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Original Article

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Clinical Efficacy and Safety of Baricitinib in Patients With Alopecia Areata in Korea

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ABSTRACT

Background: Baricitinib is an oral Janus kinase 1 and 2 inhibitor that has shown significant efficacy in phase 3 trials for alopecia areata (AA). However, real-world data on its use for AA remain limited.
Objective: This study evaluated the efficacy and safety of baricitinib in Korean patients with AA.
Methods: In this retrospective multicenter study, 117 patients with AA received oral baricitinib 4 mg daily for at least 36 weeks. Patient demographics, Severity of Alopecia Tool (SALT) scores, and adverse events were assessed.
Results: SALT scores significantly decreased from baseline at all time points (p<0.001). By week 36, 55.4% of patients with a baseline SALT score >50 and 48.9% with a baseline score >95 achieved a SALT score of 20 or less. Notably, in Group A (baseline SALT score between 50 and 100) by week 36, the percentages for SALT 75, SALT 90, and SALT 100 were 52.0%, 44.0%, and 22.7%, respectively, while in Group B (baseline SALT score ≤50), the percentages were 81.0%, 66.7%, and 54.8%, respectively. Group B showed a significantly greater mean percentage improvement in SALT scores compared to Group A (p<0.001, Welch's t-test). Repeated measures analysis of variance further revealed that both group and time had significant effects on treatment response (p<0.001). Adverse reactions were mostly mild to moderate in severity and resolved with appropriate management.
Conclusion: Baricitinib was well tolerated and resulted in clinical improvement among patients with AA in a real-world clinical setting. Baricitinib is a potential treatment option for patients with treatment-resistant AA.

Keywords: Alopecia areata; Janus kinase inhibitor

INTRODUCTION

Alopecia areata (AA) is a chronic immune-mediated disorder characterized by non-scarring hair loss resulting from immune attack on hair follicles[1]. In recent findings, it has been revealed that within the lesions of AA, cytotoxic $CD8^+NKG2D^+$ T cells become activated, contributing to the production of interferon-γ, and pivotal roles are played by interleukin-15 and Janus kinase (JAK) in promoting inflammation and hair follicle damage[2,3]. Additionally, memory regulatory T cells (mTregs; $CD8^+CD69^+CD49a^-$), located in the hair follicle microenvironment, have been implicated in both the onset and persistence of AA[4-6]. In clinical trials, JAK inhibition has demonstrated efficacy in both halting and reversing hair loss in individuals with AA[7,8].

Baricitinib, an oral JAK inhibitor, was approved for the treatment of severe AA following its evaluation in 2 phase III randomized clinical trials: BRAVE-AA1 and BRAVE-AA2[7]. To date, real-world clinical data on the use of baricitinib in patients with AA remain

unpublished. This study aimed to assess the efficacy and safety of baricitinib for the treatment of AA in adult patients.

MATERIALS AND METHODS

Study design and participants

This retrospective cohort study was conducted between July 2020 and March 2024 at adult dermatology clinics at 4 Korean University Hospitals. The study targeted adult patients aged 18 years or older diagnosed with AA, who experienced persistent symptoms for at least 3 months after the initial onset. These individuals had previously shown no response to alternative treatments, or had experienced recurrent episodes despite prior intervention. This investigation specifically focused on patients who had been administered baricitinib for more than 6 months. Ethics approval was obtained from the local Institutional Review Board (Inha University Hospital, IRB No. 2023-11-028; Chungnam National University Hospital, IRB No. 2024-05-064; Severance Hospital, IRB No. 4-2024-0389; Chonbuk National Hospital, IRB No. 2024-06-043).

The medical records of the subjects were retrospectively analyzed, including sex - gender, age, and clinical characteristics such as age at onset, mean disease duration, treatment history, extra-scalp involvement, and comorbid conditions, Severity of Alopecia Tool (SALT) scores before and after baricitinib treatment, clinical photographs taken during visits, and the presence of side effects.

1) Baricitinib administration

Baricitinib 4 mg was administered orally once daily. In cases where a rapid or marked clinical response was observed, the dose was reduced to 2 mg. Systemic medications such as methotrexate, cyclosporine, and corticosteroids were discontinued during treatment. Local corticosteroids, intralesional steroid injections, and oral minoxidil were used concurrently when clinically indicated.

2) Pre-treatment assessment

Physical examinations and interviews were conducted and baseline investigations, including complete blood counts, biochemical tests, and serological tests for B/C hepatitis and human immunodeficiency virus infection, were performed before administration. None of the patients had a history of latent tuberculosis, malignancy, or severe systemic infection.

3) Treatment efficacy assessment

The SALT score was used to quantitatively evaluate the therapeutic efficacy of baricitinib oral treatment for AA[9]. At the initiation of treatment, the extent of alopecia was quantified using the SALT score (baseline SALT score). Based on the initial SALT score, participants were categorized into Groups A (baseline SALT score between 50 and 100) and B (baseline SALT score of 50 or less). The patients were evaluated at weeks 0, 8, 12, 16, 24, and 36. In Group A, the efficacy of baricitinib was assessed by measuring the mean reduction in SALT scores at week 36 compared to baseline, as well as the percentage of patients with a SALT score ≤20. A SALT score ≤20 has been recognized as a significant treatment outcome for patients with severe AA[10]. Furthermore, we assessed the therapeutic effects of baricitinib by comparing the SALT scores with the initial SALT scores over the course of treatment. SALT 75, 90, and 100 were defined as improvements of at least 75%, 90%, and 100%, respectively, compared to the baseline condition. To further assess treatment dynamics, percentage changes in SALT scores from baseline were calculated at each time point, and group comparisons were conducted using statistical methods including t-tests and repeated measures analysis of variance (ANOVA).

4) Adverse effect assessment

To assess potential adverse reactions during the treatment period, medical history reviews and hematologic evaluations were performed at each follow-up visit to investigate medication-related side effects that occurred during the course of treatment.

Statistical analyses

Data analysis was performed using IBM SPSS Statistics software (version 25.0; IBM Corp., Armonk, NY, USA). Continuous variables were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Changes in the SALT scores before and after treatment were assessed for significance using paired-sample t-tests after confirming normality. The significance level for all statistical differences was set at $p \leq 0.05$.

To compare treatment responses between groups stratified by initial SALT scores, independent t-tests (Welch's t-test) were used to assess differences in mean percentage change from baseline. Additionally, a 2-way repeated measures ANOVA was conducted to examine the main effects of time and group, as well as their interaction on percentage changes in SALT scores. The Greenhouse-Geisser correction was applied when the assumption of sphericity was violated.

All graphs and visualizations, including SALT score trends and percentage change trajectories over time, were created using GraphPad Prism 8 (GraphPad Software, San Diego, CA, USA) and the ggplot2 package in R.

RESULTS

Baseline characteristics

In total, 117 adult patients with AA received baricitinib for more than 6 months. Of the 117 patients, 54 were male, and 63 were

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Table 1. Baseline demographics and characteristics.

Variables	Values
Sex	
Male	54 (47.0)
Female	63 (52.9)
Age of onset of AA (yr)	27 (5–54)
Duration of AA (mo)	64 (7–480)
Comorbidities	
Atopic dermatitis	43 (36.1)
Thyroid dysfunction	11 (9.2)
Ulcerative colitis	2 (1.6)
Vitiligo	2 (1.6)
Systemic lupus erythematosus	1 (0.8)
Previous treatment history	
Topical steroid	105 (88.2)
Intralesional steroid injection	90 (75.6)
Oral steroid	40 (33.6)
Oral minoxidil	58 (48.7)
Cyclosporine	63 (52.9)
Methotrexate	26 (21.8)
DPCP	74 (62.1)
AA subtype	
Patchy	25 (21.0)
Diffuse	4 (3.3)
Ophiasis	11 (9.2)
Alopecia totalis	22 (18.4)
Alopecia universalis	42 (35.2)
Extrascalp involvement	63 (52.9)
Nail involvement	15 (12.6)
Initial SALT score	
50<Initial SALT score≤100 (Group A)	83 (70.9)
0<Initial SALT score≤50 (Group B)	34 (29.0)

Values are presented as number (%) or mean (range).
AA: alopecia areata, DPCP: diphenylcyclopropenone, SALT: Severity of Alopecia Tool.

female. The mean age at onset was 27.38±10.32 years (range: 5–54 years). The mean disease duration was 64.17±40.80 months (range: 7–480 months). Initial SALT scores recorded prior to treatment initiation revealed that 83 patients (70.9%) were classified into Group A (initial SALT score 50–100), and 34 patients (29.0%) into Group B (initial SALT score 0–50). Prior to baricitinib administration, 105 patients (88.2%) received local steroid therapy, 90 patients (75.6%) received intralesional steroid injections, and 40 patients (33.6%) received oral steroid therapy. Additionally, 58 patients (48.7%) received oral minoxidil, 63 (52.9%) received cyclosporine, and 26 (21.8%) received methotrexate. Furthermore, 74 patients (62.1%) underwent local diphenylcyclopropenone immunotherapy. Comorbid conditions included atopic dermatitis in 43 patients (36.1%), thyroid dysfunction in 11 (9.2%), vitiligo in 2 (1.6%), ulcerative colitis in 2 (1.6%), and systemic lupus erythematosus in 1 (0.8%) among the total patients (**Table 1**).

Change in SALT scores after treatment

At week 36, 55.4% of patients with an initial SALT score >50 and 48.9% of those with an initial SALT score >95 achieved a SALT score of 20 or less. The mean baseline SALT score before baricitinib treatment was 65.23 (SD, 35.13). Following baricitinib administration, the mean SALT scores were 55.58 (SD, 37.26) at week 8, 43.97 (SD, 37.20) at week 12, 39.25 (SD, 36.10) at week 16, 30.78 (SD, 34.47) at week 24, and 24.60 (SD, 34.11) at week 36. All reductions in SALT scores from baseline were statistically significant at each time point (p<0.001) (**Fig. 1**).

After baricitinib administration, in Group A (Initial SALT score 50–100), the percentages of patients achieving SALT 75, SALT 90, and SALT 100 were (**Fig. 2A**):

Week 8: 5.33%, 5.33%, and 1.33%, respectively.
Week 12: 20.00%, 12.00%, and 5.33%,
Week 16: 21.33%, 16.00%, and 6.66%,
Week 24: 37.33%, 22.66%, and 10.66%,
Week 36: 52.00%, 44.00%, and 22.66%.

In Group B (initial SALT score 0–50), the percentages of patients achieving SALT 75, SALT 90, and SALT 100 were (**Fig. 2B**):

Week 8: 14.28%, 7.14%, and 2.38%, respectively.
Week 12: 45.23%, 28.57%, and 21.42%,
Week 16: 59.52%, 50.00%, and 35.71%,
Week 24: 73.80%, 61.90%, and 47.61%,
Week 36: 80.95%, 66.66%, and 54.76%.

To further illustrate individual patient responses over time, longitudinal line plots of raw SALT scores were generated for Groups A and B (**Fig. 3**). Each thin line represents the SALT score

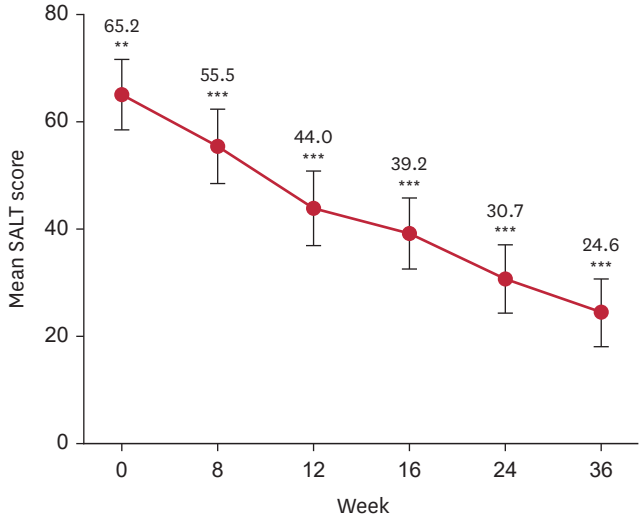

Fig. 1. Mean SALT score changes from baseline during the baricitinib treatment.
SALT: Severity of Alopecia Tool.
**p<0.01, ***p<0.001.

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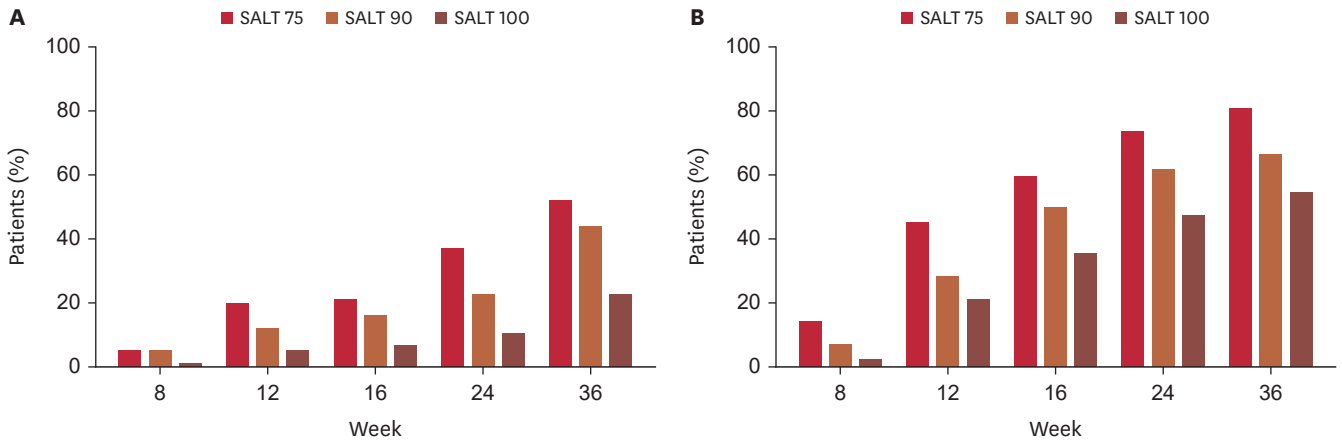

Fig. 2. Percentage of patients achieving SALT 75, SALT 90, and SALT 100 response from week 8 to week 36. (A) Group A (baseline SALT score between 50 and 100), (B) Group B (baseline SALT score ≤50).
SALT: Severity of Alopecia Tool.

trajectory of an individual patient, and the bold lines indicate the mean SALT score for the group at each time point. A consistent and progressive decline in the SALT scores was observed in both groups.

To evaluate the treatment response based on disease severity, the percentage change in SALT scores from baseline was calculated for each patient. Patients in Group B showed significantly greater reductions in SALT scores over time than those in Group A. The mean percentage change in SALT scores at week 36 was −33.56% in Group A and −51.38% in Group B. Welch's t-test confirmed a statistically significant difference in mean percentage reduction between the 2 groups (95% confidence interval, 10.45 to 25.18; $p<0.05$). To further evaluate the effects of time and baseline disease severity on treatment outcomes, 2-way repeated-measures ANOVA was performed. The analysis revealed that both group ($F(1, 697)=36.884$, $p<0.001$) and time ($F(1, 697)=265.371$, $p<0.001$) had statistically significant effects on the percentage change in SALT scores. These findings indicate not only that SALT scores improved consistently over time, but also that patients with less severe baseline disease (Group B) experienced significantly greater improvements (**Fig. 4**).

Safety

Among patients who received baricitinib, adverse reactions were reported in 20 patients (16.8%) (**Table 2**). These reactions included neutropenia in 5 patients, folliculitis in 5, acne in 4, headache in 2,

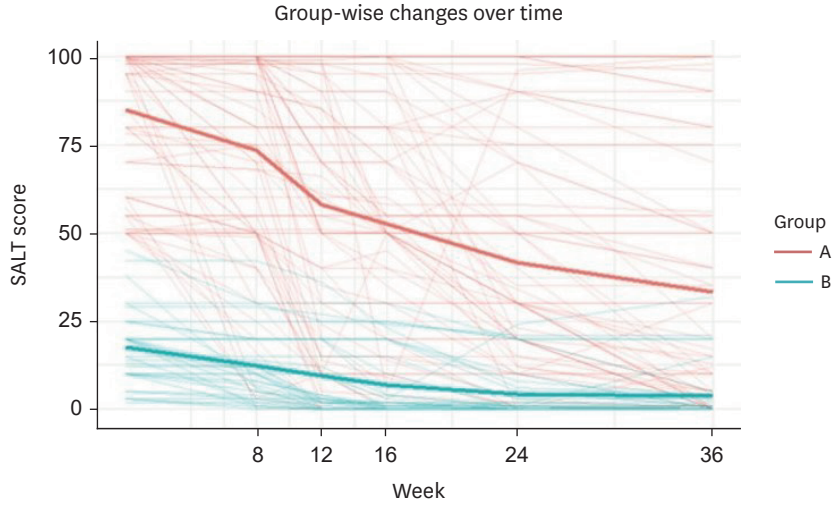

Fig. 3. Group-wise changes in SALT scores over time. Individual patient trajectories and mean SALT scores over time for Group A and Group B. Each thin line represents an individual patient's SALT score change, while bold lines represent the mean SALT scores per group.
SALT: Severity of Alopecia Tool.

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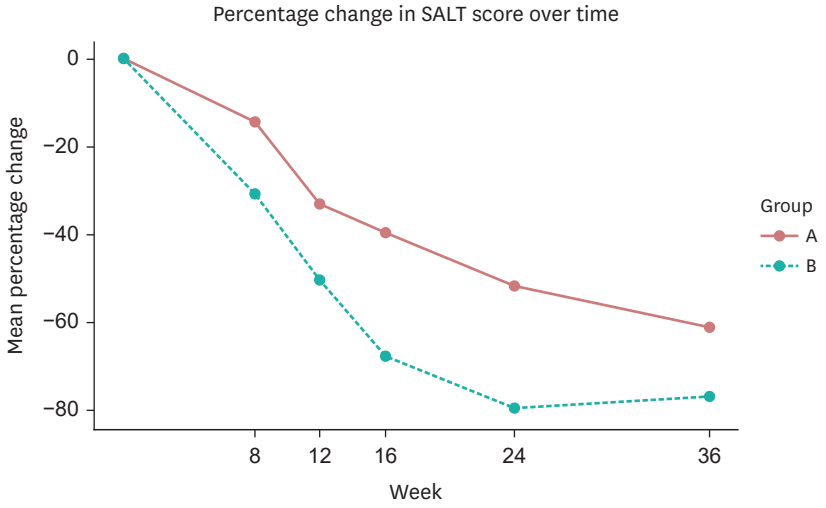

Fig. 4. Percentage change in SALT scores from baseline over time in Group A and Group B. Mean percentage change in SALT scores is plotted over time for each group.
SALT: Severity of Alopecia Tool.

Table 2. Adverse events in patients treated with baricitinib

Adverse event	Values
Neutropenia	5 (4.20)
Folliculitis	5 (4.20)
Acne	4 (3.36)
Headache	2 (1.68)
Gastroenteritis	2 (1.68)
Elevated CPK	1 (0.08)
Hyperlipidemia	1 (0.08)

Values are presented as number (%).
CPK: creatine phosphokinase.

gastroenteritis in 2, hyperlipidemia in 1. One patient showed mild, asymptomatic CPK elevation without any signs of rhabdomyolysis-related complications. Most symptoms were mild to moderate and either resolved spontaneously or improved with appropriate management. No severe adverse reactions were reported, and no patients discontinued treatment due to adverse reactions.

DISCUSSION

Baricitinib (Olumiant®; Eli-Lilly, Indianapolis, IN, USA) has recently gained approval as a treatment for AA. In June 2022, the US Food and Drug Administration approved the use of baricitinib for severe AA. Baricitinib is a selective and reversible inhibitor of JAK that has shown promising results in 2 randomized placebo-controlled phase III trials (BRAVE-AA1 and BRAVE-AA2). In these trials, 38.8% and 35.9% of patients receiving 4 mg of baricitinib achieved a SALT score ≤20 at week 36, the rates of scalp hair regrowth responses continued to increase over the 52 weeks of baricitinib treatment among adults with severe AA. By Week 52, 40.9% and 36.8% of patients in the respective trials achieved a SALT score ≤20 with baricitinib 4 mg[7,8].

Although there are currently limited data from real-world clinical settings, similar or even better or even superior treatment outcomes have been reported. In a study conducted in Milan, Italy, involving 50 patients with SALT ≥50, at weeks 24 and 36, 38.1% and 54.6%, respectively, achieved a SALT score of ≤20[11]. In addition, a study conducted in Belgium assessed the real-world effectiveness and tolerance of baricitinib in AA, involving 19 adults, with a median follow-up of 13 months. Among the 19 patients with SALT ≥50, at the conclusion of the follow-up period, 73.7% achieved a SALT score of ≤20. Complete hair regrowth (SALT=0) was observed in 36.8% of the participants[12]. In our study, conducted in real-world clinical settings across 4 university hospitals in Korea, we observed that 55.4% of patients with an initial SALT score >50 and 48.9% with an initial SALT score >95 achieved a SALT score ≤20 by week 36. These response rates were comparable or even superior to those reported in phase III trials. Similar real-world evidence has been reported in other countries.

It is worth noting that the superior treatment outcomes observed in our study compared with those reported in controlled trials may be partly attributed to the concurrent use of adjunctive therapies. In our cohort, a substantial proportion of the patients received topical corticosteroids, intralesional steroid injections, and/or oral minoxidil alongside baricitinib. These real-world combination strategies, which were not included in controlled trials, could synergistically enhance the overall therapeutic effect of baricitinib. This highlights the importance of considering combination treatment approaches when interpreting real-world data and applying clinical trial findings to clinical practice.

To further explore treatment response patterns, we analyzed the longitudinal changes in SALT scores according to baseline

severity. Stratified analysis revealed that patients with lower initial SALT scores (Group B) experienced more rapid and more substantial improvements than those with higher baseline severity (Group A). When comparing baseline characteristics, Group A had slightly higher proportions of atopic dermatitis (37% vs. 32%) and nail involvement (15% vs. 5%) than Group B, although these differences were not statistically significant. As shown in **Fig. 4**, the mean percentage change in SALT scores was consistently greater in Group B throughout the treatment period. These findings suggest that patients with milder disease at baseline may derive greater therapeutic benefits from baricitinib, particularly in terms of both speed and extent of clinical improvement.

Adverse events (AEs) were reported in 16.8% of the patients, including neutropenia, folliculitis, acne, hyperlipidemia, headache, and gastroenteritis. All AEs were mild to moderate in severity and were managed without discontinuation or dose reduction. Notably, there were no serious AEs, such as herpes zoster, tuberculosis, malignancies, or thromboembolic events. This favorable safety profile is consistent with safety data from the BRAVE-AA1 studies and other international reports[7].

This study has limitations such as a relatively small number of subjects receiving baricitinib, a short study duration of 36 weeks, and the lack of a placebo group. Additionally, we did not systematically collect detailed information on concomitant treatments such as topical corticosteroids, intralesional steroid injections, or topical minoxidil administered during baricitinib therapy, which limits our ability to assess their contribution to the observed outcomes. Despite these limitations, the significance of this study lies in providing data on the clinical efficacy and safety of baricitinib in Korean patients with AA during clinical treatment. To our knowledge, no previous study has specifically evaluated the effectiveness of baricitinib in patients with baseline SALT <50, making this finding a novel contribution to the literature. This is particularly noteworthy, considering that baricitinib is a newly introduced medication for AA. Nevertheless, further research is warranted, particularly involving long-term treatment effects, safety assessments, and comparative studies with other oral JAK inhibitors, to enhance our understanding of the sustained effects and safety profile of baricitinib in the treatment of AA.

In conclusion, baricitinib resulted in rapid, sustained, and meaningful clinical improvement in Korean patients with refractory AA. The treatment was well tolerated and its effectiveness may be further enhanced when combined with adjunctive therapies. These results support the use of baricitinib as an effective and safe therapeutic option for patients with moderate-to-severe AA.

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CONFLICTS OF INTEREST

The authors have nothing to disclose.

DATA SHARING STATEMENT

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

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