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Baricitinib for atopic dermatitis in real life: effectiveness, safety profile, and adherence

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To the Editor,

in the last decade new molecules has been offered for the treatment of severe atopic dermatitis (1, 2). Baricitinib has proved its efficacy in different clinical trials (2), but there is lacking information in real life (3, 4) and little has been studied on aspects such as adherence, tolerance, and the time needed to evaluate the clinical response before considering continuing or changing therapy. In this study we present new information in real life about baricitinib in atopic dermatitis.

Twenty-seven patients from two different centers were included and follow-up for one year. The ethics committee of the “Alma Mater de Antioquia” Hospital gave its approval for this study (pro-

tolocol IN41-2022). In the first six months, a bimonthly follow-up was carried out to evaluate the response to therapy and adherence to treatment. At the beginning of the second semester, based in clinical control, patients continued or not with baricitinib, and follow-ups were carried out every 3 months. Due to local regulations, all patients who received baricitinib were over 18 years of age, had previously received at least one immunosuppressant without adequate clinical response or with serious adverse events, and had an Atopic Dermatitis score (SCORAD) greater than 20 points. Clinical response was defined as SCORAD $\leq$ 14 points and a change from baseline of one minimum clinically important difference of the SCORAD ($\geq$ 9 points). Recruited patients with SCORAD less than 30 points had to have an Atopic Der-

matitis Control Test (ADCT) greater than 12 points and Dermatology Life Quality Index (DLQI) over 15 points. All patients received the same dose of Baricitinib: 4 mg/day. In those patients who did not achieve clinical response after six months, baricitinib was discontinued.

Table I presents the characteristics of the patients as well as the clinical changes during the first six months. A total of 14 mild adverse events were presented in 8 patients with a median duration of 14 days and none of them suspend the therapy. Thirteen (48.1%) of the patients achieved clinical control in all the scales used (DLQI, ADCT, SCORAD); clinical control was achieved in the first 2 months in 12 of the 13 patients. Among them, none experienced moderate or severe relapse during the one-year follow-up (**figure 1A**); additional 3 patients achieved pruritus control but low change in eczema extension and severity; 11 patients did not show improvement after six months with baricitinib, so it was suspended. No severe effects were reported. Adherence to treatment was calculated according to the number of days with

treatment *versus* number of days not taking it and expressed as a percentage $[(\text{Days treatment taken} / \text{total treatment days prescribed}) \times 100]$. The median adherence was 86.7% and it was not significantly different between patients who had clinical response and patients without it.

When comparing the characteristics of patients who had clinical control *versus* those who did not have clinical control, we observed that those with a clinical response had a lower SCORAD at the beginning of the treatment (**figure 1B**). Other factors were not associated with differences in clinical response.

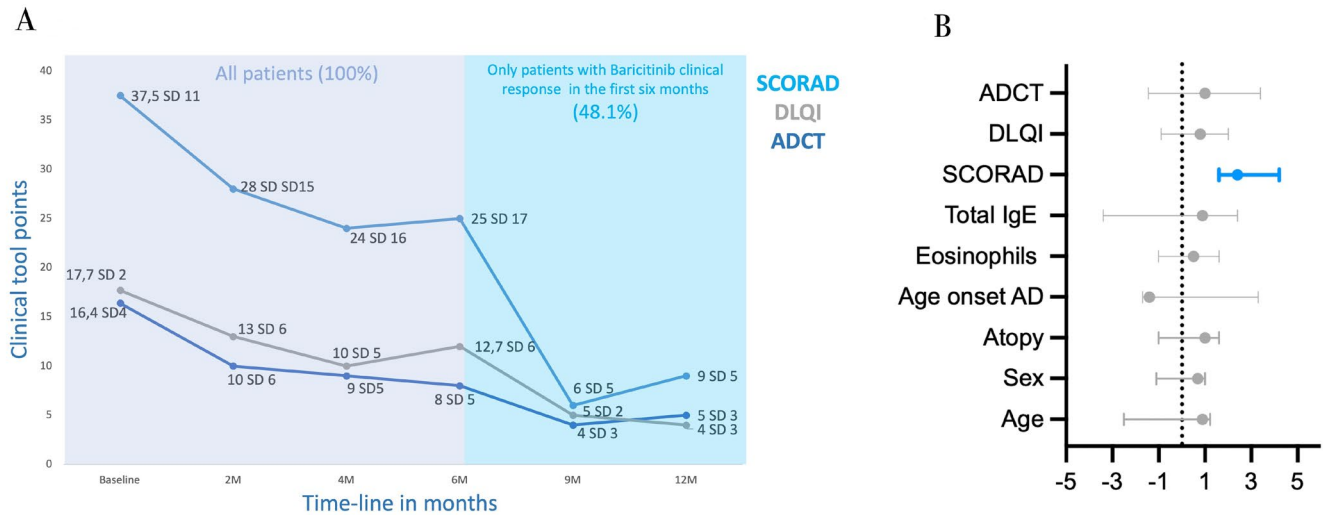
For some national health systems baricitinib is less expensive than other JAK-inhibitors or biologics. In our study, less than 50% of patients achieved an adequate response to treatment with Baricitinib but among these patients, control was nearly complete and in least than two months which is enough time to evaluate the clinical response.

According to our results, in general, adherence was high, perhaps due to the Hawthorne effect (5). Different factors affect adher-

Table I - General characteristics.

Characteristics	Baseline	After six months
Age (mean, SD)	30.19 (9.14)	30.69 (9.75)
Male sex		14 (51.9%)
Atopy		27 (100%)
AD onset in years (mean, SD)		3.3 (1.4)
Eosinophils (mean, SD)	262 (302)	234 (332)
Total IgE (mean, SD)	536 (53)	539 (58)
DLQI (mean, SD)	17.7 (2.9)	12.7 (6.48) *
DLQI ≤ 6 points	0	13
ADCT (mean, SD)	16.4 (4.6)	8.89 (5.98) *
ADCT ≤ 6 points	0	13
Pruritus	8 (3.4)	5 (2.3) *
SCORAD (mean, SD)	37.5 (11.71)	25 (17.2) *
Patients SCORAD ≤ 20 points	0	13
Patients SCORAD75%	N/A	13
Patients SCORAD90%	N/A	10
Adverse events	N/A	14
Severe	N/A	0
Gastrointestinal	N/A	4
Respiratory infections	N/A	6
Other	N/A	4

Clinical and sociodemographic characteristics of patients before and after six months with baricitinib. Atopy was defined as one positive specific IgE. Pruritus was defined according to a subjective scale from 0 (no pruritus) to 10 (intense pruritus). SCORAD: Score atopic dermatitis; DLQI: Dermatology life quality index; ADCT: Atopic dermatitis control tests; N/A: No apply. *p < 0.05.

Figure 1 - Clinical response to Baricitinib and factors associated.

(A) Score obtained according to the SCORAD (Score atopic dermatitis), DLQI (Dermatology life quality index), and ADCT (Atopic dermatitis control test) scales. In the first six months, follow-up is presented for all patients (n = 27) but from month 6 onwards, only those who had clinical control with Baricitinib are presented; **(B)** Exploration of the variables associated with clinical control with Baricitinib according to odds ratio.

ence such as patient education, support systems, and socio-economic status. In our study, none of these factors seemed to be associated with adherence failures, perhaps because the health system in Colombia covers the full cost of the therapy. However, 5 of the 13 patients who had clinical control forgot sometimes to take the medication, indicating that treatment tolerates some interruptions. AD has a major impact on mental health, unfortunately we did not assess this aspect in the study. Including additional measures to evaluate the psychological and emotional well-being of patients would provide a more holistic assessment of the treatment's effects. Finally, as an exploratory analysis, we observed that the most appropriate profile to start baricitinib therapy are patients with SCORAD lower than 40 points. Although severe skin pruritus is one of the most important clinical targets of JAK-inhibitors, it did not appear to be a determining factor to predict clinical response with baricitinib.

In conclusion, this study provides valuable insights into the use of baricitinib for severe atopic dermatitis. While the findings are promising, such as the rapid clinical response and good adherence, significant limitations, including no control group, a small sample size, and lack of long-term data, should be noted. Future research should focus on larger, more diverse populations and include detailed analyses of cost-effectiveness and long-term outcomes. This study lays the foundation for understanding the

potential role of baricitinib in treating severe atopic dermatitis and emphasizes the need for ongoing investigation.

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Contributions

JS: conceptualization. MV, MFO: writing – original draft, writing – review & editing, investigation, formal analysis.

Conflict of interests

JS, MV, and MFO have been advisors and speakers for Lilly, Pfizer, Sanofi, and Abbvie laboratories. The conflict of interests are not related to this work.

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