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RESEARCH LETTER

Treatment Outcomes of Lebrikizumab after Switching from Dupilumab in Moderate-to-Severe Atopic Dermatitis involving the Head and Neck Area

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Atopic dermatitis (AD) is a chronic inflammatory skin condition with an estimated prevalence of 15–25% in children and 3–7% in adults

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[1]. Key features include eczematous lesions with intense itch and clinical presentation varies according to lesion stage, age, ethnicity, and anatomical site [2]. The head and neck (H&N) region is recognized as a difficult-to-treat area due to its unique anatomical and immunological features combined with continuous exposure to irritants and environmental factors [3]. The overexpression of interleukin (IL)-13 is recognized as a major factor in the pathogenesis of AD. Lebrikizumab, a novel monoclonal antibody targeting IL-13 that selectively prevents formation of the IL-13Rα1/IL-4Rα heterodimer receptor signalling complex, has recently received approval for the treatment of moderate-to-severe AD in adult and adolescent populations

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[4]. However, real-world evidence regarding lebrikizumab clinical responses in the H&N region remains limited [5, 6]. In our recent retrospective multicenter study, we reported clinical outcomes of lebrikizumab up to 16 weeks in adult patients with moderate-to-severe AD, both biologic/JAK inhibitor-naïve and previously treated individuals [7]. In this post hoc sub-analysis, we evaluated the effectiveness and safety of lebrikizumab, previously switched from dupilumab due to inadequate therapeutic response or conjunctivitis, in the sensitive H&N region among adult patients with moderate-to-severe AD.

Patients received a loading dose of 500 mg lebrikizumab at baseline and week 2, followed by 250 mg lebrikizumab every 2 weeks until week 16. Primary outcomes were assessed at baseline, 4 weeks, and 16 weeks after initiation of therapy using the Eczema Area and Severity Index (EASI) and the H&N-specific EASI. Secondary outcomes to assess the overall effectiveness of lebrikizumab included pruritus severity and sleep quality, measured by numerical rating scales (NRS-itch and NRS-sleep), disease severity via the body surface area (BSA), Investigator Global Assessment (IGA), and the SCORing Atopic Dermatitis (SCORAD) index, and evaluation of patients' mental health through the Dermatology Life Quality Index (DLQI) [7]. Continuous variables are presented as mean ± standard deviation (SD) while categorical variables are reported as number and percentage. The paired *t*-test was used to assess mean changes at baseline and 16 weeks and corresponding 95% confidence intervals (CIs) using Medcalc Software (Version 23.5.5, Ostend Belgium).

In total, 19 patients with moderate-to-severe AD who switched from dupilumab to lebrikizumab and had EASI H&N values available at baseline, 4 weeks, and 16 weeks were included (Table 1). Concomitant AD therapies included topical corticosteroids (57.9%) and topical calcineurin inhibitors (10.5%). Total EASI decreased from 22.8 ± 13.3 at baseline to 9.5 ± 7.6 at week 4 (58.5% reduction) and to 6.1 ± 6.7 at week 16 (73.3% reduction; 95% CI −22.8 to −10.6, $p < 0.0001$). Mean EASI H&N also decreased from 4.6 ± 1.8 at baseline to 2.7 ± 2.2 at week 4 (41.2% reduction) and to 1.8 ± 1.8 (60.1% reduction; 95% CI −3.6 to −1.9, $p < 0.0001$) at week 16 (Fig. 1).

Table 1 Demographic characteristics of the study population ($N = 19$)

Patient characteristics	$N = 19$
Mean age (years)	43.3 ± 18.0
Male/female	9 (47.4)/10 (52.6)
Comorbidities	
≥ 1 atopic comorbidity	12 (63.2)
Asthma	6 (31.6)
Allergic rhinitis	9 (47.4)
IgE (IU/ml)	2889.0 ± 4598.8
Reason for switching to lebrikizumab	
Loss of efficacy	12 (63.2)
Lack of efficacy	3 (15.8)
AEs (conjunctivitis)	4 (21)
Concomitant AD therapies	
H1 antihistamine	1 (5.3)
Topical corticosteroids	11 (57.9)
Topical calcineurin inhibitor	2 (10.5)

Data are presented as number and % or mean and standard deviation

AD atopic dermatitis; *AE* adverse event; *IgE* immunoglobulin E

In patients switched to lebrikizumab due to lack or loss of efficacy of dupilumab ($N = 15$), similar outcomes were observed. Mean total EASI score decreased by 55.6% (22 ± 13.5 to 9.7 ± 8.1) at week 4 and by 70.3% at week 16 (6.5 ± 7.4; 95% CI −22.5 to −8.3, $p = 0.0004$), while EASI H&N decreased by 35.1% (4.4 ± 1.9 to 2.6 ± 2.2) at week 4 and 58.0% (1.9 ± 2.1; 95% CI −3.6 to −1.6, $p = 0.0001$) at week 16, respectively. In addition, in patients with and without concomitant AD, therapy revealed similar improvements at week 16, with no significant differences in reductions in total EASI (71.2% versus 77.8%; $p = 0.37$) or H&N EASI (62.2% versus 57.2%; $p = 0.27$), respectively.

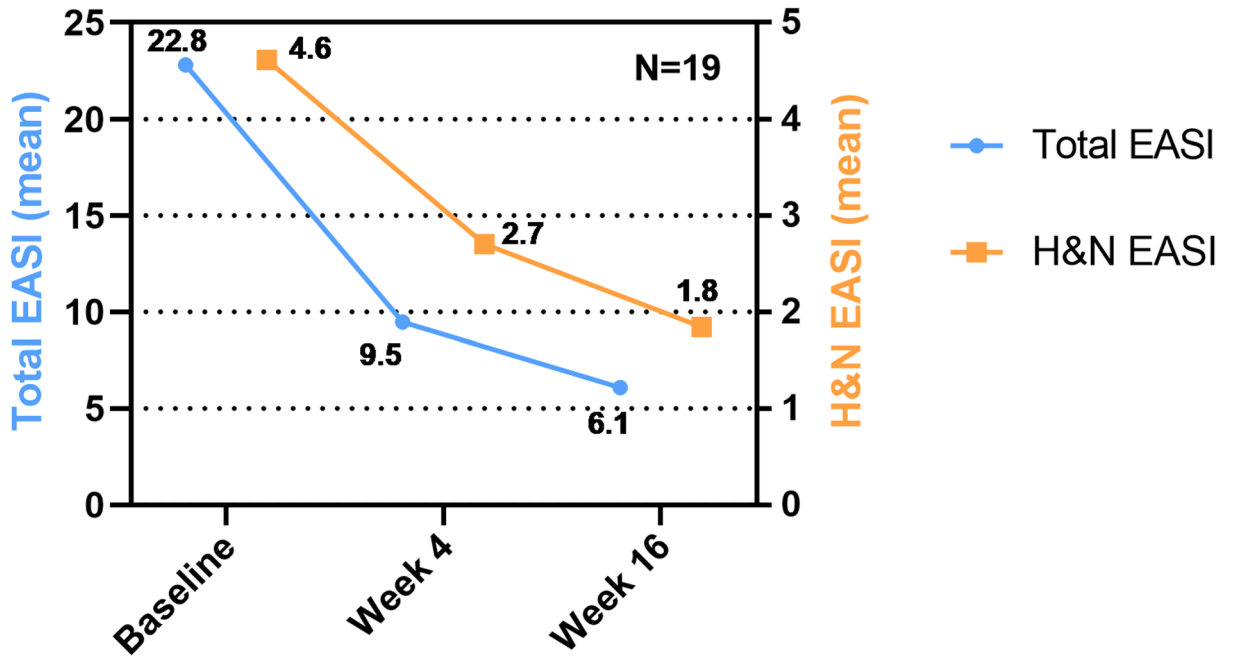

Fig. 1 Mean total Eczema Area and Severity Index (EASI) scores (blue) and mean head and neck EASI (H&N EASI) scores (orange) are shown at baseline, week 4, and week 16 in patients treated with lebrikizumab ($N = 19$). Two y-axes are displayed: the left y-axis (blue) represents mean total EASI, corresponding to the blue line, whereas the right y-axis (orange) represents mean H&N EASI, corresponding to the orange line. Data points on the x-axis indicate the study visits at baseline, week 4, and week 16

Improvements were also observed across all secondary outcomes. From baseline to week 16, mean NRS-itch ($N = 18$) decreased by 74.4% (7.2 ± 2.3 to 1.8 ± 2.2; 95% CI −6.9 to −3.8, $p < 0.0001$), NRS-sleep ($N = 18$) by 81.3% (5.1 ± 3.4 to 0.9 ± 2.2; 95% CI −5.7 to −2.5, $p < 0.0001$), and BSA ($N = 11$) by 73.7% (39.9 ± 25.9 to 10.5 ± 10.9; 95% CI −46.7 to −12.1, $p = 0.0019$). Disease severity improved markedly from baseline to week 16, with a decrease in the SCORAD index of 83.4% (49.3 ± 25.9 to 8.2 ± 9.3; 95% CI −69.5 to −12.8, $p = 0.014$) and the IGA score by 63.2% (from 3.2 ± 0.7 to 1.2 ± 1.0; 95% CI −2.6 to −1.4, $p < 0.0001$). Quality of life, assessed by the DLQI, improved by 67.3% (18.9 ± 6.2 to 6.2 ± 5.8; 95% CI −18.6 to −6.9, $p = 0.0004$). No adverse events were reported during follow-up.

The H&N region represents a challenging area in AD due to high exposure to irritants, UV radiation, *Malassezia* spp., and allergens [3].

Dupilumab, targeting IL-4/IL-13 signaling, is highly effective in overall AD management, but may show reduced efficacy in H&N involvement [8–10], and is frequently associated with conjunctivitis [11], necessitating treatment switching in some patients [12]. Lebrikizumab selectively inhibits IL-13 while preserving signalling through the type I IL-4 receptor, a mechanism that may help in maintaining ocular surface homeostasis [4, 13] and may explain the lack of conjunctivitis recurrence observed in our cohort following the switch to lebrikizumab.

In line with the ADapt phase III trial [14], this post hoc sub-analysis showed that lebrikizumab treatment led to notable improvements in overall AD clinical signs and manifestations in the H&N region among dupilumab-experienced patients. In addition, data from previous studies show a favorable clinical response following the switch from dupilumab to a selective anti-IL-13 agent such as tralokinumab, both in the H&N region and across other anatomical sites [15–17]. While the precise mechanisms underlying the improved clinical response after switching from dual IL-4/IL-13 blockade to selective

IL-13 inhibition remain incompletely understood, emerging evidence suggests that IL-13 may contribute to shaping the cutaneous microbiome. Data from the ECZTRA-1 trial show that selective IL-13 blockade normalizes skin dysbiosis and reduces *Staphylococcus aureus,* supporting a role for IL-13 in microbiome imbalance in AD [18].

This was a retrospective uncontrolled study in 19 patients. Although no patients received concomitant systemic therapies, since some patients received concomitant AD-directed topical therapy and therefore the specific effect of lebrikizumab cannot be estimated. Furthermore, due to the retrospective design, data for some patient-reported outcome measures (PROs) were not available for some patients. Moreover, the absence of molecular or microbiome analyses preclude definitive mechanistic conclusions. Nevertheless, the consistency of AD improvement across physician- and PROs, together with a favorable safety profile and coherence with prior reports, support the clinical relevance of our results. Large prospective studies evaluating the effect of IL-13 inhibition in dupilumab-experienced patients with moderate-to-severe AD in the H&N region are warranted.

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Declarations

Conflict of Interest. Luigi Gargiulo has been a consultant and/or speaker and has participated to advisory boards for Abbvie, Amgen, Almirall, Novartis, Johnson and Johnson, Eli Lilly, Sanofi, Pierre Fabre, BMS, Leo Pharma, UCB, and Pfizer; Caterina Foti has conflict of interest with AbbVie, Almirall, Amgen, Eli Lilly, Incyte, Leo Pharma,

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Ethical Approval. The study adhered to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines for cohort studies and the principles outlined in the Declaration of Helsinki. Ethical approval was granted by the Institutional Review Boards (Ethics Approval Committee Lombardia 3, protocol number: Lebri-AD-2024). All patients provided written informed consent to participate in the study and for publication.

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