Effectiveness of Tralokinumab for Moderate-to-Severe Atopic Dermatitis Involving the Head-and-Neck Area: A Multicenter Retrospective Cohort Study

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Abstract: ***Background:*** **Atopic dermatitis (AD) affecting the head and neck (H&N) area poses a clinical challenge due to the unique anatomical and physiological features of this region. Despite its well-documented impact on quality of life (QoL), evidence on the effectiveness of tralokinumab in treating AD specifically in the H&N area remains limited.**

Objective: **To assess the clinical outcomes of tralokinumab in AD patients with H&N involvement, informing clinical decision-making and improving patient care.**

Methods: **A multicenter, retrospective cohort study across 5 Italian tertiary referral hospitals. Patients were stratified by H&N involvement, and treatment outcomes were assessed using the Eczema Area and Severity Index (EASI), EASI H&N, Investigator Global Assessment (IGA), Numerical Rating Scale (NRS) pruritus, NRS sleep, Dermatology Life Quality Index, Patient-Oriented Eczema Measure, and Atopic Dermatitis Control Tool.**

Results: **Among 211 patients, 145 (68.7%) had H&N involvement. A significant reduction in EASI H&N scores from baseline to weeks 12–16 (38.1%) and week 24 (54.5%) was achieved. Significant improvements in IGA, NRS**

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Authors' Contributions: G.A., L.V., S.M.F., and S.R. had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: G.A., L.V., S.M.F., and S.R. Acquisition, analysis, or interpretation of data: G.A., L.V., G.T., L.M., M.M., E.V.D.B., E.I., F.B., D.T., P.Q., M.O., G.G., A.B., N.G., K.P., A.V.M., S.M.F., and S.R. Drafting of the article: G.A., L.V., S.M.F., and S.R. Critical revision of the article for important intellectual content: G.A., L.V., G.T., L.M., M.M., E.V.D.B., E.I., F.B., D.T., P.Q., M.O., G.G., A.B., N.G., K.P., A.V.M., S.M.F., and S.R. Statistical analysis: G.A. and L.V.

Ethics statement: Ethical approval was obtained from the Institutional Review Board of AOU Città della Salute e della Scienza di Torino (SS-Dermo-13). The patients in this article have provided written informed consent to the publication of their case details.

Data availability statement: The data that support the findings of this study are available from the corresponding author upon reasonable request.

Author Disclosure Statement: N.G. served as an advisory board member and received honoraria for lectures for AbbVie, Sanofi, Leo-Pharma, Almirall, Pfizer, and Lilly. K.P. received grants for the institution from AbbVie, Almirall, Leo Pharma, Novartis, and Sanofi and received honoraria for advisory board meeting from AbbVie, Almirall, Biogen, Leo Pharma, Lilly, Janssen, Novartis, Sanofi, Philogen, Pierre Fabre, Sun Pharma, MSD, Beiersdorf, and Boehringer. G.G. has received personal fees from AbbVie, Almirall, Amgen, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli-Lilly, Leo Pharma, Merck Serono, Novartis, Pfizer, Pierre Fabre, Samsung Bioepis, and Sanofi. A.V.M. reports consultancy/advisory board disease-relevant honoraria from AbbVie, Boehringer-Ingelheim, Bristol Myers Squibb, Incyte, Johnson & Johnson, L'Oreal, Leo Pharma, Novartis Pharma, Pfizer, Sanofi, and UCB Pharma. S.F. is principal investigator in the clinical trial to Amgen, Sanofi, Novartis, Lilly, Leo Pharma, and AbbVie, and she has served as an advisory board member or speaker to Novartis, Menarini, Sanofi, AbbVie, and Leo Pharma.

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Funding Information: None.

Correction (September 2025): *Discussion section updated to reflect that data from the ECZTRA 1 and ECZTRA 2 trials demonstrated that tralokinumab-treated patients achieved EASI-75 in 25% to 33.2% of cases by week 16, not week 52, and so EASI-75 was not observed in a higher proportion of patients and within a shorter timeframe in the authors' cohort.*

DOI: 10.1177/17103568251363249

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pruritus, and NRS sleep, and QoL measures emerged within 12–16 weeks and persisted at 24 weeks. Compared with patients without H&N involvement, those with H&N involvement exhibited a stronger atopic background and showed no evidence of reduced drug survival. Adverse events, mainly conjunctivitis, were comparable between groups.

Conclusions: **Tralokinumab is effective and well-tolerated in managing moderate-to-severe AD involving the H&N area, even in biologic-experienced patients. These findings support its use as a targeted therapy addressing both clinical and psychosocial burdens of H&N AD.**

Capsule Summary

- Tralokinumab is effective and well-tolerated in treating moderate-to-severe atopic dermatitis involving the head and neck (H&N) area, showing significant improvements in both site-specific (EASI H&N) and global disease severity scores, quality of life, and patient-reported outcomes at the time points assessed.
- Adverse events were infrequent and consistent with known safety profiles, with conjunctivitis being the most reported, especially among patients with H&N involvement, but without leading to treatment discontinuation.

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INTRODUCTION

Atopic dermatitis (AD), a chronic inflammatory skin disorder characterized by recurrent eczematous lesions and intense itching, can be associated with sleep loss and a profound impact on quality of life (QoL).[1] Its clinical presentation is highly heterogeneous, with variations in lesion morphology and distribution that often involve sensitive and highly visible anatomical regions.[2] Among these, the involvement of the head and neck (H&N) area is frequently observed, affecting up to 72% of patients.[3] Prevalence rates are influenced by demographic and geographical factors, underscoring the variability in AD presentations and highlighting the need for targeted therapeutic approaches to address region-specific challenges.[2]

The H&N area represents a unique and often complex clinical scenario due to its distinct anatomical and physiological characteristics.[4] The skin in this area is thinner and more sensitive compared with other anatomical regions, with a higher density of sebaceous glands and hair follicles, which correlates with increased colonization by *Malassezia* yeasts.[5] Furthermore, it is continuously exposed to environmental triggers such as ultraviolet radiation, pollutants, allergens, and temperature fluctuations.[5] These factors collectively can exacerbate inflammation, contributing to therapeutic resistance and disease chronicity.[6] Patch testing is therefore frequently recommended in patients with recalcitrant AD involving the H&N area to rule out concomitant allergic contact dermatitis.[7,8] Some authors also suggest empirical treatment with topical or systemic antifungals to reduce *Malassezia* load; however, the therapeutic benefit of these approaches remains uncertain.[5,6]

H&N involvement is associated with a higher psychosocial impact, leading to stigmatization, reduced self-esteem, and greater overall disease burden.[9] The use of potent topical corticosteroids, a cornerstone of AD management, is particularly challenging in this region, as prolonged application increases the risk of adverse effects such as skin atrophy and telangiectasia, further complicating treatment.[10]

The advent of biological therapies has revolutionized the treatment of moderate-to-severe AD by targeting specific cytokines implicated in its pathogenesis. The identification of patient profiles that respond optimally to these novel therapies for AD is a subject of significant interest, particularly in the context of treatment-resistant manifestations.[11–14]

Tralokinumab, a fully human monoclonal antibody that selectively inhibits interleukin-13 (IL-13), a key driver of AD inflammation, has demonstrated significant efficacy and a favorable safety profile in clinical trials.[15] Despite these advancements, most studies have focused on the overall disease outcomes, with limited stratification of results by anatomical site. Accordingly, there is a paucity of evidence evaluating the effectiveness of tralokinumab specifically in patients with AD involving the H&N region.[13,16–18] This multicenter retrospective cohort study aimed to address this knowledge gap by assessing clinical outcomes of tralokinumab in AD patients with H&N involvement, with the goal of informing clinical decision-making and enhancing patient care.

METHODS

Study Design and Population

We performed a multicenter, retrospective cohort study across 5 Italian tertiary referral hospitals. Patients were eligible if aged ≥18 years old, were diagnosed with moderate-to-severe AD according to the European Academy of Dermatology guidelines,[19] and had received tralokinumab between August 4, 2022, and June 1, 2024. Patients with a follow-up period shorter than 12 weeks were excluded. No restrictions were applied to concomitant therapies. Identification of eligible cases was achieved through a retrospective review of both electronic health records and specific data sets from the participating sites. The study protocol was approved by the Institutional Review Boards (approval number: SS-Dermo-13) and adhered to the principles of the Declaration of Helsinki. The Strengthening the Reporting of Observational Studies in Epidemiology reporting guidelines for cohort studies were followed.[20]

Data Collection

Data including demographics, medical history, clinical features (AD phenotype,[21] involved skin areas), previous and current

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AD treatments, and baseline disease severity parameters were collected. The overall AD population was stratified into 2 subgroups based on the presence of H&N involvement. Disease severity and therapeutic response were assessed by means of the Eczema Area and Severity Index (EASI), both in overall form and specifically for the H&N region (EASI H&N),[22] Investigator Global Assessment (IGA),[23] Numerical Rating Scale (NRS) pruritus,[24] and NRS sleep.[25] The NRS pruritus and sleep range from 0 (no symptoms) to 10 (severe symptoms) and assess symptom intensity over the preceding 24 hours and the last night, respectively.[24,25] Patient-Reported Outcomes (PROs) related to overall mental health were assessed using the Dermatology Life Quality Index (DLQI),[26] Patient-Oriented Eczema Measure (POEM),[27] and Atopic Dermatitis Control Tool (ADCT).[28]

Data for these measures were evaluated at baseline and at predefined follow-up visits (weeks 12–16, 24, 48, and months 18 and 24).

Primary and Secondary Outcomes

The primary outcome was the percent change from baseline to week 24 in the EASI H&N score (range 0–7.2). Secondary outcomes included: (i) percent changes in overall EASI, IGA, NRS pruritus, NRS sleep, DLQI, POEM, and ADCT, as well as their correlation with the EASI H&N score over time; (ii) a 75% improvement in the EASI score from baseline (EASI-75), an IGA score of 0 or 1, and a reduction of at least 4 points on NRS pruritus, NRS sleep, and DLQI at weeks 12–16 and week 24; (iii) differences in therapeutic response between patients with and without H&N involvement; (iv) rates of tralokinumab dose modification and treatment discontinuation; (v) incidence of Adverse events (AEs); and (vi) drug survival duration in patients with and without H&N involvement.

Statistical Analysis

Categorical variables were expressed as number and percentage of patients and chi-squared test or Fisher's exact test was applied when appropriate. Quantitative variables were reported with mean ± standard deviation as well as median and interquartile range (first and third quartiles, Q1 and Q3) in descriptive tables. Their distribution was assessed using the Kolmogorov–Smirnov test, and nonparametric tests were applied due to their asymmetrical distribution, and median with interquartile range was used for graphs. Comparisons between 2 groups were performed using the Mann–Whitney U test, while comparisons among more than 2 groups were conducted using the Kruskal–Wallis test or Friedman tests followed by Bonferroni post hoc analysis. Correlations were evaluated using Spearman's rank correlation test, with Spearman's Rho and *P* values reported in the table. Due to the decrease in the number of patients, no statistical analyses were conducted beyond week 24. Drug survival was calculated at 16 months from the date of initiation of therapy and was analyzed using Kaplan–Meier survival curves to estimate the risk of and time to drug withdrawal. Patients were censored if they received tralokinumab for up to 16 months. No cases of loss to follow-up were reported before 16 months. Statistical analyses were performed using IBM SPSS Statistics version 29.0.1.0 (IBM, ARMONK, New York, USA) and graphs were

TABLE 1. Demographic and Clinical Characteristics of Patients at Baseline with and Without the Head and Neck Involvement

	Head and Neck Involvement		
	Yes (n = 145)	No (n = 66)	*P* value
Gender, n (%)			0.75*
M	76 (52.4)	33 (50.0)	
F	69 (47.6)	33 (50.0)	
Age			
N	145	66	
Mean ± SD	39.9 ± 16.2	54.7 ± 20.3	<0.001+
Median (Q1–Q3)	35.0 (26.5–51.0)	60.0 (39.0–73.0)	
BMI			
N	114	24	
Mean ± SD	23.4 ± 5.1	25.7 ± 4.9	0.025+
Median (Q1–Q3)	23.3 (20.7–25.2)	26.7 (21.5–28.5)	
AD phenotype, n (%)			
Flexural eczema	109 (75.2)	41 (62.1)	<0.001#
Head and neck eczema	7 (4.8)	0 (0.0)	
Hand or feet eczema	2 (1.4)	1 (1.5)	
Portrait-like dermatitis	5 (3.4)	0 (0.0)	
Diffuse eczema	12 (8.3)	4 (6.1)	
Eczema nummular-like	2 (1.4)	9 (13.6)	
Prurigo nodularis-like	7 (4.8)	11 (16.7)	
Erythroderma	1 (0.7)	0 (0.0)	
Age of onset (years)			
N	135	60	
Mean ± SD	14.6 ± 20.3	33.0 ± 29.9	<0.001+
Median (Q1–Q3)	3.0 (1.0–21.0)	29.0 (2.0–64.5)	
Disease duration (years)			
N	137	62	
Mean ± SD	25.0 ± 14.0	21.4 ± 19.2	0.013+
Median (Q1–Q3)	24.0 (14.5–31.0)	17.5 (4.0–31.7)	
Hands involvement, n (%)			
Yes	54 (37.2)	12 (18.2)	0.006*
Genitals involvement, n (%)			
Yes	8 (5.5)	0 (0.0)	0.052*
Family history, n (%)			
Yes	31 (28.7)	2 (12.5)	0.171*
Smoking status			
N	59	6	0.10#
Current smoker, n (%)	9 (15.3)	3 (50.0)	
Never, n (%)	43 (72.9)	3 (50.0)	
Former smoker, n (%)	7 (11.9)	0 (0.0)	
IgE, n (%)			
N	89	21	0.017*
<200 UI/mL	30 (33.7)	13 (61.9)	
≥200 UI/mL	59 (66.3)	8 (38.1)	

**P value obtained from chi-squared test; +P value obtained from Mann–Whitney U test; #P value obtained from Fisher's exact test.*

N, number; M, male; F, female; SD, standard deviation; Q1, first quartile; Q3, third quartile; BMI, body mass index; AD, atopic dermatitis; IgE, immunoglobulin E; UI, international unit.

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generated with GraphPad prism 10.0 (GraphPad software, Inc., La jolla, CA). $P < 0.05$ was considered statistically significant.

RESULTS

Demographic and Clinical Characteristics

At the cutoff date for this analysis, we retrospectively screened the records of 251 patients with moderate-to-severe AD who were treated with tralokinumab, identifying 211 patients who met the inclusion criteria.

The cohort with H&N involvement consisted of 145 patients (68.7%), of whom 52.4% were males and 47.6% females, with a median age of 35 (26.5–51.0) years. Almost all patients were White (99.3%), with only 1 patient being Black (0.7%). The predominant AD phenotype in this group was flexural eczema (75.2%), and the median age of AD onset was 3.0 (1.0–21.0) years with a disease duration of 24.0 (14.5–31.0) years. In addition, 54 (37.2%) of these patients also presented hand involvement, while only 8 patients (5.5%) reported genital involvement. Regarding immunoglobulin E (IgE) concentrations, among patients with available data, 59 out of 89 patients had serum levels ≥200 UI/mL.

Comparing patients with H&N involvement with those without H&N involvement, a significant younger age, a lower age of AD onset, and longer disease duration were found in patients with H&N involvement. In this subgroup as well, patients were almost entirely White, with only 1 Asian patient (1.5%).

The prevalence of specific AD phenotypes also varied, being nummular-like eczema and prurigo nodularis-like patterns more common in patients without H&N involvement ($P < 0.001$), accompanied by a less prevalence of hands involvement ($P < 0.01$). Moreover, the body mass index of patients with H&N involvement was slightly lower than that of patients without H&N involvement ($P < 0.05$). The percentage of patients with elevated IgE levels was

TABLE 2. Effectiveness of Tralokinumab on Disease Scores in Patients With Head and Neck Involvement at 24 Months

	T0 Baseline	T1 Weeks 12–16	T2 Week 24	T3 Week 48	T4 18 Months	T5 24 Months
EASI						
N	145	139	105	28	7	2
Mean ± SD	23.4 ± 6.3	6.9 ± 6.1	5.5 ± 4.9	3.2 ± 4.7	1.3 ± 1.3	0.5 ± 0.7
Median (Q1–Q3)	24.0 (23.0–24.0)	5.2 (2.0–12.0)	3.8 (2.0–10.0)	1.5 (0.3–5.0)	1.0 (0.0–3.0)	0.5 (0.0)
EASI head and neck						
N	145	137	105	26	6	2
Mean ± SD	2.4 ± 1.3	1.4 ± 1.3	1.2 ± 1.0	0.9 ± 1.0	0.3 ± 0.5	0.5 ± 0.7
Median (Q1–Q3)	2.4 (1.5–3.0)	1.0 (0.5–2.0)	1.0 (0.5–2.0)	0.8 (0.0–1.2)	0.0 (0.0–1.0)	0.5 (0.0)
IGA score						
N	145	120	93	22	5	1
Mean ± SD	3.9 ± 0.4	1.6 ± 0.9	1.5 ± 0.8	1.1 ± 0.9	1.2 ± 0.5	1.0 ± 0.0
Median (Q1–Q3)	4.0 (4.0–4.0)	2.0 (1.0–2.0)	1.0 (1.0–2.0)	1.0 (1.0–1.3)	1.0 (1.0–1.5)	1.0 (1.0–1.0)
NRS pruritus						
N	143	134	100	28	7	2
Mean ± SD	8.0 ± 1.9	4.56 ± 2.5	2.4 ± 2.7	3.6 ± 2.6	3.7 ± 3.0	1.0 ± 1.4
Median (Q1–Q3)	9.0 (7.0–9.0)	5.0 (3.0–6.0)	2.0 (0.0–5.0)	4.0 (1.0–5.0)	4.0 (0.0–7.0)	1.0 (0.0)
NRS sleep						
N	139	129	100	26	6	2
Mean ± SD	6.2 ± 3.4	2.9 ± 2.9	2.4 ± 2.7	1.0 ± 2.0	2.3 ± 2.9	1.5 ± 2.1
Median (Q1–Q3)	8.0 (4.0–9.0)	3.0 (0.0–5.0)	2.0 (0.0–5.0)	0.0 (1.0–1.5)	1.5 (0.0–4.8)	1.5 (0.0)
DLQI						
N	140	122	97	23	6	2
Mean ± SD	14.5 ± 7.4	7.5 ± 5.1	7.6 ± 5.3	4.9 ± 5.5	8.1 ± 7.4	3.5 ± 4.9
Median (Q1–Q3)	14.0 (8.0–21.0)	7.0 (3.0–11.0)	8.0 (3.0–11.0)	3.0 (1.0–9.0)	8.0 (1.5–12.8)	3.5 (0.0)
POEM						
N	121	107	85	17	4	1
Mean ± SD	19.8 ± 6.5	13.0 ± 6.7	13.4 ± 6.4	9.2 ± 7.3	17.8 ± 7.7	4.0 ± 0.0
Median (Q1–Q3)	22.0 (15.5–25.0)	14.0 (7.0–19.0)	15.0 (8.0–18.5)	9.0 (3.0–13.0)	18.5 (10.0–24.8)	4.0 (4.0–4.0)
ADCT score						
N	93	97	78	17	3	1
Mean ± SD	13.0 ± 6.1	8.2 ± 5.6	8.1 ± 5.0	7.9 ± 6.3	12.3 ± 3.2	0.0 ± 0.0
Median (Q1–Q3)	12.0 (7.0–19.0)	5.0 (5.0–12.0)	5.0 (5.0–11.0)	6.0 (3.0–12.0)	11.0 (10.0-.)	0.0 (0.0–0.0)

EASI, Eczema Area and Severity Index; N, number; SD, standard deviation; Q1, first quartile; Q3, third quartile; IGA, Investigator Global Assessment; NRS, Numerical Rating Scale; DLQI, Dermatology Life Quality Index; POEM, Patient-Oriented Eczema Measure; ADCT, Atopic Dermatitis Control Tool.

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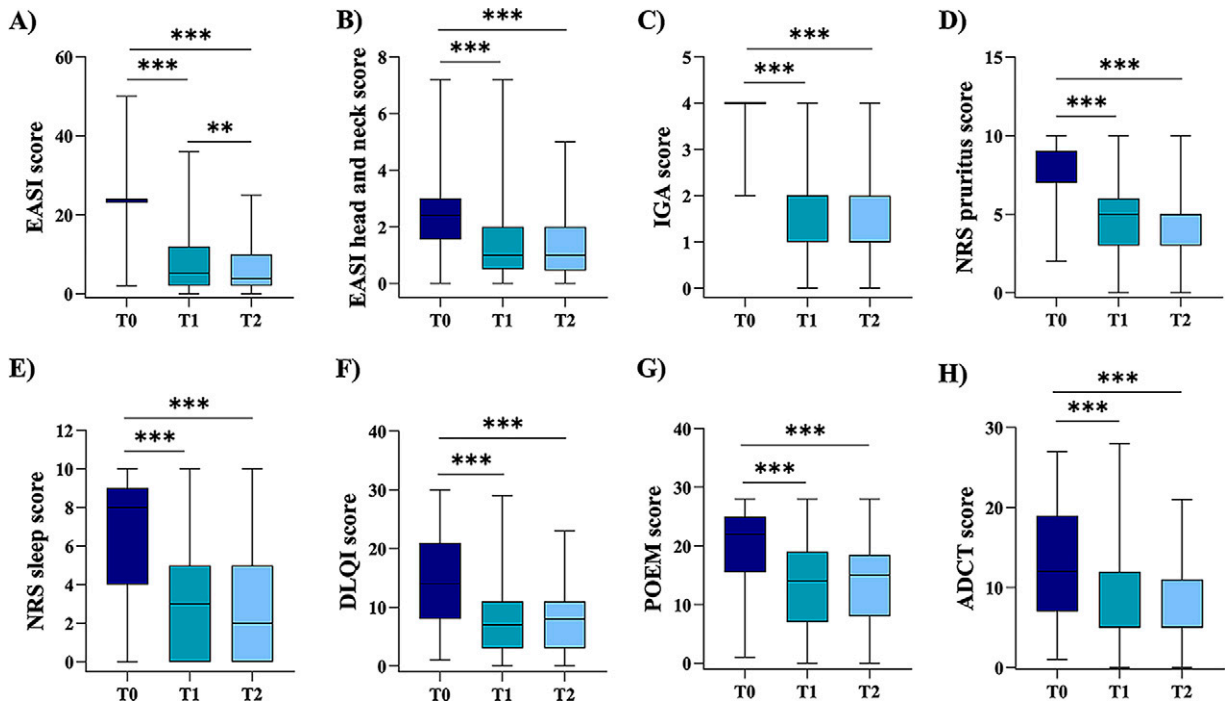


Figure 1. Effectiveness of tralokinumab on disease scores. Box plots represent median and IQR of Eczema Area and Severity Index (EASI) score **(A)**, EASI head and neck score **(B)**, Investigator Global Assessment (IGA) score **(C)**, Numerical Rating Scale (NRS) pruritus **(D)** and sleep scores **(E)**, Dermatology Life Quality Index (DLQI) score **(F)**, Patient-Oriented Eczema Measure (POEM) score **(G)**, and Atopic Dermatitis Control Tool (ADCT) score **(H)** at 3 time points: T0, baseline; T1, weeks 12–16; and T2, week 24. Kruskal–Wallis test with Bonferroni post hoc test, $^{**}P < 0.01$; $^{***}P < 0.001$.

significantly lower in the group without H&N involvement compared with those with it (Table 1).

Evaluating comorbidities, rhinitis (37.9% vs 18.2%, $P < 0.01$), asthma (25.5% vs 9.1%, $P < 0.01$), and conjunctivitis (30.3% vs 12.1%, $P < 0.01$), were significantly more prevalent in patients with H&N involvement than in those without this district involvement. In contrast, patients without H&N involvement showed a higher rate of diabetes (12.1% vs 2.8%, $P < 0.01$) and hypertension (22.7% vs 10.3%, $P < 0.05$) (Supplementary Table S1).

Topical treatments were used by nearly all patients belonging to the H&N group (99.3%) and by all patients without H&N involvement (100%), with similar rates of efficacy-related interruptions. Most patients with H&N involvement were treated before with systemic steroids (80.0%) and/or cyclosporine (68.8%), and only 43 patients (29.6%) had prior biological experience with dupilumab, upadacitinib, or both (Supplementary Table S2).

Effectiveness of Tralokinumab

When analyzing the effects of tralokinumab in patients with H&N involvement, a significant improvement in all the evaluated scores was observed after 12–16 and 24 weeks compared with baseline (Table 2). In addition, the EASI score presented a slight but significant decrease at 24 weeks compared with 12–16 weeks ($P < 0.01$) (Fig. 1A–H). The percentage reduction in EASI H&N score was 38.1% (0.0–68.2) at 12–16 weeks and 54.5% (18.3–78.5) at 24 weeks. A total of 5 and 8 patients, respectively, showed worsening at 12–16 and 24 weeks compared with baseline, while 32 patients at 12–16 weeks and 13 patients at 24 weeks showed no improvement. An EASI-75 response was observed in 54% and 61.9% of the patients at weeks 12–16 and week 24, respectively. Considering the improvement of the other

TABLE 3. Effectiveness of Tralokinumab on Disease Scores in Patients With Head and Neck Involvement

	T1 Weeks 12–16	T2 Week 24	*P* value
IGA improvement (score of 0 or 1), n (%)	5 (10.9)	31 (75.6)	<0.001
NRS pruritus improvement (reduction of at least 4 points), n (%)	9 (17.3)	43 (84.3)	<0.001
NRS sleep improvement (reduction of at least 4 points), n (%)	4 (9.5)	44 (86.3)	<0.001
DLQI improvement (reduction of at least 4 points), n (%)	3 (10.7)	57 (95.0)	<0.001

P *value from chi-squared test.*

IGA, Investigator Global Assessment; NRS, Numerical Rating Scale; DLQI, Dermatology Life Quality Index.

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TABLE 4. Bivariate Correlation Between Eczema Area and Severity Index Head and Neck Score and the Other Disease Scores in Patients With Head and Neck Involvement

	IGA score	NRS pruritus score	NRS sleep score	DLQI score	POEM score	ADCT score
T0						
EASI head and neck						
N	145	143	139	140	121	93
P	0.15	0.05	0.11	0.32	0.20	−0.36
P value	0.07	0.57	0.20	<0.001	0.03	<0.001
T1						
EASI head and neck						
N	118	132	127	120	105	95
P	0.52	0.26	0.19	0.29	0.22	0.20
P value	<0.001	0.002	0.03	0.001	0.02	0.05
T2						
EASI head and neck						
N	93	102	100	97	85	78
P	0.32	0.26	0.18	0.26	0.14	0.10
P value	0.002	0.007	0.07	0.01	0.21	0.38

P *value from Spearman rank correlation test.*

EASI, Eczema Area and Severity Index; IGA, Investigator Global Assessment; NRS, Numerical Rating Scale; DLQI, Dermatology Life Quality Index.

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scores, and in particular the IGA score of 0 or 1 as well as a ≥4-point reduction for NRS pruritus, NRS sleep, and DLQI, a further improvement at 24 weeks compared with 12–16 weeks for all scores was found ($P < 0.001$) (Table 3). The EASI H&N score showed a positive correlation with all scores except for ADCT at 12–16 weeks. This correlation was maintained with IGA, NRS pruritus, and DLQI also at 24 weeks (Table 4).

Patients without H&N involvement showed a reduction in EASI, IGA, and NRS pruritus scores at both 12–16 weeks and 24 weeks compared with baseline (Table 5). An EASI-75 response was observed in 75% and 69% of the patients at weeks 12–16 and week 24, respectively.

Comparing the 2 groups (Fig. 2A–G), no significant differences were observed in the percentage of reduction of scores at 12–16 weeks compared with baseline.

Treatment Adherence and Discontinuation

During tralokinumab treatment, a lower number of patients with H&N involvement required additional systemic therapy compared with those without involvement in this area (11.7% vs 23.9%, respectively, $P < 0.05$). The most frequent treatment in patients with H&N involvement was systemic corticosteroids, whereas methotrexate was preferred in patients without H&N involvement (Supplementary Table S3). A dose reduction from the standard tralokinumab regimen (300 mg biweekly following a 600 mg loading dose on day 0) was performed for only 1 patient with H&N involvement due to prolonged complete remission of AD. Moreover, 14.5% of patients discontinued the treatment primarily due to a primary failure. No patients discontinued therapy due to AEs; however, 22 patients (15.2%) reported AEs, including conjunctivitis (n = 18), facial redness (n = 2), herpetic infection (n = 1), and injection site reaction (n = 1). Conversely, no patients without H&N involvement required a dose reduction. Although 22.7% discontinued therapy mainly because of primary failure or AEs such as tralokinumab-associated psoriasis. As a matter of fact, 13 patients (19.7%) experienced AEs, including injection-site reactions (n = 4), tralokinumab-associated psoriasis (n = 3), conjunctivitis (n = 3), asthenia (n = 1), herpetic infection (n = 1), and night sweats (n = 1). Notably, among patients with H&N involvement, 90.5% discontinued therapy mainly due to primary failure, compared with only 26.7% of patients without H&N manifestations ($P < 0.0001$), indicating a significantly higher rate of early ineffectiveness in the H&N+ group (Supplementary Table S3).

Although not significant, a trend toward higher drug survival was observed in patients with H&N involvement compared with those without H&N involvement (log-rank = 3.83, $P = 0.05$) (Fig. 3). In particular, a mean drug survival of 14.83 ± 0.28 (confidence interval [CI]: 14.3–15.4) months for the H&N+ group and of 13.69 ± 0.57 (CI: 12.6–14.8) months for the H&N− group was observed.

DISCUSSION

This study provides insights into the effectiveness of tralokinumab in managing moderate-to-severe AD, with a peculiar focus on the H&N area. Patients with H&N involvement achieved significant improvements across all primary and secondary outcomes assessed.

Data from the ECZTRA 1 and ECZTRA 2 trials demonstrated that tralokinumab-treated patients achieved EASI-75 in 25% to 33.2% of cases by week 16.[15] In our cohort, at week 24, 61.9% (65/105) of patients with H&N involvement and 69% (20/29) of those without H&N involvement achieved EASI-75. Nevertheless, any direct comparison requires caution given the lack of restrictions on concomitant therapies in our cohort.

To more comprehensively assess treatment effectiveness, we performed a site-specific analysis of the EASI H&N score.

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TABLE 5. Effectiveness of Tralokinumab Over Time in Patients Without Head and Neck Involvement

	T0 Baseline	T1 Weeks 12–16	*P* value vs. baseline	T2 Week 24	*P* value vs. baseline
EASI score					<0.001
N	64	40	0.001	29	
Mean ± SD	20.5 ± 9.05	3.5 ± 4.9		4.9 ± 7.9	
Median (Q1–Q3)	24.0 (16.0–25.0)	1.3 (0.3–4.0)		1.6 (0.0–6.0)	
IGA score			0.004		0.001
N	64	40		29	
Mean ± SD	3.41 ± 1.05	1.1 ± 0.9		1.2 ± 1.4	
Median (Q1–Q3)	4.0 (3.0–4.0)	1.0 (0.25–1.0)		1.0 (0.0–1.5)	
NRS pruritus score					
N	64	41	<0.001	29	0.001
Mean ± SD	7.7 ± 2.47	2.9 ± 2.6		2.2 ± 3.4	
Median (Q1–Q3)	8.5 (6.0–10.0)	2.0 (0.0–5.0)		2.0 (0.0–7.0)	
NRS sleep score					
N	59	31	0.218	27	0.325
Mean ± SD	6.4 ± 3.6	1.6 ± 2.4		2.1 ± 3.1	
Median (Q1–Q3)	8.0 (4.0–9.0)	0.0 (0.0–3.0)		0.0 (0.0–3.0)	
DLQI score					
N	54	24	0.231	10	0.014
Mean ± SD	10.4 ± 5.5	3.1 ± 3.5		3.4 ± 3.9	
Median (Q1–Q3)	10.0 (7.8–12.0)	1.5 (0.0–6.0)		2.5 (0.7–4.5)	
POEM score					
N	24	11	0.745	6	0.182
Mean ± SD	15.2 ± 7.29	8.5 ± 6.3		12.0 ± 5.0	
Median (Q1–Q3)	15.5 (9.8–20.8)	8.0 (2.0–15.0)		12.5 (6.7–17.0)	
ADCT score					
N	17	11	0.130	6	0.063
Mean ± SD	12.1 ± 6.3	6.4 ± 5.7		8.2 ± 3.6	
Median (Q1–Q3)	11.0 (8.0–18.0)	5.0 (1.0–10.0)		8.0 (4.8–11.0)	

P *values were calculated with Friedman test followed by Bonferroni post hoc test.*

EASI, Eczema Area and Severity Index; N, number; SD, standard deviation; Q1, first quartile; Q3, third quartile; IGA, Investigator Global Assessment; NRS, Numerical Rating Scale; DLQI, Dermatology Life Quality Index; POEM, Patient-Oriented Eczema Measure; ADCT, Atopic Dermatitis Control Tool.

Among patients with H&N involvement, there was a statistically significant reduction in EASI H&N from baseline to 12–16 weeks and 24 weeks ($P < 0.001$ for both time points). In addition, this cohort demonstrated improvement in IGA, NRS-pruritus, and NRS-sleep scores within the first 12–16 weeks, with sustained responses at 24 weeks. These trends were associated with significant enhancements in QoL, as measured by DLQI, POEM, and ADCT scores. The positive correlation between EASI H&N score and all the other outcomes, except for ADCT, at 12–16 weeks and the maintenance of this correlation with IGA, NRS pruritus, and DLQI also at 24 weeks suggest that an improvement of EASI H&N score goes along with the improvement in other scores. These findings are in line with recent post hoc analyses of ECZTRA 1, ECZTRA 2, and ECZTEND trials, which demonstrated sustained improvements in H&N EASI scores up to 4 years and a moderate correlation between H&N involvement and DLQI, particularly regarding skin discomfort and psychosocial distress due to visible lesions.[29]

Comparison between patients with and without H&N involvement revealed a significantly higher prevalence of atopic comorbidities, including allergic rhinitis, asthma, allergic conjunctivitis, food allergies, and elevated serum IgE levels in the group with H&N involvement. These findings suggest a stronger atopic background in this subgroup, potentially contributing to the recognized challenges observed in treating AD involving the H&N area.[30] However, no significant differences were observed in the percentage of reduction of scores at 12–16 weeks compared with baseline in these 2 subgroups, supporting that the efficacy of tralokinumab extends across different AD phenotypes and anatomical sites.

During tralokinumab treatment, a lower percentage of patients with H&N involvement required additional systemic therapy compared with those without such involvement. Among the former, the most used therapy was systemic corticosteroids, while methotrexate was preferred in the latter. Considering that systemic corticosteroids are administered as isolated short courses, whereas methotrexate serves as a long-term maintenance therapy, this disparity may indicate superior management of the underlying disease in patients with H&N involvement.

Overall, treatment discontinuation rates were relatively low. However, among patients with H&N involvement, discontinuation was predominantly due to primary failure, while this was

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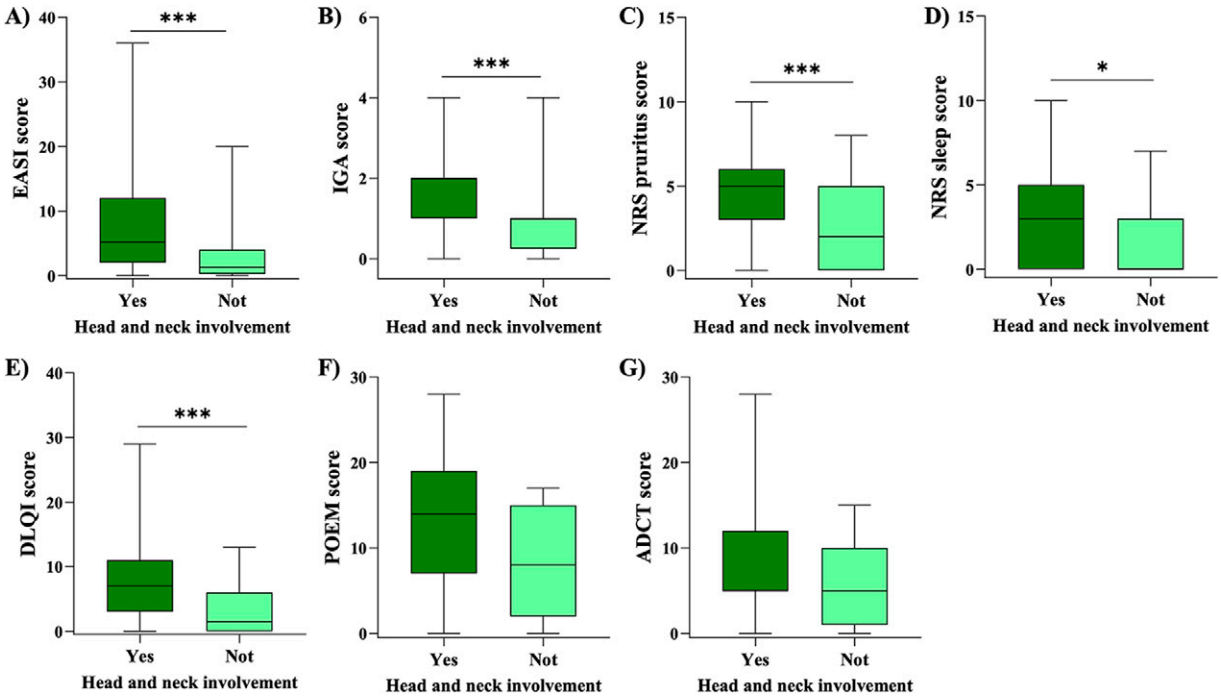


Figure 2. Comparison of scores in patients with or without head and neck involvement after 12–16 weeks of treatment. Box plots represent median and IQR of Eczema Area and Severity Index (EASI) score **(A)**, Investigator Global Assessment (IGA) score **(B)**, Numerical Rating Scale (NRS) pruritus **(C)** and sleep scores **(D)**, Dermatology Life Quality Index (DLQI) score **(E)** Patient-Oriented Eczema Measure (POEM) **(F)** between patient with or without head and neck involvement at T1 corresponding to weeks 12–16. Mann–Whitney test, *$P < 0.05$; ***$P < 0.001$.

significantly less common in those without disease in this area. This finding may suggest a different pattern of treatment response in this subgroup and warrants further investigation. Notably, although most patients in our cohort were bio-naive, 35 patients (24.1%) with H&N involvement had prior biological experience with dupilumab, upadacitinib, or both. Among these, only 10 (28.6%) discontinued tralokinumab due to primary treatment failure, highlighting the potential role of biological switching as a viable strategy for managing bio-experienced patients, even in a challenging subgroup.[31]

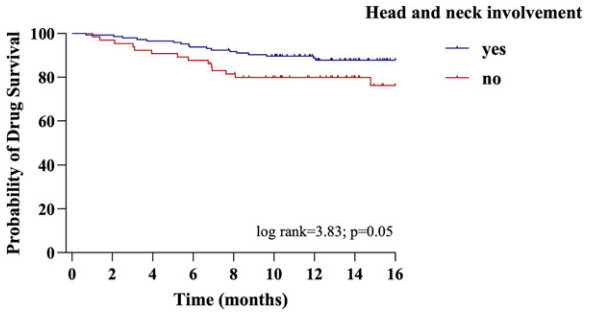


Figure 3. Kaplan–Meier drug survival. The graph illustrates the drug survival curves for 2 patient groups: those with head and neck involvement (blue curve) and those without head and neck involvement (red curve). Censored patients are indicated with vertical marks in the curve at the censoring times. The difference between the 2 groups was estimated by Kaplan–Meier analysis: Log rank = 3.83; $P = 0.05$.

AEs were infrequent and comparable between patients with and without H&N involvement, supporting the favorable safety profile of tralokinumab. Conjunctivitis, a known adverse event associated with dupilumab IL-13/IL-4 blockade,[32] has also been reported with tralokinumab, although less frequently than in dupilumab-treated patients, likely due to the sparing of IL-4 cascade pathways.[33] In ECZTRA 1 and ECZTRA 2 trials, it was reported in 10% and 5.2% of patients, respectively.[15] In our study, conjunctivitis was observed in 4.5% of patients without H&N involvement and in 12.5% of patients with such area involved by AD, but no patients required treatment discontinuation. As previously reported, there is an increased risk of conjunctivitis in patients with a history of facial AD,[34] but conjunctivitis associated with tralokinumab appears to be less impactful than that associated with dupilumab.[35]

While facial redness is a well-documented AE associated with dupilumab,[36] it has been rarely reported in patients treated with tralokinumab.[37] In our cohort, 2 cases of facial redness were observed among patients with H&N involvement, whereas no such cases were reported in patients without H&N involvement. This AE may potentially be explained by pre-existing conditions associated with H&N dermatitis, such as *Malassezia* hypersensitization or allergic contact dermatitis, which could be contributing factors.[36–38]

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The trend toward higher drug survival in the H&N group should be interpreted with caution, as the group without H&N involvement included fewer patients, potentially limiting statistical power. However, we can conclude that no lower drug survival was observed in patients with H&N involvement compared with those without, suggesting that tralokinumab is a viable long-term option for managing AD, regardless of anatomical site.[39]

Limitations

Study limitations include the retrospective setting, and the relatively small cohort of patients treated with tralokinumab. Nonetheless, our study assessed one of the largest real-world cohorts of patients with AD with H&N involvement treated with tralokinumab. Notably, our sample consists almost entirely of White patients, potentially limiting the generalizability of our findings.

CONCLUSIONS

This cohort of patients undergoing tralokinumab adds to the existing evidence concerning the effectiveness and safety of tralokinumab in AD, even in challenging cases with H&N involvement and in bio-experienced patients. Our findings are consistent with long-term data from pivotal trials, which confirmed the progressive and durable efficacy of tralokinumab in the H&N region.[29] Further studies are needed to explore the variability in clinical responses and the underlying mechanisms of these differences, with the aim of developing tailored treatment approaches for each patient.

SUPPLEMENTARY MATERIAL

Supplementary Tables

KEY POINTS

What is Already Known About This Topic?

Atopic dermatitis (AD) affecting the head and neck (H&N) area poses a complex clinical challenge, due to the region's unique anatomical and physiological features. The H&N skin is thinner and more sensitive, with a high density of sebaceous glands and hair follicles, making it prone to *Malassezia* colonization. Although the impact on quality of life (QoL) is significant, evidence regarding the efficacy of tralokinumab for AD involving the H&N area remains limited.

What Does This Study Add?

This multicenter retrospective cohort study provides evidence that tralokinumab significantly improves clinical outcomes and QoL in AD patients with H&N involvement. Patients showed substantial reductions in disease severity scores and required fewer additional systemic therapies compared with those without H&N involvement. The study supports the use of tralokinumab as an effective and safe treatment option for managing AD in the challenging H&N region, including in biologic-experienced patients.

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