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Real-world effectiveness and safety of dupilumab in children with atopic dermatitis: a Latin American single-center study

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Abstract
Background: Atopic dermatitis (AD) is common in children (affecting ~20% of children globally) and imposes a substantial burden. Many children in Latin America have moderate-to-severe AD with limited access to advanced therapies, highlighting an unmet need for safe and effective treatment options. Dupilumab, a targeted anti-interleukin-4 (IL-4)-IL-13 biologic, has demonstrated efficacy in pediatric AD, but real-world data in Latin American children are scarce.
Methods: We conducted a single-center retrospective observational study in Mexico City with children (aged 4-18 years) with moderate-to-severe AD treated with dupilumab from 2018 to 2024. Clinical outcomes (Eczema Area and Severity Index; Scoring Atopic Dermatitis [SCORAD], and pruritus Numerical Rating Scale [NRS]) and quality-of-life (Dermatology Life Quality Index) were assessed at baseline and ~3, ~6, and ~12 months. Changes over time were analyzed using nonparametric tests, and adverse events were documented.
Results: In all, 23 children (~50% female) with severe, treatment-refractory AD were included. Dupilumab led to rapid and significant improvement in all endpoints ($P < 0.001$). In 12 months, most patients achieved clear or almost clear skin with no pruritus (median SCORAD and itch NRS = 0), and quality-of-life scores improved from a median of 19 to 3. No serious adverse events occurred; mild conjunctivitis was reported in 13% patients (with one discontinuation).
Conclusion: In this Latin American pediatric cohort, dupilumab achieved marked and sustained improvements in disease severity and quality of life, with a favorable safety profile. This real-world study addresses a regional evidence gap and supports dupilumab as an effective and well-tolerated treatment for moderate-to-severe pediatric AD.

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Introduction

Atopic dermatitis (AD) is a common chronic inflammatory skin disease of childhood, affecting up to 20% of children globally.[1,2] In most cases, it begins in early life and follows a relapsing course that profoundly impairs quality of life (QoL). AD imposes a high burden on patients as well as families, and is ranked among the leading causes of non-fatal disease burden globally.[3,4] Children with AD suffer intense pruritus, sleep disturbance, and psychosocial stress, and they often have coexisting atopic conditions, such as asthma and allergic rhinitis[4,5] and chronic non-atopic conditions.[6] In Latin America, the prevalence of pediatric AD is similarly high—reported up to 20% in some populations,[7,8] and many patients experience acute preponderance with substantial unmet needs in care.[8] Socioeconomic disparities and limited access to specialist treatments in this region further contribute to the burden of AD.[8,9]

First-line therapy for AD focuses on skin-directed treatments (regular emollient use and topical anti-inflammatories) and trigger avoidance. However, often, moderate-to-severe AD cannot be controlled with topical therapy alone. In such cases, conventional systemic immunosuppressants—for example, cyclosporine, methotrexate, or systemic corticosteroids—are used, but these treatments are frequently off-label in children and carry significant safety limitations.[10-13]

Long-term use of systemic corticosteroids is generally discouraged due to potential adverse effects on growth and metabolism, and other immunosuppressants require close monitoring for toxicity.[9,10] As a result, there has been a longstanding therapeutic gap for pediatric AD patients with inadequately controlled acute disease. Recent international guidelines and consensus score the need for safer targeted therapies in this population.[3,12,14,15]

Dupilumab, a fully human monoclonal antibody against the interleukin-4 (IL-4) receptor alpha, has emerged as a novel targeted therapy addressing this unmet need. By inhibiting IL-4 and IL-13 signaling, dupilumab tackles key drivers of type 2 inflammation in AD. Clinical trials in adults first demonstrated that dupilumab significantly lessens severity of eczema, pruritus, and improves QoL, compared to placebo.[16] Subsequently, a pivotal phase III trial in adolescents (aged 12–17 years) showed marked efficacy of dupilumab monotherapy, with significant increase in skin clearance and patient-reported outcomes, beside an acceptable safety profile.[17,18] More recently, dupilumab was evaluated in younger children. In a randomized trial of children aged <12 years (including infants and preschool-aged patients), dupilumab produced rapid and sustained improvement in AD manifestations, with no new safety concerns.[19] These studies led to regulatory approval of dupilumab for pediatric AD, expanding the therapeutic arsenal for moderate-to-severe disease in children.[3,12,20,21]

Real-world evidence on dupilumab in pediatric AD is now emerging, although data from Latin America remain scarce. Differences in genetics, environment, and healthcare infrastructure underscore the importance of regional studies. Here we report a Latin-American, single-center experience on the effectiveness and safety of dupilumab in children with AD. This study aims to provide much-needed real-world insight into the outcomes of this biologic in a pediatric population, helping to inform clinical practice in the context of our region's unique challenges and patient needs.

Material and Methods

We performed a retrospective observational study of children aged 4–18 years with moderate-to-severe AD who received dupilumab at a specialized referral center in Mexico City. Data were collected over a 4-year period (January 2018–July 2024). Patients received dupilumab as part of their routine care if they had moderate-to-severe AD with an Eczema Area and Severity Index (EASI) score of ≥16. EASI, Scoring Atopic Dermatitis (SCORAD), Dermatology Life Quality Index (DLQI), and pruritus Numerical Rating Scale (NRS) scores were used to assess severity of clinical AD and its impact on QoL. Data were collected prior to starting dupilumab, then at 2–5 months, 6–9 months, and at 10–14 months (median 12 months). Demographic data (age, gender, etc.), clinical course of AD, previous use of systemic immunosuppressants, other atopic diseases, duration on dupilumab, adverse effects, and reasons for discontinuation were also recorded.

Statistical analysis

Statistical analysis was performed using SPSS (version 25.0). Continuous variables were assessed for normality using the Shapiro–Wilk test and summarized as medians with interquartile ranges (IQR). Given the non-parametric distribution and repeated measures design, differences in clinical scores (SCORAD, EASI, DLQI, and pruritus NRS) across baseline, 2–5 months, 6–9 months, and 10–52 months were evaluated using the Friedman test. *Post hoc* pair-wise comparisons were conducted using the Wilcoxon signed-rank test with Bonferroni correction for multiple testing. Categorical variables, including adverse events, were reported as frequencies and proportions. Differences in proportions were assessed using the Chi-squared or Fisher's exact test as appropriate. A two-tailed $P < 0.05$ was considered statistically significant.

Results

In all, 25 children were prescribed dupilumab at our tertiary pediatric AD referral center; of these, 2 were excluded due to lack of follow-up data, leaving 23 patients for analysis. Among the 23 included patients, the median follow-up on dupilumab was 24 months (range 3–51 months). In all, 14 patients (60%) discontinued dupilumab during the study period. In half of these cases, discontinuation was due to disease remission; one patient (4%) stopped due to lack of response, and one due to severe conjunctivitis (Figure 1). The median age at onset of AD in the study cohort was 6 years (range: 8–137 months). Of the 23 included patients, 12 (52%) were females; 2 (8%) were Canadian (Table 1). Altogether, 19 patients (82%) had at least one other type 2 inflammatory disease (e.g., asthma, allergic rhinitis, etc.). The median baseline EASI, SCORAD, and pruritus NRS

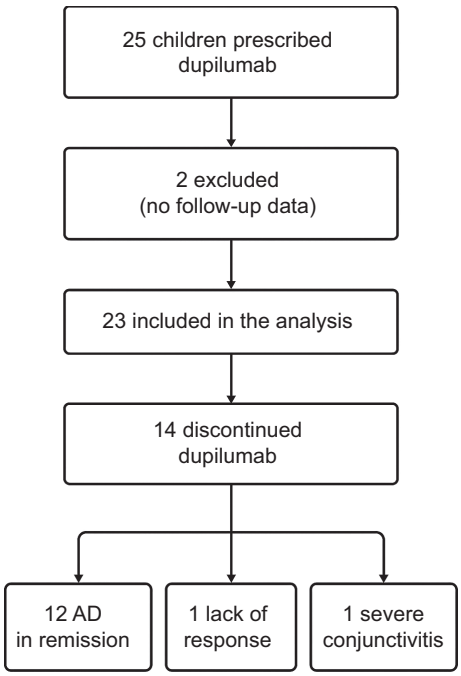

Figure 1 Flow chart of recruitment of patients.

Table 1 Demographics and atopic comorbidities.

Characteristic	n (%)
Number of patients	23
Age of AD onset (months), IQR (range)	72 (8-137)
Asthma	19 (82%)
Allergic rhinitis	20 (87%)
Food allergies	11 (48%)
Previously treated with at least one systemic immunosuppressant	23 (100%)

Notes: IQR: interquartile range; AD: atopic dermatitis.
All data are presented as n (%) unless otherwise stated.

scores were 27 (IQR: 20–31), 63 (IQR: 55–79), and 8 (IQR: 6–9), respectively, confirming moderate-to-severe AD in all children. The median DLQI was 19 (IQR: 15–22), indicating a "very large" impact on the patient's life. All 23 patients (100%) had previously been prescribed one or more oral systemic immunosuppressants (azathioprine or ciclosporin); 88% had an inadequate response and 12% experienced an AD flare upon discontinuing these medications.

Efficacy of dupilumab

Patients were followed for a median of 24 months (IQR: 11–28). All skin and QoL scores decreased from baseline to 2–5 months, 6–9 months, and 10–14 months of treatment (Table 2; Figure 2). Within 2–5 months, median EASI scores decreased to the levels consistent with mild AD (EASI 2 [IQR: 1–3]), while SCORAD scores decreased to a moderate

Table 2 Clinical scores at baseline, 2–5 months, 6–9 months, and 10–12 months after starting dupilumab.

Time point	SCORAD	EASI	DLQI	Pruritus NRS
Baseline	63 (55-79)	27 (20-31)	19 (15-22)	8 (6-9)
2-5 months	30 (10-41)	6 (3-12)	3 (2-7)	5 (4-6)
6-9 months	19 (11-26)	2 (1-3)	2 (1-4)	3 (2-4)
10-12 months	0 (0-2)	0 (0-1)	3 (1-5)	0 (0-1)

Notes: DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; NRS: Numerical Rating Scale; SCORAD: Scoring Atopic Dermatitis.
Data are presented as median (IQR).

range (SCORAD 30 [IQR: 10–41]). By 6–9 months, all median skin scores indicated mild disease, and by 10–14 months, median SCORAD and pruritus NRS were 0, indicating no visible AD and no reported itching. Median DLQI was 3 (IQR: 1–5), indicating a "small" effect on the patient's life. Table 3 summarizes percentage reduction in skin scores over time. During the initial 2–5 months, the largest decline in median scores was observed in EASI, DLQI, and SCORAD (reduction of 50%, 80%, and 56%, respectively). Pruritus NRS decreased by 33% at 2–5 months, by 60% at 6–9 months, and by 80% at 10 months. The greatest overall amelioration from baseline to the latest follow-up was in EASI, with a median reduction of 94%. There was no significant difference in the extent of amelioration in EASI or DLQI scores between male and female patients.

Reasons for discontinuation of treatment

Of the 23 patients, 14 (60%) discontinued dupilumab during the study period. Seven patients (30%) discontinued due to sustained disease remission, reporting complete clearing of their AD with no impact on daily life; none of these patients needed to restart the biologic during follow-up. One patient (4%) discontinued due to ongoing AD flares, and another discontinued due to severe conjunctivitis.

Adverse events

While receiving dupilumab, 20 of the 23 patients (87%) did not report any adverse event. The most common adverse reaction was conjunctivitis, noted in three patients (13%) (Table 4). Patients who developed conjunctivitis were referred to an ophthalmologist for management. In one acute case, characterized by marked conjunctival chemosis, dupilumab was discontinued and the eye condition resolved. In other patients with milder conjunctivitis, avoiding moisturizer application near the eyes reduced irritation and enabled continued dupilumab treatment. In all, 10 patients (43%) experienced injection site reactions. No significant difference was observed in the frequency of adverse events between males and females.

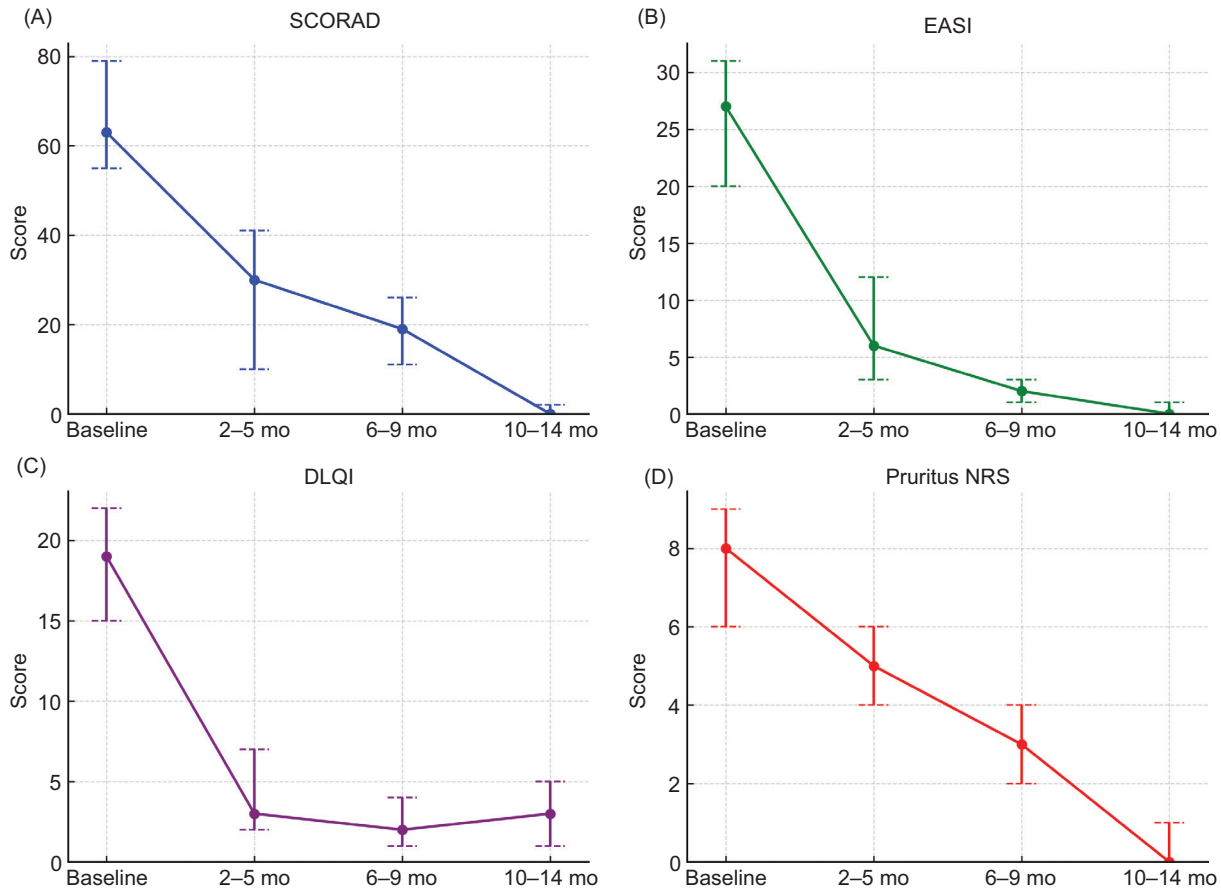

Figure 2 Improvement to skin scores and quality of life (QoL) with dupilumab.

Table 3 Percentage reduction in clinical scores from baseline to 2-5 months, 6-9 months, and 10-52 months of treatment with dupilumab.

Time point	SCORAD	SCORAD (IQR)	EASI	EASI (IQR)	DLQI	DLQI (IQR)	Pruritus NRS	Pruritus NRS (IQR)
2-5 months	52%	30 (10-41)	78%	6 (3-12)	84%	3 (2-7)	38%	5 (4-6)
6-9 months	70%	19 (11-26)	93%	2 (1-3)	89%	2 (1-4)	62%	3 (2-4)
10-52 months	100%	0 (0-2)	100%	0 (0-1)	84%	3 (1-5)	100%	0 (0-1)

Notes: DLQI: Dermatology Life Quality Index; EASI: Eczema Area and Severity Index; NRS: Numerical Rating Scale; SCORAD: Scoring Atopic Dermatitis.
Data are presented as median (IQR).

Table 4 Adverse events reported during dupilumab treatment.

Adverse event	n (%)
No adverse events	20 (87%)
Conjunctivitis	3 (13%)
Injection site reactions	10 (43%)
Severe conjunctivitis (required discontinuation)	1 (4%)

Note: Values are presented as number, n (%), of patients with adverse events.

Discussion

Our single-center, real-world study demonstrates that dupilumab therapy yields marked and sustained improvements in disease severity and QoL in Latin American children with moderate-to-severe atopic dermatitis.[9] Over a 10-14-month follow-up, patients achieved substantial reduction in clinical severity scores (EASI and SCORAD) beside improvement in patient-reported outcomes (itch NRS and DLQI). These gains were not only statistically significant but also relevant clinically. For instance, the mean itch NRS reduction in our cohort exceeded the 4-point threshold often used

to define a meaningful improvement.[22] Lessening in AD extent and severity translated into dramatically lower disease activity by 1 year, highlighting dupilumab's potential to induce disease control or even remission in a population with previously uncontrolled eczema. Importantly, these benefits were accompanied by a favorable safety profile. No new safety signals emerged in our pediatric patients, and adverse events were generally mild. The most common issue was conjunctivitis in a minority of patients—an expected adverse effect consistent with dupilumab's known safety spectrum.[23,24] Notably, our real-world findings aligned with the drug's clinical trial data and other observational studies, underscoring that dupilumab effectively targets the type 2 inflammation driving pediatric AD and thereby lessens both objective severity and subjective QoL.

Our results are in line with emerging real-world evidence from other regions, confirming that the clinical efficacy of dupilumab in children is robust across diverse populations. In a recent UK retrospective study of 72 children and adolescents on dupilumab, median EASI scores dropped by 94% from baseline (25 to 2) after long-term treatment, with 11% of patients achieving complete remission of therapy.[23] Similarly, a Chinese pediatric cohort (mean age 7 years) reported that 89.5% of patients achieved clear or almost-clear skin (Validated Investigator Global Assessment for atopic dermatitis [vIGA] 0/1) by week 24, beside significant ameliorations in EASI, SCORAD, itch NRS, and CDLQI that had sustained through 40 weeks.[25] These real-world outcomes mirror those observed in clinical trials across Europe, North America, and Asia. Pivotal randomized trials in children have shown dupilumab, combined with topical therapy, can achieve EASI-75 in roughly 67–70% of patients and a ≥4-point improvement in itch in more than 50% patients by week 16, far surpassing placebo.[22] By 1 year of continuous therapy, even higher response rates were attainable, as evidenced by global registries. For example, the international Pediatric observational study (an interim 2-year analysis) found that children aged <12 years on dupilumab had significantly greater amelioration in EASI and pruritus scores than those on methotrexate or cyclosporine, with a mean EASI reduction of 12.4 points from baseline and superior itch relief (daytime NRS reduction ~1.5 points).[26] In this cited study, dupilumab also had higher drug survival and fewer discontinuations because of adverse events (8% vs. 29–43% with conventional immunosuppressants).[26] Taken together, our data and these comparative findings reaffirm that dupilumab provides rapid, meaningful, and durable disease control in pediatric AD, consistently reducing disease severity and itch to mild levels or even better.

The concordance between our Latin American outcomes and those from Europe, Asia, and North America suggests that the biologic's efficacy is not region-specific but rather reflects a fundamental modulation of AD inflammatory pathways. Such consistency is reassuring, indicating that children in Latin America can expect lessening, comparable to their counterparts in regions where dupilumab is used more widely.[27] Several factors contribute to this disparity. Economic and healthcare system constraints in Latin America mean that biologics are often not reimbursed or widely available in the public sector, forcing many families to pay out-of-pocket.[28] Dupilumab has only recently become available in some Latin American countries, and in many it was initially approved only for adults and adolescents; as of 2020, only a few countries (e.g., Mexico and Brazil) had extended approval to children aged <12 years.[9] Even in countries where the drug is approved, its high cost and requirement of specialist prescription limit its reach to a fraction of eligible pediatric patients. Indeed, real-world analyses indicate that the uptake of dupilumab in Latin America lags far behind that in North America or Europe, reflecting an ongoing therapeutic gap.[27,28] In most Latin American nations, healthcare systems mandate objective severity scores (e.g., EASI) to authorize biologic use, yet many physicians in the region are not formally trained in these measures, creating additional barriers to access.[27] Consequently, many children with severe AD in the region remain undertreated, with a high disease burden and poor QoL prior to the advent of biologic therapy. Our study helps to bridge this knowledge and evidence gap. It provides much-needed Latin American data showing that dupilumab can dramatically ameliorate disease outcomes and daily functioning in children who previously had limited therapeutic options. This finding has important implications for the region: it supports advocacy for better access to advanced therapies and could inform local guidelines and health policy. By demonstrating that Latin American pediatric patients achieve similar benefits from dupilumab as reported in other populations, we underscore that the drug can significantly lessen the disease burden in this region's context.

Finally, the novelty and importance of generating Latin American real-world evidence cannot be overstated. Prior to this report, virtually all pediatric AD biologic data were from North America, Europe, and Asia.[28] Our study represents the largest real-life study in all Latin America published so far and is among the first to specifically evaluate dupilumab in Latin American children with moderate-to-severe AD, and it confirms that the global trial and real-world experience translate effectively to our local setting. This real-world evidence from a Latin American center adds valuable diversity to the literature, highlighting that while the pathophysiology of AD, as well as dupilumab's mechanism, is consistent globally, regional factors (such as access to treatment) influence outcomes. Bridging such gaps with local data is a key to reducing health disparities. In summary, dupilumab proved to be an effective and safe treatment in our pediatric patients, yielding significant ameliorations in clinical severity and QoL over 10–14 months of follow-up. These findings align with international data and illustrate the profound clinical relevance of dupilumab in controlling pediatric AD. Our work thus fills a regional evidence gap and supports the premise that improving access to dupilumab could substantially reduce disease burden and fulfill unmet therapeutic needs among children with severe eczema in Latin America.

Conclusion

In this real-world Latin American cohort, dupilumab demonstrated substantial and sustained efficacy in children

with moderate-to-severe atopic dermatitis, with marked amelioration in both objective and patient-reported outcomes. Therapeutic benefits were rapid and durable, with clinical ameliorations maintained through extended follow-up. Dupilumab was also well-tolerated in this population. The Latin American real-world context of this study is especially important, as regional data on biologic therapy in pediatric AD are scarce, and our findings confirmed that the profound efficacy and safety of dupilumab observed in trials translate to everyday practice in this setting. They also support a call to action for larger multicenter studies with long-term follow-up in Latin American pediatric populations to reinforce these findings and guide equitable implementation of advanced therapies.

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Ethical Statement

The Institutional Ethics Committee indicated that ethical approval was not required, as the study was part of a service evaluation of standard clinical practice, and data were anonymized for the purpose of this evaluation that summarized routine clinical care for children with moderate-to-severe AD at our center. The study followed the guidelines and principles of the Declaration of Helsinki.

Mandatory Disclosure on Use of Artificial Intelligence

The authors declare that AI-assisted tools were used as follows: ChatGPT (OpenAI), for language editing purposes only (grammar, spelling, and stylistic refinement). The tool did not contribute to study design, data analysis, or scientific interpretation. All references have been manually verified for accuracy and relevance.

Author Contributions

Victor Gonzalez-Uribe: conceptualization, data curation, methodology, investigation, resources, validation, writing of original draft, writing—review & editing, visualization, project administration. Hector Rodrigo Pastrana-Ayala: conceptualization, formal analysis, methodology, validation, writing of original draft, writing—review & editing, visualization. Luis Angel Hernandez-Zarate: conceptualization, formal analysis, methodology, validation, writing of original draft, writing—review & editing, visualization. Carlos Andres Gomez-Nuñez: conceptualization, formal analysis, methodology, validation, visualization, writing—review & editing. Ricardo Martinez-Tenopala: data curation, formal analysis, investigation, project administration, resources, writing of original draft, writing—review & editing. Tamara Hernandez-Hernandez: conceptualization, formal analysis, methodology, validation, visualization, writing—review & editing. Maria Julia Rendon-Salazar: formal analysis, data curation, investigation, project administration, resources, writing of original draft, writing—review & editing. Zaira Selene Mojica-Gonzalez: conceptualization, formal analysis, methodology, validation, writing of original draft, writing—review & editing, visualization.

Conflict of Interest

Victor Gonzalez-Uribe served on the advisory board, received support for continuing medical education and has lectured for AbbVie, Pfizer and Sanofi. Hector Rodrigo Pastrana-Ayala has served on the advisory board and received support for continuing medical education from Galderma, Lilly, AbbVie, Pfizer, and Sanofi. The remaining authors declare no potential conflict of interest with respect to research, authorship, and/or publication of this study.

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