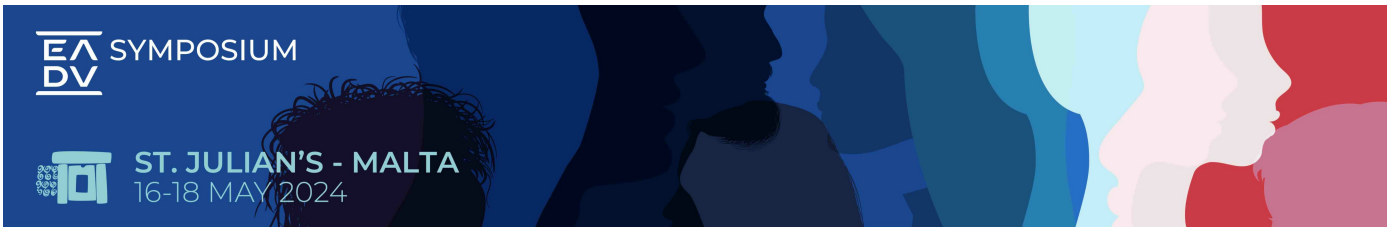

Abstract N°: 33

Treatment of Nodular Prurigo: long remission possible in clinical practice?

Ashimav Sharma[1]

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Introduction & Objectives:

Prurigo Nodularis(PN) is a chronic skin disorder, which is difficult to manage. Long remission of symptoms with presently available treatment is seldom observed. One of the reasons for this is that PN has an association with atopy. About 65-80% of individuals with PN are atopic. Atopic individuals have a persistent T-h2 response, which make them more vulnerable to pruritus and eczematization.

The aim of the study was to evaluate the efficacy of oral Low-Dose Methotrexate and oral Ketotifen in achieving longer remission in the management of pruritus in patients with PN with atopic background.

Materials & Methods:

Twenty-four adult patients (male: 21, female:3) with PN, and a history of atopy with raised IgE, were included in this study in a dermatology clinic. Duration of the study was 12 weeks. All patients who had positive growth of Staphylococcus aureus on the lesional skin swab were treated with oral antibiotic prior to trial. All patients received topical halobetasol and oral hydroxyzine on demand basis to control itching for 6 weeks. In addition, all patients in the study group(n=12) received oral Methotrexate (5mg/week) and oral Ketotifen (1mg/day) for 6 weeks. All patients were reviewed at 2 weeks' interval. After completion of trial period, each patient in the study group was followed up for another 6 weeks.

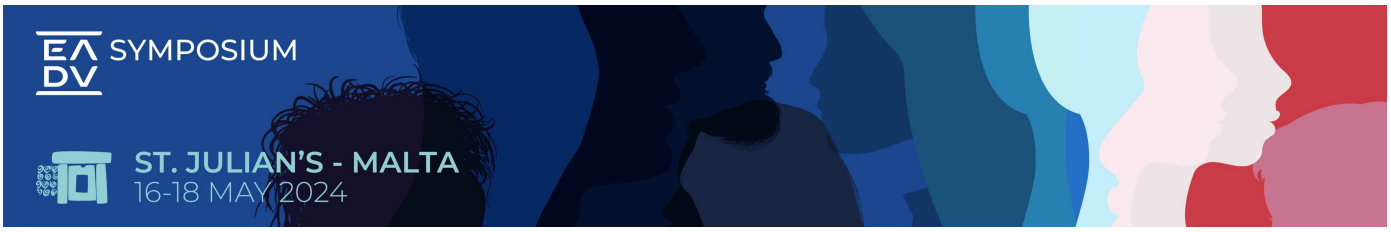
Results:

Of the 12 patients in the study group, 10 had complete relief from pruritus by 2 weeks' time and the remaining 2 had complete relief from pruritus by 4 weeks' time, and all 12 patients remained free from pruritus till the end of trial period. During the follow up period, 11out of 12 patients experienced no relapse of pruritus till the end of follow-up period. Only 1 patient experienced relapse of mild itching.

In the control group, mild to moderate reduction in the intensity of pruritus in the PN lesions of all 12 patients were noted at 2nd week. No further improvement in the level of pruritus was noted in the participants during the trial period. Pruritus returned to its original form once the treatment was stopped at 6 weeks. Differences in result of two groups are statistically significant (Mann-Whitney test).

Conclusion:

This study showed that combination of Oral Low Dose Methotrexate with oral Ketotifen is effective in achieving longer remission in the management of pruritus in patients with PN with atopic background.



Abstract N°: 171

Atopic Dermatitis Is More Than Just a Rash: It's an autoimmune-directed disease, and the progress in the immunotherapy pipeline

Husham Bayazed[1]

[1]Cihan University -Duhok - Kurdistan Region, Health Sciences , Zakho, Iraq

Introduction & Objectives:

Now, atopic dermatitis (AD) is no longer considered just a rash; it's an autoimmune-directed disease. The story started in 2014 (Donald YM Leung, Emma Guttman-Yassky), when a team of researchers at the Icahn School of Medicine at Mount Sinai deciphered and proved the basis of the autoimmune-directed nature of AD at the molecular level. Therefore, this article review and meta-analysis will address in depth the immunopathogenesis and the driven autoimmune pathways of AD, as well as what the future holds and how the immunotherapy pipeline is moving forward in AD.

Materials & Methods:

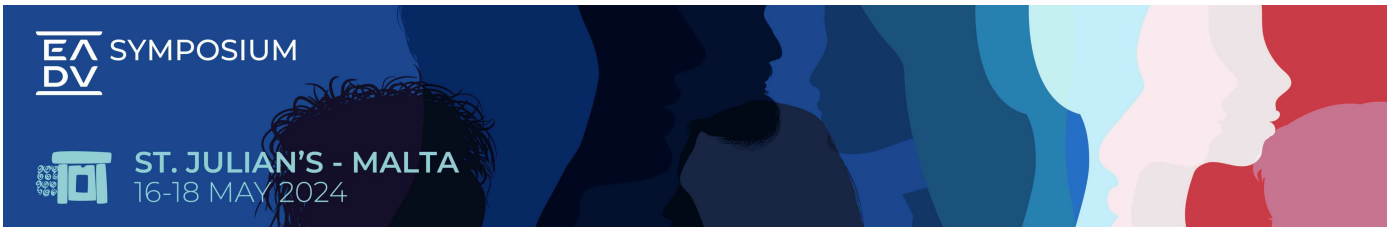
Previously published data and observational studies were collected by retrieving published literature from PubMed, Google Scholar, and the Web of Science using "Atopic Dermatitis and Immune Dysregulation." The preferred reporting items for systematic reviews analyzed the recommendations and guidelines.

Results:

There has been a lot of progress in the last ten years in understanding the immunopathogenesis of AD and ascertaining the consolidation of the two major hypotheses (inside-out and outside-in hypotheses) proposed by Silverberg NB and Silverberg JI in 2015. Implicating both theories to play parts—inflammation as the culprit and subsequent immune dysregulation—and triggering the inflammatory cytokine cascades and driving the autoimmune processes. In AD, the damaged epidermal barrier is a crucial point that allows the penetration of potential allergens and/or pathogens to activate keratinocytes, the main immune scavenger cells. Which spark the total immune responses via cross-talk between both innate and adaptive immune system arrays and subsequently play a major role in the initiation of several biological processes with the release of pro- and post-inflammatory cascades of cytokines to drive the autoimmune process and contribute to the pathogenesis of AD.

Conclusion:

Understanding the new conception of the autoimmune nature of AD is pivotal in this era and will help to map out more precise targeted immunotherapy to improve patients' quality of life. Indeed, recent and current evidence suggests cytokine-targeted therapy (IL-13 and its inhibitors, tralokinumab and lebrikizumab) to play a crucial role and seem to be a possible treatment for patients with AD. However, more in-depth studies are needed to find the right autoimmunity pathway process in AD. This will help clear up the confusion and problem of choosing the right targeted therapy, which began with Dupilumab in 2014, especially for patients with moderate to severe AD.



Abstract N°: 201

Using abrocitinib: a selective JAK-1 inhibitor on chronic hand eczema

Eleftheria Tampouratzi[1], Maria Pizimola[2], Panagiotis Rigatos[3], Ioannis Katsantonis[1]

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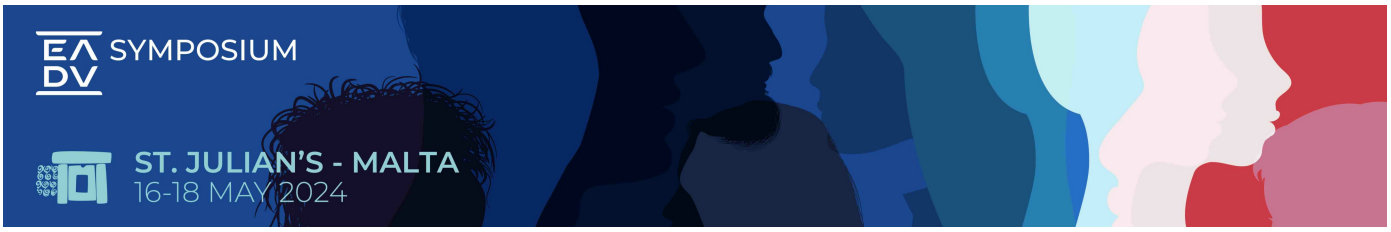
Introduction & Objectives: Chronic hand eczema affects 10% of the general population. Recent studies report that up to 82% of patients were forced to change their work situation due to the disease. There are many similarities between chronic eczema and atopic dermatitis at the pathophysiological and therapeutic level. The therapeutic algorithm is quite reminiscent of atopic dermatitis, with alitretinoin being the only systemic treatment, apart from the classics, that has been approved. On the other hand, drugs such as abrocitinib that are effective in atopic dermatitis modulate the signaling of the same cytokines involved in chronic hand eczema, leading to the conclusion of their efficacy and in this disease.

Materials & Methods: A 47-year-old Caucasian female was examined for chronic upper extremity eczema with onset in her early 20s, with frequent recurrences >4 per year. The patient presented with pruritic lichenified lesions on the dorsal surface of the upper extremities, accompanying nail involvement and lesions on the palms. Cracked eczema was found on the fingers and collateral joints. Patient's HECSI score (hand eczema severity index) was 41, VAS (Visual Analogue Scale) for itch (0–10, with 10 representing very severe itch) was 9, DLQI (Dermatology Life Quality Index) was 19. Patient was treated with cyclosporine, but due to arterial hypertension, it is now contraindicated. Treatment with alitretinoin had good initial response at the beginning but relapsed 1 year later.

Accordingly, a 26-year-old Caucasian male presented with chronic eczema of the upper extremities the last 5 years. He was facing difficulties in work-as a waiter, and everyday life. Patient had hyperkeratotic lesions with associated erosions and fissures on the palms and fingers accompanied by severe itching. Patient's HECSI score was 33, VAS for itch was 8, DLQI score was 14. Treatment with topical corticosteroids, calcineurin inhibitors and classical treatments (cyclosporine, acitretin) was not effective.Both patients were treated with abrocotinib 200 mg every day.

Results: Significant clinical and pschycological improvement was noticed in both patients in the first days of treatment, continuing one year after.

Conclusion: While the spectrum of therapeutic options for chronic hand eczema has expanded in recent years, this condition is still an open challenge for physicians and patients alike. The limited number of effective therapeutics and the relapsing-remitting course of the disease, highlight the need for new treatments. Abrocitinib, as a selective JAK-1 inhibitor, in atopic dermatitis regulates the signaling of IL-4, IL-13, IL-22 cytokines that are also involved in chronic hand eczema. More specifically, chronic eczema is characterized by activation of Th-2 cytokines producing IL-4, IL-13, IL-31 and activation of T-cells producing IL-22. With this in mind, the use of abrocitinib on chronic eczema of the extremities can be an excellent therapeutic option, as we observed in our patients. More comprehensive large scale studies could elucidate the underlying mechanisms and offer an effective, safe, alternative treatment in chronic hand eczema.



Abstract N°: 365

The effectiveness of upadacitinib in the treatment of atopic dermatitis and other concurrent immune-mediated diseases.

Gianluca Tavoletti[1, 2], Giovanni Lasagni[2], Alessandra Chiei Gallo[2], Francesca Barei[1], Angelo Valerio Marzano[1, 2], Silvia Ferrucci[1]

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Introduction & Objectives:

Atopic dermatitis (AD) is a chronic, inflammatory dermatological condition frequently associated with other immune-mediated diseases. This overlap suggests a shared pathophysiological pathway, potentially involving the Janus kinase (JAK) signaling pathway. Upadacitinib, a JAK inhibitor, has recently emerged as a promising therapeutic agent in this context. The primary objective of this study is to assess the efficacy of upadacitinib in treating AD, particularly in the presence of coexisting immune-mediated conditions, which may share a common JAK-dependent inflammatory pathway.

Materials & Methods:

This retrospective study was conducted at a single center, focusing on a cohort of patients diagnosed with AD and concurrent immune-mediated diseases. The inclusion criteria required patients to have a definitive diagnosis of AD and concurrent immune-mediated disorders. Three patients meeting these criteria were selected, each suffering from AD and, respectively, ulcerative colitis (UC), psoriatic arthritis (PsA), and Crohn's disease (CD). Detailed patient histories were reviewed, with particular attention to previous treatments and their responses. Upadacitinib was administered at a dose of 30 mg per day, and patients were monitored for clinical outcomes, focusing on the severity of AD and symptoms of the concomitant immune-mediated diseases.

Results:

The first case involves a 31-year-old woman with a history of AD and UC since childhood. AD had been unsuccessfully treated previously with topical and systemic corticosteroids, phototherapy, and dupilumab. UC had been treated with mesalazine and vedolizumab, achieving good clinical control. Due to unsatisfactory control of AD, it was decided to discontinue the ongoing systemic therapies for both conditions and introduce upadacitinib at 30 mg per day. Within five months, remission of both conditions was achieved, a result that has been maintained in subsequent follow-ups.

The second case concerns a 36-year-old man with a history of treatment-resistant AD and PsA. The introduction of upadacitinib at 30 mg per day led to rapid improvement in AD and remission of PsA. After one year, the patient demonstrated almost complete control of eczematous lesions and absence of arthritic symptoms.

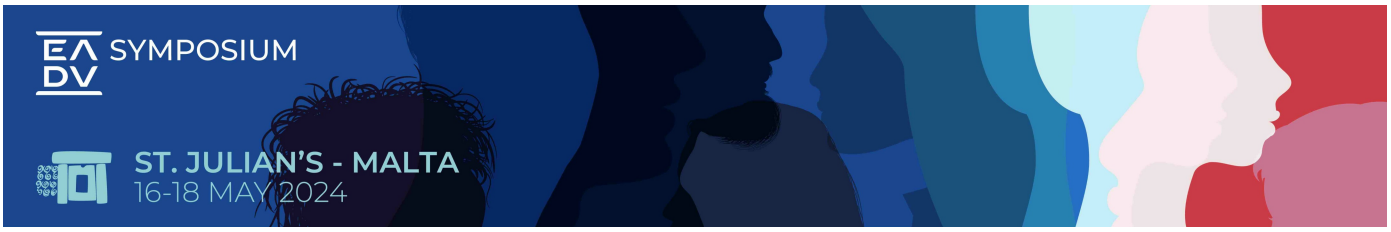
The third case involves a 41-year-old patient with AD since childhood and CD diagnosed at age 23, being treated with dupilumab and mesalazine. After discontinuing dupilumab due to a severe episode of blepharoconjunctivitis, upadacitinib 30 mg per day was introduced, resulting in maintained remission of CD and significant improvement in AD.

Upadacitinib was well tolerated by all patients described in this study without significant side effects.

Conclusion:

This study presents evidence supporting the effectiveness of upadacitinib in the management of AD and concurrent immune-mediated diseases. These findings suggest that targeting the JAK pathway may be a viable therapeutic strategy in such complex clinical scenarios. However, further studies with larger sample sizes and diverse populations are essential to

corroborate these results and establish more comprehensive treatment guidelines.



Abstract N°: 437

Efficacy and safety of lebrikizumab is maintained to two years in patients with moderate-to-severe atopic dermatitis

Emma Guttman-Yassky*[1], Stephan Weidinger[2], Eric L. Simpson[3], Melinda Gooderham[4], Alan Irvine[5], Lynda Spelman[6], Jonathan I. Silverberg[7], Hany Elmaraghy[8], Louise Deluca-Carter[8], Maria Lucia Buziqui Piruzeli[8], Chaoran Hu[8], Fan Emily Yang[8], Evangeline Pierce[8], Laia Bardolet[9], Diamant Thaçi[10]

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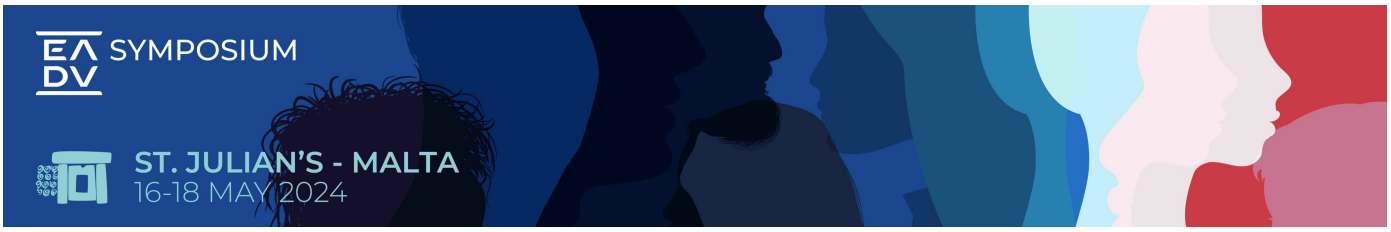
Introduction & Objectives: We report the efficacy and safety of lebrikizumab (LEB) in the long-term extension study ADjoin (NCT04392154) following 104 Weeks (W) of continuous LEB treatment with and without TCS use.

Materials & Methods: Patients in ADvocate1&2 (NCT04146363, NCT04178967) who achieved either EASI 75 or IGA 0/1 (without rescue) at W16 were re-randomized 2:2:1 to LEB250mg Q2W, LEB250mg Q4W, or placebo (LEB withdrawal). Patients who completed W52 of ADvocate1&2 were able to enroll in ADjoin. Patients in ADhere (NCT04250337) who achieved either EASI 75 or IGA 0/1 (without rescue) at W16 were able to enroll into ADjoin and randomized 2:1 to LEB250mg Q2W or LEB250mg Q4W. Data** are reported for patients originating from ADvocate1&2 and ADhere who received LEB250mg Q2W or Q4W in ADjoin. Efficacy outcomes were assessed based on all collected data (as observed analysis) up to 104W of LEB treatment. Safety was reported from ADjoin enrollment up to the data cut-off April 14, 2023.

Results: At W104, IGA 0/1 was maintained by 38/44 (86.4%; Q2W) and 42/55 (76.4%; Q4W) patients from ADvocate1&2 and 26/31 (83.9%; Q2W) and 11/14 (78.6%; Q4W) patients from ADhere. EASI 75 was maintained by 65/68 (95.6%; Q2W) and 77/80 (96.3% Q4W) ADvocate1&2 patients and 39/41 (95.1%; Q2W) and 24/25 (96.0%; Q4W) ADhere patients at W104. In patients who achieved EASI 75 at W16, EASI 90 was achieved by 56/68 (82.4%; Q2W) and 66/80 (82.5%; Q4W) ADvocate1&2 patients and 35/41 (85.4%; Q2W) and 18/25 (72.0%; Q4W) ADhere patients at 104W.

During ADjoin, 166 of 267 (62.2%) patients from the subpopulations of ADvocate1&2 and ADhere who received LEB Q2W or Q4W in ADjoin reported adverse events (AEs), most of which were mild (31.5%, n=84) or moderate (27.0%, n=72) in severity. Serious AEs were reported by 10 (3.8%) patients. There was one death in the ADhere Q2W arm. Six (2.3%) patients reported AEs leading to treatment discontinuation. The safety profile of LEB in ADjoin is consistent with that observed during ADvocate1&2 and ADhere.

Conclusion: Efficacy outcomes were maintained long-term, over 2 years of continuous LEB treatment, in both LEB250mg Q2W and Q4W arms. The safety profile of LEB in ADjoin is consistent with previous LEB studies in patients with moderate-to-severe AD.



Abstract N°: 438

Lebrikizumab demonstrates sustained efficacy in adolescent patients through 2 years of continuous treatment: results from ADjoin long term extension

Amy Paller*[1], Antonio Torrelo[2], Chin-Yi Yang[3, 4], Candrice Heath[5], Carsten Flohr[6], Stephan Weidinger[7], Hany Elmaraghy[8], Louise Deluca-Carter[8], Fan Emily Yang[8], Clara Armengol[9], Lawrence Eichenfield[10]

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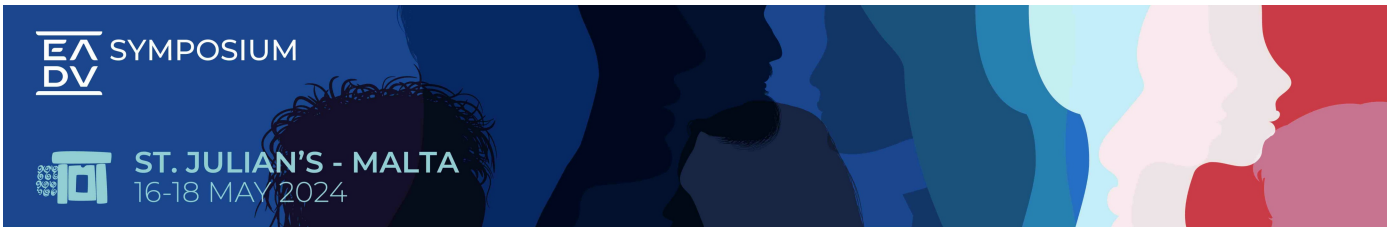
Introduction & Objectives: Lebrikizumab, a monoclonal antibody selectively targeting IL-13 with high-affinity, has demonstrated efficacy and safety in atopic dermatitis (AD) phase 3 clinical trials.

Materials & Methods: We assessed the response over time to lebrikizumab (250 mg, every two weeks [Q2W]) in adolescent patients (12 to <18 years, ≥40 kg) with moderate-to-severe AD. Efficacy measures included the proportion of patients, at each visit, with an Investigator's Global Assessment (IGA) of 0/1 with ≥2-point reduction from baseline and ≥75% reduction in Eczema Area Severity Index (EASI 75). Data are presented as observed through treatment week 104. Adolescents who completed participation in an open-label, 52-week phase 3 trial (ADore NCT04250350) were invited to enroll in an open-label, long-term extension study (ADjoin, NCT04392154).

Results: The proportion of patients with IGA 0/1 responses increased from 14.4% at treatment week 4 (N=201) to 65.1% at treatment week 52 (N=172) in the ADore study and to 70.6% at treatment week 104 assessed at ADjoin week 52 (N=119). Similarly, the proportion of EASI 75 responders increased from 28.9% at treatment week 4 (N=201) to 85.5% at treatment week 52 (N=172) in the ADore study and to 92.6% at treatment week 104 assessed at ADjoin week 52 (N=121). The safety profile in adolescents with AD at 104 weeks was consistent with previously published lebrikizumab safety data in adolescents.

Conclusion: Efficacy response rates achieved at week 52 were sustained and increased over two years in adolescent patients.



Abstract N°: 562

Effectiveness and safety of upadacitinib in adolescent and adult patients with atopic dermatitis: an interim analysis of long-term (week 52) data from a real-world multicenter retrospective review

Siddhartha Sood[1], Brian Rankin[2], Ye-Jean Park[1], Alexander Rimke[3], Abrahim Abduelmula[4], Jorge Georgakopoulos[4], Khalad Maliyar[4], Ferne-Joy Leung[5], Lauren Stark[5], Alim R. Devani[3, 5, 6], Jensen Yeung[4, 6, 7, 8], Vimal H. Prajapati*[2, 3, 5, 6, 9, 10]

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Introduction & Objectives:

Clinical trial data demonstrates the efficacy and safety of upadacitinib (UPA), a selective oral Janus kinase inhibitor (JAKi), for atopic dermatitis (AD); however, long-term real-world evidence remains limited.

Materials & Methods:

We conducted a multicenter retrospective review of one community and two academic practices in Canada. Effectiveness outcomes measured at week 52±6 included the following: Investigator Global Assessment (IGA) score of clear or almost clear (IGA 0/1) and Eczema Area and Severity Index (EASI), body surface area (BSA), IGAxBSA, and Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) improvements. Safety was assessed via incidence of treatment-related adverse events (AEs).

Results:

A total of 103 patients were included in this study. The mean age was 44 (range: 12-79) years; 53.4% (55/103) were female. Initial UPA doses were 15 mg (40.8%, 42/103) or 30 mg (59.2%, 61/103) once daily. Previous treatments prior to UPA included: topicals (100%, 103/103), light (30%, 31/103), systemic non-biologics (71.8%, 74/103), and systemic biologics/JAKi (35%, 36/103).

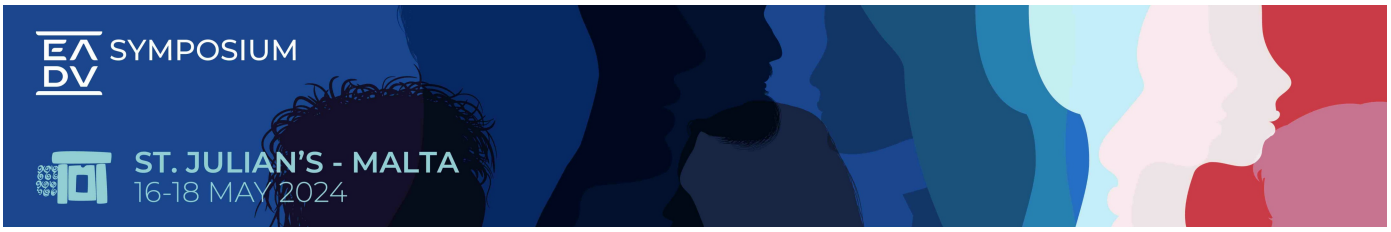
At week 52±6: 77.7% (80/103) of patients achieved IGA 0/1; 86% (49/57), 77.2% (44/57), and 49.1% (28/57) of patients achieved EASI improvements of 75% (EASI75), 90% (EASI90), and 100% (EASI100), respectively; mean EASI was reduced from 12.9 to 0.8 (p=0.0001; mean EASI improvement = 91.5%); 91.2% (52/57), 91.2% (52/57), 80.7% (46/57), and 73.7% (42/57) of patients achieved absolute EASI scores <7, <5, <3, and <1, respectively; mean BSA was reduced from 16.5% to 0.6% (p=0.0001; mean BSA improvement=87.8%); mean IGAxBSA was reduced from 52.3 to 0.8 (p=0.0001; mean IGAxBSA improvement=90.7%) mean DLQI/CDLQI was reduced from 13 to 1.8 (p=0.0001; mean DLQI/CDLQI improvement=86%) with 66% (33/50) of patients achieving DLQI/CDLQI 0/1. UPA monotherapy was utilized in 45.6% (47/103) of cases. Concomitant topical and systemic therapies were used in 52.4% (54/103) and 1.9% (2/103) of patients, respectively.

Common AEs up to week 52±6 included: acne (19.4%, 20/103), hypertriglyceridemia (16.8%, 17/103), elevated creatinine phosphokinase (13.6%, 14/103), neutropenia (6.8%, 7/103), and herpes simplex virus (5.8%, 6/103). Seven patients (6.8%) discontinued UPA due to treatment-related AEs, including one case of venous thromboembolism. Four patients (3.9%) discontinued due to patient preference, and 1 (1%) discontinued due to lack of efficacy. No serious infections, tuberculosis, major adverse cardiovascular events, gastrointestinal perforation, or malignancy were observed in 102.5

patient-years of safety follow-up.

Conclusion:

Our real-world study indicates that UPA is an effective and safe long-term therapy for AD. Further, the results demonstrate that real-world experiences of patients with AD treated with UPA are comparable and, for several outcome parameters (e.g., especially IGA 0/1, EASI90, EASI100, and DLQI 0/1), superior to those reported from 52-week Measure Up 1/2 and AD Up clinical trial data.



Abstract N°: 589

Baricitinib provides significant improvements in quality of life and functioning in adults with moderate-to-severe atopic dermatitis and baseline body surface area ≤40% and severe itch ('itch dominant')

Matthias Augustin*[1], Maddalena Napolitano[2], Rosa María Izu Belloso[3], Elise C Kleyn[4], Silvia Sabatino[5], Susanne Grond[5], Joaquín Rodrigo Otero Asman[5], Chunyuan Liu[5], Ziad Reguiai[6], Toshifumi Nomura[7]

[1]University Medical Center Hamburg-Eppendorf, Hamburg, Germany,[2]University of Naples Federico II, Napoli, Italy, [3]Basurto University Hospital, Department of Dermatology, Bilbo, Spain,[4]Dermatology Centre, Salford Royal NHS Foundation Trust, National Institute for Health Research Manchester Biomedical Research Centre, The University of Manchester, Manchester, M13 9PL, UK, [5]Eli Lilly and Company, Indianapolis, Indiana, USA,[6]Dermatology Department, Polyclinique Courlancy-Bezannes, Reims, France, [7]Department of Dermatology, University of Tsukuba, Tsukuba, Japan.

Introduction & Objectives:

Atopic dermatitis (AD) is a pruritic, chronic and highly symptomatic inflammatory skin disease. Clinical presentation is heterogeneous and might include different levels of skin involvement and itch intensity, which is known to negatively impact quality of life (QoL). Patients with moderate-to-severe AD and a body surface area (BSA) ≤40% and Itch numerical rating scale (NRS) ≥7 (BARI 'itch-dominant') have been characterized as an important group to consider for the oral janus kinase (JAK) 1/2 inhibitor baricitinib (BARI) [1]. This post-hoc analysis aims to evaluate QoL and functioning outcomes in adult patients with BSA ≤40 and Itch NRS ≥7 at baseline (BL) receiving BARI 4-mg in the topical corticosteroid (TCS) combination trial BREEZE-AD7.

Materials & Methods:

BREEZE-AD7 was a randomized, double-blind, placebo-controlled, parallel-group, outpatient study involving adult patients with moderate-to-severe AD receiving once-daily placebo or 2-mg or 4-mg BARI in combination with TCS for 16 weeks. Patients eligible for enrolment must have a BSA ≥10. This post-hoc analysis focused on placebo and BARI 4-mg for patients with BSA ≤40 and Itch NRS ≥7. QoL impairment was measured using Dermatology Life Quality Index (DLQI) of ≤5 and functioning outcomes were assessed using the Work Productivity and Activity Impairment (WPAI) questionnaire. Data was reported descriptively. Last observation carry forward (LOCF) data was reported, excluding data collected after first rescue therapy date or permanent study drug discontinuation. Non-responder imputation was used to account for missing data.

Results:

At BL, patients with BSA ≤40 and Itch NRS ≥7 (BARI 4-mg: n=26 and placebo: n=32) had high QoL impairment (Table 1). Mean DLQI score at BL for patients who received BARI 4-mg was 15.0 and 15.9 for patients who received placebo indicating a very large effect of AD on patients' QoL. Patients receiving BARI and placebo experienced significant itch burden, reporting Itch NRS scores of 8.1 and 8.2, respectively. At week 16, 61.5% of patients treated with BARI 4-mg indicated no to only a small effect on their QoL (DLQI ≤5) versus 24.1% for patients receiving placebo ($p<0.01$). Of patients with BSA ≤40 and Itch NRS ≥7, 50% completed the WPAI questionnaire at BL for both BARI 4mg and placebo. A decrease in WPAI work impairment score of -41.6 for BARI patients and -7.0 for placebo patients was observed at week 16 ($p<0.01$). Patients receiving BARI also observed a noticeable improvement in WPAI daily activity impairment, of -30.4 compared to patients on placebo who achieved -12.2 from BL at week 16 ($p<0.01$).

Conclusion:

This post-hoc analysis highlights the broader impact BARI 4-mg can have on lives of patients with BSA≤40 and Itch NRS

≥7 (itch-dominant) AD and the importance of AD phenotype being considered when assessing patients. Despite having high QoL impairment at BL, patients with itch-dominant AD treated with BARI 4-mg showed marked benefits in QoL, daily life activity, and work function compared to placebo after 16 weeks of treatment. Limitations include small sample size analyzed.

Table 1: Demographics and disease characteristics of patients with BSA ≤40 and Itch NRS ≥7 at baseline

	Placebo (n=32)	BARI 4-mg (n=26)
Patient Demographics at Baseline		
Age (years)	35.6 (15.2)	34.1 (12.0)
Female, n (%)	12 (37.5)	11 (42.3)
Duration since AD diagnosis (years)	21.1 (12.4)	26.6 (13.0)
BMI (kg/m²)	25.4 (4.1)	26.6 (4.7)
Alcohol use, n (%)	23 (71.9)	18 (69.2)
Tobacco use, n (%)	10 (31.3)	5 (19.2)
Disease Characteristics at Baseline		
Itch NRS	8.2 (0.8)	8.1 (0.8)
BSA affected by AD	27.5 (7.4)	30.4 (6.9)
EASI	20.2 (3.7)	20.5 (3.3)
DLQI	15.9 (6.6)	15.0 (7.6)
WPAI Work productivity loss Activity outside work	 63.6 (28.1) 57.5 (26.4)	 48.3 (24.9) 54.8 (21.8)
DLQI and WPAI outcomes at Week 16		
DLQI ≤ 5[a], n (%)	7 (24.1)	16 (61.5)**
WPAI Change from baseline Activity at work Activity outside work	 -7.0 (8.8) -12.2 (6.3)	 -41.6 (10.6)** -30.4 (6.6)**
All data reported as mean (standard deviation) unless otherwise stated. P-value is from the Fisher's exact test. ***p<0.01.* [a] Percentages are based on patients with baseline DLQI>5.		

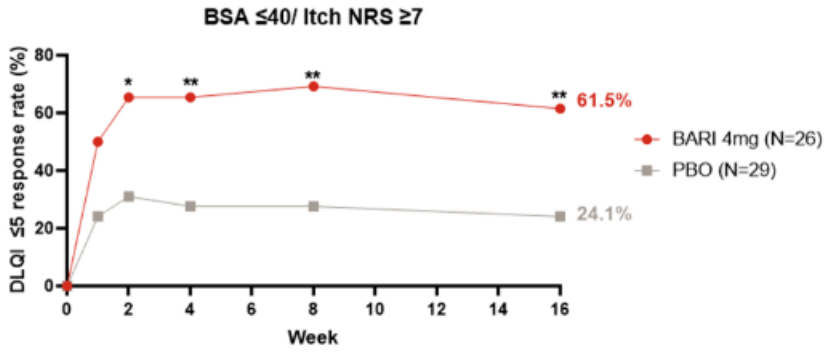
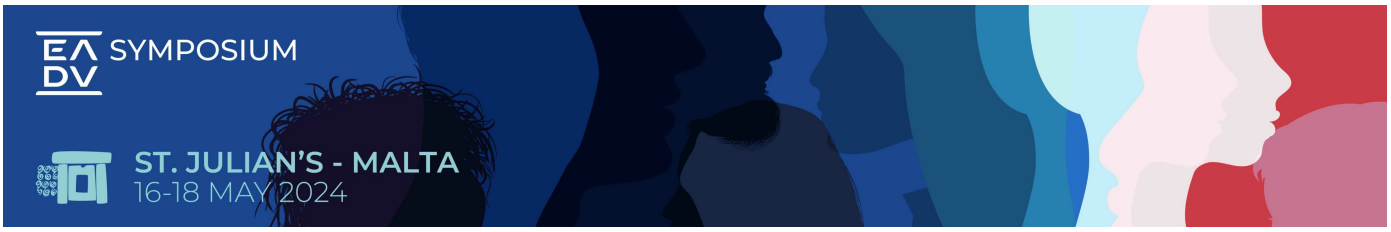


Figure 1: DLQI ≤5 response rate for patients receiving BARI 4-mg and placebo over 16 weeks. **p<0.05 and **p<0.01.*

\1. Thyssen, J.P., et al., Adv Ther, 2023.**40**(8): p. 3574-3587.



Abstract N°: 616

Efficacy and safety of alitretinoin for chronic hand eczema: A meta-analysis

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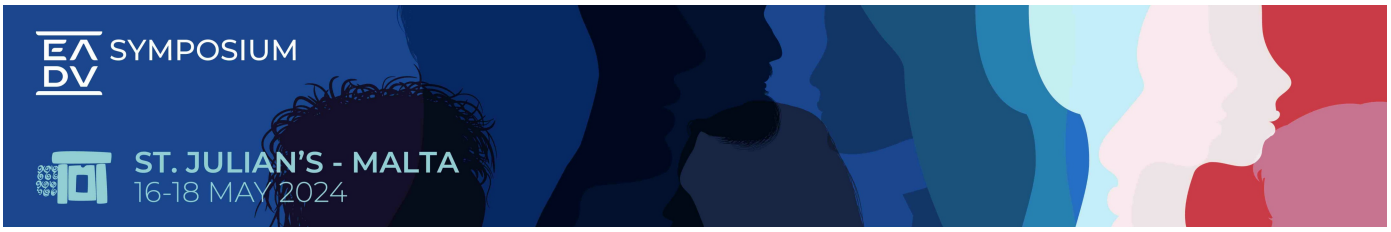
Introduction & Objectives: Hand eczema is a common inflammatory dermatosis with a significant impact on quality of life. Severe or chronic cases often need more extensive, ongoing treatment beyond conventional methods. Alitretinoin, a vitamin A derivative, is approved for patients who are unresponsive to high-potency topical corticosteroids. Usually given at 10-30 mg per day for 12-24 weeks, with 24 weeks showing effective and safe results. This study aimed to explore the effectiveness and safety of alitretinoin in chronic hand eczema patients through a meta-analysis.

Materials & Methods: Relevant articles were obtained by searching PubMed through April 10, 2023. The therapeutic effects, adverse event, and change of laboratory investigations were investigated. Parameters for evaluating efficacy included physician's global assessment (PGA), patients' global assessment (PaGA), and modified total lesion symptom score (mTLSS). To assess heterogeneity, we conducted a subgroup analyses based on dosage and treatment duration with meta-regression tests.

Results: Twenty-four studies were included. An overall improved rate was 47.8% in PGA and 36.4% in PaGA, with a more predominant improvement observed in PGA than PaGA. Subgroup analysis by dosage revealed superior efficacy for higher dosage in both PGA and PaGA. The meta-regression test showed a significant difference in PGA between the 10mg and 30mg subgroups. Subgroup analysis for treatment duration indicated superior effects in the 30mg subgroup for both PGA and PaGA scores at 24 weeks compared to 12 weeks. Additionally, the 24-week treatment group demonstrated higher efficacy for mTLSS scores compared to the 12-week group. Adverse events showed an overall incidence rate of 48.3%, with the most commonly reported events being headache, skin fissure, back pain, and dry eye. Triglyceride elevation was the most noticeable laboratory finding.

Conclusion: Alitretinoin demonstrated favorable objective and subjective efficacy for patients with chronic hand eczema. Consistent with previous studies, we observed a trend of increasing efficacy with higher dosages. Furthermore, at high dosage, greater efficacy was observed with longer durations of use. Most side effects were generally tolerable.



Abstract N°: 635

Evaluation of the quality of life of patients with atopic dermatitis and disease-related factors

Liborija Lugovic Mihic[1], Valentina Baković[1], Ena Parać[1], Matea Kuna[1], Ana Ljevar[1], Lorena Dolački[1]

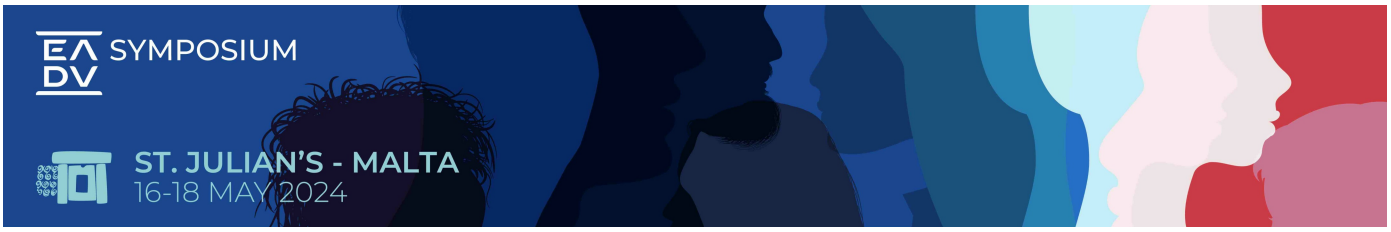
[1]Department of Dermatovenereology

Introduction & Objectives: Considerations regarding the quality of life frequently guide treatment decisions for patients, including those with atopic dermatitis (AD). AD imposes a substantial burden on affected individuals, their families, as well as on society. This condition can greatly restrict various aspects of daily functioning, leading to a significant decline in the overall quality of life (QoL).

Materials & Methods: Our study involved 84 adult patients with AD, among whom 42 individuals exhibited clinical manifestations of the disease, and 42 were in remission. To assess various aspects of the QoL of AD patients, we used several tools, including the SCORAD index for determining AD severity, the Dermatology Life Quality Index (DLQI), the Brief Illness Perception Questionnaire (Brief IPQ), the World Health Organization Quality of Life Brief Version (WHOQOL-BREF), and the Crown–Crisp Experiential Index (CCEI) to evaluate personality traits.

Results: Based on our findings, SCORAD exhibited a positive and linear correlation with DLQI ($p<0.001$), as well as with disease symptoms, disease control, and disease impact on life ($p\leq0.023$). DLQI also showed associations with specific personality traits, including somatization, obsession, depression, and free-floating anxiety disorder ($p\leq0.032$). AD patients experiencing symptoms had notably more impaired DLQI scores compared to asymptomatic patients ($p<0.001$). While differences between the two groups were observed in certain IPQ dimensions, no significant variations were found regarding WHOQOL-BREF dimensions and personality traits (CCEI). Thus, the QoL of AD patients is influenced not only by the severity of the disease but also by the interplay of the individual's personality traits and associated psychological disturbances (such as somatization, obsession, depression, and anxiety disorder).

Conclusion: Therefore, to enhance the QoL of AD patients, clinicians should adopt a multidisciplinary treatment approach that incorporates psychological support interventions.



Abstract N°: 664

Absolute EASI improvements over 16 weeks in patients with moderate-to-severe atopic dermatitis treated with lebrikizumab in monotherapy

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Introduction & Objectives: Lebrikizumab (LEB) is a monoclonal antibody that binds with high affinity and slow off-rate to interleukin (IL)-13, thereby blocking the downstream effects of IL-13 with high potency. The efficacy of LEB monotherapy for patients with moderate-to-severe atopic dermatitis (AD) as the percentage of improvement in the Eczema Area and Severity Index score (EASI) (EASI 75 and EASI 90) has been established in previous studies. However, attainment of absolute EASI thresholds indicative of mild disease or clear/almost clear skin may provide additional clinically meaningful information for patients and physicians about the response to LEB treatment. This post-hoc analysis examined the percentage of patients in the ADvocate1 (ADv1) and ADvocate2 (ADv2) trials achieving absolute EASI scores of ≤7 (mild) or ≤1 (clear/almost clear) in the overall population and stratified by different baseline EASI severity subgroups (16–21 [moderate], 21.1–50 [severe], and >50 [very severe]).

Materials & Methods: Adults (≥18 years of age) and adolescents (12 to <18 years of age, weighing ≥40 kg) were randomized 2:1 to LEB monotherapy (N=564) or placebo (PBO; N=287) for 16 weeks. LEB was given as a 500 mg loading dose at baseline and Week 2, followed by 250 mg LEB every 2 weeks (Q2W). Eligible patients had moderate-to-severe AD, with an EASI score of ≥16 at baseline. ADv1 analyses were performed on the intent-to-treat population. ADv2 analyses were performed on a modified population, excluding 18 patients (from a single study site) whose eligibility could not be confirmed. Therefore, analyses were performed on the pooled modified population of ADv1 and ADv2 patients. The proportion of patients who achieved an EASI score of ≤7 or ≤1 over 16 weeks was assessed for the overall pooled ADv1&2 population, and subgroups with baseline EASI of 16–21, 21.1–50, and >50. Missing data and data after rescue medication use were imputed using non-responder imputation. Nominal p-values were calculated with Cochran-Mantel-Haenszel test.

Results: In the overall ADv1&2 populations, a significantly greater proportion of patients treated with LEB achieved EASI ≤7 at Week 16 vs PBO (54% [n=307] vs 18% [n=52], p<0.001; Fig 1A). Of the 163 patients on LEB with moderate baseline EASI (16–21), 64% (n=104) achieved EASI ≤7 by Week 16 vs 38% PBO (n=27, p<0.001; Fig 1B). For patients with severe baseline EASI (21.1–50), 52% of patients treated with LEB (n=185) achieved EASI ≤7 at Week 16 vs 13% PBO (n=25, p<0.001; Fig 1C). For patients with very severe baseline EASI (>50), 43% of LEB patients (n=18) achieved EASI ≤7 vs 0% PBO (p<0.001; Fig 1D). For all groups, a significant difference was seen as early as Week 4. A significantly greater proportion of patients treated with LEB also achieved EASI ≤1 at Week 16 vs PBO (20% [n=113] vs 4% [n=10], p<0.001; Fig 2A). Similar proportions of patients treated with LEB in each baseline severity subgroup achieved EASI ≤1 at Week 16 (moderate 20% [n=33] vs 9% [n=6], p<0.05; severe 20% [n=73] vs 2% [n=4], p<0.001; very severe 17% [n=7] vs 0%, p<0.05; Fig 2C-D).

Conclusion: Regardless of baseline severity, over 50% of patients treated with LEB 250 mg Q2W monotherapy for 16

weeks achieved an EASI score indicating mild AD and approximately 20% achieved an EASI score indicating clear/almost clear skin.

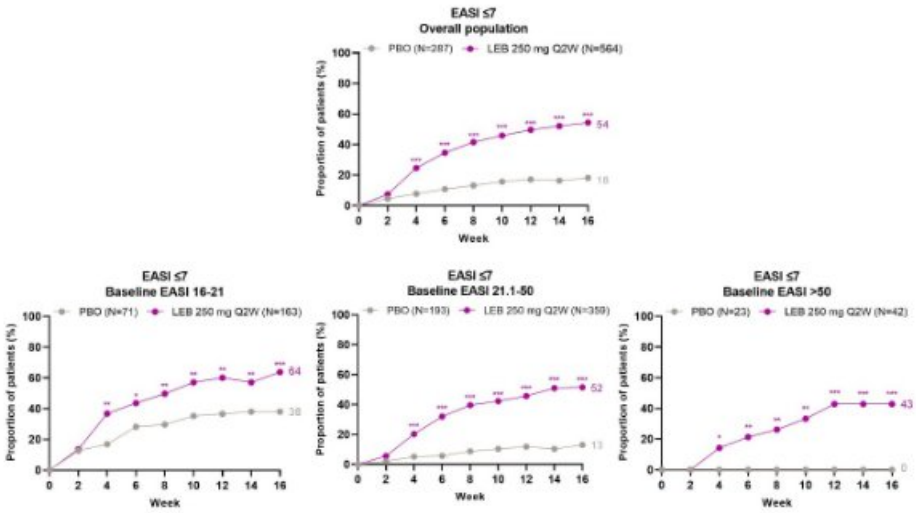


Figure 1: Proportion of patients who achieved an EASI ≤7

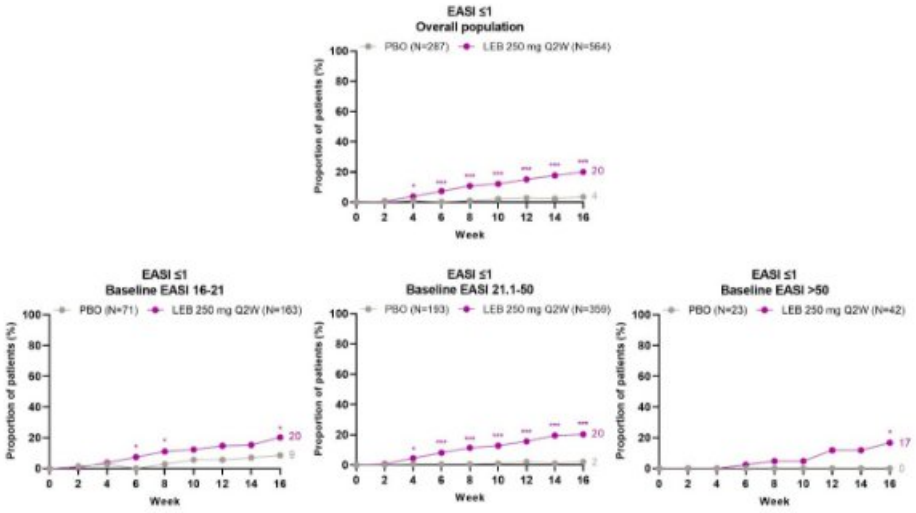
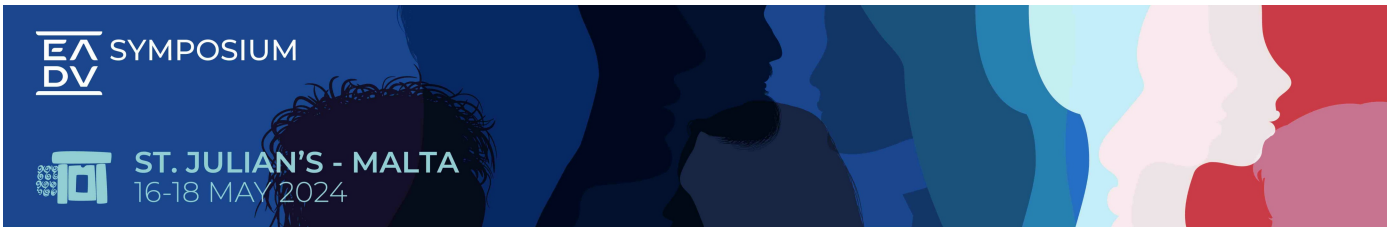


Figure 2: Proportion of patients who achieved an EASI ≤1

EASI, Eczema Area and Severity Index; LEB, lebrikizumab; PBO, placebo; Q2W, every 2 weeks.



Abstract N°: 671

Efficacy and safety of lebrikizumab in combination with topical corticosteroids in patients with moderate-to-severe atopic dermatitis not adequately controlled or non-eligible for cyclosporine: a placebo-controlled, randomized phase 3 clinical study (ADvantage)

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Introduction & Objectives: Lebrikizumab (LEB) is a novel monoclonal antibody that binds with high affinity and slow off-rate to interleukin (IL)-13, thereby blocking the downstream effects of IL-13 with high potency. LEB has previously demonstrated clinical efficacy and safety in adults and adolescents with moderate-to-severe atopic dermatitis (AD) in 3 randomized, placebo (PBO)-controlled, phase 3 trials.1-3 Cyclosporine A (CsA) is approved in the EU for treatment of severe AD, but its efficacy may not be optimal in some patients and its safety limits longer-term use. Here, we report 16-week efficacy and safety of LEB combined with low- or mid-potency topical corticosteroids (TCS) in patients with moderate-to-severe AD not adequately controlled or non-eligible for CsA in the phase 3 ADvantage study (NCT05149313).

Materials & Methods: ADvantage is a 52-week study with a 16-week, randomized, double-blind, PBO-controlled, parallel-group period followed by a 36-week open-label maintenance period. Eligible patients were adults and adolescents (≥12 to <18 years) with an Eczema Area and Severity Index (EASI) ≥16, Investigator's Global Assessment (IGA) ≥3, and ≥10% body surface area of AD involvement who were not adequately controlled or were non-eligible for CsA. Patients were randomized 2:1 to LEB 250 mg with a loading dose of LEB 500 mg at baseline and week 2, or PBO every two weeks (Q2W). All patients were to receive concomitant mid-potency TCS through week 16; dosage could be tapered to low-potency TCS once lesions were controlled and stopped after 7 days. The primary efficacy endpoint was the percentage of patients who achieved 75% reduction from baseline in EASI (EASI 75) at week 16. Secondary efficacy endpoints included percentage of patients achieving EASI 90, IGA 0/1, and ≥4-point improvement in pruritus Numeric Rating Scale (NRS) at week 16. Safety endpoints included treatment-emergent adverse events (TEAE), serious adverse events (SAE) and TEAE leading to discontinuation. Missing data due to lack of efficacy or data after rescue medication usage (high-potency TCS or systemic treatment) were imputed using non-responder imputation. Other missing data were imputed using multiple imputation.

Results: 331 patients were randomized (220 LEB+TCS and 111 PBO+TCS) and 212 and 100, respectively, completed the 16-week period. Treatment groups had similar baseline characteristics. At week 16, a significantly higher proportion of LEB+TCS vs PBO+TCS patients achieved EASI 75 (68.4% vs 40.8%, $p<0.001$) and EASI 90 (42.9% vs 20.8%, nominal $p<0.001$). Moreover, a higher percentage of patients achieved IGA 0/1 (42.0% vs 24.5%, nominal $p<0.01$) and a ≥4-point improvement in pruritus NRS (49.9% vs 29.7%, nominal $p<0.05$) at week 16. Incidence of TEAE was 61.8% LEB+TCS vs 53.2% PBO+TCS with nasopharyngitis (12.7% vs 12.6%) and conjunctivitis (11.4% vs 1.8%) being the most common TEAE. Overall, SAE and TEAE leading to discontinuation were low and similar in LEB+TCS and PBO+TCS (1.4% vs 0.9% and 0.9% vs 1.8%, respectively).

Conclusion: At week 16, LEB 250 mg Q2W administered with TCS significantly improved signs and symptoms of AD in adults and adolescents with moderate-to-severe AD and history of inadequate response to CsA, or for whom CsA was not

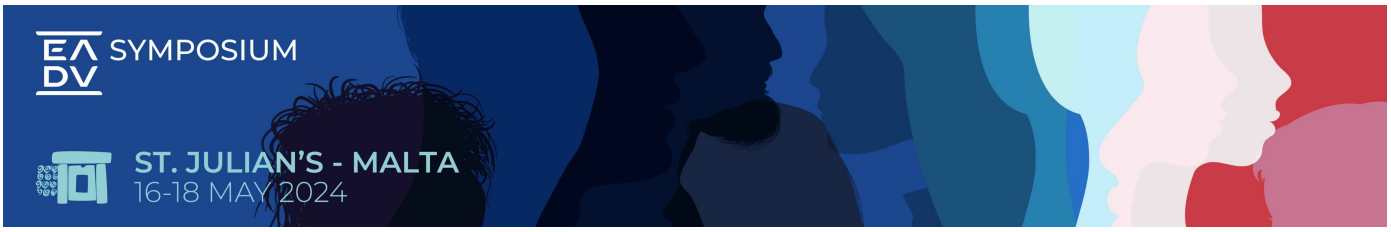
medically advisable. Safety was consistent with the known profile of lebrikizumab.

References:

1Blauvelt A, et al. BJD 2023;24;188:740-748.

2Silverberg JI, et al. NEJM 2023;388:1080-91.

3Simpson EL, et al. JAMA Dermatol 2023;159:182-91.



Abstract N°: 692

effectiveness of a gentle skincare routine in atopic dermatitis: a clinical study

Līga Brūniņa[1]

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Introduction & Objectives: Atopic dermatitis - there is no simple cure, proper skincare can help alleviate symptoms. Skincare products often contain irritating preservatives, which can be problematic for patients. Study aims to evaluate the effectiveness of a gentle skincare routine using formulations that promote balanced skin-cell interactions and reduce inflammation. **Materials & Methods:** Within the clinical study 43 participants (19 to 51 years) who showed clinical signs of dry skin, mild-to-moderate dermatitis completed the study. Subjects attended dermatologist visits at baseline and after 28 days of products use. The participants applied the washing oil (product 1) to the dermatitis/dry skin twice a day for 28 days. The product is washed off with water for not more than 1 minute. Afterwards participants applied the cream (product 2) for restoring and preserving the lipid layer of natural origin on dermatitis/dry skin. Product 1: Oil cleanser, surfactants less than 1.5% is free from any irritating preservatives, perfumes (and fragrance allergens). The antimicrobial properties are ensured with the prebiotic - Lactobacillus ferment. The product is hypoallergenic, and consists of caprylic/capric triglyceride, coco caprylate/caprate, Plukenetia Volubilis seed oil, Olea Europaea fruit oil, Vaccinium Macrocarpon seed oil and Helianthus Annuus seed oil, betaine, ceramide NP, Laminaria Ochroleuca extract and Curcuma Longa root extract, tocopherol. Product 2: O/W cream consists of Butyrospermum parkii (Shea) butter, Butyrospermum Parkii (Shea) butter extract, canola oil, coco-caprylate/caprate and C15-19 akane. The cream does not contain any traditional preservatives and is established from Lactobacillus ferment, sodium levulinate, sodium anisate and methylheptylglycerin in order to maintain healthy skin microbiome. The active ingredients - Ceramide NP, magnesium carboxymethyl beta-glucan, hydrolyzed jojoba esters, Betaine and Avena sativa (Oat) kernel extract have been found to have protective and healing effects on skin. **Results:** All the gathered data were checked using the reliability test with the Cronbach's Alpha to be acceptable from the 0.7 value. Table 1 reports comparison of the means of the overall results before and after application of the products across the whole sample. The difference is statistically significant with the p-value <0.05.

Table 1 Baseline 28 days Deviation

Severity of skin condition in the dimension of skin sensations

sting sensation/tingling 1.5116 1.2791 -0.2325

burning/heat sensation 1.7674 1.2326 -0.5348

heat wave 1.5581 1.1628 -0.3953

skin irritation/discomfort/sensitivity 1.7209 1.4419 -0.2790

Severity of skin condition in the dimension of visible skin changes diffuse redness/flushing 1.8837 1.5349 -0.3488

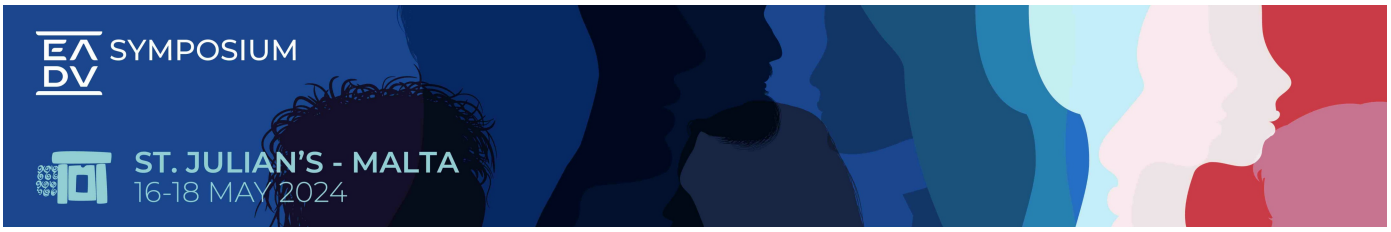
extended vascular networking 1.8372 1.3256 -0.5116

rash 1.8140 1.4651 -0.3489

edema/swelling 1.4186 1.1628 -0.2558

Conclusion: Results show the overall decrease of all sensitive and visual symptoms in both dimensions of the primary assessment measures. The most significant symptom reduction of severity of skin condition in the dimension of skin

sensations was noted in burning/heat sensation and in the dimension of visible skin changes in extended vascular networking reduction. The results of the conducted study can be interpreted as indicating the beneficial effects of the use of nature-based skincare products in case of atopic dermatitis.



Abstract N°: 700

Safety and efficacy of dupilumab in children with severe atopic dermatitis: a real-world study

Evanthia Mastoraki[1], Efi Iezekiel[1], Eleni Remountaki[1]

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Introduction & Objectives:

Atopic dermatitis (AD) is a common, often debilitating condition that can significantly impact the quality of life of young children and their caregivers. The treatment landscape of moderate-to-severe AD changed drastically since the approval of dupilumab, a monoclonal antibody blocking interleukin 4 and interleukin 13, for patients as young as 6 months old. The safety and efficacy of dupilumab have been demonstrated in several clinical trials. However, comprehensive real-world studies in the pediatric AD population are still needed. The aim of this study was to further illuminate, in real life, the treatment responses and occurrence of adverse events (AEs) of dupilumab-treated children with severe AD during dermatology follow-up assessments.

Materials & Methods:

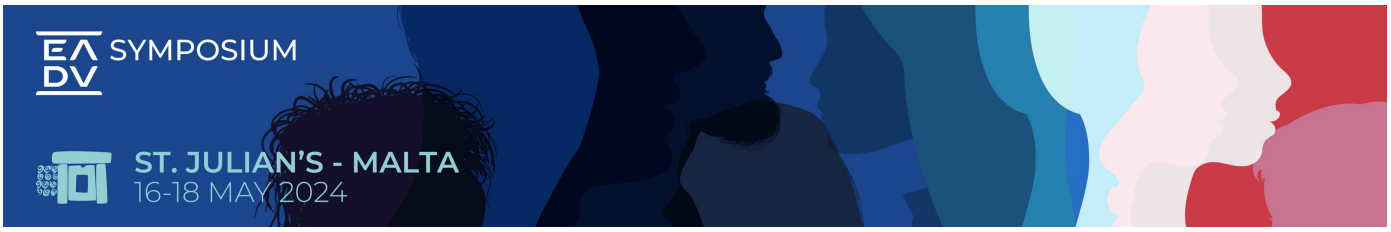
We retrospectively identified all the cases of children under the age of 16 with severe AD who were treated with dupilumab at label dosage between 1st of January 2021 and 30th of September 2023. Treatment outcome was assessed by Eczema Area and Severity Index (EASI), SCORing Atopic Dermatitis (SCORAD), Investigator's Global Assessment (IGA), and Peak Pruritus Numerical Rating Scale (PP-NRS) scores at baseline and after 16 and 52 weeks of treatment. Demographics, as well as safety data were collected.

Results:

A total of eight children [three females (37.5%) and five males (62.5%)] were identified, with a median age of 12 years (range 11 to 15 years). One patient was lost to follow-up after initial loading dose. 1/7 patient (14%) achieved >75% improvement in EASI (EASI-75) at week 16 and 3/3 (100%) at week 52. No patient achieved EASI-90 during the observed period. The mean ±SD EASI decreased from 23.9 ± 3.2 at baseline to 7.8 ± 3.9 at week 16 and 2.8 ± 0.2 at week 52. 6/7 patients (86%) with baseline IGA score ≥ 3 improved to an IGA score of ≤ 1 at week 16 post-dupilumab initiation. The mean SCORAD score also improved with dupilumab treatment from 61.9 ± 7.4 at baseline to 26.2 ± 6.7 and 13.9 ± 1 at week 16 and 52 respectively. The mean PP-NRS score at baseline was 8.5 and significantly reduced to 1.8 and 1, at week 16 and 52 respectively. Dupilumab was discontinued in two patient (29%) due to inadequate response. Discontinuation was also decided in a patient with facial dermatitis with concomitant conjunctivitis at week 56 of treatment. There were no serious adverse events.

Conclusion:

Patients treated with dupilumab in real-world clinical settings achieved considerable improvement of all clinical scores. Dupilumab was well tolerated and showed a good safety profile. Less adverse events were recorded in the real-world setting compared with clinical trials.



Abstract N°: 704

Quality of life and burden of moderate-to-severe atopic dermatitis in adult patients within the Asia-Pacific region: A cross-sectional survey

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Introduction & Objectives:

Atopic dermatitis (AD) is a common chronic and relapsing inflammatory skin disease that affects people of all ages. The burden of AD on patient is significant, with a substantial impact on quality of life (QoL), particularly for those patients suffering from more severe AD. This cross-sectional survey study aimed to ascertain the burden of AD, its impact on QoL, and associated costs among moderate-to-severe AD patients.

Materials & Methods:

Moderate-to-severe AD patients were enrolled from 8 territories, including Hong Kong, India, Japan, Mainland China, Singapore, South Korea, Taiwan, and Thailand. After screening and obtaining of informed consent electronically, eligible participants were asked to provide responses on their AD symptoms, severity, treatment and out-of-pocket costs via an online survey. QoL was assessed using EQ-5D-5L and Dermatology Life Quality Index (DLQI), while productivity loss was quantified using Work Productivity and Activity Impairment (WPAI) questionnaire. Data from completed submissions were analyzed using descriptive statistics, and costs were converted to United States Dollars (USD). The study was reviewed by the Institutional Review Board in each territory.

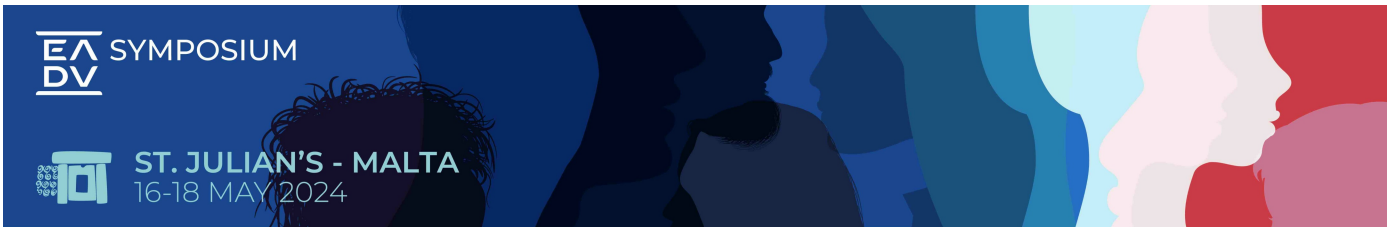
Results:

A total of 1,103 moderate-to-severe AD patients were included in the analysis. The median age of enrolled patients was 41 years (interquartile range, IQR=16.0). The majority of patients reported that their head/neck, trunk, upper limbs, and lower limbs were affected during a flare. Topical (74.2%) and oral steroids (58.7%) were frequently prescribed to manage AD. Common atopic comorbidities were allergic urticaria (64.2%), allergic rhinitis (61.8%) and allergic conjunctivitis (51.5%). Median DLQI score was 13.0 (IQR=11.0), with 65.5% of patients reporting that AD had a 'very large' or 'extremely large' effect on their life. The median EQ-5D-5L (based on China value set) score was 0.8 (IQR=0.4) and median EQ-VAS score was 64.0 (IQR=30.0). 87.2% and 77.2% of patients reported pain/discomfort and anxiety/depression on the EQ-5D-5L domains, respectively. Median total annual costs associated with AD was USD10,128.52 (IQR=12,963.26) per patient, with indirect costs being the largest component. The reported median annual direct medical costs, direct non-medical costs, and indirect costs were USD915.93 (IQR=2,023.57), USD138.58 (IQR=523.24) and USD6,655.68 (IQR=11,342.90), respectively. Findings from the WPAI indicated that presenteeism is a major contributor to productivity loss. The median percentages for absenteeism and presenteeism were 9.1% (IQR=21.4%) and 60.0% (IQR=40.0%), respectively. When absenteeism and presenteeism were both considered, the median percentage of overall work impairment was 61.5%

(IQR=37.8%). In addition, the majority of patients (73.5%) mentioned that AD caused a financial burden to some or a great extent.

Conclusion:

This multinational survey study showed that moderate-to-severe AD in Asian patients is associated with substantial impairment in QoL, labor productivity and economic burden. To alleviate the burden of AD in these patients, clinicians should be more proactive in managing concomitant conditions including psychological issues and barriers to work, and advocate for increased reimbursement for AD treatments.



Abstract N°: 706

Management of moderate-to-severe atopic dermatitis in adults: A cross-sectional survey of dermatologists within the Asia-Pacific region

Chia-Yu Chu*[1], Davis Yung Chan[2], Hao Cheng[3], Nisha Suyien Chandran[4], Ramesh Bhat[5], Sang Wook Son[6], Siriwan Wananukul[7], Demmi Liao[8], Sean Gardiner[9], Sophie Bozhi Chen[10], Qi Qing Ng[10], See-Hwee Yeo[10], Yoko Kataoka[11]

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Introduction & Objectives:

Treatment modalities of atopic dermatitis (AD) can vary across countries, potentially due to differences in patient preferences, availability of new therapies in the market, and multiple existing guidelines recommended for AD management. Currently, there is limited available evidence on real-world management of AD among Asian adults. This cross-sectional survey study aimed to assess current approaches in AD diagnosis and management in Asia.

Materials & Methods:

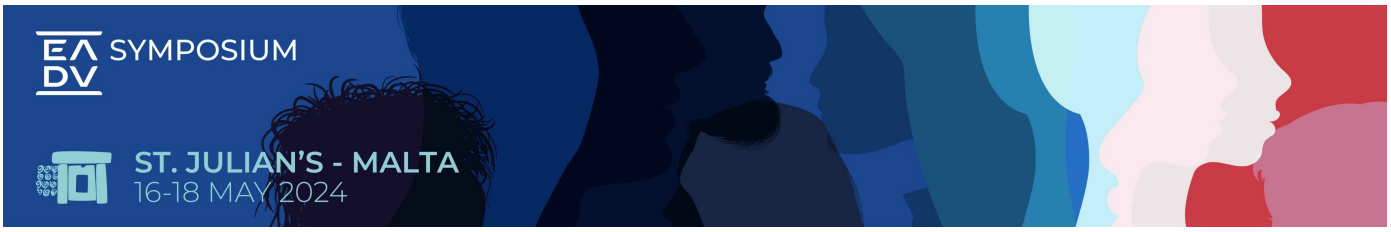
Practicing dermatologists who regularly treat patients with moderate-to-severe AD were recruited from 8 Asia-Pacific territories, including Mainland China, Hong Kong, India, Japan, Singapore, South Korea, Taiwan, and Thailand. To be eligible for participation, a physician was required to have at least two years of experience as a board-certified dermatologist, treat an average of two or more adult patients with moderate-to severe AD per month, and spend at least 60% of their working time in direct patient care (equivalent to three out of five working days). A survey was administered to eligible dermatologists after screening and taking of informed consent. Data from fully completed submissions were analysed using descriptive statistics. The study was approved by the Institutional Review Board in each territory.

Results:

Data from 271 dermatologists were included for analysis. Among them, 59.0% had >10 years of post-training experience in AD management and 32.8% practiced in university teaching hospitals. A median of 30 (interquartile range=50.0) moderate-to-severe AD patients were treated monthly. Hanifin and Rajka criteria use during diagnosis was reported by approximately one third (31.7%) of participants, while the majority of participants reported that they also relied on their clinical impression to assess AD severity and treatment response. Reduction of eczema and pruritus was the primary treatment objective when managing both acute (98.1%) and chronic (69.1%) AD. More than half (50.9%) of dermatologists preferred adding systemic anti-inflammatory medication for patients who did not respond to maximized topical treatment, while 43.6% would switch to another systemic medication for those who failed to respond to maximized systemic treatment. Corticosteroids (topical and oral) were frequently selected by dermatologists for AD treatment. Different potencies of topical corticosteroids were also chosen based on the nature (acute vs. chronic) and location (sensitive vs. non-sensitive area) of AD. For systemic therapies, participants considered cyclosporin and dupilumab. Narrow-band ultraviolet B was the most common phototherapy reported (84.9%). In addition, there was considerable variation in estimated average and maximum durations of therapies used to treat AD.

Conclusion:

This study provides insights on the real-world management of moderate-to-severe AD in the Asia-Pacific region. The diverse approaches in diagnosis and treatment highlight the multifactorial nature of AD, reliance on clinical judgement and importance of personalized care. To improve outcomes in AD patients, it remains a priority to develop biomarkers for diagnosis, reduce subjectivity in assessment, as well as promote access to newer and more effective therapies.



Abstract N°: 707

Bridging the gap: Comparing patient-clinician views on treatment goals and communication in the management of atopic dermatitis within the Asia-Pacific region

Chia-Yu Chu[1], Davis Yung Chan[2], Hao Cheng[3], Nisha Suyien Chandran[4], Ramesh Bhat[5], Sang Wook Son[6], Siriwan Wananukul[7], Demmi Liao[8], Sean Gardiner[9], See-Hwee Yeo[10], Sophie Bozhi Chen[10], Qi Qing Ng[10], Yoko Kataoka[11]

[1]National Taiwan University Hospital and National Taiwan University College of Medicine, Department of Dermatology, Taipei, Taiwan, [2]Apex Dermatology Institute, Hong Kong, China,[3]Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, Department of Dermatology, Hangzhou, China, [4]National University Hospital, Division of Dermatology, Department of Medicine, Singapore, Singapore, [5]Father Muller Medical College, Mangalore, India,[6]Korea University College of Medicine, Department of Dermatology, Seoul, Korea, Rep. of South, [7]King Chulalongkorn Memorial Hospital, Chulalongkorn University, Department of Pediatrics, Bangkok, Thailand, [8]Pfizer Ltd, Taipei, Taiwan, [9]kPfizer Ltd, Kuala Lumpur, Malaysia, [10]IQVIA Solutions Asia, Real World Solutions, Singapore, Singapore,[11]Osaka Habikino Medical Center, Department of Dermatology, Habikino, Japan

Introduction & Objectives:

Shared treatment goals and patient-clinician communication are essential for improved atopic dermatitis (AD) treatment outcomes. However, it remains unclear how AD patients and clinicians perceive the level of patient-clinician communication, and whether they are aligned in treatment goals and expectations. This cross-sectional survey study aimed to compare perspectives between AD patients and dermatologists regarding communication, treatment goals and expectations in Asia.

Materials & Methods:

Moderate-to-severe AD patients and practicing dermatologists were recruited from 8 Asia-Pacific territories, including Mainland China, Hong Kong, India, Japan, Singapore, South Korea, Taiwan, and Thailand. Patients and dermatologists completed separate surveys designed to elicit their goals and expectations regarding AD management, and their perceived level of patient-clinician communication. Patients were also asked about their treatment satisfaction, and whether they prefer additional treatment beyond what was prescribed. Both the patient and clinician surveys were first developed in English before being translated into the respective local languages for administration. Patients completed the surveys online, while dermatologists completed the surveys either online or over the telephone. Demographic information and responses were analyzed using descriptive statistics. The study was reviewed by the Institutional Review Board in each territory, and all participants provided informed consent.

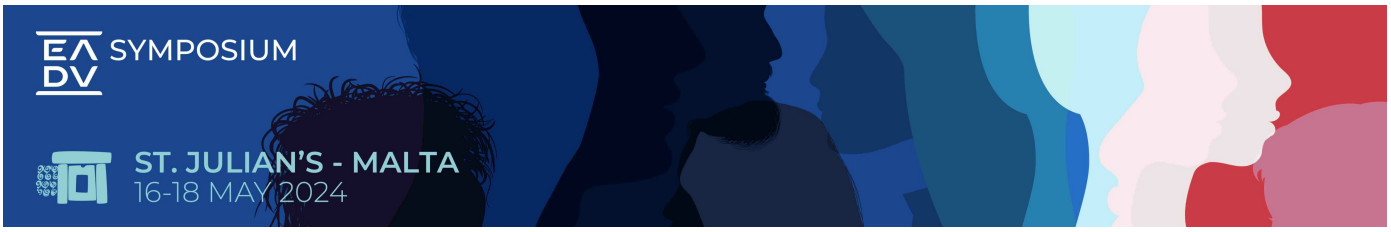
Results:

A total of 1,103 patients and 271 dermatologists completed the surveys. The median age of the enrolled patients was 41.0 years old (interquartile range=16.0). Among the recruited dermatologists, the majority reported having more than 10 years of experience in managing and treating AD (59.0%), and were working in university hospitals or academic institutions (32.8%). Overall, both AD patients and dermatologists were aligned in treatment goals for AD management. The top three shared goals were the reduction of AD symptoms, prevention of recurring AD symptoms, and having few or little treatment side effects. However, a greater proportion of patients prioritized the prevention of AD symptom recurrence (78.0% vs. 47.2%) and improvement in mental health (16.0% vs. 4.9%), compared with the dermatologists. Although patient-clinician communication was observed to be generally good, 10.9% of patients reported dissatisfaction with communication in AD management. Furthermore, there may be inadequate communication on how AD or its treatment affects COVID-19 infection. While the majority of patients reported being either ‘very satisfied’ or ‘satisfied’ with

their most recent acute AD treatment, 65.5% of patients still desired additional treatment.

Conclusion:

This multinational study provided insights on the perspectives of moderate-to-severe AD patients and dermatologists in treatment goals, expectations on AD management, and patient-clinician communication. In general, both patients and dermatologists were aligned in treatment goals and most aspects of patient-clinician communication were reported as satisfactory. However, potential areas of improvement have been identified to further enhance patient-centered care in Asia.



Abstract N°: 744

The effectiveness of the co-administration of dupilumab and risankizumab in patients with concurrent atopic dermatitis and psoriasis

Davide Termini[1], Gianluca Tavoletti[1], Alessandra Chiei-Gallo[1], Roberto Pinto[1], Carlo Carrera[1], Angelo Marzano[1], Silvia Ferrucci[1]

[1]Dipartimento di Fisiopatologia Medico-Chirurgica e dei Trapianti, Università degli Studi di Milano, SC Dermatologia, Fondazione IRCCS Ca' Granda Ospedale Maggiore Policlinico, Milano, Milano, Italy

Introduction & Objectives:

In the era of biologic drugs, new therapeutic frontiers are opening up in the management of inflammatory skin conditions, particularly psoriasis and atopic dermatitis. Although these two pathologies have distinct pathogenetic bases, it has emerged that these conditions can coexist in the same patient, both as separate entities and as manifestations unmasked by the use of specific drugs. Managing patients with multiple inflammatory skin diseases is a therapeutic challenge, often requiring the simultaneous use of various pharmacological agents.

Materials & Methods:

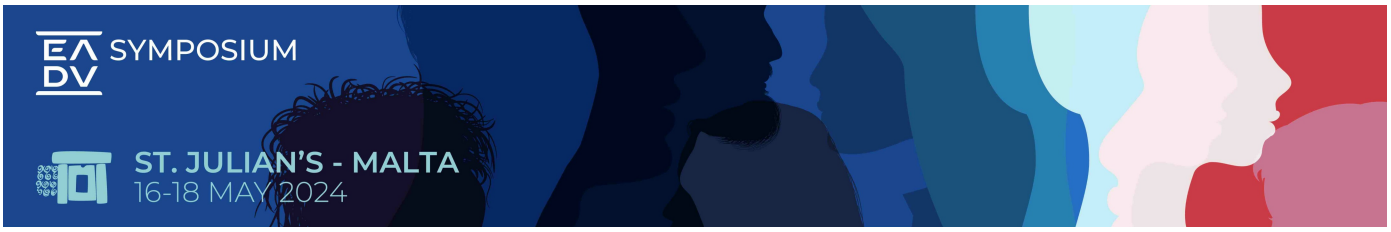
Case series on a patient affected by atopic dermatitis who developed plaque psoriasis after therapy with dupilumab. The patient was monitored through serial checks approximately every 4 months and assessed using the EASI score and various questionnaires (DLQI, ADCT, POEM, NRS itch, SD NRS and HADS) concerning atopic dermatitis. For psoriasis, the PASI score was employed.

Results:

In our study, we present the case of a 46-year-old Caucasian male suffering from atopic dermatitis with a nummular-eczema-like phenotype. The clinical picture included atopic comorbidities such as allergic rhinoconjunctivitis, positive prick tests for numerous foods and inhalants, and elevated levels of total IgE. After several years of therapy with topical corticosteroids and cyclosporine with only partial benefit, dupilumab was introduced in 2018, resulting in complete remission of eczematous lesions. However, a year later, the patient developed histologically confirmed plaque psoriasis. Dupilumab was therefore discontinued, and a new cycle with cyclosporine was initiated, replaced the following year with methotrexate due to its diminishing efficacy on psoriasis. In 2021, the reappearance of new eczematous lesions led to the replacement of methotrexate with upadacitinib, hoping to achieve benefits for both inflammatory conditions. However, after only three months of discontinuing the traditional drug, a new psoriasis flare prompted the suspension of upadacitinib and the reintroduction of methotrexate at higher doses. The condition seemed to improve until September 2022 when new clearly eczematous lesions prompted the decision to combine tralokinumab with methotrexate. However, a new reactivation of psoriasis led to the replacement of both molecules with risankizumab. As expected, there was an improvement in psoriatic lesions at the expense of eczematous ones, prompting the initiation of a dual treatment with different biologic drugs in an attempt to manage both inflammatory pathways: risankizumab and dupilumab. After several months of treatment, complete resolution of skin lesions was observed without the onset of side effects.

Conclusion:

The preliminary results of our study provide a new perspective on the combined treatment of dupilumab and risankizumab in patients with concurrent atopic dermatitis and psoriasis. Despite the importance of cost considerations and the need for long-term follow-up for safety assessment, this approach could represent a promising therapeutic strategy. Further studies, with a larger sample size and extended follow-up, are necessary to confirm the efficacy and safety of this combination therapy.



Abstract N°: 774

Epidemiological and clinical profile of atopic dermatitis in adults : a retrospective study of 18 patients.

Sara Boujloud[1], Fatima-Zahra Elfatoiki[1], Hali Fouzia[1], Soumia Chiheb[1]

[1]Ibn Rochd University Hospital, Dermatology-Venerology Department, Casablanca, Morocco

Introduction & Objectives:

Atopic dermatitis (AD) is a common inflammatory skin disorder that often begins early in life. The exact prevalence of the disease varies among studies, and its estimation remains challenging. Adult AD includes cases that have recurred or persisted since childhood, as well as those that begin as new occurrences in adulthood. This condition has a major impact on public health due to its chronic nature and its effect on quality of life.

Materials & Methods:

Over a four-year period from March 2018, we conducted a retrospective analysis of 18 cases of atopic dermatitis in adults aged over 18 years who consulted at the dermatology department of Ibn Rochd University Hospital in Casablanca, Morocco.

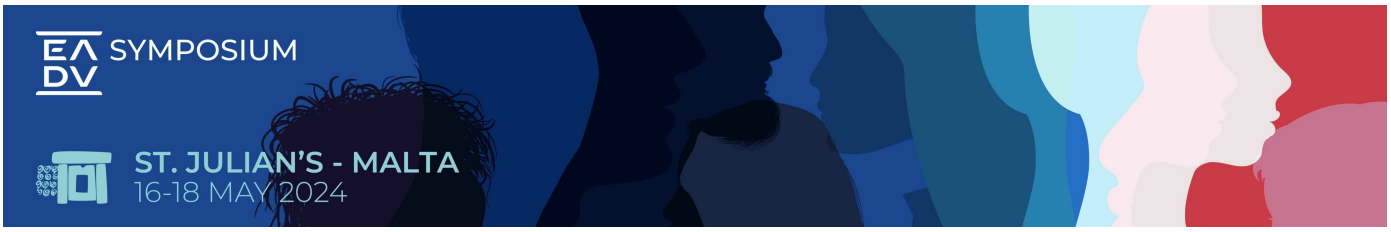
Results:

We included 18 patients in the study, 67% were female. The age ranged from 18 to 56 years, with a mean age of 31.5 years. Reported signs among our patients included: cutaneous xerosis (66%), asthma (44%), and allergic rhinitis (44%). Only one case of known aspirin allergy was found. 32% of patients presented with erythematous and pruritic lesions, 22% showed cutaneous xerosis, and 15% presented with dyshidrosis. 2 patients consulted for chronic prurigo. Only 7% of patients showed Dennie Morgan sign on clinical examination. Fold involvement was observed in 24% of our patients; selective involvement of the head and neck was found in 10% of patients. Paraclinical assessment was performed in 44% of patients, including 7 skin biopsies confirming the diagnosis of atopic dermatitis. Finally, 22% of patients experienced complications: impetiginization or herpetic superinfection.

All patients were treated with topical corticosteroids and emollients; topical calcineurin inhibitors were prescribed for only 2 patients.

Conclusion:

Atopic dermatitis is common not only in children but also in adults, making a major impact on public health. Given the heterogeneous clinical presentation of atopic dermatitis and the lack of consensus diagnostic criteria, accurately determining its worldwide prevalence remains challenging.



Abstract N°: 891

Dupilumab for hand eczema treatment in patients with atopic dermatitis in real clinical practice

Daniel Muñoz-Barba[1, 2], Trinidad Montero-Vilchez[2], Raquel Sanabria de la Torre[2], Clara-Amanda Ureña-Paniego[2], Salvador Arias-Santiago[2]

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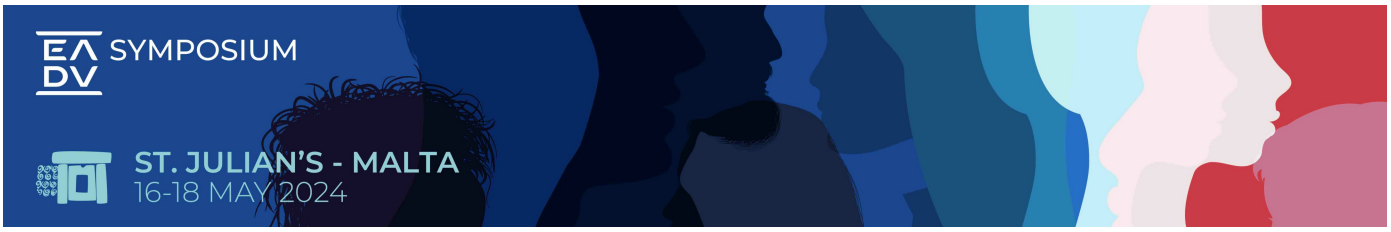
Introduction & Objectives: Atopic dermatitis (AD) is a chronic inflammatory skin disease that frequently affects hands. This subgroup of patients suffers a strong impact on their quality of life in different areas, comparable to other diseases including cancer or diabetes. So the objective of this study was to evaluate the effectiveness and safety of dupilumab for the treatment of AD in patients with and without hand eczema in real clinical practice.

Materials & Methods: A prospective cohort study was conducted including all patients with severe AD who started treatment with dupilumab for the first time and who received the treatment according to the technical data sheet for at least 48 weeks. Patients were grouped according to whether or not they had hand eczema

Results: 29 patients were included in the study, with 13 (44.8%) presenting with hand eczema. Patients in both groups showed improvement in severity scales and AD symptomatology, reflected in a decrease in Eczema Area and Severity Index (EASI), Scoring Atopic Dermatitis (SCORAD) and Visual Analogue Scales (VAS) to assess itching and sleep ($p<0.05$). No notable adverse effects were reported.

Conclusion: Dupilumab is an effective and safe drug for the treatment of severe atopic dermatitis, including patients with hand eczema



Abstract N°: 898

Minimal disease activity in patients with atopic dermatitis treated with upadacitinib: a prospective observational study

Trinidad Montero-Vilchez[1], Carolina Montero-Vilchez[1], Cristina Garrido Colmenero[2], Raquel Sanabria de la Torre[1], Salvador Arias-Santiago[1]

[1]Virgen de las Nieves University Hospital, Granada, Spain,[2]Hospital of Jaen, Jaén, Spain

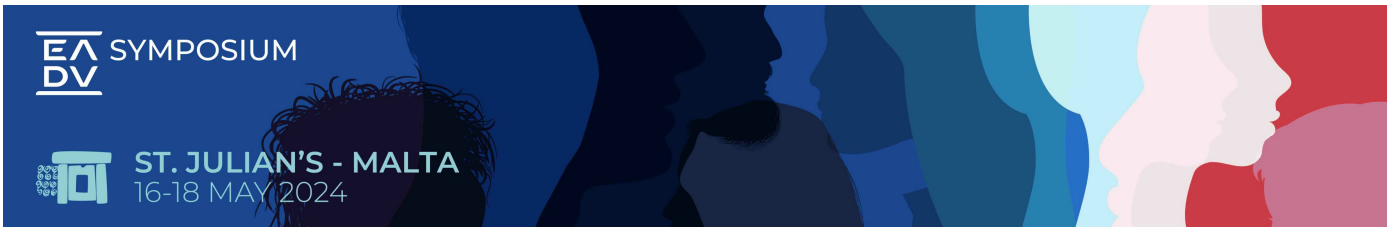
Introduction & Objectives: The therapeutic arsenal in atopic dermatitis (AD) is progressively increasing. As a result, drugs need to be highly effective in order to find a place in an increasingly competitive market. It is also necessary to include the assessment of the physician and the patient to evaluate the effectiveness of a drug. The concept of minimal disease activity (MDA) is a new measure of therapeutic efficacy that includes the patient and physician perspective. To date, there are few real-life studies using MDA to assess therapeutic outcomes. The aim of this study is to assess the percentage of patients achieving MDA after treatment with upadacitinib and to analyse their clinical and sociodemographic characteristics.

Materials & Methods: A prospective observational study was designed to include adult patients with moderate-severe AD from two hospitals in Spain who were to start treatment with upadacitinib. Patients were assessed before starting treatment and after 16 weeks.

Optimal treatment goals (OTT) include an improvement ≥90% in Eczema Area and Severity Index (EASI) and a numerical rating scale ≤ 1 for maximum pruritus.

Results: Twenty-three patients with AD treated with upadacitib were included, with a mean age of 27.70 (11.09 SD) years. 22 (95.7%) patients had been previously treated with cyclosporine and 11 (47.8%) had previously received dupilumab. An improvement in severity was observed, reflected by a decrease in EASI (24.09 vs 4.36, $p<0.001$) and pruritus (7.09 vs 2.55, $p=0.001$). After follow-up, 10 patients (43.5%) reached MDA. Patients who achieved MDA were less frequently asthmatic (20% vs 69.2%, $p=0.02$) and had lower baseline itching (5.83 vs 7.6, $p=0.08$) weeks of upadacitinib treatment. No patients had side effects after the follow-up period.

Conclusion: More than 40% of patients with moderate-severe AD treated with upadacitinib achieve optimal treatment goals. The presence of asthma and a higher baseline degree of itchiness may hinder the achievement of these targets.



Abstract N°: 922

Colonization resistance syndrome of opportunistic microflora of the Micrococcacea family in patients with skin diseases.

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Introduction & Objectives: The world has seen a steady increase in allergic skin diseases among the population. In the chronicity and recurrence of the disease, a special place is occupied by the condition of the skin, its microbiota, skin pH and local immunity. It is described that the microbial flora of the skin in a significant proportion of patients with allergic dermatoses causes complications in 45-90% of patients, aggravating the course of the underlying disease.

The purpose of the study was to assess the state of the skin microbiota and determine the degree of colonization of staphylococci on the skin during the clinical course of patients with skin diseases.

Materials & Methods: We examined 462 patients with skin diseases aged from 7 to 48 years. Of these, 200 (43.3%) patients were males and 262 (56.7%) were females. According to clinical nosology, 137 (34.2%) patients were diagnosed with atopic dermatitis (AD), seborrheic dermatitis (SD) - 134 (33.4%), allergic dermatitis (ALD) - 144 (31.2%) and rosacea - 47 (10.2%) All patients underwent clinical (SCORAD, SEDASI, DISHS), microbiological and statistical studies. The control group consisted of 72 healthy individuals of the appropriate age.

Results: The results of microbiological studies showed that among 462 patients, 403 had staphylococcus spp. inoculated on the skin of the lesions, which accounted for 87.2% of cases. According to species identification, st.aureus was most often sown - 44.4%, St. epidermidis – 32.7%, St. saprophyticus – 12.4% and St. Haemoliticus – 10.4%.

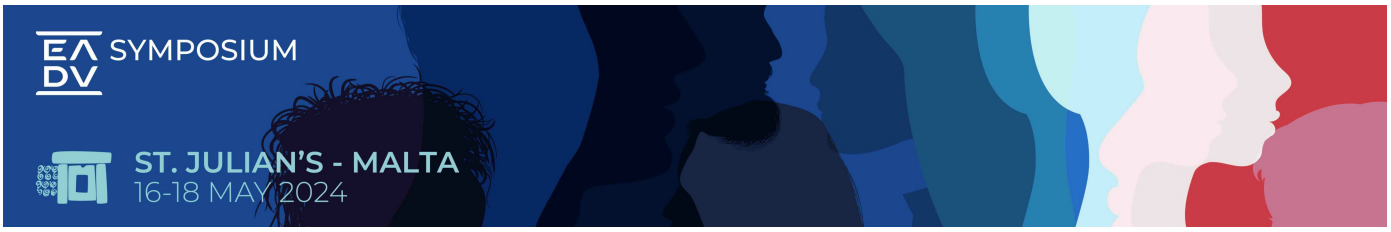
In the examined patients, increased colonization of staphylococcal flora was observed on the skin of the lesions, which was statistically significantly different from the indicators of the control healthy individuals ($P < 0.05$).

Analysis of the correlation between the degree of colonization and the severity of the clinical course of the disease was variable: with mild severity, the contamination of St. aureus had a statistical correlation $r = +0.5$ and $r = +0.4$ in patients with atopic dermatitis and allergic dermatitis ($P < 0.05$), St. epidermidis there was an inverse significant correlation in the group of patients with AlD and rosacea ($r = -0.5$) ($P < 0.05$). St. Saprophyticus – in the group of patients with AD ($r = +0.4$, $P < 0.05$) and with AlD - $r = +0.3$. St. Haemoliticus – direct correlation with blood pressure – $r = +0.4$ ($P < 0.05$).

Whereas with moderate severity of dermatoses, in the group of patients with AD, St. had a direct correlation. aureus - $r = +0.3$, St. saprophyticus – $r = +0.5$ ($P < 0.05$), in the group of patients with seborrheic dermatitis St. Haemoliticus - $r = +0.9$ ($P < 0.05$), whereas in the group of patients with rosacea a statistically significant correlation was shown with St. epidermidis - $r = +0.5$ ($P < 0.05$).

In patients with severe severity, blood pressure showed a significant correlation with St. Aureus and St. saprophyticus – $r = +0.4$ ($P < 0.05$), St. Haemoliticus – $r = +0.5$ ($P < 0.05$), respectively.

Conclusion: The results of the study indicate that patients with chronic disease have a violation of the colonization resistance syndrome of opportunistic microorganisms.



Abstract N°: 931

A case of severe atopic dermatitis with dermatopathic lymphadenopathy

Jiehyun Jeon*[1], Han-Na Kim[1], Been Woo[1], Ko Eun Kim[1], Yoo Sang Baek[1]

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Introduction & Objectives:

Dermatopathic lymphadenopathy is a histological entity characterized by enlarged lymph nodes with paracortical hyperplasia. It is usually associated with various skin diseases such as infections, inflammatory skin diseases (erythroderma, atopic dermatitis), and lymphoproliferative disorders. Herein, we report a case of severe atopic dermatitis with significant dermatopathic lymphadenopathy.

Materials & Methods:

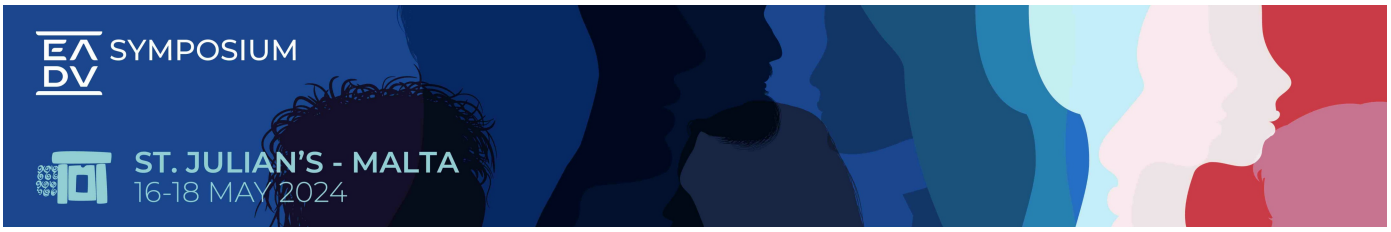
A 51-year-old female who had been treated with oral cyclosporine (200mg/day) for over a year under the impression of atopic dermatitis, was referred to our dermatology department due to ongoing severe symptoms. She also presented with multiple asymptomatic palpable lymph nodes in the neck, axillary, and inguinal regions, which first appeared 2 years ago. Ultrasound-guided biopsy from her right axillary lymph node was done. To rule out cutaneous lymphomas and other skin diseases associated with dermatopathic lymphadenopathy, skin punch biopsy was performed on her thigh.

Results:

Ultrasound-guided lymph node biopsy showed paracortical hyperplasia infiltrated with dendritic cells and Langerhans cells with preserved immunoarchitecture. Histopathologic examination of skin punch biopsy revealed spongiotic dermatitis with parakeratosis, exocytosis, and superficial perivascular lymphoeosinophilic infiltration. No atypical lymphocytes or epidermotrophism were observed. Accordingly, dermatopathic lymphadenopathy was diagnosed.

Conclusion:

Dermatologists should be aware of dermatopathic lymphadenopathy and consider differential diagnoses including cutaneous lymphomas, especially in the cases of severe atopic dermatitis or during Dupilumab treatment.



Abstract N°: 946

Improvements on patient-reported outcome (PRO) measures with 24 weeks of amlitelimab treatment in adults with moderate-to-severe atopic dermatitis: results from a Phase 2b trial (STREAM-AD)

Andrew Blauvelt*[1], Ken Igawa[2], Efstathios Zikos[3], Christine Weber[4], Jennifer Wang[5], Cori Gray[5], Stephan Weidinger[6]

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Introduction & Objectives: Atopic dermatitis (AD) significantly impairs quality of life (QoL), with negative impact correlating with disease severity. Here, we report PRO data from the STREAM-AD trial of adults with moderate-to-severe AD treated with amlitelimab (SAR445229; KY1005), an anti-OX40 ligand monoclonal antibody, vs.** placebo.

Methods: STREAM-AD (NCT05131477) is a 52-week, randomized, double-blinded, placebo-controlled, dose-ranging Phase 2b trial in 2 parts (24-week Part 1 completed and presented here; Part 2 ongoing). Adults (18 to <75 years) with moderate-to-severe AD were randomized 1:1:1:1:1 to receive amlitelimab (250 mg with 500 mg loading dose [LD], n=77; 250 mg [no LD], n=78; 125 mg, n=77; 62.5 mg, n=79) or placebo (n=79) every 4 weeks. Patient disease severity/control and QoL were measured by Patient Oriented Eczema Measure (POEM), Dermatology QoL Index (DLQI), and AD Control Tool (ADCT).

Results: Improvements from baseline (mean change) at Week 24 were seen across all amlitelimab arms. POEM (standard deviation [SD]): amlitelimab 250 mg with LD, −9.96 (7.89); 250 mg (no LD), −7.21 (8.21); 125 mg, −7.86 (8.57); 62.5 mg, −7.64 (7.01); placebo, −2.19 (7.31). DLQI (SD): amlitelimab 250 mg with LD, −8.33 (7.04); 250 mg (no LD), −6.54 (6.38); 125 mg, −6.74 (8.68); 62.5 mg, −7.69 (7.23); placebo, −2.30 (6.41). ADCT (SD): amlitelimab 250 mg with LD, −7.35 (6.70); 250 mg (no LD), −5.80 (6.19); 125 mg, −6.70 (6.57); 62.5 mg, −6.66 (5.87); placebo, −1.90 (5.05).

Conclusion: Amlitelimab improved metrics of disease severity, disease control, and QoL, with the greatest improvement seen in the 250 mg with LD arm.

Acknowledgements and funding: This study was funded by Sanofi. ClinicalTrials.gov Identifiers: NCT05131477.

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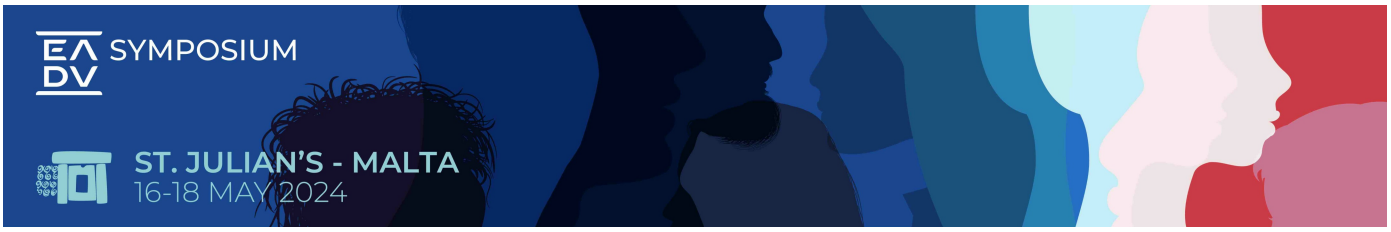

Abstract N°: 967

The landscape of atopic dermatitis burden in Europe: insights from analyzing web search data in 21 countries

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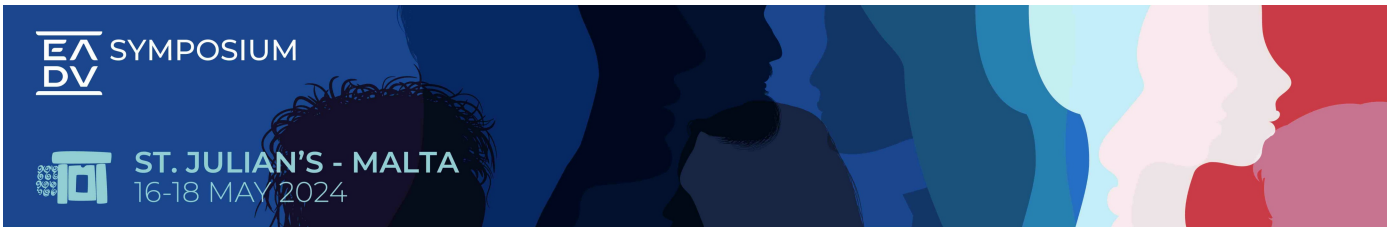
Introduction & Objectives: Atopic dermatitis poses a significant public health concern due to its complexity, high prevalence, and notable personal as well as socioeconomic implications. Leveraging crowdsourced Internet data offers an opportunity for distinctive insights into this concern, as evidenced by prior research. Nonetheless, a comprehensive cross-national examination within Europe has yet to be undertaken. This study examines atopic dermatitis-related web searches across Europe, aiming to assess spatial variations and to explore potential correlations between disease-specific factors and external influences.

Materials & Methods: For this retrospective longitudinal study, Google Ads Keyword Planner was used to generate web search data for atopic dermatitis in 21 European countries (Austria, Bosnia and Herzegovina, Croatia, Czechia, Denmark, France, Germany, Greece, Hungary, Ireland, Italy, Malta, Netherlands, Poland, Portugal, Romania, Serbia, Spain, Sweden, UK, Ukraine) from 02/2019 to 01/2023. To compare the search volume (i.e., the number of searches for a topic or search term, SV) between the countries, it was calculated per 100,000 inhabitants (SV/100k). Descriptive analyses were performed to assess spatial variations. Spearman's correlation coefficients (r) were utilized to assess the relationships between SV and disease-related metrics, socioeconomic indicators, and meteorological parameters including the number of countries with valid information.

Results: A total of 241 million atopic dermatitis-related web searches were identified, with considerable heterogeneity observed in SV/100k across European countries ($p<0.001$). Hungary, Sweden, and Romania had the highest median monthly SV/100k, while Ukraine, Serbia, and Bosnia and Herzegovina exhibited the lowest (91 [78.1; 109.1] ≤ median monthly SV/100k ≤ 3,008.8 [2,436.9; 3,670.3]). The SV showed significant correlations with the prevalence of atopic dermatitis and disability-adjusted life-years due to atopic dermatitis (both $r=0.51$, $p=0.019$). Negative correlations were noted with median population age ($r=-0.46$, $p=0.039$), as well as the numbers of general practitioners ($r=-0.29$, $p=0.226$) and specialists ($r=-0.27$, $p=0.270$). Mainly negative correlations were seen between SV/100k and mean global radiation ($r=-0.16$ [-0.38; -0.04], $n=18$), mean sunshine duration ($r=-0.29$ [-0.51; -0.18], $n=13$), mean precipitation (median $r=-0.14$ [-0.28; 0.00], $n=18$), and mean temperature ($r=-0.55$ [-0.73; -0.43], $n=19$), while positive correlations were identified for mean wind speed ($r=0.37$ [0.11; 0.49], $n=18$) and mean relative humidity ($r=0.11$ [0.02; 0.17], $n=14$).

Conclusion: The study highlights variations in web search patterns among European countries, aligning with the prevalence and impact of atopic dermatitis. Leveraging crowdsourced data presents multifaceted opportunities for enhancing comprehension of this complex dermatological condition, including the monitoring of search behavior for developments due to climate change or to reveal unmet needs in the population. Prioritizing the provision and enhancement of online health information holds significant implications for governmental bodies and healthcare providers, given the consequential benefits of ensuring the reliability of such resources for patients and physicians, particularly in light of the shortage of healthcare professionals across Europe.



Abstract N°: 1008

Effectiveness and safety of upadacitinib in adolescent and adult patients with atopic dermatitis: an interim analysis of week 20-32 data from a real-world multicenter retrospective review

Brian Rankin[1], Siddhartha Sood[2], Ye-Jean Park[2], Alexander Rimke[3], Abrahim Abduelmula[4], Jorge Georgakopoulos[4], Khalad Maliyar[4], Ferne-Joy Leung[5], Lauren Stark[5], Alim R. Devani[3, 5, 6], Jensen Yeung[4, 6, 7, 8], Vimal H. Prajapati*[3, 5, 6, 9, 10, 11]

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Introduction & Objectives:

While clinical trial data demonstrates the effectiveness and safety of upadacitinib (UPA), a selective oral Janus kinase inhibitor (JAKi) for atopic dermatitis (AD), there is still a shortfall of real-world evidence.

Materials & Methods: We conducted a multicenter retrospective review across Canada, encompassing one community and two academic practices. The efficacy endpoints evaluated at weeks 20-32 were as follows: Investigator Global Assessment (IGA) score of clear or almost clear (IGA 0/1), Eczema Area and Severity Index (EASI), Body Surface Area (BSA), IGAxBSA, and Dermatology Life Quality Index (DLQI)/Children's DLQI (CDLQI) improvements. Safety was determined via treatment-related adverse events (AEs).

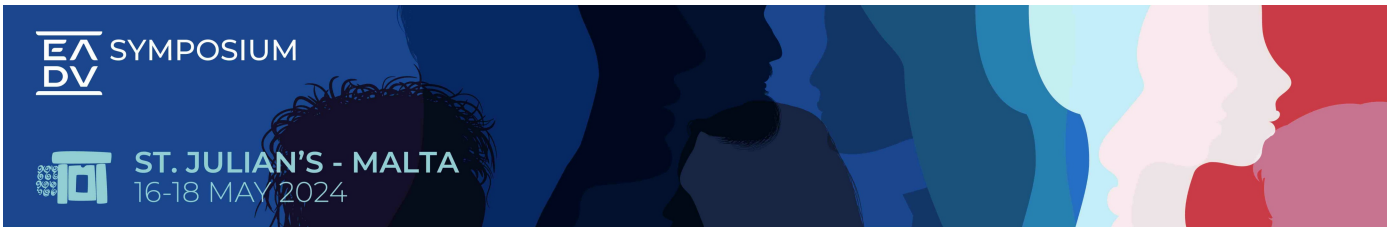
Results: A total of 131 patients were included in this study. Mean age was 44.3 ± 17.5 years; 53.4% (70/131) were female. UPA doses were 15 mg (43.5%, 57/131) or 30 mg (56.5%, 74/131) once daily. Previous treatments included: topical therapy (100%, 131/131), phototherapy (29%, 38/131), systemic non-biologic therapy (75.6%, 99/131), and systemic biologic/JAKi therapy (38.9%, 51/131).

At weeks 20-32: 85.5% (112/131) of patients achieved IGA 0/1; 84.3% (59/70), 75.7% (53/70), and 62.9% (44/70) of patients achieved EASI improvements of 75% (EASI75), 90% (EASI90), and 100% (EASI100), respectively; mean EASI was reduced from 12.7 to 0.7 (p=0.0001; mean EASI improvement = 88.8%); 94.3% (66/70), 92.9% (65/70), 90% (63/70), and 77.1% (54/70) of patients achieved absolute EASI<7, EASI<5, EASI<3, and EASI<1, respectively; mean BSA was reduced from 16.4% to 0.9% (p=0.0001; mean BSA improvement=92.5%); mean IGAxBSA was reduced from 53.5 to 1.6 (p=0.0001; mean IGAxBSA improvement=95.7%); and mean DLQI/CDLQI was reduced from 13 to 1.2 (p=0.0001; mean DLQI/CDLQI improvement=90.5%), with 84.6% (55/65) of patients achieving DLQI/CDLQI 0/1. UPA monotherapy was utilized in 38.9% (51/131) of cases. Common concomitant therapies included topical corticosteroids (56.5%, 74/131), systemic corticosteroids (5.3%, 7/131), and topical calcineurin inhibitors (3.8%, 5/131).

Frequent AEs included: acne (18.3%, 24/131), hypertriglyceridemia (18.3%, 24/131), elevated creatinine phosphokinase (12.2%, 16/131), herpes simplex virus (5.3%, 7/131), and transaminitis (5.3%, 7/131). Five patients (3.8%) discontinued UPA due to treatment-related AEs (myalgia/arthralgia [n=2]; gastrointestinal discomfort [n=1]; venous thromboembolism [n=1]; folliculitis [n=1]). No serious infections, tuberculosis, major adverse cardiovascular events, gastrointestinal perforation, or malignancy were observed in 67.4 patient-years of safety follow-up.

Conclusion:

Our real-world study shows that UPA is an effective and safe therapy for AD, with high levels of skin clearance and a favorable safety profile between weeks 20-32. These results indicate that UPA may perform better in the real-world versus clinical trial setting, as compared to the Heads Up and Rising Up studies at week 24, specifically for IGA 0/1 and EASI75/90/100 achievement. Limitations of this study include its retrospective nature and smaller sample size.



Abstract N°: 1014

Atopic dermatitis and Risk of Incident Rheumatoid arthritis: A Systematic Review and Meta-analysis of Cohort Studies

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Introduction & Objectives: ** Atopic dermatitis (AD) has been reported to be associated with the incidence of several autoimmune diseases. However, it remains unclear whether patients with AD were at an increased risk of rheumatoid arthritis (RA). We aimed to determine the association between AD and the risk of incident RA.

Materials & Methods:

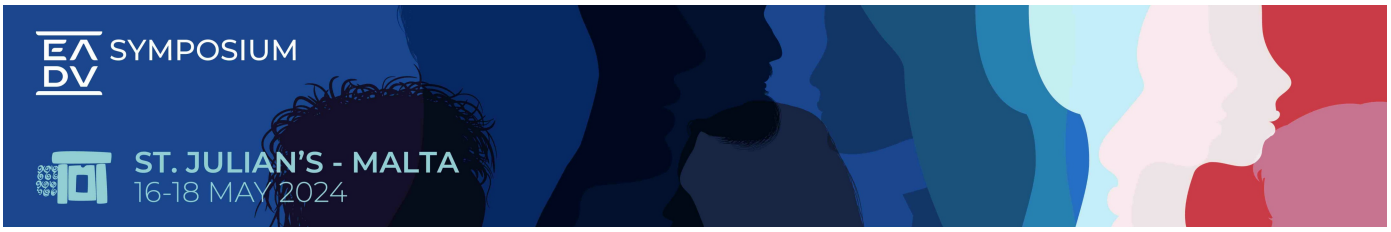
Five electronic databases (MEDLINE, Scopus, EMBASE, Cochrane Library, and medRxiv) were systematically searched from each database inception date until January 2024 to identify cohort studies examining the risk of incident RA amongst patients with AD, compared with non-AD controls. Quality assessments were performed according to the Newcastle-Ottawa Scale (NOS). Two reviewers independently extracted study characteristics and outcomes. If consensus is required, a third reviewer will be consulted. Quality assessments were performed according to the Newcastle-Ottawa Scale (NOS). The PRISMA and Meta-analysis of Observational Studies in Epidemiology (MOOSE) reporting guidelines were followed. The reported adjusted hazard ratio (aHR) from the model maximally adjusted for potential confounders were pooled using the random-effects meta-analysis. Publication bias was evaluated by funnel plot.

Results:

A total of 3 cohort studies with 4,621,878 participants investigating the association between AD and incident RA met all eligible criteria and were included in the meta-analysis. The risk of incident RA is significantly higher in patients with AD, even after adjustment for confounding factors (pooled aHR, 1.37; 95% CI, 1.25-1.49). No evidence of publication bias was observed. All studies are of high qualities

Conclusion:

In conclusion, this study suggests that patients with AD were at an increased risk of incident RA. The risk of RA should be considered in the management of patients with AD. Screening of RA may be helpful for early diagnosis and appropriate treatment in AD patients, especially in the case with baseline risk of RA. Because of the limited number of research articles, more investigations are needed to demonstrate the potential relationship between AD and incident RA.



Abstract N°: 1020

Differences in analytical parameters between patients with atopic dermatitis and healthy volunteers: A cross-sectional study

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Introduction & Objectives:

Atopic dermatitis (AD) is the most common chronic inflammatory skin disease in developed countries. All current scales for assessing the severity of the disease have a subjective component, so there are no objective parameters to assess response to treatment. It is therefore necessary to find parameters that allow us to objectively measure the severity of the disease. The aim of the study is to compare biochemical and hemogram characteristics in patients with AD and healthy volunteers.

Materials & Methods:

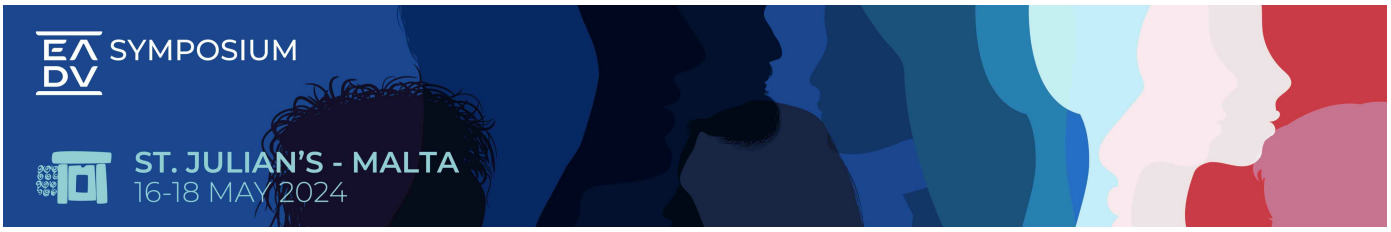
A cross-sectional study was designed to compare the analytical parameters between patients with AD and healthy volunteers. Data were collected from patients attending dermatology appointments who had been diagnosed with AD according to the criteria of Hanifi and Rajka. Controls were healthy volunteers who attended the appointments for trivial conditions such as melanocytic nevi or seborrheic keratosis. Several analytical tests were collected including creatinine phosphokinase (CPK), iron, bilirubin, alanine aminotransferase (GPT), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP), glucose, uric acid, creatinine, LDL cholesterol (LDL), HDL cholesterol (HDL), triglycerides (TG), total cholesterol (cholesterol), leucocyte, neutrophil, eosinophil, lymphocyte, monocyte and basophil counts, immunoglobulin E (IgE) and lactate dehydrogenase (LDH).

Results:

A total of 106 subjects, 53 healthy volunteers and 53 patients with AD were included in the study. Mean age of the population was 31.42 (12.17 SD) years, being 54.7% (58/106) of them female. Analytical parameters were compared between AD patients and healthy volunteers. Leukocytes (8.06 vs 6.71, $p=0.005$), monocytes (0.68 vs 0.46, $p=0.03$); eosinophils (0.47 vs 0.20, $p<0.001$), neutrophil-lymphocyte ratio (2.23 vs 1.55, $p<0.001$) were higher in AD patients. Similarly, LDH was significantly higher in patients with AD (223.64 vs 180.43, $p<0.001$). No differences were found in the rest of the parameters.

Conclusion:

There are differences in hemogram parameters and LDH between patients with AD and healthy volunteers. These values may help clinicians to make a proper diagnosis when there are doubts about the detection of AD.



Abstract N°: 1032

Efficacy and Safety of Rilzabrutinib in Patients With Moderate to Severe Atopic Dermatitis: A Proof-of-Concept Phase 2 Clinical Trial

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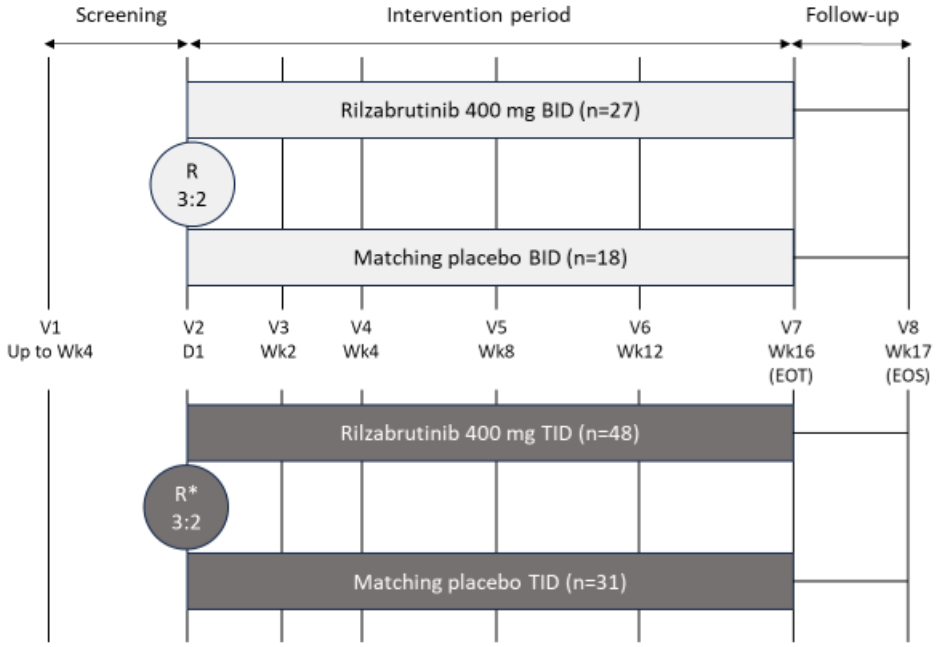
Introduction & Objectives: Rilzabrutinib (SAR444671) is an oral, reversible, covalent Bruton's tyrosine kinase (BTK) inhibitor. BTK is expressed both in mast cells and B cells, which play a critical role in multiple inflammatory diseases, including atopic dermatitis (AD). Here, we present results from the phase 2 proof-of-concept (POC) trial evaluating efficacy and safety of rilzabrutinib in adults with moderate to severe AD and inadequate response or intolerance to topical corticosteroids (TCS).

Materials & Methods: This was a phase 2, randomised, double-blind, placebo-controlled, multicentre POC clinical trial (NCT05018806). Eligible adults (aged ≥18 years) with moderate to severe AD and inadequate response or intolerance to TCS were enrolled into 2 staggered dose regimen cohorts: 400 mg twice a day (BID; n=45) or 400 mg 3 times a day (TID; n=79) and randomised 3:2 to receive rilzabrutinib (BID, n=27; TID, n=48) or placebo (BID, n=18; TID, n=31) for 16 weeks (Figure). The primary endpoint was percentage change from baseline to week 16 in Eczema Area and Severity Index (EASI) score. Secondary endpoints included the proportion of participants at week 16 with Investigator's Global Assessment (IGA) of 0 or 1, proportion of participants achieving EASI-75 (reduction of EASI score by ≥75% from baseline), and reduction in weekly average of daily peak pruritus numerical rating scale (PP-NRS) of ≥4 points from baseline. Safety was also evaluated.

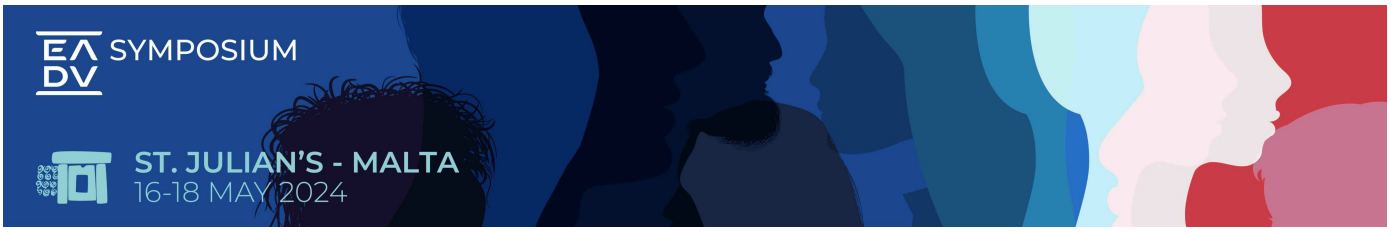
Results: Percentage reduction in EASI at week 16 was numerically greater in participants randomised to rilzabrutinib 400 mg BID vs placebo (least squares mean [LSM]; -53.6% vs -47.3%; *P*=0.62) and in those receiving rilzabrutinib 400 mg TID vs placebo (LSM: -47.2 vs -43.3%; *P*=0.67). Inconsistent trends in the proportion of EASI-75 and IGA 0/1 responders were observed between the BID and TID cohorts. The proportion of participants with a reduction in weekly average of daily PP-NRS of ≥4 points from baseline to week 16 was numerically greater with rilzabrutinib BID vs placebo (18.5% vs 11.1%) and rilzabrutinib TID vs placebo (20.8% vs 12.9%). This consistent trend favouring rilzabrutinib BID and TID vs placebo was confirmed by improvement in absolute (BID, -3.11 vs -1.60; TID, -2.07 vs -0.83) and relative (BID, -43.53% vs -21.55%; TID, -30.13% vs -10.36%) changes in weekly average of daily PP-NRS from baseline to week 16. Adverse events (AEs) were mostly mild, with a low incidence of serious AEs and no deaths. AEs occurring at a higher frequency with rilzabrutinib vs placebo included diarrhoea and nausea.

Conclusion: In this phase 2 POC trial in adults with moderate to severe AD and inadequate response or intolerance to TCS, treatment with rilzabrutinib 400 mg BID or TID did not show significant improvements vs placebo in primary and secondary endpoints; however, consistent trends favouring rilzabrutinib in pruritus/itch were observed. Rilzabrutinib was well tolerated with an acceptable safety profile.

Figure. Study design of proof-of-concept phase 2 study of rilzabrutinib in patients with moderate to severe atopic dermatitis.



*The randomisation of TID cohort started after the enrolment of the BID cohort.
BID, twice a day; D, day; EOS, end of study; EOT, end of treatment; n, number of participants; R, randomisation; TID, three times a day; V, visit; Wk, week.



Abstract N°: 1046

Patient characteristics and healthcare resource use in adults with moderate-to-severe atopic dermatitis in Finland: a population-based cohort study with matched reference adults

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Introduction & Objectives: This retrospective, observational database cohort study investigated characteristics and healthcare resource use in patients with moderate-to-severe atopic dermatitis (AD) in Finland using national registry data. Findings in identified adults with moderate-to-severe AD and matched reference adults from the general population are presented.

Materials & Methods: With a permit granted by the Finnish Social and Health Data Permit Authority Findata we linked patient-level data from Care Registers for Health Care, prescription registers, and registers of the Digital and Population Services Agency and Statistics Finland. Patients with moderate-to-severe AD were identified by at least two AD-related primary care or one secondary care visit(s) (ICD-10 L20 or ICPC-2 S87), together with purchase(s) of AD-specific drug (prescribed systemic medication or a specific threshold annual amount of topical treatment) during 1/1/2016–31/12/2020. For each patient, five reference adults matched for sex, age, and residential area were randomly selected. Patient characteristics, comorbidities, AD medication purchases, and healthcare visits were analysed descriptively.

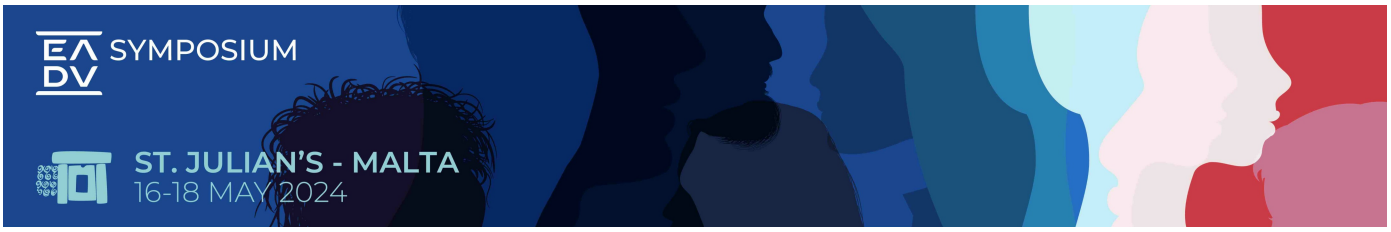
Results: In all, 34,281 adults with moderate-to-severe AD were identified in the cohort; 169,897 reference adults were selected. Characteristics of the 33,693 patients with moderate-to-severe AD at the end of 2020 are displayed in the Table; most were female (67.5%). Both AD and moderate-to-severe AD were diagnosed across all decades of life. No discernible difference in educational level or socioeconomic status was observed between adults with moderate-to-severe AD and reference adults. In a subgroup of 17,871 adults with moderate-to-severe AD who received their first AD diagnosis during 2016–2020, site of the first diagnosis was in primary care for 8745 (48.9%), in secondary care for 8938 (50.0%), and both in primary and secondary care (on the same day) for 188 (1.1%). During their follow-up, a higher proportion of adults with moderate-to-severe AD than reference adults attended primary healthcare visits (97.5% vs 90.6%) as well as secondary healthcare visits to any specialty (88.4% vs 61.7%), dermatologic (62.5% vs 4.5%), or psychiatric service (15.4% vs 9.4%). Moreover, a higher proportion of adults with moderate-to-severe AD than reference adults experienced comorbid atopic (34.9% vs 9.0%), psychiatric (17.0% vs 10.5%), gastrointestinal (11.1% vs 6.6%), or other conditions (10.9% vs 5.7%) during the follow-up. Asthma was noted in 14.2% vs 3.8%, contact allergy in 10.4% vs 0.4%, allergic rhinitis in 9.5% vs 1.7%, and depression in 9.2% vs 5.5%. Adults with moderate-to-severe AD had a higher rate of long-term (>10 days) sick-leaves for any diagnosis versus reference adults (24.2% vs 17.4%) during the follow-up. Topical corticosteroids, emollients and protectives, and oral antibiotics for skin infections were the most frequently purchased medications for AD. Systemic therapies for AD were infrequently used, although during the study, newer systemic AD treatments were not yet widely available.

Conclusion: Moderate-to-severe AD is widespread among Finnish adults. This study showed that adults with moderate-to-severe AD had a higher burden of comorbidities, healthcare visits, and long-term sick leaves than reference adults.

Table. Characteristics of Finnish adult patients with moderate-to-severe AD in 2020

Characteristic	Adults aged ≥18 years (N=33,693)
Male, n (%)	10,964 (32.5)
Female, n (%)	22,729 (67.5)
AD duration, years	
Mean (SD) / Median (IQR)	17.3 (8.3) / 19.0 (11.0, 24.0)
0–4	3830 (11.4)
5–9	3750 (11.1)
10–14	3991 (11.9)
15–19	5910 (17.5)
≥20	16,212 (48.1)
Moderate-to-severe AD duration, years	
Mean (SD) / Median (IQR)	6.1 (6.6) / 4.0 (2.0, 9.0)
0–4	20,616 (61.2)
5–9	5013 (14.9)
10–14	4026 (12.0)
15–19	1547 (4.6)
≥20	2491 (7.4)
Age at AD diagnosis, years	
Mean (SD) / Median (IQR)	23.7 (18.9) / 20.0 (7.0, 36.0)
0–4	6814 (20.2)
5–9	2781 (8.3)
10–19	6820 (20.2)
20–29	6112 (18.1)
30–39	4089 (12.1)
40–49	3130 (9.3)
50–59	2190 (6.5)
60–69	1104 (3.3)
≥70	653 (1.9)
Age at moderate-to-severe AD diagnosis, years	
Mean (SD) / Median (IQR)	34.8 (19.4) / 30.0 (20.0, 48.0)
0–4	829 (2.5)
5–9	1248 (3.7)
10–19	5859 (17.4)
20–29	8399 (24.9)
30–39	5471 (16.2)
40–49	3911 (11.6)
50–59	3410 (10.1)
60–69	2445 (7.3)
≥70	2121 (6.3)

Data are presented as n (%) unless otherwise indicated.
AD, atopic dermatitis; IQR, interquartile range; SD, standard deviation.



Abstract N°: 1071

Effectiveness and safety of upadacitinib in Canadian adult patients with atopic dermatitis who were inadequate responders or intolerant to dupilumab: Interim results from the CAN UpTIMISE phase 4 multicentre study

Vimal H. Prajapati*[1, 2, 3, 4, 5, 6], Melinda J. Gooderham[7, 8, 9], Jason K. Lee[10, 11], Vipul Jain[12], Geeta Yadav[13, 14, 15], Charles W. Lynde[13, 16], Andrew Ferrier[17, 18, 19], Melanie Labelle[20], David Prefontaine[20], H. Chih-Ho Hong[21]

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Introduction & Objectives: Evidence from an international randomised controlled trial (RCT) demonstrated superiority of high-dose once daily (QD) upadacitinib (UPA 30 mg; UPA30), an oral Janus kinase 1 selective inhibitor, versus the IL-4/IL-13 inhibitor dupilumab (DUPI), in adult patients with moderate-to-severe atopic dermatitis (AD), at Week 16. Also, patients ending 24 weeks of DUPI who received open-label UPA30 experienced additional incremental improvements in clinical responses within 4 weeks post-switch. The CAN UpTIMISE study assesses the real-world effectiveness and safety of UPA 15 mg (UPA15) and UPA30 QD in patients with AD who were inadequate responders to DUPI or discontinued DUPI due to safety/tolerability reasons.

Materials & Methods: CAN UpTIMISE (NCT05394792) is an ongoing Canadian observational study of adult patients treated with DUPI for ≥16 weeks as previous line of therapy for moderate-to-severe AD and for whom the decision to change treatment to UPA was made, per label. Effectiveness results included the proportion of patients achieving a Validated Investigator Global Assessment for AD score of clear or almost clear (vIGA-AD 0/1) and Eczema Area and Severity Index (EASI), Worst Pruritus Numerical Rating Scale (WP-NRS), and Dermatology Life Quality Index (DLQI) improvements at Months 1, 2, and 4. Descriptive statistics summarize results from an interim database lock, after ≥50% of planned patients had completed the study.

Results: At the interim cutoff date, 65 patients (n=26 [UPA15]; n=39 [UPA30]) were included in the analysis (mean age: 43.0 years (SD 15.92); male gender: 56.9%; race: White [60.0%] or Asian ([36.9%]). A majority of patients (81.5%) discontinued DUPI due to suboptimal disease control per investigator's judgment, while 18.5% of patients stopped DUPI due to safety/tolerability reasons. At baseline, despite treatment with DUPI, 24.6%, 44.6%, and 23.1% of patients had vIGA-AD scores of 4 (severe), 3 (moderate), and 2 (mild), respectively. Mean baseline EASI score was 13.29 (95% CI: 9.99 – 16.59), with patients prescribed UPA15 generally having less severe disease versus those prescribed UPA30 (mean EASI score of 9.04 [95% CI: 5.32 – 12.77] vs 16.12 [11.29 – 20.95], respectively). As a primary endpoint, 60.3% (95% CI: 47.5% – 71.9%) of patients achieved vIGA-AD 0/1 at Month 4 (Figure 1a) with either UPA dose. In patients with vIGA-AD ≥2 at baseline, >50% achieved vIGA-AD 0/1 at Month 4. A rapid decrease in mean EASI was observed at Month 1 (from 13.29

[95% CI: 9.99 – 16.59] to 3.08 [1.86 – 4.29]) and maintained up to Month 4 (2.74 [1.31 – 4.17]) (Figure 1b). Among patients with baseline EASI score ≥3, >50% had an EASI score <3 both at Month 1 and Month 4. Mean improvements in WP-NRS and DLQI scores were also observed as early as Month 1 and sustained up to Month 4 (Figures 1c and d, respectively). Effectiveness and safety results were similar between both UPA doses. UPA was well tolerated, and its safety profile was consistent with observations made across RCTs.

Conclusion: Interim findings of the CAN UpTIMISE study suggest UPA is effective and well tolerated in AD patients who were inadequate responders to DUPI or discontinued DUPI due to safety/tolerability reasons. A majority of patients achieved clear/almost clear skin and clinically meaningful improvements in disease activity (EASI), itch (WP-NRS), and quality of life (DLQI) scores, seen as early as Month 1 and maintained up to Month 4, with no new safety signal reported.

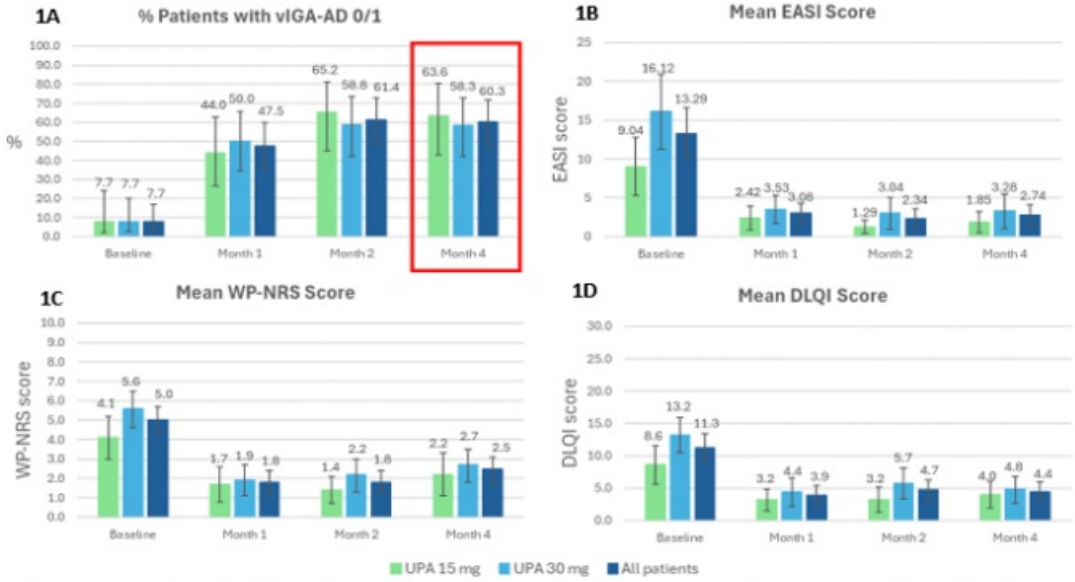
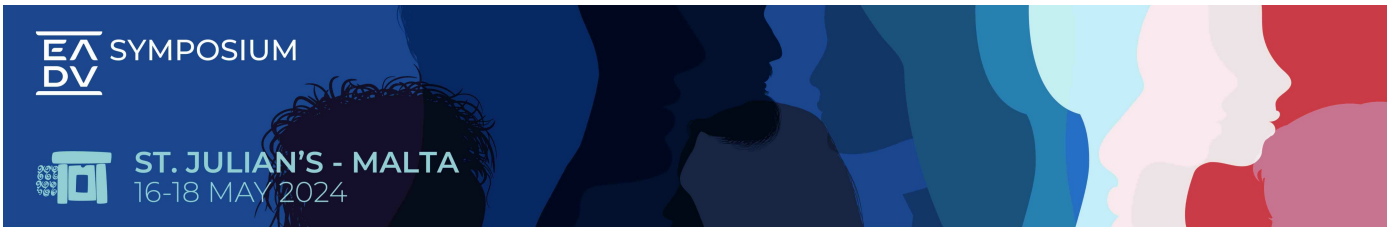


Figure 1: Proportion of adult patients with AD who were inadequate responders to DUPI or discontinued DUPI due to safety/tolerability reasons, who achieved vIGA-AD score of 0 or 1 (a) with UPA 15 mg and UPA 30 mg up to 4 months post-switch, along with changes from baseline in mean EASI (b), WP-NRS (c) and DLQI (d) scores.

Red box is indicative of the study primary endpoint. Error bars are representing 95% CI.

Abbreviations: DLQI, Dermatology Life Quality Index; DUPI, dupilumab EASI, Eczema Area and Severity Index; vIGA-AD, Validated Investigator Global Assessment for AD; WP-NRS, Worst Pruritus Numerical Rating Scale.



Abstract N°: 1080

Objective monitoring of sleep quality in patients with Atopic dermatitis

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Introduction & Objectives:

30-48% of the adult population suffers from a sleep disturbances. In a large proportion of cases, the sleep disorder is secondary to another systemic disease. According to statistics, sleep disturbances in patients with atopic dermatitis(AD) are common and range between 47-80% in children and 33-87% in adults.

Materials & Methods:

We conducted a pilot prospective sleep study in three patients with AD using an actigraph. The aim of the study was to follow up objective data on sleep and motor restlessness assessment in patients with AD - 30 days before and 30 days after their inclusion on systemic therapy with a Janus kinase inhibitor1 (Upadacitinib).

Actigraphy is a diagnostic method to objectively assess sleep and general body activity over an extended period of time. It is performed by a device (actigraph) that is placed on the dominant arm and worn continuously throughout the 60-day study period, similar to a watch. The performance of the Actigraph MotionWatchÒ has been compared with polysomnography in multiple studies and yields 96% data uniformity.

The study of sleep and motor activity by actigraphy allows tracking of general body activity as well as directed movements, in particular in atopic dermatitis-scratching and motor restlessness. The key data points are at day 1-patients are on treatment with emollients and topical corticosteroids alone; day 30-patients start Janus kinase inhibitor treatment; and day 60- the effect of therapy is assessed and overall sleep and wakefulness is evaluated - before and after therapy.

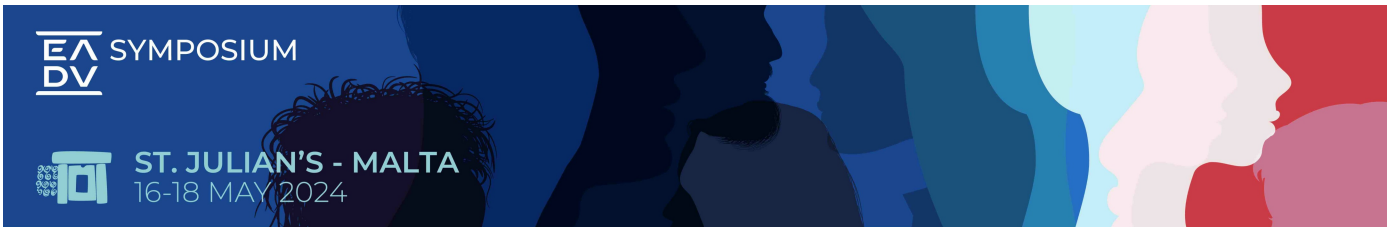
Results:

Our 3 patients were 2 women and 1 man, mean age 30.5 years. The AD in all 3 study participants started in infancy and was classified as moderate to severe with EASI of 18.80; 23.60 and 28.00, respectively. Sleep disturbances were assessed by the Pittsburgh Sleep Quality Index(PSQI) at study entry. A global PSQI score of 5 or greater is indicative of poor sleep quality among younger adults. In our patients, the PSQI score was between 13 and 29. The severity of pruritus was also reported on the Peak Pruritus Numerical Rating Scale with a mean of 8.1.

A pilot actigraphy study showed an objective reduction in activity during sleep and an impact on motor distress within 10-14 days after inclusion of Janus kinase inhibitor 1 (Upadacitinib) therapy. There was a reduction in the duration and intensity of average motor activity per day and an improvement in sleep efficiency. Bout of activity and restlessness were reduced in frequency and intensity. The reported results correlated with outcomes measured by the Pittsburgh Sleep Quality Index and Peak Pruritus Numerical Rating Scale.

Conclusion:

We present a pilot study to objectify sleep quality improvement in atopic dermatitis patients. Tracking patients by actigraphy provides measurable and comparable data on the effect of Janus kinase inhibitor 1 treatment on sleep quality in patients with moderate-to-severe AD. This is a non-invasive study with no disruption to skin integrity and no risks to participants.



Abstract N°: 1135

The role of emollients in the treatment of atopic dermatitis in children

Valeriy Mukhortykh[1, 2], Inna Larkova[1, 3], Vera Revyakina[1, 3], Natalya Tarmaeva[1]

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Introduction & Objectives:

Atopic dermatitis (AtD) is a chronic, continuously recurring, inflammatory skin disease that affects one in ten people during their lifetime. AtD is caused by a complex interaction of impaired immune regulation, mutations of epidermal genes and environmental factors, which, in turn, leads to the destruction of the structure of the skin barrier, causing intense itchy skin lesions, having a significant impact on the patient's quality of life. Thus, maintenance therapy of AtD should be aimed at restoring and maintaining the integrity of the skin barrier with regular use of emollients aimed at restoring the lipid composition of the epidermis and creating a protective barrier for damaged skin.

Materials & Methods:

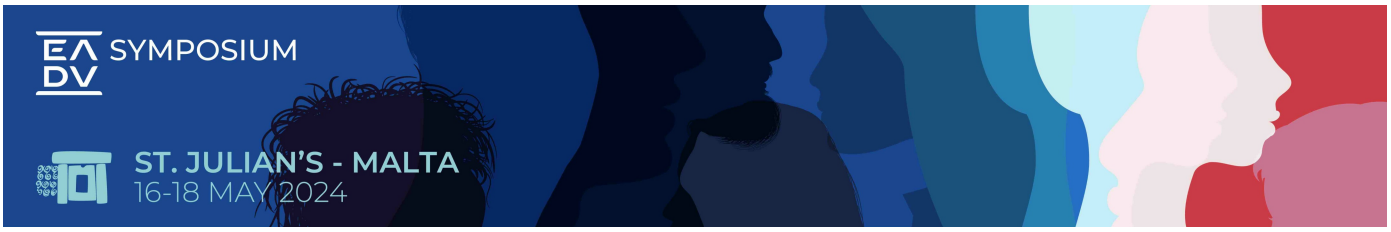
We observed 30 patients aged 1 to 3 years suffering from moderate AtD. The main complaints were skin itching of varying intensity, restless sleep, various polymorphic rashes and dry skin. Against the background of relieving the exacerbation of ATD, children were recommended to use a complex of emollients (cream, shower and bathing oil) for 3 months, aimed at achieving long-term control over the symptoms of the disease

Results:

Initially, before the appointment of therapy with emollients, the EASI index was 18.1 ± 2.3. Against the background of regular use of emollients on day 3, clinical improvement was noted in the form of relief of itching in all children, reduction of dry skin, improved sleep and reduction of the area of skin lesions. After 3 months of therapy, the EASI index was 1.4±0.3. There was no exacerbation of ATD. Good tolerability of therapy was noted.

Conclusion:

Regular application of an emollient prevents periods of acute AtD by maintaining the integrity of the protective skin barrier and is most effective in achieving long-term control of symptoms, in particular, subjective symptoms such as itchy skin and sleep disorders.



Abstract N°: 1172

Efficacy and safety of amlitelimab (an OX40 ligand antibody) in patients with moderate-to-severe atopic dermatitis: 52-week results from a Phase 2b Trial (STREAM-AD)

Stephan Weidinger[1], Andrew Blauvelt[2], Kim Papp[3], Adam Reich[4], Chih-Hung Lee[5], Margitta Worm[6], Charles Lynde[7], Yoko Kataoka[8], Peter Foley[9], Xiaodan Wei[10], Anne-Catherine Solente[11], Christine Weber[11], Fabrice Hurbin[12], Natalie Rynkiewicz[13], Karl Yen[14], John O'malley[15], Charlotte Bernigaud[11]

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Introduction & Objectives:

Amlitelimab is an OX40 ligand (OX40L) monoclonal antibody inhibiting OX40L-OX40 interactions. Data from the 28-week amlitelimab maintenance/withdrawal period (Part 2) of the Phase 2b (STREAM-AD, NCT05131477) dose-ranging trial in adults with moderate-to-severe atopic dermatitis (AD) are presented.

Materials & Methods:

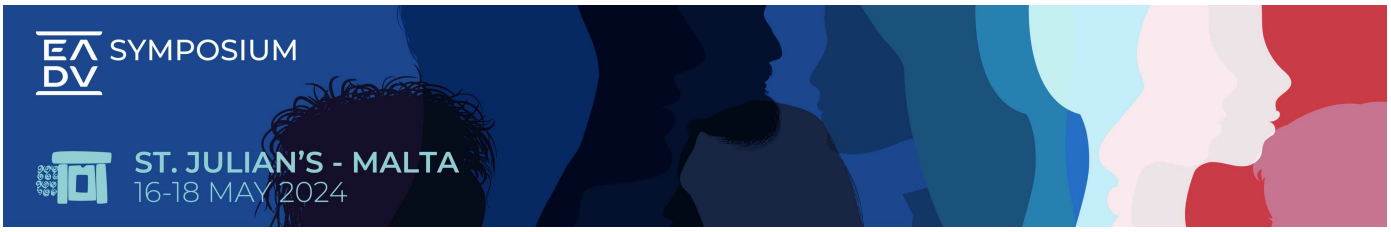
STREAM-AD Part 2 included clinical responders from Part 1, defined as participants achieving a 75% reduction from baseline in the Eczema Area and Severity Index (EASI-75) and/or Investigator Global Assessment (IGA) 0/1 at Week 24. Of 390 participants enrolled in Part 1, 190 entered Part 2. Participants were re-randomized 3:1 to withdraw treatment or continue pre-Week 24 subcutaneous Q4W dose (250mg with 500mg loading dose [LD], n=34 [treatment withdrawal]/n=13 [continuing]; 250mg, n=28/n=12; 125mg, n=33/n=12; 62.5mg, n=35/n=7; placebo responders continuing placebo, n=16), and were followed to Week 52 for efficacy. Statistical analysis was conducted using two approaches: imputing endpoint as non-responder after rescue medication use (NRI) or including all measurements regardless of rescue use (treatment policy).

Results:

Maintenance of EASI-75 and/or IGA 0/1 response at Week 52 was observed in 59%, 63%, 55%, and 66% of clinical responders withdrawn from Q4W dose of 250mg with LD, 250mg, 125mg, and 62.5mg, respectively (NRI). Using treatment policy, 77%, 82%, 67%, and 74% maintained response off-drug, respectively. Those continuing treatment had numerically higher maintenance response rates. AD-related biomarkers remained suppressed over 28 weeks; with ≥95% of the drug eliminated from serum for the last 8 weeks. The safety profile remained generally consistent with Part 1 without new concerns identified in Part 2.

Conclusion:

Maintenance of clinical responses were demonstrated for 28 weeks in the majority of patients, both on- and off-amlitelimab.



Abstract N°: 1173

Amlitelimab improves extent and severity of disease in adults with moderate-to-severe atopic dermatitis (AD): 24-week results from a Phase 2b trial (STREAM-AD)

Stephan Weidinger[1], Andrew Blauvelt[2], Ken Igawa[3], Christine Weber[4], Efstathios Zikos[5], Jennifer Wang[6], Cori Gray[6]

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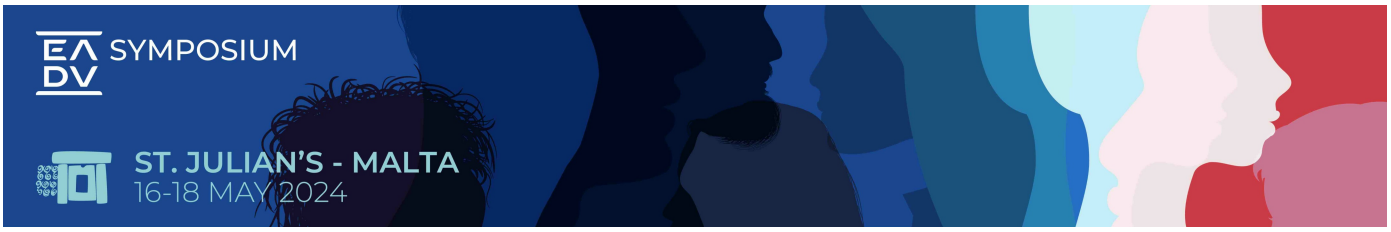
Introduction & Objectives: Amlitelimab (SAR445229; KY1005) is a fully human, non-depleting monoclonal antibody that binds OX40 ligand on antigen-presenting cells, potentially inhibiting a key driver of AD pathophysiology. Amlitelimab has previously demonstrated 24-week primary endpoint efficacy in adults with moderate-to-severe AD. Here, 24-week secondary outcomes of AD extent and severity are presented, including effects on the SCORing of AD (SCORAD) Index and percentage body surface area (BSA) affected by AD.

Materials & Methods: STREAM-AD (NCT05131477) is a 52-week, randomized, double-blinded, placebo-controlled, Phase 2b trial (24-week Part 1 completed; 36-week Part 2 ongoing). Adults (18 to <75 years) with moderate-to-severe AD were randomized 1:1:1:1:1 to receive amlitelimab (250 mg with 500 mg loading dose [LD], n=77; 250 mg [no LD], n=78; 125 mg, n=77; 62.5 mg, n=79) or placebo (n=79) every 4 weeks.

Results: Improvements in mean change from baseline at Week 24 were seen across all amlitelimab arms for SCORAD total score and BSA percentage. SCORAD (standard deviation [SD]): amlitelimab 250 mg + LD, −36.19 (24.60); 250 mg (no LD), −27.28 (22.94); 125 mg, −29.96 (25.74); 62.5 mg, -28.48 (21.79); placebo, −15.08 (22.74). Percentage affected BSA (SD): amlitelimab 250 mg + LD, −31.35 (22.43); 250 mg (no LD), −21.82 (21.88); 125 mg, −22.66 (27.32); 62.5 mg, −25.77 (22.09); placebo, −10.45 (20.84).

Conclusion: Amlitelimab improved metrics of disease extent and severity in adults with moderate-to-severe AD in the first 24 weeks of this Phase 2b trial, with greatest improvement seen in the 250 mg plus LD arm.



Abstract N°: 1198

Lebrikizumab provides long-term clinically meaningful responses in patients with moderate-to-severe atopic dermatitis

Christian Vestergaard*[1], Stephan Weidinger[2], Diamant Thaçi[3], Patrick M Brunner[4], Pablo Fernández Peñas[5], Alexandra Golant[6], Meritxell Falqués[7], Helena Agell[7], Marta Casillas[8], Marjolein de Bruin-Weller[9]

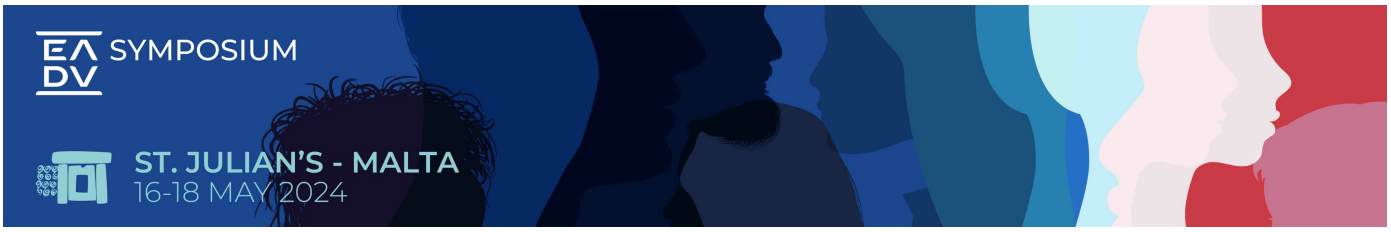
[1]Department of Dermatology and Venerology, Aarhus University Hospital, Aarhus, Denmark,[2]University Hospital Schleswig-Holstein, Kiel, Germany, [3]Institute and Comprehensive Center for Inflammation Medicine, University of Lübeck, Germany, [4]Department of Dermatology, Icahn School of Medicine at Mount Sinai, New York, NY, United States, [5]Department of Dermatology, Sydney Medical School, Westmead Hospital, The University of Sydney, Sydney, NSW, Australia, [6]Department of Dermatology and Laboratory of Inflammatory Skin Diseases, Icahn School of Medicine at Mount Sinai, New York, United States, [7]Almirall S.A., Barcelona, Spain, [8]Eli Lilly and Company, Indianapolis, United States, [9]Department of Dermatology and Allergology, National Expertise Center for Atopic Dermatitis, University Medical Center Utrecht, Utrecht, Netherlands

Introduction & Objectives: Lebrikizumab (LEB) is a novel monoclonal antibody for moderate-to-severe atopic dermatitis (AD) that binds with high affinity and slow off-rate to interleukin (IL)-13. Treatment response in AD is assessed by improvements in signs, symptoms and in quality of life (QoL) as recommended by Harmonizing Outcome Measures in Eczema (HOME) committee. The clinically meaningful response provided by LEB at week 16 in adult patients in monotherapy has been previously reported. Here, we report the clinically meaningful response provided by LEB in monotherapy at week 52 among week 16 responders of ADvocate1 (NCT04146363) and ADvocate2 (NCT04178967) clinical trials (pooled data).

Materials & Methods: ADvocate1 and ADvocate2 were two identically designed, randomized, placebo-controlled, monotherapy Phase 3 trials assessing efficacy and safety of lebrikizumab in monotherapy in patients with moderate to severe AD. Responders at week 16 were defined as patients achieving a 75% reduction in the EASI from baseline (EASI 75) or an Investigator Global Assessment (IGA) 0/1 with a ≥2-point improvement from baseline, without rescue medication use. Patients who responded to LEB 250 mg every two weeks (LEB Q2W) at the end of the 16-week induction period were re-randomized 2:2:1 to receive LEB 250 mg every Q2W, LEB 250 mg every 4 weeks LEB (Q4W), or placebo (LEB withdrawal) for 36 additional weeks (maintenance period). Clinically meaningful responses were defined as follows: for signs by EASI ≤7, for symptoms by Pruritus Numeric Rating Scale (PNRS) ≤4, and for QoL by Dermatology Life Quality Index (DLQI) ≤5. This *post-hoc* analysis reports the proportion of adult patients achieving one or more of these three clinically meaningful responses, and the proportion of adult patients achieving all three clinically meaningful responses, which can be representative of minimal residual AD. The Maintenance Primary Population (MPP) was used for efficacy analyses. Adult patients with baseline DLQI>5 and PNRS>4 were selected. Data after systemic rescue medication or missing data due to lack of efficacy were imputed with non-responder imputation. Other missing data and data after topical corticosteroid usage were imputed with multiple imputation.

Results: At week 52, 89.6% of patients in LEB Q4W, 84.3% of patients in LEB Q2W and 72.9% of patients in LEB withdrawal achieved one or more of the clinically meaningful AD responses in signs, symptoms or QoL. 57.6% of patients in LEB Q4W, 60.7% of patients in LEB Q2W and 45.8% of patients in LEB withdrawal achieved all 3 endpoints at week 52.

Conclusion: At week 52, LEB provides clinically meaningful responses in monotherapy for signs, symptoms, and QoL in adults with moderate-to-severe AD. In addition, more than half of the patients achieve response in all three domains (signs, symptoms and QoL), which represents a status of minimal disease.



Abstract N°: 1213

Comparison of different phototherapy methods and regimens efficacy in treatment of patients with atopic dermatitis.

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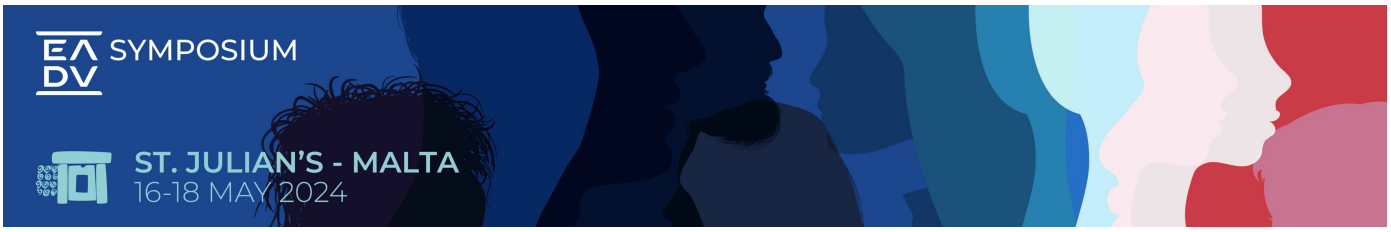
Introduction & Objectives: Different phototherapy methods with various irradiation modes are used for treatment of patients with atopic dermatitis. Nevertheless, there is insufficient data to determine which regimens of ultraviolet phototherapy are the most efficient. In this study, we aimed to compare the efficacy of NB-UVB-phototherapy and UVA1-phototherapy with medium and low UV doses in patients with atopic dermatitis.

Materials & Methods: 80 patients, 42 females and 38 males, ranging in age from 18 to 68 years with moderate-to-severe atopic dermatitis were enrolled in the study. Disease severity was evaluated by Eczema Area and Severity Index (EASI) and Investigator's Global Assessment (IGA) Scale. The intensity of itching was assessed using a visual analogue scale. 40 patients were treated with narrow-band NB-UVB-phototherapy four times weekly for 5 weeks. 40 patients were treated with UVA1-phototherapy with medium or low UV doses five times weekly for 4 weeks.

Results: Course of phototherapy included 20 procedures. Cumulative dose of NB-UVB varied from 5.8 to 18.4 J/cm2 (mean 10.9±2.6 J/cm2). 26 patients received UVA1-phototherapy with low UV doses (≤20 J/cm2). Mean cumulative dose was from 145.2 to 391.0 J/cm2, mean 318.6±64.9 J/cm2). Single irradiation dose was 12.3 J/cm2. 14 patients received UVA1-phototherapy with medium UV doses (>20–70 J/cm2). Cumulative dose varied from 400.4 to 480 J/cm2, mean 449.9±32.9 J/cm2). Single irradiation dose was 22.5 J/cm2. All ultraviolet phototherapy regimens were effective, but UVA1-phototherapy with medium irradiation doses had highest efficacy. EASI value decreasing in patients which received treatment with medium UV doses amounted 79.5±26.4% (from 19.0±9.3 to 2.9±2.1) ($p<0.05$), and in patients with low UV doses EASI value reduced from 20.5±10.8 at baseline to 7.3±5.9 (55.7±56.6%) ($p<0.05$). EASI value after 20 procedures of UV irradiation was significantly lower in patients which received UVA1-phototherapy with medium doses (2.9±2.1) in comparison with patients which received UVA1-phototherapy with low doses (7.3±5.9) ($p<0.05$). IGA scale and intensity of itching decreasing in patients after UVA1 medium doses treatment amounted 2.0±0.7 and 4.7±2.2 respectively and was much more pronounced than improvement after low doses UVA1-therapy – 1.2±0.9 and 2.7±3.0 respectively ($p<0.05$). Comparison of NB-UVB-phototherapy and UVA1-phototherapy efficacy showed that decreasing of IGA scale (2.0±0.7) and intensity of itching (4.7±2.2) after UVA1 medium doses treatment was more expressed than after NB-UVB-phototherapy – 1.40±1.15 ($p<0.05$) and 2.55±3.40 ($p<0.05$) respectively.

Conclusion: UVA1-phototherapy with medium irradiation doses in patients with moderate-to-severe atopic dermatitis has higher efficacy in comparison not only with low doses of UVA1-phototherapy, but also with NB-UVB-phototherapy (cumulative dose 10.9±2.6 J/cm2).



Abstract N°: 1242

Impact of biologic drugs and JAK inhibitors on skin barrier function in patients with atopic dermatitis

Raquel Sanabria de la Torre[1, 2, 3], Trinidad Montero-Vilchez[2, 3], Clara Ureña-Paniego[3], Arena Ramírez-Muñoz[2, 4], Salvador Arias-Santiago[2, 3, 4]

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Introduction & Objectives:

Patients with atopic dermatitis (AD) have skin barrier dysfunction that is further exacerbated by the severity of symptoms. Biologic drugs and JAK inhibitors (iJAK) are beneficial in improving severity scores and quality of life in patients with AD, but little is known about their efficacy in improving the skin barrier. Therefore, the aim of this study was to evaluate the impact of these drugs on skin barrier function in patients with AD.

Materials & Methods:

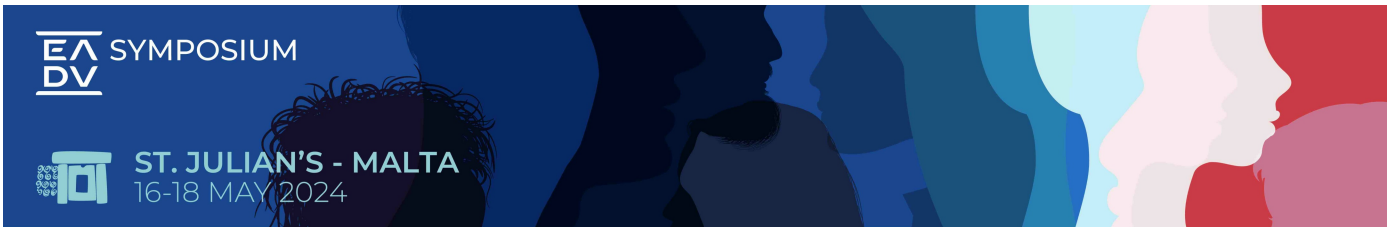
A prospective observational study was designed to include patients with moderate-to-severe AD of at least 6 months of duration who were about to start treatment with a biologic or iJAK drug. Skin barrier function was objectively assessed on an eczematous area and on healthy skin on the volar forearm. Measurements of these parameters were performed at baseline and at 4, 16 and 32 weeks after starting treatment. The barrier function parameters assessed were TransEpidermal Water Loss (TEWL), Stratum Corneum Hydration (SCH), erythema and temperature.

Results:

53 patients (50.9 % female) with a mean age of 32.09 (SD 16.35) were included. Patients were classified according to their treatment into dupilumab(D), tralokinumab(T), baricitinib(B) and upadacitinib(U). In all groups TEWL decreased from baseline to the last measurement (D)20.5 vs 15.8 (T)24 vs 20.4 (B)30.1 vs 19.8 (U)22.2 vs 14.9 (g/m/h $p<0.05$). The same was true for erythema (D) 369 vs 348, (T) 334 vs 224, (B) 403 vs 269, (U) 375 vs 304 (arbitrary units (AU). On the other hand, SCH increased after 32 weeks of treatment (D)26.3 vs 30.7 (T)17.8 vs 42.6 (B)6.67 vs 10 (U)24.1 vs 25.8 AU.

Conclusion:

The drugs studied improved skin barrier function in patients with AD, reflected in a decrease in TEWL and erythema and an increase in SCH. The iJAKs improved barrier function parameters more rapidly compared to biologics (greatest change at week 4). After 32 weeks of follow-up, all drugs had a positive impact on barrier function and thus on the aetiopathogenesis of AD.



Abstract N°: 1246

JAK inhibitors for atopic dermatitis. Experience in real clinical practice at our center.

Elia Boza Villar[1], Sara Merino Molina[1], Maria Dolores Benedicto Maldonado[1], Rosa Castillo Muñoz[1], Jorge Alonso Suárez Pérez[1], Enrique Herrera-Acosta[1]

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Introduction & Objectives:

Janus kinase (JAK) inhibitors constitute an important therapeutic option for the improvement and control of atopic dermatitis by blocking the action of multiple interleukins responsible for inflammation, epidermal barrier dysfunction and pruritus, which are fundamental factors in the pathogenesis and symptomatology of this disease.

Materials & Methods:

We carried out a retrospective study that aimed to compare the efficacy of three JAK inhibitors (Abrocitinib, Upadacitinib and Baricitinib) in 55 patients with moderate-to-severe atopic dermatitis from our center. We analyzed the response of each of them at 3 months and compared the EASI and parameters related to quality of life (NRS itch and NRS sleep) using an ANOVA statistical test with Tuckey post-hoc analysis.

Results:

A total of 55 patients started treatment with JAK inhibitors at our hospital: 5 (9%) Abrocitinib, 26 (47%) Upadacitinib and 24 (44%) Baricitinib.

Of the 5 patients treated with Abrocitinib, 2 (40%) were women and 3 (60%) were men. The mean EASI score at the beginning of treatment was 23.20 (SD 5.71), NRS itch 9.2 (SD 1.30) and NRS sleep 8.20 (SD 2.16). When analyzing the response at 3 months, the mean EASI decreased to 6.80 (SD 6.61), NRS itch to 3.20 (SD 2.04) and NRS sleep to 2.20 (SD 2.16).

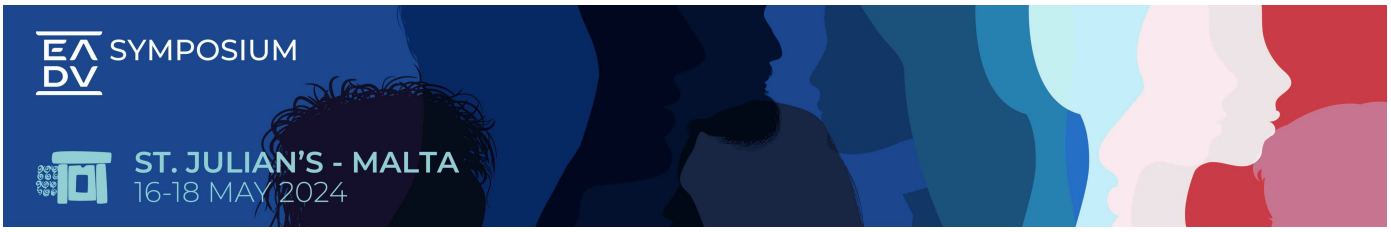
Regarding Upadacitinib, 11 of the 26 patients (42%) were women and 15 (58%) were men. The mean EASI score at the beginning of treatment was 23.20 (SD 9.02), NRS itch 8.19 (SD 2.17) and NRS sleep 6.80 (SD 3.45). The response was reassessed at 3 months; the mean EASI was 6.51 (SD 6.73), NRS itch 2.65 (SD 2.69) and NRS sleep 2.15 (SD 2.57).

As for Baricitinib, 12 of the 24 patients (50%) were women and 12 (50%) were men. The mean EASI score at the beginning of treatment was 23.66 (SD 7.76), NRS itch 6.58 (SD 2.78) and NRS sleep 4.08 (SD 4.30). At 3 months after analyzing the response, the mean EASI decreased to 11.54 (SD 13.46), the NRS itch to 3.10 (SD 3.08) and the NRS sleep to 2.29 (SD 2.99).

When comparing the groups using ANOVA, no statistically significant differences were found among the three drugs.

Conclusion:

JAK inhibitors have been shown to be effective in the treatment of moderate-to-severe atopic dermatitis in patients who do not respond to other therapies, managing to reduce symptoms early without demonstrating statistically significant differences between them.



Abstract N°: 1285

A decline in stratum corneum lipids underpins the age-associated increase in xerosis severity in people with a history of atopic dermatitis.

Simon Danby*[1], Samuel Williams[1], Paul Andrew[1], Kirsty Brown[1], John Chittock[1], Abigail Pinnock[1], Michael Cork[1, 2]

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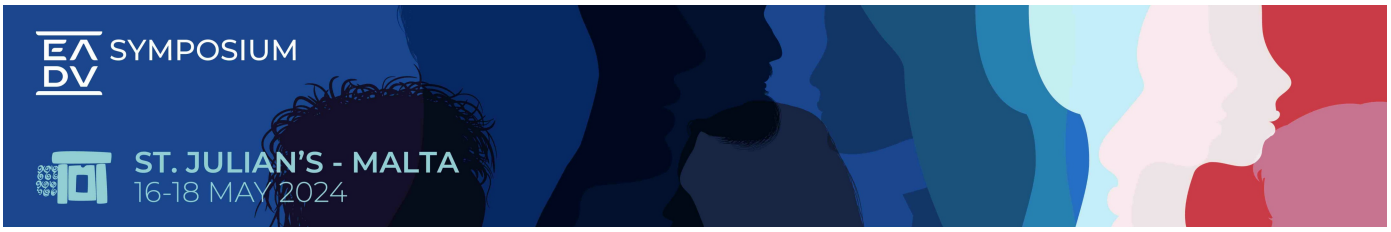
Introduction & Objectives: Advancing age is associated with an increased propensity for xerosis (skin dryness). Xerosis is also more common in people with a history of atopic dermatitis (AD). A greater understanding of the causes of xerosis is required to inform the most appropriate interventions to protect skin health through the life cycle. This study aimed to compare stratum corneum (SC) properties in adults with dry, dermatitis-prone, skin stratified by age and sex.

Materials & Methods: As part of the Barrier-Reinforcing effects of A CEramide cream (BRaCE) study the baseline properties of a cohort of adults with visibly dry skin and prior history of dermatitis were ascertained. Participants were recruited into 3 groups by age. Assessments undertaken on the forearm and/or shin included: visual scoring of skin condition, biophysical testing of skin function, analysis of SC molecular structure by attenuated total reflectance (ATR)-Fourier transform infrared (FTIR) spectroscopy and lipidomic analysis of SC samples.

Results: 58 people (34 female), were included and split into 3 groups by age: (1) 18-39 (mean 27±7) years, n=24; (2) 40-59 (47±5) years, n=16; and (3) 60+ (73±8) years, n=18. Visual skin dryness on the shin was lowest in the youngest group and highest in the oldest group (group 1, 1.59±0.86; 2, 2.36±0.93; 3, 2.78±0.96 on a 5-point scale from 0-4), exhibiting a linear relationship with age (r0.479, p<0.0001). Whilst dryness was higher in women within each age group the difference was not significant. The older group displayed the shallowest water gradient across the SC with the lowest overall water content. Regression analysis revealed significant associations between dryness and the level of SC lipids (based of CH2 groups) relative to protein (r-0.470, p<0.0001), skin-surface-pH (r0.434, p<0.0001), carboxyl (COOH, r-0.392, p<0.0001) and hydroxyl (OH, r-0.392, p<0.0001) functional groups of endogenous humectants (i.e. natural moisturizing factors and glycerol). Skin integrity, measured as transepidermal water loss (TEWL) after tape-stripping, was significantly associated with lipid structure (r0.517, p<0.0001) and cutaneous sensitivity to the irritant sodium lauryl sulfate (r0.488, p<0.0001), but only weakly associated with age in this population. Paradoxically high total lipid levels were associated with reduced skin integrity (r0.306, p=0.001).

Conclusion: Advancing age is associated with a declining capacity of the skin to hold moisture. A deficit of lipids was the strongest factor associated with dryness; however high total lipid levels had a detrimental effect on barrier integrity. This paradox along with the positive association between barrier integrity and lipid structure suggests the type and organization of lipids is more important to barrier integrity than moisturization. Together, this highlights the need to deliver the right lipids in the right amounts to maintain optimum skin barrier health and protection from irritants.



Abstract N°: 1309

The long-term proactive therapy in adolescents with moderate atopic dermatitis: what is more effective?

Inna Larkova[1, 2], Valeriy Mukhortykh[1, 3], Vera Revyakina[1, 2]

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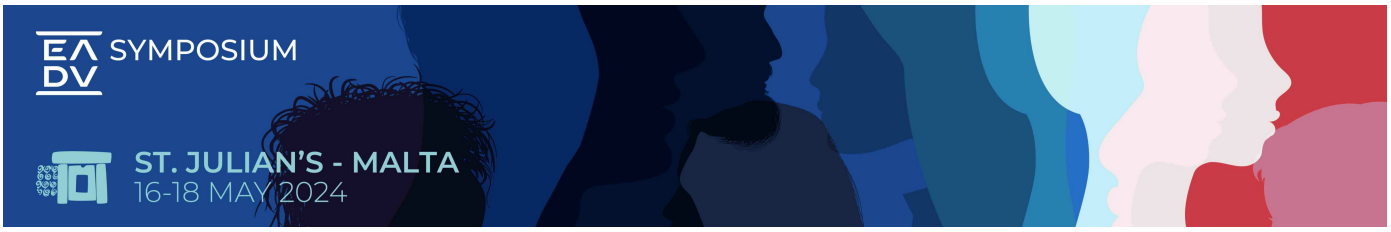
Introduction & Objectives: The adolescents moderate atopic dermatitis (AD) is characterized by difficulties in achieving prolonged disease control even with long-term use of topical corticosteroids (TCS) , which, in turn, is a risk factor for the development of adverse reactions. In recent years, the possibility of long-term proactive therapy with topical calcineurin inhibitors (TCI) in gaining prolonged disease control and reducing the number of flares has been actively discussed.

Materials & Methods: We observed 40 adolescents aged 12 to 16 years with moderate AD. The patients were randomized into 2 groups - 1 group (n= 20) - the main one, in which adolescents, after AD exacerbation, were prescribed proactive therapy with 0.03% tacrolimus for 16 weeks and the 2nd group (n = 20) - the control group, in which patients received intermittent therapy with hydrocortisone 17-butyrate also for 16 weeks. Moreover, during the first week, all patients received standard anti-inflammatory therapy with hydrocortisone 17-butyrate. From week 2, patients in group 1 for the next 3 weeks received 0.03% tacrolimus twice a day, followed by a transition to proactive therapy with the same external agent in a single application twice a week, while patients in group 2 continued to receive hydrocortisone 17-butyrate twice a day for 3 weeks, followed by a transition to therapy with the same external agent in a single application twice a week. Evaluation of the treatment effectiveness was carried out according to the clinic and the SCORAD index before the start of therapy, on days 7, 21 of treatment, as well as at 2 and 4 months of treatment.

Results: The SCORAD index in adolescents of group 1 before treatment was 45.1 ± 3.3, in group 2 – 43.2 ± 3.5. By day 7 of baseTCS therapy, an improvement was noted in patients of both groups with a decrease in the SCORAD index. After the inclusion of 0.03% tacrolimus in therapy in patients of group 1, by the 21st day of treatment the SCORAD was 10.1 ± 0.5, while during therapy with hydrocortisone 17-butyrate in patients in the control group the SCORAD was 17. 9±1.8. Against the background of subsequent topical proactive therapy with a calcineurin inhibitor, the development of clinical remission was noted in 18 adolescents (90%) in the main group, while in the control group - in 13 (65%), while in the main group only 1 patient had severe AD exacerbation, while in the control group it was in 5 patients. No side effects were observed during long-term proactive treatment with 0.03% tacrolimus, and the drug was well tolerated. A burning sensation in areas treated with tacrolimus was noted in 4 patients during the first three days of treatment, which quickly resolved on its own and did not require discontinuation of the drug.

Conclusion: The results of the study indicate that the 0.03% tacrolimus proactive therapy is an advisable treatment option for adolescents with moderate atopic dermatitis to gain prolonged disease control without side effects, more effective and safer then TCS proactive therapy.



Abstract N°: 1310

The profile of allergic sensitization and concomitant atopic diseases in adolescents with severe atopic dermatitis

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Introduction & Objectives:

Every year there is a steady trend towards an increase in the frequency of allergic diseases, and therefore research is needed to prevent their occurrence. Recently, in the scientific literature, the atopic march is considered as a natural progression sequence of allergic diseases of childhood, in which atopic dermatitis (AD) in infancy precedes the development of food allergy (FA), allergic rhinitis (AR), asthma and eosinophilic esophagitis (EoE).

Materials & Methods:

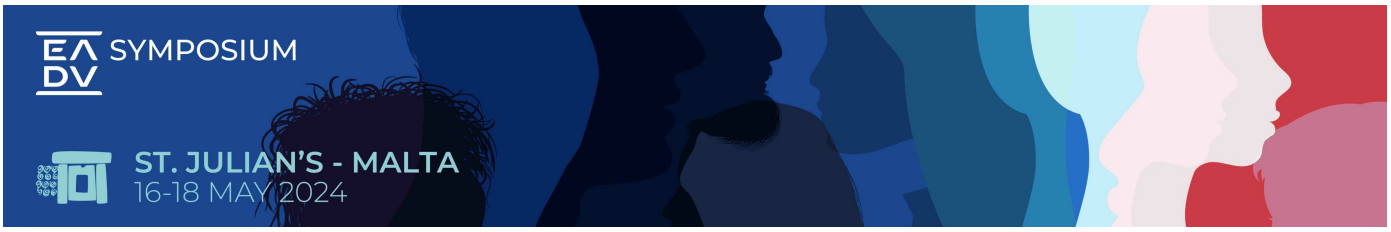
We observed 58 adolescents aged 12 to 17 years suffering from severe AD. The main complaints were skin itching of varying intensity, restless sleep, various polymorphic rashes and dry skin. All patients were diagnosed with AD clinically based on mandatory and additional criteria. The assessment of the severity of the AD was carried out using the calculation of the EASI index. All children underwent an allergological and immunological examination. Determination of the levels of the total immunoglobulin E (IgE) and allergenspecific IgE to food, household, epidermal and pollen allergens was carried out by means of the ImmunoCAP.

Results:

All adolescents had a severe course of blood pressure, the EASI index was 35.9±4.6, while AD in all was the first manifestation of atopy. The following comorbid conditions were diagnosed in adolescents with severe AD: in 43.1% - asthma, in 34.4% - AR, in 10.3% - FA. No cases of eosinophilic esophagitis were detected in the observed group. All adolescents had high levels of total immunoglobulin E (IgE) 444.6 [156.9; 897.4] IU/ml. The most common food allergens in adolescents with concomitant FA were nuts and apple (66.7%), fish (50%), milk (33.3%) and eggs (16.7%). When diagnosing respiratory allergies, it was revealed that 51.7% were sensitive to one respiratory allergen, and 34.4% were sensitive to several respiratory allergens, while plant pollen (66.7%), animals (60.0%), house dust mites (43.3%) and mold fungi (23.3%).

Conclusion:

The study demonstrates the high burden of concomitant atopic diseases and atopic sensitization in adolescents with severe AD, which confirms the need for further research not only on the treatment of blood pressure, but also on the timely prevention and treatment of these conditions.



Abstract N°: 1311

Efficacy of multi-strain probiotic in young children with atopic dermatitis

Inna Larkova[1, 2], Valeriy Mukhortykh[1, 3], Vera Revyakina[1, 2]

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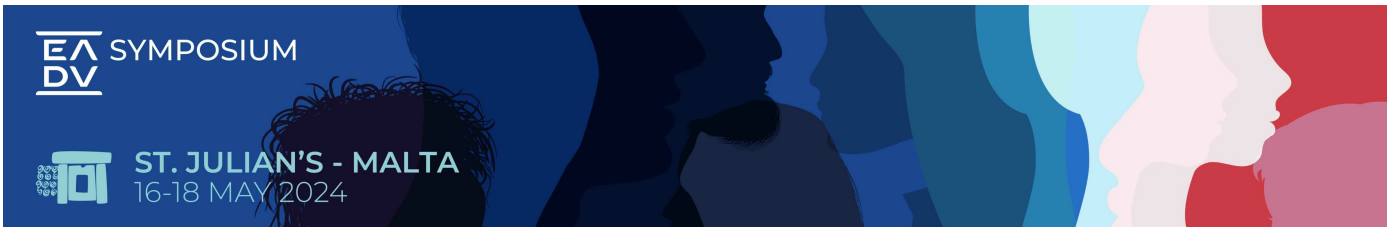
Introduction & Objectives: Atopic dermatitis (AD) is a chronic recurrent inflammatory skin disease, characterized by intense pruritus, inflammation, and skin barrier disruption. Gut microbiota may play an important immunomodulatory role in the development of normal immune tolerance. Recently an analysis of the gut microbiota of patients with AD has shown dysbiosis, that may result in a pro-inflammatory state in the gut and a loss of barrier integrity. All these data indicate the potential role of probiotics as microbiota recovery players, and consequently as potential nutritional supplements in AD treatment.

Materials & Methods: 90 children aged from 3 months to 3 years with AD and food allergy were included in an open, randomized comparative study, with 50 patients in the main group, and 40 patients in the control group. During the monthly introductory period all patients received conventional therapy and diet. Later, the multiprobiotic containing composition of 7 probiotic strains (L.casei, L.rhamnosus, Str.thermophilus, L.acidophilus, B.breve, B.infantis, B.longum in 10*9) and prebiotic inuline fructooligosaccharide was prescribed to all the children from main group during one month , 1sachet once a day. At the meantime, the children from the control group continued to receive initial therapy and diet. Initially and later during the treatment, patients were monitored for clinical AD severity using the SCORAD index; levels of the fecal secretory immunoglobulin A (sIgA), as well as microbiological indicators.

Results: There were no significant differences in the baseline characteristics between the 2 groups. After one month of the multi-strain probiotic treatment for the children from the main group there was noted a significant decline in the SCORAD index in comparison with the control group. Initially the children from both groups had the sIgA reduction. The multi-strain probiotic intervention was associated with a significant enhancement of fecal sIgA, meanwhile in the control group this enhancement was not stated. The fecal sIgA enhancement in children from the main group was statistically correlated with clinical improvement of skin symptoms in comparison with the patients from the control group. All patients from both groups, prior to treatment, had the prevalence of conditionally pathogenic flora (S.aureus, Enterobacter, Citrobacter, Klebsiella, Proteus, Candida fungi) and a reduced level of indigenous flora (Bifidobacteria, Lactobacteria, E. coli). By the end of the first month of the multi-strain probiotic treatment, there was a statistically significant increase in the number of the Bifidobacteria, Lactobacteria and E.Coli in the children from the main group compared to the children from the control group.

Conclusion: The results of our study indicate a strong positive effect in reducing the SCORAD index, enhancing of fecal sIgA and indigenous flora in children treated with the multi-strain probiotic. We suppose that multi-strain probiotic can affect allergic inflammation in young children with AD which contributes to the effectiveness of the therapy, and suggests that it could be used more extensively in clinical practice.



Abstract N°: 1335

Acute onset of psoriasis during treatment with dupilumab and tralokinumab in patients with atopic dermatitis: real-life experience from a tertiary center

Alessandra Chiei Gallo*[1], Davide Termini[2], Francesca Barei[2], Gianluca Tavoletti[2], Paolo Calzari[1], Roberto Pinto[2], Angelo Marzano[1, 2], Silvia Ferrucci[2]

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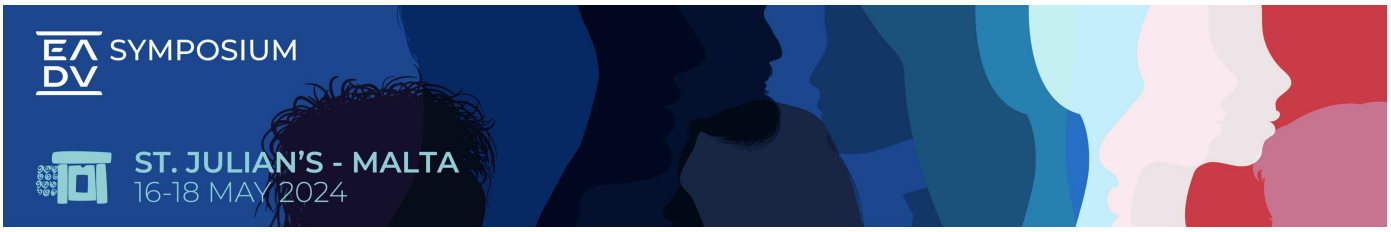
Introduction & Objectives: Psoriasis and atopic dermatitis (AD) are chronic inflammatory diseases. Psoriasis involves interleukin (IL)-17, IL-23 (Th17), and IL-12 (Th1) overproduction, while AD is characterized by Th2-polarized response with an increase of IL-13 and IL-4. Monoclonal antibodies such as dupilumab, directed against the alpha subunit of the interleukin (IL)-4 receptor with consequent inhibition of IL-4 and IL-13, and tralokinumab, selectively directed against IL-13, have been widely used in clinical practice worldwide for several years. Among the less common side effects we find the appearance of psoriasis, with an immuno-pathogenetic mechanism not yet fully clarified.

Materials & Methods: Herein, we report the experience of 11 patients (out of 852, 1.3% of the total) followed at our Center from June 2018 to January 2023 presenting a phenotypic switch from DA to psoriasis during treatment with dupilumab (10 patients) and tralokinumab (1 case) for DA severe. The trend of AD was evaluated through the following scores: Eczema Area and Severity Index (EASI), Physician's Global Assessment (PGA), Numeric Rating Scale (NRS) pruritus, NRS during night-time, Dermatology Life Quality Index (DLQI), Patient Oriented Eczema Measure (POEM), Atopic Dermatitis Control Tool (ADCT), Hospital Anxiety and Depression Scale Anxiety (HADS-A) and Depression (HADS-D).

Results: The average age of the patients (9 males and 2 females) was 55.4 years (range 22-86) with a predominantly late-onset AD pattern (72.8%). Furthermore, presence of atopic comorbidities (63.6%) with high levels of IgE (81.8%) and a family history of psoriasis was identified in 27.3% of the cases. The average time of the psoriasis onset, after the initiation of the biological therapy, was 17.8 months (range 1-49); 63.6% of patients underwent biopsy and all of them had a histological confirmation of the clinical diagnosis. Plaque psoriasis (81.8% of the patients) was the most common subtype of psoriasis reported with an average Psoriasis Area Severity Index (PASI) of 12.1 and prevalence of localization on the extremities (especially lower and upper extremities), followed by back and limbs. All patients were treated with topical calcipotriene and betamethasone dipropionate foam; 10 out of 11 underwent methotrexate (MTX) therapy (average dose of 12 mg weekly), except one patient who required hospitalization for a severe erythrodermic form and was treated with ciclosporin 200 mg/day. An almost complete control of both diseases was maintained in all patients, with the average PASI dropping from 12.4 to 3.4 and the average EASI from 27.4 to 3.9, respectively, at the onset of psoriasis and at the last follow-up. Biologic therapy was discontinued in 10 out of 11 patients (90.9%).

Conclusion: It could be hypothesized that inhibiting the Th2 pathway through blockade of IL-4 and IL-13, or IL-13 alone, might lead to an imbalance towards Th1/Th17 type inflammation, potentially playing a pivotal role in the onset of psoriatic manifestations in genetically predisposed patients. This underscores the importance of considering the patient's medical history and the clinical phenotype of AD to make the best therapeutic choice. Future studies are needed to clarify the mechanism behind this phenotypical switch for more effective management and prevention.



Abstract N°: 1480

IL-4/13 inhibition as the first line of treatment in real clinical setting

Tatiana Hurtová[1], Martin Pec[2], Barbora Kroslakova[3], Karolina Vorcakova[1]

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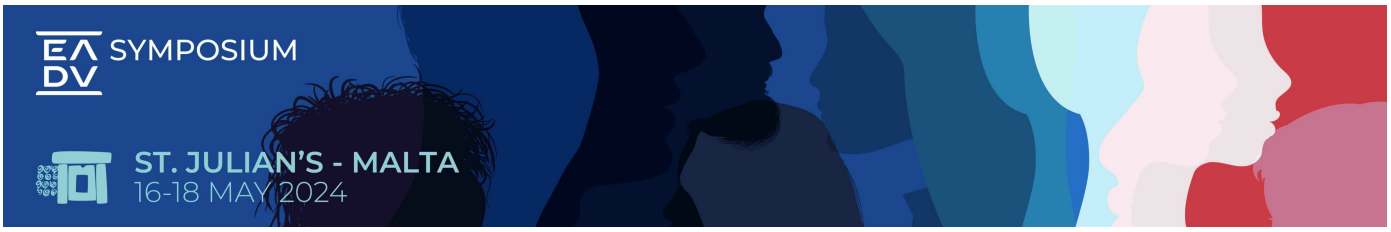
Introduction & Objectives: Atopic dermatitis (AD) is heterogenous chronic inflammatory skin condition with flares of skin inflammation accompanied by severe itch. Novel therapeutic approaches have been approved, revolutionizing the treatment. Data from clinical trials show us promising therapeutic response, achieving EASI 75 response. The first one available, dupilumab, is a fully human IgG4 monoclonal antibody that binds to the IL-4 receptor subunit, which is part of the receptor complex for IL-4 and IL-13. Treatment with dupilumab has a significant effect in assessing severity using the EASI score as well as in reducing pruritus. However, data from randomized clinical trials often do not reflect real clinical practice. We analyzed the population bionaïve patients from single center treated with dupilumab.

Materials & Methods: As part of a single-centric, retrospective analysis, we evaluated a group of patients with severe atopic dermatitis over the age of 18, who were treated at the Dermatovenerology department at the University Hospital Martin, and, from September 2021 to September 2022, were set after fulfilling the indication criteria for treatment with the IL-4/13 inhibitor, dupilumab. A cohort of 17 patients, aged between 20 and 60, was analyzed, of which 11 were men, 6 were women. Dupilumab was administered in the first line of the treatment, with no previous treatment with biologics or JAK inhibitor.

Results: The average age was 42 years, with the lowest age being 20 years and the highest age being 62 years. After the BMI (Body Mass Index) evaluation, the proportion of overweight patients was 35%, the proportion of patients with first-degree obesity was 18%, and 47% of patients had a normal weight. The most frequently occurring comorbidity was allergic rhinitis, followed by hepatopathy and chronic kidney disease. 24% had associated asthma. The effectiveness of the treatment was evaluated using the EASI (Eczema Area and Severity Index) score, all patients reached EASI 75 after 12-16 weeks of treatment (check-up dates influenced by the epidemiological situation). In 18% of patients, herpes simplex labialis occurred during treatment up to the current date, in 29% of patients mild to moderate conjunctivitis occurred without the need to stop treatment.

Conclusion: Dupilumab is effective therapeutic option in real world setting, providing clearing of the skin for the patients. The treatment was generally well tolerated and there were no drop-outs during the observation period. No severe adverse events were observed, with no new safety signals.



Abstract N°: 1609

Risks and Benefits of Dose Escalation with JAK Inhibitors in Adolescent Atopic Dermatitis Patients

Jana Kazandjieva[1], Dzhemile Dervish[2, 3]

[1]Medical University - Sofia, Dermatology and Venerology, Sofia, Bulgaria,[2]Medical University - Sofia, Dermatology and Venerology, Sofia, [3]EuroDerma Clinic, Dermatology and Venerology, Sofia

Introduction & Objectives:

Adolescent atopic dermatitis is characterized by a high disease burden affecting patients' quality of life due to chronic or relapsing course of itchy skin lesions and sleep loss. It is frequently associated with difficulties in building social relationships and in maintaining good school performance, to bullying, depression and anxiety.

Addressing severe cases of atopic dermatitis in this age group, particularly those with inadequate response to standard doses of JAK inhibitors, prompts a critical inquiry: what are the risks and benefits of dose escalation in such scenarios?

Materials & Methods:

We present a 13-year-old female patient, diagnosed with atopic dermatitis 4 years prior, with no family history of the disease. She experiences recurrent exacerbations, notably linked to emotional stressors, likely intensified by her parents' divorce, as she resides primarily with her father. Encounters with the patient's mother consistently coincide with symptom relapses. Treatment with local corticosteroids has only provided temporary relief.

Dermatological status revealed involvement of the head and neck, upper and lower extremities and the trunk. The pathological skin lesions included pruritic erythematous macules and papules, coalescing into plaques. Lichenification was present, predominantly involving the neck and upper extremities. Secondary lesions included excoriations and yellowish to dark brown crusts.

Baseline assessments included Eczema Area and Severity Index (EASI), estimated to be 21.8, Body Surface Area (BSA) - 35% and The Peak Pruritus Numerical Rating Scale Weekly Average Score (PPNRS) - 4.

The patient initiated treatment with oral JAK1 inhibitor (Upadacitinib) 15mg tablets with daily intake.

Results:

After 2 weeks of treatment the patient showed remarkable improvement in both clinical status and symptoms. At week 2 the EASI was estimated 10.8, BSA% - 25%, NRS - 3.5. The improvement continued in week 4 with EASI - 7, BSA% - 25% and PPNRS - 0.28, showing a significant decrease in pruritus severity.

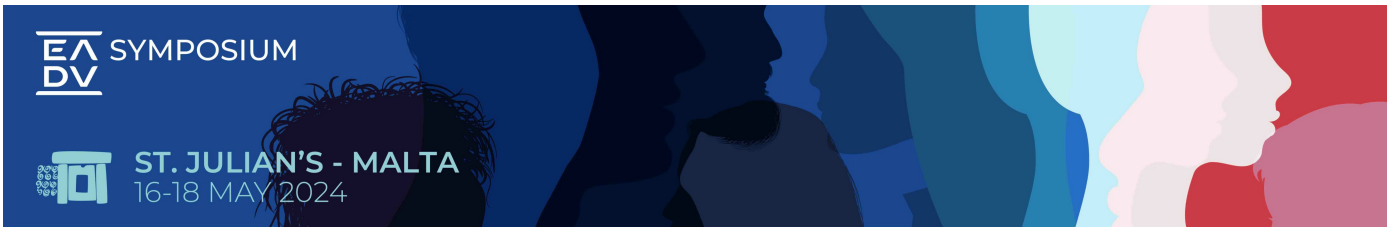
After week 4 of treatment, the patient experienced 2 relapses over the course of a month. Local corticosteroids were prescribed, showing satisfactory efficacy in the first relapse and moderate efficacy during the second relapse.

EASI at week 8 is estimated 7.2, BSA% - 20%, PPNRS - 1.66. At week 12 EASI is 8.4, BSA% - 30%, PPNRS - 6, showing significant worsening of patient's pruritus.

Due to an elevation in the PPNRS score and frequent relapses following stressful experiences, coupled with a decline in quality of life and the absence of reported medication side effects, we opted to escalate the dose to 30 mg daily. One month into this adjustment, there have been no relapses in clinical status and subjective symptoms. No side effects have been reported, prompting consideration of lowering the dose back to 15 mg.

Conclusion:

While EU guidelines recommend a dose of 15 mg for adolescent patients, in cases where significant stress, such as our patient’s situation, is coupled with more than one relapse within a two-month period, we advocate for the possibility of escalating the dose to 30 mg temporarily. This adjustment aims to regain control over relapses and alleviate both clinical and subjective symptoms. We deliberated on alternative treatments, including combining treatment with systemic corticosteroids and Cyclosporine A, but concluded that escalating the medication dose remains the safest and most effective course of action.



Abstract N°: 1614

Exploring the Autoimmune Constellation in Atopic Dermatitis: Unraveling the Interconnections

Elena Porumb-Andrese*[1, 2], Roxana-Paraschiva Ciobanu[1], Catalina Anca Munteanu[1], Antonia Clivet[1], Cristina Colac-Botoc[1], Alexandra Starica[1], Andreea-Caterina Rusu[1], Mihaela Paula Toader[1, 3], Daciana Elena Branisteanu[1, 2]

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Introduction & Objectives:

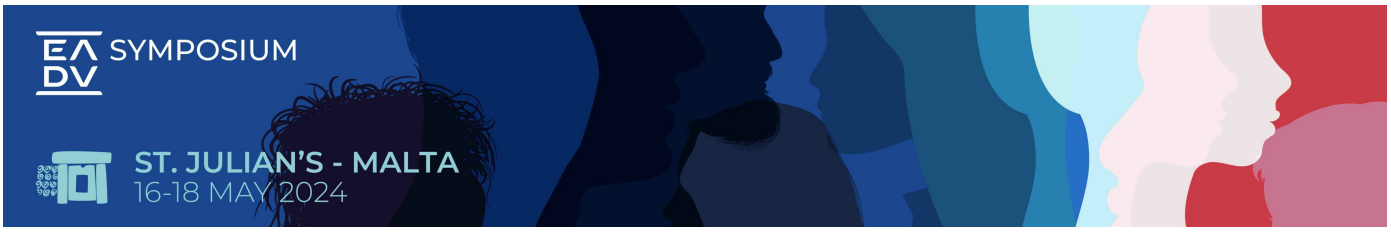
Atopic dermatitis (AD) is a chronic inflammatory skin condition marked by increased levels of interleukins (IL)-4, IL-13, IL-22, and interferon-gamma (IFN-γ). Conversely, alopecia areata (AA) is characterized by non-scarring hair loss, involving TCD8+ cell infiltration of hair follicles and secretion of IFN-γ and IL-15. Atopic dermatitis is characterized by multiple autoimmune comorbidities, among which alopecia areata is prominent, showing a bidirectional association. Both AD and AA display elevated levels of Th2 cytokines, such as IL-4, IL-5, and IL-13, which may be decreased with the use of baricitinib, a reversible, competitive inhibitor of the JAK (Janus Kinase) family. Notably, up to a third of patients with AA also have concurrent AD, underscoring the importance of researching an agent that is effective for treating these types of patients.

Materials & Methods:

We present the case of a 22-year-old woman, diagnosed with autoimmune thyroiditis and class 1 obesity. She came to our clinic in July 2023, exhibiting non-scarring alopecia patches on the scalp, with a Severity of Alopecia Score (SALT) of 67, along with several erythematous-scaly plaques and lichenification patches around multiple flexural areas. The alopecia patches first appeared approximately 2 years prior, with improvement noted during pregnancy, but a recurrence in November 2022. The atopic dermatitis lesions initially manifested around the age of 6, with multiple episodes of exacerbation and remission over the years. She has undergone various treatments, including emollients, topical and systemic corticosteroids, and phototherapy, with unsatisfactory results. The current lesions began to manifest 5 months before her visit, with no treatment initiated.

Results: Following the local examination, the diagnoses of AA and AD were established. After further biological evaluation and a pneumological consult, systemic treatment with Baricitinib 4mg daily was initiated in September 2023. During the 2 months evaluation of treatment, it was observed that the alopecia areas had decreased by at least 1 cm, and new hair strands were visible on their surface, indicating ongoing growth. At the 3-month evaluation, the SALT score is 1.2, and almost complete coverage of the alopecia patches is observed, with new hair strands on the scalp. However, there is persistent lateral madarosis at the left eyelid level. The itching associated with AD was significantly alleviated, with only a persisting slightly pruritic erythematous-squamous plaque on the right antecubital fossa. The SCORAD (SCORing Atopic Dermatitis) decreased from 35 at the initiation of Baricitinib to a score of 3 at the 3-months evaluation.

Conclusion: The risk of developing autoimmune diseases such as autoimmune thyroiditis, inflammatory bowel disease or systemic lupus erythematosus in individuals with atopic dermatitis is higher compared to healthy individuals. However, alopecia areata stands out as the primary associated autoimmune comorbidity. Although long-term data on Baricitinib is currently being collected, it has been shown to be an effective treatment for both AD and AA. This finding aligns with numerous studies demonstrating its efficacy across a range of autoimmune diseases.



Abstract N°: 1770

Safety and efficacy of abrocitinib in patients with moderate-to-severe atopic dermatitis in India: a multicentre, randomised, open-label, parallel-group study

Saswati Halder[1], Somesh Gupta[2], Ramesh Bhat[3], Anjeeta Dhawan[4], Suneel Vartak[5], Davinder Parsad[6], Sidana Neetu[7], Pradyumna Vaidya[8], Andrew Selfridge[9], Pinaki Biswas[9], Erman Guler[10], Ruffy Guilatco[11], Komal Gaur[12], Charles Adhav*[12]

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Introduction & Objectives: In India, conventional systemic therapies are currently the preferred first-line treatment for patients with moderate-to-severe atopic dermatitis (AD) whose disease is unresponsive to topical treatment. However, inadequate AD control and substantial adverse events (AEs) frequently occur with conventional systemic agents, limiting their long-term use. The oral Janus kinase 1–selective inhibitor abrocitinib was efficacious and well tolerated in patients with moderate-to-severe AD from the JADE clinical trial programme. This study assessed the safety and efficacy of abrocitinib in adult and adolescent patients with moderate-to-severe AD in India.

Materials & Methods: This randomised, open-label, parallel-group study (NCT05375929) enrolled** patients aged ≥12 years with moderate-to-severe AD (Investigator's Global Assessment [IGA] ≥3, Peak Pruritus Numerical Rating Scale ≥4, Eczema Area and Severity Index [EASI] ≥16, and percentage of body surface area affected ≥10 at baseline) from 15 sites in India. Patients were randomly assigned (1:1) to receive a known dose of oral, once-daily abrocitinib (200 mg or 100 mg) as monotherapy or with concomitant AD therapy (oral antihistamines, nonmedicated emollients, and topical treatment) for 12 weeks. Primary endpoint was the incidence of AEs and serious AEs. Secondary endpoints were the proportions of patients who achieved at Week 12 an IGA score of 0 (clear) or 1 (almost clear) with ≥2-point improvement from baseline, ≥75% improvement from baseline in EASI (EASI-75), and ≥75% improvement from baseline in SCORing Atopic Dermatitis (SCORAD-75); and change from baseline in Patient-Oriented Eczema Measure (POEM) and Atopic Dermatitis Control Tool (ADCT) scores up to Week 12.

Results: A total of 200 patients, 167 (84%) adults and 33 (16%) adolescents, received abrocitinib (200 mg, n=99; 100 mg, n=101); 109 (54%) were female and median (range) age was 33 (12-73) years. Of these, 145 (72%) received abrocitinib as monotherapy and 55 (28%) received concomitant AD therapy. All-cause treatment-emergent AEs (TEAEs) occurred in 30% of patients in the 200-mg arm and 26% in the 100-mg arm; those proportions were 18% and 14% for treatment-related TEAEs, respectively (**Table**). Most frequent treatment-related TEAEs (>2% of patients in either treatment arm) were nausea, gastroesophageal reflux disease, pruritus, vomiting, and vertigo (**Table**); most of them were mild. One all-cause serious TEAE (non–treatment-related) was reported in an adult patient in the 100-mg arm (radius fracture). Nine patients (200 mg, n=5; 100 mg, n=4) temporarily discontinued the study due to all-cause TEAEs. One adolescent patient (aged 12 years; 200-mg arm) permanently discontinued the study due to a non-serious TEAE of eczema herpeticum. No deaths were reported. At Week 12, 48% of patients in the 200-mg arm and 50% of patients in the 100-mg arm achieved IGA 0/1 response; those proportions were 72% and 69% for those who achieved EASI-75 and 47% and 43% for those who achieved SCORAD-75, respectively (**Figure**). Improvements from baseline in POEM and ADCT scores were seen with both abrocitinib doses at Week 12 (**Figure**).

Conclusion: Abrocitinib at either 200-mg or 100-mg dose was efficacious and well tolerated in adult and adolescent patients with moderate-to-severe AD in India. The safety profile of abrocitinib was consistent with that observed in the

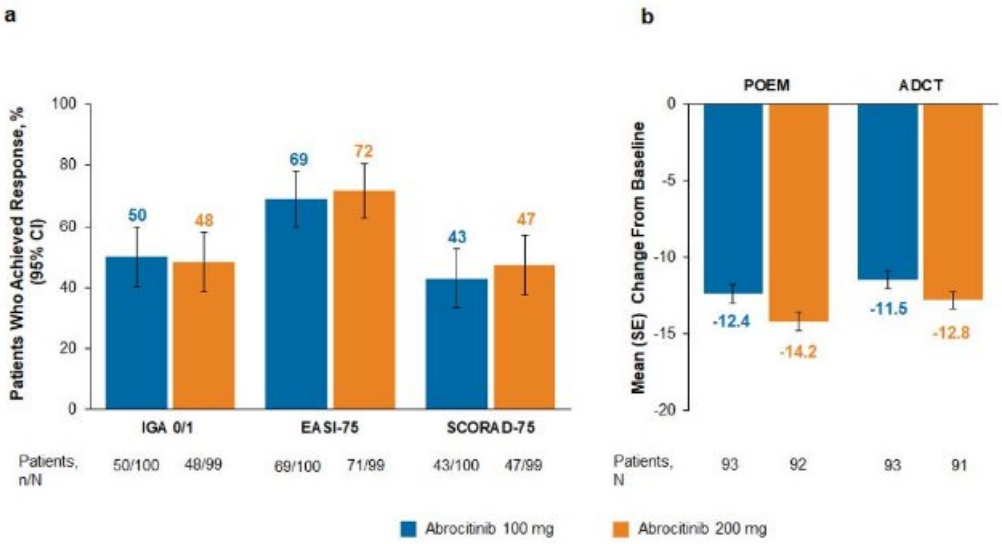
JADE clinical trials; no new safety signals were observed in Indian patients.

Table Safety summary

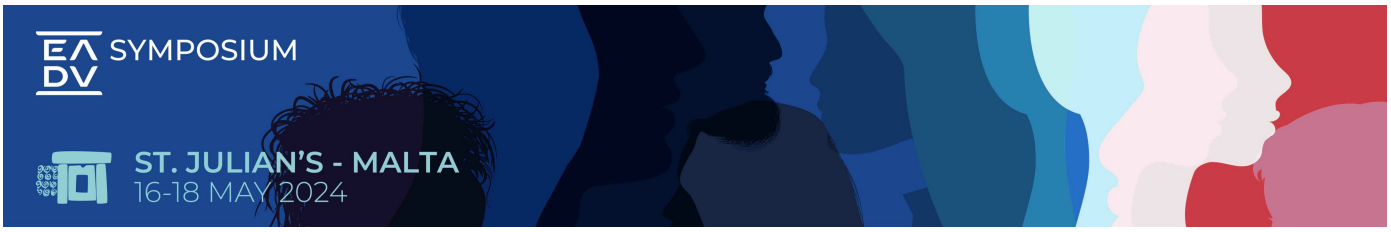
n (%)	All-Cause TEAEs		Treatment-Related TEAEs	
	Abrocitinib 100 mg n=101	Abrocitinib 200 mg n=99	Abrocitinib 100 mg n=101	Abrocitinib 200 mg n=99
Patients with TEAEs	26 (26)	30 (30)	14 (14)	18 (18)
Patients with serious TEAEs	1 (1)[a]	0 (0)	0 (0)	0 (0)
Patients with severe TEAEs	0 (0)	1 (1)[b]	0 (0)	1 (1)[b]
Patients who permanently discontinued the study due to TEAEs	0 (0)	1 (1)[c]	0 (0)	0 (0)
Patients who temporarily discontinued the study due to TEAEs	4 (4)	5 (5)	2 (2)	3 (3)
Most frequently reported TEAEs (>2% of patients in either treatment arm), n (%)				
Nausea	5 (5)	9 (9)	6 (6)	10 (10)
Gastroesophageal reflux disease	2 (2)	4 (4)	2 (2)	3 (3)
Pruritus	2 (2)	4 (4)	0 (0)	3 (3)
Vomiting	0 (0)	3 (3)	1 (1)	3 (3)
Vertigo	2 (2)	0 (0)	3 (3)	0 (0)

TEAE, treatment-emergent adverse event.
As-treated population was used for safety analyses.
[a]Radius fracture.
[b]Pruritus.
[c]Eczema herpeticum.

Figure (a) IGA 0/1, EASI-75, and SCORAD-75 responses at Week 12[a] and (b) change from baseline in POEM and ADCT scores at Week 12[b]



ADCT, Atopic Dermatitis Control Tool; EASI-75, ≥75% improvement from baseline in Eczema Area and Severity Index; IGA 0/1 response, Investigator's Global Assessment score of 0 (clear) or 1 (almost clear) with ≥2-point improvement from baseline; POEM, Patient-Oriented Eczema Measure; SCORAD-75, ≥75% improvement from baseline in SCORing Atopic Dermatitis; SE, standard error.
As-randomized population was used for efficacy analyses.
[a]Missing data after discontinuation were defined as nonresponse.
[b]Data are reported as observed.



Abstract N°: 1803

Effectiveness of JAK inhibitors in patients with prurigo-type atopic dermatitis: a small case series

Antoanela Carija[1, 2], Ranka Ivanisevic[1], Mirjana Sekulovski[1], Lina Miric Kovacevic[1, 2]

[1]University Hospital centre Split, Dermatology, Split, Croatia, [2]University of Split School of Medicine, Dermatology, Split, Croatia

Introduction & Objectives:

Prurigo-type atopic dermatitis (AD) is an AD variant characterized by excoriated papules, indurated nodules, and intense itching associated with type 2 cytokine responses(1), among them many interleukins (IL), such as IL-4, IL-6, IL-13, and IL-31.(2) Type 2 cytokines activate Janus-kinases (JAK) and signal transducers and activators of transcription (STAT) pathway, which contributes to perpetuation of itching. The molecules that play a key role are JAK1, JAK2, STAT3 and STAT6.(2). Recently, Janus kinase inhibitors have been successfully used for the treatment of prurigo nodularis(3,4,5) but the reports are still sparse.

Materials & Methods:

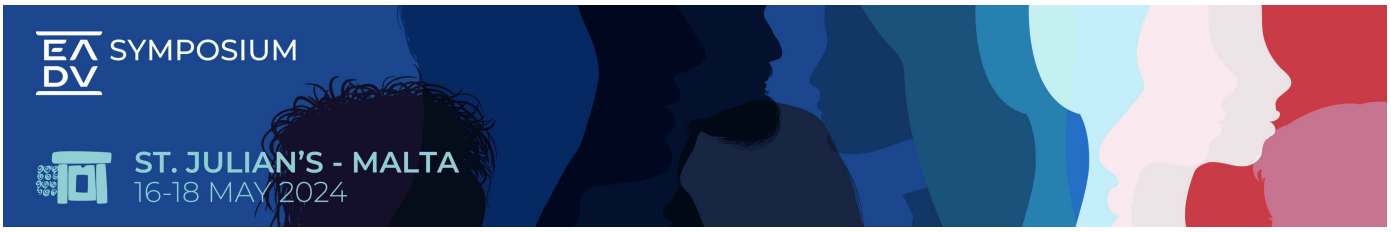
We present a small case series of four patients (three women and one man) with recalcitrant prurigo-type atopic dermatitis who were successfully treated with JAK inhibitors (three patients with upadacitinib, one with abrocitinib). Three patients had elevated IgE, one of them had extremely elevated levels. Two patients had associated hypostatic dermatitis and venous insufficiency, and one patient had diabetes mellitus.

Results:

This small case series demonstrates good clinical efficacy of the JAK inhibitors upadacitinib and abrocitinib in the treatment of prurigo-type atopic dermatitis. EASI100 was achieved in two patients (both on 15 mg upadacitinib) with NRS-pruritus 0-1/10. A patient with severe AD and diabetes mellitus treated with abrocitinib (200 mg) achieved EASI75.

Conclusion:

JAK inhibitors may be a new option for the treatment of prurigo -type atopic dermatitis and prurigo nodularis without associated atopic dermatitis, especially for patients who have failed conventional treatment.



Abstract N°: 1813

A novel, first-in-class, oral anti-inflammatory candidate therapeutic for the treatment of Atopic Dermatitis

Renee Deming[1]

[1]Enveda Biosciences, Program Strategy, Boulder, United States

Introduction & Objectives:

Atopic dermatitis (AD) remains a challenging condition to treat effectively, with a significant proportion of patients experiencing unmet need. Specifically, the pursuit of safe, oral options represents a promising avenue to address a gap in the facile treatment of patients with moderate to severe disease. We developed, ESN-A1, a novel compound that potently inhibits primary immune cell chemotaxis via a historically undrugged mechanism of action. This compound demonstrates robust efficacy in validated disease models and favorable safety margins in rodent and non-rodent toxicology studies, suggesting a high potential for clinical translation.

Materials & Methods:

Animals were randomized and dosed accordingly with test article. Inducing agent, MC903 (2 nmol, 50µl/Mice/Back) or DNFB (100µl of 0.15%/mice/back) was applied topically to all animals (except vehicle control) on alternate days for 14 days. Back skin thickness, cumulative skin score (erythema + scaling + thickness), and body weight were recorded three times a week during the study period. After 1 hour post treatment on day 14, blood was collected in K2EDTA tubes Back skin was collected for gene expression analysis, histopathology, and bioanalysis.

Results:

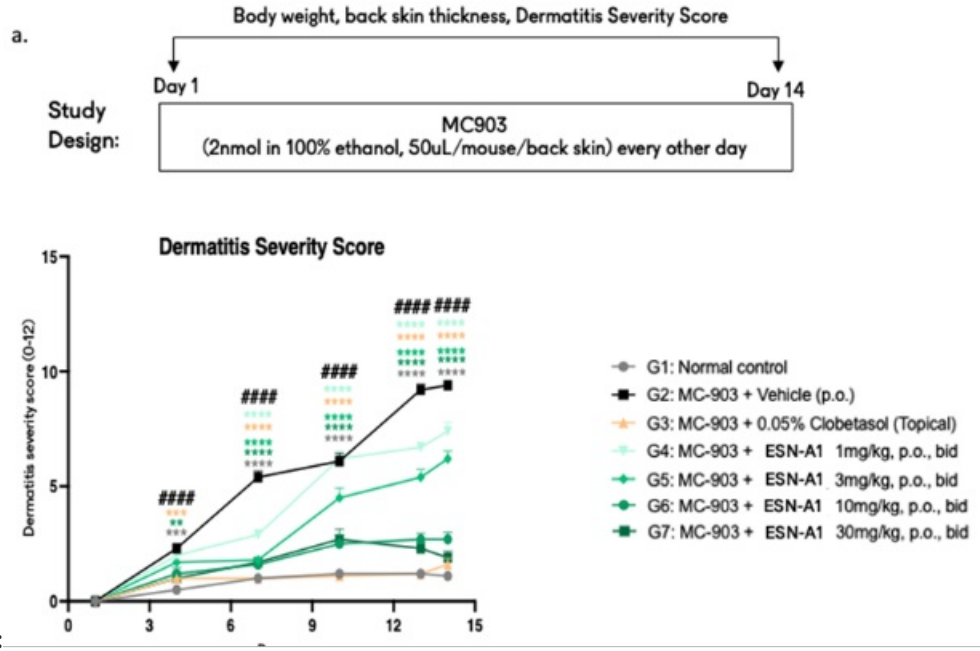
ESN-A1 potently inhibits primary human granulocyte chemotaxis in vitro induced by multiple stimuli, as opposed to a specific chemokine receptor antagonist. ESN-A1 is robustly efficacious in the MC903- and DNFB-induced models of AD. In the MC903 model, ESN-A1 exhibited near normalization of disease manifestations comparable to high potency topical corticosteroids. An overall reduction in histopathology score was observed following oral administration of ESN-A1, including the reduction in immune cell infiltration consistent with the identified target mechanism. Moreover, ESN-A1 significantly reduced key biomarkers associated with AD, including IL-4 and IL-13, which are targeted by approved biologics (Fig 1). Beyond topical corticosteroid standard of care, efficacy of ESN-A1 was comparable to approved JAK inhibitors, including oral upadacitinib, highlighting its potential as an alternative in the treatment landscape to a validated highly efficacious mechanistic class that has notable safety concerns. (Fig 2). ESN-A1 also shows similar efficacy to the systemic corticosteroid dexamethasone in the DNFB-induced model of AD with direct impacts on the dermatitis severity score, as well as a pronounced reduction in itch, a critical feature of emerging therapies for this chronic pruritic condition (Fig 3).

Safety evaluations in both rodent and non-rodent studies underscore ESN-A's favorable tolerability profile, providing substantial dose margins over the pharmacologically active range, further supporting its candidacy as a novel therapeutic option for AD.

Conclusion:

ESN-A1 is a promising novel oral therapeutic candidate for the treatment of AD. Preclinical studies suggest that ESN-A1 may harbor a Jak inhibitor-like efficacy profile with a superior safety potential, addressing the need for a safe oral thereapeutic option for patients with moderate-to-severe disease. We intend to rapidly advance ESN-A1 into clinical studies to evaluate its efficacy and safety profile in human subjects, potentially ushering in a new era of AD management via oral small molecule therapy.

Figure 1. ESN-A1 achieves near normalization of disease in the MC903-induced atopic dermatitis mouse model.



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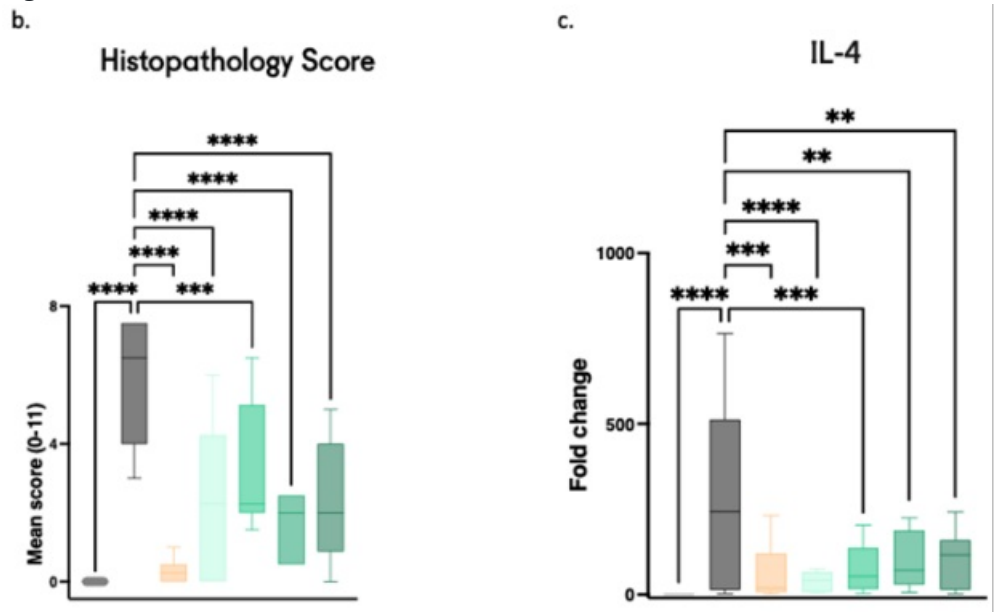


(a)ESN-A1 shows a dose-dependent reduction in dermatitis severity score comparable to topical clobetasol (b) Gross reductions in histopathology score and (c) key disease biomarkers IL-4 are observed.

Figure 2. ESN-A1 demonstrates a dose-dependent reduction in dermatitis severity score on par with oral administration of upadacitinib at clinically relevant doses.

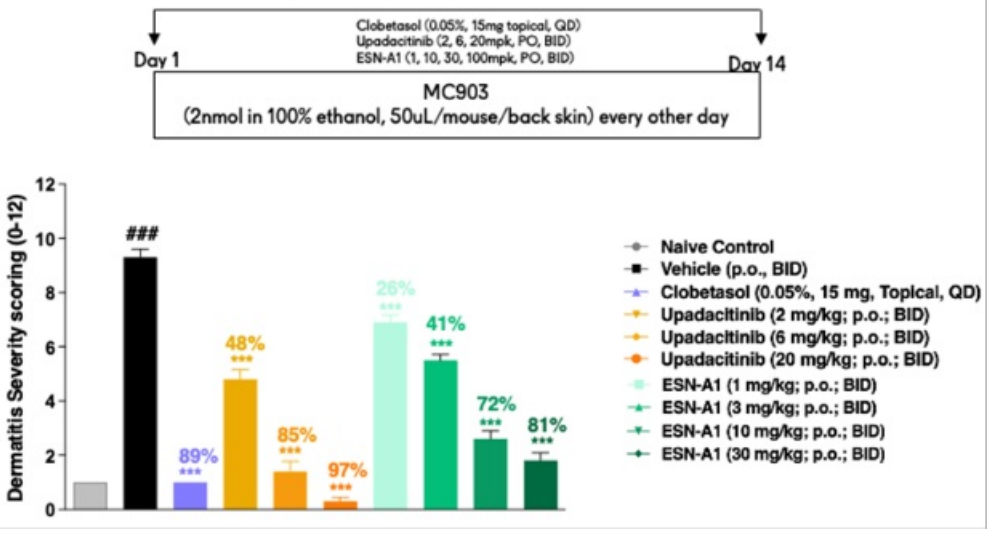
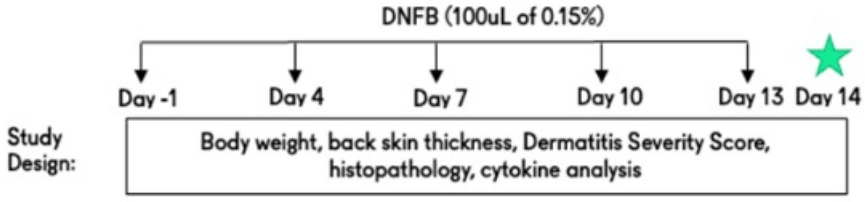


Figure 3. ESN-A1 significantly reduces dermatitis severity score and itch in the DNFB-induced model of atopic dermatitis



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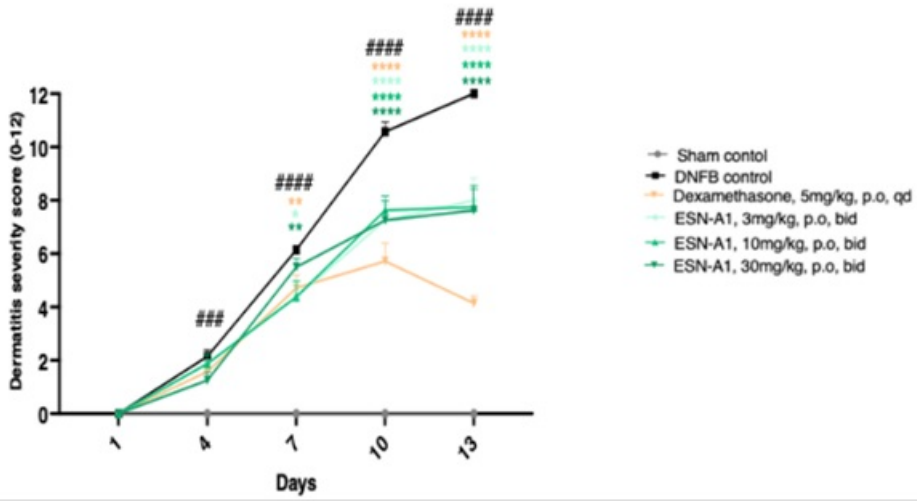

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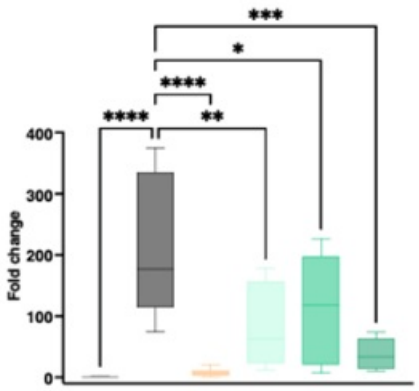

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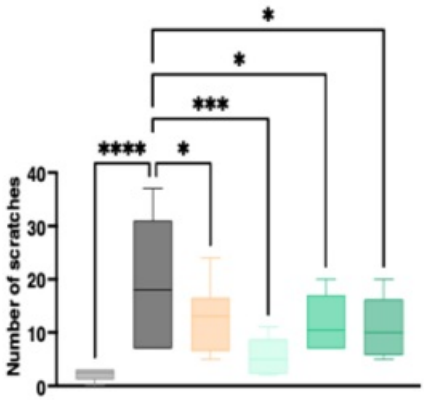
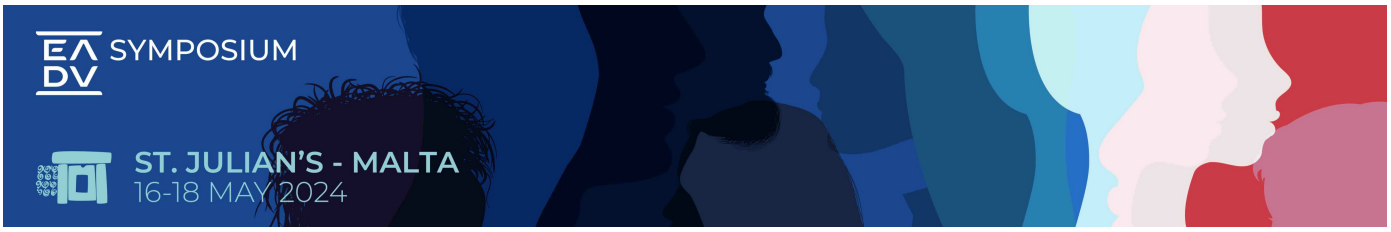


(a)ESN-A1 shows a dose-dependent reduction in dermatitis severity score comparable to oral dexamethasone as well as (b)reductions itch and (c) IL-4.



Abstract N°: 1902

Exploring Generalized Pruritic Papular Rash Post-Tick Bite: An Intriguing Case Study

Livia-Cristiana Baicoianu-Nitescu[1, 2], Andreea Maria Radu[1, 2], Corina Ionescu[1, 2], Alexandra-Maria Roman[1, 2], Ioana-Valentina Stoenica[1, 2], Florica Sandru[1, 2]

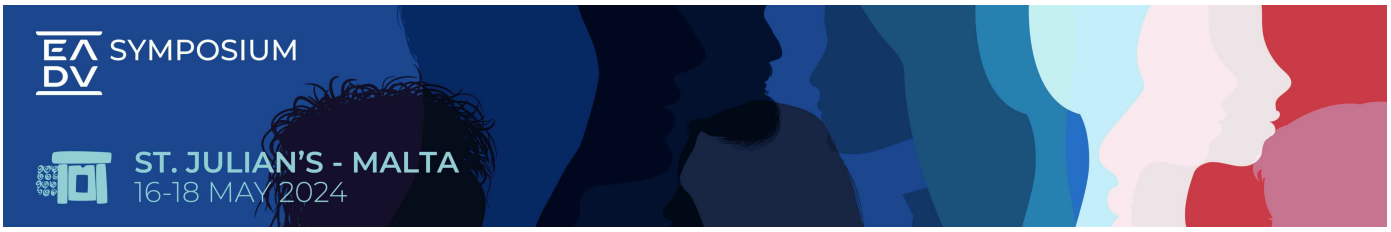
[1]Carol Davila University of Medicine and Pharmacy, București, Romania,[2]Elias Emergency University Hospital, Bucharest

Introduction & Objectives: Ticks, hematophagous arthropods, attach to human skin causing diverse initial cutaneous manifestations and potentially transmitting serious infectious diseases. Primary lesions result from toxic saliva and mouthpart penetration, leading to acute pruritic papular dermatitis primarily on lower limbs but may occur anywhere on the body, especially in body folds during massive infestations.

Materials & Methods: We present the case of a 59-year-old female who was admitted into the dermatology department with a generalized pruritic cutaneous rash manifesting four months antecedent to her clinical encounter. Physical examination revealed a polymorphic cutaneous eruption, marked by erythematous papules and vesicles, accompanied by hematic crusts, diffusely distributed across the trunk and limbs. Remarkably, the condition evoked intense pruritus without concurrent systemic manifestations.

Results: Based on the patient's personal history, it is observed that the rash emerged subsequent to a tick bite. The patient was frist referred to an infectious diseases department where the tick was extracted and systemic antibiotic therapy with doxycycline was initiated. Nonetheless, subsequent to this intervention, the patient observed the onset of a papular pruritic rash, prompting her presentation to the dermatology department. Upon the initial presentation, systemic corticosteroid therapy was initiated, resulting in an amelioration of the rash.

Conclusion: This case highlights the importance of recognizing the cutaneous manifestations following tick bites. The presentation of acute pruritic papular dermatitis, as observed in our patient, underscores the diverse clinical spectrum associated with tick-related dermatoses. Prompt referral to dermatological evaluation following tick removal is imperative, as demonstrated in our case, to facilitate appropriate management and alleviate associated symptoms.



Abstract N°: 1943

Treat-to-target in the management of moderate-to-severe atopic dermatitis in adults: A Canadian consensus

Jensen Yeung*[1], Melinda Gooderham[2], Chih-Ho Hong[3], Charles Lynde[4], Vimal H. Prajapati[5], Perla Lansang[1], Irina Turchin[6], Marni Wiseman[7], Carolyn Jack[8], Michele Ramien[5], Kerri Purdy[9], Parbeer Grewal[10]

[1]University of Toronto, Medicine, Toronto, Canada,[2]Queen's University, Medicine, [3]University of British Columbia, Dermatology, [4]Lynde Institute of Dermatology, [5]University of Calgary, Medicine, [6]Dalhousie University, [7]University of Manitoba, Medicine, [8]McGill University, Medicine, [9]Dalhousie University, Medicine, [10]Universeity of Alberta, Medicine and Dentistry

Introduction & Objectives:

Atopic dermatitis (AD) is a chronic skin disease that is associated with substantial burden and quality of life impairment. Systemic treatment may be required for moderate-to-severe AD, and although several options are available, there is limited guidance on how best to modify systemic therapies at the individual patient level to optimize long-term outcomes. The objective of this study is to offer guidance on a pragmatic treat-to-target (T2T) strategy that includes treatment outcomes, measures, and timing of assessments to optimize systemic therapy in adults with moderate-to-severe AD.

Materials & Methods:

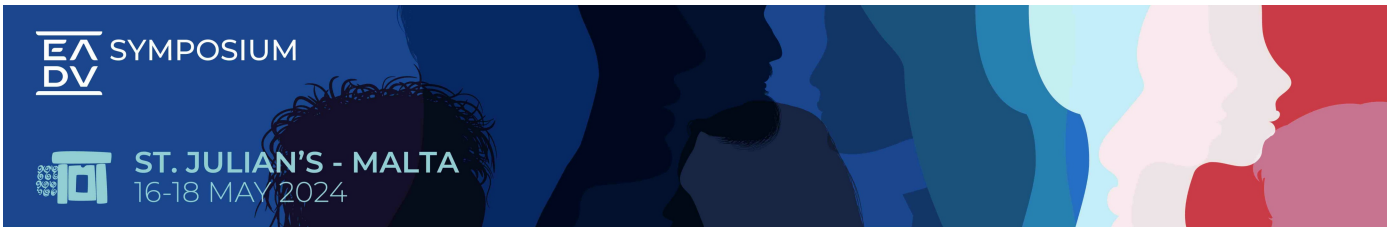
A group of 12 Canadian dermatologists with expertise in the management of AD was convened. Following the guiding principles for T2T and a review of evidence from existing guidelines and treatment pathways, a set of recommendations was proposed for assessment timepoints and treatment target criteria. The proposed T2T criteria were then evaluated and rated.

Results:

There was unanimous consensus to assess adult AD patients with at least one physician-rated outcome measure (either the Eczema Area and Severity Index [EASI] or Physician Global Assessment [PGA]) and at least one patient-reported outcome (PRO) measure (pruritus numerical rating scale [NRS], Dermatology Life Quality Index [DLQI] or Patient-Oriented Eczema Measure [POEM]). The recommended timing of assessments is 12-16 weeks, 6-8 months, and one year after the initial visit, followed by maintenance visits every 6-12 months. At each assessment point, treatment should continue if at least one of the physician-rated and one of the PROs is met; otherwise, treatment should be modified or optimized following the principles of shared decision-making.

Conclusion:

The proposed T2T algorithm sets clear outcome targets and timing of assessments for optimization of treatment in adults with moderate-to-severe AD requiring systemic therapy. This pragmatic T2T strategy incorporates scales commonly used in Canadian practice and allows for flexibility in the timing of assessments.



Abstract N°: 1956

Atopic dermatitis and Risk of Incident Psoriasis: A Systematic Review and Meta-analysis of Cohort Studies

Parkin Paramiraksa*[1], Metavee Boonsiri[2], Poramin Patthamalai[2], Amarit Tansawet[3]

[1]Faculty of Medicine Vajira hospital, Navamindradhiraj University, Faculty of Medicine Vajira hospital, Bangkok, Thailand, [2]Dermatology Unit, Department of Internal Medicine, Faculty of Medicine Vajira hospital, Navamindradhiraj University, Dermatology Unit, Department of Internal Medicine, Bangkok, Thailand, [3]Department of Surgery, Faculty of Medicine Vajira hospital, Navamindradhiraj University, Department of Surgery, Bangkok, Thailand

Introduction & Objectives:

There has been increasing evidence suggesting the association between atopic dermatitis (AD) and psoriasis, as both were involved in the intersecting pathophysiology of immune dysregulation. Although emerging longitudinal studies have reported the increased risk of incident psoriasis in patients with AD, the consistency remains among studies. This study was conducted to determine the risk of incident psoriasis in patients with AD.

Materials & Methods:

Electronic database searches across MEDLINE, Scopus, EMBASE, Cochrane Library, and medRxiv were performed to identify cohort studies published from inception to January 2024, comparing the risk of incident psoriasis in populations with AD versus non-AD controls. Quality assessments were performed according to the Newcastle-Ottawa Scale (NOS). Two reviewers independently screened studies, extracted key characteristics and outcomes, and evaluated the risk of bias. The third reviewer will be consulted when consensus is required. The PRISMA and Meta-analysis of Observational Studies in Epidemiology (MOOSE) reporting guidelines were followed. To minimize the effect of confounders, only reported adjusted hazard ratio (aHR) from the model adjusted for potential confounders were pooled using the random-effects meta-analysis. Subgroup analyses were conducted according to age and gender. Publication bias was estimated with a funnel plot and Egger's test.

Results:

A total of 3,423 studies were identified. Four cohort studies (n =17,369,547 participants) met the eligibility criteria and were included in the meta-analysis. The risk of incident psoriasis is significantly higher in patients with AD, even after adjusting for confounding factors (pooled aHR, 2.87; 95% CI, 2.51-3.29). The subgroup analysis according to age and gender revealed the persistent significant association between AD and the risk of psoriasis across all age groups and gender. No evidence of publication bias was observed. Quality assessments of the included studies were high.

Conclusion:

Patients with atopic dermatitis were at a 2.83-fold increased risk of developing psoriasis. Further studies are required to elucidate the shared underlying mechanism that explains the relationship between psoriasis and AD. Additional well-designed cohort studies are warranted due to the limited number of studies.