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ORIGINAL ARTICLE

Effectiveness and safety of baricitinib in severe alopecia areata: 48-week results

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Abstract

Background: Alopecia areata (AA) is an autoimmune condition leading to hair loss. Baricitinib, a Janus kinase (JAK) inhibitor, has demonstrated efficacy in controlled clinical trials, but real-world data on its long-term effectiveness and safety remain limited.

Objectives: This study aimed to assess the real-life effectiveness and safety of baricitinib 4 mg daily in Italian adult patients with severe AA over a 48-week treatment period.

For affiliations refer to page 229.

Methods: We conducted a 48-week retrospective, observational, multicenter study across 27 Italian university hospitals. Adult patients (18–65 years) with severe AA (Severity of Alopecia Tool [SALT] score ≥ 50) who initiated baricitinib 4 mg daily treatment between November 2022 and October 2023 were included. Effectiveness was measured by the percentage of patients achieving SALT ≤20 at week 48. Secondary outcomes included changes in mean SALT score, trichoscopic findings, patient-reported quality of life (Skindex-16, Hospital Anxiety and Depression Scale [HADS]), and Clinician-Reported Outcomes (ClinRO) for eyebrows and eyelashes. Adverse events were also documented.

Results: A total of 253 patients (66.8% females, mean age 40.0 ± 12.6 years) were included. By week 48, 63.2% achieved SALT ≤20, and 75.5% achieved SALT ≤30. The mean SALT score significantly decreased from 93.7 ± 14.1 at baseline to 26.5 ± 33.0 at week 48 ($p < 0.001$). Trichoscopic assessment showed a decline in yellow dots (97.6%–50.2%), black dots (43.5%–9.1%), and dystrophic hairs (14.6%–4.3%), whilst regrowing hairs increased (7.1%–80.2%). Skindex-16 scores improved significantly (57.1 ± 25.0 to 30.0 ± 17.8, $p < 0.001$), as did HADS Anxiety (8.21 ± 9.38 to 4.62 ± 4.21, $p < 0.001$) and HADS Depression (6.36 ± 4.55 to 3.70 ± 4.11, $p < 0.001$). Adverse events were reported in 9.4% of patients.

Conclusions: This real-world study confirms the effectiveness of baricitinib in achieving significant hair regrowth and improving psychological well-being in severe AA patients.

KEYWORDS
alopecia areata, baricitinib, HADS, Janus kinase inhibitors, SKINDEX-16, trichoscopy

INTRODUCTION

Alopecia areata (AA) is a non-scarring autoimmune disorder characterized by loss of scalp and/or body hair with different severity ranging from few alopecic patches to alopecia totalis (AT) and alopecia universalis (AU).[1–3] It may occur at any age and in any race, with a slight prevalence in females, and it significantly impairs patients' psychosocial well-being and quality of life.[1–3] The clinical diagnosis relies on clinical features and trichoscopy, which reveals hallmark features such as exclamation mark hairs and black dots in the acute phase or prevalent yellow dots in the chronic phase.[4,5] Disease severity is assessed clinically using the Severity of Alopecia Tool (SALT), which quantifies scalp hair loss as a percentage of total scalp area affected.[5,6]

The development of Janus Kinase (JAK) inhibitors has significantly changed the therapeutic approach to severe forms of AA. Among them, baricitinib is a selective inhibitor of JAK1/2 approved in 2022 by the European Medicines Agency (EMA) for the treatment of severe AA and in 2023 by the Agenzia Italiana del Farmaco (AIFA).[7,8] Previous clinical trials have demonstrated the efficacy of baricitinib in AA, showing a significant improvement in SALT score and quality of life within the first 36 weeks of treatment.[9–15] Response increased at week 52.[13] In addition, among patients with severe AA treated with baricitinib 4- and 2-mg with SALT ≤20 at week 52, regrowth of scalp hair was maintained through week 152 by a high proportion of patients.[16] However, all these observations need to be validated by real-world data in diversified patient populations.

This multicenter study aimed to evaluate the effectiveness and tolerability of a daily 4 mg dose of baricitinib in a cohort of Italian adult patients with severe AA over a 48-week treatment period. By leveraging retrospective, multicenter data, it aims to bridge the gap between controlled clinical trials and routine clinical practice.

MATERIALS AND METHODS

We conducted a 48-week retrospective, observational, multicenter study to evaluate the effectiveness of a 4 mg daily dose of baricitinib in adult patients with severe AA who initiated treatment between November 2022 and October 2023. Data were collected from patient records at 27 centers, with the IRCCS Azienda Ospedaliero-Universitaria Policlinico di Sant'Orsola in Bologna serving as the coordinating center, between November 1st, 2024, and January 31st, 2025. A subset of these patients had already been assessed for the effectiveness and tolerability of baricitinib 4 mg/die at 24 weeks, with the results previously published.[12] No prospectively defined standardized patient assessment protocol was in place before enrolment. However, assessments were largely uniform because all centers applied the same national prescribing/reimbursement criteria for baricitinib under the Named Patient Use (NPU) program, all centers followed common national AA guidelines, and only patients with complete baseline and 48-week follow-up data were included.

The patients, aged 18–65 years of both sexes, had been diagnosed with severe AA, defined as a SALT score ≥ 50,

including AA totalis and universalis subtypes. Eligibility criteria required a current episode duration ranging from 6 months to 6 years without spontaneous improvement (≤10-point reduction in SALT score) in the 6 months prior to screening, diagnosis confirmed by clinical and trichoscopic assessment. The exclusion criteria were concomitancy of other forms of alopecia, comorbidities incompatible with baricitinib, abnormal laboratory parameters (e.g., neutrophil count ≤1000 cells/mm^3, haemoglobin ≤8 g/dL), and pregnancy or lactation. Patients received baricitinib 4 mg daily in accordance with current guidelines.

The primary endpoint of this study was to evaluate the effectiveness of 4 mg Baricitinib in patients with severe AA, as determined by the SALT score, by assessing the number and percentage of patients who achieved SALT ≤20 (i.e., an achievement of a 20% or less scalp hair loss). Secondary endpoints were:

- The variation of SALT mean values;
- Trichoscopic improvement;
- The assessment of quality of life through the evaluation of mean scores from questionnaires commonly used in the management of AA patients, such as SKINDEX-16 AA and HADS A/D.
- The evaluation of the response of eyebrows and eyelashes through ClinRO EB/EL.

Exploratory endpoint evaluated the improvement of the percentage of patients achieving a SALT score < 30 (i.e., an achievement of a 30% or less scalp hair loss).

Primary, secondary and exploratory endpoints were evaluated from baseline to week 48. SALT score, trichoscopic features, laboratory tests and quality of life assessments – using Skindex-16 and HADS – were evaluated at baseline (T0) and at 48 weeks (T48w).[13–17] Clinician-reported outcomes for eyebrows and eyelashes (ClinRO EB/EL) were also assessed.[11–14] The ClinRO Measure for Eyebrow Hair Loss™ and ClinRO Measure for Eyelash Hair Loss™ use an ordinal scale of measurement, which ranges from 0 – no visible hair loss, to 3 – total loss of hair. The content validity, reliability, and accuracy of these tools have been validated in both adults and adolescents.[11]

Trichoscopic monitoring was performed to document the course of AA during treatment. Acute exacerbation of AA was defined by trichoscopic signs that included black dots, exclamation point hairs, and dystrophic hairs, whilst chronic AA was associated with the exclusive presence of yellow dots and thin, non-pigmented hairs. During the regrowth phase, the appearance of pointed, upgrowing hairs was observed.[1–5] These trichoscopic signs were photographed at baseline and follow-up and used to assess the therapeutic response (Figure 1).

The Skindex-16 and HADS were employed to measure the quality of life and psychological impact, respectively. Skindex-16 measures three domains—symptoms, emotions, and functioning—whose scores are normalized from 0 (no effect) to 96 (maximum impact).[18] HADS assesses anxiety (HADS-A) and depression (HADS-D) on a scale ranging from 0 to 21, with higher values reflecting more anxiety or depression. Patients with baseline HADS-A or HADS-D scores ≥8 were categorized as having borderline or abnormal anxiety or depression, whilst scores <8 were considered normal.[19]

Any adverse events and safety outcomes were documented at each visit. The reporting of adverse events, including severity, was left to the investigator's clinical judgement.

Data were analysed using descriptive and inferential statistical methods. Continuous variables were expressed as mean ± standard deviation (SD). Categorical variables were reported as absolute frequencies and percentages. Comparisons of continuous variables over time (e.g., SALT scores, Skindex-16 scores, and HADS scores) were conducted using paired-sample *t*-tests. For subgroup analyses, chi-square tests were employed to evaluate differences in categorical outcomes, such as severity level changes over time. Effect sizes, including Cohen's *d* for paired *t*-tests and Cramér's *V* for chi-square tests, were calculated to quantify the magnitude of changes or associations. Logistic regression analysis was performed to identify predictors of achieving SALT S0/

Why was the study undertaken?

- To assess the real-world effectiveness and safety of baricitinib (4 mg daily) in Italian adults with severe alopecia areata (AA) over 48 weeks, addressing the gap between clinical trials and routine practice.

What does this study add?

- At 48 weeks, 63.2% of patients achieved a SALT score of ≤20, indicating significant hair regrowth. Trichoscopic examination revealed increased regrowing hairs and a reduction in yellow and black dots. Patients reported a better quality of life, with improvements in Skindex-16 and HADS scores. The treatment demonstrated a favourable safety profile, with adverse events occurring in 9.4% of patients, mostly mild.

What are the implications of this study for disease understanding and/or clinical care?

- This study confirms baricitinib as a key therapy for severe alopecia areata. Trichoscopic findings can help predict treatment response before visible regrowth occurs. The psychological benefits are significant, highlighting the need for a holistic approach to patient care. Routine safety monitoring remains essential, particularly for detecting laboratory abnormalities. Future research should focus on refining treatment strategies and identifying reliable predictors of response.

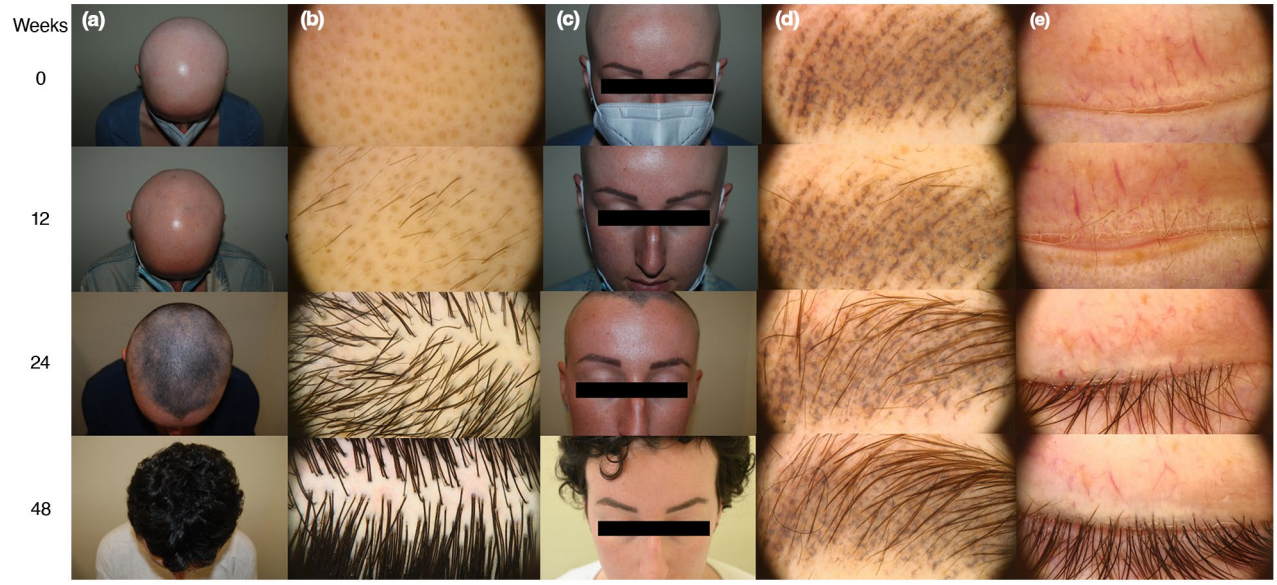

FIGURE 1 Patient with SALT ≥50 after 12, 24 and 48 weeks of treatment: Clinical presentation [scalp (a) and eyebrows (c)] and (c) trichoscopy [scalp (b), eyebrows (d) and eyelashes (e)].

S1 at 48 weeks, with odds ratios (ORs) and 95% confidence intervals (CIs) reported. Kaplan–Meier survival analysis was used to evaluate the timing of treatment discontinuations or the clustering of adverse events over time, and the log-rank test was applied to compare response rates among alopecia subtypes. Spearman's correlation coefficients (ρ) were calculated to assess associations between changes in SALT scores and other outcomes, such as Skindex-16 and HADS scores. Statistical significance was set at $p < 0.05$, and all tests were two-tailed. Data anonymization and management were performed using REDCap hosted at the University of Bologna.

The study adheres to Good Clinical Practice (GCP) guidelines, AIFA 2024 guidelines and the Declaration of Helsinki, whilst ethical approval was obtained prior to data collection (641/2024).

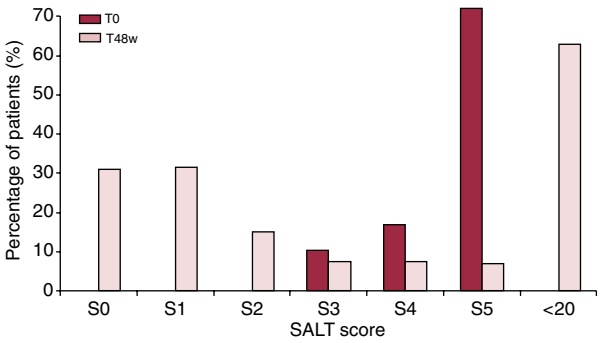

FIGURE 2 Variation of SALT score during treatment [S0 = no hair loss; S1 = <25% hair loss; S2 = 25%–49% hair loss; S3 = 50%–74% hair loss; S4 = 75%–99% hair loss; S5 = 100% hair loss].

RESULTS

A total of 27 University hospitals from Italy participated in this study, enrolling 253 patients with AA, comprising 169 (66.8%) females and 84 (33.2%) males. The mean age at enrollment was 40.0 (±12.6 SD), whilst the mean age at AA first diagnosis was 28.1 (±14.5 SD). Regarding the severity and type of AA, 52 (20.6%) patients showed patchy alopecia, 32 (12.6%) patients had AA totalis (AT), and 169 (66.8%) patients had AA universalis (AU); specifically, 56 patients (22.13%) had severe AA (SALT 50–95) whilst 197 patients (77.87%) were very severe (SALT >95).

Previous treatments included high-potency topical steroids (98.0%), topical immunotherapy (squaric acid dibutyl ester or diphenylcyclopropenone) (35.6%), anthralin (3.6%), and intralesional corticosteroids (1.6%). Systemic treatments included steroids (89.3%), cyclosporine A (17.0%), and methotrexate (11.9%). Notably, the outcomes of previous treatments resulted in no response (76.3%) or partial response (23.7%).

Familial occurrence of AA in was observed in 25 patients (9.9%). Comorbidities observed among AA patients included autoimmune thyroiditis (21.7%), atopy (11.9%), celiac disease (3.2%), psoriasis (1.6%), vitiligo (1.2%) and other rarer conditions. Other systemic diseases noted were hypercholesterolemia (7.9%) and arterial hypertension (2.4%).

To address the *primary endpoint* of this study, a total of 63.2% (160/253) patients achieved a SALT <20 by week 48. In response to the *secondary endpoints*, the SALT score decreased from an average of 93.7 (±14.1 SD) at T0 to 26.5 (±33.0 SD) at T48w, showing a significant difference ($p < 0.001$) (Figure 2).

We identified some factors that predicted treatment response: 65% of responders were females; responders were

on average younger than non-responders (38.6 ± 11.4 vs. 42.0 ± 12.1 years) and had a shorter mean disease duration (9.1 ± 6.3 vs. 11.4 ± 7.1 years). Patients with severe AA achieved a clinical response (SALT ≤20) earlier than those with very severe AA, with a mean time to response of 19.2 ± 6.8 weeks versus 25.7 ± 7.9 weeks, respectively ($p = 0.021$). Early responders—defined as those achieving SALT ≤20 between week 12 and week 24—were more frequently observed among patients with severe AA. Specifically, 14 of 56 patients (25.0%) in the severe group were early responders, compared to 25 of 197 patients (12.7%) in the very severe group ($p = 0.035$, Fisher's exact test). The duration of the current AA episode did not significantly influence time to response, with similar mean durations in early responders (8.9 ± 5.7 months) and late/non-responders (9.4 ± 6.1 months; $p = 0.42$).

Patients with baseline SALT scores ≥95 exhibited a greater absolute reduction in SALT scores at week 48 compared to those with SALT <95 (71.89 vs. 56.28, respectively). However, their mean SALT score at week 48 remained higher (27.47 vs. 22.63). An independent *t*-test showed no statistically significant difference in final SALT scores between the two groups ($p = 0.484$). Trichoscopic signs observed throughout the study showed notable changes through time. The mean number of patients showing yellow dots decreased from 247 (97.6%) at T0 to 127 (50.2%) at T48w. Likewise, black dots declined from 110 (43.5%) patients to 23 (9.1%) during the same period. Dystrophic hairs reduced from 37 (14.6%) to 11 patients (4.3%), exclamation mark hairs decreased from 23 (9.1%) to 17 (6.7%) patients, and regrowing hairs increased from 18 (7.1%) to 203 (80.2%) cases (Figure 3). Skindex-16 mean score decreased from 57.1 (±25.0 SD) to 30.0 (±17.8 SD), HADS Depression mean score from 6.36 (±4.55 SD) to 3.70 (±4.108 SD), and HADS Anxiety scores from 8.21 (±9.38 SD) to 4.62 (±4.21 SD), showing a statistically significant improvement ($p < 0.001$ for both) in both the psychological symptoms and quality of life of the patients during the study period.

The correlation between SALT score and Skindex-16 at week 48 was significant (Spearman's Rho Coefficient; $p < 0.001$).

An analysis regarding ClinRo eyelashes and eyebrows was conducted on a subgroup of 45 patients. In this subgroup, the mean ClinRO score for eyebrows at baseline (T0) was 2.54, which decreased to 0.84 at 48 weeks. Similarly, the mean ClinRO score for eyelashes was 2.54 at T0 and declined to 0.69 at 48 weeks. These findings indicate a substantial reduction in ClinRO scores for both eyebrows and eyelashes in this subset of patients over the 48-week period.

As exploratory objective, a total of 75.5% (191/253) patients reached SALT <30 by week 48.

Adverse events that emerged during the treatment period were reported in 24 (9.4%) patients with 4-mg baricitinib. The laboratory test abnormalities reported were hypercholesterolemia (>200 mg/dL) in 62 (24.5%) patients; hypertriglyceridemia (>150 mg/dL) in 13 (5.1%); neutropenia (moderate neutropenia, as always >1000 cells/mm^3), increased creatininemia, and hypertransaminasemia in four cases; whilst increased gamma-GT was reported in only one case.

The most frequently reported adverse event was upper respiratory tract infection, which occurred in 3 (1.2%) patients. Other events reported included acneiform rash and fatigue, each observed in two patients (0.8%). Less commonly reported events included cystitis, fever, hand-foot-mouth disease, eczema, and chalazion, each affecting 1 (0.4%) patient.

At 48 weeks, a total of 18 patients (7.1%) discontinued treatment for different reasons. The most frequent cause was non-response to therapy, reported in 13 (5.1%) patients. Other reasons included lost compliance (1 patient), pregnancy desire (1 patient), recurrent cystitis (1 patient), the occurrence of eczema (1 patient) and a persistent hypercholesterolemia (1 patient).

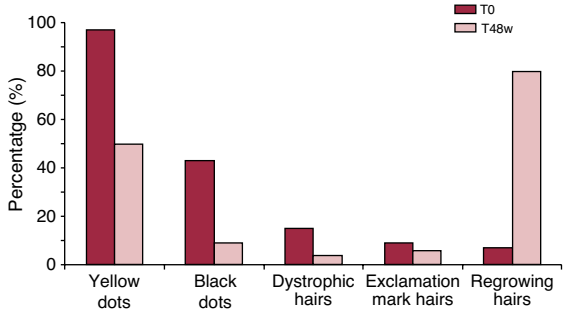

FIGURE 3 Variation of trichoscopic signs during treatment.

DISCUSSION

Our study confirms the effectiveness and safety of baricitinib for severe AA in adult patients, supplementing the clinical trial data with information about real-world outcomes.[1–6] The results show great improvements in SALT scores, ClinRO eyebrows and eyelashes scores, trichoscopic signs, and psychosocial well-being, thus providing proof for the place of baricitinib among first-line therapies for severe AA in adult patients.[1–6]

The pathophysiology of AA involves immune-mediated disruption of hair follicle privilege, driven by pro-inflammatory cytokines like IL-15 and IFN-γ via the JAK signalling pathway.[2–6] Baricitinib's targeted inhibition of JAK1/2 effectively disrupts this pathway, reducing inflammation and restoring hair growth, as demonstrated.[12,13,15,20] Unique to this mechanism, JAK inhibitors not only halt disease progression, but they achieve a durable clinical response, as showcased in our cohort with 63.2% of the patients achieving SALT ≤20 at 48 weeks. Furthermore, patients with very severe AA (SALT ≥95) exhibited consistently lower response rates throughout the study period compared to those with severe AA. In addition, we observed that 65% of responders were female and on average younger than non-responders (38.6 vs. 42.0 years). Finally, responders had a shorter mean disease duration (9.1 vs. 11.4 years). Our data show that patients with severe AA were significantly more likely to

achieve an early clinical response compared to those with very severe AA. Whilst 25% of patients with severe disease responded within 24 weeks, only 12.7% of very severe cases did so, despite identical treatment. This finding suggests that baseline disease burden may influence treatment kinetics, reinforcing the importance of early intervention. However, since response was still observed in a subset of very severe patients, baricitinib remains a valuable option across the severity spectrum. In trials BRAVE-AA1 and BRAVE-AA2,[15] 38.8% and 35.9% of patients treated with Baricitinib 4 mg, respectively, attained SALT ≤20 at 36 weeks compared with 6.2% and 3.3% in a placebo-treated group. Most patients were treated with baricitinib under the NPU program, according to the Italian ministerial decree of September 7th, 2017. This NPU was intended only for patients with AU and AT, which affected the severity of our population, with approximately 80% of patients meeting NPU criteria. These controlled settings demonstrate baricitinib's effectiveness and real-world data from our study and others[12,13,15,21] suggest comparable response rates. Slight differences between studies may reflect differences in patient populations, adherence, or adjunctive care in real-world settings.

The deep psychological impact of AA on anxiety and depression underlines the importance of a holistic approach in treatment.[1–4] Our study showed significant decreases in HADS scores, which mirror results seen by Craiglow et al.,[22] who described large improvements in quality-of-life measures during baricitinib treatment; specifically, we demonstrated a reduction from 8.21 (±9.38 SD) to 4.62 (±4.21 SD), showing a statistically significant improvement ($p < 0.001$) in both the psychological symptoms and quality of life of the patients during the study period. These results certainly reinforce the need for addressing both the clinical and psychological dimensions of AA in view of the high rates of psychological distress that may critically undermine adherence to treatment and overall patients' quality of life.

Our trichoscopic findings of a decrease in yellow dots and an increase in regrowing hairs further support the efficacy of baricitinib. The trichoscopic changes often preceded clinical regrowth, as noted in a previous study,[12] suggesting that trichoscopy could serve as a valuable tool not only for diagnosis but also during follow-up to monitor therapeutic progress.

Safety concerns are common when prescribing a JAK inhibitor therapy[12–17,21–23] but the safety profile of baricitinib, as seen in our study, is consistent with the findings from previous trials, where the most common adverse events included upper respiratory infections and acne.[12–17,21–23] More importantly, the absence of serious adverse events in our cohort further supports its use in routine practice, provided that close monitoring, particularly for laboratory abnormalities, is carried out.

Our study offers valuable insights into baricitinib's effectiveness and safety in real-life scenarios. However, its retrospective nature represents a limitation, as well as the lack of a control group, which limits causal inferences. Also in Italy, baricitinib was initially accessible only through a Named Patient Use (NPU) programme and, later, under national reimbursement criteria that limit its prescription to adults aged 18–65 years with severe forms of AA (SALT ≥50). As a result, our study population does not include patients over 65 years, those with disease duration >6 years, or those treated with lower dosages. Whilst these criteria ensured consistency in patient selection, they also limit the generalizability of our findings to broader real-world populations. We are continuing the study with a 52-week follow-up to evaluate long-term responders, analyse their trajectories, and assess whether they align with those reported in the literature.

Overall, future research should focus on head-to-head comparisons of JAK inhibitors, identifying predictors of early and sustained response, and exploring potential combination strategies to maximize therapeutic outcomes.

CONCLUSIONS

Baricitinib is a game-changing option for severe AA in adults, ensuring clinically and psychologically important benefits with trichoscopic confirmation. This study provides real-world perspectives to further establish baricitinib as a cornerstone of treatment for this condition and points to a future of personalized therapies, ultimately improving patient outcomes.

AUTHOR CONTRIBUTIONS

Bianca Maria Piraccini, Stephano Cedirian, Francesca Pampaloni, Luca Rapparini, Federico Quadrelli, Francesca Bruni, and Michela Starace contributed to the study conceptualization, data collection, data analysis, result interpretation, and manuscript drafting. All other authors contributed to the critical revision of the manuscript for important intellectual content and approved the final version for publication. All authors have read and approved the manuscript and take responsibility for their respective contributions to the work.

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CONFLICT OF INTEREST STATEMENT
Bianca Maria Piraccini has received consulting fees from Pierre Fabre-Ducray, Difa Cooper, Dercos-L'Oreal, Legacy Healthcare, Pfizer, and Eli Lilly. Francesca Ambrogio declares having received consulting fees and honoraria for lectures, presentations, or educational events from Eli Lilly. Valeria Boccaletti has received payment or honoraria for lectures and educational events from Sanofi, Lilly, and AbbVie; support for attending meetings and/or travel from Sanofi and Lilly; and has served on an advisory board for Sanofi. Angelo Valerio Marzano has received honoraria for lectures and educational events from AbbVie, Boehringer-Ingelheim, Bristol Myers Squibb, Incyte, Johnson & Johnson, L'Oréal, Leo Pharma, Novartis Pharma, Pfizer, Sanofi, and UCB Pharma; and has served on advisory boards for the same companies. Valentina Dini has received grants or contracts from Eli Lilly and UCB (investigator-initiated research); and honoraria for lectures or educational events from AbbVie, Almirall, Convatec, Eli Lilly, Janssen, Leo Pharma, Novartis, Pfizer, Sanofi, and UCB. Flavia Manzo Margiotta has received honoraria for lectures or educational events from AbbVie, Almirall, Eli Lilly, Leo Pharma, Pfizer, and Sanofi. Serena Lembo has received consulting fees, honoraria for lectures, support for attending meetings, and participated in advisory boards for Eli Lilly, AbbVie, Novartis, Janssen, Almirall, UCB, and Sanofi. She also reports a leadership or fiduciary role in other boards or societies. Annunziata Raimondo has received consulting fees from Eli Lilly, Abbvie, Novartis, Janssen, Almirall, and Sanofi. All the other authors have no conflict of interest to disclose.

DATA AVAILABILITY STATEMENT
The datasets generated and analysed during the current study are not publicly available due to patient confidentiality and ethical restrictions but are available from the corresponding author upon reasonable request. Access to the data will require approval from the relevant ethics committee and compliance with applicable data protection regulations.

ETHICAL APPROVAL
The study was approved by the local IRB (protocol n°641/2024).

ETHICS STATEMENT
The patients were informed about the use of their clinical information according to the Declaration of Helsinki principles and photos for publication intent. The informed consent was appropriately obtained during the medical examination.

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