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LETTER TO THE EDITOR

Lebrikizumab for difficult-to-treat atopic dermatitis in a Portuguese cohort

Lebricizumab na dermite atópica difícil de tratar numa coorte Portuguesa

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Dear Editor,

Lebrikizumab is a humanized monoclonal antibody that selectively and with high affinity inhibits interleukin-13, currently approved for moderate-to-severe atopic dermatitis (AD). Although its efficacy and safety were demonstrated in pivotal clinical trials, real-world evidence – particularly in challenging AD populations – is still evolving.[1,2] In Portugal, lebrikizumab prescription is currently restricted to an Early Access Program (EAP), available only to patients who are refractory to, or have contraindications to, at least two conventional systemic immunosuppressants, dupilumab and Janus kinase inhibitors (JAKi) approved for AD (baricitinib, abrocitinib, and upadacitinib). This framework defines a particularly challenging patient subgroup.

We conducted a prospective observational study including all patients treated with lebrikizumab under the EAP and followed at a multidisciplinary AD consultation in a tertiary hospital in Lisbon, Portugal. Objective scores, patient-reported outcomes (PRO), and clinical photographs were collected at weeks 4-6, 12-16, and 20-24. Treatment consisted of subcutaneous injections with an induction dose of 500 mg at weeks 0 and 2, followed by 250 mg every other week (EOW). Injections were spaced every 4 weeks (E4W) at weeks 16 or 24 according to clinical response. All patients provided written informed consent for participation and use of clinical data and images. One breastfeeding patient consented to off-label treatment after being fully informed of potential risks and benefits.

Six adult patients were treated with lebrikizumab; detailed clinical and therapeutic characteristics are summarized in Table 1. Four (67%) were women; the mean age was 41 ± 10.9 years. Five had contraindications to JAKi: three due to a history of malignancy, one with thrombophilia, and one breastfeeding. All patients had previously received dupilumab, which was discontinued due to adverse events or lack/loss of efficacy; one had also been treated with baricitinib and upadacitinib. Baseline Eczema Area and Severity Index (EASI) scores ranged from 2.1 to 36.4 (Fig. 1).

At weeks 4-6, 3/6 (50%) patients achieved EASI-50, 1/6 (17%) achieved EASI-75, and 1/6 (17%) reached an itch numeric rating scale (INRS) score of 0-1. By weeks 20-24, 1/6 (17%) achieved EASI-50, and 2/6 (33%) achieved EASI-75; 1/6 (17%) reached INRS 0-1. The mean percentage reduction in EASI over 24 weeks was 42.1% (with one patient worsening); INRS scores decreased overall by a mean of 37.6%; sleep numeric rating scale scores showed a mean reduction of 82.5%, with complete resolution in most cases; in contrast, dermatology life quality index scores reduced on average by 28.8%. Among four patients with dupilumab-related adverse events, two with head-and-neck dermatitis (HND) and one with inflammatory arthralgias showed partial/complete resolution (Fig. 2).

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Table 1. Detailed clinical and therapeutic history of each patient

S. No.	Gender	Age (years)	Disease duration (years)	Family history	Comorbidities	Previous treatments	Cause of interruption
1	F	51	49	No	Breast cancer, arterial hypertension, pulmonary sarcoidosis	Dupilumab	Adverse event (HND)
2	F	24	23	No	Allergic rhinitis, asthma, allergic conjunctivitis, breastfeeding	Cyclosporine	Loss of efficacy
						Phototherapy	Lack of efficacy
						Methotrexate	Patient decision
						Dupilumab	Adverse event (HND), Loss of efficacy
3	F	51	34	No	Breast cancer, allergic rhinitis	Systemic corticosteroids	Other
						Cyclosporine	Adverse event
						Azathioprine	Lack of efficacy
						Dupilumab	Adverse event (HND)
						Tralokinumab	Lack of efficacy
4	M	32	31	Yes	None relevant	Cyclosporine	Lack of efficacy
						Phototherapy	Loss of efficacy
						Methotrexate	Lack of efficacy
						Dupilumab	Lack of efficacy
						Baricitinib	Loss of efficacy
						Upadacitinib	Adverse event (cytopenia)
5	M	42	40	No	S protein deficiency, filaggrin and FOXP3 mutation, arterial hypertension, smoking, allergic rhinitis, food allergy	Systemic corticosteroids	Loss of efficacy
						Phototherapy	Lack of efficacy
						Methotrexate	Loss of efficacy
						Dupilumab	Loss of efficacy
6	F	46	44	Yes	Malignant melanoma, asthma	Systemic corticosteroids	Loss of efficacy
						Dupilumab	Adverse event (arthralgias), Loss of efficacy

F: female; M: male; HND: head and neck dermatitis.

Patient 3 exhibited a clinical-symptomatic dissociation, with localized head-and-neck eczema but severe PRO scores. No adverse events were reported during treatment. The lactating patient started lebrikizumab shortly after birth and overlapped it with breastfeeding for longer than 6 months; the infant accompanied the mother to all appointments, and potential adverse events were excluded through clinical observation and psychomotor development and growth parameters recorded by the family physician.

We present patients with adverse events or contraindications to innovative systemic therapies who were treated with lebrikizumab. Comparative studies suggest equivalent – or potentially superior – maintenance of efficacy (EASI-75) with lebrikizumab E4W versus dupilumab EOW, with similar adverse-event rates.[3] Considering mechanistic differences and patient heterogeneity, lebrikizumab may represent a valuable option for individuals who failed or experienced limiting adverse events with dupilumab and

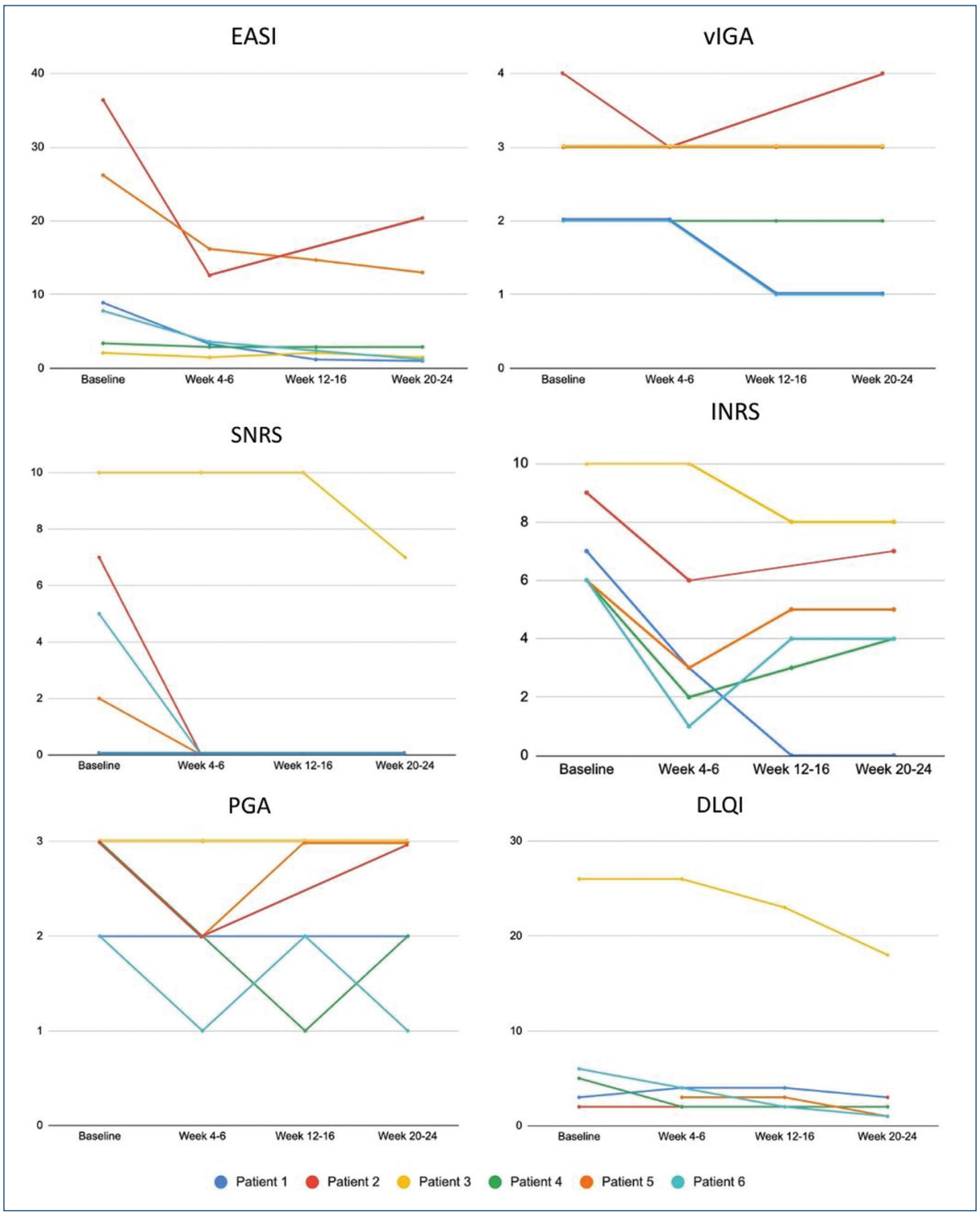


Figure 1. Evolution of objective scores (EASI and vIGA) and patient-related outcomes (SNRS, INRS, PGA, and DLQI) from baseline through to weeks 20-24. EASI: eczema area and severity index; vIGA: validated investigator global assessment; SNRS: sleep numeric rating scale; INRS: itch numeric rating scale; PGA: patient global assessment scale.

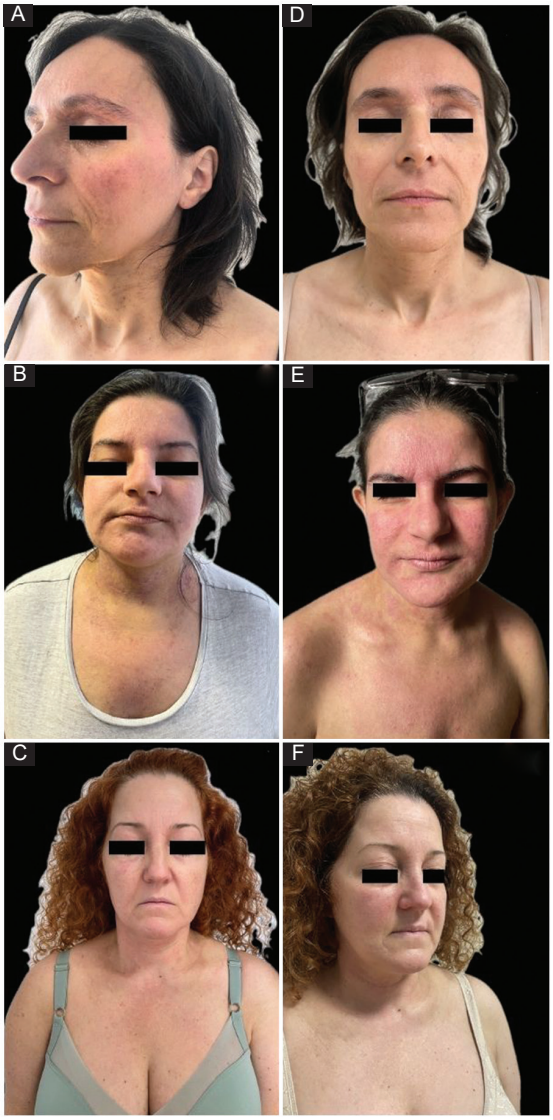


Figure 2. Patients with dupilumab-related head-and-neck dermatitis at baseline (**A, B,** and **C**) and after 24 weeks of treatment with lebrikizumab (**D, E,** and **F**). Patient 1 (**A** and **D**) had a complete resolution of HND; patient 2 (**B** and **E**) showed no improvement in HND; patient 3 (**C** and **F**) had an almost complete resolution of HND but showed a clinical-symptomatic dissociation. HND: head-and-neck dermatitis.

who have contraindications to other drug classes, such as JAKi.[3] In our series, at 20-24 weeks, 4/6 (67%) patients achieved EASI <5 and 5/6 (83%) showed improvement compared with baseline, including those who switched due to adverse events rather than primary or secondary failure.

HND remains a challenging adverse event that may lead to treatment discontinuation.[4] Previous case reports have shown efficacy of lebrikizumab in managing HND, whether induced by dupilumab or not, without reproducing the same adverse event.[5-7] Consistently, 3/4 (75%) patients in our cohort experienced improvement in dupilumab-related adverse manifestations (two with HND; one with arthralgias), whereas AD control was maintained and no safety concerns emerged.

In summary, this case series supports lebrikizumab as a promising biological therapeutic alternative for complex patients with AD, particularly those who are intolerant or contraindicated to other advanced systemic agents.

Conflicts of interest

M.C. Fialho, P. Simões-Farinha, and A. Ferreirinha have no conflicts of interest to declare. B. Duarte has received honoraria as a speaker for Sanofi, Almirall, Pfizer, AbbVie, Leo Pharma, Janssen, Lilly, and Galderma.

Ethical considerations

Protection of human subjects and animals. The authors declare to have followed the ethical standards of the relevant experimentation committee, according to the World Medical Association and the Declaration of Helsinki. The procedures were approved by the institutional Ethics Committee.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from all patients, and secured approval from the Ethics Committee. SAGER guidelines have been followed as applicable to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing or creation of the content of this manuscript.

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