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Concise report

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Real-life effectiveness and safety of lebrikizumab in older patients with atopic dermatitis: a multicentre study

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Abstract

Lebrikizumab, a monoclonal antibody targeting interleukin-13, has demonstrated efficacy and safety in adults with moderate-to-severe atopic dermatitis (AD), but data for older patients remain limited. We conducted a retrospective multicentre study including 90 patients aged ≥ 60 years with moderate-to-severe AD treated with lebrikizumab across 23 Italian dermatology centres. Clinical outcomes were assessed at baseline and at weeks (W) 16, 24 and 52. Mean (SD) Eczema Area and Severity Index (EASI) decreased from 23.24 (7.93) at baseline to 6.33 (6.54) at W16, 3.57 (3.74) at W24 and 2.70 (4.83) at W52 ($P < 0.0001$). EASI 75 (75% improvement from baseline) was achieved by 58%, 82% and 87% of patients at W16, W24 and W52, respectively. Clinical responses were similar across age groups and independent of prior biologic or Janus kinase inhibitor exposure. Adverse events occurred in 8% of patients and were mainly mild. These findings support the effectiveness and safety of lebrikizumab in older patients with AD in real-world clinical practice.

The prevalence of atopic dermatitis (AD) in older individuals is increasing.[1] In this population, the management of moderate-to-severe AD may be challenging due to the presence of comorbidities, polypharmacy, potential contraindications to conventional systemic immunosuppressive therapies, and the clinical and immunological heterogeneity related to age at disease onset.[2,3] Lebrikizumab is a monoclonal antibody selectively targeting interleukin (IL)-13, a key cytokine involved in the inflammatory cascade underlying AD. Phase III randomized trials (ADvocate-1, ADvocate-2 and ADhere) demonstrated the efficacy and safety of lebrikizumab in adults with moderate-to-severe AD.[4,5] Older patients are under-represented in lebrikizumab clinical trials, and real-life evidence addressing the effectiveness and safety of lebrikizumab in this population remains limited.[6]

Report

We conducted a retrospective, multicentre, real-life study including consecutive patients aged ≥ 60 years with moderate-to-severe AD treated with lebrikizumab at the labelled dosage. Patients were consecutively enrolled in 23 Italian dermatological referral centres across the national territory. Demographic and clinical data were retrospectively collected from medical records. Disease severity and treatment effectiveness were assessed at baseline and during follow-up visits at weeks (W) 16, 24 and 52 using the Eczema Area and Severity Index (EASI), Pruritus Numeric Rating Scale (P-NRS), Sleep Numeric Rating Scale (S-NRS) and Dermatology Life Quality Index (DLQI). Treatment response rates were evaluated according to the proportion of patients achieving

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EASI 75, EASI 90 and EASI 100 (75%, 90% and 100% improvement from baseline, respectively) at each timepoint. Safety was assessed by recording all adverse events (AEs) occurring during treatment. Rescue topical and systemic therapies referred only to treatments introduced during follow-up and not to concomitant therapies systematically used at baseline. Patch-testing results, when available in the clinical records, were also collected to evaluate the prevalence of contact sensitization in this population.

Continuous variables are presented as mean (SD), whereas categorical variables are reported as absolute numbers and percentages. Changes in continuous outcomes from baseline to follow-up visits were analysed using the Wilcoxon matched-pairs signed-rank test. Comparisons of categorical variables between independent subgroups were performed using Fisher's exact test. Statistical analyses were performed using GraphPad Prism software, and a two-sided P-value < 0.05 was considered statistically significant.

In total, 90 patients aged ≥ 60 years met the inclusion criteria. Of these, 77 (86%) reached W16 follow-up, whereas 50 (56%) and 23 (26%) completed W24 and W52, respectively. The reduction in sample size at W24 and W52 reflected variable follow-up duration across centres, incomplete records or ongoing treatment not yet reaching later timepoints.

Clinical and demographic data of the study population are reported in Table 1. The study population had a mean (SD) age of 73.4 (6.9) years and included 71 men (79%); all patients were White European. The mean (SD) age at AD diagnosis was 52.5 (27.6) years, with a mean (SD) disease duration of 16.8 (23.5) years. Disease onset occurred before 18 years of age in 20 of 90 patients (22%), consistent with persistent childhood-onset AD, whereas 70 of 90 patients (78%) had adult-onset/late-onset AD; among these, 56 of 90 patients (62%) developed AD at ≥ 60 years and were classified as older-onset AD. Overall, 42 of 90 (47%) had previously received at least one biologic or targeted therapy, including dupilumab, tralokinumab or Janus kinase inhibitor (JAKi) (Table 1). Baseline mean (SD) values were: EASI 23.24 (7.93), DLQI 16.24 (7.63), P-NRS 7.75 (2.14) and S-NRS 6.65 (3.01). A statistically significant improvement in disease severity was observed at each follow-up timepoint. Mean (SD) EASI decreased to 6.33 (6.54) at W16, 3.57 (3.74) at W24 and 2.70 (4.83) at W52, corresponding to a mean percentage reduction from baseline of 72.0%, 84.5% and 90.6%, respectively ($P < 0.0001$ for all comparisons; Figure 1a). Similarly, a statistically significant reduction of P-NRS, S-NRS and DLQI scores was observed at each timepoint (Figure 1a). In terms of response rates, EASI 75 was achieved by 45 of 77 (58%) patients at W16, 41 of 50 (82%) at W24 and 20 of 23 (87%) at W52, whereas EASI 90 was reached by 22 of 77 (29%) at W16, 22 of 50 (44%) at W24 and 17 of 23 (74%) at W52. Complete clearance (EASI 100) was observed in 13 of 77 (17%) patients at W16, 14 of 50 (28%) at W24 and 5 of 23 (22%) at W52 (Figure 1b). A subgroup analysis according to prior biologic or JAKi exposure showed comparable W16 EASI 75 response rates between bio/JAKi-naive and bio/JAKi-experienced patients [26 of 46 (57%) vs. 19 of 31 (61%); $P = 0.81$].

In a descriptive analysis according to age groups among the 77 patients evaluable at W16 [60–64 years: 3 (4%); 65–69: 21 (27%); 70–74: 16 (21%); 75–79: 20 (26%); ≥ 80: 17 (22%)], clinical responses appeared similar across age categories. Notably, very old patients (≥ 80 years) showed descriptively similar response rates to those observed in less old individuals, with EASI 75 achieved by 12 of 17 (71%) patients at W16 (Figure 2).

Table 1 Baseline characteristics and safety of 90 older patients with moderate-to-severe atopic dermatitis (AD) treated with lebrikizumab

Variable	Value
Baseline characteristics	
Age (years), mean (SD)	73.4 (6.9)
Age (years), range	61–95
Male sex, *n* (%)	71 (79)
Body mass index, mean (SD)	24.8 (3.2)
Age at AD diagnosis (years), mean (SD)	52.5 (27.6)
Disease duration (years), mean (SD)	16.8 (23.5)
Age groups (years), *n* (%)	
60–64	3 (3)
65–69	30 (33)
70–74	18 (20)
75–79	22 (24)
≥ 80	17 (19)
Disease severity at baseline, mean (SD)	
EASI	23.24 (7.93)
DLQI	16.24 (7.63)
Pruritus-NRS	7.75 (2.14)
Sleep-NRS	6.65 (3.01)
Eosinophils (cells μL^{-1})	234.8 (284.9)
Total IgE (IU mL^{-1})	503.3 (959.1)
Atopic comorbidities, *n* (%)	
Asthma	12 (13)
Rhinitis	32 (36)
Conjunctivitis	17 (19)
Food allergy	5 (6)
Previous treatments, *n* (%)	
Systemic corticosteroids	62 (69)
Ciclosporin	36 (40)
Phototherapy (NB-UVB)	16 (18)
Methotrexate	10 (11)
Antitumour necrosis factor	3 (3)
Dupilumab	24 (27)
Tralokinumab	16 (18)
JAKi	6 (7)
Biologic exposure, *n* (%)	
Bio/JAKi-naive	48 (53)
Bio/JAKi-experienced	42 (47)
Allergic sensitization, *n* (%)	
Patch-test performed	28 (31)
Patch-test positive (of 28)	13 (46)
Safety, *n* (%)	
Any adverse event	7 (8)
Ocular adverse events	5 (6)
Other adverse events	3 (3)
Rescue systemic therapy	6 (7)
Rescue topical therapy	29 (32)
Treatment discontinuation	8 (9)

DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; JAKi, Janus kinase inhibitor; NB-UVB, narrowband ultraviolet B; NRS, Numeric Rating Scale.

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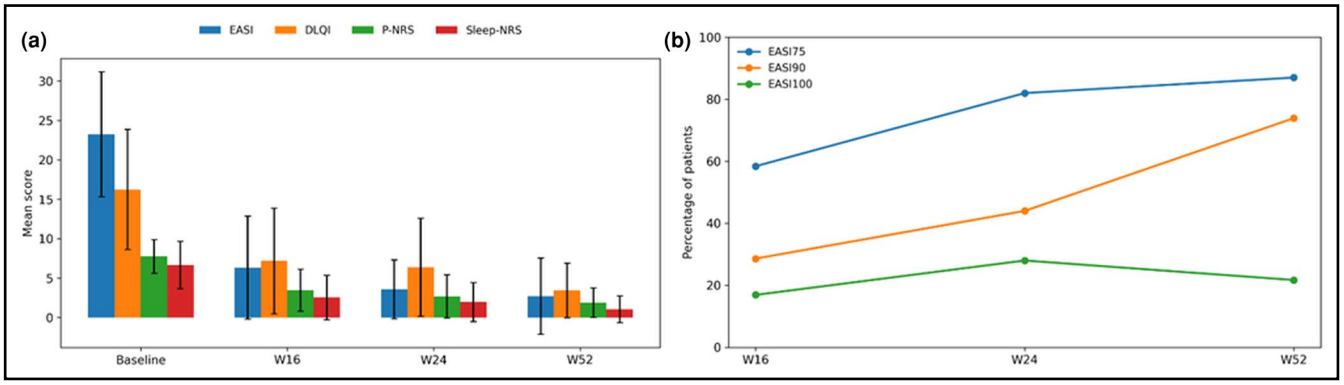


Figure 1 Clinical outcomes during lebrikizumab treatment. (a) Mean values of Eczema Area and Severity Index (EASI), Dermatology Life Quality Index (DLQI), Pruritus Numeric Rating Scale (P-NRS) and Sleep Numeric Rating Scale (S-NRS) at baseline and during follow-up [week (W) 16, W24 and W52]. Error bars represent SD. $P < 0.0001$ for all comparisons. (b) Percentage of patients achieving EASI 75, EASI 90 and EASI 100 (75%, 90% and 100% improvement from baseline, respectively) responses at each follow-up timepoint.

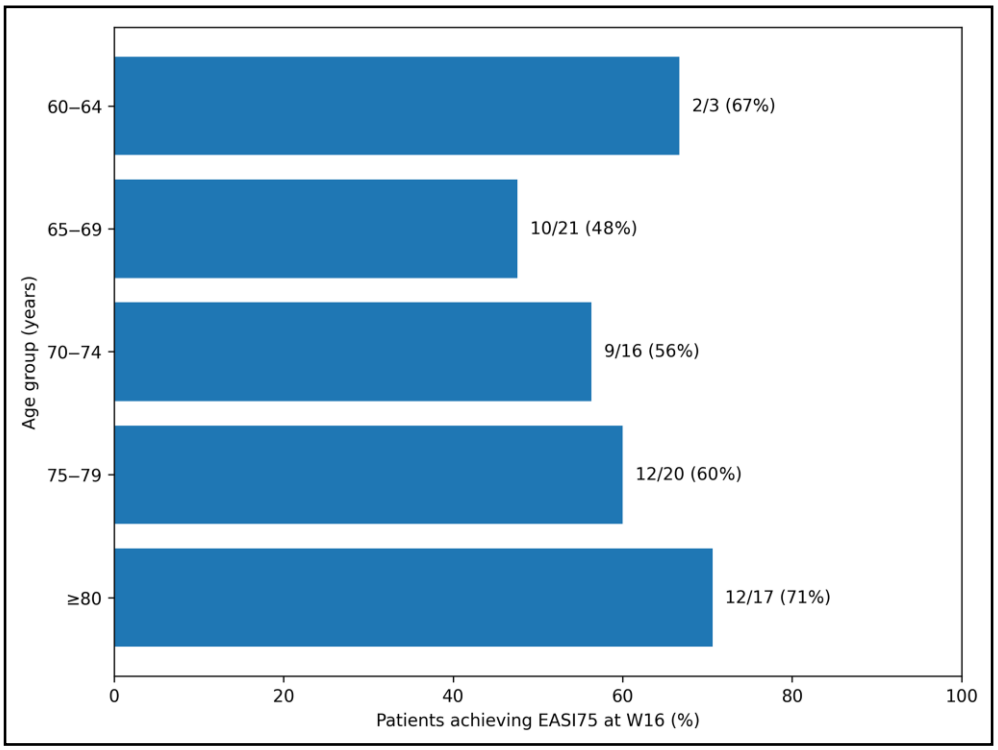


Figure 2 Percentage of patients achieving EASI 75 response at week (W) 16 stratified by age group (60–64, 65–69, 70–74, 75–79 and ≥ 80 years). Response rates were 2 of 3 (67%) in patients aged 60–64 years, 10 of 21 (48%) in those aged 65–69 years, 9 of 16 (56%) in those aged 70–74 years, 12 of 20 (60%) in those aged 75–79 years, and 12 of 17 (71%) in patients aged ≥ 80 years. EASI 75, 75% improvement from baseline Eczema Area and Severity Index score.

Regarding safety, 7 of 90 (8%) patients experienced at least 1 AE during treatment. The most common AEs were ocular events, including conjunctivitis in 5 of 90 (6%) patients, all occurring in bio/JAKi-experienced subjects; 3 of these patients had a history of allergic conjunctivitis at baseline. Ocular events resolved after appropriate topical treatment. Other AEs were reported in 3 of 90 (3%) patients, including injection-site reactions. Treatment discontinuation occurred in 8 of 90 (9%) patients, mainly due to lack of effectiveness ($n = 5$) or AEs ($n = 3$). AEs leading to discontinuation included conjunctivitis associated with diplopia ($n = 1$, at W16), persistent conjunctivitis ($n = 1$, at W24) and facial redness ($n = 1$, at W52). The patient who discontinued lebrikizumab because of facial redness was also bio-experienced and had previously received tralokinumab. No serious AEs were reported.

Patch-test results were available for 28 of 90 (31%) patients, of whom 13 (46%) showed at least one positive reaction, corresponding to 13 of 90 (14%) of the overall cohort. However, no significant differences in treatment response were observed between patients with positive and negative patch-test results.

Real-life data are essential for managing AD in older patients, who are often under-represented in randomized trials. Phase III randomized trials demonstrated efficacy and safety of lebrikizumab in

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adults with moderate-to-severe AD. In the ADvocate-1 and ADvocate-2 trials, significantly higher proportions of patients treated with lebrikizumab achieved EASI 75 at W16 compared with placebo.[4] In the integrated analysis set including 1720 patients with moderate-to-severe AD exposed to lebrikizumab, only 123 (7.2%) were aged ≥ 65 years and 29 (1.7%) were ≥ 75 years.[7] In a large Italian multicentre real-life study by Patruno *et al*., including 276 patients aged ≥ 65 years, clinical data at W16 were available for 253 patients (91.7%) treated with dupilumab.[8] In this cohort, the mean (SD) EASI score decreased from 29.2 (8.7) at baseline to 9.1 (6.3) at W16, corresponding to a 68.8% mean percentage reduction, together with significant improvements in pruritus and quality of life scores.[8]

In a multicentre real-life study including 122 older patients with AD treated with tralokinumab, EASI 75 was achieved by 38 patients (31.1%) at W16, increasing to 32 of 37 patients (86%) at W24 and 24 of 28 patients (86%) at W52, with progressive improvement in EASI, DLQI and pruritus scores throughout follow-up.[9]

Our W16 findings are broadly consistent with those of a recent nationwide real-world study of lebrikizumab in a predominantly nonolder-adult population, which reported EASI 75, EASI 90 and EASI 100 rates of 61.5%, 28.2% and 9.0%, respectively, and treatment-related AEs in 5.1% of patients.[10] In our older cohort, W16 EASI 75 and EASI 90 rates were similar (58% and 29%), while AEs were slightly more frequent (8%), as expected in an older population with greater comorbidity burden and previous systemic treatment exposure. Our study showed clinically meaningful and sustained effectiveness of lebrikizumab in older patients with AD in real-world practice. Short-term outcomes were not significantly influenced by prior biologic/JAKi exposure, with similar W16 EASI 75 rates in bio/JAKi-naive and bio/JAKi-experienced patients. Contact sensitization was observed in 13 of 28 tested patients (46%; 14% of the overall cohort), but did not significantly influence lebrikizumab response.

The main limitations of our study include the retrospective design and the reduced number of patients reaching longer follow-up timepoints, which mainly reflects differences in treatment duration among participating centres.

In conclusion, to the best of our knowledge, this study represents one of the first real-life analyses specifically investigating the effectiveness and safety of lebrikizumab in older patients with AD. Our findings confirm that selective IL-13 inhibition provides significant clinical improvement with a favourable safety profile in this population.

Learning points

- Lebrikizumab is effective in older patients with moderate-to-severe atopic dermatitis in real-world clinical practice.
- Significant clinical improvement is observed as early as week 16 and maintained over time.
- Treatment response appears consistent across different older age groups, including patients aged ≥ 80 years.
- Previous exposure to biologic or Janus kinase inhibitor therapies does not significantly impact treatment effectiveness.
- The safety profile is favourable, with mainly mild and manageable adverse events.
- Contact sensitization is relatively frequent but does not influence clinical response to treatment.

Author contributions

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Conflicts of interest

The authors declare they have no conflicts of interest.

Data availability

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

Ethics statement

The study adhered to the STROBE reporting guidelines for cohort studies, and the principles outlined in the Declaration of Helsinki. Ethical approval was granted by an institutional review board (Ethics Approval Committee Lombardia 3, protocol number Lebri-AD-2024).

Patient consent

All patients provided written informed consent.

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