Letter: Effectiveness and Safety of Tralokinumab for the Elderly with Atopic Dermatitis in a Real-World Setting—IL AD

To the Editor:

The prevalence of atopic dermatitis (AD) in elderly individuals is increasing, reaching up to 10%.[1,2] While mild AD is effectively managed with topical medications and moisturizers, recognizing and treating severe cases can be challenging, particularly in the elderly.[1,2] On the one hand, elderly AD may present with atypical clinical phenotypes (compared with younger individuals, elderly patients with AD more frequently present with atypical phenotypes, such as generalized eczema, prurigo nodularis, such as nummular eczema, and less commonly with the classical flexural pattern); on the other hand, the use of conventional systemic immunosuppressive drugs may be contraindicated due to the presence of comorbidities in older patients, possible drug interactions, risk of adverse events (AEs), and patients' cognitive ability and functional independence impairment.[3] Furthermore, elderly patients are often excluded from clinical trials, making real-life data essential to guide clinicians in daily clinical practice.[3] Recent knowledge of AD pathogenesis has led to the development of new selective drugs. Among these, tralokinumab, a fully human monoclonal antibody that targets interleukin 13, has been recently approved for treating moderate-to-severe AD in adults and adolescents aged 12 and older.[4] Although its efficacy and safety have been reported in both clinical trials and real-life experiences, data concerning its use in the elderly are scarce, mainly related to case reports and small case series with short follow-up periods.[5–10]

Therefore, we performed a retrospective, observational, real-life study enrolling patients aged ≥60 years with moderate-to-severe AD receiving tralokinumab at the labeled dosage for at least 16 weeks from 26 Italian dermatological referral centers to evaluate its efficacy and safety in these subjects. A total of 122 patients (60 males [49.18%]; mean age 70.93 ± 8.59 years [range = 61–102]) met the inclusion criteria. Of these, 122 (100%) reached week (W) 16 follow-up, whereas 37 (30.33%) and 28 (22.95%) completed W24 and W52, respectively. The reduction in sample size at W24 and W52 was primarily due to the retrospective design of the study and the variability in follow-up durations among centers. Reasons for missing data included incomplete clinical records or still ongoing treatment not yet reaching W24 or W52 at the time of data collection.

Clinical and demographic data of the study population are reported in Table 1. At baseline, Eczema Area and Severity Index (EASI) was 25.53 ± 9.06, Pruritus Numeric Rating Scale (P-NRS) 8.31 ± 2.02, and Dermatology Life Quality Index (DLQI) 15.97 ± 8.07. A statistically significant improvement of EASI was observed at each timepoint, as indicated by a mean percentage reduction from baseline of 50.93% at W16, 71.61% at W24, and 84.18% at W52 ($P < 0.0001$, Table 1, Fig. 1a, b). Similarly, a statistically significant reduction of P-NRS and DLQI was observed at each timepoint (Table 1, Fig. 1a). Investigating the effectiveness of tralokinumab by stratifying the study population into five age groups (60–64 years: n = 33, 27.05%; 65–69: n = 29, 23.77%; 70–74: n = 19, 15.57%; 75–79: n = 24, 19.67%; >80: n = 17, 13.93%), although not statistically significant, a higher percentage of patients aged >75 years achieved EASI75 at W16 compared with younger patients (Fig. 2). Regarding safety, no serious AEs were reported. The most common AEs were conjunctivitis (6/122; 4.92%), which healed after corticosteroid or tacrolimus eye drops treatment in all cases. Injection site reactions were reported by 4 out of 122 (3.28%) patients. No treatment interruption due to AEs or lack of effectiveness was observed.

Real-life data are mandatory for guiding clinicians in the management of AD, particularly in special populations such as elderly subjects.[3] Currently, real-life data on the use of tralokinumab in these patients are scarce.[5–10] A secondary analysis of 3 randomized clinical trials conducted by Merola et al on 75 elderly patients (≥65 years) with moderate-to-severe AD showed that more patients receiving tralokinumab (n = 75) achieved EASI75 response as compared with placebo (n = 29) at W16 (33.9% vs 4.8%; $P < 0.001$), in line with our data (EASI75 at W16: 31.15%).[10] Regarding the safety, 3 out of 75 patients (4%) in the tralokinumab arm and 3 out of 29 (10.3%) in the placebo arm experienced severe AEs, leading to treatment interruption in 4 (5.3%) and 2 (6.9%) cases, respectively, conversely from our study where no serious AEs were observed.

The main limitations of our study are its retrospective design and the reduced number of patients achieving the W24 and W52 follow-up.

In summary, to the best of our knowledge, our study is the first specifically investigating the effectiveness and safety of tralokinumab for elderly AD patients in real life, even in long term, showing a statistically significant improvement for each investigated score since W16, continuing to improve up to W52.

Data that support the findings of this study are available from the corresponding author upon reasonable request.

All authors read and approved the final version of the article.

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TABLE 1. Demographic Data and Clinical Outcomes of Study Patients Treated with Tralokinumab

Study Population (n = 122)	Value
Age (mean ± SD), years	70.93 ± 8.59
Age groups, no. (%)	
60–64 years	33 (27.05%)
65–69 years	29 (23.77%)
70–74 years	19 (15.57%)
75–79 years	24 (19.67%)
>80 years	17 (13.93%)
Male, no. (%)	60 (49.18%)
Duration of AD, mean (SD), years	30.32 (±22.13)
Family atopic history, no. (%)	21 (17.21%)
Patients with ≥1 concurrent atopic comorbidity, no. (%)	59 (48.36%)
Rhinitis	48 (39.34%)
Asthma	39 (31.96%)
Conjunctivitis	15 (12.29%)
Other comorbidities, no. (%)	
Hypertension and cardiovascular disorders	78 (63.93%)
Diabetes mellitus	35 (28.68%)
Obesity	30 (24.59%)
Osteoporosis	21 (17.21%)
Chronic obstructive pulmonary disease	19 (15.57%)
Kidney failure	11 (9.01%)
Psychiatric/psychological disorders	9 (7.37%)
Benign prostatic hyperplasia	7 (5.73%)
Malignancies	5 (4.09%)
Clinical phenotype, no. (%)	
Flexural dermatitis	53 (43.44%)
Prurigo nodularis	53 (43.44%)
Generalized eczema	10 (8.19%)
Nummular eczema	6 (4.91%)
Previous treatments, no. (%)	
Systemic corticosteroids	40 (32.78%)
Cyclosporine	33 (27.04%)
Methotrexate	6 (4.91%)
Phototherapy	14 (11.47%)
Dupilumab	29 (23.77%)

	Clinical Outcomes			
	[a]Baseline (n = 122)	[a]Week 16 (n = 122)	[a]Week 24 (n = 37)	[a]Week 52 (n = 28)
Mean EASI ± SD (Δ %)	25.53 ± 9.06	12.53 ± 6.95 (–50.93%)*	7.25 ± 6.47 (–71.61%)*	4.04 ± 3.95 (–84.18%)*
Mean DLQI ± SD (Δ %)	15.97 ± 8.07	8.03 ± 5.46 (–49.72%)*	5.63 ± 5.11 (–64.75%)*	3.84 ± 5.04 (–75.96%)*
Mean P-NRS ± SD (Δ%)	8.31 ± 2.02	4.63 ± 2.29 (–44.29%)*	2.89 ± 3.10 (–65.23%)*	1.88 ± 2.23 (–77.38%)*
EASI75	/	38 (31.15%)	32 (86.49%)	24 (85.71%)
EASI90	/	22 (18.03%)	21 (56.76%)	15 (53.57%)
EASI100	/	11 (9.02%)	12 (32.43%)	8 (28.57%)

[a]*The collected data were processed using GraphPad Prism software (GraphPad Inc., La Jolla, CA). Student's t test was used to assess the statistical significance of the differences in values obtained at the different timepoints of treatment. No adjustments for multiple comparisons were applied, as the analyses were primarily exploratory and descriptive in nature. P values <0.05 were statistically significant.*

*$P < 0.0001$ *if compared with the same value at baseline.*

AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; Δ %, mean percentage reduction from baseline to each timepoint; n, number of patients; P-NRS, Pruritus Numerical Rating Scale; SD, standard deviation.

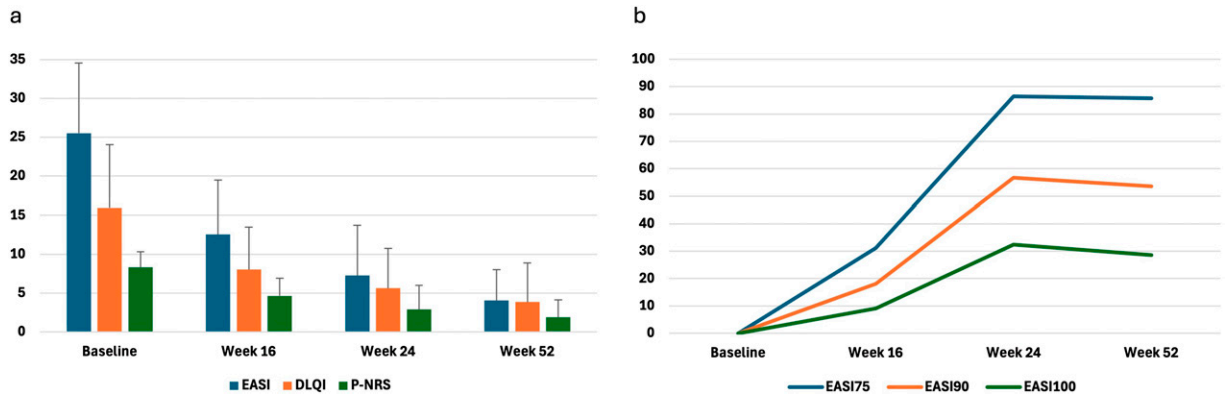

Figure 1. Clinical outcomes (EASI, DLQI, P-NRS) **(a)** and percentage of patients achieving EASI75/90/100 response **(b)** at each follow-up. A total of 122 (100%) reached week (W) 16 follow-up, whereas follow-up data at W28 and W52 were available for 37 (30.33%) and 28 (22.95%) patients at the moment of the analysis, respectively. DLQI, Dermatology Life Quality Index; EASI, Eczema Area Severity Index; P-NRS, Pruritus Numerical Rating Scale.

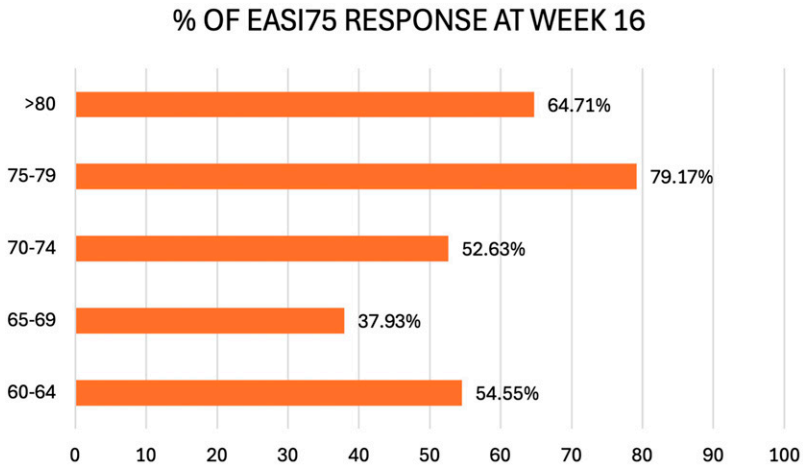

Figure 2. Percentage of patients achieving EASI75 response at week 16 divided for age groups: 60–64 years: n = 33 (27.05%); 65–69: n = 29 (23.77%); 70–74: n = 19 (15.57%); 75–79: n = 24 (19.67%); >80: n = 17 (13.93%). EASI, Eczema Area Severity Index.

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