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Original Article

Baricitinib for Itch-Dominant Atopic Dermatitis: A 52-week Baricitinib Real-World Experience in Korea

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ABSTRACT

Background: Baricitinib is one of the front-runners among targeted agents for the treatment of atopic dermatitis (AD). Although many studies have been conducted on the real-world use of baricitinib, the sample size is often small and data is focused primarily on Caucasians.
Objective: The objective of this study was to demonstrate the real-world itch-relieving property of baricitinib in adult AD patients in South Korea.
Methods: Electronic medical records of AD patients treated with baricitinib at the National Medical Center in Korea from May 2021 to April 2023 were analyzed retrospectively.
Results: Seventy patients completed 16 to 52 weeks of baricitinib treatment, with most patients showing mild-to-moderate baseline lesions and moderate-to-severe baseline itch. At Week 16 of baricitinib treatment, there was a 50% reduction in Itch numerical rating scale from baseline, and 50.7% of patients showed 50% improvement in Eczema Area and Severity Index score. The efficacy of baricitinib was also reflected in the patient reported outcomes, with 55%–58% improvements in Patient-Oriented Eczema Measure, Atopic Dermatitis Control Tool, and Dermatology Life Quality Index scores seen within 2 weeks of treatment. No new safety signals were detected in this study.
Conclusion: Baricitinib treatment for 52 weeks in Korean patients with itch dominant AD confirmed long term effectiveness and safety.

Keywords: Atopic dermatitis; Baricitinib; JAK inhibitor; Pruritus

INTRODUCTION

Atopic dermatitis (AD) is a chronic, relapsing, inflammatory skin disorder characterized by eczematous skin lesions and pruritus[1,2]. In Korea, AD affects approximately 14% of children and 1%–3% of adults[3-5]. While predominately a pediatric disease, it may persist into or develop in adulthood[2]. Moderate to severe AD can significantly impair quality of life and is frequently refractory to first-line therapies such as emollients, topical corticosteroids (TCS) and topical calcineurin inhibitors[6,7]. In such patients, phototherapy and systemic agents are recommended; however, phototherapy is limited by the inconvenience of frequent clinical visits[2] and the long-term use of systemic agents is not advocated owing to adverse events (AEs)[1,2,8].

Progress in understanding the multifactorial pathogenesis of AD has led to the development of targeted therapies that modulate various inflammatory mediators implicated in the disease process. While T helper lymphocyte (Th) type 2 cytokines are

central to AD inflammation, contributions from Th 1, 17, and 22 axes are also recognized[6,9]. Many of these cytokines rely on the Janus kinase (JAK)-signal transducer and activator of transcription (STAT) signaling pathway, which enriches Th type 2 milieu and promotes inflammatory responses in AD[10]. Among these, interleukin (IL)-31, a Th2 cytokine strongly implicated in pruritus, activates sensory neurons via JAK1-mediated signaling and prolongs eosinophil survival, perpetuating itch and inflammation[10,11].

Baricitinib, an oral selective JAK1/JAK2 inhibitor, interrupts this cascade by blocking multiple cytokine signals including IL-4, IL-13 and IL-31, thereby targeting both inflammatory and pruritogenic components of AD[12,13]. It is the first oral JAK inhibitor approved for adult AD in South Korea, with a recent label expansion to include pediatric patients. Though multiple real-world studies on baricitinib have been conducted, most are limited by their small sample size and predominantly Western study population[14,15]. Therefore, to evaluate the real-world efficacy and safety of baricitinib in Korean patients, focusing specifically on patients with itch-dominant AD—a clinical phenotype underrepresented in other trials—we conducted a comprehensive retrospective data analysis on the largest single-center sample in South Korea to date.

MATERIALS AND METHODS

Ethics statement

A retrospective analysis of the electronic medical records of adult AD patients treated with baricitinib at National Medical Center in Korea between May 2021 and April 2023 was conducted upon approval by the Institutional Review Board (IRB) of National Medical Center (approval number: NMC-2023-05-053). The study was conducted in accordance with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained for publication of clinical images and case details. For retrospective data analysis of anonymized records, IRB approval included a waiver of formal consent.

Study population

The electronic records of patients 18 years of age or older with diagnosed AD who were treated with baricitinib for at least 16 weeks during the study period were analyzed, including sex–gender, age, and clinical characteristics such as age of onset, baseline severity based on Eczema Area and Severity Index (EASI) and Itch numerical rating scale (NRS) scores and previous treatment history. The itch-dominant phenotype was defined as an Itch NRS ≥7 regardless of EASI score. Patients participating in another clinical trial for AD as well as those under concurrent treatment with another systemic immunologic therapy such as cyclosporine, methotrexate, or dupilumab were excluded.

Outcomes

The primary outcome of this study was the percentage change in Itch NRS from baseline. The secondary outcomes included the proportion of patients who achieved 50%, 70% and 90% improvement in EASI score (EASI-50, 75 and 90), the percentage change in EASI scores from baseline in subgroups divided according to itch severity, as well as the change in patient reported outcomes measured by Patient-Oriented Eczema Measure (POEM), Dermatology Life Quality Index (DLQI), and Atopic Dermatitis Control Tool (ADCT).

Exploratory outcomes included the percentage change in EASI score by body regions and signs (erythema, papulation, excoriation and lichenification); the change in laboratory indicators including immunoglobulin E (IgE), lactate dehydrogenase (LDH), and total eosinophil count (TEC); prognostic factors contributing to 50% improvement in Itch NRS (NRS-50) by Week 2 of treatment.

Statistical analysis

Continuous variables are presented as the means with standard error or median with interquartile range, while categorical variables are presented as frequency with percentages. The change in efficacy outcomes and laboratory indicators between the baseline and Weeks 16, 32, and 52 of treatment was analyzed using the Wilcoxon signed rank test with Bonferroni correction. Longitudinal analyses were conducted per-protocol on patients completing at least 16 weeks. Missing values were handled via pairwise deletion. In addition, univariable and multivariable logistic regression analyses were performed in order to determine the potential prognostic factors affecting the achievement of NRS-50 at Week 2 of treatment. All statistical analyses were performed using the R software (version 4.1.2; www.r-project.org; R Foundation for Statistical Computing, Vienna, Austria). Statistical significance was determined at a p-value less than 0.05.

RESULTS

Patient disposition and baseline characteristics

Seventy patients in total were included in this study. Baseline demographics and disease characteristics of the study population are listed on **Table 1**. The median baseline of EASI score of the study population was 4.65, with most patients (n=62) showing EASI score below 16 at baseline. In contrast, the median baseline of Itch NRS was 5.30, with 82.9% of patients showing moderate-to-severe baseline pruritus, defined as Itch NRS ≥4, demonstrating an itch-dominant demographic despite generally low EASI scores.

Patients who at least completed 16 weeks of baricitinib treatment were included in this study. Of those 70 patients, 41 patients

Table 1. Baseline demographics and disease characteristics

Patient characteristics	Values (n=70)
Age (yr)	32.2±11.3
Sex	
Male	46 (65.7)
Female	24 (34.3)
AD onset	
Childhood	48 (68.6)
Adult	22 (31.4)
Baseline severity based on EASI	
Mild (EASI<16)	62 (88.6)
Moderate (16≤EASI<23)	7 (10)
Severe (EASI≥23)	1 (1.4)
Baseline severity based on Itch NRS	
Mild (NRS<4)	12 (17.1)
Moderate (4≤NRS<7)	34 (48.6)
Severe (NRS≥7)	24 (34.3)
Baseline EASI	4.65 (2.62–4.90)
Baseline Itch NRS	5.30 (4.00–7.00)
Previous treatment	
Topical	
TCS	62 (88.6)
TCI	45 (64.3)
Systemic	
Systemic steroids	39 (55.7)
Cyclosporine	43 (61.4)
Methotrexate	4 (5.7)
Dupilumab	6 (8.6)
Others	
Phototherapy	17 (24.3)
Immunotherapy	5 (7.1)
Home remedy	8 (11.4)
Korean traditional medicine	19 (27.1)

Values are presented as number (%), mean ± standard deviation, or median (first and third quartiles).
AD: atopic dermatitis, EASI: Eczema Area and Severity Index, NRS: numerical rating scale, TCS: topical corticosteroid, TCI: topical calcineurin inhibitor.

completed 32 weeks of treatment, and 25 patients completed 52 weeks of treatment.

Efficacy outcomes

1) Itch NRS

At Week 2 of baricitinib treatment, a 40% improvement in Itch NRS score was observed. The percentage improvement seen in Itch NRS scores at Weeks 16, 32, and 52 of baricitinib treatment were 50%, 57.14%, and 53.57%, respectively (**Fig. 1**).

2) EASI

Improvements in EASI scores were seen in the early weeks of baricitinib treatment, with 47.5% of patients achieving EASI-50 within 2 weeks. Similarly, 18% and 14.8% of patients achieved EASI-75 and EASI-90 within 2 weeks of treatment, respectively. These effects were well maintained throughout the duration of treatment, with 60%, 43.3%, and 16.7% of patients achieving EASI-50, 75 and 90, respectively, at Week 52.

EASI scores improved with baricitinib treatment across all body regions at Week 16. The most notable improvement was seen in the lower extremities, with 75% improvement of EASI score. Improvements of EASI scores were also observed across all individual signs, with 53% improvement seen in erythema, 57% in induration, 71% in excoriation, and 77% in lichenification.

Improvements in EASI scores with baricitinib treatment were also assessed in subgroups divided based on patients' itch severity at baseline. In patients with severe baseline itch (Itch NRS ≥7), the percentage change in EASI score from baseline was greater compared to those with mild to moderate baseline itch. The greatest difference was seen early in the treatment, with patients with severe baseline itch showing 62% decrease in EASI score compared to 36% in those with mild-to-moderate baseline itch (**Fig. 2**).

This result was also supported by the 2-step univariable and multivariable logistic regression analysis on the potential prognostic factors for Itch NRS-50 at Week 2 of treatment. This analysis showed that moderate-to-severe baseline severity according to EASI scores is a significant prognostic indicator for Itch NRS-50 at Week 2.

Decrease in both Itch NRS and EASI scores with baricitinib treatment is well demonstrated in **Fig. 3**, of a 26-year-old male who presented with a baseline EASI score of 14.1 and Itch NRS score of 7. At Week 16 of baricitinib, he showed significant improvement with EASI of 1.1 and NRS of 4, which was maintained throughout 32 weeks of treatment. Marked improvements were also seen in patient reported outcomes.

Patient reported outcomes

Patient perception of symptoms, disease control, and quality of life in relation to AD was measured using various tools, including POEM, ADCT, and DLQI. Marked improvements in all indices

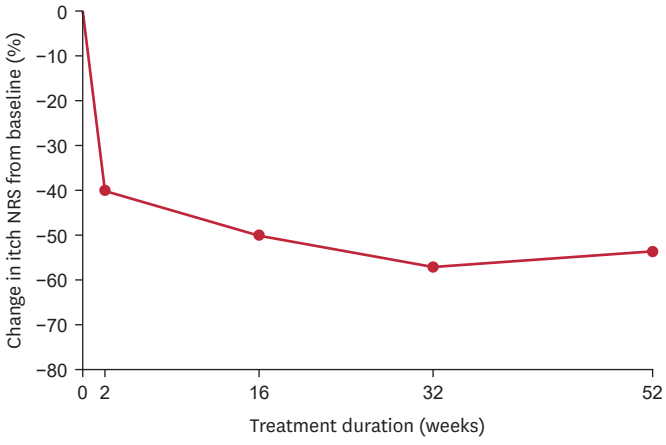

Fig. 1. Change in Itch NRS scores in total population at discrete timepoints during treatment compared to baseline.
NRS: numerical rating scale.

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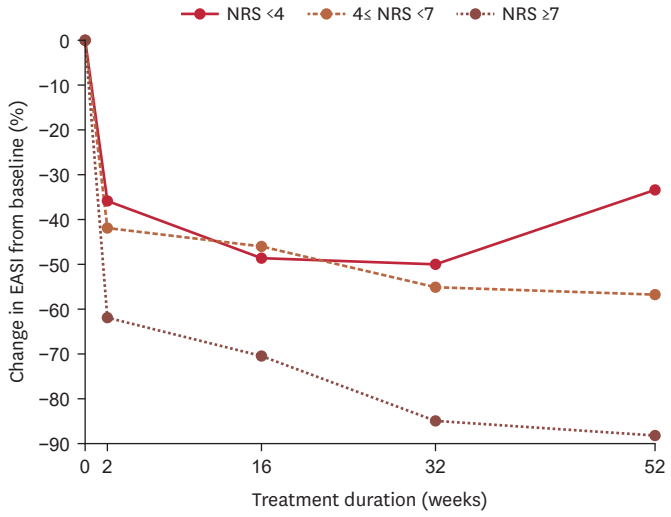


Fig. 2. Percentage change in disease severity by EASI according to baseline severity by Itch NRS.
EASI: Eczema Area and Severity Index, NRS: numerical rating scale.

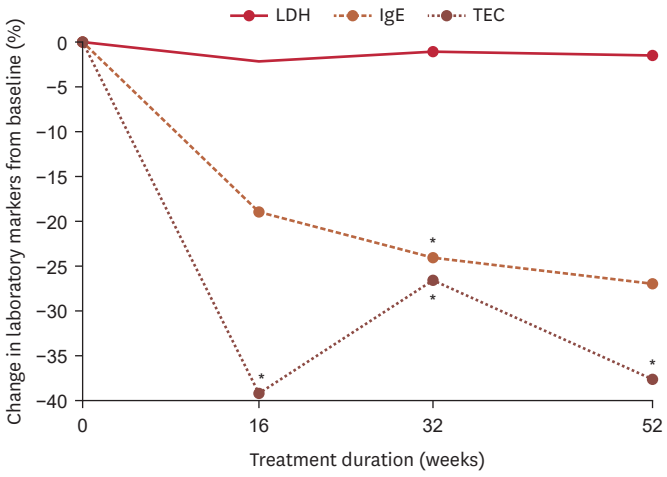


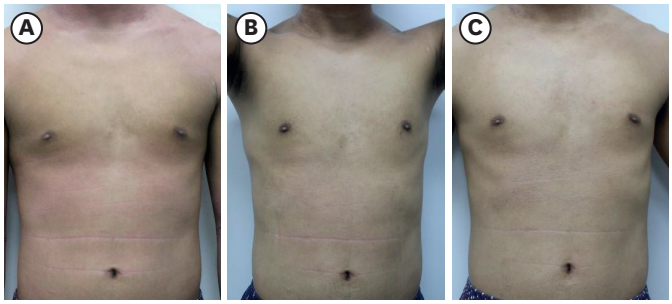
Fig. 4. Percentage change in laboratory markers from baseline at discrete timepoints during baricitinib treatment.
LDH: lactate dehydrogenase, IgE: immunoglobulin E, TEC: total eosinophil count.
*p<0.05 by Wilcoxon signed rank test.

were seen with 55%–58% change from baseline within 2 weeks of treatment and this was maintained throughout the duration of treatment.

Laboratory indices

Laboratory markers of disease control, including IgE, TEC and LDH were measured at Weeks 16, 32, and 52 of baricitinib treatment. IgE level decreased significantly at Week 32 of treatment compared to baseline but did not achieve statistical significance at Weeks 16 and 52. TEC demonstrated significant decrease compared to baseline at Weeks 16, 32, and 52 of treatment. On the other hand, LDH level did not show a statistically significant percentage change from baseline throughout the duration of this study period (**Fig. 4**).

Interestingly, of the 3 laboratory indices, baseline IgE level of >1,000 was found to be a significant prognostic factor for Itch NRS-50 at Week 2 of treatment.



Week 0	Week 16	Week 32
EASI 14.1	EASI 1.1	EASI 1.2
Itch NRS 7	Itch NRS 4	Itch NRS 4
POEM 23	POEM 7	POEM 7
DLQI 24	DLQI 6	DLQI 6
ADCT 21	ADCT 4	ADCT 6

Fig. 3. Clinical characteristics, EASI score and patient reported outcomes of a 26-year-old male who underwent treatment with baricitinib at (A) Week 0, (B) Week 16 and (C) Week 32.
EASI: Eczema Area and Severity Index, NRS: numerical rating scale, POEM: Patient-Oriented Eczema Measure, DLQI: Dermatology Life Quality Index, ADCT: Atopic Dermatitis Control Tool.

Safety outcomes

Generally acceptable and manageable safety and tolerability profile was seen with baricitinib treatment in the described patient group. The 42.8% of all patients (n=30) experience any-cause AEs, with the most common AE being acne (n=25, 35.7%), followed by herpes simplex infection (n=9, 12.9%). There was no dose reduction or interruption nor drug discontinuation due to AEs. Of the 25 patients who reported acne during baricitinib treatment, 5 had a prior history of acne. Of these 5 patients, 3 reported aggravation of acne after baricitinib treatment, and 2 reported stable symptoms. Acne was well managed with standard therapy, with 18 out of the 25 patients receiving oral isotretinoin, and the other 7 receiving topical treatments only.

Experience with baricitinib after dupilumab discontinuation

Six out of 70 patients received dupilumab prior to initiating baricitinib treatment. All 6 patients were receiving dupilumab at a reduced frequency of every 4 to 8 weeks and discontinued dupilumab treatment due to flare-up of AD symptoms. Two out of the 6 patients received 52 weeks of baricitinib treatment, 1 received 32 weeks of baricitinib treatment, and the remaining 3 received

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Table 2. Univariate and multivariate analyses of potential prognostic factors for relief of itch at week 2 by Itch numerical rating scale-50

Variables	Univariable		Multivariable	
	OR (95% CI)	*p*-value	OR (95% CI)	*p*-value
Age	1.018 (0.970–1.072)	0.481	1.023 (0.947–1.113)	0.574
Sex				
Female	Reference		Reference	
Male	0.762 (0.250–2.254)	0.625	0.810 (0.164–3.835)	0.788
Baseline EASI severity				
Mild	Reference		Reference	
Moderate, severe	4.043 (0.844–29.355)	0.105	19.930 (2.149–502.945)	0.021
AD onset				
Childhood	Reference		Reference	
Adult	1.035 (0.346–3.071)	0.950	1.254 (0.205–8.200)	0.806
Baseline IgE				
≤200	Reference		Reference	
200–1,000	0.400 (0.078–1.906)	0.251	0.300 (0.049–1.639)	0.170
>1,000	0.211 (0.061–0.665)	0.010	0.161 (0.028–0.723)	0.024
Baseline TEC				
≤500	Reference		Reference	
>500	0.275 (0.038–1.267)	0.128	0.194 (0.007–2.651)	0.254
Baseline LDH				
≤250	Reference		Reference	
>250	0.321 (0.044–1.543)	0.187	1.636 (0.141–16.001)	0.669
Baseline uric acid				
≤7	Reference		Reference	
>7	0.400 (0.054–2.041)	0.299	0.900 (0.074–9.271)	0.929
Number of prior treatments	0.600 (0.317–1.088)	0.101	0.644 (0.290–1.359)	0.256

OR: odds ratio, CI: confidence interval, EASI: Eczema Area and Severity Index, AD: atopic dermatitis, IgE: immunoglobulin E, TEC: total eosinophil count, LDH: lactate dehydrogenase.

16 weeks of baricitinib treatment at the time of data cut-off. All 6 patients showed adequate disease control with baricitinib.

Prognostic factors for Itch NRS-50

Univariate and multivariate regression analysis was performed to identify potential prognostic factors affecting the achievement of Itch NRS-50 at Week 2 of baricitinib treatment (**Table 2**). Factors included in this analysis were age; sex; baseline severity by EASI; time of AD onset; baseline IgE level; baseline TEC level; baseline LDH level; baseline uric acid level; and the number of prior treatments. Of the factors described, baseline IgE level of >1,000 was identified as a significant prognostic factor upon univariate analysis. Multivariate analysis identified moderate-to-severe baseline EASI and baseline IgE level of >1,000 as significant prognostic factors for achieving Itch NRS-50 at Week 2.

DISCUSSION

This study evaluates the efficacy and safety of baricitinib in adult AD patients treated at National Medical Center in South Korea between May 2021 and April 2023. To our knowledge, this is the largest single-center Korean sample studied to date.

It is now well known that AD is associated with acute Th2-dominant inflammatory response that leverages JAK-STAT pathway to induce numerous cytokine-mediated downstream gene transcription[10,11]. IL-31 is one such Th2 cytokine that not only delays the apoptosis of eosinophils and stimulates other pro-inflammatory cytokines and chemokines but also is a principal culprit behind pruritus. Indeed, pruritus is an important symptom of AD only moderately correlated to lesion severity, as seen in a prospective observational study by Chovatiya et al.[16] that showed nearly a quarter of all AD patients had severe itch but mild-to-moderate lesions (SI-ML subtype).

Our study demonstrates an itch-dominant population that corresponds to the SI-ML phenotypic subtype, with only 1.4% of patients showing severe lesions (EASI >23) while 34.3% showed severe itch (Itch NRS ≥7). Hence, we here describe the treatment outcomes with baricitinib using various efficacy measures to address the multifaceted nature of AD. This is of particular importance because patient perception of treatment outcome in AD is dependent not only on the objective measures of disease severity but also on the subjective symptoms. A previous retrospective study on Korean AD patients demonstrated that EASI bears no correlation to patient quality of life, while subjective measurement tools such as POEM and NRS show strong correlation[17].

Patients showed improvements in both lesion severity and itch severity as early as Week 2 of treatment with baricitinib, which were well maintained throughout treatment. When comparing our data to placebo-controlled phase 3 clinical trials of baricitinib

monotherapy, namely BREEZE-AD 1 and 2[18], the percentage change from baseline in Itch NRS at Week 2 of treatment were −30.1 and −23.6 for BREEZE-AD 1 and 2 respectively, and −40.0 for this study. The proportion of patients who achieved EASI-75 by Week 16 of treatment were 24.8 and 21.1 for BREEZE-AD 1 and 2 respectively, and 30.4 for this study. However, the percent change from baseline of EASI score at Week 16 of treatment were higher in clinical trials; 59.4 and 54.9 for BREEZE-AD 1 and 2 respectively and −50.0 for this study. A possible explanation for this phenomenon is that our patient group had a much lower baseline EASI score than the patient groups of clinical trials. When comparing our data to phase 3 clinical trials of baricitinib with TCS rescue, BREEZE-AD 7[19], our results showed less improvement in EASI score. The proportion of patients who achieved EASI-75 by Week 16 of treatment were 48 and 30.4 for BREEZE-AD 7 and our study respectively. While the rapid NRS response appears more pronounced than in pivotal trials, caution is needed when comparing to phase III trials due to differing baseline EASI scores and treatment settings. Patterns of improvements in EASI by body region were similar to those seen in the pivotal trials, with greatest improvement seen in the lower extremities. It is noteworthy that, upon assessing individual signs in EASI scale, the most marked improvement was observed with lichenification, which is a feature that is more prominent in Asian patients[20]. Similarly, patient reported outcomes measured by POEM, ADCT, as well as DLQI scales all showed marked improvements by Week 2 of treatment. This effect was maintained throughout 52 weeks of therapy.

IgE, LDH, and TEC were measured at baseline and at Weeks 16, 32, and 52 of treatment of baricitinib to assess its effect on laboratory markers which are possibly related to AD disease severity. A significant decrease in TEC was seen consistently throughout treatment. This may be attributable to inhibition of JAK2 pathway by baricitinib, which disrupts IL-5 signaling in eosinophils and downregulates eosinophilic proliferation, survival, and effector functions[10]. Though baseline TEC was not an independent prognostic factor for Itch NRS-50 based on our univariate and multivariate analyses, we may postulate that baricitinib would be a reasonable treatment option for hypereosinophilic patients. Because baricitinib is the only JAK inhibitor that targets JAK2, we can assume that it would be more effective in hypereosinophilic AD patients compared to upadacitinib and abrocitinib which mainly targets JAK1 only. Furthermore, dupilumab, the first advanced systemic biologic approved for AD in South Korea, seems to show poorer prognosis in hypereosinophilic patients. It has been previously observed that the absence of hypereosinophilia is a predictive biomarker of response to dupilumab at Week 4 of treatment[21]. We have also previously reported 4 cases of poor responders to dupilumab, all of who exhibited baseline hypereosinophilia[22]. Though numerical decrease in IgE levels were seen with baricitinib, statistical significance was achieved only at Week 32 due to large error margins at Weeks 16 and 52. On the other hand, baseline IgE of >1,000 was identified as a prognostic factor for achieving Itch NRS-50 at Week 2. Elevated IgE may indicate more active Th2 signaling, particularly IL-4 and IL-13 mediated pathways that contribute to itch via IL-31 upregulation[23]. This may explain early NRS response with JAK inhibition. However, further studies are needed to validate this predictive association.

It seems evident that baricitinib presents a characteristic clinical evolution unlike other systemic biologics, perhaps due to its dual JAK inhibition and involvement in various cytokine pathways, including IL-1 and IL-17 axes. Further study is needed to establish the clinical and laboratory implications of this unique mode of action and leverage them for patient-tailored treatment.

No new safety concerns associated with baricitinib were seen in this study. No dose delay, interruption, or discontinuation was seen. All 30 patients who experienced any-cause AE after initiating baricitinib showed improvement of symptoms over time with appropriate supportive therapy. However, acne incidence was relatively high (35.7%) compared to existing studies. This may be due to baricitinib's modulation of the JAK-STAT/IL-22 axis, potentially affecting sebaceous gland function leading to de novo acne or acne exacerbation[24].

After the approval of baricitinib for moderate-to-severe AD, 2 more oral JAK inhibitors, upadacitinib and abrocitinib, have also been approved. Although head-to-head trials are lacking, meta-analyses suggest baricitinib offers a safer profile[25,26] and therefore is the only drug to be approved for pediatric patients under age 12[12,13].

This study is limited by its non-clinical, retrospective nature. However, the results of this study should nevertheless be considered with interest as it was conducted not only on the largest single-center sample in South Korea but also on itch-dominant population, in contrast to previous studies conducted predominantly on patients with moderate-to-severe lesion severity.

AD is a complex disease with heavily heterogenous pathogenesis and widely varying phenotypes and endotypes. We here present the real-world experience with baricitinib in Korean patients with predominantly SI-ML type AD. This study confirms baricitinib as an effective and safe treatment for AD and reinforces the need for further exploration of its therapeutic characteristics.

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CONFLICTS OF INTEREST

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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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