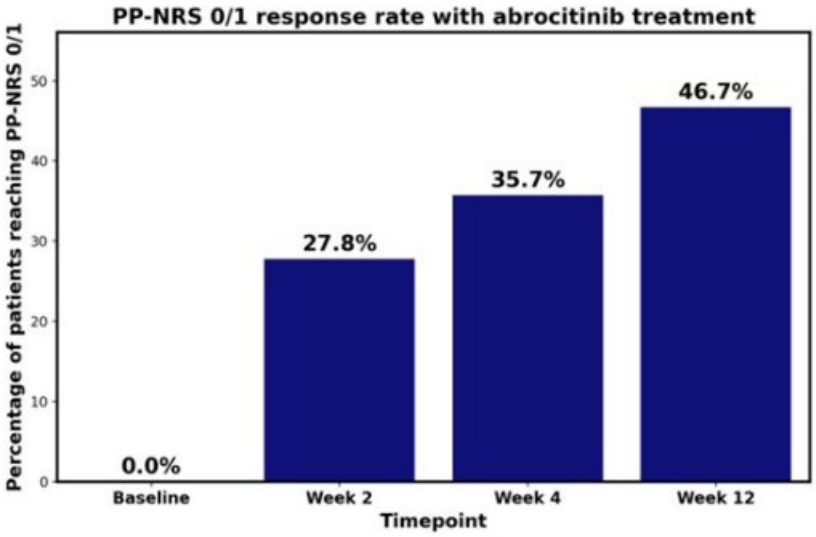
As of November 2024, 55 patients were enrolled from 8 sites in Taiwan (70.9% male), with a mean age of 40.8 ± 20.2 years and a mean age at initial AD diagnosis of 31.8 ± 24.7 years. Median follow-up was 72 days (IQR: 43–102). At the data cutoff, all patients had completed the baseline visit; and among those eligible for each timepoint, 41.8% had reached week 2, 76.4% had reached week 4, and 27.3% had reached week 12. Prior treatments comprised topical agents (41.8%), systemic agents (30.9%), dupilumab (10.9%), phototherapy (5.5%), and JAK

inhibitors (upadacitinib: 3.6%; baricitinib: 1.8%). Two of six dupilumab treated patients and two of three JAK inhibitor treated patients discontinued prior therapy due to lack of efficacy. Majority of the patients (83.6%) received a 200 mg dose and self-paid their abrocitinib therapy (83.6%), while 16.4% were covered by national health insurance. At baseline, the mean Eczema Area and Severity Index (EASI) score was 16.0 ± 11.4. By week 2, the mean EASI had declined to 6.7 ± 5.4, with a further reduction to 4.4 ± 5.9 at week 4, and 4.4 ± 5.7 at week 12 (72.4% reduction at week 12 from baseline). The mean Peak Pruritus Numerical Rating Scale (PP-NRS) was 6.5 ± 3.0 at baseline. By week 2, PP-NRS decreased to 3.9 ± 3.2, with 27.8% achieving a PPNRS score 0/1. At week 4, the mean fell further to 3.0 ± 2.8, and 35.7% patients reached a PPNRS 0/1. By week 12, the mean PPNRS was 2.3 ± 2.6 with 64.5% reduction from baseline, and 46.7% patients achieving a score of 0/1 (Figure 1). Table 1 summarises the improvements in various effectiveness measures from Baseline to Week 12. By the data cutoff, three patients experienced adverse events—two reported nausea and one reported upper abdominal pain—consistent with previously documented safety profiles. No new safety signals emerged during this interim analysis.

Conclusion:

These interim findings from the ongoing ATTRACT registry in Taiwan indicate that majority of patients with moderate-to-severe AD initiating abrocitinib had significant disease improvement. The rapid improvements observed across multiple clinical and patient-reported outcomes support the effectiveness abrocitinib in routine clinical practice. Nevertheless, extended follow-up periods and larger patient cohorts are essential to validate the durability of response and to thoroughly characterize the safety profile of abrocitinib.

Figure 1. PP-NRS 0/1 response rate progression in enrolled analysis set; N=55



Data cut-off: November 30, 2024

PP-NRS: Peak Pruritus Numerical Rating Scale

Table 1. Mean (SD) for various clinical and PRO measures with abrocitinib treatment in enrolled analysis set; N=55

Outcome	Baseline	Week 2	Week 4	Week 12
EASI	16.0 (11.4)	6.7 (5.4)	4.4 (5.9)	4.4 (5.7)
PP-NRS	6.5 (3.0)	3.9 (3.2)	3.0 (2.8)	2.3 (2.6)
IGA	3.2 (0.6)	2.3 (1.1)	1.7 (1.0)	1.3 (1.4)
BSA (%)	27.6 (23.8)	12.0 (13.7)	8.4 (12.6)	9.0 (12.9)
HECSI	23.8 (29.5)	6.7 (12.6)	5.5 (10.5)	7.9 (14.4)
POEM	21.0 (6.6)	10.6 (9.4)	7.9 (7.5)	6.9 (8.9)
ADCT	17.2 (5.7)	9.1 (8.4)	6.2 (6.3)	5.4 (5.5)
DLQI	17.3 (7.7)	9.0 (6.9)	7.5 (7.7)	5.8 (7.7)

Data cut-off: November 30, 2024

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's Global Assessment; NA, not applicable; POEM: Patient-Oriented Eczema Measure; PP-NRS: Peak Pruritus Numerical Rating Scale; PRO, patient reported outcomes



Abstract N°: 6126

The role of maternal, fetal and newborn anthropometrics in risk of atopic dermatitis development by three years of age

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Introduction & Objectives:

Background Maternal gestational weight gain has been associated with childhood atopic dermatitis (AD), while the role of maternal pre-pregnancy body mass index (ppBMI), fetal and newborn anthropometric measurements in AD development is not clear.

Objective

The aims were to determine primarily if maternal ppBMI, secondarily anthropometric measurements in the newborn and thirdly fetal thoracal and abdominal circumference growth from mid-pregnancy were associated with offspring AD by three years of age.

Materials & Methods:

The present study comprised 2107 mother-child pairs (54% boys) from the Scandinavian general population-based prospective Preventing Atopic Dermatitis and Allergy in Children (PreventADALL) cohort study with

available information on maternal weight and AD by three years in the child (Figure 1). Non-selected pregnant women were enrolled during the general ultrasound examination around gestational age 18 and their babies included at birth (born from week 35 and onwards). Maternal ppBMI was calculated from electronic questionnaire information at enrolment, using the WHO classification of BMI (kg/m2) of normal weight (18.5-25; reference), underweight (<18.5), overweight (25-30) and obese (>30). Anthropometric measures at midpregnancy in the fetus included thoracal and abdominal circumference as well as calculated weight by Combs formula. Additionally, we measured left upper arm circumference and length in the newborn. Fetal growth was calculated as fetal weight gain, as well as thoracal and abdominal circumference growth per day from midpregnancy ultrasound examination until birth (newborn).

Atopic dermatitis was defined as fulfilling either UK Working Party or Hanfin & Rajka diagnostic criteria at any time-point based on clinical assessments at 3, 6, 12, 24 and 36 months of age and phone interview at 36 months. Anthropometric measurements were used as continuous as well as categorical values (10th, 50th and 90th percentiles). Risk of AD was analyzed by univariable and multivariable logistic regression for ppBMI as continuous and categorical variable, and as continuous data for anthropometric measures adjusting for relevant confounders including maternal education, ppBMI and AD.

Results:

Atopic dermatitis was diagnosed in 525/2107 (25%) children by three years of age. Maternal ppBMI was within the normal range in 1637 (78%), while 326 (2%) were underweight, 326 (16%) were overweight and 113 (5%) were obese. Increasing ppBMI was significantly associated with increased risk of offspring AD by three years (adjusted odds ratio (aOR) (95% CI) 1.03(1.00-1.06), p=0.043). However, BMI categories were not significantly associated with offspring AD (Figure 2A). Birth length (mean (SD) 50.5 (2.0) cm.) was associated with AD by 3 years, with low birth length (<48 cm) conferring a significant decreased risk of offspring AD ((aOR)(95% CI) 0.71(0.51-1.0) p=0.048)(Figure 2B).Birth weight (mean (SD) 3.6 (0.5)) kg was not associated with AD by 3 years of age, nor were thoracal, abdominal or upper arm circumference (Figure 2C). Neither fetal weight gain nor fetal thoracal and abdominal growth from midpregnancy were associated with AD by three years.

Conclusion:

Increasing ppBMI conferred a higher risk, while lower birth length reduced the risk of offspring AD by three years of age.

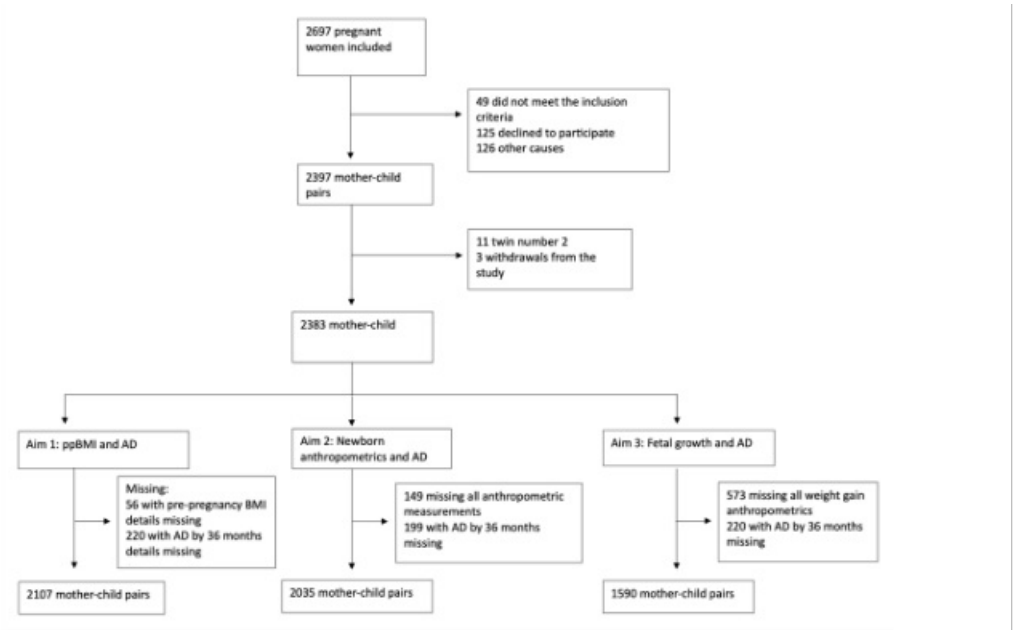


FIG 1. Flowchart showing the selection process of the study population with inclusion and exclusion criteria of each aim in this substudy from the PreventADALL cohort.

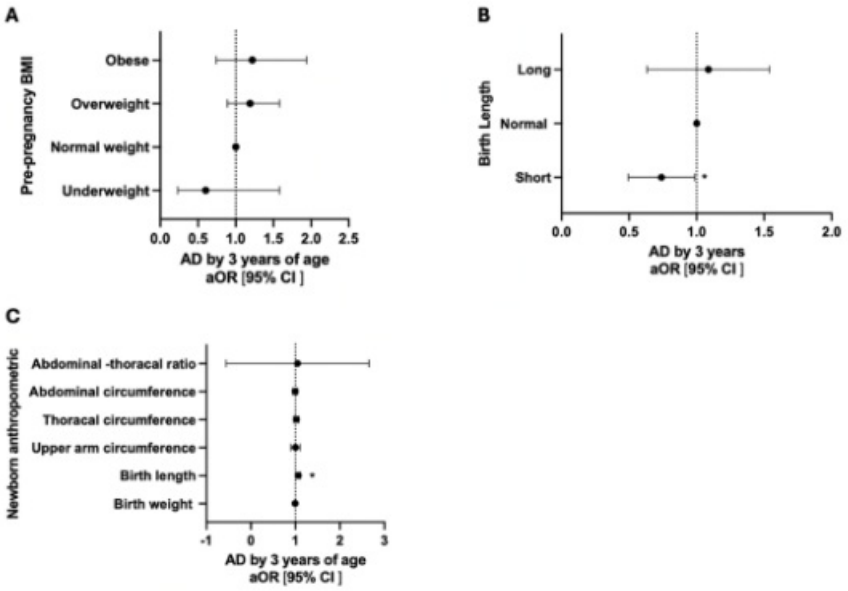


FIG 2. Forest plot for pre-pregnancy BMI (n=2107)(A), birth length (n=1590)(B) and newborn anthropometrics (n=2035) (C) and atopic dermatitis (AD) by 3 years of age, shown as odds ratio (OR) with 95% confidence interval (CI). Obese, overweight, normal weight and underweight are categorized based on the World Health Organization's definition. Multivariable logistic regression models were used adjusting for the following confounders identified by direct acyclic graph: maternal AD and maternal socio-economic status. In Figure 2C the CI are narrow, except for abdominal thoracal ratio.

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Abstract N°: 6165

Dupilumab Monotherapy for 1 Year Provides Rapid and Sustained Improvement in SCORAD Across Dose Regimens in Adults With Moderate-to-Severe Atopic Dermatitis

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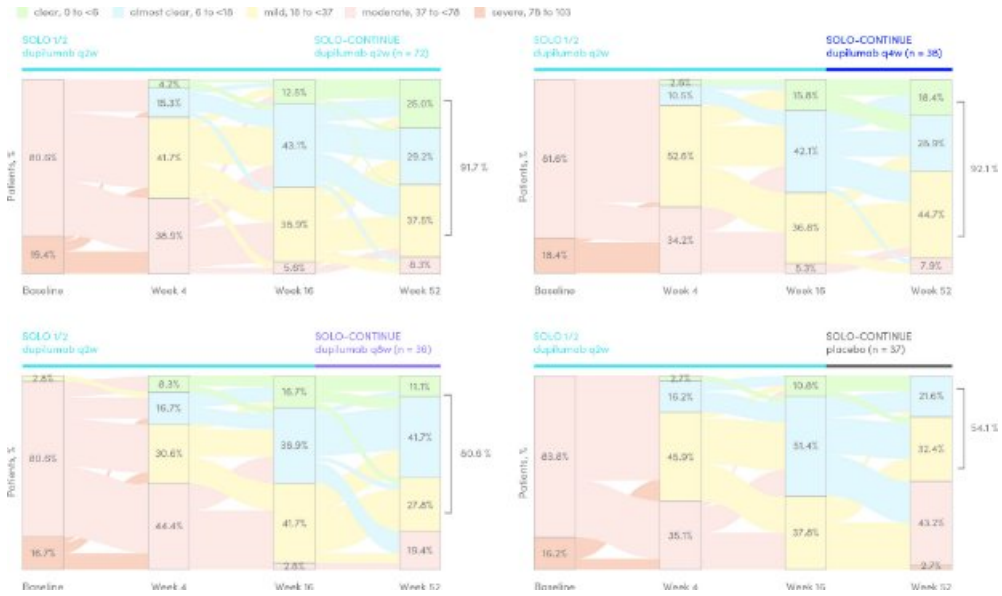
Introduction & Objectives: SCORing Atopic Dermatitis (SCORAD) is recommended by European AD guidelines and can quantify disease activity. Dupilumab 300 mg every 2 weeks (q2w, approved dose) monotherapy or in combination with topical corticosteroids provides rapid and sustained improvement in SCORAD outcomes. We expand these findings by reporting the proportion of patients achieving and maintaining low disease activity, as measured by total SCORAD, in patients with moderate-to-severe AD receiving 1 year of dupilumab monotherapy across multiple dose regimens.

Materials & Methods: In this post hoc analysis, 183 adults with moderate-to-severe AD who received dupilumab 300 mg q2w in the LIBERTY AD SOLO 1/2 trials (NCT02277743/NCT02277769) and achieved an optimal response of Investigator's Global Assessment 0/1 and/or ≥75% reduction in Eczema Area and Severity Index at Week 16 were rerandomized in SOLO-CONTINUE (NCT02395133) for 36 additional weeks to dupilumab monotherapy at different intervals (q2w [n = 72], every 4 weeks [q4w, n = 38], every 8 weeks [q8w, n = 36]) or placebo (n = 37). Total SCORAD severity categories were clear (0–<6), almost clear (6–<18), mild (18–<37), moderate (37–<78), and severe (78–103). Data were analyzed as observed.

Results: At baseline of SOLO 1/2, 99% of patients had moderate (81%) or severe (18%) AD as measured by SCORAD (Figure). Rapid improvement was observed after 4 weeks of dupilumab q2w; 62% of patients had mild, almost clear, or clear AD at Week 4 and most patients had improved by ≥1 severity category from baseline. At Week 16, 96% of patients had mild, almost clear, or clear disease, which was maintained up to 1 year by most patients (92%) continuing dupilumab q2w treatment to Week 52 and those switching to dupilumab q4w (92%) or q8w (81%). In contrast, only 1/2 (54%) of patients rerandomized to placebo for 36 weeks of dupilumab withdrawal had a mild or better SCORAD score at Week 52. Safety findings remained consistent with dupilumab's established safety profile.

Conclusion: Dupilumab monotherapy provided rapid and sustained improvement in AD severity as measured by SCORAD. Low or no disease activity (mild, almost clear, or clear scores) for 1 year was maintained by most patients across all dupilumab dose regimens (q2w, q4w, q8w).

Figure. Dupilumab monotherapy provided rapid and sustained improvement in total SCORAD for 1 year



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Abstract N°: 6175

Kaposi's Varioliform Eruption in Severe Atopic Dermatitis: A Case of Successful Management with a Janus Kinase Inhibitor

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Introduction & Objectives:

Atopic dermatitis is a chronic inflammatory disease that, until recently, was primarily managed with general treatments that were often ineffective in severe cases. Recently, several targeted therapies have been developed, focusing on specific pathways involved in its pathophysiology. This case report describes a patient with severe atopic dermatitis who developed Kaposi's varioliform eruption, treated successfully with a Janus kinase inhibitor.

Objective: To describe the use of a Janus kinase inhibitor in the treatment of severe atopic dermatitis and its impact on disease management.

Materials & Methods:

We present the case of a 33-year-old female patient with severe atopic dermatitis and Kaposi's varioliform eruption who attended our clinic within the past year.

Results:

The patient, with a history of allergic rhinitis, atopic dermatitis, hypothyroidism, and Castleman disease, was undergoing treatment with rituximab and dexamethasone. She consulted the dermatology service due to the development of a dermatosis over a four-day period. The dermatosis involved all four body segments, with a predominance on the face. It was characterized by multiple vesicles on an erythematous base, clinically consistent with Kaposi's varioliform eruption. She was treated with acyclovir, leading to resolution of the lesion.

Despite prior treatments with calcineurin inhibitors, corticosteroids, and folic acid antagonists, the patient continued to experience poor control of her atopic dermatitis. As a result, treatment with a Janus kinase inhibitor (JAK1 and JAK2) was initiated. In the following weeks, she developed a perioral herpes simplex lesion, which was managed with acyclovir. Notably, the patient showed significant improvement in eczema, pruritus, and a reduction in quality of life, as measured by the Dermatology Life Quality Index (DLQI).

Conclusion:

Kaposi's varioliform eruption is a cutaneous manifestation that can occur in patients with atopic dermatitis, particularly during acute flare-ups. It is characterized by vesicular lesions and erythematous papules, which may progress to ulcers, typically affecting the face and trunk.

Current treatment strategies for atopic dermatitis focus on alleviating symptoms and reducing flare-ups. While topical therapies remain the cornerstone of management, systemic treatments are recommended for patients who do not achieve adequate control with first-line therapies.

Advances in the understanding of molecular mechanisms have facilitated the development of more targeted therapies for atopic dermatitis. However, the high cost and limited accessibility of these therapies present significant challenges. Personalized treatments may offer a promising approach to improving disease

management and outcomes in the future.



Abstract N°: 6187

Delgocitinib cream improves pain and health-related quality of life in patients with Chronic Hand Eczema with severe pain

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Introduction & Objectives:

Chronic Hand Eczema (CHE) is a long-term, multifactorial, inflammatory skin disease of the hands and wrists. Pain is frequently reported by patients as the most burdensome symptom of CHE, arising due to a combination of inflammation and cracking/fissuring of the skin. Greater pain severity may be associated with poor sleep, anxiety, depression, and lower health-related quality of life (HRQoL). This *post hoc* analysis aimed to evaluate the effect of treatment with the pan-Janus kinase inhibitor delgocitinib cream on HRQoL in patients with CHE characterised by a high severity of baseline pain.

Materials & Methods:

DELTA 1 (NCT04871711) and DELTA 2 (NCT04872101) were phase 3 trials of identical design. In both trials, adult patients with moderate to severe CHE were randomised (2:1) to double-blind treatment with delgocitinib cream 20 mg/g or cream vehicle twice daily for 16 weeks. Data were pooled from both trials with the Hand Eczema Symptom Diary (HESD) used to assess patient-reported baseline pain on a 0–10 numeric rating scale. Patients with severe pain were defined as those with a HESD pain baseline score ≥7. The proportions of patients with severe pain achieving clinically meaningful improvements in HESD, HESD pain, EuroQol 5-dimension (EQ-5D), Dermatology Life Quality Index (DLQI), Hand Eczema Impact Scale (HEIS), HEIS Proximal Daily Activity Limitations (PDAL), and HEIS Embarrassment scores at 16 weeks were compared across treatments.

Results:

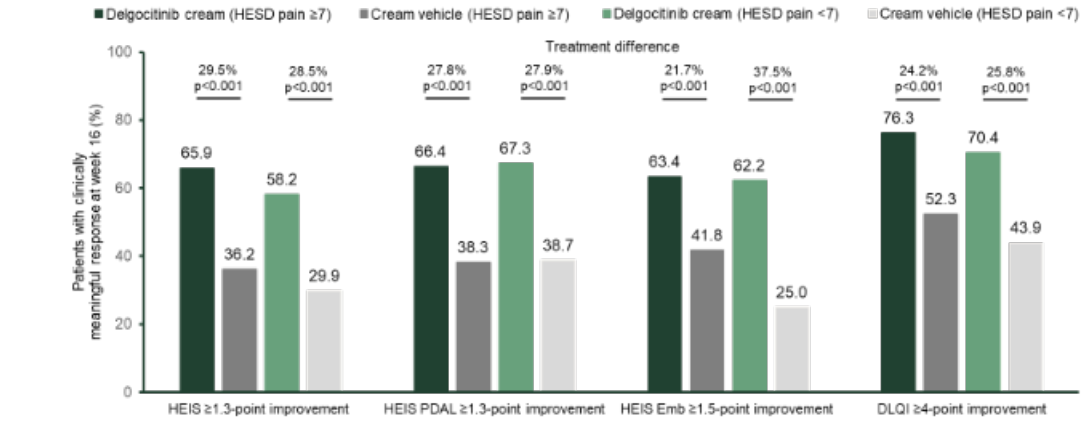
Across the two trials, 50% of patients (n=473/955) randomised to treatment had CHE characterised by severe pain (baseline HESD ≥7: delgocitinib cream, n=315; cream vehicle, n=158). Compared to patients with baseline HESD <7, patients with severe pain were more likely to have severe CHE as assessed by Investigators Global Assessment-CHE (37% vs. 20%) with worse HRQoL scores. At 16 weeks, reductions in HESD and HESD pain scores were significantly greater ($p<0.001$) with delgocitinib cream versus cream vehicle in patients with baseline HESD ≥7 (least-squares mean [SE] change −3.8 [0.2] vs. −2.0 [0.2] and −4.1 [0.2] vs. −2.2 [0.3]) and patients with baseline HESD <7 (−2.9 [0.1] vs. −1.1 [0.2] and −2.6 [0.1] vs. −0.9 [0.2]). Improvements in HESD and HESD pain scores with delgocitinib cream were rapid and significantly greater versus cream vehicle from week 1 onwards. The proportions of patients with severe pain achieving clinically meaningful improvements in HEIS, HEIS PDAL, HEIS

embarrassment and DLQI at 16 weeks were significantly greater with delgocitinib cream versus cream vehicle (Figure). Mean improvements in EQ-5D were also rapid and significantly greater with delgocitinib cream versus cream vehicle in patients with severe pain at 16 weeks (0.2 vs. 0.9; p<0.001).

Conclusion:

Delgocitinib cream resulted in rapid and significant improvements in pain and HRQoL in patients with CHE associated with severe pain.

Figure. Patients with severe baseline pain achieving clinically meaningful improvements in HEIS, HEIS PDAL, HEIS embarrassment and DLQI at 16 weeks



Primary analysis of the composite estimand strategy with missing data imputed as non-response for both groups. Data after initiation of rescue treatments or permanent discontinuation of study treatment are treated as missing. Mantel-Haenszel risk difference and Cochran-Mantel-Haenszel test stratified by trial ID, region and baseline IGA-CHE score.

DLQI, Dermatology Life Quality Index; HEIS, Hand Eczema Impact Scale; HEIS Emb, HEIS embarrassment; HEIS PDAL, HEIS Proximal Daily Activity Limitations; HESD, Hand Eczema Symptom Diary



Abstract N°: 6193

Incidence, Risk Factors, and Management of Conjunctivitis in Atopic Dermatitis Patients Treated with Dupilumab or Tralokinumab: Results from a Multicentre, Observational, Retrospective Study

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Introduction & Objectives:

Conjunctivitis is a common adverse event (AE) observed in patients with atopic dermatitis (AD) treated with biologics. However, comparative real-world data regarding incidence, risk factors, and management strategies remain limited. This study aimed to compare the incidence, clinical features, and management of conjunctivitis in patients with moderate-to-severe AD treated with dupilumab or tralokinumab in a real-life setting.

Materials & Methods:

A retrospective, multicentre observational study was conducted across 35 Italian dermatology centres. Adult patients with moderate-to-severe AD who received dupilumab or tralokinumab for at least 16 weeks were included. Demographic, clinical, and treatment data were collected. For patients who developed conjunctivitis, detailed information on onset, severity, ophthalmologic referral, and management was analysed.

Results:

A total of 6668 patients were analysed (5899 treated with dupilumab, 769 with tralokinumab). Conjunctivitis occurred in 10.76% of dupilumab-treated and 12.61% of tralokinumab-treated patients, with no statistically significant difference in incidence. However, tralokinumab was associated with a significantly earlier onset of conjunctivitis (15.27 ± 14.47 weeks) compared to dupilumab (35.46 ± 45.18 weeks; $p < 0.0001$). Ophthalmologic management predominantly involved lubricating and corticosteroid-based eye drops in both groups. Treatment discontinuation or switching due to conjunctivitis was more frequent in the dupilumab group (25.35% vs. 14.43%, $p < 0.05$). No significant predictors of conjunctivitis severity were identified through logistic regression analysis.

Conclusion:

Conjunctivitis continues to represent a common and clinically significant AE in patients with AD receiving biologic therapies, with notable differences observed between dupilumab and tralokinumab in terms of onset and clinical management. Early recognition of ocular symptoms is essential, and dermatologists should promptly initiate supportive eye care and refer to ophthalmologists when appropriate. Further prospective research is warranted to elucidate underlying mechanisms, identify predictive risk factors, and establish evidence-based strategies for prevention and treatment.



Abstract N°: 6225

Dupilumab Normalizes Type 2 Inflammation and Normalizes/Does Not Perturb Type 1/3 Inflammation in Atopic Dermatitis

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Introduction & Objectives: Atopic dermatitis is a complex disease predominantly driven by type 2 (T2) inflammation and a disrupted epithelial barrier that clinically manifests with pruritic skin lesions. Blocking IL-4 and IL-13 signaling with dupilumab, a monoclonal antibody specific for IL-4Rα, has shown efficacy in moderate-to-severe atopic dermatitis and has demonstrated normalization of T2 inflammatory biomarkers. Less is understood about the molecular effects of dupilumab on the type 1 (T1) or type 3 (T3) inflammation that is also observed in patients with atopic dermatitis.

Materials & Methods: Unbiased transcriptional analysis was performed using lesional skin isolated from adults with moderate-to-severe atopic dermatitis (N=27) and skin isolated from healthy controls (N=45). In parallel, unbiased transcriptional analysis was conducted using lesional and non-lesional skin isolated in two studies including patients with moderate-to-severe atopic dermatitis treated with dupilumab (N=47). Normalized Enrichment Scores (NESs) from Gene Set Enrichment Analysis were used to interrogate expression of T1, T2, and T3 inflammation pathways in 1) atopic dermatitis patients vs. healthy controls and 2) post-dupilumab vs. pre-treatment samples.

Results: Relative to skin isolated from healthy controls, lesional and non-lesional skin isolated from adults with moderate-to-severe atopic dermatitis are significantly enriched for expression of genes associated with T1, T2, and T3 inflammation.

Further, compared with pre-treatment samples, both lesional and non-lesional skin isolated from dupilumab-treated patients showed a significantly lower T2 inflammation NES. Expression of genes within T1 or T3 inflammation NESs were either unchanged or were normalized by dupilumab treatment.

Conclusion: Patients with atopic dermatitis exhibit molecular heterogeneity, with predominant expression of genes associated with T2 inflammation as well as enriched expression of genes associated with T1 and T3 inflammation. Treatment with dupilumab normalized the expression of genes associated with T2 inflammation towards expression levels observed in healthy controls. Further, treatment with dupilumab either normalized or did not perturb the expression of genes associated with both T1 and T3 inflammation. These data indicate that dupilumab can normalize genes associated with inflammation in atopic dermatitis patients.



Abstract N°: 6241

Safety, tolerability, and pharmacokinetic (PK) results from the single-ascending dose (SAD) portion of the Phase 1 study of BBT001—a novel bispecific IL-4Rα/IL-31 antibody—conducted in healthy volunteers and patients with atopic dermatitis

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Introduction: Type II cytokines (IL-4, IL-13, IL-31) play critical yet distinct roles in Th2 inflammatory dermatological diseases like atopic dermatitis (AD). BBT001 is a novel tetravalent "2+2" bispecific antibody engineered to simultaneously target the IL-4/IL-13 and IL-31 pathways, featuring Fc modifications to extend its half-life. This first-in-human (FIH) study aims to evaluate the safety, tolerability, pharmacokinetics (PK), immunogenicity, pharmacodynamics (PD) and exploratory clinical activity of BBT001 following single- and multiple-ascending doses (SAD and MAD) in healthy volunteers (HVs) and adults with moderate-to-severe atopic dermatitis (AD). This abstract reports data from the SAD portion; the MAD portion is ongoing and will be reported separately.

Methods: In nonclinical studies, BBT001 demonstrated efficacy in multiple mouse models of AD and pruritus. A GLP toxicology study in monkeys showed that BBT001 was safe with the no-observed-adverse-effect level (NOAEL) up to 200 mg/kg. The nonclinical results were used to enable the FIH study. This FIH study is a randomized, double-blind, placebo-controlled, SAD and MAD study (NCT06808477) being conducted in HVs and in patients with moderate-to-severe AD. The study consists of three parts: Part A (SAD study in HVs), Part B (MAD study in HVs), and Part C (MAD study in AD patients). In Part A SAD study, up to 38 HVs across 5 cohorts receive a single intravenous dose of BBT001 ranging from 50 mg to 1200 mg. Safety assessments include adverse events (AEs), vital signs, clinical laboratory tests, electrocardiograms (ECGs), physical examinations, and immunogenicity (anti-drug antibodies, ADA). Blood samples are collected for PK and PD analyses.

Results: The study is ongoing. Subjects have been dosed with either BBT001 or placebo. To date, all dose levels administered have been well tolerated. Interim data from up to 38 subjects in the SAD portion of the trial, including preliminary safety, tolerability, and PK results, will be presented.

Conclusion: This Phase 1 SAD study characterizes the safety, tolerability, and PK profile of BBT001 in healthy volunteers. The findings support dose selection and scheduling for subsequent MAD cohorts in healthy individuals and patients with AD, and contribute to the early clinical development profile of BBT001.

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Abstract N°: 6281

Abrocitinib in combination with dupilumab for refractory atopic chronic hand eczema

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Introduction & Objectives:

Targeted immune inhibitors (biologics) and Janus kinase (JAK) inhibitors have revolutionized the management of moderate- to- severe atopic dermatitis. However, some patients remain insufficiently controlled with new systemic immunomodulatory treatments (SITs) in monotherapy, especially in "difficult to treat areas", as hand eczema.

Materials & Methods:

A-25-year-old man of Asian ethnicity, who works as a warehouse operative, with severe atopic dermatitis from early infancy, with concomitant severe atopic chronic hand eczema (CHE) for 5 years. He has a history of moderate/severe asthma and allergic rhinitis. Treatment history included ultra-potent topical corticosteroids, topical calcineurin inhibitors, prednisone, methotrexate, cyclosporine, azathioprine and phototherapy. Routine patch testing was performed with positive results to lanolin.

The patient began treatment with dupilumab 300mg every 2 weeks. By week 32, the Eczema Area and Severity Index (EASI) dropped from 22 to 4, and the Peak Pruritus Numerical Rating Scale (pp-NRS) from 8 to 4, but he maintained severe hand eczema with Investigator global assessment of Chronic Hand Eczema (IGA-CH) score of 4 points, with great impact on his quality of life, and causing work-related problems. We recommended starting oral alitretinoin, but the patient could not afford it.

We associated dupilumab treatment with abrocitinib 200mg per day, but the patient experienced nausea and dizziness, so dosage was tapered to 100mg per day. After 16 weeks of treatment, the CHE improved to "mild eczema", IGA-CH score of 2, and 52 weeks after starting the association, "almost clear", IGA-CH score of 1. The patient's quality of life improved from "strongly impaired" to "not at all impaired" based on the Quality of Life in Hand Eczema.

No major adverse events were reported. No remarkable abnormalities were observed during treatment in complete blood count, lipid panel, coagulation function or comprehensive metabolic panel, except for creatine kinase elevation (CPK: 977U/L).

Results:

The JAK–STAT signaling pathway is involved in the signaling of several cytokines that have been shown to play a role in the pathophysiology of atopic CHE, such as interleukins: IL-4, IL-13, IL-22 and IL-31. Although dupilumab is highly effective and used as monotherapy, it might insufficiently treat atopic dermatitis predominantly involving "difficult to treat areas", necessitating the use of adjunctive therapy. Considering that JAK-inhibitors target several cytokine pathways instead of one single pathway, are an alternative option for rescue therapy for refractory CHE.

However, the high cost of combination therapy may hinder its use.

Conclusion:

The combination of biologic (dupilumab) and JAKi (abrocitinb) could be a favorable option for refractory severe atopic dermatitis, especially in cases with recalcitrant chronic hand eczema.



Abstract N°: 6284

Dupilumab Safety and Efficacy Up to 3 Years Across Racial Subgroups in Pediatric Patients Aged 6 Months to 11 Years With Atopic Dermatitis

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Introduction & Objectives: Racial differences in the presentation, prevalence, and severity of atopic dermatitis (AD) are well-documented. Prior studies have shown efficacy and safety of dupilumab treatment across racial subgroups among adults with AD. Long-term data on disease characteristics and treatment response across pediatric racial subgroups are lacking. Safety and efficacy of dupilumab were evaluated for up to 3 yr in infants and children with AD from different racial subgroups.

Materials & Methods: Infants and children aged 6 mo–5 yr with moderate-to-severe AD and children aged 6–11 yr with severe AD enrolled in an open-label extension study (NCT02612454) after prior dupilumab trials (NCT03346434, NCT03345914). Patients received weight-based doses of dupilumab (200/300 mg every 4 or 2 weeks). Topical treatments were allowed. For this analysis, patients were categorized into 2 subgroups based on self-reported race: White vs Asian, Black/African American, and Other. Safety and percentage change from baseline in body surface area (BSA), Eczema Area and Severity Index (EASI), and SCORing Atopic Dermatitis (SCORAD) were reported through Week 152. Data were reported as observed.

Results: Of 554 patients, 400 (72.2%) self-identified as White and 154 (27.8%) as Asian, Black/African American, and Other. Study completion rates for White vs Asian, Black/African American, and Other patients were 88.8% vs 81.8% at Week 52, 77.5% vs 62.3% at Week 104, and 68.0% vs 47.4% at Week 152. Mean (SD) treatment exposure was 117.9 (45.4) weeks for White and 104.2 (50.5) weeks for Asian, Black/African American, and Other patients.

Patients from the Asian, Black/African American, and Other subgroup had more severe baseline disease and higher rates of treatment discontinuation compared to White patients. By Week 152, 22.3% of White and 39.6% of Asian, Black/African American, and Other patients discontinued treatment, most often due to patient withdrawal (6.3% and 11.0%) or other reasons (9.0% and 11.0%); differences may reflect a contrast in sample size between subgroups. Discontinuation due to lack of efficacy or adverse events (AEs) occurred in less than 2.0% of patients in either group.

Treatment-emergent AEs (TEAEs) occurred in 89.5% of White and 84.4% of Asian, Black/African American, and Other patients. Common treatment-related TEAEs (White vs Asian, Black/African American, and Other) included allergic conjunctivitis (2.5% vs 3.2%), nasopharyngitis (2.3% vs 1.3%), and blepharitis (0.5% vs 2.6%). Most TEAEs

causing permanent discontinuation (5/6), including one serious food-related anaphylaxis in a White patient, resolved or resulted in recovery. Both drug-related serious TEAEs (1 patient per subgroup) also resolved or resulted in recovery.

At Week 152, consistent decreases in disease signs and symptoms were observed in both subgroups. From parent study baseline, BSA reduced by over 80% (−85.5% White vs −80.3% Asian, Black/African American, and Other), SCORAD decreased by approximately 70% (−71.2% vs −69.4%), EASI scores improved by over 85% (−89.6% vs −85.5%), and nearly 90% of all patients achieved EASI-75 by Week 152.

Conclusion: Dupilumab treatment provided meaningful improvements in clinical outcomes for infants and children with AD across racial subgroups. The safety profile remained consistent with the established safety data for dupilumab, supporting its use in diverse pediatric populations with AD.



Abstract N°: 6297

Similar Patient Profiles and High Early Persistence Rates of Abrocitinib Among Adolescents and Adults with Moderate-to-Severe Atopic Dermatitis: A Real-World U.S. Analysis

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Introduction:

Atopic dermatitis (AD) is a chronically relapsing inflammatory skin disease with variable age of onset. For moderate-to-severe AD, treatment guidelines recommend medium or high-potency topical therapies. When these fail, systemic treatments such as immunomodulators, steroids, and advanced systemics, including monoclonal antibodies or oral Janus kinase (JAK) inhibitors, are recommended. Abrocitinib, an oral JAK1 inhibitor, was approved by the FDA in 2022 for adults and in 2023 for adolescents aged 12 -<18. This retrospective, real-world study evaluated patient characteristics and clinical utilization since abrocitinib received approval in the US.

Methods:

This retrospective study used real-world data from the Komodo Health claims database (1/1/2021 – 1/31/2025) to characterize US adolescents and adults with moderate-to-severe AD treated with abrocitinib. Demographic and clinical characteristics were assessed descriptively overall and by treatment positioning of abrocitinib among all approved advanced systemic treatments. Co-prescription with topicals at abrocitinib initiation was evaluated among patients with ≥30 days of follow-up and defined as the presence of a prescription for a topical treatment within 30 days before or after abrocitinib initiation. Early persistent use of abrocitinib (early persistence) was defined as the proportion of patients with ≥60 days of follow-up with an abrocitinib refill within 30 days of the first fill end date and was assessed descriptively.

Results:

A total of 3,542 patients met the inclusion criteria; with 315 (9%) adolescents (ages 12-<18) and 3,227 (91%) adults (ages 18+). Median age at treatment initiation was 15 years for adolescents, and 41 years for adults. Abrocitinib was most commonly prescribed as a second-line (2L) advanced systemic for both adolescent and adult patients **(Table 1)**. However, 27% of adolescents and 31% of adults received abrocitinib treatment as their first advanced systemic. Among patients with ≥60 days of follow-up (n=309 adolescents; n=3,166 adults), early persistence was 77% in adolescents and 75% in adults. The proportion of White patients ranged from 21% (1L) to 30% (2L) in adolescents and from 37% (1L/2L) to 33% (3L+) in adults, however there was high missingness in race/ethnicity data (38% adolescents, 31% adults). The most common prescriber specialties of abrocitinib were dermatologists (47% adolescents; 55% adults), physician assistants/nurse practitioners (39% adolescents; 32% adults) and allergists (9% adolescents; 6% adults). Notably, among patients with ≥30 days of follow-up (n=313 adolescents; n=3,200 adults), 74% of adolescents and 78% of adults did not have a co-prescription with topicals at abrocitinib initiation.

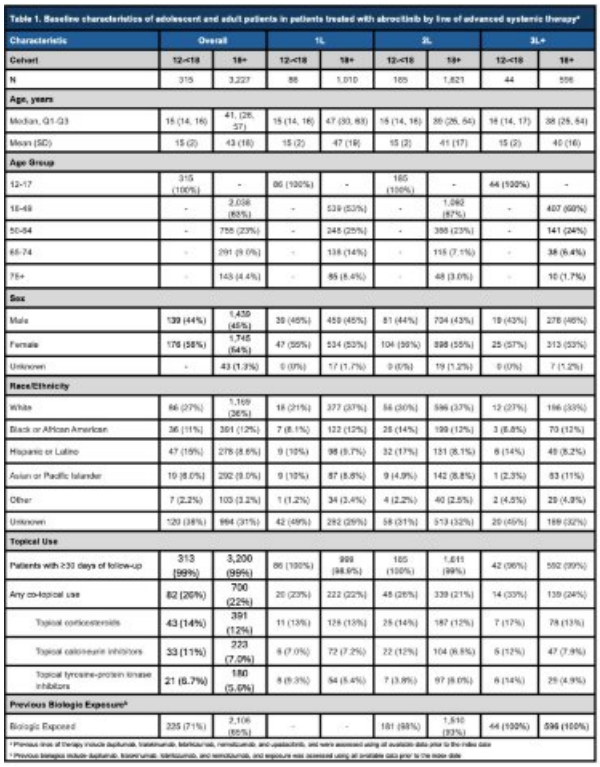


Table 1. Baseline characteristics of adolescent and adult patients in patients treated with abrocitinib by line of advanced systemic therapy*

Characteristic	Overall		1L		2L		3L+	
Cohort	12-<18	18+	12-<18	18+	12-<18	18+	12-<18	18+
N	315	3,227	86	1,010	185	1,821	44	556
Age, years								
Median, Q1-Q3	16 (14, 16)	41 (28, 57)	15 (14, 16)	47 (30, 63)	16 (14, 16)	39 (26, 54)	16 (14, 17)	38 (25, 54)
Mean (SD)	15 (2)	43 (16)	15 (2)	47 (16)	15 (2)	41 (17)	15 (2)	40 (16)
Age Group								
12-17	315 (100%)	-	86 (100%)	-	185 (100%)	-	44 (100%)	-
18-49	-	2,056 (63%)	-	539 (53%)	-	1,092 (67%)	-	407 (60%)
50-64	-	755 (23%)	-	345 (25%)	-	388 (23%)	-	141 (24%)
65-74	-	291 (9.0%)	-	138 (14%)	-	115 (7.1%)	-	38 (6.4%)
75+	-	143 (4.4%)	-	85 (8.4%)	-	48 (3.0%)	-	10 (1.7%)
Sex								
Male	139 (44%)	1,459 (45%)	39 (45%)	459 (45%)	81 (44%)	704 (43%)	19 (43%)	276 (46%)
Female	176 (56%)	1,745 (54%)	47 (55%)	534 (53%)	104 (56%)	898 (55%)	25 (57%)	313 (53%)
Unknown	-	43 (1.3%)	0 (0%)	17 (1.7%)	0 (0%)	19 (1.2%)	0 (0%)	7 (1.2%)
Race/Ethnicity								
White	86 (27%)	1,169 (36%)	18 (21%)	377 (37%)	56 (30%)	596 (33%)	12 (27%)	196 (35%)
Black or African American	36 (11%)	391 (12%)	7 (8.1%)	122 (12%)	26 (14%)	199 (12%)	3 (6.8%)	70 (13%)
Hispanic or Latino	47 (15%)	278 (8.6%)	9 (10%)	98 (9.7%)	32 (17%)	131 (8.1%)	6 (14%)	46 (8.2%)
Asian or Pacific Islander	10 (3.0%)	292 (9.0%)	9 (10%)	87 (8.6%)	9 (4.9%)	142 (8.8%)	1 (2.3%)	63 (11%)
Other	7 (2.2%)	103 (3.2%)	1 (1.2%)	34 (3.4%)	4 (2.2%)	40 (2.5%)	2 (4.5%)	29 (4.9%)
Unknown	120 (38%)	994 (31%)	42 (49%)	292 (29%)	58 (31%)	513 (32%)	20 (45%)	189 (32%)
Topical Use								
Patients with ≥30 days of follow-up	313 (99%)	3,200 (99%)	86 (100%)	999 (98.9%)	185 (100%)	1,811 (99%)	42 (96%)	552 (99%)
Any co-topical use	82 (26%)	700 (22%)	20 (23%)	222 (22%)	48 (26%)	339 (21%)	14 (33%)	139 (24%)
Topical corticosteroids	43 (14%)	391 (12%)	11 (13%)	125 (13%)	25 (14%)	187 (12%)	7 (17%)	78 (13%)
Topical calcineurin inhibitors	33 (11%)	223 (7.0%)	6 (7.0%)	72 (7.2%)	22 (12%)	104 (6.5%)	5 (12%)	47 (7.9%)
Topical tyrosine-protein kinase inhibitors	21 (6.7%)	180 (5.6%)	8 (9.3%)	84 (8.4%)	7 (3.8%)	97 (6.0%)	6 (14%)	25 (4.9%)
Previous Biologic Exposure^								
Biologic Exposed	225 (71%)	2,106 (65%)	-	-	181 (98%)	1,510 (83%)	44 (100%)	596 (100%)

* Previous lines of therapy include dupilumab, tralokinumab, lebrikizumab, nemolizumab, and upadacitinib, and were assessed using all available data prior to the index date
^ Previous biologics include dupilumab, tezepelumab, lebrikizumab, and nemolizumab, and exposure was assessed using all available data prior to the index date

Conclusion:

Compared to the JADE TEEN trial, adolescent patients in this real-world study were similar in age but received less co-prescription with topicals at initiation, consistent with rates seen for adult co-topical use. Early persistence across age groups suggests that the majority of patients who initiate abrocitinib refill their prescription on schedule. Adolescent initiators of abrocitinib had similar demographic profiles to those of adult initiators. These findings suggest that abrocitinib is being used in a broader range of real-world scenarios than clinical trials, warranting further investigation into treatment outcomes and adherence drivers in adolescent and adult patients with a longer post-approval follow-up.

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Abstract N°: 6337

Efficacy of Abrocitinib Flexible Dose Escalation and Reduction Versus Consistent Dosing in Adolescent and Adult Patients With Moderate-to-Severe Atopic Dermatitis: Results From the Real World–Simulating Expanded Access Protocol Study, JADE REAL

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Introduction & Objectives: JADE REAL (NCT04564755) was a global, open-label, expanded access protocol study initiated in 2020 (completed September 2024) to provide abrocitinib access to patients with moderate-to-severe atopic dermatitis (AD) for whom available and approved topical and systemic AD medications were inadequate. The unique study design simulated a real-world clinical setting. This post hoc analysis aimed to evaluate the dosing patterns (dose escalation and reduction vs consistent dosing) and efficacy of abrocitinib in adolescent and adult patients with moderate-to-severe AD in JADE REAL.

Materials & Methods: Eligible patients aged ≥12 years with moderate-to-severe AD were initiated on once-daily abrocitinib 100 mg or 200 mg per investigator's discretion. The dose could be changed throughout the treatment period. Patients were stratified by initial dose (abrocitinib 100 mg or 200 mg) and the number of dose changes (continuous dosing or ≥1 dose change/s). Dose change groups included patients with a dose escalation (abrocitinib 100 mg to 200 mg) and patients with a dose reduction (abrocitinib 200 mg to 100 mg). Efficacy assessments included the proportion of patients achieving ≥75%/≥90% improvement from baseline in Eczema Area and Severity Index (EASI-75/-90), and EASI-90 plus Peak Pruritus Numerical Rating Scale score of 0 or 1 (PP-NRS 0/1) at Week 72; for dose change groups efficacy responses were also assessed at the visit before dose change (visit 0) and at visits 1 and 2 following dose change.

Results: Of 312 patients in JADE REAL, 120 (38.5%) and 192 (61.5%) were initiated on abrocitinib 100 mg and 200 mg, respectively, with a mean (SD) treatment duration of 379.1 (203.3) days. Of patients initiated on abrocitinib 100 mg and 200 mg, 78 (65.0%) and 119 (62.0%) received continuous dosing, and 42 (35.0%) and 73 (38.0%)

patients had ≥1 dose change, respectively. A higher proportion of patients aged ≥12 to 18 and ≥65 years, who were Black/African American, and who had moderate AD were initiated on abrocitinib 100 mg, while a higher proportion of patients aged ≥18 to <65 years, who were Asian, and who had severe AD were initiated on abrocitinib 200 mg (**Table**). Across all treatment subgroups, the proportion of patients achieving efficacy responses at Week 72 ranged from 75.6% to 92.6%, 53.3% to 75.0%, and 28.9% to 57.9% for EASI-75, EASI-90, and EASI-90+PP-NRS 0/1, respectively. In the dose escalation subgroup, a comparable or numerically greater proportion of patients achieved efficacy responses at visit 2 post dose escalation versus visit 0 for EASI-75 (59.4% vs 41.9%), EASI-90 (40.6% vs 29.0%), and EASI-90+PP-NRS 0/1 (19.4% vs 20.0%); in the dose reduction subgroup, response rates were comparable at visit 2 post dose reduction versus visit 0 for EASI-75 (81.7% vs 80.0%), EASI-90 (65.0% vs 60.0%), and EASI-90+PP-NRS 0/1 (45.0% vs 46.0%).

Conclusion: Abrocitinib demonstrated improvements in severity and extent of AD across all treatment subgroups of patients for whom available and approved topical and systemic AD medications were inadequate. Patients initiated on abrocitinib 200 mg may decrease dosage to 100 mg with a low risk of losing efficacy, while patients initiated on abrocitinib 100 mg with lower efficacy may benefit from switching to 200 mg. As the JADE REAL trial simulates the real-world use of Janus kinase inhibitors, these results may support clinical decision making around initial dose selection and dosage optimisation based on individual patient needs.

Table. Patient Demographics and Baseline Disease Characteristics

	Total		Consistent Dose Subgroups		Dose Escalation Subgroup	Dose Reduction Subgroup
	Abrocitinib 100 mg (N=120)	Abrocitinib 200 mg (N=192)	Abrocitinib 100 mg (n=78)	Abrocitinib 200 mg (n=119)	Abrocitinib 100 mg/200 mg (n=42)	Abrocitinib 200 mg/100 mg (n=73)
Age (years), n (%)						
≥12 to <18	20 (16.7)	13 (6.8)	13 (16.7)	9 (7.6)	7 (16.7)	4 (5.5)
≥18 to <65	81 (67.5)	164 (85.4)	50 (64.1)	105 (88.2)	31 (73.8)	59 (80.8)
≥65	19 (15.8)	15 (7.8)	15 (19.2)	5 (4.2)	4 (9.5)	10 (13.7)
Mean (SD)	38.8 (19.58)	37.5 (17.78)	41.0 (20.57)	33.4 (16.16)	34.9 (17.09)	44.0 (18.45)
Gender, n (%)						
Male	56 (46.7)	111 (57.8)	33 (42.3)	69 (58.0)	23 (54.8)	42 (57.5)
Female	64 (53.3)	81 (42.2)	45 (57.7)	50 (42.0)	19 (45.2)	31 (42.5)
Race, n (%)						
Asian	10 (8.3)	34 (17.7)	4 (5.1)	29 (24.4)	6 (14.3)	5 (6.8)
Black or African American	24 (20.0)	19 (9.9)	22 (28.2)	13 (10.9)	2 (4.8)	6 (8.2)
White	82 (68.3)	135 (70.3)	50 (64.1)	74 (62.2)	32 (76.2)	61 (83.6)
Other[a]	4 (3.3)	4 (2.0)	2 (2.6)	3 (2.5)	2 (4.8)	1 (1.4)
Ethnicity, n (%)						
Hispanic or Latino	15 (12.5)	28 (14.6)	8 (10.3)	16 (13.4)	7 (16.7)	12 (16.4)
Not Hispanic or Latino	97 (80.8)	164 (85.4)	66 (84.6)	103 (86.6)	31 (73.8)	61 (83.6)
Not Reported	8 (6.7)	0	4 (5.1)	0	4 (9.5)	0
IGA, n (%)						
Clear (0)	0	0	0	0	0	0
Almost clear (1)	0	0	0	0	0	0
Mild (2)	0	0	0	0	0	0
Moderate (3)	98 (81.7)	100 (52.1)	66 (84.6)	61 (51.3)	32 (76.2)	39 (53.4)
Severe (4)	22 (18.3)	92 (47.9)	12 (15.4)	58 (48.7)	10 (23.8)	34 (46.6)

IGA, Investigator's Global Assessment.

[a]Other includes Native Hawaiian or Other Pacific Islander, Multiracial, and Not Reported.



Abstract N°: 6343

Dupilumab Treatment Up to 3 Years Improves Symptoms and Quality of Life Across Racial Subgroups in Infants and Children Aged 6 Months to 11 Years With Atopic Dermatitis

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Introduction & Objectives: Atopic dermatitis (AD) significantly impairs quality of life (QoL) in infants and children, with intense itch and discomfort affecting daily activities, emotional well-being, and social interactions. Population variations in AD presentation and severity warrant further analysis of dupilumab treatment effects on patient-reported outcomes across racial subgroups. This study assessed long-term changes in patient-reported QoL, sleep loss, and itch intensity, as well as safety and discontinuation rates across self-identified racial subgroups in pediatric patients treated with dupilumab for ≤3 yr.

Materials & Methods: Infants and children (6 mo–5 yr) with moderate-to-severe AD and children (6–11 yr) with severe AD who participated in prior dupilumab studies (NCT03346434, NCT03345914) were eligible for an open-label extension study (NCT02612454). Dosing was weight-based: 200 mg every 4 weeks (q4w; 5–<15 kg), 300 mg q4w (15–<30 kg), 200 mg every 2 weeks (q2w; 30–<60 kg), or 300 mg q2w (≥60 kg). Topical treatments were allowed. Race was self-reported and patients stratified into 2 subgroups for this analysis: White vs Asian, Black/African American, or Other. Changes in Children's Dermatology Life Quality Index (CDLQI; patients aged ≥4 yr), SCORing Atopic Dermatitis (SCORAD) Sleep Loss Visual Analog Scale (VAS), SCORAD Pruritus VAS, and safety through Week 152 were evaluated. Data are presented as observed.

Results: As of September 2024, 87.0% (490/563), 73.7% (415), and 62.7% (353) of patients completed 52, 104, and 152 weeks of treatment, respectively. Mean treatment duration (standard deviation [SD]) was 114.7 (47.1) weeks. Of 554 patients, 400 (72.2%) identified as White and 154 (27.8%) as Asian, Black/African American, or Other. Baseline disease severity and discontinuation rates were higher in the Asian, Black/African American, and Other subgroup vs White patients. By Week 152, 89 (22.3%) White and 61 (39.6%) Asian, Black/African American, and Other patients discontinued, often due to withdrawal (6.3% vs 11.0%). Differences in sample size may skew percentages. In both groups, <2.0% discontinued due to lack of efficacy or adverse events (AEs).

CDLQI scores (0–30) showed a large QoL impact of AD at baseline, which improved to a mild effect at Week 152. Mean (SD) CDLQI scores improved from 16.2 (7.0) to 3.5 (3.6) in White patients (n = 227) and from 14.2 (3.6) to 3.1 (3.0) in Asian, Black/African American, and Other patients (n = 63).

Sleep loss VAS mean (SD) scores improved from 6.6 (2.9) to 1.1 (2.0) in White patients (n = 263) and from 6.4

(2.9) to 1.8 (2.5) in Asian, Black/African American, and Other patients (n = 72). Itch VAS scores improved from 7.7 (1.9) to 1.9 (2.2) in White patients (n = 266) and from 7.9 (2.0) to 2.3 (2.3) in Asian, Black/African American, and Other patients (n = 73).

Drug-related treatment-emergent AEs (TEAEs) were reported in 93 (23.3%) White and 37 (24.0%) Asian, Black/African American, and Other patients. Common TEAEs included allergic conjunctivitis (White vs Asian, Black/African American, and Other: 2.5% vs 3.2%), nasopharyngitis (2.3% vs 1.3%), and blepharitis (0.5% vs 2.6%).

Conclusion: Long-term treatment with dupilumab resulted in meaningful improvements in symptom severity and QoL in infants and children with AD across racial subgroups. The safety profile remains consistent with the established safety data for dupilumab, supporting use in diverse pediatric populations.



Abstract N°: 6363

Integrated Safety Analysis of Abrocitinib in 3850 Patients With Moderate-To-Severe Atopic Dermatitis: Data From More Than 9600 Patient-Years With Up to 6.5 Years of Exposure

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Introduction & Objectives: 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 assessed select adverse events of special interest (AESIs) analyzed by age (18 to <65 years [y] and ≥65 y) and smoking status in 3802 pts, including data from >5200 pt-y (PY) with up to 4 y of abrocitinib exposure and a subsequent updated analysis looked at AESIs stratified by refined baseline age categories and cardiovascular risk factors in 3848 pts, including data from >7000 PY with a safety profile up to 4.5 y of abrocitinib exposure. The current study evaluated safety events stratified by refined age categories and smoking status using complete data for most pts in the JADE integrated safety analysis up to 6.5 y of abrocitinib exposure.

Materials & Methods: Analysis included pts from 8 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]; data cutoff: December 31, 2024) in the JADE clinical program. Incidence rates (IRs; number of pts with events/100 PY) 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) and smoking status (never and current/former smoker).

Results: Of 3850 pts in the pooled safety population, 3052 received the same abrocitinib dose throughout (consistent-dose cohort, described herein) and 798 pts comprised the variable-dose cohort; both cohorts represent a total of 9655.4 PY 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 PY 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: 0.79 [0.32-1.63]; and ≥65 y: 2.03 [0.74-4.41]) and death (<18 y: 0.00 [95% CI, 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: 2.02 [0.74-4.40]). Similar trends were observed for other AESIs, including serious infections,

herpes zoster, malignancies (excluding nonmelanoma skin cancer [NMSC]), NMSC, deep vein thrombosis (DVT), and venous thromboembolism (VTE). IRs for serious infections, malignancies (excluding NMSC), NMSC, MACE, DVT, VTE, and death were higher or numerically higher in current/former smokers compared with never smokers; all events of NMSC and DVT occurred in current/former smokers. IRs for herpes zoster were comparable between groups (current/former smokers: 3.48 [95% CI, 2.70-4.41] and never smokers: 3.56 [3.05-4.13]). Data from the variable-dose cohort generally showed similar trends.

Conclusions: These long-term follow-up abrocitinib safety data with >9600 PY of exposure in pts with moderate-to-severe AD are consistent with the previously reported risk profile. No new safety signals were reported. IRs tended to be higher in older pts and current/former smokers, known risk factors for many AESIs included in this analysis.**



Abstract N°: 6404

Atopic Dermatitis in a Patient with Severe Autism: Treatment with Dupilumab

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Introduction & Objectives:

An increase in the global incidence of atopic and neurodevelopmental diseases has been observed. In particular, Atopic Dermatitis (AD) and Autism Spectrum Disorders (ASD) have gained significant relevance due to their impact on patients' quality of life. Population studies have proposed the hypothesis that AD may act as an early precursor of ASD, suggesting that AD in the first years of life implies a higher risk of developing ASD later in childhood, especially in the presence of other atopic comorbidities such as allergic rhinitis or asthma. AD triggers an immunological cascade involving mast cell activation, the release of proinflammatory cytokines (mainly IL-6), and elevated levels of Th2 cytokines, which can cross the blood-brain barrier, leading to neuroinflammation or direct damage to microglia and neurons. This may play a key role in the etiopathogenesis of ASD and other neuropsychiatric conditions.

Materials & Methods:

This is a 7-year-old male patient with a prior diagnosis of Autism Spectrum Disorder and severe atopic dermatitis refractory to topical treatments and systemic therapy such as methotrexate.

Results:

The patient began experiencing generalized xerosis at 2 years of age, accompanied by pruritus and eczematous lesions. These symptoms were associated with behavioral disturbances and environmental disconnection. Initial treatment included topical corticosteroids and emollients.

At age 5, his atopic dermatitis became generalized. A punch biopsy was performed, confirming the diagnosis.

Systemic therapy with oral methotrexate was initiated. Although there was an initial clinical improvement, poor adherence to oral medication necessitated switching to subcutaneous administration after 6 months. During methotrexate therapy, the patient experienced several bacterial superinfections, requiring hospitalization on one occasion.

Given that the patient underwent a stepwise treatment approach—including topical therapy (topical corticosteroids, tacrolimus) followed by conventional systemic therapy (oral and subcutaneous methotrexate)—without satisfactory clinical response and with recurrent skin infections due to impaired skin barrier function, treatment with dupilumab was initiated.

After three months of therapy, a significant improvement was observed in clinical symptoms, behavior, and environmental engagement.

Conclusion:

Studies have shown that, in addition to genetic and environmental factors, Atopic Dermatitis (AD) and Autism Spectrum Disorders (ASD) may also share common pathways of immune dysregulation and chronic inflammation.

Emerging evidence suggests overlapping immunopathogenic mechanisms, including altered cytokine profiles and impaired skin and neuroimmune barriers. However, further research is needed to fully elucidate the nature and extent of this association, with the aim of developing innovative and targeted therapeutic strategies for both conditions.



Abstract N°: 6417

Microbiome-targeted Topical Therapy for Atopic Dermatitis: A New Strategy for Drug Delivery

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Introduction & Objectives:

The incidence of inflammatory skin diseases is rising in western societies, due to the urbanization, dietary shifts and reduced microbial diversity. Atopic dermatitis (AD) affects 15–20 % of children and 1–3 % of adults in Chile, generating a considerable socioeconomic burden. In addition, a key factor is the loss of the cutaneous microbiome equilibrium (dysbiosis), where the bacteria *Staphylococcus aureus (S. aureus)* proliferates and exacerbates the pathology. In Chile* the microbiome of patients has not been characterized. In this context, nanoencapsulation offers an opportunity to codeliver antibacterial and antiinflammatory agents directly to the epidermis while enhancing stability, penetration and patient tolerability. Objectives were: (i) Characterize the skin microbiome of Chilean AD patients versus healthy controls; (ii) develop sub300 nm oilinwater nano encapsulates (NE) loaded with actives molecules; (iii) validate their physicochemical performance and *in vitro* activity.

Materials & Methods:

Twelve mildtomoderate AD patients (12 to 56 years olds) and matched to controls (Oct 2021–Mar 2022) were evaluated. DNA was extracted and fulllength 16S rRNA sequenced in all samples; taxonomic and diversity indices were studied using Clustal series of programs. NE were produced by highenergy sonication with pharmaceuticgrade surfactants; size, polydispersity, ζpotential and encapsulation efficiency (EE) were measured by dynamic light scattering and HPLC, respectively. Antibacterial activity against *S. aureus* ATCC 29213 was determined by broth microdilution; antiinflammatory activity was evaluate using enzymatic COX-1/COX2 assay.

Results:

Lesional AD sites displayed a 45 % relative abundance of *S. aureus* versus 4 % in control skin, with a Shannon αdiversity drop from 2.8 to 1.2. Optimized NE exhibited a hydrodynamic diameter of 180 ± 12 nm with a ζpotential of −32 mV and EE > 89 %. NC inhibited *S. aureus* growth (MIC = 64 µg mL^{-1}) and suppressed COX2 enzymatic activity by 58 ± 4 % compared with NE without actives molecules as a control.

Conclusion:

This first microbiome survey in Chilean AD confirms severe dysbiosis dominated by *S. aureus*. The stable, highEE nano encapsulates deliver synergistic antibacterial and antiinflammatory effects, positioning them as promising topical candidates for mildtomoderate AD. Scaleup (>250 mL), Franzcell permeation and a Phase I/II clinical trial are slated for early 2025 with a greater number of patients



Abstract N°: 6513

Effectiveness of 12-months tralokinumab treatment in 654 adults with atopic dermatitis with head & neck area involvement: Final real-world data from the prospective, non-interventional, international, single-cohort TRACE study

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Introduction & Objectives:

Around 70% of patients with moderate-to-severe atopic dermatitis (AD) have head & neck (H&N) area involvement, associated with embarrassment, stigmatization, and negative impact on QoL and mental health. AD in the H&N area can be difficult to treat. Tralokinumab, a monoclonal Ab targeting IL-13 indicated for treating moderate-to-severe AD, was effective and well-tolerated in Phase 3 clinical trials. Here, we present real-world effectiveness data from 12-months tralokinumab treatment in AD patients with H&N involvement

Materials & Methods:

TRACE is a prospective, non-interventional, international, multi-center, single-cohort study of adults with AD, who received tralokinumab according to national approved label at treating physician's discretion; concomitant medications were allowed. Of 835 patients enrolled (Nov-2021 to Jun-2023), we evaluated 654 patients with baseline AD involvement on the face, scalp, and neck. Assessments included AD localization and disease severity scores (IGA, EASI, DLQI, PP-NRS, Sleep-NRS), per individual clinical practice. Data are presented as observed.

Results:

The proportion of AD patients with H&N involvement decreased markedly to 68.1% (n=565) and 51.8% (n=367) at months 3 and 12. Treatment with tralokinumab reduced AD severity across all endpoints (Tables 1 & 2). Among those with data, the proportion of patients with clear or almost clear skin (IGA 0/1) increased from 1.5% at baseline (n=619) to 36.2% (n=509) and 64.7% (n=317) at months 3 and 12. Among patients with baseline IGA ≥2, 45.0% (n=489) at month 3 and 70.7% (n=304) at month 12 had a ≥2-point IGA improvement. The proportion of patients with severe disease (IGA 4) decreased markedly from 40.1% at baseline (n=619) to 4.3% (n=509) and 2.2% (n=317) at months 3 and 12. The proportion of patients with EASI ≤7 (no or mild eczema) increased dramatically from 13.0% (n=525) at baseline to 69.5% (n=426) and 89.3% (n=290) at months 3 and 12. The mean DLQI score improved from 13.1 at baseline (n=373) to 5.1 (n=143) at month 12, while the proportion of patients with DLQI ≤5 (no to small QoL impairment) increased from 19.0% at baseline to 67.8% at month 12. From baseline to month 12: mean PP-NRS decreased from 6.4 (n=395) to 3.3 (n=140); and proportion with PP-NRS ≤4 increased from 21.0% to 70.0%. Mean sleep NRS decreased from 5.2 (n=313) at baseline to 2.2 (n=108) at month 12. Among patients with baseline Sleep-NRS ≥2, 70.7% had a ≥2-point improvement at month 12. Dupilumab-naive (n=510) and dupilumab-experienced (n=144) patients improved similarly, though higher baseline disease severity was seen in dupilumab-naive patients.

Conclusion:

In adult AD patients with H&N involvement, 12-months treatment with tralokinumab improved H&N involvement, overall AD severity, and QoL in a real-world setting. Improvements were similar regardless of prior dupilumab use.

Table 1 Assessments of head and neck involvement and effectiveness in patients with AD and head & neck involvement at baseline during 12 months of tralokinumab treatment (TRACE study)

		Baseline (N=824)	3 months (N=708)	6 months (N=596)	9 months (N=500)	12 months (N=460)
Head & neck involvement						
All, n1/n2 (%)	Yes	654 / 654 (100.00%)	385 / 565 (68.14%)	272 / 475 (57.26%)	221 / 402 (54.98%)	190 / 367 (51.77%)
	No	-	147 / 565 (26.02%)	159 / 475 (33.47%)	130 / 402 (32.34%)	138 / 367 (37.60%)
	Unknown[1]	-	33 / 565 (5.84%)	44 / 475 (9.26%)	51 / 402 (12.69%)	39 / 367 (10.63%)
Effectiveness in patients with head & neck involvement						
IGA responders (IGA 0/1), n1/n2 (%)		9 / 619 (1.45%)	184 / 509 (36.15%)	224 / 417 (53.72%)	204 / 341 (59.82%)	205 / 317 (64.67%)
IGA 4 (severe disease), n1/n2 (%)		248 / 619 (40.06%)	22 / 509 (4.32%)	10 / 417 (2.40%)	11 / 341 (3.23%)	7 / 317 (2.21%)
IGA ≥2-point improvement[2], n1/n2 (%)		-	220 / 489 (44.99%)	248 / 398 (62.31%)	220 / 328 (67.07%)	215 / 304 (70.72%)
EASI ≤7 (no or mild eczema), n1/n2 (%)		68 / 525 (12.95%)	296 / 426 (69.48%)	288 / 357 (80.67%)	243 / 294 (82.65%)	259 / 290 (89.31%)

Percentages are calculated using 'n2' as denominator. Full analysis set comprise 824 patients of whom 654 patients had H&N involvement.

[1] 'Unknown' includes patients without recorded AD body area and with a recorded %BSA above zero.

[2] Among patients with baseline IGA ≥2.

AD = atopic dermatitis; BSA = body surface area; EASI = eczema area and severity index (clinician-rated scoring system that grades the area and severity of eczema across 4 body regions [total range 0–72; higher score indicate worse disease]); H&N = head & neck; IGA = investigator global assessment (clinician-rated 5-point scoring system for global AD disease severity (range from 0 [clear] to 4 [severe]); IGA 0/1 = clear (IGA score 0) or almost clear (IGA score 1); N = number of patients in full analysis set; n1 = patients with H&N involvement achieving endpoint; n2 = number of patients with H&N AD involvement with data.

Table 2 PRO assessments of AD disease severity in patients with AD and head & neck involvement at baseline during 12 months of tralokinumab treatment (TRACE study)

	Baseline (N=824)	3 months (N=708)	6 months (N=596)	9 months (N=500)	12 months (N=460)
PROs in patients with head & neck involvement					
Head & neck involvement, n1/n2 (%)	654 / 654 (100.00%)	386 / 565 (68.14%)	272 / 475 (57.26%)	221 / 402 (54.98%)	190 / 367 (51.77%)
PROs in patients with head & neck involvement					
DLQI, n2 Mean (SD)	373 13.13 (7.57)	201 6.99 (5.79)	166 5.83 (5.49)	138 5.75 (6.28)	143 5.07 (5.12)
DLQI ≤5 (no-to-small effect on life), n1/n2 (%)	71 / 373 (19.03%)	95 / 201 (47.26%)	101 / 166 (60.84%)	91 / 138 (65.94%)	97 / 143 (67.83%)
PP-NRS score, n2 Mean (SD)	395 6.39 (2.55)	210 4.29 (2.62)	176 3.45 (2.55)	136 3.36 (2.60)	140 3.33 (2.52)
PP-NRS ≤4, n1/n2 (%)	83 / 395 (21.01%)	110 / 210 (52.38%)	121 / 176 (68.75%)	96 / 136 (70.59%)	98 / 140 (70.00%)
Sleep-NRS score, n2 Mean (SD)	313 5.21 (3.12)	166 2.81 (2.70)	128 2.44 (2.67)	105 2.37 (2.59)	108 2.22 (2.79)
Sleep NRS ≥2-point improvement[1], n1/n2 (%)	-	81 / 121 (66.94%)	64 / 93 (68.82%)	55 / 74 (74.32%)	58 / 82 (70.73%)

Percentages are calculated using 'n2' as denominator. Full analysis set comprise 824 patients of whom 654 patients had H&N involvement.

[1] Among patients with baseline Sleep-NRS ≥2.

AD = atopic dermatitis; DLQI = dermatology quality of life index (10-item questionnaire assessing health-related quality of life over the last week in patients with dermatological symptoms [total DLQI score range: 0-30; higher score indicate worse quality of life]); N = number of patients in full analysis set; n1 = patients with H&N involvement achieving endpoint; n2 = number of patients with H&N involvement with data; NRS = numeric rating scale; PP-NRS = peak pruritus NRS (single-item patient-reported measure for assessing the maximum severity of itch during the previous 24 hours in patients with pruritic skin disorders [range 0-10, higher score indicating worse itch]); PRO = patient-reported outcome; SD = standard deviation; Sleep NRS = a single-item patient-reported measure for assessing the severity of sleep disturbance over the past week in patients (range 0-10; higher score indicating worse sleep).

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Abstract N°: 6515

Understanding the Burden of Flares in Patients with Moderate-to-Severe Atopic Dermatitis: A Targeted Literature Review

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Introduction: Atopic dermatitis (AD) is a chronic, immune-mediated, inflammatory condition of the skin, characterized by intense pruritus and recurrent eczematous lesions.1 Patients with AD experience flares associated with worsening signs and symptoms, often requiring intensification of treatment.2

Objective: To summarize the clinical, humanistic, and economic burden of flares in adult patients with moderate-to-severe AD.

Methods: A targeted literature review of English-language publications was conducted** using Embase and Medline on January 26, 2024. Additionally, AAD and EADV conference websites were reviewed to supplement database searches. Real-world evidence studies including patients with moderate-to-severe AD (≥60% of study cohort) aged ≥12 years were included. Outcomes of interest encompassed proportions of patients experiencing flares; frequency and duration of flares; and flare-associated healthcare resource utilization (HCRU), costs, and impact on quality of life (QoL).

Results: A total of 26 studies (United States:8; Europe:12; others:6) were included in the review. The definition of flares differed across studies. Proportion of patients currently experiencing flares ranged from 36.4% to 58.4%. Average number of flares over the past year ranged from 2.1 to 11.3, with duration ranging from 1 day to ≥2 months. The frequency of flares was higher among patients with severe AD compared to moderate AD. Although a reduction is seen among patients treated with a systemic therapy, some patients still continue to experience flares. The proportion of patients with AD experiencing frequent severe flares was higher for those with a Dermatology Life Quality Index (DLQI) score >10 than for those with a score ≤10, with frequent severe flares as a strong predictor of poor AD-related QoL. The mean Patient-Oriented Eczema Measure, DLQI, peak pruritis numeric rating scale, and Work Productivity and Activity Impairment scores were worse for currently flaring patients than those who were not flaring. An increase in median out-of-pocket costs was observed with an increase in flare days. Higher HCRU was observed in AD patients with flares than in those without flares, such as days off from regular activities (non-work), healthcare provider office visits, and sick leaves.

Conclusion: This literature review found that** flares in patients with moderate-to-severe AD are associated with a higher clinical, humanistic, and economic burden highlighting the need for treatments that prevent or reduce flares in this patient population.

References:

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2. Girolomoni G, et al. *Ther Adv Chronic Dis*. 2022;13:20406223211066728. doi: 10.1177/20406223211066728.



Abstract N°: 6549

"Waiting well" for Patients: Addressing Barriers to Timely Atopic Dermatitis Care in the UK National Health Service

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin condition with significant patient impact. Prolonged waiting times for specialist dermatology referral leave many patients underserved, leading to frustration and inadequate management. This study investigates key barriers to timely AD care in the UK National Health service (NHS) and explores solutions to improve interim support before specialist consultation.

Materials & Methods: A mixed-methods approach was employed to understand issues around delayed management of AD. Data were acquired from 3 sources: in-depth one-on-one interviews with 2 patients living with AD and 7 healthcare professionals (HCPs) involved in AD management; a Delphi survey to achieve expert consensus (≥70%) of UK HCPs (round 1: N=96) working in primary and secondary care; and an advisory board meeting with 7 experts and 2 patient representatives to gain advice on the Delphi and interview findings and identify potential actionable solutions. Thematic analysis was applied to qualitative data, while survey responses were analysed for consensus.

Results: 2/2 patients and 5/7 HCPs reported that general practitioners (GPs) need to do more to support their AD patients. 2/2 patients reported feeling like a "burden" to their GP for seeking help initially and had to strongly advocate to receive treatment beyond topical steroids.

There was consensus from Delphi respondents (77%) that GPs know the signs and symptoms of AD; however, consensus was not reached on management of AD in primary care being optimal (50% of Delphi respondents agreed) or that quality information was provided by GPs to patients (45% of Delphi respondents agreed).

Delphi respondents reported that provision of quick guides (90% agreed) and more comprehensive clinical guidelines (95% agreed) would be beneficial to primary care AD management. 7/7 expert HCPs and 2/2 patient representatives agreed that meeting minimum standards in primary care through completion of checklists could support better management of AD patients.

Waiting times were reported to negatively impact patients (93% of Delphi respondents, 2/2 patient representatives and 7/7 HCPs agreed). No consensus was reached on referral to secondary care being timely (59% of Delphi respondents disagreed).

In secondary care dermatology 73% of Delphi respondents reported that there was a high level of understanding of all AD treatment options among HCPs; however, only 50% agreed that management in secondary care was comprehensive and satisfactory, and only 27% of Delphi respondents agreed that there was timely access to specialist care.

Conclusion: Interviews with patients and expert HCPs together with Delphi survey findings demonstrated that whilst GPs are generally knowledgeable, there are critical gaps in AD care, particularly in referral pathways and primary care management. HCPs agreed on the urgent need for practical tools to optimise treatment before patients reach specialist care. Implementing checklists and quick guides could improve consistency of care and ensure minimum standards of AD management are consistently met across the UK. This would improve confidence amongst less experienced HCPs and help address the identified barriers, which are vital for enhancing patient outcomes and reducing delays in AD care.



Abstract N°: 6587

"Associations Between Maternal and Infant Intestinal Microbiota and the Risk ofAtopic Dermatitis: A Systematic Review"

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Introduction & Objectives: : Atopic dermatitis (AD) is recognized as one of the most prevalent chronic inflammatory skin disorders, with its incidence steadily increasing in developed nations. It has been hypothesized that the maternal gut microbiota during pregnancy plays a crucial role in shaping the composition of the infant intestinal microbiota, potentially influencing susceptibility to AD. The objective of this systematic review was to evaluate and synthesize contemporary evidence regarding the associations between maternal and infant gut microbiota profiles and the subsequent risk of developing AD during early childhood.

Materials and Methods: A comprehensive systematic search was performed across databases including PubMed, Embase, and the Cochrane Library. Eligible studies included cohort studies, clinical trials, and observational research published between 2015 and 2025 that examined maternal fecal microbiota and AD outcomes in offspring. A total of 12 studies met the inclusion criteria, with sample sizes ranging from several dozen to a maximum of 2,082,785 participants in a single study. Analytical methodologies utilized included 16S rRNA gene sequencing, metabolite profiling, and immune response assays applied to stool samples.

Results: Significant differences in gut microbiota composition and diversity were observed between study groups. Higher alpha diversity in maternal gut microbiota was associated with healthy offspring, whereas lower alpha diversity correlated with AD development in infants. Reduced microbial diversity in infants, including notably lower Shannon and Simpson diversity indices, was strongly associated with an

increased risk of AD. Furthermore, the presence of beneficial butyrate-producing

bacterial taxa, such as Ruminococcus, was predominantly observed in the

microbiota of healthy children.Neonatal immune responses characterized by diminished interleukin-10 (IL-10)production in response to microbial stimulation were identified as independent risk factors for AD. Despite the presence of favorable Gram-positive bacteria, these immune abnormalities appeared to exacerbate AD risk. Additionally, prenatal

exposure to organophosphate esters (OPEs) was linked to notable alterations in

infant gut microbiota, including reductions in beneficial bacterial taxa (e.g.,

Bifidobacterium and Lactobacillus) and increased prevalence of potentially pathogenic microorganisms (e.g., Pseudomonas), thereby amplifying ADsusceptibility. Maternal probiotic supplementation was found to modulate the infant gut microbiota composition; however, the degree of influence varied according to probiotic strain and the timing of administration relative to birth. Certain evidence suggested that Lactobacillus rhamnosus supplementation may reduce the risk of AD by affecting metabolic functions within the infant gut microbiome, whereas probiotics based on Bifidobacterium did not consistently demonstrate similar protective effects.

Conclusion: This systematic review highlights that maternal gut microbiota alterations, particularly reduced microbial diversity and specific dysbiosis, are significantly associated with an elevated risk of early-onset atopic dermatitis in offspring. These findings underscore the necessity for future interventional research aimed at evaluating the efficacy of maternal microbiome modulation as a potential preventive strategy for AD.

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Abstract N°: 6628

The Impact of Dupilumab on Sleep Quality and Quality of Life in Adults with Atopic Dermatitis: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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Introduction & Objectives: Atopic dermatitis (AD) significantly impairs quality of life (QoL), with pruritus and sleep disturbance being major burdens. While dupilumab has proven efficacy in reducing skin symptoms, its direct impact on sleep and QoL deserves further investigation. This systematic review and meta-analysis aims to assess the effect of dupilumab on QoL and sleep in adults with AD.

Materials & Methods: A systematic search was conducted in PubMed, Embase, and Cochrane, following PRISMA guidelines. Only randomized controlled trials were included. Statistical analyses were performed using Review Manager. A random-effects model was performed to determine the proportion with a 95% confidence interval (CI). Heterogeneity was evaluated through I2 statistics.

Results: A total of 9 studies were included, comprising 3,351 patients, of whom 2,129 (63.5%) received dupilumab. The mean age of participants was 35.6 years, with a mean proportion of male patients of 58.2%. At baseline, the average Dermatology Life Quality Index (DLQI) score was 15.2.

There was a significant reduction in DLQI scores in the dupilumab group compared to placebo (*Figure 1*; MD = −4.98; 95% CI: −5.59 to −4.37; $P < 0.00001$; $I^2 = 13\%$), with consistent results across the monotherapy and topical corticosteroid subgroups. Dupilumab also led to a significant improvement in sleep quality, as shown by a reduction in the SCORAD sleep Visual Analogue Scale (VAS) (*Figure 2*; MD = −2.34; 95% CI: −2.75 to −1.92; $P < 0.00001$; $I^2 = 25\%$), with slightly greater effects observed in the 300 mg weekly (qw) subgroup. Additional outcomes favoured dupilumab as well, with a significant decrease in Patient-Oriented Eczema Measure (POEM) scores (MD = −7.56; 95% CI: −8.46 to −6.67; $P < 0.00001$; $I^2 = 49\%$), as well as improvements in Peak Pruritus Numeric Rating Scale (PP-NRS), and Hospital Anxiety and Depression Scale (HADS) total scores.

Conclusion: Dupilumab appears to significantly improve sleep quality and overall quality of life in adults with atopic dermatitis. Our findings highlight that the benefits of dupilumab extend beyond skin symptom control.

Figure 1 – Dupilumab (300 mg every 2 weeks) versus placebo on DLQI scores

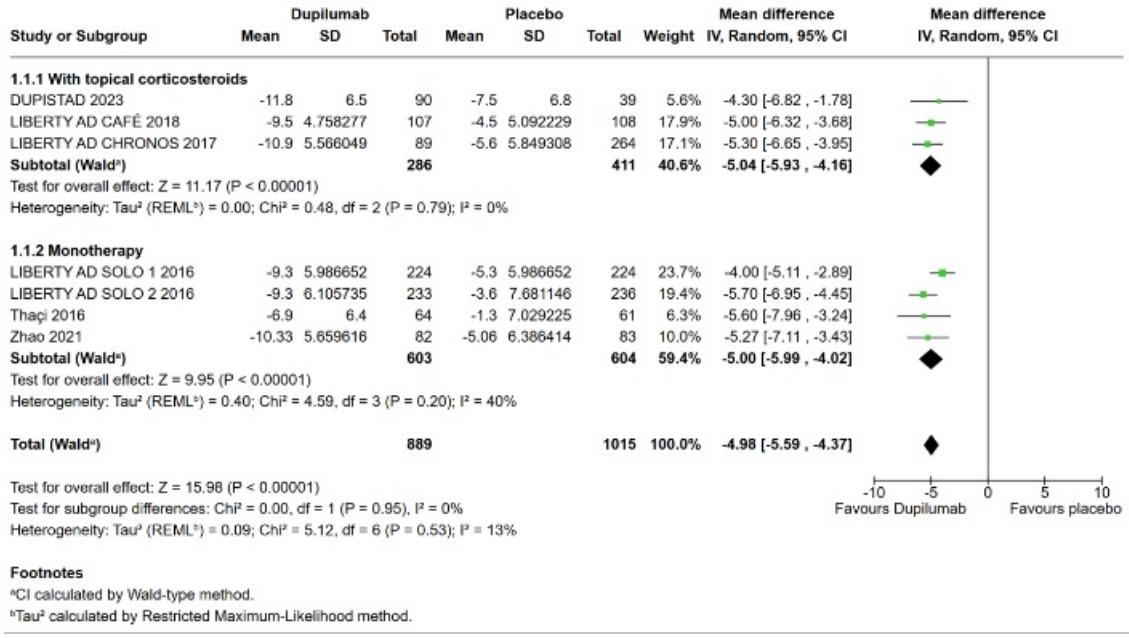
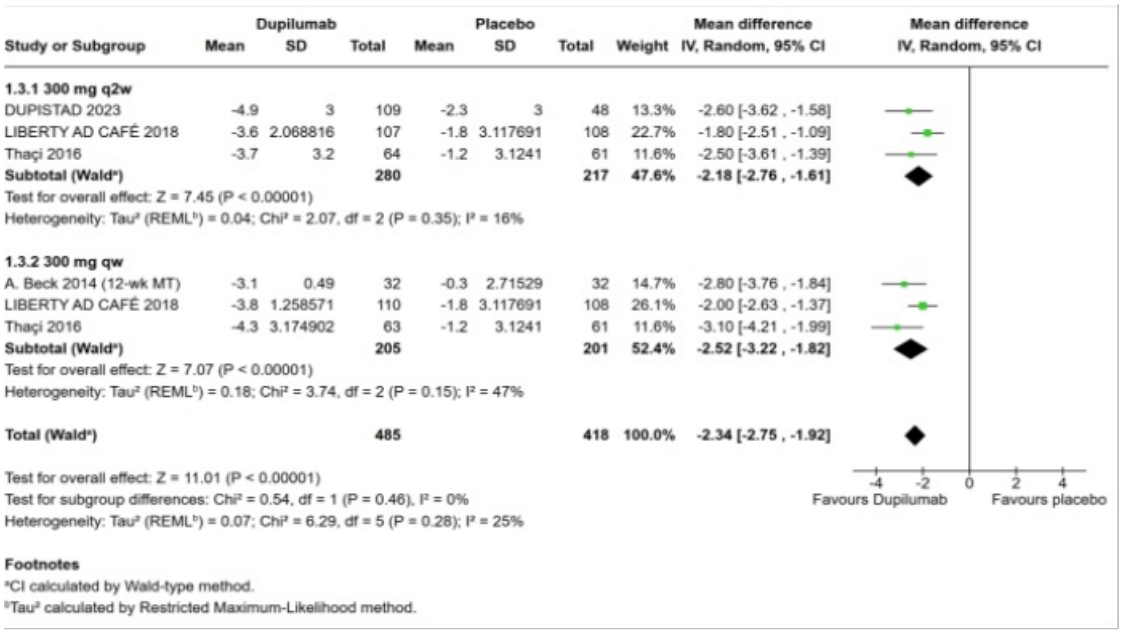


Figure 2 - Dupilumab versus placebo on SCORAD sleep VAS scores





Abstract N°: 6674

Environmental-Mental health pathways in dermatitis: Insights from an Infodemiological causal Bayesian network

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Introduction & Objectives: Environmental and mental conditions are known risk factors for dermatitis and symptoms of skin inflammation, but their interplay is difficult to quantify; epidemiological studies rarely include both, along with possible confounding factors. Infodemiology leverages large online datasets to address this issue, but fusing them produces strong patterns of spatial and temporal correlation, missingness, and heterogeneity, requiring sophisticated modeling approaches to derive valid causal insights about the complex interactions between environmental factors, mental health conditions, and skin inflammation.

Materials & Methods: In this paper, we design a causal network that correctly models these complex structures in large-scale infodemiological data from Google, EPA, NOAA and US Census (434 US counties, 134 weeks). Our model accounts for temporal dependencies by duplicating nodes across time points, spatial dependencies through a covariance matrix as a function of geographical location, group heterogeneity through weights, and missing data patterns by allowing weights greater than zero only for locally complete observations, with validation performed using statistical tests for autocorrelation, spatial dependencies, and heterogeneity alongside predictive accuracy assessment through temporal and spatial cross-validation.

Results: Our model successfully captures known causal relationships between weather patterns, pollutants, mental conditions, and dermatitis. Key findings reveal that anxiety accounts for 57.4% of explained variance in dermatitis, followed by NO2 (33.9%), obesity (7.7%), and PM2.5 (0.8%). Environmental factors show significant mediation effects through mental conditions - the effects of PM2.5, NO2, and SO2 change by factors of 0.54, 0.93, and 0.56 respectively when their impact on mental conditions is blocked. For weather variables, the combined proportion of variance explained by temperature and thermal excursion changes by 0.11 after removing mental conditions' mediation effect. In 2024, the EPA reduced the legal limit on PM2.5 by 25% to 9μg/m^3, an action expected to prevent approximately 4,500 premature deaths annually. Our model predicts this 25% reduction in PM2.5 could also decrease dermatitis incidence by 18%, while more ambitious reductions to 8μg/m^3 could yield a 21% decrease. Counterfactual analysis reveals cold spells must persist for approximately 4 weeks before producing meaningful increases (+5%) in dermatitis.

Conclusion: Through statistical validation and causal inference, we provide insights into the complex interplay between environmental and mental health factors affecting dermatitis, offering guidance for policy development. Our findings show environmental regulation adjustments can significantly impact outcomes, while addressing both mental health and pollution creates synergistic benefits. While robust, our approach has limitations: the correspondence between search frequencies and actual disease prevalence remains an assumption; conclusions about aggregate data may not apply to individuals; and unmeasured confounders may introduce spurious relationships. Nevertheless, our approach demonstrates the power of infodemiological data fusion for understanding complex health relationships difficult to investigate through traditional methods.

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Abstract N°: 6707

Treatment with delgocitinib cream is associated with a reduction of Staphylococcus aureus density and pain in patients with mild to severe Chronic Hand Eczema

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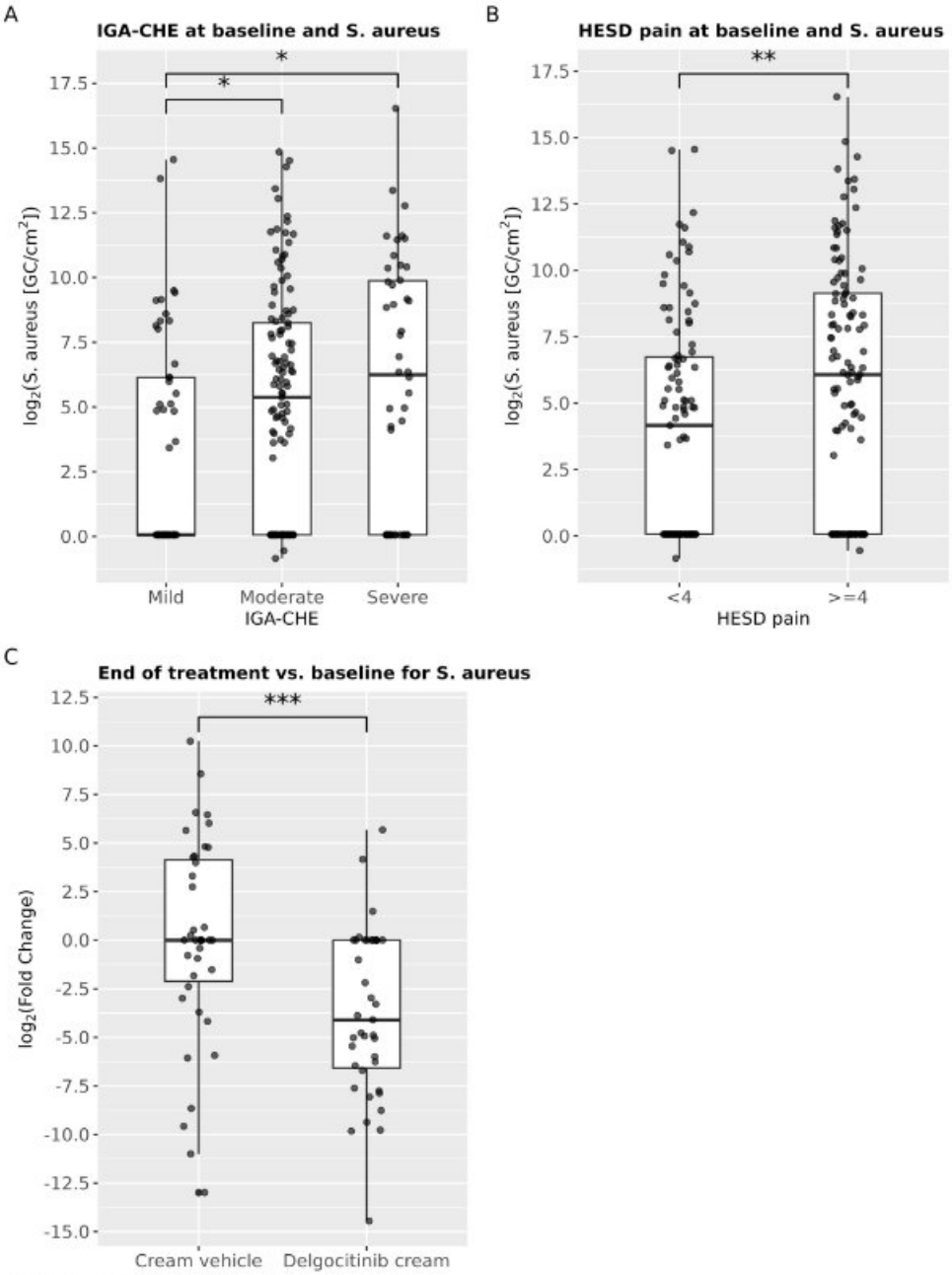
Introduction & Objectives: Chronic Hand Eczema (CHE) is a multifactorial inflammatory skin disease related to skin barrier dysfunction and immune cell dysregulation. Pain is one of the most common and burdensome symptoms of CHE, negatively affecting patients' quality of life. More than 50% of patients with moderate to severe CHE are colonized with *Staphylococcus aureus* (*S. aureus*). The severity of CHE has been shown to be associated with an increase in *S. aureus* colonization and a change in the composition of the microbiome has been reported. In a phase 2b dose-ranging trial, the twice-daily application of delgocitinib cream, a pan-Janus kinase inhibitor, for 16 weeks was efficacious and had a favourable safety profile in adults with mild to severe CHE. Here, we report changes in *S. aureus* density in patients with CHE who were treated with delgocitinib cream. In addition, we investigated the correlation between *S. aureus* density and pain.

Materials & Methods: In a phase 2b dose-ranging trial (NCT03683719), 258 adult patients with mild to severe CHE were randomised 1:1:1:1:1 to delgocitinib cream 1, 3, 8, 20 mg/g, or cream vehicle twice-daily for 16 weeks. Eligibility criteria included mild to severe disease according to the Investigator's Global Assessment for CHE (IGA-CHE) and a recent history of inadequate response or contraindication to topical corticosteroids. The Hand Eczema Symptom eDiary (HESD) captured patient-reported worst severity of pain over the past 24 hours on an 11-point numeric rating scale (from 0=no pain to 10=severe pain). From each patient (N=220), a representative lesional (n=216) and/or non-lesional (n=217) skin area of approximately 2 cm x 5 cm on the dorsal hand, wrist, or fingers was swabbed before start of treatment (i.e., baseline) and at the end of treatment (Week 16). The number of *S. aureus* gene-copy numbers was quantified by qPCR, by targeting the *femA* gene, and calculated per cm2 of skin (*S. aureus* density). The Spearman's rank correlation coefficient test was used to assess the correlation between *S. aureus* density and disease severity (IGA-CHE), as well as between *S. aureus* density* and* HESD pain.

Results: In all patients, *S. aureus* density was higher in lesional compared with nonlesional CHE skin at baseline ($P<0.001$). In lesional CHE skin samples, positive correlations were found between disease severity (IGA-CHE) and *S. aureus* density at baseline ($P<0.05$), as well as between HESD pain and *S. aureus* density at baseline ($P<0.01$) (**Figure**). From the end of treatment to baseline, a positive correlation was observed between *S. aureus* density and HESD pain ($P<0.001$). Patients treated with delgocitinib cream at a dose of 20 mg/g showed a larger reduction in *S. aureus* gene-copy numbers* from baseline to Week 16 compared with cream vehicle ($P<0.001$).

Conclusion: In patients with mild to severe CHE, *S. aureus* density was positively correlated to disease severity as well as HESD pain. Treatment with delgocitinib cream at a dose of 20 mg/g for 16 weeks was associated with a significant reduction in *S. aureus* density.

Figure. Correlations between (A) IGA-CHE at baseline and *S. aureus* density, (B) HESD pain at baseline and *S. aureus* density, and (C) the end of treatment and baseline for *S. aureus* density.



*P<0.05, **P<0.01, ***P<0.001.
Log_2-transformed gene-copy numbers/cm^2 or fold changes in log_2-transformed gene-copy numbers/cm^2 are displayed on the y-axis.
CHE, Chronic Hand Eczema; GC/cm^2, gene-copy numbers per cm^2; HESD, Hand Eczema Symptom eDiary; IGA-CHE, Investigator's Global Assessment for Chronic Hand Eczema; log_2, log_2-transformed value; *S. aureus*, *Staphylococcus aureus*.



Abstract N°: 6726

Dupilumab Monotherapy in Patients With Skin of Color and Moderate-to-Severe Atopic Dermatitis: Results From a Phase 4, Open-Label Study

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Introduction & Objectives: Skin of color (SoC) patients with atopic dermatitis (AD) experience high disease prevalence, severity, and quality-of-life burden, but have historically been underrepresented in clinical trials. Subgroup analyses of dupilumab phase 3 studies, despite limited sample size, showed a risk-benefit profile in patients with SoC comparable to that of the overall AD population.1 The DISCOVER, phase 4, open-label, single-arm, 24-week study aimed to further evaluate the efficacy and safety of dupilumab in patients with SoC and moderate-to-severe AD.

Materials & Methods: Eligible patients were ≥12 years old, had Fitzpatrick skin types IV/V/VI, and moderate-to-severe AD. Patients self-reporting as White/Caucasian were ineligible. Patients received dupilumab monotherapy every 2 weeks for 24 weeks (≥30 to <60 kg: 200 mg; ≥60 kg: 300 mg). The primary endpoint was 75% improvement in Eczema Area and Severity Index score (EASI-75). The secondary endpoint was ≥4-point improvement on Peak-Pruritus Numeric Rating Scale (PP-NRS). Pigmentary changes were evaluated using clinician-reported Post-Inflammatory Hyperpigmentation Severity Scale (PHSS; 0 [normal] to 8 [severe]) and the newly developed patient-reported Xerosis NRS. Safety was also evaluated. Data are reported as observed.

Results: From the 120 patients in this study, 81.7% were Black, 10.8% Asian, and 7.5% Other; 42.5%, 48.3%, and 9.2% had Fitzpatrick skin types IV, V, and VI, respectively. At Week 24, 76.0% achieved EASI-75 (primary endpoint). 52.7% and 65.6% achieved ≥4-point or ≥3-point improvement in PP-NRS at Week 24, respectively. Mean PHSS score decreased by 52.9%, from 5.1 at baseline (moderate/marked) to 2.4 at Week 24 (slightly noticeable). Patients “very/extremely bothered” by dry skin per Xerosis NRS decreased from 77.8% at baseline to 17.5% by Week 24. No treatment-related serious adverse events were reported.

Conclusion: Dupilumab monotherapy improved AD signs and symptoms, and reduced AD-related post-inflammatory hyperpigmentation and patient-reported xerosis in SoC patients with moderate-to-severe AD.

Reference:

1. Alexis AF, et al. Efficacy of dupilumab in different racial subgroups of adults with moderate-to-severe atopic dermatitis in three randomized, placebo-controlled phase 3 trials. J Drugs Dermatol. 2019;18:804-13.



Abstract N°: 6772

Efficacy of Ceramide-Containing Moisturizer in Multivesicular Emulsion as a Steroid-Sparing Agent in Patients with Atopic Dermatitis: A Prospective Randomized Controlled Trial

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disorder characterized by impaired skin barrier function, including reduced hydration and depletion of key stratum corneum lipids such as ceramides. Although topical corticosteroids are the mainstay of AD treatment, prolonged use is associated with potential adverse effects. Barrier repair with ceramide-containing moisturizers offers a potential strategy to reduce steroid reliance.

This study primarily evaluated the efficacy of a ceramide-containing moisturizer in a multivesicular emulsion (MVE) versus a simple cream base in reducing corticosteroid use, with secondary outcomes including clinical efficacy, tolerability, skin biophysical parameters, and patient-reported measures.

Materials & Methods:

This double-blinded, randomized controlled trial enrolled 40 adult participants (≥18 years) with mild-to-moderate AD, diagnosed per the Hanifin-Rajka criteria. Participants were randomized to apply either a ceramide-containing cream in MVE or a simple cream base twice daily for 4 weeks, with 0.1% triamcinolone acetonide cream for as-needed use. The primary outcome was corticosteroid use frequency, recorded daily. Secondary outcomes included clinical efficacy, comprised of physician-evaluated Eczema Area and Severity Index (EASI) scores, Scoring Atopic Dermatitis (SCORAD), and Global physician assessment (GPA), stratum corneum hydration, and transepidermal water loss (TEWL). Tolerability was monitored through clinical evaluation. Follow-up occurred at baseline and weeks 1, 2, and 4.

Results:

As of now (April 2025), only 33 from 40 participants has completed the study with 16 received a ceramide-containing cream in MVE and 17 received the simple cream base. Baseline demographic and clinical characteristics did not differ between the two groups. The ceramide-containing cream in MVE group demonstrated an earlier significant reduction in corticosteroid use by week 2 (from 5.56 to 3.69 days/week; $p = 0.020$), whereas the simple cream base group reached a significant reduction by week 3 (from 5.76 to 3.73 days/week; $p = 0.034$). Compared to baseline, both groups demonstrated significant improvements in EASI, SCORAD, and GPA scores from week 1 onward, with greater percentage reductions across all clinical scores in the ceramide-containing cream in MVE group. Stratum corneum hydration improved significantly from baseline in the ceramide-containing cream in MVE group from week 1 and continued to increase throughout the study ($p=0.006$), whereas the simple cream base group significantly improved only by week 4 ($p=0.021$). TEWL in lesional site decreased significantly from baseline in the ceramide-containing cream in MVE group by week one ($p=0.016$), while significant improvements in the simple cream base group were found at week two ($p=0.027$). No adverse events were reported in either groups,

though two cream base participants withdrew due to worsening symptoms at week 2. The full results will be presented in the conference.

Conclusion:

Addition of topical moisturizers demonstrated efficacy in reducing topical corticosteroid use, improving clinical outcomes and enhancing skin barrier, with a more rapid onset of these effects from ceramide-containing MVE cream compared to a simple cream base. This earlier therapeutic response highlights its benefits as a safe and effective steroid-sparing adjunctive therapy for patients with mild-to-moderate AD.



Abstract N°: 6802

Patients with Cardiovascular Risk Factors and Atopic Dermatitis: Long-Term Safety of Upadacitinib for Major Adverse Cardiovascular Events, Venous Thromboembolism, or Malignancy (Excluding Nonmelanoma Skin Cancer)

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease that can be associated with comorbidities, including major adverse cardiovascular (CV) events (MACE), venous thromboembolism (VTE), and malignancy (excluding nonmelanoma skin cancer [exNMSC]). In an integrated safety analysis from phase 3 studies in patients with moderate-to-severe AD treated with the Janus kinase inhibitor upadacitinib (UPA) for up to 6 years, the incidence of MACE, VTE, and malignancy (exNMSC) was comparable to or lower than background rates reported in the general US AD population. We evaluated long-term incidence rates of MACE, VTE, and malignancy (exNMSC) by CV risk category among patients with moderate-to-severe AD with up to 6 years of UPA treatment.

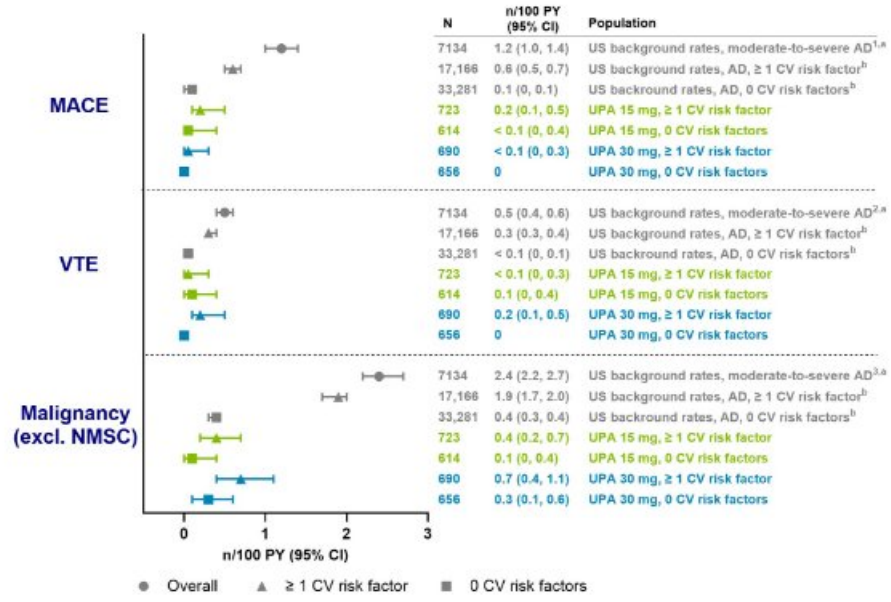
Materials & Methods: Data were pooled from the phase 3, randomized, double-blind, multicenter, placebo-controlled Measure Up 1 & 2 (NCT03569293, NCT03607422) and AD Up (NCT03568318) trials. Patients with moderate-to-severe AD were randomized 1:1:1 to once-daily oral UPA 15 mg, UPA 30 mg, or placebo. After the 16-week double-blind treatment period, patients receiving UPA continued their assigned treatment, while patients treated with placebo were rerandomized 1:1 to UPA 15 mg or 30 mg. Incidence rates for MACE (CV death, nonfatal myocardial infarction, or nonfatal stroke), VTE (deep vein thrombosis or pulmonary embolism [fatal and nonfatal]), and malignancy (exNMSC) were evaluated as exposure-adjusted incidence rates per 100 patient-years (n/100 PY). MACE, VTE, and malignancy (exNMSC) background rates in the general US AD population were assessed in a retrospective observational claims-based analysis from Optum's deidentified Clinformatics Data Mart database; this real-world reference population included patients with an AD diagnosis during the study period

(March 2017–September 2024) determined by International Classification of Diseases 9th or 10th edition codes (≥ 1 inpatient or ≥ 2 outpatient claims for AD), and age restrictions from the UPA studies (12–75 years) were implemented. Background rates were weighted to mimic the age and sex distribution in the combined UPA trial population. Cohort stratification was based on the presence of CV risk factors at baseline (0 vs ≥ 1); UPA phase 3 data were further stratified by 1 vs 2 CV risk factors. CV risk factors included prior CV event, hypertension, diabetes mellitus, tobacco/nicotine use (current and former), elevated low-density lipoprotein cholesterol, or lowered high-density lipoprotein cholesterol.

Results: The analysis included a total of 2683 UPA-treated patients (UPA 15 mg, n = 1337, PY = 4435.2; UPA 30 mg, n = 1346, PY = 4752.5). MACE, VTE, and malignancy (exNMSC) background rates from the claims-based study were evaluated in 50,447 patients with AD. Long-term incidence rates in patients with up to 6 years of UPA treatment were low for MACE and VTE (all ≤ 0.2 n/100 PY) and malignancy (exNMSC; all ≤ 0.7 n/100 PY) and similar for patients who had 0 vs ≥ 1 CV risk factor (**Figure**). Rates from UPA phase 3 studies were similar to real-world US incidence rates in patients with AD. Rates remained low when UPA-treated patients were stratified by 1 vs 2 CV risk factors (**Table**).

Conclusion: Incidence rates of MACE, VTE, and malignancy (exNMSC) in patients with moderate-to-severe AD who received up to 6 years of UPA treatment remained low and consistent with those observed in the overall population of patients with AD, regardless of CV risk category.

Figure. Incidence of MACE, VTE, and Malignancy (Excluding NMSC) by Cardiovascular Risk Category



AD, atopic dermatitis; CV, cardiovascular; excl, excluding; HDL-C, high-density lipoprotein cholesterol; LDL-C, low-density lipoprotein cholesterol; MACE, major adverse cardiovascular event; n/100 PY, number of patients with ≥ 1 event per 100 patient-years; NMSC, nonmelanoma skin cancer; UPA, upadacitinib; VTE, venous thromboembolism.

MACE was defined as CV death, nonfatal myocardial infarction, or nonfatal stroke.

VTE was defined as deep vein thrombosis or pulmonary embolism (fatal and nonfatal).

CV risk factors included prior CV event, hypertension, diabetes mellitus, tobacco/nicotine use (current and former), elevated LDL-C, or lowered HDL-C.

[a]Patients with moderate-to-severe AD were defined via proxy of dupilumab use at any time during the follow-up period.

[b]Background rates by CV risk category were measured in a real-world cohort of patients from the claims analysis who had a diagnosis of AD during the study period. Age restrictions from the UPA phase 3 studies (12–75 years) were implemented for the real-world reference population, and background rates were weighted to mimic the age and sex distribution in the combined UPA trial population.

[1]Bunick CG, et al. Risk of major adverse CV events in patients with moderate-to-severe atopic dermatitis: a United States population-based study. *Br J Dermatol*. 2024;191(Supplement_2):ljae266.057. https://doi.org/10.1093/bjd/ljae266.057.

[2]Bunick CG, et al. Risk of venous thromboembolism in patients with moderate-to-severe atopic dermatitis: a United States population-based study. Poster presented at the 2025 American Academy of Dermatology Annual Meeting (AAD 2025), March 7–11, 2025, Orlando, FL, USA.

[3]Vleugels RA, et al. Risk of malignancy excluding nonmelanoma skin cancer in patients with moderate-to-severe atopic dermatitis in the United States: a population-based study using claims data. *Br J Dermatol*. 2024;191(Supplement_2):ljae266.055. https://doi.org/10.1093/bjd/ljae266.055.

Table. Incidence of MACE, VTE, and Malignancy (Excluding NMSC) by CV Risk Category

	AESI, n/100 PY [95% CI]		
CV Risk Factors[a]	**MACE[b]**	**VTE[c]**	**Malignancy (Excl. NMSC)**
UPA 15 mg			
0 (n = 614)	< 0.1 (0, 0.4)	0.1 (0, 0.4)	0.1 (0, 0.4)
≥ 1 (n = 723)	0.2 (0.1, 0.5)	< 0.1 (0, 0.3)	0.4 (0.2, 0.7)
1 (n = 484)	0	< 0.1 (0, 0.4)	0.2 (0, 0.6)
2 (n = 175)	0.3 (0, 1.2)	0	0.2 (0, 0.9)
UPA 30 mg			
0 (n = 656)	0	0	0.3 (0.1, 0.6)
≥ 1 (n = 690)	< 0.1 (0, 0.3)	0.2 (0.1, 0.5)	0.7 (0.4, 1.1)
1 (n = 451)	0	0.1 (0, 0.5)	0.4 (0.2, 0.9)
2 (n = 176)	0.2 (0, 0.9)	0.5 (0.1, 1.4)	0.5 (0.1, 1.4)

AESI, adverse event of special interest; CV, cardiovascular; excl, excluding; HDL-C, high-density lipoprotein cholesterol; LDL-C, low density lipoprotein cholesterol; MACE, major adverse cardiovascular event; n/100 PY, number of patients with ≥ 1 event per 100 patient-years; NMSC, nonmelanoma skin cancer; VTE, venous thromboembolism.

[a]CV risk factors included prior CV event, hypertension, diabetes mellitus, tobacco/nicotine use (current and former), elevated LDL-C, or lowered HDL-C.

[b]MACE was defined as CV death, nonfatal myocardial infarction, or nonfatal stroke.

[c]VTE was defined as deep vein thrombosis or pulmonary embolism (fatal and nonfatal).

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Abstract N°: 6873

Baseline characteristics, and treatment patterns of a Canadian phase IV study (CANDID) of dupilumab for the management of moderate-to-severe atopic dermatitis.

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Introduction & Objectives:

Insights into the real-world treatment of atopic dermatitis (AD) are key to clinical decision making. The aim of this analysis was to characterize patients who receive dupilumab for moderate-to-severe AD in a real-world setting within Canada.

Materials & Methods:

The CANDID phase 4 study is an ongoing, prospective, observational study of patients with moderate-to-severe AD who receive dupilumab according to Canadian-specific prescribing information. We report baseline characteristics, and treatment patterns for patients enrolled from October 4, 2023 to March 2, 2025. Analyses are descriptive; no formal statistical comparisons were performed.

Results:

Data from 305 Canadian patients (249 adults; 34 adolescents [aged 12-17 years]; 22 children [aged 6-11 years]) from 8 Canadian provinces were included in this analysis with 60 patients (19.7%) living in urban cities and 245 patients (80.3%) living in rural settings, and females accounting for 51.1% of patients enrolled.

Patients experienced a high disease burden before starting dupilumab at enrollment with mean (± standard deviation) scores being 30.8% (21.0%) for body surface area, 20.9 (11.3) for Eczema Area and Severity Index, 7.6 (2.4) for Peak Pruritus Numerical Rating Score, 6.6 (2.5) for Skin Soreness Numerical Rating Score, 6.2 (2.69) for Sleep Disturbance Numerical Rating Score, 16.1 (5.4) for Dermatology Life Quality Index [DLQI] total score, 15.2 (5.6) for Children's DLQI, and 14.6 (7.5) for Dermatitis Family Impact.*** In the previous 12 months, 97.8%, 39.2%, and 25.4% patients were treated with topical corticosteroids, systemic corticosteroids, and conventional systemic non-corticosteroid immunosuppressants, respectively.

Conclusion:

Canadian patients enrolled in CANDID demonstrated considerable multidimensional burden of disease across signs/symptoms despite previous use of topical and systemic AD treatments. This is the first real world evidence assessment of Canadian patients aged 6 years and older living in both urban and rural areas across the country, demonstrating the burden of disease for Canadians living with atopic dermatitis.



Abstract N°: 6886

Multicenter Study of 209 Patients with Moderate-to-Severe Atopic Dermatitis Treated with Tralokinumab in a Real-World Practice. Efficacy and Safety Data at 52 Weeks

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Introduction & Objectives:

The advent of targeted therapy has revolutionized the treatment of moderate-to-severe atopic dermatitis. We aim to study the long-term efficacy and safety of tralokinumab.

Materials & Methods:

We conducted a retrospective, multicenter study in the Community of Madrid, describing the clinical and epidemiological characteristics of 209 patients with moderate-to-severe atopic dermatitis, as well as efficacy measured using the Eczema Area and Severity Index (EASI), Investigator's Global Assessment (IGA), and Peak-Pruritus Numerical Rating Scale (NRS pp) over 52 weeks of treatment according to the approved technical guidelines.

Results:

A total of 209 patients were included. Of these, 159 reached week 52 (30.14% discontinued due to lack of efficacy,

1.91% due to adverse events, and 1.43% for other reasons). Data for 28 patients was available at week 104. Baseline characteristics showed a predominance of males (57.42%), with a mean age of 37.46 years and an average disease duration of 20 years. Atopic comorbidities were present in 55.98% of patients, most commonly asthma and allergic conjunctivitis. Cardiovascular risk history was present in 11%, and 3.43% had a history of prior tumors. The most common clinical phenotypes were classical flexural (43.06%) and generalized (39.71%). Notably, 80.38% of patients had not received prior advanced therapies.

At baseline, the mean EASI was 25.78, 91.86% had IGA scores of 3 or 4, and the mean NRS pp was 7.6. During treatment, mean absolute EASI decreased to 9.24 at week 16, 6.03 at week 24, 5.89 at week 52, and 5.31 at week 104. At week 16, 48.45% of patients achieved IGA 0/1, increasing to 66.66% at week 52. Pruritus NRS decreased from 7.61 at baseline to 4.13 at week 16, 3.63 at week 24, 3.53 at week 52, and 3.25 at week 104.

Better EASI responses at week 52 were observed in patients diagnosed at an older age ($p<0.005$). Female patients of older age responded better, although this was not statistically significant.

Our data show that patients who achieve EASI 75 or EASI 90 at week 16 are more likely to maintain response at week 52. ($p<0.005$). At week 52, 16.74% of patients were able to space out their treatment regimen.

Adverse events (AEs) occurred in 18% of patients by week 16 and in 6.5% by week 52. Most AEs occurred in the early weeks of treatment, were mild, and most frequently involved ocular surface disorders.

Conclusion:

Tralokinumab appears to be a safe long-term treatment that maintains efficacy over time, as demonstrated in clinical trials and supported by real-world evidence. Furthermore, early response at week 16 is predictive of sustained response at week 52.



Abstract N°: 7127

Efficacy and Safety of Abrocitinib Versus Dupilumab in Patients Who Self-Identified as Having Skin of Colour: A Post Hoc Analysis of JADE DARE

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[2]Weill Cornell Medical College, New York, United States
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[4]Dermatology Hospital, Southern Medical University, Guangzhou, China
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[7]Pfizer Inc, New York, United States

Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disorder characterised by recurrent eczematous lesions and intense pruritus. The oral, once-daily, Janus kinase 1-selective inhibitor abrocitinib is efficacious and well-tolerated in patients (pts) with moderate-to-severe AD. Although AD is present in pts of all racial backgrounds, clinical presentations of the disease and treatment efficacy vary among racial subgroups. Variations in pigmentary changes, erythema, and inflammatory response underscore the need for further contextualisation of treatment efficacy and safety in people with skin of colour (SoC) with AD. This study aimed to assess short-term efficacy and safety of abrocitinib versus dupilumab in pts with SoC and moderate-to-severe AD in the head-to-head phase 3 study, JADE DARE (NCT04345367).

Materials & Methods: This post hoc analysis included data from pts aged ≥18 years with moderate-to-severe AD who received abrocitinib 200 mg or dupilumab 300 mg with concomitant background topical therapy for 26 weeks in JADE DARE. Pts who self-reported their race as non-White or did not report their race but identified as Hispanic or Latino were categorised as having SoC, and pts who self-reported their race as White or did not report their race but did not identify as Hispanic or Latino were categorised as White. Efficacy assessments included the proportion of pts achieving ≥75% improvement from baseline in Eczema Area and Severity Index (EASI-75) score, Investigator's Global Assessment score of 0 (clear) or 1 (almost clear) (IGA 0/1), ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale score (PP-NRS4; used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi), Dermatology Life Quality Index score of 0 or 1 (DLQI 0/1), and the composite endpoint of ≥90% improvement from baseline in EASI plus PP-NRS score of 0 or 1 (EASI-90 + PP-NRS 0/1) to Week 26. Safety was assessed via treatment-emergent adverse event (TEAE) monitoring.

Results: Of 727 pts in JADE DARE, 205 (28.2%) were categorised as having SoC (abrocitinib, n=91; dupilumab, n=114) and 522 (71.8%) were categorised as White (271; 251). At Week 2, greater proportions of pts with SoC treated with abrocitinib versus dupilumab achieved EASI-75 (abrocitinib, 28.6% vs dupilumab, 19.3%), IGA 0/1 (15.4% vs 6.1%), PP-NRS4 (50.0% vs 27.2%), DLQI 0/1 (22.5% vs 5.3%), and EASI-90 + PP-NRS 0/1 (4.4% vs 0.9%); similar findings were reported for White pts (EASI-75: 29.6% vs 22.2%; IGA 0/1: 14.1% vs 7.7%; PP-NRS4: 47.6% vs 24.8%; DLQI 0/1: 23.0% vs 6.9%; EASI-90 + PP-NRS 0/1: 6.3% vs 1.2%). The proportions of pts achieving efficacy responses were higher or comparable in pts treated with abrocitinib versus dupilumab through Week 26 of treatment and responses were comparable across available skin colour categories (Table). TEAEs in the abrocitinib and dupilumab groups, respectively, were reported by 71.4% and 61.4% of pts with SoC and 74.9% and 67.3% of White pts. In both subgroups, acne and herpes zoster were reported more frequently with abrocitinib, while

conjunctivitis was reported more frequently with dupilumab (Table).

Conclusion: Regardless of skin colour, greater proportions of pts with moderate-to-severe AD achieved efficacy responses with abrocitinib compared with dupilumab as early as Week 2 of treatment. The safety profiles of abrocitinib and dupilumab were consistent with previous analyses of the overall population from JADE DARE.

Table. Efficacy and Safety Outcomes in Patients With Skin of Colour[a] and White[b] Patients Included JADE DARE

		SoC n=205		White n=522	
		Abrocitinib 200 mg n=91	Dupilumab 300 mg n=114	Abrocitinib 200 mg n=271	Dupilumab 300 mg n=251
Efficacy endpoints, n (%)					
EASI-75	Week 2	26 (28.6)	22 (19.3)	80 (29.6)	55 (22.2)
	Week 26	61 (70.1)	79 (69.9)	193 (73.9)	182 (73.4)
EASI-90	Week 2	8 (8.8)	6 (5.3)	34 (12.6)	20 (8.1)
	Week 26	46 (52.9)	49 (43.4)	144 (55.2)	123 (49.6)
IGA 0/1	Week 2	14 (15.4)	7 (6.1)	38 (14.1)	19 (7.7)
	Week 26	46 (52.9)	51 (45.1)	147 (56.5)	134 (53.8)
PP-NRS4	Week 2	45 (50.0)	31 (27.2)	127 (47.6)	62 (24.8)
	Week 26	58 (65.2)	67 (58.8)	183 (69.1)	162 (65.1)
DLQI 0/1	Week 2	20 (22.5)	6 (5.3)	61 (23.0)	17 (6.9)
	Week 26	32 (36.8)	30 (26.8)	105 (40.5)	84 (34.1)
EASI-90 + PP-NRS 0/1	Week 2	4 (4.4)	1 (0.9)	17 (6.3)	3 (1.2)
	Week 26	26 (28.9)	22 (19.3)	82 (30.5)	57 (22.8)
Safety, n (%)					
TEAE		65 (71.4)	70 (61.4)	203 (74.9)	169 (67.3)
Acne		19 (20.9)	4 (3.5)	27 (10.0)	6 (2.4)
Conjunctivitis		2 (2.2)	5 (4.4)	6 (2.2)	27 (10.8)
Herpes zoster		1 (1.1)	0	8 (3.0)	2 (0.8)

EASI-75/-90, ≥75%/≥90% improvement from baseline in Eczema Area and Severity Index score; DLQI 0/1, Dermatology Life Quality Index score of 0 or 1; IGA 0/1, Investigator's Global Assessment score of 0 (clear) or 1 (almost clear); PP-NRS 0/1, Peak Pruritus Numerical Rating Scale score of 0 or 1; PP-NRS4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale; SoC, skin of colour.

[a]Patients with SoC included patients who self-reported their race as non-White or did not report their race but identified as Hispanic or Latino.

[b]White patients included patients who self-reported their race as White or did not report their race but did not identify as Hispanic or Latino.



Abstract N°: 7152

Patients With Moderate-to-Severe Atopic Dermatitis Maintained Depth of Response up to 2 Years With Continuous Abrocitinib Treatment

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Introduction & Objectives: Patients with moderate-to-severe atopic dermatitis (AD) have a longitudinal disease course with fluctuating AD severity over time, and static assessments may not accurately capture disease severity. The majority of patients with moderate-to-severe AD treated with systemic AD therapies experience recurrent flares, with substantial disease burden during flares irrespective of baseline AD severity. Abrocitinib, an oral Janus kinase 1-selective inhibitor is approved for the treatment of adolescents and adults with moderate-to-severe AD in multiple regions including Europe. The objective of this study was to assess the frequency of breakthrough disease flare activity and the severity of any such flare activity in patients receiving continued abrocitinib treatment.

Materials & Methods: Data were included from patients randomly assigned to abrocitinib (200 mg/100 mg) or placebo as monotherapy or in combination with topical therapy in the phase 3 JADE MONO-1 (NCT03349060), MONO-2 (NCT03575871), REGIMEN (NCT03627767), COMPARE (NCT03720470), TEEN (NCT03796676), MOA (NCT03915496), and DARE (NCT04345367) trials and subsequently enrolled in the ongoing extension study, JADE EXTEND (NCT03422822; data cutoff: 5 September 2022) and achieved response criteria (Investigator's Global Assessment score of 0 or 1 with ≥2 points improvement from baseline [IGA 0/1] or ≥75% improvement from baseline in Eczema Area and Severity Index [EASI-75]) at Week 16. Patients received their first abrocitinib dose in JADE EXTEND if they received placebo in the qualifying phase 3 trials. Assessments included the proportion of patients in the long-term efficacy pool who maintained response for EASI-75/-90, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale (PP-NRS4; used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi), PP-NRS score of 0 or 1 (PP-NRS 0/1), ≥4-point improvement from baseline in Dermatology Life Quality Index (DLQI-4) and ≥6-point improvement from baseline in Children's Dermatology Life Quality Index (CDLQI-6) to 116 weeks at 100% of visits and at 80% of visits, respectively. Missing data were handled with nonresponder imputation.

Results: At Week 16 of abrocitinib treatment, response criteria were met by 663 and 361 patients in the abrocitinib 200-mg and 100-mg arms, respectively. Substantial proportions of patients treated with abrocitinib at either dose maintained response at 80% of visits to Week 116 for EASI-75 (200 mg: 62.3%, 100 mg: 52.6%), PP-NRS4 (47.1%, 35.5%), the high-threshold responses EASI-90 (38.9%, 29.9%) and PP-NRS 0/1 (25.0%, 16.9%), and

patient-reported outcomes DLQI-4 (61.1%, 53.4%) and CDLQI-6 (57.6%, 40.0%). Furthermore, a notable proportion of patients treated with abrocitinib at either dose maintained response without excursion (ie, at 100% of visits after Week 16) to Week 116 for EASI-75 (200 mg: 53.4%; 100 mg: 39.9%), PP-NRS4 (37.3%, 24.1%), EASI-90 (30.2%, 19.4%), PP-NRS 0/1 (19.3%, 10.8%), DLQI-4 (55.0%, 44.4%), and CDLQI-6 (46.7%, 30.5%) through Week 116 (Figure).

Conclusion: Most patients did not experience frequent breakthrough flare activity and maintained their level of disease control with continuous abrocitinib treatment up to Week 116.

Figure. Proportions of Patients Maintaining EASI-75, EASI-90 and PP-NRS4 Response (**A**) at 80% of Visits[a] and (**B**) Without Excursion[b] to Week 116[c]



EASI-75/90, ≥75/≥90% improvement from baseline in Eczema Area and Severity Index; IGA 0/1, Investigator's Global Assessment score of 0 or 1 with ≥2-point improvement from baseline; PP-NRS4, ≥4-point improvement from baseline in Peak Pruritus Numerical Rating Scale; QD, once daily.

Data are reported with nonresponder imputation after study discontinuation for any reason.

Analysis population included all patients who were randomly assigned to and who received at least 1 dose of abrocitinib or placebo in JADE MONO-1, MONO-2, REGIMEN, COMPARE, TEEN, MOA, and DARE and subsequently enrolled in JADE EXTEND who were either an IGA 0/1 or EASI-75 responder at Week 16 of abrocitinib treatment.

Baseline was defined as the baseline visit from the relevant parent study. All visits represent time since first abrocitinib dose.

PP-NRS used with permission from Regeneron Pharmaceuticals, Inc., and Sanofi.

[a]Patients who maintained response at 80% of visits between Week 16 and Week 116 or until the data cutoff date, whichever was earlier.

[b]Patients who maintained response at 100% of visits between Week 16 and Week 116 or until the data cutoff date, whichever was earlier.

[c]Data cutoff date: 5 September 2022 (JADE EXTEND is an ongoing trial, and not all patients had reached Week 116 visits at the clinical data cutoff).

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Abstract N°: 7163

Interpretable Deep Learning Framework for Automated EASI Scoring in Atopic Dermatitis Assessment

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Introduction & Objectives: The Eczema Area and Severity Index (EASI) is a primary endpoint to assess severity and response to treatment for Atopic Dermatitis (AD) patients in clinical trials. Traditionally, EASI scoring requires in-person clinic visits, the scoring process is time-consuming, and scoring has inherent variability between different raters and even for the same rater over time. This study addresses these challenges by introducing a method for automated EASI scoring using photographs taken by patients remotely using a smart phone application.

Materials & Methods: We developed a novel AI model based on Vision Transformers, a state-of-the-art deep learning architecture, to automate EASI scoring using remotely captured photographs taken from smartphone. We recruited AD patients for this observational study who met inclusion criteria: 1) age ≥ 18 years, 2) not currently pregnant, and 3) adhere to taking full body photos. A smart phone application was used to take skin photos and upload image sets (44 images/set) captured across the full body at up to four different time points. We augmented the dataset by cropping each image into four quadrants, obtaining 176 images from the 44 images per set. Data were divided into training/validation/test splits of 739/100/214 visits (from 291/33/81 patients). We used Inter-class correlation coefficient (ICC) and Mean-absolute-error rate (MAE) to compare EASI scoring outcomes (range 0-72) between the model and two sets of dermatologists (Rater A and Rater B) who remotely assessed EASI scores using the image sets. Inter-rater variability was assessed by calculating ICC and MAE between Rater A and Rater B.

Results: The study enrolled 681 AD patients. Each provided 1-4 skin image sets (44 images/set) taken remotely at different time points, totaling 1390 image sets. After removing patients without active disease, 55,189 images remained from 416 patients (1088 image sets). After removing incomplete or incorrect sets and blurry images, 46,332 images from 405 patients (1053 image sets) were used for model training and testing. Using the Fitzpatrick scale, 66.9% of participants had Type I-III skin, and 33.1% had Type IV-Type VI skin. Mean EASI score was 3.25 +/- 4.91. The best model (i.e., max validation ICC) consists of a ViT pre-trained encoder block, followed by an attention block that calculates the attention scores of each of the features and aggregates the scores. Finally, a fully connected layer outputs a single EASI value (range: 0-72). We performed a three-way comparison between our AI model, Rater A, and Rater B. The ICC for each comparison was: AI model vs Rater A: 74.7% [95% CI: 68%-81%]; AI model vs Rater B: 66.5% [95% CI: 58%-73%]; and Rater A vs Rater B: 70.3% [95% CI: 63%-77%] and is reported in Fig 1. And MAE is as follows: AI model vs Rater A: 2.28 +/- 3.33; AI model vs Rater B: 2.51 +/- 2.61; and Rater A vs Rater B: 2.29 +/- 3.60.

Conclusion: Remote photography using smart phones could greatly reduce the burden of participating in and conducting AD trials for both patients and clinicians. Our novel deep learning models, created and validated by using remotely collected images, were comparable to ratings by board-certified dermatologists, highlighting their potential utility as tools in clinical trials.

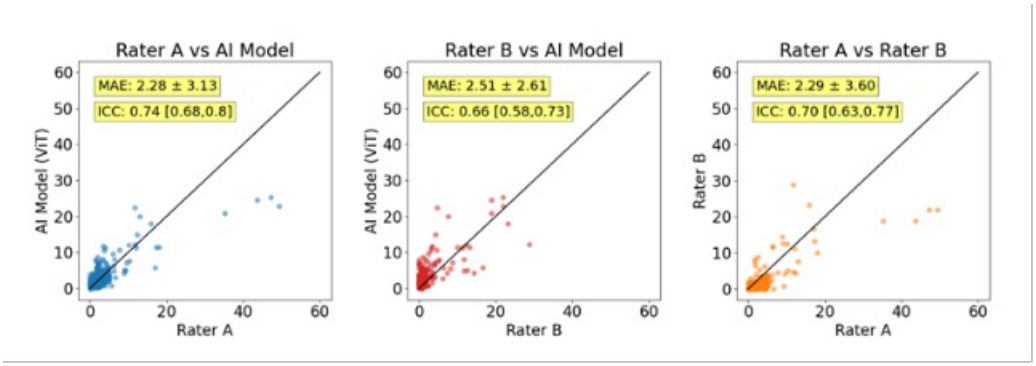


Figure 1. Three-way comparison between Rater A, Rater B, and AI Model. The inter-class correlation coefficient (ICC) and mean-absolute error (MAE) of the Raters A vs AI model, the Raters B vs the AI model, and the Raters A vs Raters B is reported.



Abstract N°: 7188

Patient Perception of Life Course Impairment With Moderate-to-Severe Atopic Dermatitis

Alexa B. Kimball[1], Min Yang[2], Bruno Martins[2], Ashley Holub[2], Jingdong Chao[3], Gaelle Le Bagousse-Bego[4], Kerry Noonan[5], Jason Wang*[3]

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic systemic disease associated with significant clinical and psychological burden, which can lead to cumulative life course impairment (CLCI), defined as an increasing disease burden over time that leads to irreversible effects such as negative impact on career trajectory, missed life opportunities, and financial and social impact. However, there are limited data on the extent of CLCI due to uncontrolled AD from the patient's perspective. A qualitative interview study of adult patients with moderate-to-severe AD was conducted to investigate AD-related life impact.

Materials & Methods: Adult patients with moderate-to-severe AD enrolled in RELIEVE-AD (a prospective, long-term survey study) who completed the Year 6 survey, were invited to participate in qualitative one-on-one interviews lasting up to 60 minutes. The semi-structured interview consisted of questions focusing on different domains of life before and after initiating dupilumab, including disease experience; education, career, and financial impact; relationships and social life; and psychological impact. Content analysis using ATLAS.ti was conducted to analyze the qualitative data obtained from the interviews. Here we report the data on the impact of AD before receiving dupilumab.

Results: 50 patients participated in the interview study. The mean age was 26.3 years at the time of AD diagnosis and 45.4 years at the time of dupilumab initiation, and 31 (62.0%) were female participants. Among participants diagnosed with AD before the age of 30 years, 65% of them reported a negative impact of AD on their education, primarily in reduced concentration (42%) and lowered class attendance (26%). When asked about employment, 72% of all participants noted negative impacts, including reduced work performance (34%) and reduced concentration (28%). Participants reported a negative impact of AD on their family relationships (62%), dating (58%), friendships (54%), and intimacy (32%). AD also impacted patients' daily life and ability to participate in leisure activities (100%), clothing choices (94%), vacation planning (58%), as well as contributing to dietary restrictions (48%). All participants discussed the negative impacts of AD on mental and emotional well-being, with many reporting poor self-image (78%) and stress or worry (76%) often as a result of their AD symptoms. Participants also reported shame or embarrassment (56%), and even hopelessness (46%) due to living with AD.

Conclusion: Participants reported substantial negative impact of AD on various domains of their lives such as education and career, relationships, ability to live and enjoy a normal life, and mental and emotional well-being. Due to the irreversible nature of some aspects of CLCI, clinical care of AD should focus on both physical and psychosocial aspects of the disease and consider effective treatments early in the disease course to help minimize CLCI.



Abstract N°: 7201

Ceramide-Containing Moisturiser as Atopic Dermatitis Monotherapy: Clinical Efficacy and Tolerability in Pediatric and Adult Patients

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Introduction & Objectives:

Atopic dermatitis (AD) is the most common chronic inflammatory skin disease worldwide affecting 103 million children and 101 million adults globally. Characterized by impaired skin barrier function and altered lipid composition, AD results in increased transepidermal water loss (TEWL), reduced hydration, and increased susceptibility to infection and inflammation, resulting in symptoms that can significantly impact patients' quality of life (QoL). Effective moisturisers play a crucial role in restoring skin barrier function and reducing reliance on more potent medications such as corticosteroids. This study evaluated the clinical efficacy and tolerability of a ceramide-containing moisturising cream in a diverse panel of pediatric and adult subjects with mild to moderate AD.

Materials & Methods:

This before-and-after clinical study enrolled 102 subjects from Brazil with mild to moderate AD, including 48 adults and 54 children aged 4 months to 63 years. At baseline, 22% of subjects presented with mild AD and 78% had moderate AD. The study population comprised of Fitzpatrick skin phototypes I-VI. Subjects applied the ceramide-containing moisturising cream twice daily for four weeks. Efficacy was assessed through instrumental measurements of transepidermal water loss (TEWL) and skin hydration. Clinical evaluations included AD severity score (SCORAD), Overall Dryness Score (ODS), Scaling, Roughness, Redness, and Cracks Sum Score (SRRC), and subject-reported itch assessment. Both clinical and instrumental evaluations were assessed at baseline, immediately after application, at week 2, week 4, and 3- and 7-day regression. Tolerability was evaluated via subjective patient reporting and investigator assessment at week 2 and 4. QoL was measured using a validated questionnaire.

Results:

The ceramide-containing moisturising cream demonstrated statistically significant improvements across all parameters. SCORAD scores showed significant 38% reduction at 2 weeks and 51% at 4 weeks, with sustained improvement observed even after discontinuation (36% reduction at 3-day regression and 21% reduction at 1-week regression) ($p<0.001$). SRRC exhibited similar significant reductions (39% at week 2, 50% at week 4, 31% at 3-day regression, and 19.9% at 1-week regression), consistent across both mild and moderate AD subgroups ($p<0.001$). ODS revealed quick and significant improvement in overall dryness, with a 32% reduction immediately after application, further improving to 29% at week 4 and maintaining a 12% improvement at the 3 3-day regression ($p<0.001$). Visual symptoms as assessed by the investigator, significantly improved after 4 weeks of treatment. Subject-reported average and worst itch within 24 hours showed significant improvement. The ceramide-containing moisturising cream resulted in significant improvements in QoL, with a 61% increase at week 2 and a 79% increase at week 4 ($p<0.001$). Excellent tolerability was demonstrated throughout the study.

Conclusion:

This study demonstrates the efficacy and tolerability of a ceramide-containing moisturising cream in managing

mild to moderate AD across a diverse patient population. The significant improvements observed in SCORAD, SRRC, ODS, and patient-reported itch, coupled with the sustained benefits after discontinuation of use, highlight the ceramide-containing moisturizer's ability to effectively address AD symptoms and enhance QoL for a diverse patient population.



Abstract N°: 7234

Clinical Evaluation of the Efficacy and Tolerance of a Novel Topical Cream for Managing Sensitive, Weakened and Compromised Skin Barrier

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Introduction & Objectives:

Chronic inflammatory skin conditions, characterized by dryness, pruritus, and inflammation, negatively impact quality of skin and necessitate effective yet well-tolerated topical treatments. Long-term management is often hampered by poor adherence due to unpleasant product aesthetics, highlighting the need for elegant, efficacious formulations that seamlessly integrate into daily routines. The present study evaluates a lightweight, non-greasy, oil-in-water cream combining colloidal oatmeal, bisabolol, panthenol, and squalane in a single formulation for its efficacy in alleviating dryness, redness, discomfort, and improving skin quality in these conditions.

Materials & Methods:

A four-week, single-center, double-blinded, controlled clinical study was conducted on 62 subjects (26 male, 36 female), aged 15-27, with Fitzpatrick phototypes I-VI and diverse ethnicities, all reporting sensitive, eczema-prone skin and a compromised skin barrier. Inclusion criteria included mild to moderate visible erythema, dryness/desquamation, rough iskin texture, and lack of resilience and suppleness.

Subjects applied the investigational topical cream twice daily to facial skin. Expert grading and high resolution clinical photographic were performed and captured at baseline, immediately post- first application, 8 hours post-fist application, and at weeks 1, 2, and 4. Subjective assessments via questionnaires were collected concurrently with clinical evaluations. Transepidermal water loss (TEWL) measurements were obtained from a randomly assigned cheek at baseline, weeks 1, 2, and 4. Objective and subjective tolerance evaluations were conducted at baseline and week 4.

Results:

After 1 week of product use, statistically significant improvements ($p<0.01$) compared to baseline were observed for visible redness (-29%), dryness/desquamation (-62%), rough skin texture (-43%), resiliency (+38%), suppleness (+40%), overall skin quality (+40%). TEWL also decreased significantly compared to baseline after 1 week of use (-17%, $p<0.01$). These improvements were sustained and further enhanced through week 4.

Objective and subjective tolerance indicated excellent tolerability of twice daily use. No product related adverse events were reported.

Subject self-assessments demonstrated a high level of agreement that the product possesses a melting, lightweight, non-greasy texture, while providing a soothing and protective sensation on compromised, sensitive skin.

Conclusion:

This oil-in-water cream containing colloidal oatmeal, bisabolol, panthenol and squalane demonstrated significant and sustained improvements in dryness, redness, skin texture, resilience, and suppleness in sensitive, eczema-

prone skin, along with reduced TEWL and excellent tolerability, supporting its potential as an effective and cosmetically elegant solution for managing chronic inflammatory skin conditions.



Abstract N°: 7243

Impact of Dupilumab on the Lives of Patients With Moderate-to-Severe Atopic Dermatitis

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic systemic disease associated with significant disease burden, which can lead to cumulative life course impairment (CLCI), a persisting and accumulating disease burden over time, leading to irreversible effects on various domains of patient life. There are limited data on the extent of AD on patients' CLCI and how effective treatments may positively affect the lives of these patients. Here we report the patients' perspective relating to the impact of dupilumab on various aspects of their lives due to improvement in AD.

Materials & Methods: Adult patients with moderate-to-severe AD enrolled in RELIEVE-AD (a prospective, long-term survey study) who completed the Year 6 survey, were invited to participate in qualitative one-on-one interviews lasting up to 60 minutes. The semi-structured interview consisted of questions focusing on different domains of life before and after initiating dupilumab, including disease experience; education, career, and financial impact; relationships and social life; and psychological impact. Content analysis using ATLAS.ti was conducted to analyze the qualitative data obtained from the interviews. Here we present the data on the impact of AD following dupilumab treatment.

Results: 50 patients participated in the interview study. The mean age was 26.3 years at the time of AD diagnosis and 45.4 years at the time of dupilumab initiation, and 31 (62.0%) were female participants. When asked about employment, 54% of the participants reported a positive impact after dupilumab initiation, including improved concentration (28%) and improved work performance (18%). Participants reported improvement in family relationships (46%), friendships (42%), and their dating life (36%) after dupilumab treatment. Participants also reported improved daily life/leisure activities (92%), and they experienced improved vacations (52%), fewer clothing restrictions (74%), and improved diet (32%) after dupilumab treatment. Participants reported improved mental and emotional well-being after dupilumab, with many reporting less stress/worry (78%), increased happiness (66%), and improved self-image (66%).

Conclusion: Participants reported an improvement in various domains of their life after the initiation of dupilumab treatment, such as career, relationships, ability to live and enjoy life, and mental and emotional well-being. The use of effective AD treatment in patients with moderate and severe AD may reduce the effects of CLCI.



Abstract N°: 7266

The real-world, long-term risk of infections associated with dupilumab in atopic dermatitis: A global cohort study

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Introduction & Objectives:

A low risk of infections was found in the randomized placebo-controlled trials of dupilumab in atopic dermatitis (AD). The real-life long-term risk of infections associated with dupilumab remains unclear.

In the current study, we aimed to assess the risk of infectious complications in patients with AD managed by dupilumab relative to those treated with methotrexate and cyclosporine.

Materials & Methods:

Using the TriNetX global dataset, a retrospective cohort study comprised two distinct analyses comparing patients with AD under different treatments: (i) initiators of dupilumab (n=10,913) versus methotrexate (n=10,913) and (ii) initiators of dupilumab (n=6,943) versus cyclosporine (n=6,943). Study groups were compared regarding the risk of 32 infections during the initial three years following drug initiation. Propensity score matching was conducted to optimize inter-group comparability.

Results:

During the first year of treatment, relative to methotrexate and cyclosporine, dupilumab was associated with a decreased risk of herpetic (HR, 0.59; 95% CI, 0.47-0.74 and HR, 0.65; 95% CI, 0.50-0.85, respectively) and non-herpetic skin infection (HR, 0.55; 95% CI, 0.49-0.63 and HR, 0.68; 95% CI, 0.58-0.80, respectively) and systemic infections (HR, 0.39; 95% CI, 0.34-0.44 and HR, 0.47; 95% CI, 0.40-0.56, respectively).** More **s**pecifically**,** relative to cyclosporine, dupilumab was associated with a reduced risk of pneumonia, urinary tract infection (UTI), upper respiratory tract infection (URTI), otitis media, sinusitis, herpes simplex, herpes zoster, hepatitis B virus (HBV) and HCV reactivation, cytomegalovirus, Epstein-Barr virus, infective gastroenteritis, influenza, parasitic diseases, Pneumocystis jirovecii pneumonia, cellulitis, folliculitis, mucocutaneous candidiasis, and dermatophytosis. Compared to methotrexate, dupilumab conferred a decreased risk of the aforementioned infections (apart from herpes simplex and HCV reactivation) as well as septicemia, meningitis, encephalitis, osteomyelitis, and tuberculosis. The risk of eczema herpeticum was not increased among dupilumab-treated patients.

Conclusion:

Dupilumab was associated with a decreased real-world risk of herpetic and non-herpetic skin infections relative to cyclosporine and methotrexate. Dupilumab might be positively considered in fragile patients with susceptibility to infections. The pathomechanism underlying these observations should be further investigated.



Abstract N°: 7280

Baseline Confocal Microscopy Findings and Skin Barrier Alterations in Moderate-to-Severe Atopic Dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) is the most prevalent chronic inflammatory dermatosis across all age groups. Skin barrier dysfunction plays a pivotal role in AD pathophysiology. Reflectance confocal microscopy (RCM) offers a non-invasive, real-time imaging tool to assess epidermal and superficial dermal changes.

The aim of this study is to evaluate the association between skin characteristics assessed by RCM and severity scores in patients with moderate-to-severe atopic dermatitis.

Materials & Methods:

A prospective multicenter cohort study was initiated in April 2024 to evaluate patients with moderate-to-severe atopic dermatitis, inadequately controlled and with indication for systemic therapy. This long-term project presents interim results describing the baseline characteristics of currently enrolled participants. Clinimetry, patient-reported outcomes (PROs), and reflectance confocal microscopy (RCM) images were obtained at baseline. All RCM imaging was performed at a single hospital.

Results:

Twenty-six consecutives patients with moderate-to-severe atopic dermatitis were enrolled. Twenty were male (76.9%). The median age at study enrollment was 16 years (IQR 10–26). Clinical phenotypes, comorbidities, and prior treatments are summarized in Table 1. At baseline, the median (IQR) scores were: EASI 29 (19–33), DLQI 11.5 (8–17), ADCT 13.5 (10–20), SCORAD 64 (51–79), and IGA 3 (3–4).

Main findings on reflectance confocal microscopy (RCM) included disorganized epidermis and spongiosis in all patients (26, 100%), exocytosis (24, 92.3%), inflammatory infiltrates in the epidermis (24, 92.3%), and inflammatory infiltrates in the dermis (7, 26.9%). Other findings were loss of papillary edges (22, 84.6%), acanthosis (14, 53.8%), hyperkeratosis (14, 53.8%), parakeratosis (13, 50%), dilated vessels (26, 100%), dermal melanophages (1, 3.8%), and vesicles (3, 11.5%).

Table 1. Clinical characteristics of the study population

Category	Feature	n (%)
Clinical phenotypes	Classic flexural lichenified dermatitis	21 (80.8%)
	Generalized lichenified eczema	5 (19.2%)
Comorbidities	Asthma	7 (26.9%)
	Food allergies	5 (19.2%)
	Hand eczema	3 (11.5%)
Prior treatments	Methotrexate	13 (50.0%)
	Phototherapy	8 (30.8%)
	Cyclosporine	3 (11.5%)
	Dupilumab	2 (7.7%)
	Abrocitinib	1 (3.8%)
	Baricitinib	1 (3.8%)
	Upadacitinib	1 (3.8%)
	Lebrikizumab	1 (3.8%)
	Topical/systemic corticosteroids or calcineurin inhibitors	17 (65.4%)

Conclusion:

Reflectance confocal microscopy emerges as a valuable, non-invasive tool for assessing skin barrier alterations in atopic dermatitis. Baseline findings—including inflammatory infiltrate, spongiosis, and dermoepidermal junction irregularities—highlight its potential for real-time disease monitoring during systemic therapy. These preliminary results support the integration of RCM into personalized treatment strategies. Further studies are needed to validate the predictive value of RCM findings for therapeutic outcomes.



Abstract N°: 7389

Long-term efficacy and safety of nemolizumab in adolescents with moderate-to-severe atopic dermatitis: Post hoc analyses from ARCADIA LTE 1-year cut-off

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Introduction & Objectives: Nemolizumab, a first-in-class interleukin-31 receptor alpha antagonist, has demonstrated continuous improvements in itch, skin lesions and sleep in adolescent population with moderate-to-severe atopic dermatitis (AD) up to week (W)16. Since AD is a chronic condition, long-term clinical data are crucial to confirm long term safety and additional efficacy benefit for patients. This analysis evaluates the efficacy of nemolizumab in adolescent patients with moderate-to-severe AD up to W56 in the long-term extension study.

Materials & Methods: This prospective, multicentre, open-label, long-term study (NCT03989206) enrolled nemolizumab-previously experienced (NPE), nemolizumab-naïve (NN) patients from ARCADIA 1&2 phase 3 and other nemolizumab studies, along with 37 newly recruited adolescents. Interim data analysis was conducted on all efficacy and safety data available at the data cut-off at W56. Here, we present efficacy and safety data in adolescent patient population (12-17 years old) administered nemolizumab 30mg subcutaneously every 4 weeks (Q4W) with concomitant background topical corticosteroids (TCS) of low/medium potency with/without topical calcineurin inhibitors (TCI). Efficacy assessments include the proportion of patients with Investigator's Global assessment (IGA) score of 0/1 (clear/almost clear), ≥75% and ≥90% improvement in the Eczema Area and Severity Index (EASI-75 and EASI-90) from initial baseline, improvement in visual analogue scale (VAS, 0-10) Pruritus and Sleep loss of SCORing Atopic Dermatitis (SCORAD) score and Dermatology Life Quality Index (DLQI) score. All efficacy analyses are summarised using observed data .

Results: At data cut-off, 248 adolescents (NPE=141, NN=107; mean age=15 years) were analyzed in the study. At W56, 72% of NPE and 53% of NN patients achieved an IGA 0/1 score; 86% and 80% reached EASI-75; 72% and 57% achieved EASI-90; 79%, and 59% reported ≥4-point improvement in SCORAD VAS Pruritus; 64% and 38% achieved VAS score <2, respectively. Improvements in sleep mirrored those in itch (85%, 41%). DLQI score improved over time in >87% of patients. The most frequent adverse events (incidence rate ≥5%) were atopic dermatitis, COVID-19, and nasopharyngitis. Most treatment-emergent adverse events were non-serious and mild/moderate in severity.

Conclusion: Overall, nemolizumab 30 mg Q4W with TCS/TCI improved key signs and symptoms of AD - pruritus, skin lesions and sleep disturbance in adolescent patients with moderate-to-severe AD during W56 follow-up.



Abstract N°: 7420

Dupilumab Monotherapy Improves Multiple Skin Measures in Skin of Color Patients With Atopic Dermatitis as Measured by Line-Field Optical Coherence Tomography

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Introduction & Objectives: Atopic dermatitis (AD) presents with distinct clinical manifestations in skin of color (SoC) patients, which may contribute to diagnostic uncertainty and complicate assessment of disease severity and treatment response (Kaufman BP, et al. *Exp Dermatol*. 2018). Detailed evaluation of unique clinical features and mechanisms of AD progression in SoC in response to dupilumab treatment can provide valuable insight into disease activity and management in this patient population. In this study, we evaluated AD lesional, perilesional, and post-inflammatory pigmentary skin structural changes in SoC patients with moderate-to-severe AD before and after dupilumab treatment using non-invasive line-field confocal optical coherence tomography (LC-OCT).

Materials & Methods: 10 patients (aged ≥18 years, Fitzpatrick skin type IV/V/VI) from the phase 4, open-label DISCOVER trial (NCT05590585) participated in this investigator-initiated single-center analysis. Patients received dupilumab 200/300 mg q2w monotherapy for 24 weeks.

Representative areas of AD lesional (Eczema Area and Severity Index [EASI] erythema and papulation severity subscores > 0), post-inflammatory hyperpigmentation (PIH; Post-Inflammatory Hyperpigmentation Severity Scale [PHSS] > 1 and EASI erythema and papulation severity subscores = 0), and non-lesional (PHSS ≤ 1 and EASI erythema and papulation severity subscores = 0) skin were imaged by LC-OCT (2–3 3D stacks per site) at baseline, and at Weeks 4, 16, and 24.

Changes in skin layer (stratum corneum [SC] thickness, epidermal thickness, and dermal–epidermal junction [DEJ] undulation) and keratinocyte nuclei (volume, shape, atypia) metrics were assessed through segmentation and measurement analysis (DAMAE Medical).

Results: Compared to non-lesional skin at baseline, AD lesional skin had thicker SC (mean 19.49 µm; 35% thicker) and thicker total epidermis (mean 172.56 µm; 73% thicker), and had more highly undulated DEJ (mean 97%; 134% more undulated). AD lesional skin also contained enlarged keratinocyte nuclei in the epidermis (mean 161.75 μm^3; 6% larger vs non-lesional skin) and an atypical keratinocyte network (mean 0.316; 47% more atypical vs non-lesional skin). While no statistically significant differences were observed, all PIH skin metrics were intermediate between those of AD lesional and non-lesional sites.

At Week 24, AD lesional sites showed a progressive improvement with dupilumab treatment, with metrics approaching normal skin values. SC thickness differences between AD, PIH, and non-lesional areas were no longer significant. While values remained significantly higher in AD lesional areas vs non-lesional areas, decreases in total epidermal thickness and DEJ undulation were observed (31.5% and 32.8%, respectively). There were no significant differences in keratinocyte metrics in lesional vs non-lesional skin after treatment.

Conclusion: In SoC patients with AD, dupilumab monotherapy resulted in progressive improvements in multiple skin measures, with lesional skin approaching normal skin values, as measured by in vivo 3D skin imaging

techniques.

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Abstract N°: 7424

Efficacy and safety of ruxolitinib cream monotherapy for atopic dermatitis: An updated systematic review and meta-analysis of randomized vehicle-controlled trials with trial sequential analysis

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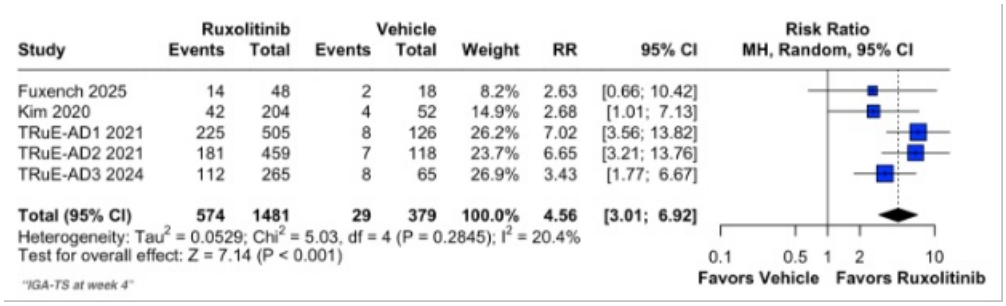
Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by inflammation, intense itching, and a disrupted skin barrier. Although topical corticosteroids remain the standard treatment, their long-term use is associated with adverse effects. This meta-analysis assesses the efficacy and safety of ruxolitinib cream, a topical JAK1/JAK2 inhibitor, compared to vehicle in AD treatment.

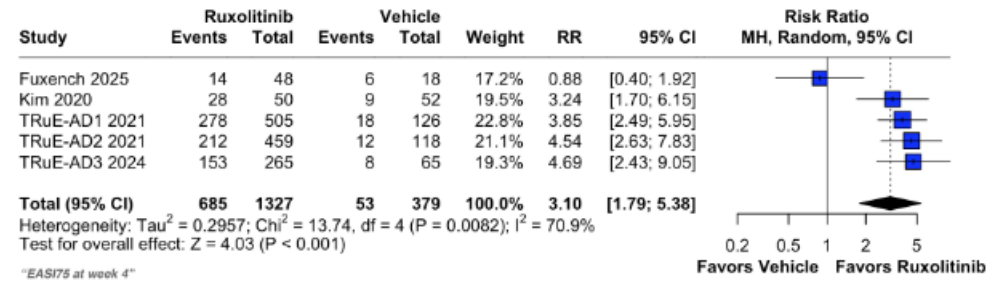
Materials & Methods: This systematic review and meta-analysis, registered in PROSPERO (CRD420251026000), followed the Cochrane Handbook and PRISMA guidelines. PubMed, Embase, and Cochrane were searched for randomized controlled trials (RCTs) up to April 2025. Primary endpoints included Investigator's Global Assessment - Treatment Success (IGA-TS), and 75% improvement in the Eczema Area and Severity Index (EASI75) at weeks 4 and 8. Secondary endpoints included a 4-point improvement in pruritis Numeric Rating Scale (NRS) at week 8, and the incidence of at least one treatment-emergent adverse event (TEAE). A DerSimonian-Laird random-effects model was used, with heterogeneity assessed using I2. Statistical analyses were performed using Studio.

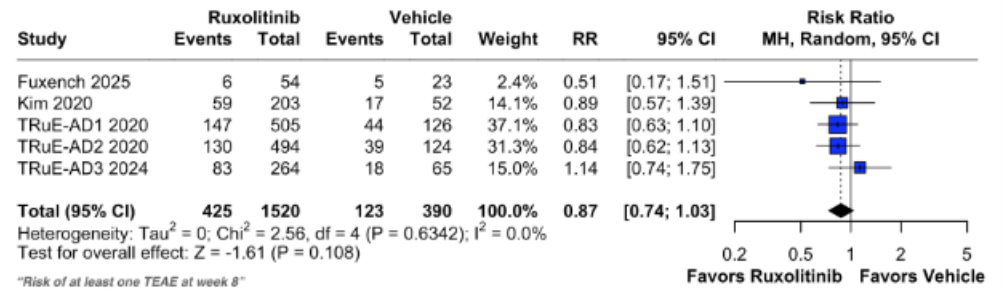
Results: We included 1,912 patients from 5 RCTs, with ages ranging from 2 to 70 years and 60.25% of them being female.** Ruxolitinib significantly increased IGA-TS achievement at 4 weeks (RR 4.56; 95% CI 3.01–6.92; p<0.001) and 8 weeks (RR 4.00; 95% CI 2.97–5.38; p<0.001). Subgroup analysis showed no significant difference between adolescents/adults and children (p=0.35), though both groups benefited (RR 5.07; 95% CI 3.12–8.25; p<0.001 and RR 3.43; 95% CI 1.77–6.67; p<0.00001, respectively). No significant dosage-based variation was observed (p=0.08). Regarding EASI75, outcomes improved at both 4 weeks (RR 3.10; 95% CI 1.79–5.38; p<0.001) and 8 weeks (RR 3.16; 95% CI 2.21–4.51; p<0.001), with heterogeneity reduced by sensitivity analysis. Benefits were significant in adolescents/adults (RR 2.30; 95% CI 1.08–4.89; p=0.001) and children (RR 4.69; 95% CI 2.43–9.05; p<0.00001), with no difference between groups (p=0.16) or dosage levels (p=0.36). Trial sequential analysis for IGA-TS and EASI75 confirmed that the required information size was reached and the Z-curve crossed the monitoring boundary, supporting the robustness of the findings and favoring ruxolitinib. Ruxolitinib also improved pruritus NRS by ≥4 points (RR 2.39; 95% CI 1.62–3.53; p<0.001). Finally, the incidence of at least one TEAE did not differ significantly between groups (RR 0.87; 95% CI 0.74–1.03; p=0.10), though adolescents/adults had fewer TEAEs (RR 0.83; 95% CI 0.69–1.00; p=0.04), and children showed a nonsignificant increase (RR 1.14; 95% CI 0.74–1.75; p=0.55).

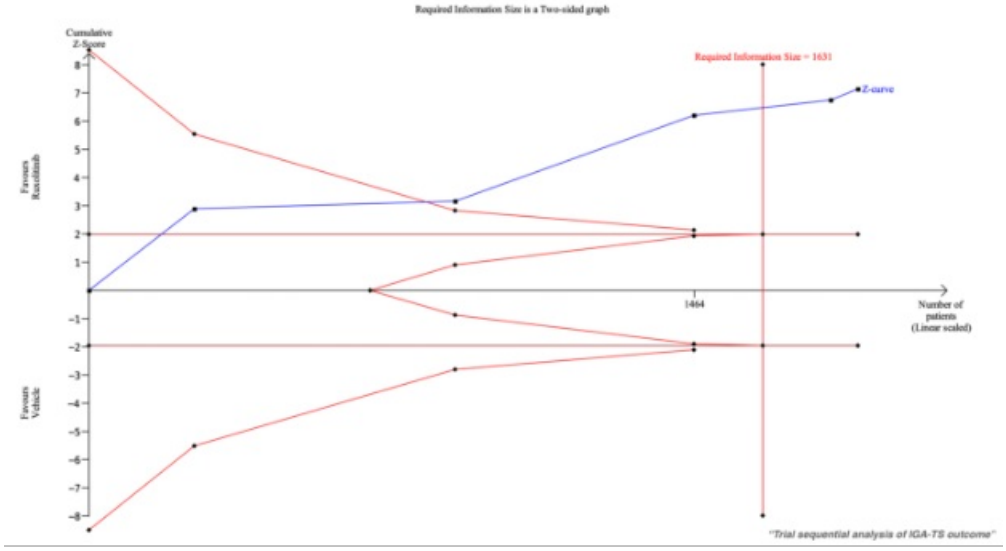
Conclusion: Our study suggests that ruxolitinib significantly increases the likelihood of achieving IGA-TS, EASi75, and a 4-point change in pruritis NRS, without a significant increase in the risk of TEAEs. Further trials are needed to determine the optimal dosage and assess its safety in children.

Study	Phase	Follow up, weeks	Age, median (range), y	Female, n (%)	White, n (%)	Intervention, dosage (frequency)	Patients, n	Baseline BSA, % mean (SD)	Disease duration, median (range), y	IGA 2 (mild), n (%)	IGA 3 (moderate), n (%)
Fuxench 2025	II	4	36.5 (18-66)	46 (85.2)	20 (37)	RUX 1.5% (BID)	54	5.3 (4.1)	19.1 (1.4-62.8)	16 (29.6)	37 (68.5)
			41 (17-63)	16 (69.6)	11 (47.8)	Vehicle (BID)	23	5.6 (3.7)	20.9 (1.9-60.8)	8 (34.8)	15 (65.2)
Kim 2020	II	8	38 (18-69)	26 (51)	27 (52.9)	RUX 0.15% (QD)	51	9.2 (5.6)	22.3 (2.3-60.9)	16 (31.4)	35 (68.6)
			37 (18-70)	27 (52.9)	33 (64.7)	RUX 0.5% (QD)	51	8.9 (5.1)	19.8 (2.0-66.1)	17 (33.3)	34 (66.7)
			37 (18-65)	31 (59.6)	24 (46.2)	RUX 1.5% (QD)	52	9.7 (6.2)	20.2 (0.7-56.9)	15 (29.4)	36 (70.6)
			35.5 (18-70)	24 (48)	33 (66)	RUX 1.5% (BID)	50	10.5 (5.2)	21.2 (01-64.8)	14 (28)	36 (72)
			31.5 (18-69)	32 (61.5)	27 (51.9)	Vehicle (BID)	52	9.5 (5)	19.5 (2.2-65.3)	15 (28.8)	36 (69.2)
TRuE-AD1 2021	III	8	34 (19-51)	154 (61.1)	171 (67.9)	RUX 0.75% (BID)	252	9.9 (5.4)	14.1 (1-68.8)	61 (24.2)	191 (75.8)
			30 (19-49)	158 (62.5)	177 (70)	RUX 1.5% (BID)	253	9.3 (5.2)	16 (0-69.2)	60 (23.7)	193 (76.3)
			31.5 (20-49)	79 (62.7)	85 (67.5)	Vehicle (BID)	126	9.2 (5.1)	17.9 (1.9-79.1)	31 (24.6)	95 (75.4)
TRuE-AD2 2021	III	8	33 (19-52)	150 (60.5)	174 (70.2)	RUX 0.75% (BID)	248	10.1 (5.3)	15.9 (0.1-68.8)	64 (25.8)	184 (74.2)
			32 (21-49)	150 (61)	178 (72.4)	RUX 1.5% (BID)	246	9.9 (5.4)	16.6 (0-70.7)	63 (25.6)	183 (74.4)
			37.5 (21.5-53.5)	80 (64.5)	85 (68.5)	Vehicle (BID)	124	10.1 (5.8)	15.9 (0.8-70.7)	33 (26.6)	91 (73.4)
TRuE-AD3 2024	III	8	6.6† (2-11)	73 (54.5)	75 (56)	RUX 0.75% (BID)	134	NR	NR	NR	NR
			6.4† (2-11)	68 (51.9)	68 (51.9)	RUX 1.5% (BID)	131	NR	NR	NR	NR
			6.3† (2-11)	38 (58.5)	37 (56.9)	Vehicle (BID)	65	NR	NR	NR	NR








Required Information Size is a Two-sided graph
Cumulative Z-Score
Required Information Size = 1631
Z-curve
Favours Ruxolitinib
Favours Vehicle
1464
Number of patients (Linear scaled)
"Trial sequential analysis of IGA-TS outcome"



Abstract N°: 7425

evaluation of serum ige levels and peripheral eosinophilia in seborrheic dermatitis: a case-control study

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Introduction & Objectives:

Seborrheic dermatitis (SD) is a chronic, inflammatory, and recurrent skin disorder in which various factors contribute to pathogenesis. Immunoglobulin E (IgE) is a molecule that contributes to allergic and inflammatory responses. Atopy, defined as a genetically determined tendency to develop exaggerated immune responses to environmental allergens, is characterized by elevated levels of IgE antibodies and can lead to the development of diseases such as atopic dermatitis, allergic rhinitis, and asthma. Eosinophils are multifunctional leukocytes involved in the regulation of immune responses, particularly in allergic inflammation. It is thought that some shared mechanisms may play a role in the pathophysiology of SD and atopic conditions, both of which are chronic, inflammatory, and recurrent in nature. This study aimed to investigate the presence of atopic diseases such as allergic rhinitis, conjunctivitis, and asthma in SD patients without atopic dermatitis or other inflammatory skin disorders, and to assess their serum IgE levels and peripheral eosinophil counts as a marker of atopy.

Materials & Methods:

This prospective, single-center, case-control study included 83 SD patients and 69 age- and sex-matched healthy controls. Participants with any additional inflammatory dermatosis including atopic dermatitis, systemic inflammatory disease, or systemic medication use were excluded.

Results:

There were no significant differences in terms of age or sex between the SD and control groups ($p = 0.62$ and $p = 0.76$, respectively). No significant differences were observed between two groups regarding history of conjunctivitis, rhinitis, or asthma ($p = 0.487$, $p = 0.229$, $p = 0.557$; respectively). Total serum IgE levels were significantly higher in SD patients compared to controls (301.67 ± 935.64 kU/L vs. 70.34 ± 78.46 kU/L; $p = 0.018$). Both the serum eosinophil percentage and absolute eosinophil count were significantly higher in SD patients ($p = 0.00$, $p = 0.036$; respectively). A significant positive correlation was observed in the patient group between the facial scores of the Seborrheic Dermatitis Area Severity Index (SASI) and both serum eosinophil count and percentage ($r = 0.360$, $p = 0.001$; $r = 0.233$, $p = 0.034$, respectively). A positive and significant correlation was also found between total SASI scores (face + scalp) and absolute serum eosinophil count ($r = 0.265$, $p = 0.016$). Serum IgE levels were positively correlated with both absolute eosinophil count and eosinophil percentage ($p = 0.045$, $r = 0.221$; $p = 0.044$, $r = 0.221$; respectively).

Conclusion:

In this study, total serum IgE levels were significantly higher in SD patients than in healthy controls. The elevated eosinophil levels and their correlation with disease severity may indicate an eosinophil-driven inflammatory

component in a subset of SD patients. The elevated IgE levels and eosinophil counts, known to be associated with allergic and atopic processes, suggest that allergens and hypersensitivity responses may play a greater role in the pathogenesis of SD than previously thought.



Abstract N°: 7436

Real-world effectiveness and safety of upadacitinib for atopic dermatitis in adults and adolescents: a retrospective multicenter analysis of minimal disease activity criteria

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Introduction & Objectives:

While randomized controlled trials have investigated the efficacy and safety of upadacitinib for atopic dermatitis (AD), real-world data remains limited. We conducted a retrospective multicenter study of upadacitinib for AD as per the minimal disease activity (MDA) criteria.

Materials & Methods:

Our retrospective multicenter study included adult and adolescent patients with AD from three Canadian institutions who were initiated on upadacitinib treatment. The primary outcome was achievement of optimal targets at week 16±8 as per the MDA criteria, which included achievement of 1 clinician-reported outcome (Eczema Area and Severity Index [EASI] improvement of 90% [EASI90], EASI ≤3, or IGA 0/1 and body surface area [BSA] ≤2%) and 1 patient-reported outcome Worst Pruritus Numeric Rating Scale [WP-NRS] 0/1 or Dermatology Life Quality Index [DLQI] 0/1). A nonresponder imputation (NRI) analysis was used to account for missing data. Safety was assessed via incidence of adverse events (AEs).

Results:

This analysis included a total of 222 patients. The mean age was 45 (range: 12-79) years, with 49.1% (109/222) being male. At weeks 16±8: optimal targets for MDA were achieved by 70.7% (157/222) of patients in total. Clinician-reported outcomes (EASI90, EASI ≤3, or IGA 0/1 and BSA ≤2%) were achieved by 81.1% (180/222), while patient-reported outcomes (WP-NRS 0/1 or DLQI 0/1) were achieved by 74.8% (161/222).

In total, 40 treatment-emergent adverse events (TEAEs) occurred (18%, 40/222). The most common AEs were elevated creatine kinase (2.7%, 6/222), elevated triglycerides (2.3%, 5/222), acne (1.4%, 3/222), folliculitis (1.4%, 3/222), herpes simplex (1.4%, 3/222), and myalgia/arthragia (1.4%, 3/222). Six treatment discontinuations (2.7%) were noted (AEs; myalgia/arthralgia [n=2], new-onset lung malignancy [n=1], uveitis [n=1], and venous thromboembolism [n=1]). No serious infections, hypersensitivity reactions, major adverse cardiac events, or hepatic abnormalities were observed during the treatment period analyzed.

Conclusion:

Our real-world effectiveness outcomes indicate that the majority of patients with AD treated with upadacitinib achieved at least one clinician- and patient-reported outcome as per the optimal targets for MDA criteria at weeks 16±8. Study limitations include its retrospective nature and a lack of complete real-world documentation for certain metrics (e.g. WP-NRS).



Abstract N°: 7438

Dupilumab Treatment Restores Stratum Corneum Lipid Structure and Skin Barrier Function in Patients Aged 6 to 11 Years With Moderate-to-Severe Atopic Dermatitis

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Introduction & Objectives: Atopic dermatitis (AD), a systemic type 2 inflammatory disease, is characterized by significant skin barrier dysfunction. Previous reports show that, compared with healthy persons, patients with moderate-to-severe AD have altered lipid composition in their stratum corneum (SC), which contains significantly fewer ceramides with very long-chain fatty acids that are critical for lipid matrix assembly and skin barrier integrity. This analysis reports the impact of dupilumab treatment on SC lipid structure and skin barrier function in patients aged 6 to 11 years with moderate-to-severe AD.

Materials & Methods: PELISTAD (NCT04718870) was an open-label, exploratory study on skin barrier function in children aged 6 to 11 years with moderate-to-severe AD, who were treated with dupilumab for 16 weeks (follow-up: 12 weeks) based on baseline patient weight (300 mg every 4 weeks: ≥15 kg to <30 kg; 200 mg every 2 weeks: ≥30 kg to <60 kg) and matched with healthy volunteers. Transepidermal water loss (TEWL, g/m2/h) area under the curve (AUC) 20 was calculated as an integral of TEWL measurements at baseline and after 5, 10, 15, and 20 skin tape strippings and was assessed longitudinally in lesional and non-lesional skin of patients with AD treated with dupilumab, and in healthy skin. Lipid structure was assessed by lipid chain conformation in the SC using attenuated total reflectance Fourier transform infrared spectroscopic measurements. This is based on the frequency of the lipid peak, ranging from low frequency (~2,848 cm-1, associated with tight lipid conformation) to high frequency (~2,853 cm-1, associated with loose lipid conformation). Least squares (LS) means were obtained based on mixed models for repeated measures. All *P* values were nominal and there was no adjustment for multiple testing.

Results: At baseline, mean (standard error [SE]) TEWL AUC20 was significantly higher in the lesional skin of patients with AD (1,440.0 [119.0]) than in healthy skin (431.3 [58.7]; $P < 0.0001$). Following 16 weeks of dupilumab treatment, a significant improvement in mean TEWL AUC20 was observed in lesional skin (903.5 [72.3]; $P < 0.001$), which was sustained through Week 28 (797.5 [71.9]; $P < 0.001$). At Week 16, there was no significant difference in LS mean (SE) TEWL AUC20 between lesional (754.2 [76.0]) and healthy skin (648.8 [91.6]; $P = 0.59$). By Week 28, LS mean TEWL AUC20 in lesional skin (650.5 [79.8]) was still comparable to that of healthy skin (611.4 [92.0]; $P = 0.77$). Mean (standard deviation [SD]) baseline measurements of lesional SC showed high frequency of the lipid peak (2,850.1 cm-1 [0.7]), characteristic of a disorganized lipid chain conformation associated with greater SC permeability, compared with the low frequency (2,848.9 cm-1 [0.5]) observed in healthy SC, indicative of a tightly organized lipid structure ($P < 0.0001$). By Week 16, the mean peak frequency observed in lesional SC had

significantly reduced (2,849.4 cm-1 [0.8]; $P < 0.01$), and persisted to Week 28 (2,849.3 cm-1 [0.6]; $P < 0.0001$). A strong positive correlation was shown between lipid chain conformation and TEWL AUC20 (Pearson correlation coefficient = 0.71; $P < 0.001$).

Conclusion: Dupilumab treatment restores SC lipid structure and improves skin barrier function in patients aged 6 to 11 years with moderate-to-severe AD, highlighting the importance of the lipid structure in establishing proper skin barrier function. Improvements were sustained for up to 3 months after the end of treatment.



Abstract N°: 7482

Oral Probiotics as an Adjunctive Therapy in Pediatric Atopic Dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic skin disease marked by itching, barrier disruption, and frequent flare-ups. Recent studies point to a link between microbial dysbiosis and worsening symptoms, especially involving the gut-skin axis. Probiotics are being explored as a safe adjunct to standard care, but clinical data from low-resource settings remain limited.

To examine whether an 8-week oral probiotic course could reduce disease severity and flare frequency in children receiving conventional treatment for AD.

Materials & Methods:

We conducted a randomized controlled trial at a medical center, involving 20 children (aged 1–18 years) diagnosed with moderate to severe atopic dermatitis. Participants were randomly assigned to two groups. The intervention group received standard care (emollients and topical corticosteroids as needed) plus a daily oral probiotic containing Lactobacillus and Bifidobacterium strains (1×10^{10} CFU) for 8 weeks. The control group received standard care alone.

SCORAD scores were assessed at baseline and after 8 weeks. Flare-up episodes were documented throughout the study, along with caregiver-reported symptoms, including itching and sleep disturbance. Although microbiome profiling was not available due to resource constraints, the study offers real-world insight into the clinical utility of probiotics in pediatric AD, particularly in low-resource healthcare settings.

Results:

Eighteen children completed the study (9 in each group). After 8 weeks, the probiotic group saw a greater reduction in SCORAD scores (−51.8% vs. −27.3%; $p<0.05$). They also had fewer flare-ups (0.7 vs. 1.6), and more participants remained flare-free during the study (55.6% vs. 22.2%). Caregivers in the probiotic group more often reported improvements in itching and sleep. No adverse effects were observed.

Conclusion:

In this study, oral probiotics showed promise as a safe, helpful addition to standard therapy in pediatric AD. Children receiving probiotics had fewer symptoms and flare-ups. These findings are especially relevant in low-resource settings, where access to advanced diagnostic tools is limited. Larger trials are needed to confirm these benefits and better understand the role of microbial balance in AD.



Abstract N°: 7492

Comparative real-world sociodemographic and severity profiles of atopic dermatitis patientstreated with lebrikizumab

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Comparative real-world sociodemographic and severity profiles of atopic dermatitis patients treated with lebrikizumab

Introduction & Objectives:

Lebrikizumab, an anti–IL-13 monoclonal antibody, has emerged as a promising treatment for moderate-to-severe atopic dermatitis (AD). However, real-world data comparing the profiles of patients selected for lebrikizumab versus other therapies are limited. The aim of this study is to compare the sociodemographic characteristics and baseline disease severity of AD patients treated with lebrikizumab versus those receiving other treatments (including other advanced therapies, systemic or topical corticosteroids) in a real-world setting.

Materials & Methods:

A cross-sectional analysis including patients with AD attending our Atopic Dermatitis Unit was conducted. Patients receiving lebrikizumab were compared to those on other treatments. Variables analyzed included age, sex, familial atopy, age at disease onset, and baseline severity scores: POEM, DLQI, ADCT, IGA, EASI, and SCORAD

Results:

A total of 262 patients were included (5 receiving lebrikizumab). Lebrikizumab patients had a mean age of 50.2 (24.3) years versus 26.5 (14.1) years in the non-lebrikizumab group, with later disease onset (35.4 [35.4] vs. 19.9 [24.7] years). Male sex was slightly more frequent among lebrikizumab patients (60%, 3/5) compared to controls (45.5%, 117/257). Baseline severity scores were higher in the lebrikizumab group: POEM 18.0 (8.7) vs. 14.1 (7.9); DLQI 10.3 (11.2) vs. 7.8 (6.1); ADCT 17.3 (9.9) vs. 10.5 (6.2); IGA median 3.0 (IQR 3.0–3.0) vs. 2.0 (IQR 1.0–3.0); EASI 21.8 (1.4) vs. 12.2 (18.5); SCORAD 54.6 (11.4) vs. 36.2 (23.0). Baseline systemic treatment exposure was higher in the lebrikizumab group compared to controls: ciclosporin 60% vs. 13.2%; dupilumab 40% vs. 6.2%; tralokinumab 40% vs. 1.2%; upadacitinib 20% vs. 2.7%. No prior methotrexate, baricitinib or abrocitinib use was recorded in the lebrikizumab group.

Conclusion: ** In this real-life cohort, patients selected for lebrikizumab were older, with later disease onset, higher disease severity, and greater prior exposure to systemic and biologic therapies compared to those on other treatments. These findings suggest that lebrikizumab is being prescribed in a more treatment-refractory population in real-world practice, highlighting its potential role in managing difficult-to-treat cases.



Abstract N°: 7497

Safety of abrocitinib in adolescent patients with moderate-to-severe atopic dermatitis in India: Findings from an MRI sub study of a multicenter, randomized, open-label parallel-group study

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Introduction and Rationale

Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by dry skin, pruritus, and defective skin barrier function. Systemic therapies are often required for moderate-to-severe cases when topical treatments fail. Current systemic agents in India have limited efficacy and are associated with adverse events (AEs) that restrict long-term use. Abrocitinib is an oral, once-daily (QD) Janus kinase 1 (JAK1) selective inhibitor for treating moderate-to-severe AD.

Materials and Methods

In this substudy of a randomized, open-label, parallel-group study (NCT05375929) potential effects of abrocitinib on bone development in adolescents using knee magnetic resonance imaging (MRI) were assessed. All adolescent participants 12 to <18 years of age continued to receive abrocitinib (100 or 200 mg) as a monotherapy or combination therapy until 1 year after randomization in the main (NCT05375929) study. This analysis evaluated safety events and baseline and post-baseline knee MRI results for the adolescent participants in the sub-study.

Results

The substudy analyzed 35 adolescents, 19 participants received abrocitinib 200 mg QD; 16 participants received abrocitinib 100 mg QD. The median age was 14 years, with a median weight of 45.9 kg and a median body mass index (BMI) of 20.5 kg/m^2. All participants received at least one dose of the study intervention, with a median exposure duration of approximately 50 weeks. All 35 participants were evaluated via MRI scan at baseline for potential abnormal finding(s) in the knee (i.e., any ‘potential bone safety finding’ or ‘other finding’), which were required to be reviewed by the adjudication committee. The proportion of participants with all-causality treatment-emergent adverse events (TEAEs) was numerically higher in the abrocitinib 200 mg group (42.1%) compared to the 100 mg group (31.1%). Common TEAEs included nausea, pyrexia, nasopharyngitis, and atopic dermatitis. No severe AEs or serious AEs (SAE) were reported. Knee MRI scans showed no potential bone safety findings or other findings in any participants at the end of the treatment period identified on independent adjudication.

Conclusion

The overall safety profile of abrocitinib in adolescents was consistent with the safety profile observed in the entire study population. No unexpected major safety findings were reported, and no bone safety findings were observed in knee MRI scans of 35 abrocitinib-treated adolescents enrolled in this substudy indicating no evidence of clinically relevant bone safety concerns in adolescents treated with abrocitinib. Abrocitinib demonstrated a favorable safety profile, making it a promising treatment option for adolescents with moderate-to-severe AD in India.

Safety Results Representation: The safety results are summarized in the following table:

Safety Endpoint	Abrocitinib 100 mg n (%)	Abrocitinib 200 mg n (%)
Participants evaluable for adverse events	**16**	**19**
Number of adverse events	13	14
All-causality TEAEs (%)	5 (31.1)	8 (42.1)
Temporary discontinuations due to AEs (%)	2 (12.5)	4 (21.1)
Severe AEs (%)	0.0	0.0
SAEs (%)	0.0	0.0
Laboratory abnormalities (%)	10 (62.5)	16 (84.2)
Total individual participants with MRI scans with Bone Safety Finding requiring adjudication, n (%)	0	0



Abstract N°: 7510

Real-world use of tralokinumab: monotherapy versus overlapping treatment with conventional immunosuppressants in atopic dermatitis

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Introduction & Objectives:

Biologic therapies have transformed the therapeutic arsenal for atopic dermatitis (AD), offering superior efficacy and safety compared to conventional immunosuppressants. However, in current practice, the use of a biologic is generally preceded by a course of immunosuppressive treatment. Tralokinumab, an anti–interleukin-13 monoclonal antibody, has been established as an effective and safe long-term treatment option for patients with moderate-to-severe AD. Nevertheless, transitioning from conventional immunosuppressants to tralokinumab poses a clinical challenge, as limited evidence exists to guide optimal management during this period. In clinical practice, an initial overlap between both treatments may be necessary to reduce the risk of flares. The objective of this study was to compare the effectiveness of tralokinumab monotherapy (TM) versus an initial overlapping strategy with ciclosporin (OS).

Materials & Methods:

We conducted a prospective observational study including patients with moderate-to-severe AD treated with tralokinumab for at least 16 weeks. TM was defined as the use of tralokinumab in combination with emollients, topical corticosteroids, or topical calcineurin inhibitors. OS was defined as the concomitant use of tralokinumab with a conventional immunosuppressant for up to 12 weeks. Sociodemographic and clinical data, including AD severity scores, were collected at baseline and weeks 0, 16, 24, and 52.

Results:

A total of 27 patients were included, with a mean age of 40.3 (±15.3) years; 59.3% (16/27) were female. TM was performed in 85.2% (23/27) of patients, while OS was performed in 14.8% (4/27). Both groups showed improvement in AD severity at week 52. The OS group showed a mean reduction of 15 points in EASI, 2 points in IGA, and 3.5 points in pruritus NRS, whereas the TM group showed a mean reduction of 18.66 points in EASI, 2.21 points in IGA, and 4.49 points in pruritus NRS. No statistically significant differences were observed between the groups in EASI ($p = 0.52$), IGA ($p = 0.46$), or pruritus NRS ($p = 0.49$) reduction.

Conclusion:

Both therapeutic strategies were equally effective after 52 weeks of follow-up in patients with AD. Transitioning from conventional systemic therapy to biologic treatment with tralokinumab can be achieved either through monotherapy or an overlapping approach.



Abstract N°: 7514

Nemolizumab treatment did not impair immune response to vaccination in patients with atopic dermatitis – Results from a randomised, double-blind, placebo-controlled study.

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Introduction & Objectives: Nemolizumab, an interleukin-31 receptor alpha antagonist, improves key signs and symptoms of moderate-to-severe atopic dermatitis (AD). Understanding immunogenicity of vaccines in nemolizumab-treated patients is crucial to ensure effective immunisation and to optimise long-term AD treatment. This phase 2, randomised, double-blind, placebo-controlled study assessed the effect of nemolizumab on humoral immune responses to tetanus and meningococcal vaccinations in patients with moderate-to-severe AD.

Materials & Methods: Patients (≥12 to 54 years) with moderate-to-severe AD and inadequate response to topical AD medications were randomised 1:1 to receive either 30 mg nemolizumab (with a 60 mg loading dose at baseline) or placebo every 4 weeks until week (W) 16. At W12, patients also received single doses of tetanus toxoid, reduced diphtheria toxoid and acellular pertussis (Tdap) and quadrivalent meningococcal conjugate (MCV4) vaccines. Immune responses to Tdap and MCV4 were assessed via blood samples collected 4 weeks after vaccination, i.e. at W16. The primary endpoint was the proportion of patients with positive serum immunoglobulin G (IgG) response to tetanus toxoid (≥4-fold increase in anti-tetanus IgG concentrations from baseline in patients with pre-vaccination anti-tetanus IgG concentrations ≥0.1 IU/mL or ≥0.2 IU/mL anti-tetanus IgG concentrations in patients with pre-vaccination anti-tetanus IgG concentrations <0.1 IU/mL).

Results: A total of 242 patients (123 nemolizumab; 119 placebo) were randomised. The achievement of primary endpoint was similar between nemolizumab (67.5%) and placebo (65.4%) groups (difference [90% confidence interval {CI}]: 2.1 [-10.3, 14.5]). Using different criteria, the proportion of patients with a positive serum IgG response to tetanus toxoid (≥2-fold increase in anti-tetanus IgG concentrations from baseline in patients with pre-vaccination anti-tetanus IgG concentrations ≥0.1 IU/mL or ≥0.2 IU/mL anti-tetanus IgG concentrations in patients with pre-vaccination anti-tetanus IgG concentrations <0.1 IU/mL) at W16 was similar between nemolizumab (78.8%) and placebo (83.3%) groups (difference [90% CI]: -4.6 [-14.9, 5.7]). At W16, all patients had a serum anti-tetanus IgG concentration of ≥0.1 IU/mL. At W16, the proportion of patients with a serum anti-tetanus IgG concentration of ≥1.0 IU/mL was similar between nemolizumab (97.5%) and placebo (96.2%) groups (difference [90% CI]: 1.4 [-3.2; 5.9]). At W16, the proportion of patients with a positive serum bactericidal antibody response to meningococcal group C capsular (MenC) polysaccharide (≥4-fold increase in serum bactericidal assay [SBA] reciprocal titer from baseline [using non-imputed values]) was greater in the nemolizumab group (77.0%) than in the placebo group (63.6%) (difference [90% CI]: 13.3 [0.1, 26.4]); using imputed values, the proportion was similar between nemolizumab (63.9%) and placebo (57.6%) groups (difference [90% CI]: 6.2 [-8.2, 20.6]). At W16, the proportion of patients with a positive serum bactericidal antibody response (SBA reciprocal titer ≥8) to MenC polysaccharide was similar between nemolizumab (83.3%) and placebo (81.9%) groups (difference [90% CI]: 1.3 [-9.3, 11.9]). Dermatitis atopic and headache were most common adverse events.

Conclusion: Nemolizumab treatment did not affect immune responses induced by tetanus and meningococcal

vaccinations in patients with moderate-to-severe AD.



Abstract N°: 7523

Effectiveness of abrocitinib in patients with atopic dermatitis: results of a federated analysis of real-world evidence in the DREAM TO TREAT AD consortium

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Introduction & Objectives: Atopic dermatitis (AD) is a common inflammatory skin disease, with around 10% of patients requiring systemic therapy. Currently, there is a lack of real-world evidence on treatment outcomes using systemic medications. DREAM TO TREAT AD (D2T AD) is a pan-European register-based study aimed at evaluating treatment effectiveness of abrocitinib and conventional systemic therapies in routine clinical practice in Germany (GY), the United Kingdom (UK), Denmark (DK), the Netherlands-Belgium (NL/BE) and Ireland (IR).

Materials & Methods: Patients who received abrocitinib in four registers (ASTAR UK, TREATgermany, TREAT NL/BE, SCRATCH Denmark) were included. It is important to note that in GY, novel systemic medications, including abrocitinib, can be prescribed first-line in patients requiring systemic therapy, unlike DK, NL/BE, and the UK, where it is required to fail or have contraindications to at least one conventional systemic medication.

Data were pre-processed in each register into an analytical dataset that has a common data structure across all registers. Federated statistical analysis was conducted in the secure DataSHIELD environment using R.

The effectiveness of abrocitinib was described as the average percentage monthly reduction in Eczema Area and Severity Index (EASI) from drug initiation to week 16 of follow-up, as well as the percentage of patients reaching

EASI-50, EASI-75, and EASI-90 at that time point. EASI scores at target date (baseline and follow-up) were calculated as the average of the closest scores before and/or after baseline (within a window of -42 to +7 days) and follow-up (+- 42 days), weighted by the inverse of the numbers of days between the EASI measurement and the target date. Patient baseline characteristics were summarised. Heterogeneity tests between registers were conducted. Multivariable linear and logistic regression models were run to explain the impact of patient characteristic on EASI outcomes.

Results: Across the four registers (GY, UK, DK, NL/BE) 218 patients received abrocitinib, of which 44, 24, 12, and 20, respectively, had baseline and follow-up EASI available for the analysis. The average age of patients ranged from 30.1 in UK to 39.4 in DK, proportion of women ranged from 30% in NL/BE to 46% in UK. EASI scores at baseline varied between registers (although not statistically significantly due to sample size), ranging from 17.6 in DK and GY to 23.4 in the UK. Numbers and types of previous systemic treatments varied significantly, from an average of one previous systemic treatment in GY to an average of 3.5 in DK (Table 1).

At week 16, almost all measures of EASI changes varied significantly between registers, with GY showing the strongest and NL/BE showing the smallest improvements (Table 1). The regression models in Table 2 demonstrated that effectiveness increased with higher EASI at baseline, with age and in females, and decreased with higher number of previous systemic treatments.

Conclusion: Using a novel federated analysis approach, we could estimate the effectiveness of abrocitinib in reducing EASI in the real-world clinical practice in four European registers. The differences in effectiveness between countries could be linked to differences in healthcare settings and baseline patient characteristics. Further analyses will focus on comparing treatment effectiveness of novel and conventional systemic medications and incorporate more follow-up data.

Table 1. Baseline characteristics and EASI changes at 16 weeks in patients receiving abrocitinib, in DREAM TO TREAT AD*.

Variable	TREAT Germany (GY)	ASTAR UK (UK)	Scratch Denmark (DK)	TREAT-NL/BE (NL/BE)	P-value for hetero-geneity
Number of patients	44	24	12	20	
Age at treatment initiation	38.0	30.1	39.4	33.0	P=0.127
% of females	34	46	42	30	P=0.685
EASI at baseline	18.1	23.4	17.6	18.1	P=0.366
Patients received any systemic therapy in the past, %	55	96	100	95	P<0.001
Number of previous systemic treatments, mean	1.0	3.3	3.5	2.2	P<0.001
Patients received conventional systemic therapy in the past, %	41	83	92	90	P<0.001
Patients received biologic therapy in the past, %	30	92	50	45	P<0.001
Patients received JAKi therapy in the past, %	14	25	83	15	P<0.001
Mean EASI difference between baseline and week 16	-14.4	-12.5	-11.1	-5.7	P=0.121
Mean EASI improvement at week 16, %	71	53	56	12	P=0.034
% EASI improvement per month at week 16	24	15	17	4	P=0.002
Patients achieving EASI-50 at week 16, %	82	62	58	45	P=0.023
Patients achieving EASI-75 at week 16, %	68	50	58	30	P=0.035
Patients achieving EASI-90 at week 16, %	43	33	42	20	P=0.303

*ASTAR Ireland dataset have not been included into the analysis due to the insufficient number of patients.

Table 2. Regressions to explain the impact of baseline characteristics on EASI outcomes at week 16.

Outcome	For each previous treatment	EASI (10 units)	Age (10 years)	Female
Per month[1]:	-1.44 (P=0.002)	0.61 (P<0.001)	0.04 (P=0.808)	4.79 (P=0.008)
EASI-50[2]:	0.83 (P<0.001)	1.65 (P<0.001)	1.07 (P=0.047)	1.70 (P<0.001)
EASI-75[2]:	0.89 (P=0.057)	1.36 (P<0.001)	1.10 (P=0.007)	1.59 (P<0.001)
EASI-90[2]:	0.90 (P=0.061)	1.25 (P<0.001)	1.13 (P<0.001)	1.77 (P<0.001)

(1) Linear regression model to explain the percentage of EASI reduction per month, the coefficients are % reduction of EASI. (2) Logistic regression models for achieving the binary EASI outcomes (the coefficients are OR).



Abstract N°: 7554

Clinical efficacy of Ophiopogon japonicus oligofructans on children and adults with atopic dermatitis

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Introduction & Objectives:

Topical treatments to fight against atopic dermatitis (AD) include corticosteroids and calcineurin inhibitors, although they are often associated with adverse events such as skin atrophy, itching and burning sensations. Good alternatives able to prolong disease relief in between flare-ups are therefore needed. To overcome this issue, a natural active ingredient from *Ophiopogon japonicus*, was developed. Oligofructans (OFs) were extracted from this natural raw material and this study aimed to assess the clinical efficacy of OFs in decreasing the frequency and intensity of AD flare-ups in AD patients.

Materials & Methods:

For this purpose, a randomized, single-blind, placebo-controlled, multicenter clinical trial was conducted on a cohort of 90 children and 144 adults with mild-to-moderate AD, that applied tested products twice daily for 60 days.

Results:

The OFs from *Ophiopogon japonicus* were successful in significantly reducing the SCORAD, including erythema, pruritus and body surface area in both cohorts: 3.9 ± 1.3 for children and 6.6 ± 1.1 for adults, compared to baseline (children: 5.7 ± 5.1; adults: 13.7 ± 0.8). Regarding QoL indexes, OFs improved children's and parents's IDQOL and DFI, as well as adults DLQI, at both D30 and D60. Finally, OFs reduced the intensity and the frequency of AD flare-ups in children compared to placebo, as depicted by the favorable Investigator Global Assessment (IGA), whereas no difference could be detected between both treatments in adults.

Conclusion:

Altogether, these results prove the beneficial effects of OFs in the course of AD. The mechanism of action of this natural molecule was also demonstrated in a 3D *in vitro* skin model mimicking the molecular characteristics of this skin disease. Therefore, this natural active ingredient, available in preservative-free powder could be used in skin care products, as a complementary relay for corticosteroid treatment.



Abstract N°: 7561

Consensus on core domains for hand eczema trials: Signs, symptoms, control and quality of life

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Introduction & Objectives:

Hand eczema (HE) is a common and complex skin disease. A uniform set of core outcomes and related measures for use in clinical trials is lacking, making it difficult to compare results across HE studies. We aimed to reach consensus on a set of core domains and subdomains that should be measured in future therapeutic HE trials.

Materials & Methods:

In 2024, we conducted a two-round online Delphi (eDelphi) survey among international HE experts, including physicians, patients and their relatives, researchers and industry representatives. A domain/subdomain was included in the core set when ≥80% of participants rated is as 'critically important'; 50% agreement or less resulted in its exclusion. Results from 50% to 80% were deemed controversial and subject for further discussion. During a hybrid consensus meeting, the stakeholders reviewed, completed and, if necessary, revised the preliminary eDelphi consensus.

Results:

In the first and second round of the eDelphi, 208 and 134 persons, respectively, participated. Forty participants from 18 countries attended the consensus meeting. Consensus was reached to include the core domains 'signs of HE' (with five core subdomains), 'symptoms of HE' (two subdomains), 'HE-related quality of life' (four subdomains) and 'HE control over time' (four subdomains). The subdomains 'desquamation/scaling' and 'emotional impact/mental health' remained controversial. Consensus was reached that the domains 'skin barrier function' and 'patient-reported treatment experience' and 28 subdomains should not be part of the core outcome set.

Conclusion:

To produce comparable and meaningful results, future trials evaluating the effectiveness of HE treatments should measure signs and symptoms of HE, HE-related quality of life and HE control over time as core outcome domains. The next step of the HE core outcome set initiative (HECOS) is to identify appropriate measurement instruments.



Abstract N°: 7621

Exploring the language gap in clinical terminology and patient-reported experience in Atopic Dermatitis

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Introduction & Objectives:

Clinical severity classifications for Atopic Dermatitis (AD) typically rely on standardized terminology (mild, moderate, severe) and scoring systems used by healthcare professionals (HCPs)1. However, clinical severity classifications for AD often fail to capture the nuanced way patients experience and describe their condition, resulting in a potential disconnect in patient-HCP communication which could affect treatment satisfaction and adherence2. This study aimed to analyze the natural language patients use when describing AD severity compared to clinical classifications, in order to identify patterns in patient expression and opportunities for improving patient-centered communication.

Materials & Methods:

A global social intelligence analysis of AD-related conversations was conducted between December 2023-December 2024. Using Ipsos' Synthesio platform, over 12,300 social media posts containing "atopic dermatitis" within 5 words of a pronoun were extracted from multiple sources including Reddit, Instagram, X, Facebook, YouTube, TikTok, blogs and forums. Although the scope was global, we focused on English-language posts. Text analytics and qualitative analysis were employed to identify language patterns related to severity descriptions.

Results:

Analysis revealed that the posts rarely use clinical terminology like 'mild,' 'moderate,' or 'severe' when describing AD severity. Instead, they express severity through descriptive and emotive language that combines both physical symptoms and emotional impact. Patients with mild AD typically described their condition as 'manageable' or 'inconvenience', using terms like 'patches of skin' and noting that symptoms are 'persistent' but 'controllable' with proper care. Those with moderate AD used escalating language, describing their condition as 'disruptive' that causes emotional distress. In severe cases, the language became more intense, with terms like 'excruciating', 'burning,' 'unbearable,' and 'throbbing' being used when describing their condition. Expressions of frustration were also noted with regards to the disconnect in terminology used between patients and HCPs.

Conclusion:

This study highlights a potential communication gap between clinical severity classifications and patients' lived experiences with AD. By incorporating patients' natural language into clinical discussions, it could aid HCPs in improving diagnostic accuracy, treatment adherence and patient satisfaction. Developing assessment tools that bridge this terminology divide could transform AD management by enabling more meaningful patient-HCP interactions and more accurate evaluations of treatment efficacy from the patient perspective. Further research is warranted.

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Abstract N°: 7671

Nemolizumab long-term safety and efficacy up to 104 weeks in ARCADIA open-label extension study in adolescents and adults with moderate-to-severe atopic dermatitis.

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Introduction & Objectives: Long-term clinical data on atopic dermatitis (AD) treatments are crucial to confirm long-term safety and efficacy of treatment. Nemolizumab treatment has already demonstrated continuous improvements in itch, skin lesions and sleep and good safety profile until week (W)56 in patients with moderate-to-severe AD. The ARCADIA long-term extension study (NCT03989206; 200-week duration) aimed to evaluate the safety and efficacy of nemolizumab in adolescents and adults with moderate-to-severe AD.

Materials & Methods: This prospective, multicentre, open-label, long-term study enrolled patients who were either nemolizumab-previously experienced [NPE] or nemolizumab-naïve [NN] from ARCADIA 1&2 phase 3 and other nemolizumab studies. Patients received nemolizumab 30mg every 4 weeks (Q4W) alongside background topical corticosteroids (low/medium potency) with or without topical calcineurin inhibitors. The primary objective of the study was to evaluate the long-term safety of nemolizumab in adults and adolescents with moderate-to-severe AD. Efficacy endpoints included Investigator's Global assessment (IGA) score of 0/1 (clear/almost clear), ≥75%/≥90% improvement from lead-in baseline in the Eczema Area and Severity Index (EASI-75/EASI-90), changes from lead-in baseline in visual analogue scale [VAS] Pruritus and Sleep loss of SCORing Atopic Dermatitis (SCORAD) score and Dermatology Life Quality Index (DLQI). Efficacy results presented here include multiple imputation (MI) analysis for missing data (missing at random [MAR]) at W56 visit and observed data (OC) analysis for patients at W104 visit.

Results: At data cut-off, 1062/1901 (56%) patients completed W104. The study discontinuation (due to adverse events) rate was 5% in both groups (NPE: 63/1164 and NN: 37/737). At W56, the proportion of NPE and NN patients achieving efficacy outcomes (MI analysis for MAR data) was 50% and 48% for IGA 0/1, 65% and 64% for EASI-75, 46% and 44% for EASI-90, 66% and 61% for a ≥4-point improvement from lead-in baseline in SCORAD VAS Pruritus and 50% and 45% for SCORAD VAS Pruritus<2, respectively. At W104, the proportion of NPE and NN

patients achieving efficacy outcomes (OC analysis) was 63% and 58% for IGA 0/1, 88% and 85% for EASI-75, 68% and 64% for EASI-90, 87% and 82% for a ≥4-point improvement from lead-in baseline in SCORAD VAS Pruritus and 70% and 67% for SCORAD VAS Pruritus<2, respectively. Improvements in sleep parameters mirrored those observed in itch parameters. DLQI improved over time. The most frequently reported adverse events were COVID-19, nasopharyngitis and dermatitis atopic. Exposure-adjusted incidence rates for any treatment emergent adverse events were 112.8 cases/100 person year and 117.1 cases/100 person year in NPE and NN patients, respectively. Safety results corroborated those previously reported.

Conclusion: Nemolizumab was effective and well tolerated up to W104 of treatment with low study discontinuation rate due to adverse events. Sustained and continuous improvements with long-term nemolizumab treatment were observed in skin lesions, itch relief, sleep disturbance and quality of life.



Abstract N°: 7788

Acceptability and feasibility of patient-reported outcome measures for atopic eczema

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Introduction & Objectives:

In atopic eczema (AE) research, patient reported outcome measures (PROMs) are used to capture data on symptoms, quality of life and long-term disease control. To help homogenization of trial data, the Harmonising Outcome Measures for Eczema (HOME) initiative established a core outcome set (COS) which contains four PROMs. Previous studies have identified patient-level barriers to completing PROMs, that may lead to inadequate utilization and hindered implementation of a COS. For the PROMs in the HOME COS for AE, such an exploration has not been conducted.

This study investigates the feasibility and acceptability of the PROMs in the HOME COS for AE and identifies potential barriers and facilitators to further implementation, by exploring patient's views and experiences with completing these PROMs.

Materials & Methods:

A qualitative interview study was conducted, embedded in a prospective cohort study and a randomized controlled trial that utilize the HOME COS for AE. During study participation, patients completed the PROMs from the HOME COS. At baseline and at 6 months, patients were interviewed about their views on the PROMs. Audio captures were transcribed verbatim. A thematic analysis was conducted by two independent researchers.

Results:

In total, 13 patients were included and 25 interviews were conducted. Data saturation was reached. Thematic analysis yielded five themes regarding feasibility and four themes regarding acceptability. In feasibility, patients perceived the length and frequency of the PROMs as adequate. Digital surveys were preferred over paper, and in-hospital administration was preferred over completing the PROMs at home. In acceptability, patients report neutral affect during survey completion. Disease severity influenced the ease of completion and the perceived value of the PROMs. The act of answering questions about AE increased disease awareness among patients. Participants report a presence of (partly) overlapping questions in the PROMs, but do not regard this overlap as bothersome. Familiarization with the questions after 6 months did not affect perceived feasibility or acceptability.

Conclusion:

From the perspective of AE patients that participate in clinical research, the PROMs from the HOME COS are feasible and acceptable. No major barriers to (continued) implementation of the HOME COS were reported.



Abstract N°: 7837

Medication supply for atopic dermatitis 2010 - 2024: Analysis of the national AtopicHealth 1 to 3 healthcare studies in Germany

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Introduction & Objectives:

The series of studies AtopicHealth1 (2010), AtopicHealth2 (2017-19) and AtopicHealth3 (2024/25) analyses the healthcare of patients with atopic dermatitis (AD). There were no improvements between 2010 and 2017-19. As therapeutic innovations are now available, the healthcare situation will be analysed again as part of the AtopicHealth3 study.

Materials & Methods:

Like AtopicHealth 1 and 2, the latest Germany-wide multicentre cross-sectional study 'AtopicHealth3' also records clinical data, the severity of AD (SCORAD), the impairment of quality of life (DLQI, EQ VAS), current therapies as well as previous therapies and the treatment benefit assessed by the patients. This analysis refers to an interim status of the AtopicHealth3 study. Data collection is ongoing and enrolment of 1,000 patients with AD in AtopicHealth 3 is planned.

Results:

Since May 2024, 107 dermatological practices and outpatient clinics throughout Germany have been recruited to participate in AtopicHealth 3 (2024/25). By mid-March 2025, 300 fully completed, valid questionnaire sets from 35 dermatological practices were returned to the study centre. Of the 300 patients, 58% described themselves as female, 41.7% as male and 0.3% as diverse. The mean age was 43 years. As in 2010 and 2017-19, glucocorticosteroids (TCS) were the most frequently used topical therapy on the day of the survey (64.0% of patients, 45.2% in 2010), followed by calcineurin inhibitors (TCI) (31.0%, 17% in 2010). At the time of the survey, 52.3% of the patients were being treated with systemic therapies (2017-19: 35.3% ever used according to doctor). On the day the questionnaire was completed, 38.0% had received biologics and 13.1% non-biological immunosuppressants (excluding steroids). The proportion of systemic glucocorticosteroids (sGCS) as current therapy was 9.0% vs. 3.6% in 2017-19 vs. 3.5% in 2010. Among the systemic therapies that patients reported having received at some point in the past 5 years, biological treatments (52.8% vs. 1.6% in 2017-19 vs. 0% in 2010) and sGCS (33.3% vs. 35.3% in 2017-19 vs. 28.0% in 2010) were the most common. Patients currently receiving biological treatment showed lower burdens according to their DLQI, SCORAD, EQ VAS scores and better subjective skin health than patients not receiving a biological treatment. In addition, the patient-defined treatment benefit was higher in those who received a biologic.

Conclusion:

Subject to the still small sample, the quality of care with systemic therapeutics for AD in Germany has improved significantly compared to 2017-19 and 2010 and the biologics and JAK inhibitors now approved for long-term therapy are increasingly being used. The patient-reported outcomes show that patients with AD benefit from these

medications in many ways.

The study received financial support from Sanofi.



Abstract N°: 7885

Treatment with dupilumab improves skin barrier biomarkers in patients with atopic dermatitis

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Introduction & Objectives:

The stratum corneum, composed of corneocytes and lipids like cholesterol sulfate and glucosylcholesterol, plays a crucial role in skin barrier function and the pathophysiology of atopic dermatitis (AD). Natural Moisturizing Factors (NMF), derived from filaggrin breakdown, are essential for moisture retention and barrier integrity. Although previous studies have explored NMF and lipid alterations in AD, none have examined how dupilumab treatment alters these skin barrier biomarkers over time. The objective was to investigate the impact of dupilumab on disease severity and skin barrier biomarkers (NMF, cholesterol sulfate, and glucosylcholesterol), and the role of filaggrin mutations.

Materials & Methods:

Sixty patients with moderate-to-severe AD initiating dupilumab were enrolled in the TREatment of ATopic eczema registry in the Netherlands and Belgium (TREAT NL/BE registry) and included in this substudy. Clinical outcomes and tape strips from lesional and non-lesional skin were collected at baseline, and after 1, 3, 6, and 12 months of treatment, with continued clinical follow-up thereafter. NMF and lipid levels were measured in stratum corneum tape strips, and filaggrin mutations were assessed using blood samples. Long-term clinical response was categorized using predefined EASI-based criteria.

Results:

Dupilumab improved Eczema Area and Severity Index (EASI) and Peak Pruritus Numerical Rating Scale (NRS) scores at all follow-up points ($P < .001$). Lesional NMF levels increased significantly ($P < .001$ at months 1, 3, 6, and 12), while non-lesional levels remained stable. NMF levels were initially lower in lesional skin compared to non-lesional skin ($P < .001$), but increased toward non-lesional levels by month 12 ($P = .116$). FLG mutation carriers had significantly lower NMF levels in both lesional and non-lesional skin. The strongest NMF reductions were seen in patients with homozygous or compound heterozygous mutations ($P < .001$ for both lesional and non-lesional),

followed by heterozygous carriers (P = .004 for lesional and P = .002 for non-lesional), but FLG status did not affect clinical response. Lesional cholesterol sulfate and glucosylcholesterol levels decreased significantly over time (P < .001 at month 12 vs baseline), whereas non-lesional lipid levels remained unchanged. Although lesional lipid levels remained significantly higher than non-lesional levels at all timepoints (P < .05), the absolute difference narrowed over time, suggesting partial normalization.

Conclusion:

Dupilumab improves both clinical outcomes and markers of skin barrier function in AD. NMF levels increased and elevated lipid levels decreased in lesional skin, shifting toward the levels observed in non-lesional skin over time.



Abstract N°: 7888

Serine determines tissue targeted efficacy of PKM2 modulators in atopic dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) is a complex, chronic inflammatory, non-contagious skin disease with high unmet need and no curative treatment options. Elevation of serine synthesis enzymes and transporters have previously been described in psoriatic tissues, presenting a potential metabolic vulnerability for therapeutic intervention (Cappello et al., 2022). This study demonstrates that serine is also limiting in AD skin, accompanied by elevation of serine synthesis enzymes and transporters. Furthermore, Th2 cells and IgE-expressing B cells play a crucial role in the pathogenesis of AD and these cell types require serine for proliferation and inflammatory responses (D'Avola et al., 2022; Ma et al., 2017). This study describes a novel therapeutic approach to exploit serine limitation in inflammatory tissues by small molecule modulation of a key glycolytic enzyme, pyruvate kinase M2 (PKM2), resulting in anti-inflammatory activity in human Th2 cells and IgE-expressing B cells.

Materials & Methods:

Gene expression and metabolite profiles were studied in human skin from AD patients and human cells using RNA sequencing and metabolomics, respectively. Human Th2 and B cell assays were performed in RPMI media containing 100 µM serine or 10 µM serine. Proliferation and expression of cell surface markers, CD20, CD27 and CD38 were assessed using flow cytometry. Release of IL-13, IL-31, IgG or IgE were measured using Homogeneous Time Resolved Fluorescence (HTRF) or Meso Scale Diagnostics (MSD) assays. The *in vivo* pharmacology of PKM2 modulators was determined in the 2,4 dinitrofluorobenzene (DNFB) contact dermatitis model.

Results:

Differentially regulated metabolites and metabolic genes were characterised in AD skin, healthy skin, DNFB skin and human CD4 T cells. Serine was decreased in AD skin compared to healthy, with a corresponding increase in serine synthesis enzymes and transporters. When Th2 cells were cultured in serine limited conditions, a PKM2 modulator inhibited Th2 cell proliferation and release of IL-13 and IL-31. Similarly, when B cells were cultured in serine limited conditions, PKM2 modulation inhibited release of IgE or IgG. These anti-inflammatory effects of PKM2 modulation were caused by channeling of the glycolytic intermediate, 3-phosphoglycerate towards pyruvate production, reducing carbon flux through serine biosynthesis.

Conclusion:

Serine limitation in AD is characterised by by high expression of serine biosynthesis genes and transporters. This presents a potential metabolic vulnerability for therapeutic intervention with a novel PKM2 modulator that inhibits Th2 and IgE-releasing B cells in serine limited conditions. The tissue-targeted efficacy of PKM2 modulation at AD inflammatory sites enables a differentiated safety profile. This oral PKM2 modulator has recently entered clinical trials in healthy volunteers and patients with moderate to severe AD. It could address the major unmet needs of AD as a safe, convenient and effective therapy where there are limited treatment options under the current

standard of care.

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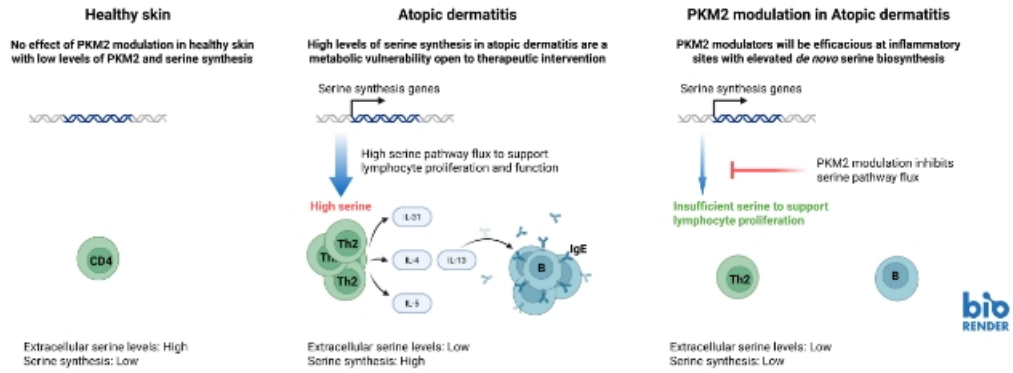


Figure - Serine determines tissue targeted efficacy of PKM2 modulators in atopic dermatitis



Abstract N°: 7901

Atopic Dermatitis Following Blaschko's Lines: When A Chronic Inflammatory Disease In A Mosaic Pattern Is A Diagnostic Challenge

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Introduction & Objectives:

Atopic dermatitis (AD), among the most prevalent chronic inflammatory skin disorders, typically presents with symmetrical, flexural involvement. The Blaschkolinear pattern - reflecting embryonic pathways of clonal skin cell expansion - is a well-established hallmark of genetic mosaicism, particularly in monogenic dermatoses. In contrast, this distinctive segmental presentation remains exceptionally rare in polygenic conditions like AD, with only isolated cases reported to date.

We present a case of 41-year-old-man, presenting with atopic dermatitis along the lines of Blaschko. The aim of our case report is to improve recognition of Blaschkolinear presentations in clinical practice to ensure a timely diagnosis and an effective treatment to these typically severe treatment-resistant variants.

Materials & Methods:

We report a case of a 41-year-old man, who presented to our dermatology department, with erythematous, pruritic and lichenified plaques. His medical history includes allergic rhinoconjonctivis, chronic cough, and bilateral incomplete hearing loss since he was 6 years old.

Three months prior to his admission, he presented erythematous, papulo-vesicular, and pruriginous lesions on his forearms and abdomen, with progressive extension to his trunk and legs. He received numerous local treatments, including antiobiotics, antihistamines, and topical emollients, with no improvement.

Dermatologic examination revealed erythematous lichenified plaques, with excoriated papules along Blaschko's lines on the arms, buttocks, multiples excoriated papules on the abdomen, with palmar hyperkeratosis.

A skin biopsy of the lesions showed hyperkeratosis and spongiosis, compatible with an atopic dermatitis.

Results:

The Blaschkoid distribution of skin lesions is common in monogenic disorders but exceptional in polygenic diseases like atopic dermatitis. The most plausible explanation is loss of heterozygosity (LOH) along Blaschko lines —an early postzygotic event causing hemizygosity or homozygosity of disease-predisposing alleles. This results in pronounced linear lesions superimposed on milder generalized disease.

The presence of lichenified plaques with excoriated papules along Blaschko lines in our patient, with a history of atopic dermatitis, made us consider a patterned distribution of atopic dermatitis. This superimposed atopic dermatitis is exceptional, with only isolated reports to date. This could be due to misdiagnosis, as the differentials for acquired linear dermatoses may be considered, such as lichen striatus and ILVEN (inflammatory linear verrucous epidermal nevus). Moreover, when systemic atopy is absent, the diagnosis remains uncertain, and the term Blaschkitis or acquired Blaschko dermatitis is chosen.

Conclusion:

These cases of segmental severe patterns of polygenic diseases provide unique models to investigate mosaicism and LOH in dermatology. The cutaneous manifestations reflect early postzygotic mutations, offering insights into disease mechanisms. A deeper understanding could improve diagnostic accuracy in these atypical presentations that are often treatment-resistant.

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Abstract N°: 7922

Real-life long-term experience on intra-class JAK1 selective inhibitors switch for atopic dermatitis

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease for which Janus kinase (JAK) inhibitors (JAKi) have been approved as an effective treatment option. Patients receiving JAKi often show improvements in clinical scores such as the Investigator Global Assessment (IGA), Dermatology Life Quality Index (DLQI), and Eczema Area and Severity Index (EASI). Efficacy comparisons among selective JAK1 inhibitors rely on network meta-analyses, as head-to-head trials are still lacking. However, JAKi can induce adverse events that lead patients to discontinue treatment, and about 30% fail to achieve at least 75% reduction in EASI at week 16, prompting a change in therapy. While intraclass switching among JAKi is not typically considered a first-line strategy after discontinuation of one drug, we report six cases demonstrating promising outcomes, suggesting that switching between JAK1 inhibitors may be a viable option for non-responders or those experiencing adverse events.

Materials & Methods:

We selected patients diagnosed with AD from a university hospital eczema expert center who underwent a therapeutic switch between two JAK1 inhibitors (abrocitinib and upadacitinib) as a treatment strategy after discontinuation either for adverse events or lack of efficacy of the first drug.

Results:

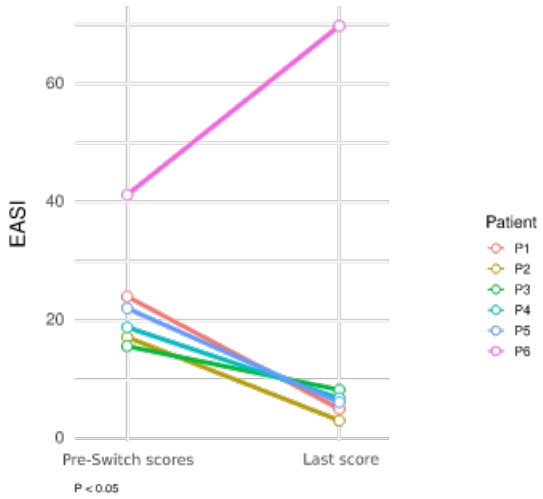
All six patients (100%) had previously received at least one systemic treatment for AD before initiating JAKi therapy. The follow-up period ranged from 14 to 74 months. The cohort included two males (33%) and four females (66%), with a mean age of 37 years (range: 29–53). Most patients (83%) had been treated with dupilumab (monoclonal antibody anti-IL4R) prior to starting JAKi therapy. Upadacitinib was the first JAKi used in 66% of cases, followed by abrocitinib after switching. EASI scores were assessed at the time of switching and after initiation of the second JAKi, showing a general trend toward improvement (Figure 1), although changes were not statistically significant.

Conclusion:

These findings highlight the variability in clinical response among JAK1 inhibitors used as initial treatment options. JAKi selectivity across isoforms is influenced by factors such as: dose, cell type, tissue distribution, and patient genetics. Real-life data may diverge from clinical trial in terms of both tolerability and efficacy. Our long-term follow-up (up to 74 months) indicates that intraclass switching can be beneficial, although clinical responses often stabilize after about four weeks and may even decline over time. Further studies are needed to better understand the long-term efficacy and safety of JAKi therapy, as well as the potential role of intraclass switching.

FIGURE 1:

Figure Legend: EASI score of all 6 patients before and after switching JAKi


EASI
60
40
20
0
Pre-Switch scores
Last score
P < 0.05
Patient
P1
P2
P3
P4
P5
P6



Abstract N°: 7943

Investigating the JAK/STAT pathway in pharmacological activities of Broussonetia papyrifera extract using 2D and 3D in vitro models

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory dermatosis characterized by skin manifestations such as intense itching and inflammation, leading to a decreased quality of life. The disease is marked by a compromised skin barrier, an imbalance in skin microbiota, and a type 2 inflammatory response. This study examined the anti-inflammatory effects of *Broussonetia papyrifera* (B.p.) plant extract in several in vitro models involving the JAK/STAT pathway.

Materials & Methods:

The anti-inflammatory properties of B.p. extract, particularly the involvement of the JAK/STAT pathway, were evaluated using 2D and 3D in vitro models. First, STAT6 and STAT3 phosphorylation assays were performed on Th2- and IL6-stimulated normal human epidermal keratinocyte (NHEK) models, respectively. Furthermore, to demonstrate the involvement of cytokines associated with atopic dermatitis, we used a TSLP-stimulated human mast cell model to assess the inhibition of Th2 cytokine release. To highlight the beneficial effects of B.p. extract on barrier function restoration, we used a reconstructed human epidermis (RHE) stimulated by a cytokine cocktail mimicking the atopic environment. Finally, we also used a 3D model to evaluate an emollient containing our active ingredient as well as a medical benchmark on the modulation of STAT pathway phosphorylation and the modulation of biomarkers associated with atopic dermatitis.

Results:

Phosphorylation studies showed that the B.p. extract was able to modulate the phosphorylation of STAT6 and STAT3 after stimulation of NHEK by Th2 and IL-6 cytokines respectively. Correlated with its JAK/STAT pathway inhibitory activity, the B.p. extract inhibited IL-5 and IL-13 cytokines released in a TSLP stimulated human mast cell model. In a Th2-stimulated RHE model, B.p. extract prevented the cytokine induced atopic dermatitis phenotype (restoration of layer thickness and induction of Filaggrin and Caspase- 14 proteins expression in IHC). Once formulated in an emollient dedicated to atopic pathophysiology and used topically, the resulting activity of B. p. extract and associated ingredients showed inhibition of STAT3 phosphorylation in a Th2-stimulated RHE model. Additionally in this same model, this emollient also showed a positive modulation of defensin and periostin expression after quantification of IHC staining.

Conclusion:

This comprehensive investigation demonstrated that Broussonetia papyrifera extract exert

potent anti-inflammatory activity in targeting the Th2 axis implicated in AD pathophysiology. Particularly, its JAK/STAT pathway inhibitory activity was highlight on 2D but also 3D in vitro models. Overall, these results suggest that the pharmacological activities of Broussonetia papyrifera extract enhance the soothing and barrier-

enhancing capabilities of the emollient formula and provide therapeutic benefit in alleviating the burden of AD.



Abstract N°: 7954

Targeting SaeRS to disarm S. aureus: An Innovative Emollient with Aquaphilus dolomiae extract-G1 and dextran sodium sulfate validated in a Reconstructed Human Epidermis Model

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Introduction & Objectives:

Staphylococcus aureus, upon colonizing the skin, transitions from a commensal organism to a pathogen, producing virulence factors that exacerbate atopic dermatitis. In this bacterium, virulence is tightly controlled by a network of two-component system (TCS) signal transduction pathways, which allow the bacteria to activate virulence programs in response to host defense systems. Targeting the TCSs of *S. aureus* offers an innovative approach for the discovery of antivirulence treatments. A recent *in-vitro* study has shown that the combination of *Aquaphilus dolomiae* extract-G1 (ADE-G1) and dextran sodium sulfate (DSS)** can inhibit *S. aureus* virulence by targeting SaeRS system, one of the key virulence regulators in *S. aureus*. This strategy could be a promising way to counteract *S. aureus* proliferation in re-empowering the host's natural immune defenses, while preserving the commensal community and limiting the risk of raising antimicrobial resistance. The aim of the study was to validate the anti-SaeRS effect to a more physiologically relevant model.

Materials & Methods:

An experimental model based on Reconstituted Human Epidermis (RHE) co-colonized with *Staphylococcal* strains* was developed. Digital PCR (dPCR) analysis was then performed to investigate the anti-*SaeRS* effects of topical formulas and actives.

Results:

dPCR analysis revealed that the combination of DSS and ADE-G1 significantly repressed *saeR*, a key regulatory system for virulence as observed in the previous study. Moreover, this effect was higher when active ingredients were in formulation underscoring the potential of the emollient as an effective strategy to target *S. aureus* pathogenicity, without impacting its viability.

Conclusion:

The novel emollient containing DSS and ADE-G1 effectively inhibits *SaeR*, one of the key genes of the SaeRS virulence regulator in *S. aureus*. These new insights, provided by a RHE model study, confirm the association DSS and ADE-G1 as a promising anti-virulent approach for reducing *S.aureus* pathogenicity and thus decreasing its competitivity inside the microbiota.

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Abstract N°: 7968

A first-in-patient 18-week study of galvokimig, a multispecific antibody–based therapeutic targeting interleukin (IL)-13, IL-17A, and IL-17F in participants with moderate-to-severe atopic dermatitis (AD)

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Introduction & Objectives:

The role of IL-13 and T-helper (Th)2 inflammation in the pathophysiology of AD is well established; however, other T-cell mediated pathways including Th17 may also play a role in disease pathogenesis.1 By targeting both Th2 and Th17 pathways, combined IL-13, IL-17A, and IL-17F inhibition with a single agent may improve treatment outcomes in people with AD. Galvokimig is a multispecific antibody–based therapeutic that inhibits IL-13, IL-17A, and IL-17F with an extended half-life through albumin binding. Here we report 12-week efficacy and 18-week safety results of galvokimig from the UP0089 study in participants with moderate-to-severe AD.

Materials & Methods:

UP0089 (NCT04643457) is a two-part, randomised, first-in-human, proof-of-concept, double-blind Phase 1/2a study of galvokimig monotherapy. Participants with AD were enrolled in Part B of UP0089 and randomised 2:1 to receive intravenous galvokimig or placebo. The primary endpoints were ≥75% improvement from baseline in Eczema Area and Severity Index (EASI75) response rate at week 12 and incidence of treatment-emergent adverse events (TEAEs) and serious TEAEs from baseline through week 18.

Results:

Participants (N=47) received galvokimig (n=33) or placebo (n=14). At week 12, a median of 64.9% participants achieved EASI75 with galvokimig (95% credible interval [CrI] 46.0–81.0) versus 12.3% with placebo (95% CrI 4.3–22.0) (posterior probability difference >0.999; all CrI reported using non-responder imputation method). A median of 46.6% participants achieved EASI90 with galvokimig (95% CrI 28.2–65.5) compared with 3.5% (95% CrI 1.3–7.9) receiving placebo at week 12 **(Figure)**. Differences in combined EASI percent change from baseline between galvokimig and placebo were observed as early as week 2 and were clinically meaningful at week 12 (least-square mean difference -55.1%, 95% confidence interval: -70.4% to -39.8%).

TEAEs were reported in 72.7% of participants who received galvokimig and 50.0% of those who received placebo.

The most common TEAEs with galvokimig were rhinitis, nasopharyngitis, headache, dizziness, and oropharyngeal pain (12.1% each). The most common TEAEs with placebo were rhinitis and dermatitis atopic (21.4% each). One serious TEAE of haemorrhagic diarrhoea was reported and considered related to galvokimig.

Conclusion:

This first-in-patient study met its primary endpoints, with galvokimig demonstrating a clinically meaningful and rapid improvement in efficacy measures, and safety outcomes associated with an acceptable benefit–risk profile. Phase 2/3 studies will further determine the benefit–risk profile of galvokimig administered subcutaneously in participants with AD.

References:

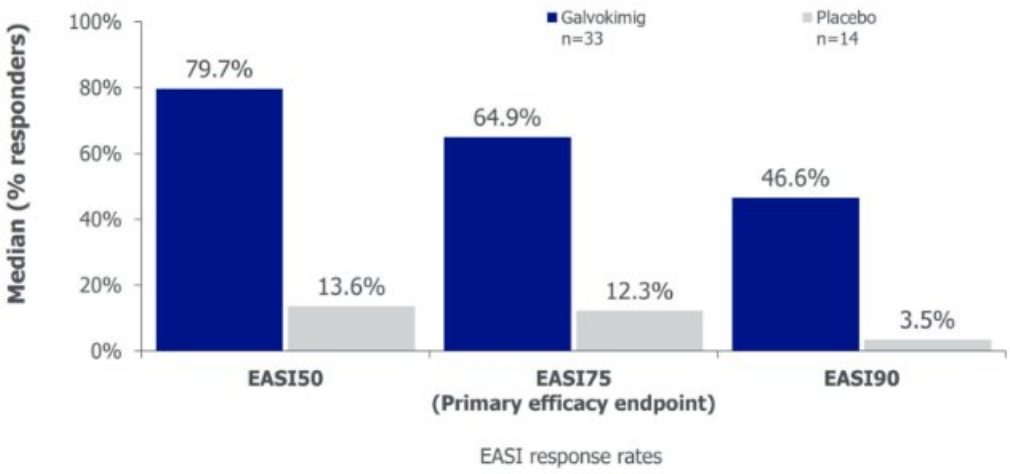
1. Bieber T *et al. J Eur Acad Dermatol Venereol.* 2022;36:1432–49

Acknowledgements:

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Figure:

Figure. EASI50, EASI75 (primary endpoint) and EASI90 at week 12 Bayesian analysis (FAS; NRI)



EASI50 and EASI90 are secondary endpoints. Posterior probability differences (>0%) were >0.999 between galvokimig and placebo with EASI50, EASI75, and EASI90.
EASI, Eczema Area and Severity Index; FAS, full analysis set; NRI, non-responder imputation.



Abstract N°: 7971

Restoring Microbial Balance: A Novel Emollient with Aquaphilus dolomiae extract-G1 and dextran sodium sulfate reduces S. aureus Virulence and Shifts the Skin Microbiota

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disorder exacerbated by *Staphylococcus aureus* colonization. As the dysbiosis state set up, the microbiome no longer benefits from the positive role of the commensal communities, such as *S. epidermidis.* Targeted antivirulence strategies offer a promising approach to managing skin dysbiosis by disarming *S. aureus*, without killing it. Among these, the SaeRS two-component system (TCS), a key regulator of *S. aureus* virulence, emerges as an ideal target for the development of novel strategies to treat skin conditions like atopic dermatitis, without disrupting the commensal skin microbiota. A recent study has shown that a new emollient containing an association of *Aquaphilus dolomiae* extract-G1 (ADE-G1) with dextran sodium sulfate (DSS)** significantly inhibits the SaeRS system. The aim of the work was to investigate the impact of the actives prior and after formulation on bacterial growth and on key virulence genes expression governed by SaeRS.

Materials & Methods:

An experimental model based on Reconstituted Human Epidermis (RHE) co-colonized with*S. epidermidis* and *S. aureus* was developed to assess the efficacy of topical formulas and their actives in promoting*S. epidermidis* adhesion while counteracting *S. aureus* proliferation by using viable cell counts on selective media. Simultaneously, digital PCR (dPCR) analysis was conducted to investigate the anti-virulent effects on *S. aureus* virulence gene expression.

Results:

The results showed that the adhesion of *S. epidermidis* was notably enhanced by the association of ADE-G1 and DSS alone or in formula, whereas *S. aureus* adhesion remained comparatively lower. This highlights the efficacy of their actives and this new emollient in promoting *S. epidermidis* colonization while limiting *S. aureus* proliferation.

Furthermore, dPCR analysis shows that the actives significantly repressed virulence genes linked to toxin synthesis (α-toxin), and to innate immune evasion factors (*sbi*, *scn*). Moreover, this effect was higher when active ingredients were in formulation reinforcing the potential of the formulas as an effective strategy to reduce *S. aureus* virulence, without impacting its viability.

Conclusion:

By reducing the expression of key virulence genes, including innate immune evasion factors, the new emollient, containing ADE-G1 and DSS, weakens *S. aureus* and increases its vulnerability to the skin's innate immune system. Additionally, this product helps restore a more balanced skin microbiota. These new findings, provided by a RHE model study, have confirmed the association ADE-G1 and DSS as a promising antivirulence strategy for improving skin immune function, reducing inflammation, and preventing *S. aureus* flare-ups commonly associated with

atopic dermatitis.

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Abstract N°: 7979

Digital Patient-Centered Endpoints of Nocturnal Scratch and Sleep in Patients With Moderate-To-Severe Atopic Dermatitis Treated with Upadacitinib: Results from the Flex Up Wearable Sensor Sub-Study

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Introduction & Objectives: Patients with atopic dermatitis (AD) often suffer from substantial sleep impairment, caused partly by the debilitating itch, with significant impact on quality of life (QoL) and psychosocial well-being. Objective measurements, such as digital sensor-based approaches, may overcome some of the limitations of patient-reported outcomes (PROs). In the phase 3b/4 Flex Up (NCT05507580) digital sub-study, patients wore an inertial sensor to objectively and remotely monitor nocturnal scratch and sleep. Here, we investigate the clinical validity of sensor-based scratch and sleep measurements using PROs and evaluate treatment efficacy across study visits.

Materials & Methods: In the Flex Up phase 3b/4, randomized, blinded, treat-to-target and dose-flexibility study of upadacitinib (UPA) 15 mg and 30 mg in adult patients with moderate-to-severe AD, patients at select sites participated in a digital sub-study. Eligible patients wore the ADvanced Acousto-Mechanic (ADAM) hand-worn inertial sensor on the back of their dominant hand while sleeping for 7 nights prior to the baseline visit, then for 7 nights following visits at Week 4, 12, and 24. The digital parameters collected included total scratch time and sleep efficiency (SE). These digital parameters were summarized per night, then aggregated by median over the 7-day visit period. To evaluate clinical validity of the measures, repeated measures correlation was used to assess the association of digital scratch and sleep measurements with patient-reported measures of itch (Worst Pruritus Numeric Rating Scale [WP-NRS]), itch while asleep (Atopic Dermatitis Symptom Scale [ADerm-SS] item 1), AD-related sleep disturbance (Atopic Dermatitis Impact Scale [ADerm-IS] Sleep domain score), and QoL (Dermatology Life Quality Index [DLQI]). Furthermore, scratch and sleep features were compared between pre- and post-treatment periods to evaluate treatment efficacy.

Results: Of the 55 total patients enrolled at the digital sub-study target sites,12 patients met the eligibility criteria, with a mean age of 35.3 years and median time since diagnosis of 26.9 years. Correlations indicate a moderate to strong association between total scratch time and itch (WP-NRS; r = 0.56), itch while asleep (ADerm-SS Item 1; r = 0.65), and QoL (DLQI; r = 0.76) PROs. Correlations also indicate moderate to strong associations between SE and AD-related sleep disturbance (ADerm-IS Sleep; r = -0.46) and QoL (DLQI; r = -0.70) PROs. There was improvement from baseline in total scratch time after 4 weeks of treatment with UPA (**Figure 1**), with 100% of the patients showing a decrease in total scratch time at Week 4. Similarly, there was improvement from baseline in SE after 4 weeks of treatment with UPA (**Figure 2**), with 87.5% of patients showing increased SE at Week 4.

Conclusion: Scratch and sleep measurements indicate positive correlations with patient-reported itch, sleep disturbance, and QoL, suggesting clinical validity of sensor-based measurement of nocturnal scratch and sleep. Furthermore, at-home scratch and sleep measurements show efficacy of UPA in AD for decreasing nocturnal scratch and improving SE. The efficacy detected by the sensor at week 4 in a relatively small number of patients

shows the potential utility of objectively measured scratch and sleep as clinical endpoints to inform treatment benefit for patients using novel and meaningful outcomes with minimal patient burden.

Figure 1. Decrease in Total Scratch Time Between Baseline and Week 4 With Upadacitinib Treatment

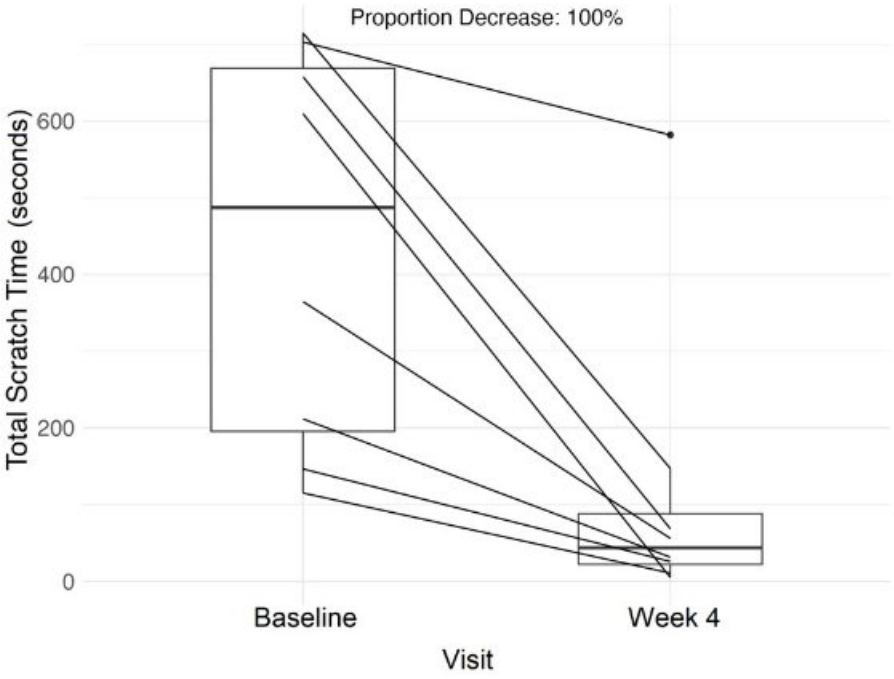
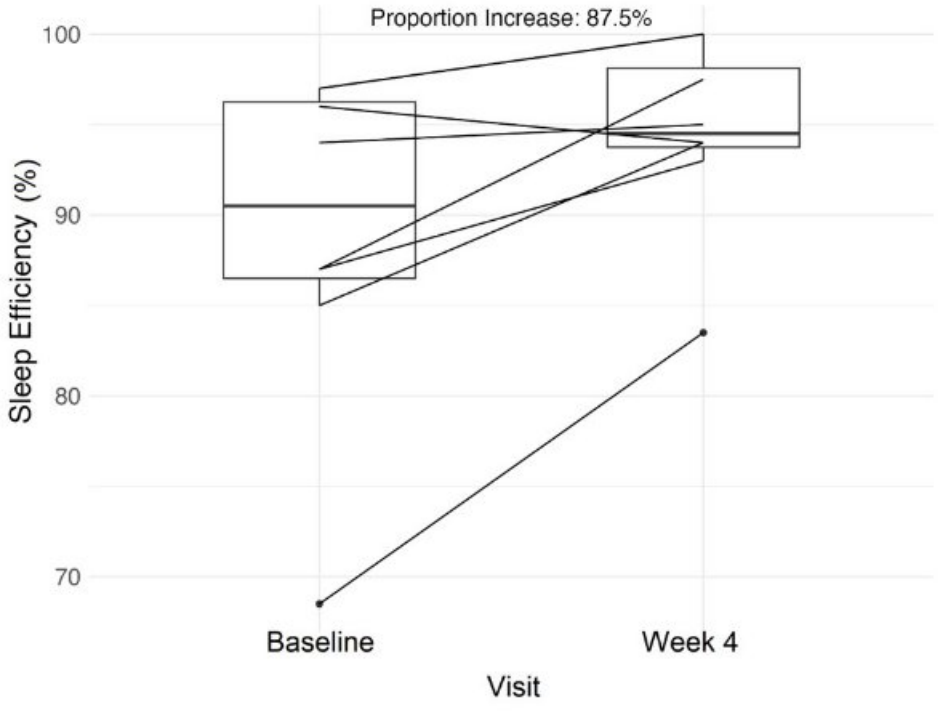


Figure 2. Increase in Sleep Efficiency Between Baseline and Week 4 With Upadacitinib Treatment





Abstract N°: 7991

Tolerance and efficacy of a new emollient "Plus" containing Aquaphilus Dolomiae and Dextran sodium sulfate extracts in improving long-term atopic skin condition

Marine Rodeghiero[1], Camille BOUDET[2], Gautier Doat[2], Marie-Dominique Thouvenin*[1]

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Introduction & Objectives: Emollients are considered as the first-line therapy of atopic dermatitis (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, children and adults. This study aimed to assess the tolerance and efficacy of a new emollient "Plus" containing *Aquaphilus Dolomiae* and *Dextran sodium sulfate* extracts, intended to improve long-term atopic skin condition.

Materials & Methods: 66 Subjects from 5 months to 56 years old were included in a 3-month-long open clinical study. Main inclusion criteria were mild AD with SCORAD between 10 and 25, 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 tolerance, AD severity (SCORAD index), quality of life (Dermatology Life Quality Index for adults, children and infants; DLQI, CDLQI, IDLQI), number of peaks of xerosis and pruritus, tolerance, and cosmetic acceptability. **

Results: After 3 months of twice-daily use, tolerance was assessed as very good by the investigators (dermatologist and pediatrician). AD severity significantly improved with a SCORAD index decrease by –77% ($p<0.0001$). Xerosis and pruritus respectively decreased by 79% and 85% ($p<0.0001$) and a significant improvement in quality of life was observed (DLQI: + 66%, CDLQI +91%, IDLQI +57%, ($p<0.0001$)). Moreover, 97% of the subjects did not report any peak of xerosis and itching during the study. Finally, the cosmetic acceptability of the product was evaluated as very good with subjects declaring their skin comfortable and soothed.**

Conclusion: The efficacy results of this study demonstrate the benefits of this new emollient "Plus" in improving the long-term management of atopic skin conditions. Moreover, its very good tolerance and acceptability by the patients could help to ensure long-term compliance.



Abstract N°: 8010

Tolerance and efficacy of an innovative emollient gel containing Aquaphilus Dolomiae and Dextran sodium sulfate extracts

Marine Rodeghiero[1], Julie Noharet[1], Cécile Viodé[1], Camille BOUDET*[2], Gautier Doat[2], Marie-Dominique Thouvenin[1]

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Introduction & Objectives: Daily emollients application is the mainstay of atopic dermatitis (AD) management and has been shown to improve skin condition and space out flare-ups. Therefore, it is important to provide patients with safe and effective products with suitable galenic textures to promote adherence, even during summer season. We present here the safety, efficacy and acceptability assessment of a new emollient gel containing *Aquaphilus Dolomiae and Dextran sodium sulfate* extracts* intended to improve long-term atopic skin condition while offering an innovative texture.

Materials & Methods: First, 31 subjects from 12 to 56 years old were included in a 3-month-long open clinical study. Main inclusion criteria were mild AD with SCORAD between 10 and 25, xerosis intensity ≥ 1 (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 tolerance, AD severity (SCORAD index), quality of life (Dermatology Life Quality Index / DLQI), number of peaks of xerosis and pruritus. Then, a consumer Home Use Test (HUT) was conducted with 68 regular users of emollients products to evaluate the product's cosmetic acceptability.

Results: After 3 months of twice-daily use, the tolerance was deemed good by the dermatologist. AD severity was significantly improved with a mean SCORAD index decrease by 66% ($p<0.0001$). Xerosis and pruritus respectively decreased by 51% and 82% ($p<0.0001$) and a significant improvement in quality of life was observed (DLQI: +90%, $p<0.0001$). Finally, the results from the HUT showed a good perceived efficacy and acceptability thanks to the product's light texture and ease of application.

Conclusion: The efficacy results demonstrate the benefit of this new emollient gel in improving atopic skin condition in adults and adolescents. Moreover, its good tolerance and acceptability could help to ensure long-term compliance which is a major challenge in the management of this chronic condition.



Abstract N°: 8027

Tolerance and efficacy of a new dermo-cosmetic product containing Aquaphilus dolomiae and Broussonetia extracts dedicated to pruritus associated with dry skin

Marine Rodeghiero[1], Camille BOUDET*[2], Gautier Doat[2], Marie-Dominique Thouvenin[1]

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Introduction & Objectives: Dry skin and pruritus are the main features of atopic dermatitis (AD) that can be encountered in other dermatological conditions such as eyelid eczema and psoriasis. Repeated itchy periods can significantly impact patients' daily life. We developed a new dermo-cosmetic product, dedicated to pruritus associated with localized dry skin. It contains two active ingredients *Aquaphilus dolomiae* and *Broussonetia* extracts; this latter having demonstrated anti-inflammatory effects involving the JAK/STAT pathway. We investigated the tolerance and efficacy of the product in patients with atopic dermatitis and other skin disorders.

Materials & Methods: Two monocentric and open studies have been conducted on patients who applied the product four times a day on localized areas of dry and pruritic skin during 22 days: 26 subjects (aged from 19 to 43 years old) with atopic dermatitis (study 1) and 44 subjects (aged from 24 to 89 years old) with other skin conditions (as eyelid eczema and psoriasis) (study 2). Inclusion criteria included a xerosis score ≥ 2 (moderate) on a 0-3 scale and a pruritus score ≥ 4 (over the previous 24 hours) on a 0-10 numerical rating scale (NRS) on at least one localized area. Primary objective was to assess the tolerance of the product. Secondary objectives included pruritus evaluation (daily assessment, over the previous 24 hours by NRS at home during the first week, Chronic Itching Burden Scale), physical and functional signs assessment at each visit, local SCORAD (study 1 only), cosmetic acceptability questionnaire and standardized photographs.

Results: Tolerance was assessed as good in both studies. A significant decrease of the pruritus intensity (NRS) was observed during the first week, from D2 (study 1: -33%, $p<0.0001$; study 2: -52%, $p<0.0001$) to D8 (study 1: -67%, $p<0.0001$; study 2: -88%, $p<0.0001$). Also, physical and functional signs assessed by the investigators significantly decreased during the study, especially itching and dryness (respectively - 86,8% and - 80% at D8 in study 1 and

-99% and - 91% at D8 in study 2 ($p<0.0001$)). AD severity on a target area was significantly improved as Local-SCORAD decreased by -54,7% at D8 and by -69% at D22 ($p<0.0001$). Moreover, 77% and 95% subjects declared their skin immediately soothed after application, respectively in study 1 and 2. Finally, the cosmetic acceptability was evaluated as very good, with subjects reporting the product as efficient in reducing intense itching and their skin as soothed and more comfortable.

Conclusion: Tolerance and efficacy results as well as the cosmetic acceptability of this new dermo-cosmetic product demonstrated its benefit in the prompt relief of significant pruritus associated with dry skin.

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Abstract N°: 8043

First evidence for the utility of the novel "Patient-Reported Impact of Dermatological Diseases" (PRIDD) as a patient-centered tool in the development of a new emollient Plus for atopic dermatitis

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Introduction & Objectives: PRIDD™ is the first fully validated dermatology patient-reported outcome measure (PROM) that was developed in partnership with patients – 5600 in total. PRIDD is a multi-dimensional PROM that assesses physical, psychological, life responsibilities and social impacts on the lives of patients with any skin condition. We report the first intervention study evaluating the utility of PRIDD as a quality-of-life assessment in a clinical trial of a new emollient containing *Aquaphilus Dolomiae* in people with atopic dermatitis (AD).

Materials & Methods: 33 adults aged 18-56 years presenting with mild to moderate AD (SCORAD index 10 to 25) were consented and enrolled in a 3 months open-label study. Main inclusion criteria were dry to very dry skin with xerosis intensity ≥ 2 (scale 0-3) and both pruritus and discomforts sensation intensities ≥ 3 (scale 0-10). Assessments of impact included AD severity (SCORAD index), the Dermatology Life Quality Index (DLQI) and the PRIDD.

Results: After 3 months of twice-daily use, AD severity significantly improved with a SCORAD index decrease by –70% ($p<0.0001$). These results were correlated with a statistically significant ($p<0.0001$) improvement in participants' quality of life as assessed by both patient-reported outcome measures DLQI (66%) and PRIDD (overall reduction of 30%) (**Figure1**). All 4 categories of PRIDD were significantly improved: Physical (-39%) responsibilities (-42%), psychological (-51%) and social impacts (-52%); ($p<0.0001$). (**Figure 2**)

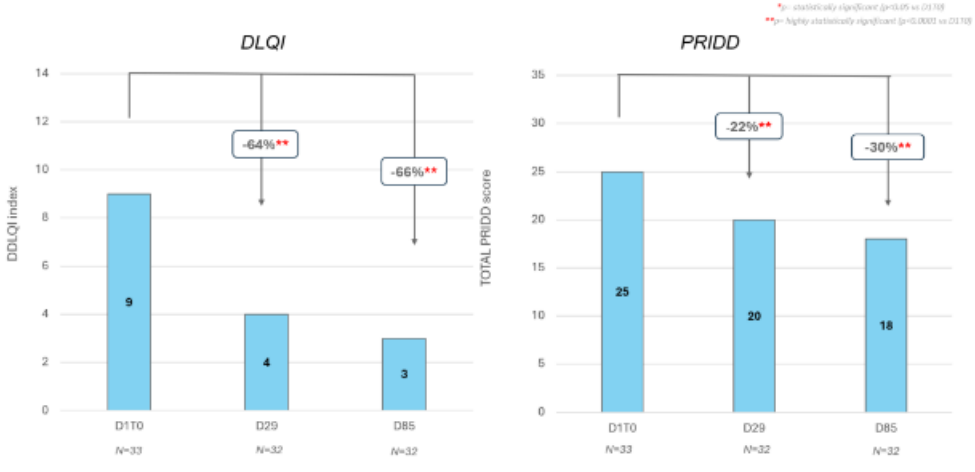


Figure 1 : Total PRIDD and DLQI scores at baseline (D1T0) and following intervention

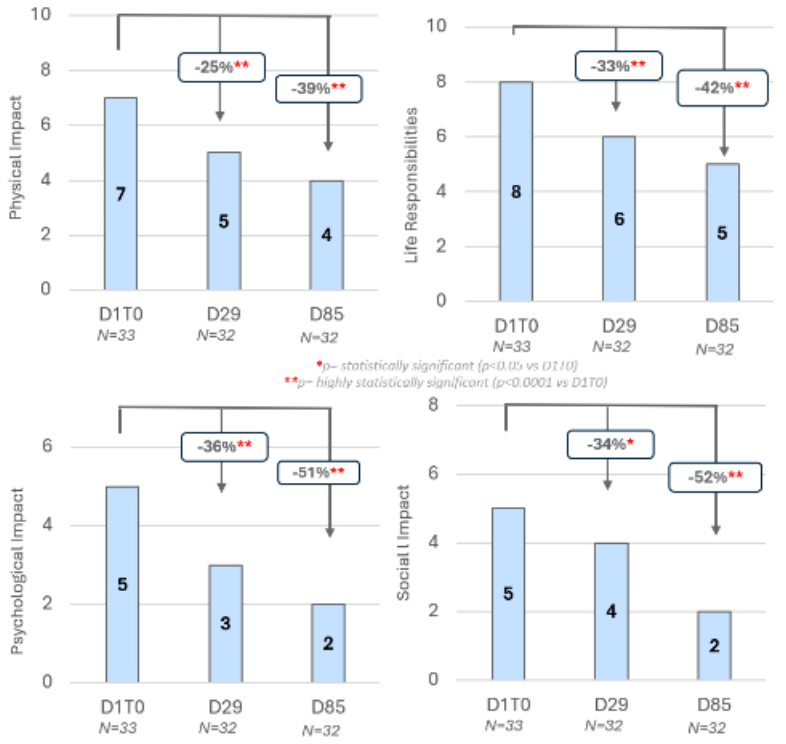


Figure 2 : PRIDD categories at baseline (D1T0) and following intervention

Conclusion: This first assessment demonstrated that the four impact domains of PRIDD conferred a more holistic understanding of the impacts of intervention on the lives of people with AD. These results provide further evidence supporting the use of PRIDD as a shared decision-making tool in dermatology and continued evaluation of PRIDD as a patient-centered development tool, in this case, within the context of dermo-cosmetic product development.



Abstract N°: 8045

Abrocitinib Treatment for Moderate-to-Severe Atopic Dermatitis Observed in Electronic Health Records and Administrative Claims in a US-Based Real-World Dermatology Setting: Patient Characteristics and Baseline Disease Severity

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Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease with significant heterogeneity in its clinical presentation and treatment response. Abrocitinib, an oral Janus kinase 1 (JAK1) inhibitor, was approved in the United States (US) for adults (2022) and adolescents (2023) and clinical trials have demonstrated efficacy in patients with moderate-to-severe (M2S) AD. Exploration of real-world use of abrocitinib in M2S AD is limited and this study leverages claims, patient and clinician reported data to characterize M2S AD patients initiating abrocitinib in outpatient dermatology practices nationwide.

Materials & Methods: This retrospective, observational study characterized adolescents (12 - <18) and adults (≥18) with M2S AD and a claim for abrocitinib between 01/22 and 02/25 (study period) in the OMNY Health Database. These data are sourced from general and dermatology electronic health records (EHRs) and linked to open claims. The study included patients with a confirmed AD diagnosis and some patients were excluded per label. Patient characteristics, Itch Numeric Rating Scale (NRS), and Investigator Global Assessment (IGA) were characterized based on available data collected on or during the 42 days pre-index. Prior treatments and comorbidities were characterized using all available EHR or claims data (01/1/17 to index).

Results: Overall, 315 patients with M2S AD initiated abrocitinib during the study period [8.3% adolescent, 91.7% adult], with 111 (35%) patients with prior AD biologic exposure. Top prior systemic treatments included oral prednisone (49.2%) and dupilumab (34.6%). Top comorbidities included overweight or obesity (43.5%), anxiety (41.3%), allergic rhinitis (38.7%), contact dermatitis (37.8%) and depression (34.3%). Proportionally, more adolescents than adults (23.1% vs 13.8%) initiated abrocitinib at the 200 mg dose. Among the 42 (13.3%) patients with Itch NRS and/or IGA documented at index or 42 days prior had, nearly all (95.2%) reported AD in the upper extremities, most reported a severe Itch NRS (52.8%) but moderate IGA (40.5%).

Conclusion: This study is the first to robustly evaluate abrocitinib treatment of AD patients in a real-world setting with administrative (claims) and clinical (EHR) data. It provides valuable insight into the characteristics of AD patients treated with abrocitinib in US dermatology practices. These findings characterize the demographics, treatment, comorbidities, and clinician and patient reported severity of AD patients upon abrocitinib treatment. Results suggest that most, particularly adolescents, initiated at the higher dose and proportions reporting severe in Itch NRS and IGA varied Additional longitudinal studies are needed to evaluate the long-term effectiveness for bio-experienced and -naïve abrocitinib patients, including disease severity at treatment initiation, dose change patterns, and potential predictors of treatment response.

	All Patients		Index Dose					
			100 mg		200 mg		50 mg	
Gender (N=315)								
Female	182	57.80%	154	59.90%	25	54.40%	3	25.00%
Male	133	42.20%	103	40.10%	21	45.70%	9	75.00%
Age band (N=315)								
12-17	26	8.30%	19	7.40%	6	13.00%	1	8.30%
18-29	73	23.20%	60	23.40%	11	23.90%	2	16.70%
30-44	56	17.80%	44	17.10%	12	26.10%	0	0.00%
45-64	74	23.50%	63	24.50%	11	23.90%	0	0.00%
65+	86	27.30%	71	27.60%	6	13.00%	9	75.00%
Comorbidities at Baseline (Baseline = any time prior to index date, N=315)								
Atopic and allergic conditions	201	63.80%	159	61.90%	33	71.70%	9	75.00%
Allergic rhinitis	122	38.70%	101	39.30%	16	34.80%	5	41.70%
Immune-mediated conditions	174	55.20%	138	53.70%	28	60.90%	8	66.70%
Contact dermatitis	119	37.80%	89	34.60%	24	52.20%	6	50.00%
Mental health and substance use	168	53.30%	137	53.30%	25	54.40%	6	50.00%
Anxiety	130	41.30%	105	40.90%	20	43.50%	5	41.70%
Depression	108	34.30%	86	33.50%	18	39.10%	4	33.30%
Cardiovascular disease	109	34.60%	86	33.50%	15	32.60%	8	66.70%
Circulatory diseases	22	7.00%	17	6.60%	1	2.20%	4	33.30%
Metabolic Disorders	148	47.00%	117	45.50%	25	54.40%	6	50.00%
Overweight obesity	137	43.50%	107	41.60%	24	52.20%	6	50.00%
Bone Health	13	4.10%	9	3.50%	2	4.40%	2	16.70%
Skin infection	104	33.00%	87	33.90%	13	28.30%	4	33.30%
Ophthalmologic	128	40.60%	100	38.90%	20	43.50%	8	66.70%
Baseline AD Treatment (N=315)								
Systemic AD Treatment	270	85.70%	219	85.20%	40	87.00%	11	91.70%
Systemic biologics	111	35.20%	96	37.40%	10	21.70%	5	41.70%
Dupilumab	109	34.60%	94	36.60%	10	21.70%	5	41.70%
Oral JAK inhibitors	105	33.30%	84	32.70%	18	39.10%	3	25.00%
Conventional systemic immunosuppressants	48	15.20%	39	15.20%	8	17.40%	1	8.30%
Oral systemic corticosteroids	175	55.60%	138	53.70%	27	58.70%	10	83.30%
Prednisone oral	155	49.20%	125	48.60%	25	54.40%	5	41.70%
Parenteral systemic corticosteroids	157	49.80%	124	48.30%	26	56.50%	7	58.30%
Topical AD Treatment	276	87.60%	225	87.60%	42	91.30%	9	75.00%
Topical corticosteroids	256	81.30%	207	80.50%	40	87.00%	9	75.00%
Topical calcineurin inhibitors	132	41.90%	105	40.90%	20	43.50%	7	58.30%
Topical JAK inhibitors	69	21.90%	54	21.00%	12	26.10%	3	25.00%
Phosphodiesterase 4 (PDE4) inhibitors	59	18.70%	51	19.80%	6	13.00%	2	16.70%
Phototherapy	31	9.80%	28	10.90%	1	2.20%	2	16.70%
AD Severity at Index (N=42)								
Moderate-to-Severe, Overall (N=42)								
M2S at index	29	80.60%	29	80.60%	6	100.00%	--	--
Not M2S at index	7	19.40%	7	19.40%	0	0.00%	--	--
Itch, Categorized (N=36)								
No itch (0)	2	5.60%	2	6.70%	0	0.00%	--	--
Mild itch (1-3)	5	13.90%	5	16.70%	0	0.00%	--	--
Moderate itch (4-6)	10	27.80%	9	30.00%	1	16.70%	--	--
Severe itch (>=7)	19	52.80%	14	46.70%	5	83.30%	--	--
IGA, Raw (N=37)								
Clear	4	10.80%	4	12.90%	0	0.00%	--	--
Almost Clear	2	5.40%	2	6.50%	0	0.00%	--	--
Mild	4	10.80%	3	9.70%	1	16.70%	--	--
Moderate	15	40.50%	13	41.90%	2	33.30%	--	--
Severe	12	32.40%	9	29.00%	3	50.00%	--	--
Body region (N=42)								
Head and neck	24	57.10%	19	52.80%	5	83.30%	--	--
Upper Extremeties	40	95.20%	34	94.40%	6	100.00%	--	--
Trunk	34	81.00%	28	77.80%	6	100.00%	--	--
Lower Extremeties	34	81.00%	29	80.60%	5	83.30%	--	--



Abstract N°: 8070

Experimental and clinical evidence suggests that treatment with IL-37 can improve skin barrier function

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Introduction & Objectives: Interleukin-37 (IL-37) is an anti-inflammatory cytokine that plays a regulatory role in immune responses; however, its function in atopic dermatitis (AD) remains unclear. In particular, the impact of IL-37 on skin barrier function, a key pathological feature of AD, has yet to be fully understood. In this study, we examined IL-37 expression levels in lesional and non-lesional skin of AD patients, analyzed its relationship with pro-inflammatory cytokines and barrier-related components, and evaluated IL-37 potential as a biomarker for disease severity and treatment response. The aim of this study is to clarify the role of IL-37 in AD pathogenesis and its value as a therapeutic target.

Materials & Methods: Skin samples from healthy donors, as well as nonlesional and lesional skin from patients with AD, were obtained from the GEO database. Gene expression analysis was performed to compare *IL37* expression levels among healthy individuals, nonlesional and lesional skin from AD patients. Further analyses were conducted to evaluate *IL37* expression in relation to SCORAD scores, and pre- and post-biologic treatment status. Immunohistochemistry was used to assess *IL37* expression in skin tissues from healthy donors and AD patients. To investigate the effect of IL-37, primary normal human keratinocytes were stimulated with recombinant IL-37, and the expression of key skin barrier components was evaluated at both mRNA and protein levels. An AD-like phenotype was induced in keratinocytes using IL-4 and IL-13, and the modulatory effects of IL-37 on barrier-related gene expression were examined. Furthermore, transepithelial electrical resistance (TER) measurements and a 3D human skin equivalent model were employed to assess the impact of IL-37 on skin barrier function.

Results: *IL37* gene expression was significantly reduced in the lesional skin of AD patients compared to healthy controls. Moreover, *IL37* levels were markedly lower in patients with moderate to severe AD than in patients with mild AD or healthy skin. Notably, *IL37* expression increased following biologic treatment, suggesting its responsiveness to therapeutic intervention. Receiver operating characteristic analysis demonstrated that *IL37* had high sensitivity and specificity in distinguishing AD lesions from healthy skin. Correlation analyses revealed that *IL37* expression was negatively associated with pro-inflammatory cytokines and chemokines, while showing a positive correlation with the barrier-related gene filaggrin. *In vitro*, treatment of human keratinocytes with recombinant IL-37 significantly upregulated the expression of filaggrin, loricrin, claudin-1, and *zonula occludens*-1 at both mRNA and protein levels. Additionally, IL-37 enhanced TER in keratinocyte monolayers. In a 3D skin equivalent model, IL-37 restored skin barrier integrity compromised by IL-4 and IL-13, indicating the potential of IL-37 to reverse barrier dysfunction in AD.

Conclusion: IL-37 is associated with disease severity and treatment response in AD and promotes skin barrier restoration by upregulating key structural components. These findings suggest that IL-37 is a promising biomarker and therapeutic target for AD treatment.



Abstract N°: 8092

Safety and Efficacy of up to 3 Years of Dupilumab Treatment in Infants and Children With Severe Atopic Dermatitis

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Introduction & Objectives: Compared to patients with mild or moderate atopic dermatitis (AD), those with severe AD have more intense chronic signs and symptoms, higher disease burden, and worse quality of life. Dupilumab has been previously shown to provide an acceptable safety profile and sustained efficacy for up to 2 years in infants and children with moderate-to-severe AD. We report long-term (up to 3 years) safety and efficacy outcomes (body surface area [BSA], SCORing Atopic Dermatitis [SCORAD] and its components) of dupilumab treatment in pediatric patients with severe AD.

Materials & Methods: Children (6 months to 11 years) with severe AD (Investigator's Global Assessment score of 4) from prior studies (NCT03346434, NCT03345914) were treated with dupilumab (200 mg every 4 weeks [q4w] for body weight 5 to <15 kg, 300 mg q4w for 15 to <30 kg, 200 mg every 2 weeks [q2w] for 30 to <60 kg, or 300 mg q2w for ≥60 kg) in an open-label extension study (LIBERTY AD PED-OLE [NCT02612454]). Topical treatments were allowed. Absolute SCORAD score, SCORAD-50 (defined as 50% reduction in absolute value from baseline of parent study), and BSA were assessed at baseline of the parent study through Week 152. Data are reported as observed.

Results: Of the 125 patients with severe AD in this analysis, 62.0% of patients aged 6 months to 5 years (n = 31/50) and 66.7% of patients aged 6 to 11 years (n = 50/75) had completed 152 weeks of treatment. Mean (SD) treatment exposure was 124.2 (48.6) weeks in children aged 6 months to 5 years and 116.0 (48.5) weeks for those aged 6 to 11 years. Treatment-emergent adverse events (TEAEs) were reported in 86.0% of 6-month to 5-year-old children and in 89.3% of 6- to 11-year-old children, the majority of which were mild or moderate; treatment-related TEAEs occurred in 22.0% and 36.0%, respectively. In both groups, TEAEs including conjunctivitis (4.0%, 4.0%), upper respiratory tract infection (2.0%, 4.0%) and blepharitis (2.0%, 2.7%) were most frequently reported.

SCORAD scores decreased from 73.1 to 20.8 in 6-month to 5-year-old children and from 73.9 to 22.7 in 6- to 11-year-old children. SCORAD-50 was achieved by over 80% of patients aged 6 months to 5 years (n = 27/31) and 6 to 11 years (n = 42/50) by Week 152. Across all SCORAD components (erythema, edema/papulation, oozing/crusting, excoriation, lichenification, and dryness), the proportion of patients with moderate or severe scores decreased from parent study baseline (52–100%) to Week 152 (0–25%; 33–38% of patients had missing

data at Week 152). Mean affected BSA decreased from 55.6 to 14.2 in 6-month to 5-year-old children and from 62.4 to 8.9 in 6- to 11-year-old children.

Conclusion: An acceptable and consistent long-term safety profile was demonstrated for up to 3 years of dupilumab treatment in infants and children (6 months to 11 years) with severe AD. Moderate and severe scores for all SCORAD components generally improved to absent or mild, reflecting reduced intensity across all AD signs.

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Abstract N°: 8159

Risk of major adverse cardiovascular events in patients with chronic hand eczema.

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Introduction & Objectives: Chronic hand eczema (CHE) is a common debilitating inflammatory skin disease linked to several lifestyle factors including tobacco use and being overweight. While moderate-to-severe CHE has been associated with elevated levels of cardiovascular biomarkers, it is unknown whether adults with CHE have an increased occurrence of cardiovascular events and whether any increase risk is caused directly by CHE itself or driven by other comorbidities or lifestyle factors.

Materials & Methods: Data were extracted from danish national patient registries, including all individuals aged 18 years or older who received an international classification of diseases, 10th revision diagnostic code for CHE between January 1st, 1994, and December 31st, 2020. Patients were classified as having mild-to-moderate or severe CHE based on their treatment history and were matched 1:10 by age- and sex to the general population without CHE, creating a control cohort for each severity group. Mild-to-moderate CHE patients were reclassified as severe if their CHE worsened during the study period, thus included in both severity groups. The study period was from January 1st, 2002, to December 31st, 2020, with the primary end point being major adverse cardiovascular events (MACEs) defined as myocardial infarctions (MI), ischemic stroke (IS), or cardiovascular death (CD), or a composite of these. Kaplan-Meier curves illustrated time to MACE. Cox-regression models were used to calculate unadjusted hazard ratios (HR) and adjusted HR (aHR) with 95% confidence intervals (CI), adjusting for previous MACE events, smoking history, history of alcohol abuse, diabetes, hypertension, cardiac dysrhythmias, inflammatory bowel disease, sex, and age but not body mass index as this data was not available.

Results: The study comprised 18,253 patients with CHE including 7,545 (41.3%) (median age: 35.7 years [interquartile range (IQR) 26.4-48.9], 61.8% women) categorized as having mild-to-moderate CHE and 13,107 (71.8%) (median age: 44.5 [IQR 32.4-56.0], 59.9% women) with severe CHE. Patients with mild-to-moderate or severe CHE were matched with 75,450 and 131,070 individuals without CHE, respectively. Unadjusted analyses revealed no risk of MACEs when comparing mild-to-moderate CHE with controls (HR: 1.00; 95% CI: 0.97-1.03), including MI (HR: 1.01; 95% CI: 0.98-1.03), IS (HR: 1.00; 95% CI: 0.97-1.02), and CD (HR: 1.01; 95% CI: 0.99-1.03). The risk of MACEs remained insignificant after adjusting for potential confounders.

In contrast, patients with severe CHE had significantly higher unadjusted risk of MACEs compared to controls (HR: 1.08; 95% CI: 1.05-1.011), including MI (HR: 1.04; 95% CI: 1.02-1.06) and IS (HR: 1.05; 95% CI: 1.03-1.08). After adjusting for potential confounders, patients with severe CHE continued to have a slightly increased risk of MACEs (aHR: 1.04; 95% CI: 1.01–1.06), MI (aHR: 1.02; 95% CI: 1.00–1.04) and IS (aHR: 1.03; 95% CI: 1.01–1.06), which increased further (aHR: 1.06; 95% CI: 1.03-1.09, aHR: 1.03; 95% CI: 1.01-1.05, aHR: 1.05; 95% CI: 1.03-1.08, respectively) when not adjusting for smoking.

Conclusion: This study shows a marginally but significantly increased risk of MACEs among patients with severe CHE. The slightly increased risk was observed prior to adjustment for demographics, comorbidities, and lifestyle factors, suggesting that these factors may be the primary drivers of such risk. Finally, residual confounding cannot be excluded.

Figure 1: Kaplan-Meier curve including chronic hand eczema patients stratified by severity and their respective matched control group illustrating time to major adverse cardiovascular event (MACE).

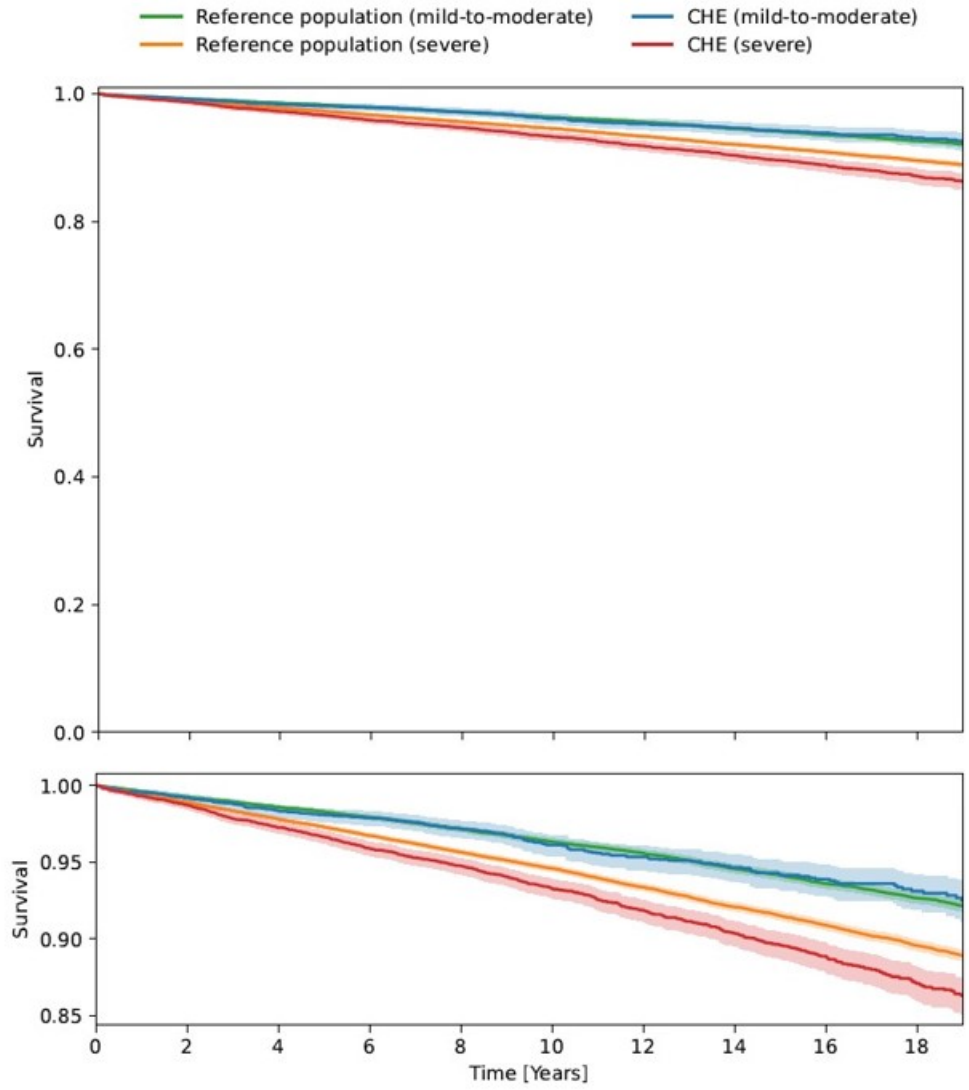
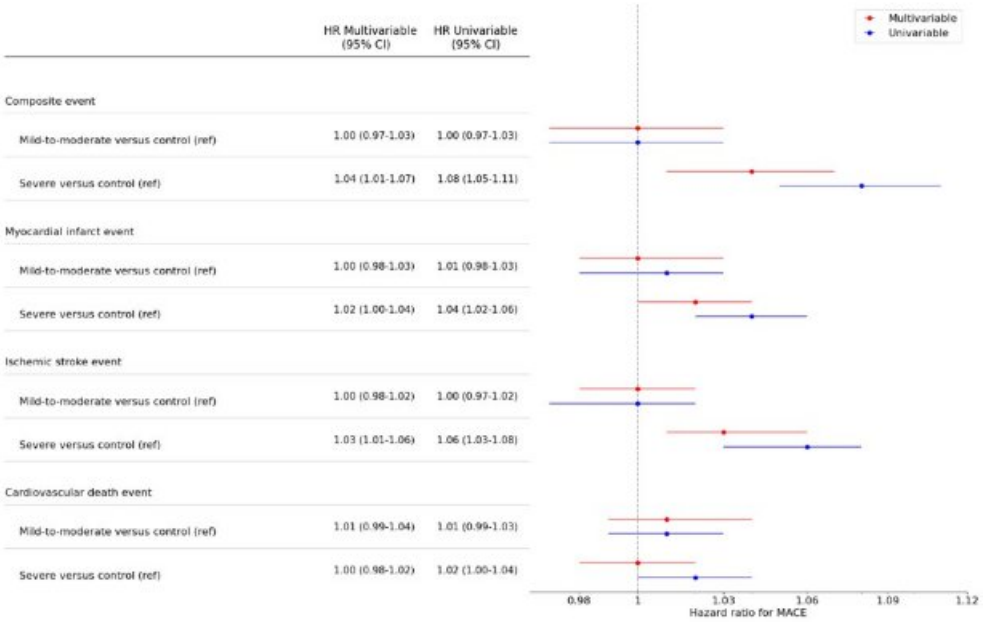


Figure 2: Association between chronic hand eczema by severity and cardiovascular outcomes: major adverse cardiovascular event, myocardial infarct, ischemic stroke and cardiovascular death.



*Adjusted for previous MACE events, smoking history, history of alcohol abuse, diabetes, hypertension, cardiac dysrhythmias, inflammatory bowel disease, sex, and age. Comorbidities including alcohol abuse, cardiac dysrhythmia, diabetes, hypertension, and inflammatory bowel disease were adjusted within five years prior to index date.

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Abstract N°: 8168

Cross-regional University Migration Triggering Keratotic Eczema in an Adolescent—A Case Report

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Introduction & Objectives:

Keratotic eczema is a chronic inflammatory dermatosis characterized by hyperkeratosis, pigmentation and lichenification, with a multifactorial aetiology involving genetic, immunological and environmental elements. For students who relocate to another region for study, abrupt changes in climate, water quality, daily routine and psychological stress create a typical “study-related migration dilemma”, yet their impact on cutaneous barrier integrity and inflammatory susceptibility has received little attention. By reviewing an adolescent who experienced several relapses after enrolling at an out-of-province university, we explore how regional conversion and campus-related stress may precipitate or aggravate keratotic eczema, providing guidance for the clinical management of students facing this dilemma.

Materials & Methods:

The complete disease course of a 19-year-old male was retrospectively analysed. Campus accommodation conditions, lifestyle, clinical manifestations, histopathology, treatment regimens and follow-up data were collected. After other dermatoses and systemic diseases were ruled out, a diagnosis of keratotic eczema was confirmed by skin-biopsy pathology.

Results:

The first episode occurred after the patient left his hometown and began studying in a hot and arid region. Eight weeks into the semester, frequent hand-washing with detergents and late-night studying led to cracked, pruritic, scaly lesions on the dorsa of the hands, followed by grey-brown scaly plaques around the elbows, knees and ankles. Biopsy revealed basket-weave hyperkeratosis of the epidermis and sparse perivascular lymphocytic infiltration in the superficial dermis. When the patient took leave and returned to his warm, humid hometown, topical betamethasone-urea ointment, oral levocetirizine and avoidance of detergents resulted in complete clearance of lesions. After resuming studies the next term, profuse sweating under high temperatures triggered a relapse; during the vacation he again improved with intensified moisturising and anti-inflammatory therapy. The condition is currently stable, but another recurrence is anticipated upon returning to school.

Conclusion:

This case indicates a definite association between keratotic eczema and regional environmental change. Hot, dry climate, hard water and frequent detergent use may impair the skin barrier, while psychological and lifestyle alterations caused by academic migration act as additional triggers. For susceptible students, personalised prevention strategies are recommended: environmental adaptation guidance with enhanced moisturising and reduced exposure to irritant cleansers before and after returning to campus; behavioural interventions to avoid mechanical injury such as picking of scales; and dynamic follow-up with timely adjustment of therapy during high-risk seasons or environmental transitions. Further studies on how environmental change and psychological stress jointly influence the cutaneous barrier are warranted to establish evidence-based long-term management for migrating adolescents.



Abstract N°: 8194

Promising Biomarkers - objective sleep parameters in patients with atopic Dermatitis

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Introduction & Objectives:

Sleep disturbances in patients with AD is a common yet underrated life course impairment. Several studies focused on assessing the subjective impairment of sleep disturbances, however objective data are lacking. We aimed to further explore and assess the sleep architecture in these patients using the diagnostic tool of polygraphy.

Materials & Methods:

27 patients with moderate to severe AD and 6 healthy controls were included in this cross-sectional exploratory study. 4 patients received additional examination in an overnight sleep lab.

Objective sleep parameters (deep sleep (N3), REM sleep, apnea/hypopnea index (AHI), sleep efficiency, skin temperature) and patient-rated outcome measures (PROMS) for sleep quality, daytime sleepiness, quality of life and pruritus were assessed. Associations between sleep parameters and PROMs were analyzed using Pearson or Spearman correlation. Independent t-tests or Mann-Whitney U tests were used to compare AD patients with healthy controls

Results:

A marked discrepancy was observed in the sleep quality of healthy controls as compared to patients suffering from AD. In the AD group, REM and sleep efficiency significantly correlated with the EASI score ($p<0.05$). The AHI significantly correlated with EASI ($p<0.05$) and deep sleep significantly correlated with itch NRS ($p<0.05$). We recognized a significant correlation with the skin temperature spread during the night and EASI score ($p<0.001$).

Conclusion:

We managed to objectify the relevance and extent of sleep impairment in patients with AD. Surprisingly it is shown, that PROMs alone did not fully reflect the impact. The data suggest that further research and discussion is required on other potential factors beyond itch, that may affect sleep in AD, such as skin temperature or AHI.



Abstract N°: 8222

The Effectiveness and Safety of JAK Inhibitors in a Cohort of Real-World patients with Moderate to Severe Atopic Dermatitis

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Introduction & Objectives:

Janus kinase inhibitors (JAKi) offer a targeted mechanism of action to modulate inflammatory pathways in immune mediated diseases. Abrocitinib, baricitinib, and upadacitinib are licensed in the U.K for the treatment of atopic dermatitis (AD). Despite their promise in clinical trials real world data is still emerging and adverse events such as infections, thromboembolism, major cardiovascular events and malignancy have led to warnings about their use. We report on the real-world outcomes of a cohort of patients with AD from the U.K. who have received JAKi therapy.

Materials & Methods:

Patients prescribed JAKi for AD were identified through pharmacy records. Clinical records for each patient were reviewed. Demographics, treatment history, disease severity, adverse events (AEs) and treatment duration were recorded. Effectiveness at 16 weeks was defined according to recommendations from the National Institute for Health and Care Excellence (NICE): at least 50% reduction in Eczema Area and Severity Index (EASI) and at least a 4-point reduction in Dermatology Life Quality Index (DLQI) from when treatment started.**

Results:

There were 85 patients included in the study. Their demographics and clinical characteristics are reported in Table 1. The mean number of treatments for each patient before JAKi was 3.8. Previous systemic treatments included methotrexate (n=59), azathioprine (n=38), ciclosporin (n=57), MMF (n=11) and phototherapy (n=46). 73 patients (86%) had received a biologic prior to JAK inhibitor therapy (dupilumab = 61, Tralokinumab =12). In these patients, 46 (63%) discontinued biologics because of lack of efficacy and 27 (37%) discontinued because of adverse events. 10 patients were prescribed multiple JAKi.

Mean baseline EASI and DLQI scores for each JAKi are outlined in Table 1.** Efficacy at week 16 as defined by NICE was achieved by 81% (n=30) of the upadacitinib group, 49% (n=19) of the baricitinib group, and 22% (n=2) of the abrocitinib group. The mean treatment duration ranged between 32.8 to 60.4 weeks depending on the JAKi. 95% (n=37) of baricitinib, 73% (n=27) of upadacitinib and all (n=9) abrocitinib patients received the higher dose of treatment.

Treatment was discontinued due to lack of efficacy in 29% (n=25) of patients and due to adverse events in 11% of patients (n=9) (Table 1). Adverse effects leading to discontinuation were nausea (n=2), chest infection (n=2), chest pain (n=1), generally unwell (n=1), abdominal pain (n=1), seborrheic dermatitis (n=1) and HSV reactivation (n=1). Two deaths occurred in the baricitinib group (ages 96 and 66) due to staphylococcus aureus bacteraemia and pneumonia. Other adverse events reported include acne (n=5), HSV reactivation (n=2) and dyslipidaemia (n=1).

Conclusion:

In our real-world cohort of patients with moderate-to-severe AD, who have already been extensively treated with

systemics and biologics, JAK inhibitors achieved NICE criteria for effectiveness in 60% of patients. Upadacitinib was the most effective JAKi in our cohort. Limitations include variability in baseline disease severity and previous treatment exposure between different JAKi groups and low numbers of patients who were prescribed abrocitinib. JAKi were generally well tolerated with adverse events consistent with those reported in clinical trials. New treatments for AD with novel mechanisms of action beyond biologics and JAK inhibition are required for patients who do not respond to existing therapies.

Table 1: Clinical Characteristics of Patients Prescribed JAK Inhibitor Therapy for AD

	Baricitinib (n=39)	Upadacitinib (n=37)	Abrocitinib (n=9)
Male, n (%)	22 (56.4%)	22 (59.4%)	5 (55.6%)
Mean age, years (Range 17 - 96)	44	31	38
Mean baseline EASI (Range 7 - 56)	20.6	24.4	28
Mean baseline DLQI (Range 8-30)	21.7	21.3	24.9
Proportion of patients who satisfy NICE criteria for continuation, n (%)	19 (49%)	30 (81%)	2 (22%)
Treatment failure leading to discontinuation, n (%)	15 (38%)	5 (14%)	5 (56%)
Adverse events leading to discontinuation, n (%)	5 (13%)	2 (5%)	2 (22%)
Average treatment duration, weeks (range)	60 (1-348)	41 (1-115)	33 (3-82)
Previous biologic treatment, n (%)	19 (49%)	31 (84%)	9 (100%)
Previous JAK inhibitor treatment, n (%)	0 (0%)	8 (22%)	4 (44%)



Abstract N°: 8239

Patients with Atopic Dermatitis Using Oral Contraceptive Pills or Hormone Replacement Therapy: Long-Term Safety of Upadacitinib for Major Adverse Cardiovascular Events, Venous Thromboembolism, or Malignancy (Excluding Nonmelanoma Skin Cancer)

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Introduction & Objectives: Atopic dermatitis (AD), a chronic inflammatory skin disease, can be associated with major adverse cardiovascular events (MACE), venous thromboembolism (VTE), and malignancy (excluding nonmelanoma skin cancer [exNMSC]). An integrated analysis of up to 6 years of safety data from phase 3 studies of upadacitinib (UPA) in patients with moderate-to-severe AD showed the incidence of MACE (cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke), VTE (deep vein thrombosis or pulmonary embolism [fatal and nonfatal]), and malignancy (exNMSC) to be similar to or lower than the United States (US) background rates reported in patients with AD. Risk factors contributing to MACE, VTE, and malignancy (exNMSC) may include oral contraceptive pill (OCP) or hormone replacement therapy (HRT) use. Here, long-term incidence rates of MACE, VTE, and malignancy (exNMSC) according to baseline OCP and HRT use were assessed among patients with moderate-to-severe AD with up to 6 years of UPA treatment.

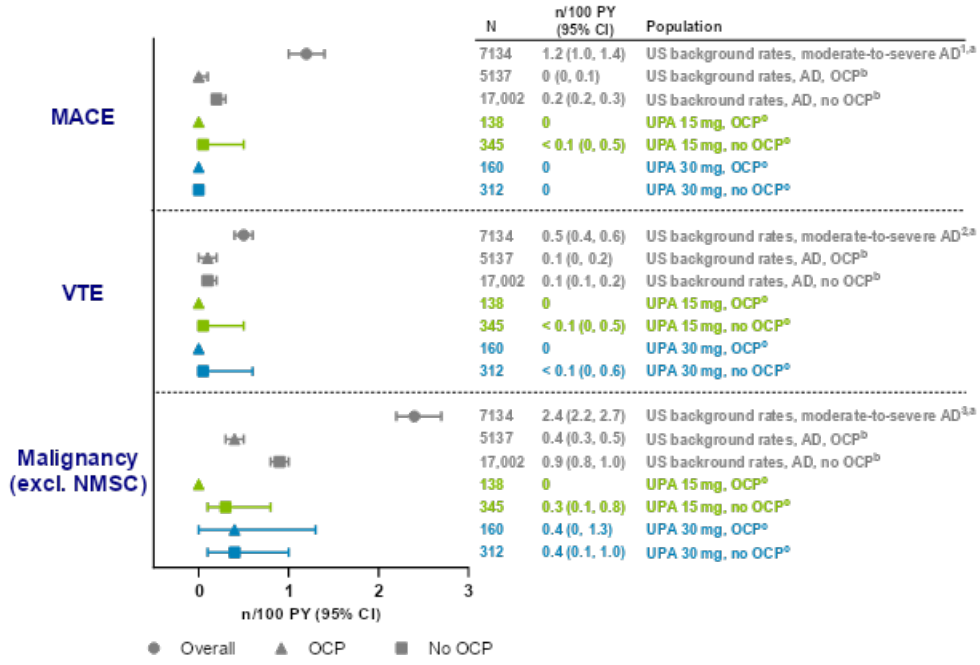
Materials & Methods: This analysis evaluated pooled data from the randomized, double-blind, multicenter, placebo-controlled, phase 3 Measure Up 1/2 (NCT03569293/NCT03607422) and AD Up (NCT03568318) studies. Patients with moderate-to-severe AD (aged 12–75 years) were randomized 1:1:1 to receive once-daily oral UPA 15 mg, UPA 30 mg, or placebo as monotherapy (Measure Up 1/2) or with concomitant topical corticosteroids (AD Up) for 16 weeks. At week 16, patients receiving placebo were rerandomized 1:1 to UPA 15 mg or 30 mg, while patients initially randomized to UPA continued their assigned treatment. Incidence of MACE, VTE, and malignancy

(exNMSC) was reported as exposure-adjusted incidence rates per 100 patient-years (n/100PY). For context, background rates of MACE, VTE, and malignancy (exNMSC) in the general US AD population were assessed in a retrospective observational claims-based analysis from Optum's deidentified Clinformatics Data Mart database; this analysis included females who had a diagnosis of AD during the study period (March 2017–September 2024) determined by International Classification of Diseases 9th or 10th edition codes (≥ 1 inpatient or ≥ 2 outpatient claims for AD). Age restrictions from the UPA phase 3 studies (12–75 years) were implemented for the real-world reference population and background rates were weighted to mimic the age and sex distribution in the combined UPA trial population. Safety cohorts were stratified by OCP use (yes vs no) among females aged 15–55 years or HRT use (yes vs no) among females aged > 55 years.

Results: A total of 1178 females in the UPA phase 3 studies were evaluated (UPA 15 mg, n = 593; UPA 30 mg, n = 585). Long-term incidence rates were low for MACE and VTE (all < 0.1 n/100PY) and malignancy (exNMSC; all ≤ 0.4 n/100PY) among UPA-treated females in the OCP and non-OCP groups (**Figure**). There were no MACE or VTE events in patients using OCP or HRT and no malignancy (exNMSC) events in the HRT group; however, HRT results are limited by a small sample size (n = 5). Among patients using OCPs, incidence rates from UPA long-term studies were consistent with real-world incidence rates in patients with AD in the US (n = 5137).

Conclusion: In females with moderate-to-severe AD who received up to 6 years of UPA treatment, long-term incidence rates of MACE, VTE, and malignancy (exNMSC) were low, regardless of OCP use, and similar to those in the real-world population of patients with AD.

Figure. Incidence of MACE, VTE, and Malignancy (Excluding NMSC) by OCP Use



AD, atopic dermatitis; excl, excluding; MACE, major adverse cardiovascular event; n/100 PY, number of patients with ≥ 1 event per 100 patient-years; NMSC, nonmelanoma skin cancer; OCP, oral contraceptive pill; UPA, upadacitinib; VTE, venous thromboembolism.

MACE was defined as cardiovascular death, nonfatal myocardial infarction, or nonfatal stroke.

VTE was defined as deep vein thrombosis or pulmonary embolism (fatal and nonfatal).

[a]Patients with moderate-to-severe AD were defined via proxy of dupilumab use at any time during the follow-up period.

[b]Background rates from the claims analysis by OCP use were measured in females who had a diagnosis of AD during the study period. Age restrictions from the UPA phase 3 studies (12–75 years) were implemented for the real-world reference population and background rates were weighted to mimic the age and sex distribution in the combined UPA trial population.

[c]Incidence rates from the UPA long-term studies by OCP use were evaluated in females aged 15–55 years.

[1]Bunick CG, et al. Risk of major adverse cardiovascular events in patients with moderate-to-severe atopic dermatitis: a United States population-based study. *Br J Dermatol*. 2024;191(Supplement_2):ljae266.057. https://doi.org/10.1093/bjd/ljae266.057.

[2]Bunick CG, et al. Risk of venous thromboembolism in patients with moderate-to-severe atopic dermatitis: a United States population-based study. Poster presented at the 2025 American Academy of Dermatology Annual Meeting (AAD 2025), March 7–11, 2025, Orlando, FL, USA.

[3]Vleugels RA, et al. Risk of malignancy excluding nonmelanoma skin cancer in patients with moderate-to-severe atopic dermatitis in the United States: a population-based study using claims data. *Br J Dermatol*. 2024;191(Supplement_2):ljae266.055. https://doi.org/10.1093/bjd/ljae266.055.



Abstract N°: 8263

Evaluation of the efficacy of a medical device repairing emollient cream in adults with mild to moderate head and neck atopic dermatitis

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Introduction & Objectives:

Head and neck atopic dermatitis (HNAD) is probably the most characteristic form of adult AD, with a strong impact on quality of life. The management of these sensitive areas, often exposed to environmental triggers is particularly challenging and specific datas on this location are sparse. The objective of the study was to evaluate the efficacy of a medical device repairing emollient cream in this indication.

Materials & Methods:

Adults with mild to moderate HNAD (3 ≤ Local SCORAD ≤ 10) were included in a multicentric exploratory clinical trial in Germany and applied the product twice daily for 4 weeks. Main assessments included local SCORAD and PO-SCORAD, HNAD extent, local investigators and patients global assessment (IGA and PGA), pruritus and skin pain intensity (average over the past 24 hours; numerating rating scale), quality of life (Dermatology Life Quality Index / DLQI, Chronic Itch Burden Scale) and biometric evaluations (Hydration Index /HI, Trans-Epidermal Water Loss/TEWL). Safety was also recorded.

Results:

Nineteen patients (from 22 to 47 years old) were included in the study which took place during the COVID pandemic. 37 % of them reported more than 6 HNAD flare-up per year. At the end of the study (D29), we observed a significant decrease of: Local PO-SCORAD ($p<0.001$; -46%), extent of HNAD ($p<0.001$; -33%), mean pruritus intensity ($p=0.037$; -32%), mean skin pain intensity ($p=0.038$; -40%). An improvement of HNAD was assessed by investigators for 58 % of the patients and by 53 % of patients themselves. A significant decrease in DLQI score was also observed ($p<0.005$; -38%). Local SCORAD, HI and TEWL also improved ($p>0.05$). Nine subjects had dermatological adverse events (DAEs) suspected to be related to the product (mostly functional signs as pruritus, skin pain). For 7 of them, DAEs were also suspected to be related to HNAD worsening.

Conclusion:

The results of this study highlight the benefit of a medical device repairing emollient cream in head and neck atopic dermatitis.** Despite the pandemic context during the study, including potential aggravating factors of HNAD (stress,** wearing of masks, …), a significant effect of the product on clinical parameters and quality of life was demonstrated.



Abstract N°: 8277

Integrated Single-Cell Atlas of Atopic Dermatitis Enables Cell-Type-Resolved Deconvolution of Bulk RNA-Seq During Dupilumab Treatment

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease with complex pathogenesis. Single-cell RNA sequencing (scRNA-seq) has recently emerged as a powerful tool to dissect cellular heterogeneity and immune dysregulation in multifactorial diseases. Although it provides high-resolution insights into individual cell populations, its statistical power is often limited by data sparsity due to dropout events.

Herein, we aimed to (1) increase single-cell data power by integrating multiple datasets into the most comprehensive single-cell atlas of atopic dermatitis (AD) generated to date, (2) use this atlas to deconvolve bulk RNA-seq data from dupilumab-treated patients, and (3) validate findings by analysing gene expression in tape strips collected longitudinally from an independent cohort of AD patients we prospectively recruited.

Materials & Methods:

We integrated four public scRNA-seq datasets from human AD-affected and non-affected skin, as well as healthy control skin using Seurat pipeline. Quality control excluded cells with <500 or >10,000 counts, >10% mitochondrial reads, and potential doublets (UMIcounts >3000). We then applied the ENIGMA framework to deconvolve publicly available bulk RNA-seq profiles before and after dupilumab treatment and predicted cell-type-specific gene expression changes using the sc-RNAseq atlas. To validate our findings, we collected tape strips from an independent prospective cohort of 19 moderate-to-severe AD patients before and after 16 weeks of dupilumab therapy. Multiplex qPCR was used to assess the relative expression of the identified candidate genes in response to therapy.

Results:

Our final atlas comprised 53 skin biopsies (lesional and non-lesional) from 31 AD patients and 22 healthy controls, profiling a total of 189,806 high-quality cells. Louvain clustering revealed 18 distinct cell populations, with keratinocytes (27%), T cells (17%), and fibroblasts (16%) being the most abundant in AD skin. Compared to healthy controls, AD patients exhibited significantly increased proportions of monocytes/macrophages (P=0.01), proliferating T cells (P=0.001), proliferating keratinocytes (P=0.006), and activated dendritic cells ($P=1\times10^{-5}$), while melanocytes (P=0.04) and lymphatic endothelial cells were reduced in AD.

We next leveraged this comprehensive atlas to deconvolve bulk RNA-seq data from a longitudinal dupilumab treatment study in 24 AD patients, enabling cell type–specific gene expression profiling in response to therapy and prediction of treatment outcomes. Focusing on suprabasal keratinocytes, we identified 2,435 differentially expressed genes over the course of treatment. To validate these findings, we performed multiplex qPCR on tape-strip samples collected longitudinally from 19 prospectively recruited AD patients. This confirmed the predicted upregulation of candidate genes such as *SBSN* and *DMKN,* and downregulation of *S100A9* and *SERPINB3/4* in response to dupilumab treatment.

Conclusion:

We present a comprehensive single-cell atlas of AD skin, providing a valuable resource for dissecting cell-type–specific gene expression patterns. Integrated with a deconvolution approach, this atlas enables robust interpretation of bulk RNA-seq data, even in the absence of matched single-cell profiles, and facilitates insights into treatment responses in AD.



Abstract N°: 8294

Real-world effectiveness and safety of abrocitinib, baricitinib and upadacitinib in atopic dermatitis: A systematic review and meta-analysis

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Introduction & Objectives:

While the efficacy and safety of oral Janus kinase inhibitors (JAKi) is well-demonstrated in clinical trials, there remains continued concern for the risk of rare but potentially severe adverse events. Real-world evidence of JAKi use in atopic dermatitis (AD) is accumulating and provides important insight into safety and effectiveness for routine clinical practice. This systematic review and meta-analysis assessed the real-world effectiveness and safety of abrocitinib, baricitinib and upadacitinib in the treatment of AD based on real-world evidence.

Materials & Methods:

PubMed and EMBASE were systematically searched from inception until 3rd January 2025 for observational studies investigating effectiveness and safety of abrocitinib, baricitinib and upadacitinib for the treatment of AD. The primary outcomes were the proportion of patients achieving a ≥75% improvement in the Eczema Area and Severity Index (EASI-75) after 12 and 16 weeks, respectively. Secondary outcomes included the proportion of patients achieving EASI-90 and the proportion of patients experiencing adverse events (AE). As most studies reported outcomes combined for all doses of JAKi and only few studies reported exclusively for the different dosages, all outcomes are reported for all dosages combined.

Results:

A total of 58 real-world studies with 336 patients treated with abrocitinib, 586 with baricitinib, and 2,599 with upadacitinib were included. The proportion of patients achieving EASI-75 was 62% (95% confidence interval [CI]: 34-84%) and 62% (95% CI: 48-74%) for abrocitinib, 53% (95% CI: 39-67%) and 51% (95% CI: 31-70%) for baricitinib, and 70% (95% CI: 65-75%) and 82% (95% CI: 73-88%) for upadacitinib after 12 weeks and 16 weeks, respectively. The proportion of patients achieving EASI-90 was 46% (95% CI: 24-70%) and 23% (95% CI: 15-34%) for abrocitinib, 29% (95% CI: 21-37%) and 24% (95% CI: 16-34%) for baricitinib, and 59% (95% CI: 47-71%) and 60% (95% CI: 43-68%) for upadacitinib after 12 weeks and 16 weeks, respectively. The most frequently reported AEs across all JAKi were acne, HSV infection, nausea, and headache occurring in 22.0% (95% CI: 15.7-30.0%), 5.2% (95% CI: 1.5-16.8%), 9.8% (95% CI: 4.9-18.7%), and 5.5% (95% CI: 2.1-13.7) of patients treated with abrocitinib, 6.2% (95% CI: 2.8-13.4%), 6.7% (95% CI: 3.7-11.7%), 7.1% (95% CI: 3.8-12.7%), and 3.7% (95% CI: 1.8-7.7%) of patients treated with baricitinib, and 14.4% (95% CI: 10.6-19.3%), 6.8% (95% CI: 4.2-11.0%), 3.1% (95% CI: 1.4-7.05), and 5.1% (95% CI: 3.2-8.7%) of patients treated with upadacitinib, respectively.

Conclusion:

JAKis demonstrate high effectiveness and safety in real-world as observed in trials. Importantly, HSV and acne appear to be the most common adverse events reported in published real-world studies. However, lack of reporting of outcomes according to dosages complicates conclusion and the risk of channeling bias (healthy user effect) cannot be refuted.



Abstract N°: 8306

Tralokinumab therapy in head and neck atopic dermatitis: a case series of 18 patients

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Introduction & Objectives:

The head and neck area is frequently affected in atopic dermatitis (AD). Lesions in visible areas such as in the head and neck AD subtype are associated with significant impact in the quality of life of these patients. Treatment of this specific location can be challenging given the limitations of treatment with topical corticosteroids and the scarcity of literature on this matter. In our study we describe the efficacy of tralokinumab therapy in 18 patients with head and neck AD.

Materials & Methods:

Retrospective observational single-center study including patients with atopic dermatitis affecting the head and neck area treated with tralokinumab.

Results:

A total of 18 patients were identified. The median age was 38 years. All of them had already received systemic therapy and 33.3% of the patients in our group, prior biologic therapy. About 83.3% of patients had at least another comorbidity. In our study, a mean basal EASI score of 22.7 and mean NRS of 6.4 were found. After three months of treatment, 63.6% of the patients with head and neck dermatitis showed complete remission of lesions in this area, with a mean NRS of 3.6.

Conclusion:

Head and neck dermatitis is a difficult-to-treat area in atopic dermatitis. Tralokinumab may represent a suitable therapeutic option in this group of patients.

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Abstract N°: 8355

A Case of Phosphoglucomutase 3 Deficiency Presenting with Severe Atopic Dermatitis and Recurrent Infections: Response to Dupilumab Therapy

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Introduction & Objectives:

Phosphoglucomutase 3 (PGM3) deficiency is a rare autosomal recessive disorder characterized by immune dysregulation and abnormal glycosylation. The clinical spectrum ranges from hyper-IgE syndrome-like phenotypes to combined immunodeficiency, with features including severe atopic manifestations, recurrent infections, elevated IgE, eosinophilia, and variable neurocognitive and skeletal abnormalities.

We describe a 3-year-old boy with homozygous PGM3 variant presenting with severe atopic dermatitis, recurrent infections, markedly elevated IgE, and eosinophilia who responded to dupilumab therapy.

Materials & Methods:

A 3-year-old boy born to consanguineous parents presented with a 2-year history of progressively worsening skin lesions. The patient presented with multiple, erythematous, eroded, hypertrophic lesions over extremities along with eczematization and serous drainage in head and neck region. Bilateral conjunctivitis with crusting and hyperemia was noted. His medical history included bronchiolitis at 5 months of age, anaphylaxis following chickpea ingestion at age 2, and multiple food allergies to lentils, beans, and eggs.

Growth parameters including weight, height and head circumference were within normal percentiles. However, the patient exhibited neurodevelopmental delay with absence of sentence formation.

Laboratory studies included CBC, immunoglobulin levels, complement studies, and genetic testing for primary immunodeficiency disorders.

Results:

Laboratory investigations revealed persistently elevated eosinophilia with percentages ranging from 1.5% to 51.2% (normal 0-7%) and absolute counts of 0.31-4.77 × 10^3/µL (normal 0-0.8 × 10^3/µL). Total IgE was markedly elevated at >2500 IU/mL (normal <100 IU/mL). Complement studies showed consistently low C4 levels of 0.03-0.04 g/L (normal 0.1-0.4 g/L).

Initial management with topical corticosteroids, emollients, and antimicrobial wash therapy provided minimal benefit. The patient was subsequently hospitalized with fever (38.7°C) and vesicular eruptions consistent with eczema herpeticum. Treatment with intravenous acyclovir, intravenous immunoglobulin, wet wrap therapy, and intensified topical steroids yielded limited improvement.

Genetic testing identified a homozygous missense variant in the PGM3 gene (NM_015599.3:c.145A>T (p.Arg49Trp)), classified as a variant of uncertain significance associated with autosomal recessive

Immunodeficiency 23. Skeletal and neurologic findings of the patient were in line with the diagnosis of PGM3 deficiency.

Following diagnosis, dupilumab therapy (200 mg sc) was initiated, resulting in marked improvement in the patient's skin condition starting after the first dose of dupilumab. Eosinophil counts decreased from 45-51% to 7.5% after treatment. Total IgE levels also showed a decreasing trend. He had no further episodes of skin infections during the 4 month follow-up period.

Conclusion:

This case emphasizes the importance of considering monogenic immune disorders in patients with early-onset, severe atopic dermatitis accompanied by recurrent infections and elevated IgE. Genetic testing is essential for accurate diagnosis, and dupilumab therapy represents a promising targeted approach for managing the cutaneous manifestations of PGM3 deficiency. In addition, this case illustrates the efficacy of dupilumab in managing the cutaneous manifestations of PGM3 deficiency.



Abstract N°: 8385

Lipid and Hepatic Changes in Patients Treated with Upadacitinib: A 52-Week Follow-Up Study

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Introduction & Objectives:

Upadacitinib, a selective JAK inhibitor, has been associated with changes in lipid, and hepatic parameters in clinical trials. Reported alterations include dose-dependent increases in lipid parameters, and elevations in liver enzymes (Gamma-glutamyl transferase, GGT, and alanine aminotransferase ALT). However, the long-term real-world impact of these changes remains uncertain. This study aims to evaluate the analytical changes in patients treated with upadacitinib over 52 weeks.

Materials & Methods:

We conducted a prospective observational study including AD patients who initiated upadacitinib for the first time. Lipid, and hepatic parameters were monitored at baseline and throughout the 52-week follow-up period. Changes in lipid profile and liver enzymes were analyzed.

Results:

After 52 weeks of treatment, 37 AD patients were included. Mean age of the patients was 29.38 (12.02 SD) years, being 62.2% (23/37) of them female. No significant changes were observed in liver enzyme levels compared to baseline, ALT (20.00 vs 23.51, p=0.13), GGT (19.67 vs 23.52, p=0.07). Changes in total cholesterol were observed, (169.93 vs 189.13 p=0.015), however no other significant changes were reported in any other lipid parameters; LDL (112.50 vs 120.80, p=0.18), HDL 60.30 vs 62.70 p=0.32). No cases of significant lipid alterations requiring intervention, or drug-induced liver injury were detected.

Conclusion:

In this real-world cohort, upadacitinib treatment did not lead to significant lipid or hepatitc alterations over 52 weeks. These findings suggest that routine laboratory monitoring, while recommended, may not frequently detect clinically relevant alterations. Further studies with larger populations are warranted to confirm these results.



Abstract N°: 8404

Patients with Atopic Dermatitis in visible Areas have a high Disease Burden and respond well to Treatment with Biologics and JAK Inhibitors: Results from the TREATgermany Registry

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Introduction & Objectives:

TREATgermany is a prospective registry for moderate to severe atopic dermatitis (AD) in adult patients, in which currently 2,369 patients are followed up. Patients with AD often suffer from a high disease burden, especially when visible parts of the body such as the face and arms are affected.

Materials & Methods:

Here we analyzed a subgroup of 1169 patients who received a new systemic therapy with a follow-up visit (FUV) no earlier than 28 days after the start of systemic therapy. The target population included 786 patients with visible involvement (Eczema area severity index (EASI) head >=2 or EASI arms >=4), of whom n=586 received a biologic (dupilumab, tralokinumab or lebrikizumab) and n=119 a JAK inhibitor (upadacitinib, baricitinib or abrocitinib).

Results:

The Dermatology life Quality Index (DLQI) of patients with visible skin lesions treated with biologics decreased from 14.5 to 5.4 (minus 9.1) at the first follow-up visit. In patients treated with JAK inhibitors, the treatment response was similar, with an improvement from 14.9 to 4.3 (minus 10.6). In comparison, patients who did not have facial and arm involvement showed an improvement of the DLQI from 11.9 to 5.0 (minus 6.9) when treated with biologics (n= 318) and from 10.8 to 4.7 (minus 6.1) when treated with JAK inhibitors (n= 49).

Sleeplessness in the last 3 nights and pruritus in the last 3 days of patients with visible area involvement were also significantly improved both with biologic therapy (improvement of 4.0 and 3.7, respectively, on the numeric rating Scale (NRS) from 0-10) and with JAK inhibitor therapy (improvement of 4.3 and 4.4, respectively, on the NRS).

When visible areas were involved, the initial POEM (Patient Oriented Eczema Measure) was elevated and a clear improvement could be achieved with both, biologics (20.1 at the initial visit and reduction of the 1st FUV to 9.0, improvement of 11.1) and JAK inhibitors (from 20.6 to 7.7, improvement of 12.9). The initial POEM score was lower in patients when visible areas were not affected: an improvement from 17.5 to 8.3 (9.2 point improvement) was seen in patients treated with biologics, and from 16.1 to 7.9 (8.2 point improvement) in patients treated with JAK inhibitors.

Conclusion:

In summary, patients with visible area involvement reported a significant improvement in their quality of life and their symptoms with both biologic and JAK inhibitor therapy.



Abstract N°: 8426

Treatment with an abrocitinib surrogate molecule alleviates disease phenotype and prevents skin barrier impairment during flare-up in a humanized mouse model of atopic dermatitis

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Introduction & Objectives:

Treatment with the JAK1 inhibitor Abrocitinib (Abro) alleviates clinical signs of atopic dermatitis (AD) and inhibits flare activity in patients. Here, we aimed to explore mechanisms whereby Abro functions to reduce AD disease recurrence using a humanized AD mouse model where disease relapse can be observed following exposure to sonic stress.

Materials & Methods:

Abdominal skin from 3 healthy donors was transplanted onto 60 beige-SCID mice. 30 days after transplantation, grafted skin was injected intradermally with autologous *in vitro* Th2-polarized peripheral blood mononuclear cells (PBMCs). After xenograft development of an AD phenotype, mice received a daily oral administration of vehicle or PF-06667291 (PF; abro surrogate molecule) for 14 days. One day after treatment discontinuation, mice were exposed to sonic stress for 24h. 14 days following sonic stress exposure, macroscopic imaging confirmed the sonic-stress-induced flare. Xenografts were also analysed by histochemistry, quantitative (immuno-)histomorphometry or RNA-Seq.

Results:

Treatment with PF in the AD xenografts was found to significantly reduce epidermal thickness, and tendentially increased filaggrin and claudin-1 expression. PF also slightly decreased the number of CD3 T-cells , including those expressing the resident marker CD45RO or the skin homing molecule CLA. Thus, in line with clinical data for Abro, therapeutic treatment with PF led to alleviation of AD signs in our humanized mouse model.

RNASeq analysis after disease amelioration and induction of lesion recurrence revealed upregulation of genes associated with skin barrier (*IVL, HRNR, CLDN8*) and lower expression of genes associated to inflammation, i.e. alarmins (*S100A7, S100A8*), Th1 (*CXCL9, CXCL10*), Th17 (*CXCL1, DEFB2*), and Th2 (*CCL13, -17, -18, -22,*) in grafted skin from at least two donors in the PF treated group.

The number of CD3 T-cells were just slightly lower in xenotranplants exposed to PF before flare up induction, as compared to those deriving from vehicle treated mice. Similarly, epidermal thickness and the expression of involucrin did not differ between treated and untreated xenotransplants after sonic stress. However, higher level of filaggrin, keratin-1 and in particular claudin-1 were detected with the latter reaching significance, in PF treated-samples compared to vehicle xenotransplants after lesion reappearance.

Conclusion:

Thus, PF was found to reduce the severity of sonic stress-induced inflammatory relapses and enhance barrier integrity in AD-induced xenografts. These data suggest that keratinocyte responses to Abro may contribute to its ability to inhibit AD flare reappearance.



Abstract N°: 8432

TADPol study: a real-world evidence on dupilumab and upadacitinib in the treatment of moderate-to-severe atopic dermatitis in Poland.

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Introduction & Objectives:

TADPol (Treatment of Atopic Dermatitis in Poland) study is a prospective multicenter project aimed to compare the effectiveness and safety of dupilumab (DUPI) and upadacitinib (UPA) in the treatment of moderate to severe atopic dermatitis (AD) over a 52-week period among AD patients in Poland.

Materials & Methods:

This real-world observational study included 118 patients diagnosed with moderate-to-severe atopic dermatitis (AD). The cohort consisted of 53.4% males and 46.6% females, with a mean age of 25.4 ± 15.5 years. Patients received either dupilumab (DUPI; 52.6%) or upadacitinib (UPA; 47.4%). Most patients (71.2%) were biologically naïve at the start of therapy. The follow-up period was 52 weeks.

Baseline characteristics varied slightly between treatment arms. In the DUPI group (n=62): mean age 23.5 years, Eczema Area and Severity Index (EASI) 26.7, SCORing of Atopic Dermatitis (SCORAD) 67.5, itch Visual Analogue Scale (VAS) 7.5, Dermatology Life Quality Index/Children's Dermatology Life Quality Index (DLQI/CDLQI) 18.2, and 19.3% with prior biologic use. In the UPA group (n=56): mean age 27.5 years, EASI 29.7, SCORAD 60.2, itch VAS 7.3, DLQI/CDLQI 18.1, and 39.2% with prior biologic exposure.

Results:

Both DUPI and UPA significantly improved EASI scores. UPA demonstrated a faster onset of action, with early response evident by Week 4 and a slight edge in achieving full clearance. However, DUPI showed progressive improvement, with comparable or superior outcomes by Week 52.

Long-term symptom control favored DUPI. At Week 52, itch VAS was 1.7 in the DUPI group compared to 3.8 in the UPA group. DUPI also outperformed UPA in pain reduction starting at Week 16, with final values of 0.6 vs. 1.9,

respectively. Treatment persistence beyond Week 24 was higher in the DUPI group, suggesting improved tolerability and long-term adherence.

Conclusion:

Preliminary real-world findings highlight distinct response dynamics between DUPI and UPA. While UPA provides faster initial improvement in moderate-to-severe AD, DUPI offers superior long-term control of itch and pain, along with better treatment retention. These results support a personalized approach to treatment selection based on clinical presentation, patient expectations, and therapeutic goals.



Abstract N°: 8466

Latest Research Hot Spots of Atopic Dermatitis Management Using Janus Kinase Inhibitor: A Bibliometric Analysis and Visualized Review

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Introduction & Objectives:

Atopic dermatitis (AD) affects 5–20% globally, with severe cases requiring systemic therapies. Advancements like Janus kinase inhibitors highlight the need to explore the evolving research landscape for better treatments.

Materials & Methods:

The databases used to search for publications were Web of Science Core Collection with the search strategy that included the search terms "(Janus kinase inhibitors OR JAK) AND (atopic dermatitis)." A total of 797 publications were identified, of which 776 were included in the study after exclusions. The following tools were employed to analyze the publication output, citations, keyword co-occurrence, and international collaborations of the included studies: VOSviewer, Excel, and Draw. io.

Results:

The USA had the highest number of publications (34%), followed by Germany (12.62%), Japan (11.87%), and China (8.5%). Pfizer funded 38 studies, AbbVie supported 35, and Eli Lilly contributed to 32. Emma Guttman-Yassky authored 25 publications, while Eric Simpson contributed 22. Among journals, The Journal of Allergy and Clinical Immunology and The Journal of Dermatological Treatment were notable, with 20 and 26 publications, respectively. Highly cited references included "Oetjen (2017)" with 674 citations and "Wollenberg (2018)" with 393.

Conclusion:

This study highlights global research trends and collaboration networks, offering insights to guide future research on JAK inhibitors for atopic dermatitis.

Keywords: The following keywords were frequently used; these include "atopic dermatitis" and "JAK inhibitors".



Abstract N°: 8472

An animated educational video is effective for improving treatment outcomes in pediatric patients with atopic dermatitis: A prospective trial.

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Introduction & Objectives: Compliance with treatment of pediatric atopic dermatitis (AD) is low, despite parents' distress over their children's suffering.

We aimed to assess whether viewing an educational video that explains the pathophysiology of AD and the rationale behind the treatment protocol improves disease outcomes in children with atopic dermatitis.

Materials & Methods: We scripted an educational video which was animated by a professional studio. 100 pediatric patients with AD were enrolled and treated according to the standard treatment protocol for AD, based on the Consensus-based European guidelines for treatment of AD in adults and children.

The patients were divided into two groups, matched by age and disease severity. The intervention group received the animated video by email as well an individualized printed treatment plan, while the control group received only the individualized printed treatment plan. Disease severity and quality of life were assessed at 1and 3 months after the initial visit.

Results: Eighty-two patients completed the requirements and were included in the statistical analysis. The intervention group showed statistically significant improvement in all outcomes, with EASI SCORAD, pPNRS, and CDQLI scores improving significantly at both at 1 month and at 3 months compared to the control group.

Conclusion: An animated educational video can improve patient outcomes in pediatric AD.



Abstract N°: 8496

Drug survival of systemic off-label therapies for treatment of hand eczema

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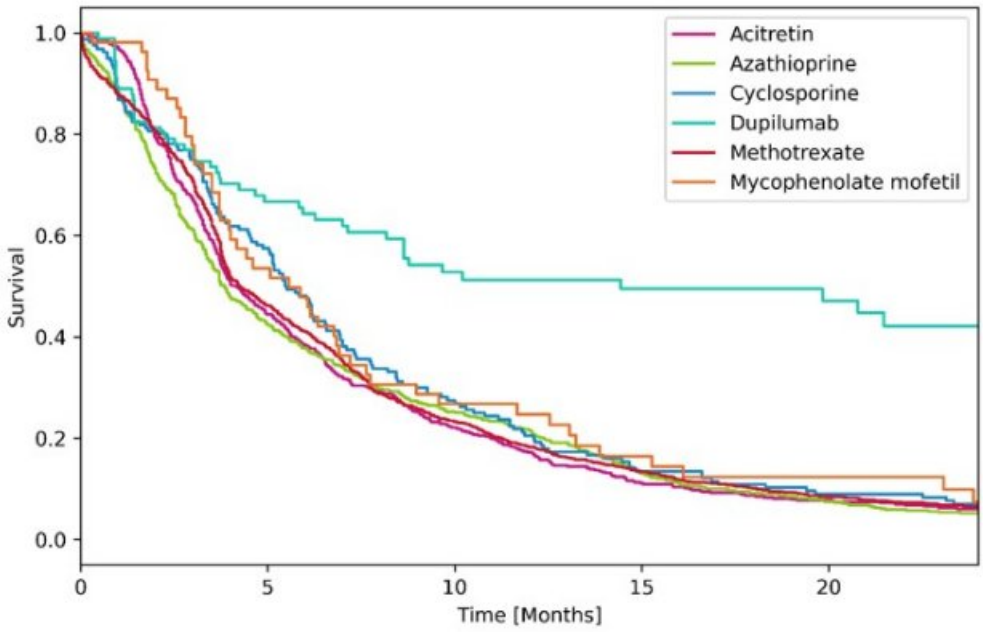
Introduction & Objectives: Hand eczema (HE) is a common and often chronic inflammatory skin disease. First-line treatment includes trigger avoidance, emollients, and topical corticosteroids (TCS) or topical calcineurin inhibitors (TCI), and recently delgocitinib was approved as an additional topical treatment option. Alitretinoin is the only systemic treatment approved for HE, however a large proportion of patients receive off-label therapies when initiating systemic therapy. Prior studies, investigating drug survival of off-label treatments in HE, have often been limited by small sample sizes and not included biologics. This study aimed to assess drug survival of off-label treatments, including biologics, in a nationwide HE cohort.

Materials & Methods: All Danish patients diagnosed with HE who were treated with off-label systemic therapy between 2008 and 2024 were included in the study. Off-label treatment included acitretin, azathioprine, cyclosporine, dupilumab, methotrexate and mycophenolate mofetil. Data was extracted from Danish national patient registries. Treatment series started at initiation and terminated at the end of drug supply, migration, death or initiation of another HE treatment. A period of 120 and 180 days was considered an allowable gap in drug supply. Patients could be included in multiple groups, but only the first treatment series with each drug was included. Unadjusted survival curves were presented using Kaplan-Meier curves and a frailty model (Cox-regression models) was used for risk assessment. The frailty model was adjusted for sex, age, asthma, atopic dermatitis, calendar year, socioeconomic status, and time since hospital-confirmed diagnosis.

Results: This study comprised 2,251 patients with HE [mean age: 50.3, standard deviation (SD) 14.7, 57.0% female] and 2,783 treatment series. A total of 1,236 (54.9%) patients received methotrexate, 594 (26.4%) acitretin, 648 (28.8%) azathioprine, 160 (7.1%) cyclosporine, 91 (4.0%) dupilumab and 54 (2.4%) mycophenolate mofetil. Majority of patients had been treated with either potent and/or very potent TCS (95.8% and 76.7%, respectively) prior to systemic treatment. When comparing off-label therapies using Cox proportional hazard regression model with acitretin as reference, dupilumab and cyclosporine showed significantly higher drug survival compared to acitretin (HR: 0.43, 95% CI: 0.32-0.58 and HR: 0.81, 95% CI: 0.67-0.98, respectively) with dupilumab having the highest drug survival of all treatments both for HE patients with (n=41) and patients without AD (n=55), although drug survival was highest in HE patients with AD treated with dupilumab. In contrast, azathioprine (HR: 1.02, 95% CI: 0.91–1.16), methotrexate (HR: 0.99, 95% CI: 0.89–1.10), and mycophenolate mofetil (HR: 0.84, 95% CI: 0.63–1.13) did not show a significant difference in drug survival when compared to acitretin. Finally, 869 (38.6%) patients had been treated with >1 off-label systemic therapy.

Conclusion: Drug survival of traditional systemic therapies was comparable with cyclosporine showing slightly higher drug survival compared to acitretin, but comparable to most other systemic therapies. Dupilumab demonstrated the highest drug survival among off-label treatments, potentially reflecting higher efficacy and tolerability. This may indicate that most off-label treatment options in HE are inadequate in achieving disease control.

Figure 1: Kaplan-Meier curve stratified by off-label treatment for CHE illustrating time to treatment discontinuation.





Abstract N°: 8498

Adverse events following systemic therapy targeting the immune system in patients with atopic dermatitis

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Introduction & Objectives: Targeted therapies with monoclonal antibodies, biologics, as well as Janus kinase inhibitors (JAKi) have become important tools in the clinical management of patients with moderate to severe atopic dermatitis (AD). Upon therapy with biologics, the development of a *de novo* or worsening of a pre-existing immune-mediated disorder have been reported. We aimed at investigating the spectrum of adverse events (AE) observed in AD patients on systemic therapies and at identifying possible interferences with the immune system.

Materials & Methods: This single-center retrospective study provides a descriptive analysis of AE observed in 145 patients on systemic therapies (n=288) for AD.

Results: Overall, 269 AE had been reported in AD patients treated with oral immunosuppressants, biologics (dupilumab, tralokinumab) and/or JAKinh, of which most were mild (67.3%), but in 27.1% the culprit drug had to be stopped. AE arising from immune or cytokine imbalance upon biologics were ocular surface disease (67/75 events), the onset or worsening of autoimmune/-inflammatory diseases, including Crohn's disease, sarcoidosis, vitiligo, alopecia areata, and psoriasis, as well as cutaneous herpes virus infections. AE upon immunosuppressant and JAKi therapy were mainly related to infections and abnormal laboratory results, e.g. increased creatinine and liver enzyme levels.

Conclusion: Novel therapies interfering with the immune system may cause dysbalances followed by unexpected, paradoxical AE. Assessing the spectrum of AE to biologics and JAKi is important for further patient management, but also for understanding immunologic mechanisms and interactions *in vivo*.



Abstract N°: 8504

Diagnostic and Treatment Challenges in Atopic Dermatitis Associated with Food Allergies

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Introduction & Objectives:

Atopic dermatitis is a chronic inflammatory skin condition frequently associated with food allergies, particularly among children. The complexity of this interaction leads to significant diagnostic and therapeutic challenges, with a considerable impact on patients' quality of life.

Materials & Methods:

This paper aims to analyze the difficulties in diagnosing and managing atopic dermatitis associated with food allergies and to provide solutions based on the latest scientific evidence.

Results:

Accurate diagnosis is often hindered by the overlapping symptoms of atopic dermatitis and food allergies. Sensitization tests, such as skin prick tests and specific IgE measurements, can be useful but have limitations. Therapeutic interventions, including elimination diets and topical or systemic treatments, require careful individualization to avoid adverse effects and nutritional deficiencies.

Conclusion:

Atopic dermatitis associated with food allergies represents a multidimensional challenge in family medicine and pediatrics. Diagnosis and treatment should be approached in an integrated manner, involving a multidisciplinary team, in order to optimize clinical outcomes and improve patients' quality of life.



Abstract N°: 8519

CD1a-targeted PD-1 agonist bispecifics achieve localized inhibition of inflammatory T cells in Atopic Dermatitis

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Introduction & Objectives:

T cells are central in the pathogenesis of atopic dermatitis (AD), reacting to environmental allergens, driving the inflammatory response, thereby causing a compromised skin barrier. In the regulation of T cell activation, the PD-1 receptor serves as a crucial immune checkpoint. By delivering inhibitory signals, PD-1 helps maintain the threshold for T cell activation, thereby limiting the responses of effector T cells, promoting the resolution of inflammation, and establishing T cell tolerance.

Materials & Methods:

In an effort to address inflammatory skin diseases, such as AD, we developed a skin-targeted PD-1 agonist as a novel therapeutic strategy. This approach utilizes a PD-1 agonist attached to cell-bridging bispecific antibodies containing an affinity enhanced targeting domain, which selectively binds to CD1a. CD1a is a non-restricted, HLA-related molecule that is prominently expressed on skin antigen-presenting cells (APCs). The PD-1 agonist component is designed to inhibit T cell activity at the immune synapse when the bispecifics attach to CD1a during antigen presentation.

Results:

Binding specificity of the bispecifics to APCs was shown in co-culture assays where IL-2 secretion from CD4 T cells was inhibited in APCs positive for CD1a but not in CD1a negative APCs, confirming no systemic activity. Furthermore, we could confirm that the PD-1 binding domain of the bispecifics does not compete with the binding of natural PD-1 ligands (PD-L1 and PD-L2) and instead acts additively with endogenous PD-L1 to inhibit T cell activation, demonstrated in a co-culture assay of primary monocyte derived Langerhans cells (MoLCs) and T cells. Finally, treatment with the bispecifics reduced house dust mite (HDM)-stimulated IL-13 release in autologous MoLC - T cell assays. Thus, the *in vitro* results validate that the bispecifics specifically and effectively inhibit MoLC-stimulated T cell activation.

Target engagement experiments conducted on healthy human skin *ex vivo* revealed co-localization of the bispecifics and CD1a, confirming the specific binding of fluorescently labeled molecules to APC. Additionally, in AD lesional skin, bispecific-labelled APCs were found in proximity to T cells, further highlighting their potential to target T cells in the affected tissue. Quantitative (immuno-)histomorphometry demonstrated that the CD1a-targeted PD-1 bispecific effectively suppress T cell proliferation and cytokine array analyses confirmed reduced release of pro-inflammatory mediators in AD lesional and peri-lesional skin of 3 patients.

Conclusion:

These findings underscore the potential of CD1a-targeted PD-1 agonists to achieve localized inhibition of inflammatory T cells within the skin. This localized approach offers the significant advantage of circumventing

systemic immunosuppression, making it a promising therapeutic strategy for managing inflammatory skin conditions such as AD.



Abstract N°: 8586

Enhanced Skin Condition in Atopic Dermatitis Through Multi-Omics Analysis of an Emollient Cream with Rhealba Oat and Helichrysum

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin condition characterized by itchy, red, and swollen skin. It affects millions of individuals worldwide, significantly impacting their quality of life. Despite advances in understanding the pathophysiology of AD, the precise mechanisms underlying its development and progression remain incompletely understood. Recent research has highlighted the potential of metabolomics — a comprehensive study of small molecules and metabolic pathways — as a powerful tool to unravel complex biological processes and identify novel biomarkers for various diseases. The aim of this study was to investigate the impact of emollient cream containing Rhealba Oat and Helichrysum on cutaneous metabolome to evaluate the improvement of atopic dermatitis skin conditions.

Materials & Methods:

A study on 21 women with mild to moderate AD (SCORAD 30.5) applying Rhealba Oat/ Helichrysum emollient cream once daily for 28 days. Samples were taken before and after treatment for microbiota, metabolites, and lipidomic analysis. Metabolomics used UHPLC-HRMS, processed with XCMS and W4M, and mapped with Metexplore. Lipidomics used a QExactive mass spectrometer with LipidXplorer software. Microbiota sequencing was done by GeT-PlaGe, INRAe Toulouse, amplifying the V1V3 region from genomic DNA.

Results:

Rhealba Oat/Helichrysum emollient cream application resulted in a marked increase in tryptophan metabolism and microbiota diversity. Additionally, indoles derivates and kynurenine were increased and can act on skin inflammation. Changes in branched-chain amino acids were observed, with dipeptides Gly-Leu and Leu-Gly enhancing skin hydration clinically.

Application of Rhealba Oat/Helichrysum emollient cream improves skin barrier function by increasing the synthesis of long-chain ceramides and acyl-ceramides, while reducing short-chain ceramides, notably CER NS. The study also revealed a significant increase in the levels of CER EOS, an essential component of the skin’s lamellar structure, and an improvement in the synthesis of the CER NP class. These changes contribute to strengthening and protecting skin barrier function, reducing skin dryness, and balancing ceramide levels in pathologies such as atopic dermatitis. All these results were associated to a significant improvement of the clinically observed skin barrier with a significant decrease in the severity of AD from SCORAD assessment.

Conclusion:

The application of Rhealba Oat/Helichrysum emollient cream significantly improves skin conditions in women with mild to moderate atopic dermatitis over 28 days. The treatment enhances tryptophan metabolism, microbiome diversity, and increases indole derivatives and kynurenine, which may reduce skin inflammation and cytokines production. Furthermore, the cream improves skin barrier function by increasing long-chain ceramides and acyl-ceramides while reducing short-chain ceramides, notably CER NS.



Abstract N°: 8592

Which primary endpoint should I choose for an AD study to best discern a difference from placebo?

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Introduction & Objectives:

Choosing a primary endpoint that will discern a difference in active treatment versus placebo in early phase atopic dermatitis (AD) studies is key to a successful study. We examined several continuous and binary endpoints that are commonly used in AD studies and using statistical methodologies, we present our recommendations. We also examined the trend over time to assess the potential impact of higher placebo rates being observed on the choice of endpoint.

Materials & Methods:

Using data from 10 (ten) in-house studies in atopic dermatitis conducted over the last five years, we compare power and variability for the following endpoints: Change from baseline in EASI, Percent change from baseline in EASI, clinical success rate (defined as a 2-point decrease from baseline in IGA and a score of 0 or 1 at the primary endpoint visit), 2-point decrease from baseline in IGA, EASI50, EASI75. Linear mixed models and Chi-squared based tests were used for continuous and binary primary endpoints, respectively.

Results:

Results show that using binary variables such as clinical success or EASI50/EASI75 are less robust than continuous ones when trying to discern a difference from placebo in earlier phase studies. Through the assessment of *p*-values and point estimates, we see that power is greater when using continuous endpoints to examine a separation from placebo.

Conclusion:

Statistical theory generally supports the choice of a continuous endpoint versus a binary one and this work supports this recommendation.



Abstract N°: 8611

Atopic dermatitis (AD) in patients with skin of colour: A retrospective analysis from a tertiary dermatology centre

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Introduction & Objectives:

Despite recent advances in management of atopic dermatitis, patients with skin of colour remain underrepresented in clinical trials and real-world data studies. Variations in genetics, phenotypes, comorbidities and tolerability may influence treatment choise and real-world outcomes. This study assessed the effectiveness, tolerability, and patient experience of EMA-approved advanced therapies (biologics and JAK inhibitors) in patients with skin of colour diagnosed with moderate-to-severe AD.

Materials & Methods:

Fifty consecutive adult patients with skin of colour diagnosed with moderate-to-severe atopic dermatitis seen from 10/24 to 05/25 in our specialist clinic were included. Baseline characteristics, such as age, sex, ethnicity, and Fitzpatrick skin type were noted. Disease history, comorbidities, treatment course, clinical outcomes (EASI, DLQI), and adverse events were extracted and analysed retrospectively using SPSS. At baseline patients were already on a conventional systemic treatment or on an advanced treatment.

Results:

Mean age was 29.6 years; 56% were male. Most were of Bangladeshi (64%), Chinese (14%), or Pakistani (6%) background. Commonest Fitzpatrick skin types were IV and V. Disease onset was typically in childhood. Asthma (48%), hay fever (42%), and food/environmental allergies (38%) were common comorbidities. Ocular disease (24%), eczema herpeticum (20%), and psychological comorbidities (12%) were also reported. Most patients had ≥2 comorbidities, highlighting the complex clinical profile of this cohort.

Dupilumab was most used (58%), followed by upadacitinib (22%), tralokinumab (8%), lebrikizumab (8%), and abrocitinib (4%). Most were on their first advanced therapy (70%), 24% on second, and 6% to their third. Switching to another therapy was mainly due to suboptimal disease control. Side effects such as conjuctivitis, were another reason for switching, while some patients opted for oral treatments due to being unable to self-inject.

Baseline EASI and DLQI were 21.2 and 16.9. At last visit, these improved to 5.0 and 6.0, respectively. For biologics (n=37), baseline mean EASI was 22.7 (SD 13.2) and DLQI 17.6 (SD 7.1); at last follow-up EASI 6.1 (SD 8.5) and DLQI 6.8 (SD 7.4). For JAK inhibitors (n=13), baseline mean EASI was 16.7 (SD 10.4) and DLQI 14.8 (SD 7.6); follow-up EASI 1.8 (SD 4.0) and DLQI 3.5 (SD 4.9), suggesting a stronger response. However, several patients remained on biologics despite suboptimal control due to some improvement or concerns around JAK inhibitors' safety.

Adverse effects in biologics included ocular surface disease in 32.4% (e.g. conjuctivitis, dry eyes), and facial involvement (24.3%), mostly with dupilumab. JAK inhibitors side effects included acneiform rash (15.4%) and infections (7.7%). Real-world barriers such as medication delays, needle aversion, and topical non-adherence also impacted outcomes.

Conclusion:

In this skin of colour cohort, patients tended to have severe disease and multiple comorbidities. Advanced therapies improved disease severity and quality of life, though responses varied by drug class. Treatment decisions were often influenced by comorbidities, patient preferences, and practical factors, supporting a personalized care approach. Finally, further research is required to better understand the disease and treatment options in this underrepresented group.



Abstract N°: 8702

Long-term use and negative impact of systemic glucocorticosteroids in individuals with atopic dermatitis – analysis of German claims data

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic inflammatory skin disease often associated with severe pruritus and a significant reduction in quality of life. While topical therapies are often the first line of treatment, systemic treatment options are needed in most moderate to severe cases. To date, n=7 systemic drugs are approved for longerm use in Germany. By contrast, systemic glucocorticosteroids (sGCS) are considered as a short-term treatment option only due to their side effect profile.

Materials & Methods:

To investigate the extend of use of sGCS in patients with AD and the incidence of adverse effects using routine claims data from the German Statutory Health Insurance (SHI) system.

A retrospective cross-sectional and longitudinal analysis was performed using anonymised claims data from DAK-Gesundheit (2016-2020), a nationwide statutory health insurance. Individuals with AD were identified using ICD-10 codes (L20). Frequency of sGCS prescription was defined as: 1) the number of quarters with at least one sGCS prescription and 2) the defined daily doses (DDD). Propensity score matching (PSM) was used to control for confounding. Possible side effects (e.g. osteoporosis, diabetes) were modelled in an adjusted logistic regression.

Results:

The prevalence of AD in 2020 was 4.07% (4.12% women, 3.71% men). In the same year, 9.91% of people with AD received sGCS compared to 5.54% of people without AD ($p<0.01$). The prescription rate was significantly higher in women (10.20% vs. 9.42% in men, $p=<0.01$) and in older people. The prevalence of AD and sGCS varied regionally. During 3 years of follow-up, 51% of people with AD who received sGCS were prescribed sGCS for > 1 quarter and 15% for > 6 quarters. The odds of developing osteoporosis (odds ratio 3.95 [definition 1] and 1.80 [definition 2]) and diabetes (odds ratio 1.90 [definition 1] and 1.38 [definition 2]) were significantly higher in people with AD receiving sGCS.

Conclusion:

A significant proportion of people with AD in Germany receive long-term sGCS therapy, contrary to guideline recommendations. The incidence of conditions known to be adverse effects of steroids was significantly higher in people receiving long-term sGCS for AD compared to short-term users and patients without any sGCS use, suggesting the need for optimised care.



Abstract N°: 8706

Dropout rate in digital strategies for the management of atopic dermatitis: Systematic Review and Meta-analysis

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Introduction & Objectives:

Digital interventions offer promising tools for the management of atopic dermatitis (AD), a chronic inflammatory skin condition with significant impact on patients' quality of life. However, high dropout rates in randomised controlled trials (RCTs) may compromise the validity of outcomes and hinder implementation in clinical practice.

Materials & Methods:

A systematic review with meta-analysis and meta-regression was conducted following PRISMA 2020 guidelines. Five databases (PubMed, Scopus, Web of Science, Cochrane Library, CINAHL) were searched from inception until April 2025. RCTs reporting dropout rates in digital interventions for AD were included. The Joanna Briggs Institute tool assessed risk of bias. A meta-analysis of proportions estimated overall and subgroup dropout rates. Odds ratio (OR) meta-analyses compared dropout likelihood between digital and control groups. Meta-regression explored the influence of sex, type of digital strategy, follow-up duration, and sample size.

Results:

From 11 RCTs comprising 13 study arms and 2,089 participants, the overall pooled dropout rate was 12.4%. Digital strategies showed a dropout rate of 13.2% versus 11.4% in control arms. No statistically significant difference was found (OR = 1.06; p = 0.67) between groups of study. Meta-regression revealed no significant moderators of attrition.

Conclusion:

Digital interventions for AD present slightly higher dropout rates compared to controls, although differences are not statistically significant. These findings support the inclusion of a 12.4% attrition rate when calculating sample sizes for future trials. Transparent reporting of dropouts is essential to improve the reliability and implementation of digital health research.



Abstract N°: 8853

Safety and efficacy of non-steroidal topical aryl hydrocarbon receptor agonists for the treatment of atopic dermatitis: a systematic review and meta-analysis of randomised controlled trials

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Encore Abstract

Introduction & Objectives:

Current first-line topical treatments for atopic dermatitis (AD) are often limited by concerns related to age, systemic absorption, especially when applied to large body surface areas or under maximal usage conditions and undesirable adverse events (AEs), highlighting the need for alternative therapies.

Materials & Methods:

We performed a systematic review and meta-analysis of seven randomised controlled trials (RCT) comparing topical aryl hydrocarbon receptor agonists (TAHRA), including tapinarof and benvitimod cream, to vehicle at different concentrations and application frequencies in patients with AD, which evaluated outcomes such as Investigator Global Assessment (IGA) scores/Validated Investigator's Global Assessment (vIGA), the Eczema Area and Severity Index (EASI-75), change from baseline in body surface area (BSA) and pruritus score (PS) and safety profiles.

Results:

A total of 1631 patients, 1086 received TAHRA, while 545 received vehicle. Overall, TAHRA led to a significant improvement in the IGA/ vIGA scores (RR 2.38; 95%CI 1.68 to 3.37; $p<0.00001$; Figure 1), EASI-75 (RR 2.94; 95%CI 2.07 to 4.17; $p<0.00001$; Figure 2). Similar findings were observed for mean change from baseline in BSA (MD -6.08; 95%CI -8.00 to -4.16; $p<0.00001$; Figure 3), and PS (Std MD -0.90; 95%CI -1.41 to -0.39;$p=0.0006$; Figure 4). The incidence of AE was significantly higher in the TAHRA group (RR 1.48; 95%CI: 1.19 to 1.85; $p=0.0005$; Figure 5). We found no significant difference in the incidence of serious adverse events (SAEs) (RR of 1.51; 95%CI: 0.34 to 6.64; $p=0.59$; Figure 6). Treatment-emergent adverse events (TEAE), such as folliculitis, were more frequent in the TAHRA group (RR 8.06; 95%CI: 2.75 to 23.60; $p=0.0001$; Figure 7).

Conclusion:

Our findings support the efficacy of TAHRA among different metrics with minimal and tolerable AEs and its use as

a valuable new non-steroidal option for the treatment of AD.

Figure 1. The improvement in the IGA score in the overall population

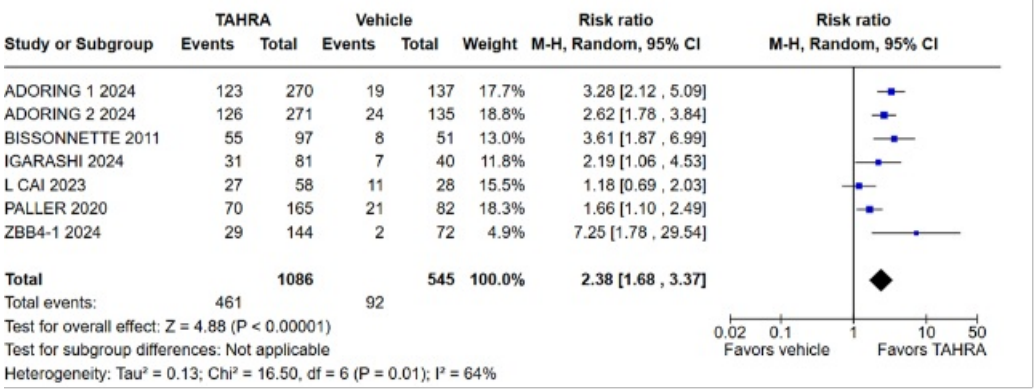


Figure 2. The improvement in the EASI75 score in the overall population

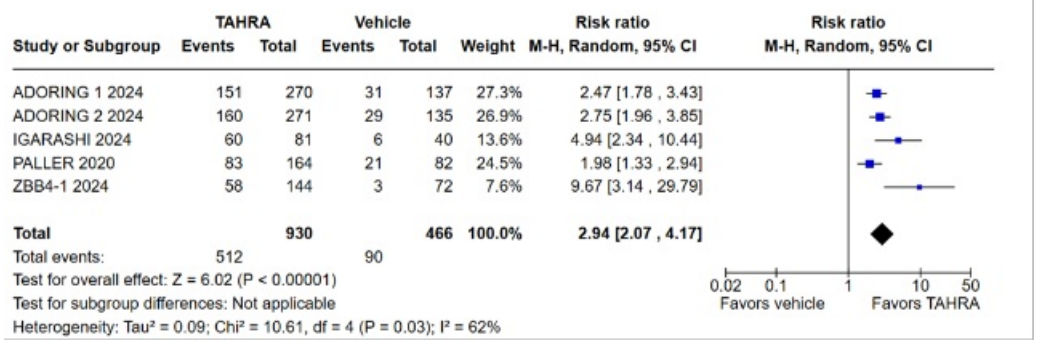


Figure 3. The mean change from baseline in the BSA in the overall population

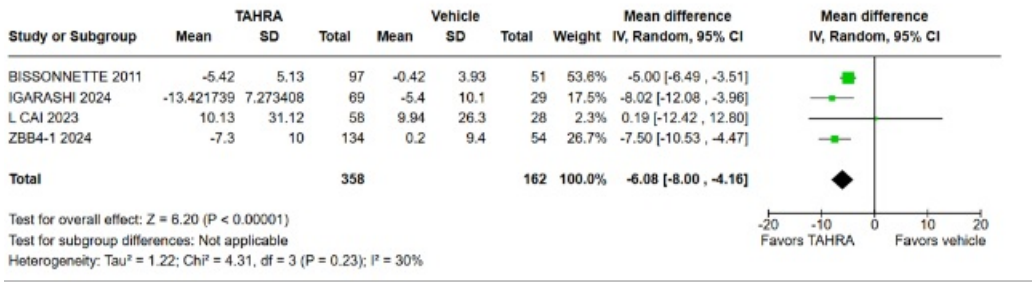


Figure 4. The mean change from baseline in the pruritus score in the overall population

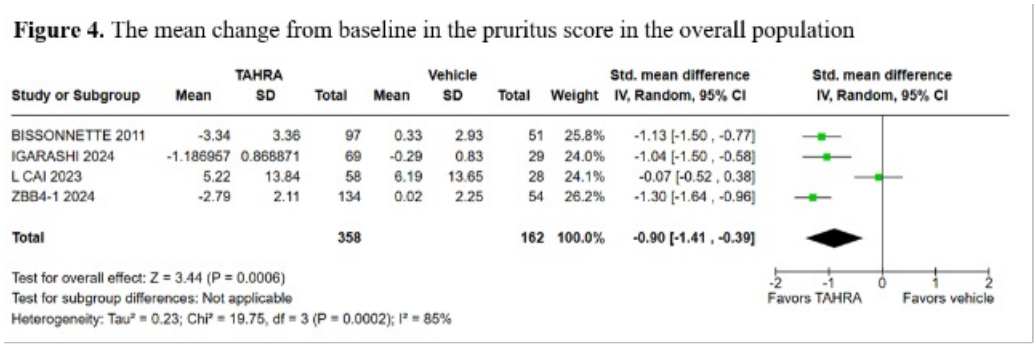


Figure 5. The incidence of any adverse effect in the overall population

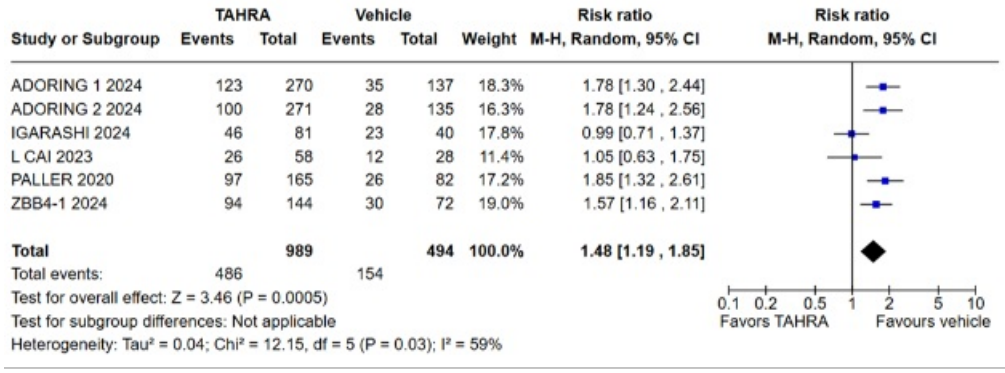


Figure 6. The incidence of serious adverse events in the overall population

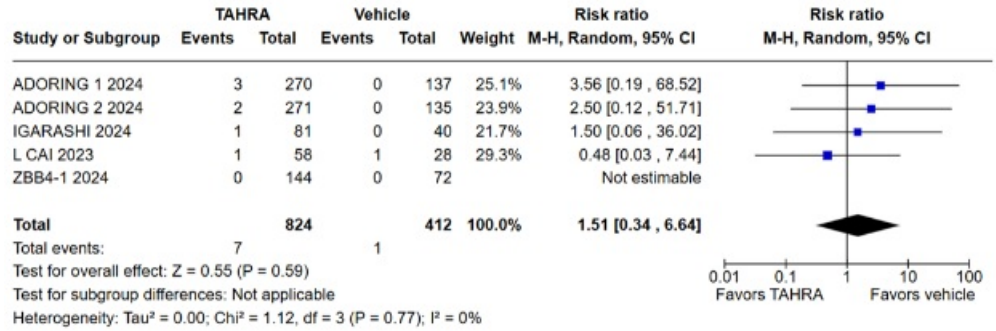
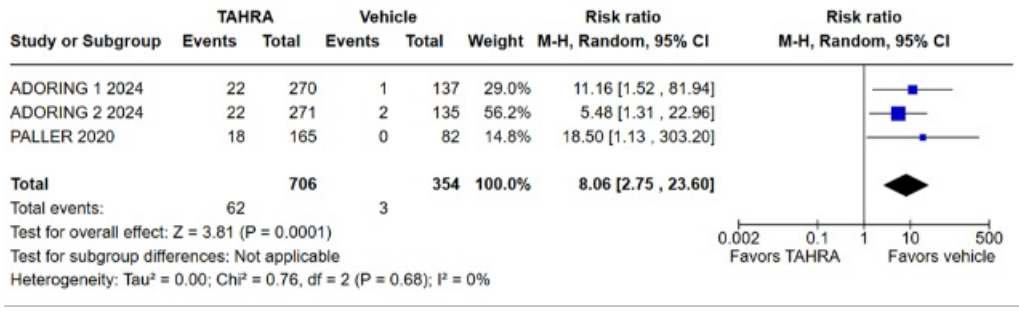


Figure 7. The incidence of folliculitis occurring in ≥ 5% of the overall population





Abstract N°: 8875

Two Sides of the Same Inflammation: Clinical Coexistence of Hidradenitis Suppurativa and Atopic Dermatitis

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Introduction & Objectives:

Hidradenitis suppurativa (HS) is a chronic, inflammatory, and recurrent skin disease, primarily affecting post-pubertal women. It presents with painful nodules, abscesses, and fistulas in intertriginous areas such as the axillae, inframammary folds, groin, and buttocks. These regions contain hair follicles and apocrine glands, central to disease pathogenesis. The impact on quality of life is significant due to chronic pain, drainage, odor, and functional limitations. Management is based on severity and includes topical agents, antibiotics, hormonal therapies, biologics, and surgery. Atopic dermatitis (AD) is a common chronic inflammatory skin condition with a genetic basis. It typically presents with pruritus, xerosis, and characteristic distribution, often beginning in childhood. AD is associated with other atopic disorders such as asthma and allergic rhinitis. Both HS and AD significantly affect quality of life and may share underlying immune dysregulation.

Materials & Methods:

A 19-year-old woman has been followed for HS since 2018, with lesions in the genital area, buttocks, and inframammary folds. These presented as nodules, abscesses, cysts, and fibrotic bands. Her condition worsened after weight gain. In April 2023, isotretinoin was started without significant response. Adalimumab was introduced in August 2023 as a biologic treatment. By March 2024, semaglutide was added, resulting in 12 kg of weight loss (current weight: 102 kg). She also had a history of atopic dermastitis.

Results:

This case report explores the clinical association between hidradenitis suppurativa and atopic dermatitis, and the therapeutic strategies employed for disease management. Biologic therapies for HS have been discussed in the literature; however, treatment options remain limited and often include hormonal therapies or antibiotics. In this case, the patient’s atopic background overlaps with known HS risk factors such as female sex, African descent, and smoking. There appears to be a meaningful connection between the two diseases, suggesting a shared etiopathogenic basis, including impaired signaling, defective epidermal barrier, and dysregulation of antimicrobial peptides (AMPs). This implies the possible involvement of common genetic factors. Studies indicate that HS patients may develop AD, and the most significant clinical link lies in the reduced therapeutic response to HS treatments in atopic patients, and worsening of HS in the presence of AD. This is thought to result from a continuous inflammatory response due to epidermal barrier dysfunction, potentially linked to deficient Notch signaling. Although few studies have directly addressed this comorbidity, clinical experience supports a correlation based on shared pathophysiological traits.

Conclusion:

This case highlights the clinical complexity in managing patients with coexisting chronic dermatologic diseases such as hidradenitis suppurativa and atopic dermatitis. Both conditions significantly impair quality of life and share immunological pathways, supporting the rationale for integrated treatment strategies. While their coexistence is

rarely detailed in the literature, it underscores the importance of an individualized, multidisciplinary approach, with emphasis on early diagnosis and improved access to immunomodulatory therapies in severe or refractory cases.



Abstract N°: 8907

Baseline characteristics, and treatment patterns of skin of colour patients in a Canadian phase 4 study (CANDID) of dupilumab for the management of moderate-to-severe atopic dermatitis.

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Introduction & Objectives:

Insights into the real-world treatment of atopic dermatitis (AD) are key to clinical decision making. The aim of this analysis was to characterize skin of colour patients who receive dupilumab for moderate-to-severe AD in a real-world setting within Canada.

Materials & Methods:

The CANDID phase 4 study is an ongoing, prospective, observational study of patients with moderate-to-severe AD who receive dupilumab according to Canadian-specific prescribing information. We report baseline characteristics and treatment patterns for patients enrolled from October 4, 2023 to March 2, 2025. Analyses are descriptive; no formal statistical comparisons were performed. Of the 305 patients enrolled into CANDID, 46% (n=139) were from diverse backgrounds with skin of colour; this also included Indigenous patients (First Nations, Inuit, and Metis).

Results:

Data from 139 pediatric, adolescent, and adult patients with skin of colour (Asian [19.3%]; Indigenous [11%]; South Asian [8%]; Black/African American [4.3%]; Arab [0.7%]; and Latin [0.7%]) were enrolled from the total study

population of 305 patients (46% of enrolled patients), with 75%, 15%, and 10% being adults, adolescents, and pediatric patients, respectively.

Patients had a high disease burden prior to dupilumab start at enrollment with mean (± standard deviation) scores being 30.7% (21.4%) for body surface area, 20.4 (11.8) for Eczema Area and Severity Index, 7.6 (2.2) for Peak Pruritus Numerical Rating Score, 6.0 (3.0) for Skin Soreness Numerical Rating Score, 4.0 (3.3) for Sleep Disturbance Numerical Rating Score, 17.3 (5.0) for Dermatology Life Quality Index [DLQI] total score, 16.7 (5.1) for Children's DLQI, and 15.4 (7.3) for Dermatitis Family Impact. In the previous 12 months, 97.3%, 37.4%, and 27.9% patients were treated with topical corticosteroids, systemic corticosteroids, and conventional systemic non-corticosteroid immunosuppressants respectively.

Conclusion:

Canadian patients with skin of colour enrolled in CANDID demonstrated considerable multidimensional burden of disease across signs/symptoms despite extensive previous use of topical, systemic and non-systemic AD treatments. This is the first real world evidence assessment of Canadian patients from diverse backgrounds and skin of colour including the Indigenous population, demonstrating the burden of disease for diverse Canadians living with atopic dermatitis.