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Effectiveness of baricitinib in severe alopecia areata in real life: a retrospective study of 87 patients

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Abstract

Introduction: Alopecia areata (AA) is an autoimmune condition characterized by non-scarring hair loss. The Janus kinase (JAK)–signal transducer and activator of transcription (STAT) pathway is believed to play a central role in the autoimmune inflammatory processes underlying AA. Baricitinib, an oral JAK inhibitor, has been approved by the Food and Drug Administration (FDA) for the treatment of severe AA. This study evaluates the efficacy and safety of baricitinib in the management of AA.
Methods: A retrospective cohort study was conducted on patients with AA receiving baricitinib 4 mg daily and that had completed a 1-year follow-up. Disease severity was assessed at baseline and the end of follow-up using the Severity of Alopecia Tool (SALT) score. Adverse events were systematically recorded.
Results: Among 87 patients included in the analysis, the mean age was 29.84 years, and the mean baseline SALT score was 77.07%. After a mean of 52 weeks, 37.20% of patients achieved a SALT score ≤ 20. A significant reduction in SALT scores was observed at the end of follow-up ($p < 0.001$). In addition, 72.40% of patients experienced mild or no adverse events, and no serious adverse events were reported.
Conclusions: In this 52-week real-world cohort, baricitinib demonstrated both effectiveness and good tolerability in the treatment of severe AA. These findings contribute to the understanding of long-term outcomes with baricitinib therapy.

Keywords: alopecia areata, baricitinib, efficacy, Janus kinase inhibitors, safety

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Introduction

Alopecia areata (AA) is a disorder characterized by non-scarring hair loss that may involve the scalp, eyebrows, eyelashes, or other body hair. AA is relatively common in the Saudi population. It affects individuals of all races equally and can appear at any age, from birth through late adulthood. The peak incidence is observed between 15 and 29 years of age (1). AA often leads to substantial emotional and psychological distress and may be associated with other autoimmune conditions (2, 3).

Systemic Janus kinase (JAK) inhibitors now have a strong and growing evidence base supporting their use in AA. Although individual responses vary, approximately 50% of patients can be expected to achieve more than 50% hair regrowth, and ongoing therapy is usually required to maintain these benefits (4–6).

Baricitinib is currently approved for the treatment of adults with severe disease. Real-world data on treatment effectiveness and adverse event profiles are crucial to help dermatologists counsel patients before initiating therapy. Previous real-life studies have consistently shown that baricitinib is effective and generally well tolerated, with lipid abnormalities being the most frequently reported adverse effects (7–14).

This study, conducted in a Saudi population at a single-center hair unit, evaluates the real-world effectiveness and tolerance of baricitinib in the management of AA.

Methods

Study design

This observational retrospective study was conducted using data obtained from a hospital electronic medical record system. The study was conducted in Riyadh at Prince Sultan Military Medical City. The study and data collection were conducted with approval from a hospital and faculty institutional board review (approval number: E-2362).

Study participants

All patients with severe AA, defined as a Severity of Alopecia Tool (SALT) score of 50 or higher (range: 0 = no scalp hair loss to 100 = complete scalp hair loss), who were treated with baricitinib 4 mg orally once daily and met the inclusion criteria from July 2022 to July 2024, were included. Patients were followed at 0, 3, 6, 9, and 12 months.

The primary outcome was the percentage of patients achieving a SALT score ≤ 20 at the end of follow-up (52 weeks). All adverse events were recorded throughout the study period.

Patients seen at the dermatology clinic had to meet the following criteria for inclusion: 1) age between 18 and 60 years, 2) severe AA with a SALT score ≥ 50, and 3) no concomitant use of other

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immunosuppressive agents. Exclusion criteria were 1) patients younger than 18 years of age, and 2) AA with a SALT score < 50.

Patients that had received previous treatment modalities for AA were not excluded from the study. Prior and concurrent medications were recorded, and no washout period was required before initiating baricitinib.

Statistical analysis

Data were analyzed using SPSS (IBM, New York, USA) version 29.0 and Jeffrey's Amazing Statistics Program (University of Amsterdam, NL) version 0.19.0. Descriptive statistics were used to summarize patient characteristics and clinical outcomes. Continuous variables were assessed for normality using the Shapiro–Wilk test and are reported as mean ± standard deviation (*SD*) for normally distributed data, or as median with interquartile range (IQR) for non-normally distributed data. Categorical variables are presented as frequencies and percentages.

Because the SALT score data did not meet normality assumptions, comparisons before and after treatment were conducted using the Wilcoxon signed-rank test.

Results

A total of 87 patients with severe AA were included. The mean age was 29.84 years (*SD* = 9.03), and 52.9% were male (Table 1). The most prevalent subtype was AA universalis (51.7%), followed by patchy AA (35.6%) and AA totalis (10.3%). A history of extra-scalp involvement, including eyebrows, eyelashes, and body hair, was reported in 75.9% of cases.

Regarding previous treatment, 81.6% (*n* = 71) of participants had received at least one form of treatment. Only five patients (5.7%) received a single treatment, and the remaining 66 patients (75.9%) underwent combination therapy. The most common previously used treatments included intralesional steroids (39.1%), topical steroids (35.6%), oral steroids (34.5%), and topical minoxidil (29.9%). The JAK inhibitor tofacitinib had previously been received by 10.3% of patients.

Among the 87 patients, 31.0% (*n* = 27) continued using topical minoxidil and/or topical corticosteroids concurrently with baricitinib.

Regarding efficacy, data on the onset of clinical response were available for 75 patients (86.2%). The median time to response was 17.4 weeks, and the interquartile range was 13.1 weeks, indicating moderate variability among participants. The distribution of onset times demonstrated positive skewness (1.55) and moderate kurtosis (2.34).

Among the valid cases, 37.2% (*n* = 32) showed a positive response to treatment (achieved SALT score < 20). The mean percentage change in SALT scores was 53.3% (*SD* = 30.0), indicating that, on average, patients experienced a 53% improvement in their SALT scores by the end of follow-up (Table 2). The Wilcoxon signed-rank test revealed a statistically significant reduction in SALT scores following treatment with baricitinib ($Z = -6.697$, $p < .001$).

Regarding safety, 72.4% (*n* = 63) of the 87 participants reported no adverse events. Among those that did, the most frequent were high lipid levels (8.0%), borderline lipid levels (4.6%), and weight gain (2.3%). Less commonly reported side effects included acne, upper respiratory tract infections, depression, and low platelet count (each ≤ 2.3%). One patient had persistently elevated platelet levels, which led to discontinuation of treatment. Hallucinations were reported in one patient, who was later lost to follow-up. It remains unclear whether this event was related to baricitinib or to an underlying psychiatric or neurological condition.

Discussion

The prevalence of AA in Saudi Arabia was found to be between 2.3% and 5.2% in recent studies (15, 16). It can be patchy, affecting parts of the scalp, or it can be more severe, affecting the entire scalp (alopecia totalis) or the entire body (alopecia universalis). The diagnosis can be made clinically, with no need for biopsy unless the diagnosis is unclear.

The treatment includes topical and intralesional steroids, topical anthralin, topical minoxidil, topical immunotherapy, and phototherapy. Systemic immunosuppressive agents such as cyclosporine, methotrexate, azathioprine, mycophenolic acid, and sulfasalazine have shown variable efficacy; however, none of these agents are approved by the Food and Drug Administration (FDA) for the treatment of AA (17, 18).

Recent insights into the immunopathogenesis of AA, particularly the role of the JAK–signal transducer and activator of tran-

Table 1 | Demographic data and patient baseline characteristics (*n* = 87).

Parameter	Value
Age (years), mean (*SD*)	29.8 (9.0)
Sex, *n* (%)	
Female	41 (47.1)
Male	46 (52.9)
Type of AA, *n* (%)	
Alopecia universalis	45 (51.7)
Alopecia totalis	31 (35.6)
Patchy AA	9 (10.3)
Disease duration (years), median (IQR)	10 (13)
Extra scalp involvement, *n* (%)	
Yes	66 (75.9)
No	21 (24.1)
Previous treatments, *n* (%)	
Yes	71 (81.6)
No	16 (18.4)
Single treatment	5 (5.7)
Combined treatments	66 (75.9)
Intralesional steroids	(39.1)
Topical steroids	(35.6)
Oral steroids	(34.5)
Topical minoxidil	(29.9)
Tofacitinib	(10.3)
Adverse events, *n* (%)	
Yes	24 (27.6)
No	63 (72.4)
Elevated lipid panel	7 (8.0)
Borderline lipid panel	4 (4.6)
Weight gain	2 (2.3)
Acne	2 (2.3)
URTI	2 (2.3)
Depression,	2 (2.3)
Hallucination	1 (1.1)
Low platelet count	1 (1.1)
Onset of response (weeks), median (IQR)	17.4 (13.1)
Response to treatment (< 20% SALT score), *n* (%)	32 (37.2)

AA = alopecia areata, IQR = interquartile range, SALT = severity of alopecia tool, *SD* = standard deviation, URTI = upper respiratory tract infections.

Table 2 | Change in SALT scores from baseline.

SALT Score	Mean (*SD*)
Before treatment	77.07 (28.27)
After follow-up	37.43 (37.79)

SALT = severity of alopecia tool, *SD* = standard deviation, IQR = interquartile range.

scription (JAK–STAT) pathway, have provided a rationale for targeted therapeutic approaches. One of the proposed mechanisms underlying AA involves the activation of $CD8^+$ $NKG2D^+$ T cells through cytokine signaling via the JAK1 and JAK3 pathways, resulting in increased production of interferon (IFN)-γ. IFN-γ then acts on follicular epithelial cells, stimulating interleukin (IL)-15 production through JAK1 and JAK2 activation. IL-15, in turn, further activates $CD8^+$ T cells, promoting additional IFN-γ release and establishing a positive feedback loop that sustains inflammation around the hair follicle. Other cytokines, including IL-12 and IL-23, have also been implicated through the JAK–STAT signaling pathway, contributing to downstream Th1 and Th17 responses. Given the central role of these pathways, JAK inhibitors have emerged as promising therapeutic options for AA (19).

In June 2022, baricitinib, an oral JAK inhibitor, was approved by the FDA for adults with severe AA. Baricitinib selectively inhibits JAK1/2 and, to a lesser extent, JAK3 (7).

In this retrospective study comprising 87 patients, 37.2% of those treated with baricitinib achieved a SALT score ≤ 20 at a mean of 52 weeks. This outcome is consistent with the findings of BRAVE-AA1 and AA2 studies, which reported 52-week response rates of 40.9% and 36.8%, respectively (20). Whereas the BRAVE trials excluded patients with prior JAK inhibitor therapy, our cohort included those that had previously received JAK inhibitors. Previous studies suggest that patients that fail other JAK inhibitors may still achieve hair regrowth with baricitinib, indicating that switching between JAK inhibitors may be effective (21, 22).

Previous 1-year studies demonstrated higher response rates. In a study conducted in Spain on 36 patients treated with baricitinib 4 mg once daily, 58.8% of patients achieved SALT ≤ 20 at week 24, and 66.6% at week 52 (9). In addition, a retrospective multicenter study of 96 patients treated with baricitinib 4 mg once daily reported that 61.5% achieved a SALT score ≤ 20 at week 52 (12). Similarly, our result was lower than that reported in a study by De Greef et al. (73.7%) (7), which may reflect the inclusion of a larger number of patients and variability in prior treatment exposure.

Moreover, studies of ≤ 36 weeks duration reported high short-term efficacy; for example, 55.4% of patients with a baseline SALT > 50 achieved a SALT score of ≤ 20 at 36 weeks (14), and another study reported that 68.8% of patients had > 80% scalp coverage at 24 weeks (8). Our long-term data showed that effectiveness is maintained, supporting the durability of JAK inhibitor therapy.

This study demonstrated a statistically significant reduction in SALT scores from baseline, indicating an improvement in disease severity in the majority of patients. Notably, the mean SALT score at baseline for our patients was comparable to that reported in previously published data (12, 20). Our findings are consistent with a systematic review comparing JAK inhibitors in alopecia areata, which reported the greatest mean reduction in SALT score with brepocitinib 30 mg, followed by baricitinib 4 mg, ritlecitinib 50 mg and 30 mg, and ivarmacitinib 4 mg and 8 mg (23). This aligns with the intermediate efficacy observed in our real-world baricitinib cohort.

These findings also align with previously published data in the Middle East. In a retrospective study of 26 patients that received baricitinib, 96.6% of them showed a mean improvement from baseline at 12 months (11). Another study categorized patients based on therapeutic burden (TB), with high TB defined as having received more than three prior systemic treatments for AA, and low TB indicating earlier intervention with fewer prior treatments. At 12 months, the mean SALT score reduction in the high TB group was 30.4%, compared to 69.8% in the low TB group. The authors theorized that patients with lower TB may exhibit less immune system resistance or adaptation, thereby allowing JAK inhibition to be more effective (10).

Although a systematic review of JAK inhibitors identified baricitinib as having a relatively higher rate of adverse events (23), the safety profile of baricitinib was favorable. Mild lipid elevation was observed in 8.0% of patients. Only one patient discontinued treatment due to platelet elevation. No serious adverse events were reported during the 12-month treatment period. These findings are consistent with previous studies (8, 12, 24).

It is also worth noting that all psychiatric events were patient-reported, and no structured baseline mental health assessment or routine psychiatric referral was performed as part of this study, which limits causal inference.

Real-world data on the JAK inhibitors, particularly baricitinib, remain limited in Saudi Arabia. This study underscores the need for further long-term research evaluating baricitinib as an emerging biologic treatment in diverse patient populations that have failed previous therapies.

Limitations of this study include its retrospective design and the single-center setting. In addition, clinician-reported outcomes (ClinRO) for eyebrows and eyelashes were not included in the analysis.

Conclusions

Baricitinib demonstrated a favorable safety profile and clinical efficacy in a real-world setting over 52 weeks in patients with severe AA. Further prospective multicenter studies are warranted to validate long-term outcomes.

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