SHORT COMMUNICATION

Effectiveness of Baricitinib in Treating Atopic Dermatitis in Difficult-to-treat Areas: A Retrospective Real-world Study

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Atopic dermatitis (AD) is a chronic inflammatory skin disease associated with pruritus, sleep disturbance and impaired quality of life (QoL) (1). Involvement of difficult-to-treat areas, including the head and neck, hands and/or feet, scalp and genital/perianal region, may cause a disproportionate burden because of visibility, functional impairment, sensitivity of the affected sites and limited tolerability of long-term topical treatments (2). Baricitinib, an oral Janus kinase 1/2 inhibitor, has demonstrated efficacy in moderate-to-severe AD (3). However, real-world data focusing on difficult-to-treat areas remain limited (4). We aimed to describe global, regional and patient-reported outcomes (PROs) in adults with AD involving difficult-to-treat areas treated with baricitinib in routine clinical practice.

MATERIALS, METHODS AND RESULTS

This multicentre, observational, retrospective real-world study included adult patients (≥18 years) with dermatologist-confirmed moderate-to-severe AD involving at least one difficult-to-treat area (head and neck, hands and/or feet, scalp and genital/perianal region) and treated with baricitinib.

Baricitinib was administered at 4 or 2 mg once daily according to approved indications, patient characteristics and Italian Medicines Agency reimbursement criteria. Concomitant emollients and topical anti-inflammatory therapies for flares were allowed.

Clinical and PROs were collected at baseline and during follow-up visits at weeks (W) 4, 16, 24 and 52. Global disease severity was assessed using EASI, pruritus using P-NRS, sleep disturbance using S-NRS, QoL using DLQI, and sexual health using SDI-2. Severity of difficult-to-treat areas was assessed using site-specific EASI-derived subscores (sub-EASI).

Global clinical response was defined as EASI50 and EASI75, and regional response as a ≥50% reduction from baseline in the corresponding site-specific sub-EASI score at W16. Safety data were collected from clinical records. Continuous variables were reported as mean±standard deviation (SD), and categorical variables as number and percentage. Changes from baseline were assessed using paired statistical tests, as appropriate. Analyses were performed as observed, with no imputation for missing data; $p<0.05$ was considered statistically significant.

Fifty patients were included. During follow-up, three patients (6.0%) were lost to follow-up after achieving sustained clinical improvement: 1 by W24 and 2 additional patients by W52. No treatment discontinuations occurred due to lack of efficacy or safety concerns. Baseline demographic and clinical characteristics are summarized in **Table I**. Mean age was 41.2±13.5 years, 27 patients (54.0%) were female and mean disease duration was 14.7±7.8 years. The most frequently involved difficult-to-treat areas were the head and neck (30/50, 60.0%) and hands and/or feet (26/50, 52.0%), followed by the scalp (14/50, 28.0%) and genital/perianal region (9/50, 18.0%).

Changes from baseline were statistically significant at all follow-up visits for the reported outcomes ($p<0.05$; **Table II**).

Sub-EASI scores decreased across all evaluated difficult-to-treat areas (**Table III**).

At W4, EASI50 and EASI75 were achieved by 15/50 (30.0%) and 5/50 (10.0%) patients, respectively.

Table I. Baseline demographic and clinical characteristics of the study population

Characteristic	Value
Patients, *n*	50
Age, years, mean±SD	41.2±13.5
Sex, *n* (%)	
Female	27 (54.0)
Male	23 (46.0)
Body mass index (BMI), kg/m², mean±SD	25.3±4.1
Disease duration, years, mean±SD	14.7±7.8
Family history of atopy, *n* (%)	27 (54.0)
At least one atopic comorbidity, *n* (%)	22 (44.0)
Asthma	11 (22.0)
Allergic rhinitis	10 (20.0)
Food allergy	5 (10.0)
Involved difficult-to-treat areas, *n* (%)	
Head and neck	30 (60.0)
Hands and/or feet	26 (52.0)
Scalp	14 (28.0)
Genital/perianal area	9 (18.0)
Previous treatments, *n* (%)	
Topical corticosteroids	50 (100)
Topical calcineurin inhibitors	21 (42.0)
Systemic corticosteroids	11 (22.0)
Cyclosporine	10 (20.0)
Dupilumab	9 (18.0)
Baricitinib starting dose, *n* (%)	
4 mg once daily	44 (88.0)
2 mg once daily	6 (12.0)

Table II. Global clinical and patient-reported outcomes over time

Outcome	Baseline (*n*=50)	Week 4 (*n*=50)	Week 16 (*n*=50)	Week 24 (*n*=49)	Week 52 (*n*=47)
EASI	18.5±7.5	12.8±6.9 (−30.8%)	8.6±6.1 (−53.5%)	6.9±5.4 (−62.7%)	5.8±5.0 (−68.6%)
Pruritus NRS (P-NRS)	8.6±1.2	3.8±1.8 (−55.8%)	2.3±1.5 (−73.3%)	2.0±1.4 (−76.7%)	1.8±1.3 (−79.1%)
Sleep NRS (S-NRS)	8.3±1.4	4.0±1.7 (−51.8%)	2.6±1.5 (−68.7%)	2.2±1.4 (−73.5%)	1.9±1.3 (−77.1%)
DLQI	16.0±5.0	9.6±4.5 (−40.0%)	6.3±4.1 (−60.6%)	5.0±3.9 (−68.7%)	4.1±3.6 (−74.4%)
SDI-2	22.3±10.7	36.1±11.5 (+61.9%)	57.0±9.5 (+155.6%)	63.0±7.7 (+182.9%)	76.0±8.5 (+240.8%)

Data are presented as mean±SD (as observed). Percentage change refers to variation from baseline. SDI-2 was analysed as an exploratory patient-reported outcome. Changes from baseline were statistically significant at all follow-up visits for all reported outcomes ($p<0.05$).

Response rates increased over time: at W16, 29/50 (58.0%) achieved EASI50 and 14/50 (28.0%) achieved EASI75; at W24, 33/49 (67.3%) and 18/49 (36.7%) patients achieved EASI50 and EASI75, respectively; and at W52, the corresponding rates were 36/47 (76.6%) and 20/47 (42.6%). At W16, ≥50% regional response was observed in 17/30 patients (56.7%) with head and neck involvement, 14/26 (53.8%) with hands and/or feet involvement, 9/14 (64.3%) with scalp involvement and 6/9 (66.7%) with genital/perianal involvement. The latter result should be interpreted descriptively because of the small subgroup size. Adverse events (AEs) were reported in 6/50 patients (12.0%) and included hypercholesterolaemia in 3 patients (6.0%), acne in 2 (4.0%) and herpes zoster in 1 (2.0%), which was managed without hospitalization. No major adverse cardiovascular events, venous thromboembolism, serious infections, or treatment discontinuations due to AEs were recorded.

DISCUSSION

In our study, baricitinib treatment was associated with improvement in global disease severity, pruritus, sleep disturbance, QoL and regional disease involvement in patients with AD affecting difficult-to-treat areas. These findings are consistent with clinical trial and real-world evidence (2–6). However, most available data focus primarily on global severity measures, whereas regional outcomes in anatomically or functionally challenging areas remain less frequently reported (2). Difficult-to-treat areas may cause a disproportionate burden because of visibility, functional impairment, sensitivity of the affected sites and limited tolerability of long-term topical treatments (2, 7–9). In this context, the observed reduction in site-specific sub-EASI scores provides clinically relevant real-world information. The hands and/or feet findings are clinically relevant because these sites are associated with functional limitation (8). The genital/perianal involvement is usually underassessed (10, 11); in this context, our SDI-2 data seem to suggest that sexual well-being may deserve greater attention in AD assessment. However, as this subgroup included only 9 patients, the corresponding regional response should be considered purely descriptive. Furthermore, sexual desire may be influenced by multiple disease-related and non-disease-related factors, and no validated minimal clinically important difference for SDI-2 is currently available in patients with AD. Therefore, SDI-2 results should be regarded as exploratory and hypothesis-generating.

This study has limitations. Its retrospective observational design and absence of a comparator group limit causal inference and prevent direct comparison with other systemic therapies or the natural course of disease. In addition, the sample size was relatively small, particularly for some anatomical subgroups, and site-specific sub-EASI scores were EASI-derived descriptive measures rather than independently validated regional indices. Analyses were performed as observed; however, all patients lost to follow-up had achieved clinical remission, suggesting that week-52 completers may represent a slightly more refractory subgroup and that long-term response may have been conservatively estimated. Despite these limitations, the 52 week follow-up, multicentre setting, assessment of regional disease severity and inclusion of safety data support the clinical relevance of these findings.

In conclusion, our real-world data suggest that baricitinib treatment is associated with improvement in global, regional and patient-reported outcomes in AD involving difficult-to-treat areas. Further prospective controlled studies are needed to confirm these findings and better define patient-centred outcomes in this setting.

Table III. Regional outcomes in difficult-to-treat areas during baricitinib treatment

Difficult-to-treat area	Baseline sub-EASI	Week 16 sub-EASI	Week 52 sub-EASI	Regional response at Week 16*, *n* (%)
Head and neck (*n*=30)	4.5±2.5	2.1±2.0	1.4±1.8	17/30 (56.7)
Hands and/or feet (*n*=26)	3.6±2.2	1.7±1.8	1.1±1.5	14/26 (53.8)
Scalp (*n*=14)	2.4±1.8	1.1±1.4	0.8±1.3	9/14 (64.3)
Genital/perianal area (*n*=9)	1.6±1.2	0.7±1.0	0.5±0.8	6/9 (66.7)

Data are presented as mean±SD unless otherwise specified. Changes from baseline in sub-EASI scores were statistically significant at W16 and W52 for evaluated regions ($p<0.05$).
*Regional response was defined as a ≥50% reduction from baseline in the corresponding site-specific sub-EASI score at Week 16.

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

Ethics committee: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Committee of University of Molise (Italy) (n. 26752, 12 May 2025). Written informed consent was obtained from all participants prior to inclusion in the study.

Conflict of interest: MN acted as speaker, consultant and advisory board member for Sanofi, AbbVie, LEO Pharma, Amgen, Pierre Fabre, and Eli Lilly. CP acted as investigator, speaker, consultant and advisory board member for AbbVie, Almirall, Amgen, Eli Lilly, Galderma, Incyte, La Roche-Posay, Leo Pharma, Novartis, Pfizer, Pierre Fabre, and Sanofi. The other authors have no conflicts of interest to declare.

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