ORIGINAL REPORT

Effectiveness and Safety of Tralokinumab in Atopic Dermatitis: 1-year Results From a Real-world Multicentre Study

Laura CALABRESE[1,2], Elisa CINOTTI[1], Martina D'ONGHIA[1], Alessandra CARTOCCI[1], Pietro RUBEGNI[1], François MACCARI[3,4], Claire BOULARD[5], Ziad REGUIAI[6], Pierre André BECHEREL[7], Caroline JACOBZONE[8], Edouard BEGON[9], Charlotte FITE[10], Beatrice WALLS[10], Anne Laure LIEGEON[11], Josiane PARIER[3], Guillaume CHABY[12] and Jean-Luc PERROT[13], for the Omcci Group

[1]Dermatology Unit, Department of Medical, Surgical and Neurological Sciences, University of Siena, Siena, Italy, [2]Institute of Dermatology, Catholic University of the Sacred Heart, Rome, Italy, [3]Cabinet médical, Saint-Maur-des-Fossés, France, [4]Department of Dermatology, Hôpital d'Instruction des Armées Begin, Saint Mandé, France, [5]Department of Dermatology, Centre Hospitalier du Havre, Le Havre, France, [6]Department of Dermatology, Polyclinique Courlancy, Reims-Bezannes, France, [7]Dermatology and Clinical Immunology Unit, Antony Hospital, Antony, France, [8]Department of Dermatology, Centre Hospitalier Bretagne Sud, Lorient, France, [9]Department of Dermatology, Centre Hospitalier René Dubos, Pontoise, France, [10]Department of Dermatology, Hôpital Saint Joseph, Paris, France, [11]Department of Dermatology, Centre Hospitalier regional Metz-Thionville, Thionville, France, [12]Department of Dermatology, CHU Amiens-Picardie, Amiens, France, [13]Department of Dermatology, CHU Saint Etienne, Saint Etienne, France

Tralokinumab is a monoclonal antibody selectively targeting IL-13, approved for moderate-to-severe atopic dermatitis (AD), for which real-world data are scarce. This prospective, observational, multicentric study aimed to assess the long-term effectiveness and safety of tralokinumab in patients with AD in a real-world setting. Primary outcomes included 50%, 75%, and 90% improvement in Eczema Area and Severity Index score (EASI50, EASI75, EASI90, respectively) and improvements in Dermatology Life Quality Index (DLQI) at 1 year. A total of 136 patients with AD were enrolled in the study; data at 1-year follow-up were available for 111 patients. After 1 year, 68.5% and 33.3% of patients achieved an EASI75 and EASI90, respectively. A significantly higher percentage of patients with than without foot involvement achieved EASI50 ($p = 0.009$) and EASI75 ($p = 0.022$). Similarly, hand involvement was significantly associated with higher EASI50 response ($p = 0.005$). Median DLQI score decreased from 9.00 (interquartile range (IQR): 6.00, 13.75) to 1.00 (IQR: 0.00, 4.00) after 1 year of treatment. Adverse events included blepharitis ($n = 10$), conjunctivitis ($n = 6$), and injection-site reactions ($n = 2$). Tralokinumab can be an effective and safe treatment for patients with moderate-to-severe AD. Involvement of certain body areas, such as hands and feet, might positively predict a clinical response to tralokinumab.

Key words: atopic dermatitis; tralokinumab; antibodies, monoclonal; clinical effectiveness, patient-relevant outcomes.

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Corr: Laura Calabrese; Dermatology Unit, Department of Medical, Surgical and Neurological Sciences, University of Siena, Siena, Italy. E-mail: laura.calabrese@unisi.it

SIGNIFICANCE

Tralokinumab is a monoclonal antibody targeting IL-13 and is approved for moderate-to-severe atopic dermatitis. This study evaluates its long-term effectiveness and safety in a real-world setting. A total of 136 patients were treated with tralokinumab, with 1-year follow-up data available for 111. Results showed that most patients experienced significant improvement and 33.3% achieved almost complete clearance of their symptoms after 1 year. Quality of life improved significantly for many patients. Adverse events mainly included ocular surface alterations, conjunctivitis, and injection-site reactions. Tralokinumab appears effective and safe for moderate-to-severe atopic dermatitis, and involvement of certain body areas might have an impact on drug response.

Atopic dermatitis (AD) is a chronic, immune-mediated skin disease with a multifactorial pathogenesis. It is the most common inflammatory skin disorder and affects an increasing number of patients, with a worldwide prevalence of up to 7% in adults and 25% in children (1, 2). Typical features include symmetrical, eczematous lesions involving flexural areas, face, neck, and distal extremities (3, 4). The pivotal symptom of AD is chronic itching; therefore, the disease is frequently associated with a high incidence of sleep disturbances, depression, and attention deficit hyperactivity disorder, and frequently causes social isolation and work impairment (5–7).

Recently, major discoveries on the pathogenesis of the disease have led to the development of biotechnological therapeutic agents that selectively target the interleukin (IL)-4/IL-13 pathway in AD. Dupilumab is a fully human monoclonal antibody blocking IL-4 and IL-13 by binding the shared IL-4 receptor α (IL-4Rα). It was the first AD-specific agent to be approved in both adults and adolescents with moderate-to-severe AD (8). Despite being a truly significant milestone in AD management, only 35–40% of patients achieve clear or almost clear skin (Investigator Global Assessment [IGA] score 0/1), thus endorsing the need for additional treatment options (9, 10). A few years after dupilumab entered the market, tralokinumab was approved – a fully human immunoglobulin G4 monoclonal antibody that specifically

binds to IL-13 with high affinity, thereby inhibiting its interaction with IL-13 receptors, the IL-13Rα1/IL-4Rα receptor complex, and neutralizing the biological activity of IL-13 (11).

The phase III clinical trial programme demonstrated significantly greater efficacy of tralokinumab vs placebo in reducing disease signs and symptoms in an adult population with moderate-to-severe AD (12–14). To date, no head-to-head trials comparing dupilumab and tralokinumab have been conducted, and therefore no direct comparative data are available. Being a relatively new drug, long-term data for tralokinumab in AD patients in a real-world setting are still scarce. The present study aimed to investigate the long-term effectiveness and safety of tralokinumab in patients with moderate-to-severe AD, retrieved from the French prospective, multicentric, Observatory of Chronic Inflammatory Skin Diseases ("Observatoire Maladies Cutanées Chroniques Inflammatoires" [OMCCI]) registry.

MATERIALS AND METHODS

Study design

We included adult patients (≥18 years old) with moderate-to-severe AD from the OMCCI registry (https://www.reso-dermatologie.fr/omcci/). All patients in the registry treated with tralokinumab who confirmed their agreement to participate after receiving an information note and who provided oral informed consent were enrolled. Patients who did not speak fluent French, who were subject to a legal protection measure, or unable to express their non-opposition, or who were participating in an interventional study, were excluded. The study was approved by the Ethics Committee of the French National Data Protection Commission and the Committee for the Protection of Individuals Île-de-France X (Protocol Number 62-2020). The study protocol conformed to the tenets of the Helsinki Declaration.

Data collection

The following data were collected for each patient: gender, age at diagnosis, age at baseline, AD onset (defined as late onset if diagnosis was after 18 years of age), education, and socioeconomic status. At baseline and after 1 year of treatment, the Eczema Area and Severity Index (EASI) was assessed (15). To evaluate the extension of skin involvement, the body was divided into 9 areas (i.e., scalp; face, neck, and ears; arms and armpits; hands, fingers, and fingernails; thorax, abdomen, back and shoulders; genital area; buttocks and thighs; knees, lower legs and ankles; feet, toes, and toenails). At baseline, 6 months and 1 year, the following patient-reported outcome measures (PROMs) were assessed: Dermatology Life Quality Index (DLQI) (16), the 12-item Short-Form health survey (SF-12) (from SF-12 were derived the Mental Component Score [MCS12] and the Physical Component Score [PCS12]) (17, 18), as well as the impact of AD on sleep over the previous 7 days (evaluated as *often*, *occasionally*, *rarely/never)*. MCS12 and PCS12 scores range typically from 0 to 100, where 50 represents the average score in the general population. Scores above 50 indicate better than average health, while scores below 50 indicate worse than average health (18). Data on previous medication undertaken in the 2 years before starting tralokinumab were also collected and causes of discontinuation and adverse events (AE) were recorded.

Outcomes

The primary outcomes of our study were to assess the percentages of patients achieving clinically meaningful treatment goals after 1 year of treatment with tralokinumab, including: EASI ≤7 and 50%, 75%, and 90% improvement in EASI score (EASI50, EASI75, and EASI90, respectively), as well as the percentages of patients who achieved a ≥4-point improvement in DLQI score and a DLQI score ≤ 5. Additional outcomes were to evaluate the drug survival and drug retention rates (DRRs) at 6 and 12 months and the safety profile of tralokinumab. Secondary aims of the study were to assess whether clinical variables, including age of AD onset, previous treatments, and involvement of specific body areas, could influence outcome achievement and the drug survival/DRR.

Statistical analysis

Descriptive statistics were carried out; absolute frequencies and percentages were calculated for qualitative variables, and means, standard deviations (SDs), 95% confidence intervals (CIs) or median and interquartile range (IQR) were calculated for the quantitative variables. Comparisons of scores and body involvement at baseline and after 1 year were assessed with the Wilcoxon test (scores), or the McNemar test (qualitative variables). The Kruskal–Wallis test was performed to independently compare DLQI, MCS12, and PCS12 between the 3 time points (baseline, 6 months, and 1 year). When the Kruskal–Wallis test was significant, post-hoc analysis was performed with multiple Mann–Whitney tests and the false discovery rate as a *p*-value correction. Drug survival and DRR at 6 and 12 months were examined using the Kaplan–Meier survival analysis taking into account: (*i*) any reason for discontinuation (overall DRR); and (*ii*) only "loss of effectiveness". Univariate Cox regression was estimated to evaluate the impact of body area involvement, previous treatments, and age of AD onset on overall drug survival/DRR and on the loss of effectiveness. Hazard ratios (HRs) and their 95% CIs were estimated. A p-value <0.05 was considered statistically significant. All the analyses were carried out with R version 4.3.1 (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

A total of 136 AD patients treated with tralokinumab from May 2022 to November 2023 were enrolled in 8 French centres. The mean (SD) age at diagnosis was 18.33 (22.96) years. Overall, 41 (30.1%) patients presented with late-onset AD. Sociodemographic, clinical features at baseline, and details on previous treatments are summarized in **Table I**.

In total, 36 (26.4%) and 11 (8.1%) patients were previously treated with cyclosporine and methotrexate, respectively, and 121 (89.0%) patients with topical treatments (including steroids and calcineurin inhibitors). Forty-two (30.9%) and 26 (19.1%) patients had previously undergone treatment with dupilumab and JAKi, respectively, both primarily discontinued due to loss of effectiveness. Fifteen (11.0%) patients adjusted the dosage of tralokinumab by altering the dosing interval; 2 out of 15 (13.3%) patients extended the interval to 300 mg every month and 1 (6.7%) to every 3 weeks, due to a satisfactory response; while 12/15 (80.0%) patients reduced the interval to 300 mg weekly due to insufficient response. Analysing in detail the 12 patients whose administration

Table I. Demographic and clinical characteristics at baseline

Characteristics	Overall ($n=136$)
Age at baseline, mean (SD)	44.31 (19.24)
Female, *n* (%)	66 (48.5)
Age at diagnosis, mean (SD)	18.33 (22.96)
Late-onset atopic dermatitis, *n* (%)	41 (30.1)
Marital status, *n* (%)	
Single	44 (32.4)
Married	77 (56.6)
Divorced/separated	9 (6.6)
Widowed	6 (4.4)
Previous treatments, *n* (%)	
Topical treatments	121 (89.0)
Cyclosporine	36 (26.5)
Methotrexate	11 (8.1)
Dupilumab	42 (31.5)
Upadacitinib	6 (4.5)
Baricitinib	22 (16.5)
EASI at baseline, median (IQR)	13.75 (8.90, 20.00)
DLQI at baseline, median (IQR)	9.00 (6.00, 14.00)

EASI: Eczema Area and Severity Index; DLQI: Dermatology Life Quality Index; IQR: interquartile range; SD: standard deviation.

time was reduced, we observed that 4 out of 12 achieved EASI50 after 6 months from the dosage adjustment. For 2 of them, the dosage was subsequently extended, but this coincided with the last available follow-up, therefore no additional follow-up data are available. The remaining 8 patients did not achieve EASI75. Nevertheless, in 4 out of 8, the reduction in dosage occurred at the 1-year follow-up, while for the other 4 patients only 3 months elapsed before the evaluation. Data at 1 year of tralokinumab treatment were available for 111 patients, and data at 6 months were available in 77 patients; for 15 patients, only baseline was present.

EASI

The median baseline EASI score of the entire cohort was 13.75 (IQR: 8.90, 20.00). In the subgroup with data at 1 year ($n=111$), the EASI score significantly decreased over time from a median (IQR) of 15.00 (IQR: 10.20, 21.35) at baseline, to 2.10 (IQR: 0.90, 4.85) after 1 year ($p<0.001$), with a mean (SD) percentage change from baseline of 71.03 (57.26). After 1 year, 66 (57.01%) patients had an EASI score ≤7, and 98 (88.3%), 76 (68.5%), and 37 (33.3%) achieved an EASI50, EASI75, and EASI90, respectively (**Table II**). After 1 year of tralokinumab, the involvement of all body areas had a statistically significant decrease (Table II).

At 1 year of follow-up, involvement of the feet ($p=0.032$) and hands ($p=0.011$) was significantly associated with a greater mean percentage change in EASI score compared with patients without hand/foot involvement. In contrast, genital involvement was found to be significantly correlated with a lower mean percentage change in EASI score ($p=0.027$). A significantly higher percentage of patients with foot involvement achieved EASI50 and EASI75 ($p=0.009$ and $p=0.022$, respectively), in comparison with patients without foot involvement. Moreover, a significantly higher percentage

Table II. Disease severity reported as mean scores for EASI, DLQI, SF-12, body site involvement, and impact on sleep at baseline and after 1 year of treatment

Variables	Baseline $n=111$	1 year $n=111$	*p*-value
EASI			
EASI, median (IQR)	15.00 (10.20, 1.35)	2.10 (0.90, 4.85)	<0.001
Mean (SD) % change	–	71.03 (57.26)	–
EASI90 response, *n* (%)	–	37 (33.3)	–
EASI75 response, *n* (%)	–	76 (68.5)	–
EASI50 response, *n* (%)	–	98 (88.3)	–
EASI ≤ 7, *n* (%)		66.32 (57.01)	–
DLQI			
DLQI, median (IQR)	9.00 (6.00, 13.75)	1.00 (0.00, 4.00)	<0.001
Mean (SD) % change	–	81 (74.3)	–
≥4-points reduction of DLQI, *n* (%)	–	95 (85.6)	–
DLQI ≤ 5, *n* (%)	–	92 (83.6)	–
SF-12			
PCS12, median (IQR)	49.37 (41.97, 4.71)	57.72 (51.66, 9.49)	<0.001
MCS12, median (IQR)	31.24 (27.35, 7.97)	35.86 (29.97, 1.54)	0.012
Body site involvement, *n* (%)			
Scalp	63 (56.8)	17 (15.3)	<0.001
Face, neck, and ears	85 (76.6)	54 (48.6)	<0.001
Arms and armpits	94 (84.7)	55 (49.5)	<0.001
Hands, fingers, and fingernails	76 (68.5)	28 (25.2)	<0.001
Thorax, abdomen, back, and shoulders	75 (67.6)	21 (18.9)	<0.001
Genital area	34 (30.6)	9 (8.1)	<0.001
Buttocks and thighs	66 (59.5)	28 (25.2)	<0.001
Knees, lower legs, and ankles	60 (54.1)	26 (23.4)	<0.001
Feet, toes, and toenails	41 (36.9)	5 (4.5)	<0.001
Impact of AD on sleep, *n* (%)			
Rare/never	18 (16.2)	91 (82.0)	–
Sometimes	33 (29.7)	9 (8.1)	–
Often	60 (54.1)	11 (9.9)	–

AD: atopic dermatitis; EASI: Eczema Area and Severity Index; DLQI: Dermatology Life Quality Index; SD: standard deviation; SF-12: 12-item Short Form Health Survey; PCS12: Physical Component Score; MCS12: Mental Component Score.

of patients without genital involvement achieved the outcome of absolute EASI ≤7 ($p=0.035$) (Table SI). A significantly higher percentage of patients with late-onset AD vs early-onset had an EASI score ≤7 ($p=0.033$) (Table SII). Finally, previous treatments with biologics and/or JAKi had no significant impact on achievement of objective outcomes (Table SIII).

Quality of life

The median DLQI score decreased from 9.00 (IQR: 6.00, 13.75) at baseline to 1.00 (IQR: 0.00, 4.00) after 1 year of treatment ($p<0.001$). A decrease of ≥ 4 points from baseline was observed in 95 (85.6%) patients, while 92 (83.6%) patients reached a DLQI score ≤5 (Table II). Regarding the MCS12 (31.24 [IQR: 27.35, 37.97] at baseline, 35.86 [IQR: 29.97, 41.54] after 1 year; $p=0.012$) and PCS12 questionnaires (49.37 [IQR: 41.97, 54.71] at baseline, 57.72 [IQR 51.66, 59.49] after 1 year, $p<0.001$), a significant improvement over time was observed (**Fig. 1**).

A higher percentage of patients with hand involvement achieved a DLQI decrease of ≥4 points from baseline ($p=0.034$). Additionally, face and neck involvement was significantly associated with a greater mean percentage change in DLQI score ($p=0.042$). A positive association

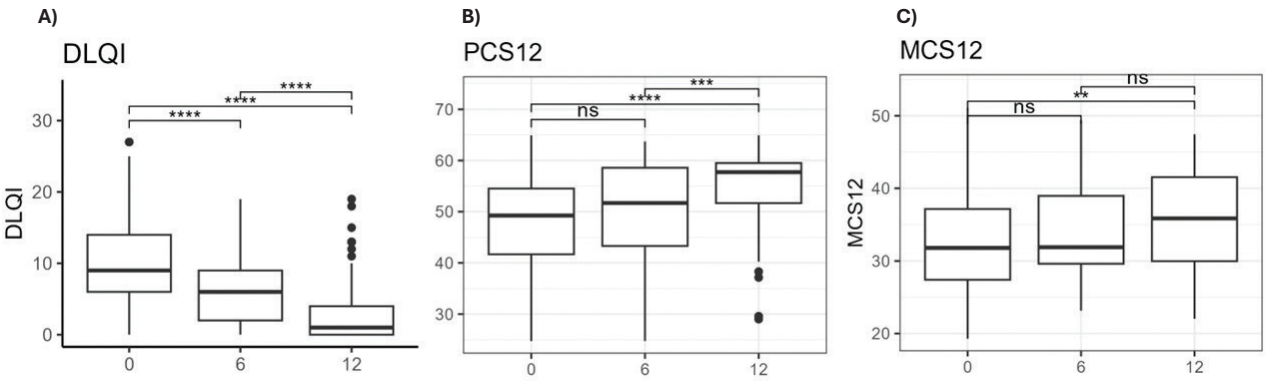

Fig. 1. Patient-reported outcomes measures assessed at 3 timepoints. (A) Median Dermatology Life Quality Index (DLQI) score assessed in tralokinumab-treated patients at baseline, 6 months, and 1 year; (B) median MCS-12 score assessed in tralokinumab-treated patients at baseline, 6 months and 1 year; and (C) median PCS-12 score assessed in tralokinumab-treated patients at baseline, 6 months, and 1 year. MCS-12, Mental Component Score; PCS-12, Physical Component Score.

between hands ($p=0.034$) and scalp ($p=0.040$), knees and lower legs ($p=0.026$), and feet ($p=0.014$) and mean percentage change in PCS12 score was assessed (Table SI). Time of AD onset was not significantly correlated with any change in PROMs (Table SII).

Finally, patients naive to dupilumab showed a significantly higher mean percentage change in DLQI ($p=0.016$) and PCS12 score ($p=0.008$) compared with bio-experienced patients, whereas patients naive to both dupilumab and JAKi exhibited a significantly higher mean percentage change in PCS12 score ($p=0.003$) (Table SIII).

Drug retention rates and safety

The Kaplan–Meier survival curves considering any reason for discontinuation (overall DRR) and only loss of effectiveness are shown in **Fig. 2**. Overall, 29 patients discontinued tralokinumab: 23 for loss of effectiveness and 6 for AEs (conjunctivitis). Twelve AEs not leading to discontinuation developed in 12 patients. Specifically, 10 cases of blepharitis and 2 injection-site reactions were reported. The overall tralokinumab DRRs at 6 and 12 months were 87.6% and 76%, respectively. When considering only loss of effectiveness as a discontinuation reason, DRRs at 6 and 12 months were 91.4% and 80.1%, respectively.

The involvement of the hands (HR 0.43 [CI: 0.21–0.89]; $p=0.024$) and the buttocks (HR 0.41 [CI: 0.19–0.86]; $p=0.019$) was significantly associated with a lower incidence of tralokinumab discontinuation (overall drug survival) upon Cox regression analysis (Table SIV). Previous treatment with JAKi significantly influenced the overall drug survival (HR 2.41 [CI: 1.09–5.33]; $p=0.03$)

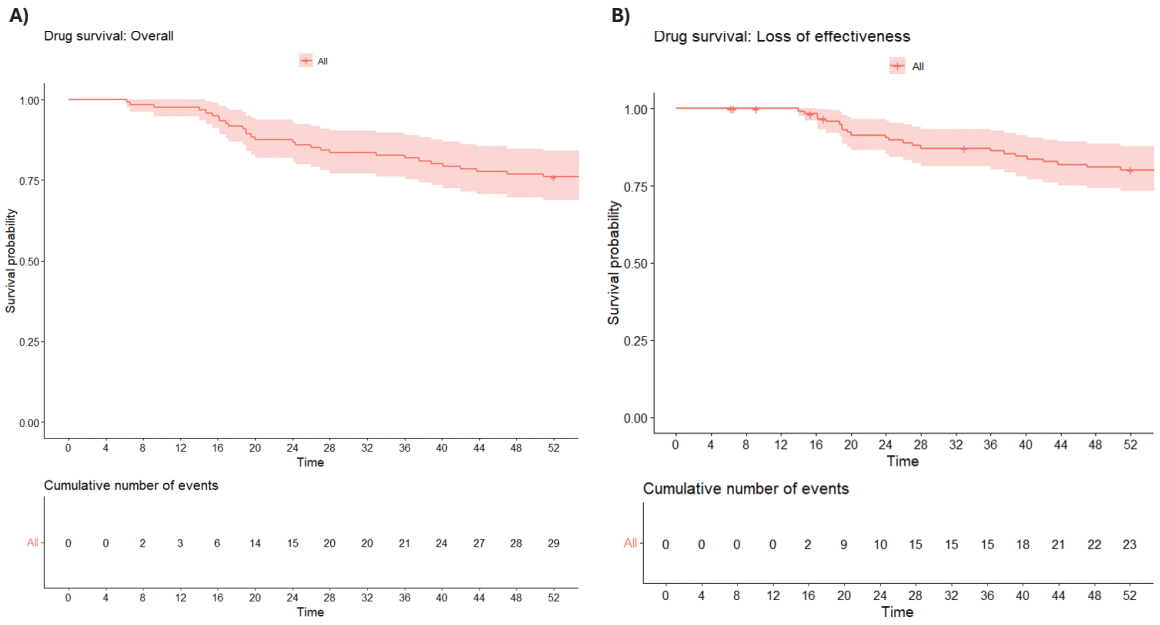

Fig. 2. Kaplan–Meier survival curves considering for any reason for discontinuation: (A) overall drug retention rates and (B) discontinuation for the loss of effectiveness only.

and discontinuation due to loss of effectiveness (HR 2.98 [CI: 1.25–7.11]; $p=0.014$). Conversely, previous treatment with dupilumab had no impact on drug survival (Tables SIV and SV).

DISCUSSION

Tralokinumab was the first US Food and Drug Administration- and European Medicines Agency-approved selective IL-13-targeting biologic for AD (11, 19). The phase III ECZTRA 3 and ECZTRA 7 studies demonstrated the significantly greater efficacy of tralokinumab plus topical corticosteroids (TCS) than placebo plus TCS in reducing disease signs and symptoms in an adult population with moderate-to-severe AD, with an overall frequency and severity of AEs comparable with placebo (12, 13). To date, some studies have investigated the effectiveness and safety of tralokinumab in a real-world setting (20–26). In a recent study, Pezzolo et al. (24) analysed a cohort of AD patients up to week 52. The overall drug survival rate at week 52 ($n=22$) was 85.9%, and the proportions of patients achieving EASI50, EASI75, and EASI90 at week 52 were 100%, 95.4%, and 95.4%, respectively (24).

Pereyra-Rodrìguez et al. (26) evaluated the effectiveness of tralokinumab on 85 patients with AD in the short term. At week 16, 82%, 58%, and 21% of the patients achieved EASI50, EASI75, and EASI90, respectively. A European multicentric study of 194 patients with moderate-to-severe AD treated with tralokinumab with a follow-up of 32 weeks reported that the proportion of patients achieving EASI75 continued to increase up to week 32 (75.9%), while EASI90 response rates plateaued at week 16 without significant improvements thereafter (44.8% at week 32) (27).

Our study was conducted on a relatively large French cohort (111 patients), and 88.3%, 68.5%, and 33.3% of patients achieved EASI50, EASI75, and EASI90, respectively, at 1 year. Results from our study differ from those of Pezzolo et al. (24), who reported a higher proportion of patients achieving EASI50, EASI75, and EASI90 at 1 year as well as higher DRRs in comparison with our study. However, in this study only 22 of the 171 baseline patients were analysed at week 52. Our results are more like those reported by Chiricozzi et al. (27) and Pereyra-Rodrìguez et al. (26), despite these studies having shorter follow-up periods. Therefore, it is possible that, in these last studies, the EASI75 scores could have continued to increase beyond these timepoints. Moreover, in the studies mentioned, the mean EASI scores at baseline were higher compared with ours: Pezzolo et al., mean EASI 24.4; Chiricozzi et al., mean EASI 21.6; Pereyra-Rodriguez et al., mean EASI 25.4 (24, 26, 27); our study, mean EASI: 15. This might partly explain the lower percentages of patients achieving EASI75 and EASI90 in our cohort. A significant number of patients previously treated with methotrexate or cyclosporine, or enrolled by non-hospital investigating centres in our study, may explain the lower mean EASI at inclusion.

An interesting finding of our study concerns the influence of the involvement of different body areas on the effectiveness of tralokinumab and its ability to improve patients' quality of life. It is well known that certain "difficult-to-treat" body areas, such as head-and-neck AD, are poorly responsive to dupilumab (28). Chiricozzi et al. (27) found that head-and-neck involvement negatively affected the effectiveness of tralokinumab, obtaining significantly lower rates of EASI75 and EASI90 responses. In contrast, in our study, involvement of the head-and-neck region did not have a significant impact on the effectiveness of tralokinumab and was even associated with a higher mean percentage change in DLQI from baseline to 1 year. Surprisingly, our study showed that both hand and foot involvement were associated with significantly higher mean percentage changes in the EASI score, as well as higher percentages of patients reaching EASI50 at 1 year, and even EASI75 in the case of foot involvement, compared with patients without AD lesions in these areas. Furthermore, hand involvement had a significant positive impact on tralokinumab overall drug survival. Because the hands and feet are also considered difficult-to-treat areas, our study could suggest that the presence of AD in those areas might positively predict a response to the drug and thus even direct the physician's choice towards tralokinumab in these cases. However, confirmation of these data in larger studies as well as experimental studies investigating possible reasons for these findings should be encouraged. Of note, a recent study reported the successful use of tralokinumab in AD patients with genital lesions (29). Our study confirmed the effectiveness of tralokinumab on genital AD, although patients without genital involvement achieved better outcomes.

To date, only a few studies have investigated the impact of previous AD treatments on response to tralokinumab in a real-world setting. Pereyra-Rodrigez et al. (26) found that the percentages of EASI75 response at week 16 were significantly higher in the "naive to biologics/JAKi" versus the "non-naïve to biologics/JAKi" group. Chiricozzi et al. (27) reported that an EASI75 response was significantly more frequent within dupilumab-naive patients at week 32 (93.7% vs 44.4%, $p=0.006$). These results were not confirmed in our study, where there was no difference between dupilumab-naive and -experienced subjects in terms of objective outcomes and drug survival at 1 year.

A recent study by De Greef et al. analysed tralokinumab effectiveness in patients with previous experience with JAKi. The authors reported that tralokinumab response (measured as median percentage change of EASI and SCORAD) was better in patients who were naïve to immunomodulatory treatments. Conversely, patients with recalcitrant disease, inadequately control-

led with a previous biotherapy and/or JAKi, showed poorer responses, with the worst responses observed among JAKi non-responders (22). On the other hand, a recent case series described the successful response to tralokinumab in patients unresponsive to dupilumab (n=17/17) and JAKi (upadacitinib; n=9/17) in terms of both objective outcomes and PROMs (30). In our study, previous treatment with JAKi had no impact on any of the outcomes analysed but negatively influenced both overall drug survival and survival related to loss of effectiveness. This might be influenced by patient expectations and perceptions shaped by their previous experience with JAKi. Indeed, patients who experience rapid symptom relief with JAK inhibitors might perceive tralokinumab, which might have a slower onset of action, as less effective, leading to higher discontinuation rates (31). However, having prior experience with at least 1 agent (dupilumab and/or JAKi) did not affect effectiveness outcomes or drug survival rates. Given the conflicting evidence, whether the administration of a previous treatment could actually have an impact on tralokinumab effectiveness is yet to be clarified.

Furthermore, we found that better outcomes (EASI score ≤7) were achieved in the late-onset vs early-onset AD patients (p=0.033). One possible explanation could be that the late-onset AD variant likely has a shorter disease duration compared with early-onset AD. Acute or not long-standing forms of AD are generally characterized by stronger involvement of the Th2 pathway. In contrast, chronic forms of the disease demonstrate greater molecular heterogeneity, with a shift toward the activation of other immunological axes, such as the Th17 pathway (32). Given this, it is plausible that the late-onset AD variant, due to its shorter disease duration and a possible predominant Th2-driven immune response, exhibits a more favourable response to tralokinumab.

The safety profile of tralokinumab in our study was consistent with what has previously been reported in the literature (33). AEs mainly included ocular conditions (conjunctivitis and blepharitis) and injection-site reactions. Among these, only conjunctivitis led to drug discontinuation.

The present study has some limitations, particularly the lack of short- and medium-term effectiveness data with physician-reported scores. Nevertheless, data from clinical trials and real-world studies have shown that tralokinumab effectiveness even tends to increase up to week 52, suggesting that tralokinumab probably needs more time to reach peak effectiveness; therefore, intermediate time points may not be useful to assess the overall effectiveness of the drug. Moreover, specific scores for itch, such as the Peak Pruritus Numerical Rating Scale, were not included in the registry. Concerning safety, laboratory findings were not available in the OMCCI registry.

In conclusion, our study provides important insight on the long-term effectiveness and safety of tralokinumab as well as on the effectiveness of the drug in subgroups of AD patients. Further investigations in large cohorts should be encouraged as they are instrumental in better defining the drug effectiveness and safety profiles, and in better delineating the ideal patient candidate profile for treatment with tralokinumab in a real-world setting.

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