



Original Article

Treatment of atopic dermatitis with abrocitinib in real practice in Spain: efficacy and safety results from a 24-week multicenter study

Jose Carlos Armario-Hita,^{1,†} Jose Juan Pereyra-Rodriguez,^{2,3,†}  Alicia González-Quesada,⁴ Pedro Herranz,⁵ Ricardo Suarez,⁶ Manuel Galan-Gutiérrez,⁷ Mercedes Rodríguez-Serna,⁸ Javier Ortiz de Frutos,⁹ José Manuel Carrascosa,¹⁰  Esther Serra-Baldrich,¹¹ Mariano Ara-Martin,¹² Ignasi Figueras-Nart,¹³ Juan Francisco Silvestre,¹⁴ Violeta Zaragoza-Ninet,¹⁵ and Ricardo Ruiz-Villaverde,¹⁶

¹Department of Dermatology, University Hospital of Puerto Real, University of Cádiz, Spain, ²Department of Dermatology, University Hospital Virgen del Rocío, Sevilla, Spain, ³Department of Medicine, School of Medicine, University of Sevilla, Sevilla, Spain, ⁴Department of Dermatology, University Hospital Dr. Negrin, Gran Canarias, Spain,

⁵Department of Dermatology, University Hospital La Paz, Madrid, Spain,

⁶Department of Dermatology, University Hospital Gregorio Marañón, Madrid, Spain,

⁷Department of Dermatology, University Hospital Reina Sofía, Córdoba, Spain,

⁸Department of Dermatology, University Hospital La Fe, Valencia, Spain,

⁹Department of Dermatology, University Hospital 12 de Octubre, Madrid, Spain,

¹⁰Department of Dermatology, University Hospital Germans Trias i Pujol, Badalona, Spain,

¹¹Department of Dermatology, University Hospital San Pau, Barcelona, Spain,

¹²Department of Dermatology, University Hospital Lozano Blesa, Zaragoza, Spain,

¹³Department of Dermatology, University Hospital of Bellvitge, Barcelona, Spain,

¹⁴Department of Dermatology, University Hospital of Alicante, Alicante, Spain,

¹⁵Department of Dermatology, University Hospital of Valencia, Valencia, Spain; and

¹⁶Department of Dermatology, University Hospital of san Cecilio, Granada, Spain

Abstract

Background Abrocitinib, a selective JAK 1 inhibitor, was recently approved in Europe. Despite its approval, real-world data on its efficacy and safety in treating moderate-to-severe atopic dermatitis (AD) remains limited.

Objectives This study aimed to evaluate the short-term effectiveness and safety of abrocitinib in a real-life setting for patients with moderate-to-severe AD.

Methods We conducted a retrospective multicenter study involving adult patients with moderate-to-severe AD who started abrocitinib treatment between May 1, 2023, and September 30, 2023, in 15 Spanish hospitals. Treatment doses were 100 or 200 mg daily, based on clinical assessment. Data collection included patient demographics, AD history, comorbidities, previous treatments, and disease severity indicators such as SCORing atopic dermatitis (SCORAD), Eczema Area and Severity Index (EASI), body surface area, and Peak Pruritus NRS scores at baseline, 4, 12, and 24 weeks. Quality of life was measured using the Dermatology Life Quality Index (DLQI), and safety was assessed by monitoring adverse reactions and various biochemical parameters.

Results The cohort comprised 76 patients with an average age of 33.93 years; 57.89% were male. Before abrocitinib, 36.84% were naïve to advanced therapies. The baseline mean scores were SCORAD 47.04, EASI 21.79, and DLQI 15.01. At Week 24, there were significant improvements: EASI was reduced to 2.81, and 70.58% of the patients achieved EASI 75. However, 18.42% discontinued treatment mainly due to inefficacy or adverse effects. The safety profile was favorable, with 22.37% reporting mild adverse events (AEs) and one serious case of cutaneous lymphoma.

Conclusions This first Spanish series assessing abrocitinib in real-world conditions reveals a significant improvement in AD symptoms and quality of life in a range of severity and prior treatment failures. Abrocitinib was well-tolerated, with few serious AEs, highlighting its potential as an effective treatment option for AD.

Keywords

atopic dermatitis; treatment; abrocitinib; JAK inhibitors; Spain.

Correspondence

Jose-Juan Pereyra-Rodríguez
Department of Dermatology
University Hospital Virgen del Rocío
Avda. Manuel Siurot s/n

Sevilla 41013
Spain
E-mail: jpereyra@us.es

†These two authors have contributed equally to the work.

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Introduction

Atopic dermatitis (AD) is one of the most common skin diseases, with a classically estimated prevalence of more than 20% in children and 1%–3% in adults.¹ The prevalence of severe AD in Spain is 0.10%.² The clinical course and presentation are heterogeneous. Meanwhile, 85% of patients first develop the disease before the age of 5, with spontaneous resolution during childhood. In most cases, AD can remain a chronic condition during adulthood for a significant number of patients, estimated by some reviews to be as high as 40% of cases.¹

Treatment goals are to reduce symptoms, prevent exacerbations, and minimize treatment risks. The standard of care for mild cases focuses on topical therapy with calcineurin inhibitors or topical corticosteroids (TCS). Topical treatments for AD show limited efficacy, and the use of TCS is limited in the short term due to the identified side effects associated with long-term use and their potential rebound effect after discontinuation.³ On the other hand, there is consensus on the need to use systemic treatment in all patients with moderate–severe AD in whom lesions and/or pruritus are not controlled with topical treatment, potentially associated with narrow-band UV phototherapy (UVB-BE).⁴ The decision to initiate systemic treatment should be individualized among patients, including a severity assessment using scales and patient-reported outcomes such as quality of life or itching, in addition to other individual factors such as efficacy and compliance with previous treatments, presence of comorbidities, and patient preferences.³ The complementary evaluation of the quality of life using various scoring systems in AD is crucial, as highlighted in the Italian guidelines. These guidelines emphasize the significance of a comprehensive approach that assesses the patient's well-being and considers the impact on caregivers.⁵ By incorporating multiple quality-of-life scores, healthcare providers can gain a more holistic understanding of the disease burden, ensuring a more effective and empathetic treatment plan supporting patients and their caregivers.

The therapeutic options for the management of moderate-to-severe AD have increased substantially in the last two years, and after the use of cyclosporine (except in cases of intolerance or contraindication), a range of biological drugs were introduced (IL4/13 inhibitor—dupilumab; IL13 inhibitors—tralokinumab and lebrikizumab; and JAK inhibitors—baricitinib and upadacitinib), with abrocitinib being the last molecule to be incorporated for use in real life.

Abrocitinib is a selective Janus kinase (JAK)1 inhibitor. JAK1 inhibition reduces the signaling of various mediators that control the signs and symptoms of AD, eczema, and itching. Its use is recommended in monotherapy or in combination with topical corticosteroids (TCS), avoiding its combination with cyclosporine or other potent immunosuppressants in AD, as the consequences of additive immunosuppressive effects have not been thoroughly studied.⁶

One year after the incorporation of abrocitinib into our therapeutic arsenal, we believe it is appropriate to evaluate its performance in real clinical practice and to assess the differences with published pivotal clinical trials in which the efficacy of abrocitinib is revealed in monotherapy and in combination with TCS. Consequently, we conducted a retrospective observational non-interventional study under real clinical practice conditions of patients treated with abrocitinib 100 or 200 mg orally in 15 hospitals in Spain to assess both efficacy and safety.

Patients and Methods

Study design and participant selection

A multicenter observational prospective noninterventional study was conducted involving adult patients diagnosed with moderate-to-severe AD who initiated treatment with abrocitinib between May 1, 2023, and March 31, 2024, in 15 hospitals in Spain. Experienced dermatologists carried out diagnosis confirmation. The funding conditions in Spain include the presentation of moderate-to-severe AD, an Eczema Area and Severity Index

(EASI) score greater than 21, and lack of control, intolerance, or contraindication to cyclosporine A.

Treatment regimens and data collection

Dermatologists prescribed the patients abrocitinib in doses of 100 or 200 mg, as both doses are approved for use in adults. Patients over 65 years of age had to start with 100 mg. No washout was performed for patients already treated with another medication. Patients could simultaneously use TCS or antihistamines.

The data collected included demographic characteristics, disease duration, comorbidities, and previous systemic, biological, and JAK inhibitor treatments. At each visit, the SCORing atopic dermatitis (SCORAD), EASI, body surface area, Investigator Global Assessment (IGA), and the numerical rating scale of the peak pruritus (PP-NRS) were calculated, as well as the Dermatology Life Quality Index (DLQI). Follow-up visits were scheduled at Weeks 4, 12, and 24. Blood tests were performed, including complete blood count and liver, lipid, CPK, and IgE profiles. Adverse events (AEs) were also recorded, and the follow-up period lasted 24 weeks.

Patients had to give their written informed consent to participate in this study before the study was started. This study was approved by the Virgen del Rocío Hospital (Seville) Ethics Committee with reference 1631-M2-22.

Statistical analysis

Data collection was done in an Excel sheet at different visits. For statistical analysis and graph creation, GraphPad v.9.2 was used. The descriptive analysis included frequencies and percentages for categorical variables and mean and standard deviation for numerical variables. Before inferential statistics, normality was checked using the *D'Agostino-Pearson* test. Differences observed at follow-up visits were analyzed using the Student's *t*-test if normality was met or the Wilcoxon test if not. Statistical significance was considered $P < 0.05$. Finally, the chi-square test was used to compare the differences in the proportion of EASI 75 responders between naïve and non-naïve patients.

Results

Patients and baseline characteristics

A total of 76 patients were included. Both patients who discontinued treatment and those who achieved at least 24 weeks of follow-up were included in the analysis. The baseline characteristics are summarized in Table 1. 57.89% of the patients were male. The mean duration of the disease was 20.21 years (SD = 10.89). The mean weight was 73.37 kg (SD = 16.37), and the BMI was 25.40 (SD = 5.91). The patients had the following concomitant diseases: allergic rhinitis 42.11%, asthma 34.21%, conjunctivitis 22.37%, food allergies 9.21%, nasal polyps 2.63%, and eosinophilic esophagitis 1.32%. 86.84% of

Table 1 Baseline demographic and clinical characteristics ($n = 76$)

Characteristic	Value
Age, years (mean \pm SD)	33.93 \pm 12.22
Sex, male (n , %)	44, 57.89
AD duration, years (mean \pm SD)	20.21 \pm 10.89
BMI	25.40 \pm 5.91
Comorbidities (n , %)	
Allergic rhinitis	32, 42.11
Extrinsic asthma	26, 34.21
Conjunctivitis	17, 22.37
Alimentary allergies	7, 9.21
Nasal polyps	2, 2.63
Eosinophilic esophagitis	1, 1.32
Previous treatments (n , %)	
Oral corticosteroids	76, 100
Cyclosporine	66, 86.84
Dupilumab	33, 43.42
Tralokinumab	21, 27.63
Upadacitinib	17, 22.37
Baricitinib	8, 10.53
Baseline SCORAD (mean \pm SD)	47.04 \pm 12.02
Baseline EASI (mean \pm SD)	21.79 \pm 9.64
Baseline pruritus NRS (mean \pm SD)	7.50 \pm 2.00
Baseline DLQI (mean \pm SD)	15.01 \pm 6.69
Baseline PGA = 4 (n , %)	39, 51.32

BMI, body mass index; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; NRS, numerical rating scale; PGA, Physician Global Assessment; SCORAD, SCORing atopic dermatitis; SD, standard deviation.

the patients had previously received cyclosporine, 43.42% dupilumab, 27.63% tralokinumab, 22.37% upadacitinib, and 10.53% baricitinib. 36.84% of patients were naïve to advanced therapy. The baseline SCORAD was 47.04 (SD = 12.02), EASI 21.79 (SD = 9.64), DLQI 15.01 (SD = 6.69), PGA 3.39 (51.32% PGA 4), and PP-NRS for itching was 7.50 (SD = 2.00).

Effectiveness

Rapid improvement was observed at Week 4 in patients treated with abrocitinib (Figure 1). At the 12-week follow-up visit, EASI decreased to 4.51 (SD = 6.27), and PP-NRS reduced to 2.47 (SD = 2.86). In the 24-week follow-up visit, EASI decreased to 2.81 (SD = 3.19) and PP-NRS to 2.38 (SD = 3.09).

78.95% of the patients achieved EASI 75 in Week 12, and 60.53% achieved EASI 90. Regarding other effectiveness measures, 72.13% achieved IGA 0/1 at Week 12. 70.58% of the patients achieved EASI 75 at Week 24 and 55.88% achieved EASI 90. 67.10% achieved IGA 0/1 at Week 24 (Figure 2).

A significant difference was observed in the achievement of EASI 75 at Week 24, depending on whether they were naïve to advanced therapy (92.86%) compared with non-naïve patients (70.83%; Figure 3). In absolute terms, at Week 24, 64.47% of patients achieved an EASI less than 7, an IGA <1, and a pruritus NRS <4, reaching the minimum activity of the disease.

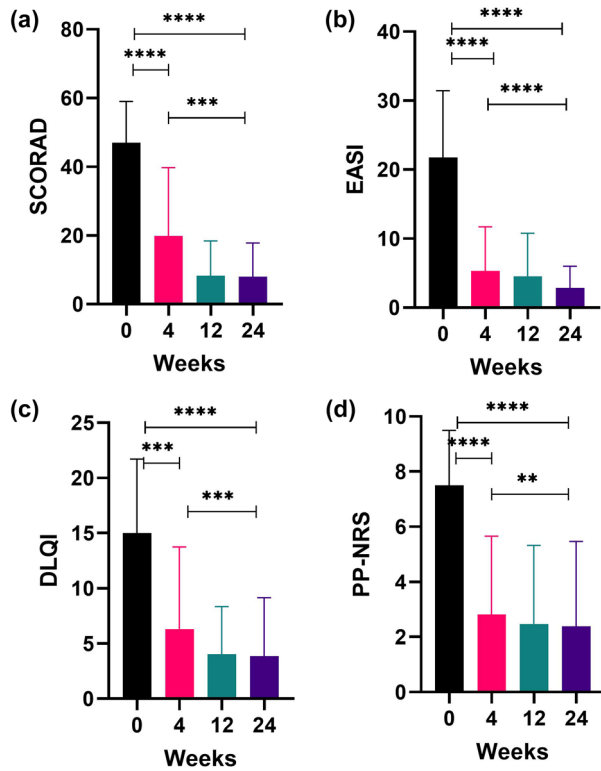


Figure 1 (a) SCORAD, (b) EASI, (c) DLQI, and (d) PP-NRS pruritus were measured at baseline visits and weeks 12 and 24. Differences in means were analyzed using the Wilcoxon test. ** $P < 0.01$; *** $P < 0.001$; **** $P < 0.0001$

Dosing regimens

Three patients (3.95%) started with abrocitinib 100 mg QD and continued with this dose until Week 24. Two patients reached EASI 90 and IGA 1; one lost efficacy at Week 24. In two patients who achieved IGA at Weeks 4 and 12, the abrocitinib dose was adjusted to 100 mg. These patients maintained efficacy until Week 24 with the 100 mg dose.

Safety

The safety profile was generally favorable. Some mild AEs were found in 17 patients (22.37%). The most frequently reported AEs were gastrointestinal discomfort, including nausea (3.95%), CPK elevation (3.95%), asthenia (2.63%), headache (1.32%), and herpes zoster (1.32%). In laboratory controls, only one case of mild lymphopenia was found. Three patients had to discontinue treatment, including the diagnosis of cutaneous lymphoma, 1 month after starting treatment.

Treatment discontinuation

A total of 14 (18.42%) patients discontinued abrocitinib during follow-up. Eleven of these patients (78.57%) discontinued treatment due to ineffectiveness. Of these, 9/11 patients had previously received advanced therapy (7 biologics, 5 JAKi, and 3 both types of therapies) (Table 2). Three patients (21.43%) discontinued due to adverse effects. Two patients developed gastrointestinal intolerance, and one patient was diagnosed with cutaneous lymphoma 1 month after starting treatment.

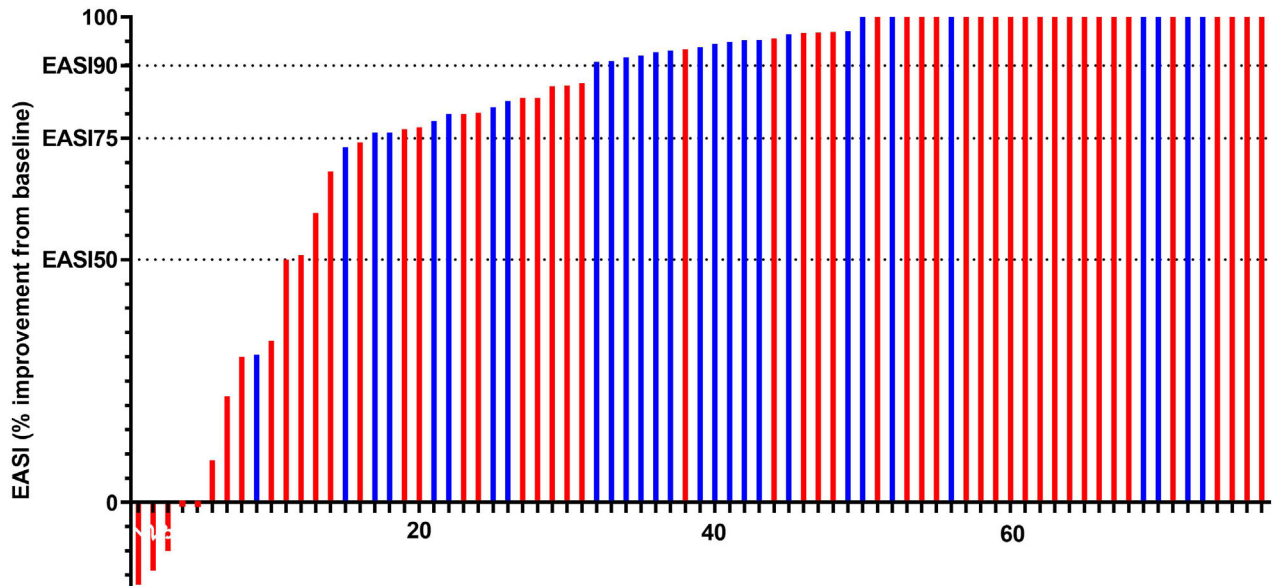


Figure 2 Percentage reduction in EASI compared with the baseline value. Each bar represents the value of each patient in the study, ordered from lowest to highest. The blue color represents naive patients, while the color red represents non-naive patients

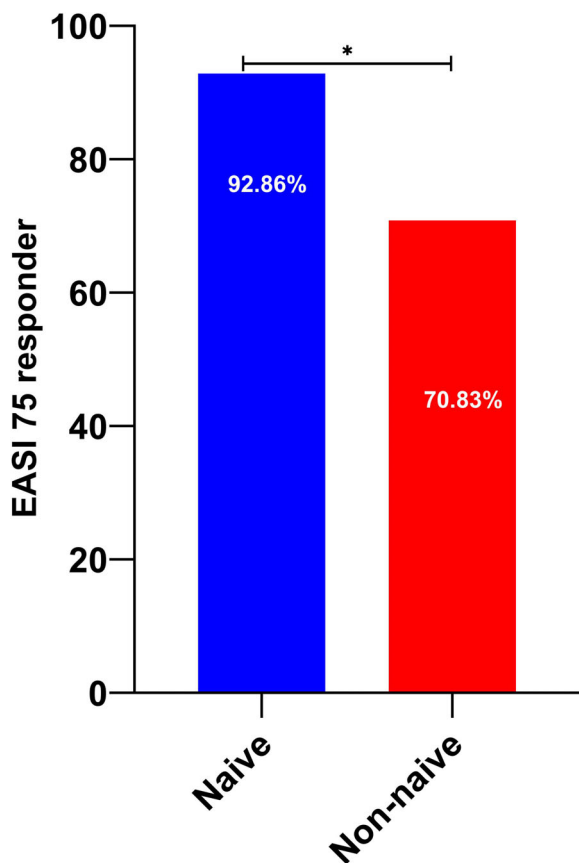


Figure 3 Difference in percentage of EASI 75 responders between naive and non-naive patients. * $P < 0.05$

Table 2 Previous treatment in patients discontinued due to ineffectiveness

Patient number	Dupilumab	Tralokinumab	Baricitinib	Upadacitinib
4	X			
10				X
17				
20	X		X	X
21	X	X		
51	X			
54	X			X
71				
73				X
75	X	X		X
76	X			

Discussion

This real-world evidence study is the largest to date, and it evaluates the effectiveness and safety of abrocitinib up to Week 24. Abrocitinib treatment rapidly improved both the severity of eczema and patient-reported symptoms. Patients had

long-standing severe AD and had failed multiple previous treatments, including biological therapies or JAK inhibitors. Specifically, it should be noted that 70.59% (12 out of 17 patients) who had not responded to upadacitinib showed a good response to abrocitinib. This is not a new finding in our series but has been previously reported.^{7,8} It has been suggested that although both drugs share the exact mechanism of action by selectively inhibiting JAK1, they are not identical molecules and differ in their pharmacodynamic properties, affinity, and selectivity for JAK isoforms. However, it must be considered that of the 11 patients who discontinued treatment due to lack of efficacy, 9 had previously received advanced therapy.

So far, only a few previous studies have been published on the real-world experience with abrocitinib.⁷⁻¹² These studies include patients with different follow-up times. In contrast, our study only analyzes patients who complete at least a 24-week follow-up period. Olydam *et al.*⁷ conducted a single-center prospective study with 41 patients with AD treated with abrocitinib. Although the authors report a median follow-up of 28 weeks, the results only show the outcomes of the last follow-up visit in relation to the baseline visit. The lack of a report on the temporal evolution of the disease does not allow us to compare it with our results.

Two real-world evidence studies have been conducted on the Asian population. In the first single-center prospective study, Hu *et al.*⁹ included 21 AD patients in China treated with abrocitinib. EASI 75 and EASI 90 responses were achieved in 89% and 56% of the patients, respectively, at Week 12. No serious AEs were found. Another study with an identical methodology (single-center, observational, and prospective) was conducted by Uchiyama *et al.*¹⁰ They included only 12 Japanese patients with AD treated with abrocitinib. Responses to EASI 75 and EASI 90 were achieved in 41.6% and 16.7% of the patients, respectively, at Week 12. No serious AEs were found. These two studies support the effectiveness and safety of abrocitinib in AD patients. However, they are single-center studies with a small sample size. In addition, different endotypes and immunotypes of AD associated with the Asian population have been published, making it difficult to compare these studies with our results.¹¹

Tong *et al.*¹² reported a study of 16 patients with moderate-to-severe AD. All patients had previously used dupilumab, which was suspended due to ineffectiveness. Furthermore, the use of abrocitinib decreased the sustained paradoxical effect of IL-17 shown by dupilumab since IL-4/IL-13 blockers do not unexpectedly protect against humoral autoimmune diseases but dynamically divert immune responses toward some diseases related to the IL-23/IL-17 cytokine pathway.¹³ The only dose they received was abrocitinib 100 mg QD for 12 weeks. EASI 75 was achieved in only 29.4% at Week 12. Our study and others previously cited reported a higher proportion of patients who achieved EASI 75 at Weeks 12-16. The lower dose of abrocitinib (100 mg QD) used in this study probably explains a poorer response compared to our series.

Finally, a study with a methodology more comparable to ours has recently been published, carried out by Kamphuis *et al.*⁸ It is a multicenter, prospective, observational study involving six hospitals in the Netherlands. Although 103 patients were included, only 61 had follow-ups at Week 16. In this cohort, all measured variables, including EASI, pruritus NRS, POEM, and DLQI, significantly improved ($P < 0.001$). EASI 75 and EASI 90 were achieved in 52.6% and 22.8% of the patients, respectively, at Week 16, while 83.3% achieved an absolute EASI ≤ 7 . At Week 28 ($n = 39$), EASI 75 and EASI 90 were achieved in 57.6% and 18.2% of the patients, respectively, and 66.7% had EASI ≤ 7 . In this study, 73.8% of patients experienced at least one AE. The most frequently reported AEs were nausea and acneiform rash. 81.6% of the reported AE were mild. 17 patients (16.5%) discontinued treatment due to inefficacy, and nine (8.7%) were due to AE. In our study, the safety and effectiveness outcomes were similar. However, we found a higher rate of patients achieving EASI 75 and EASI 90, considering the comparison at Week 12, which is available in our study. A possible explanation for this difference could be the higher proportion of patients naïve to advanced therapy included in our series.

In addition to real-world studies, data from several clinical trials are available.^{14–18} Comparing real-world studies with clinical trials is challenging. These trials reflect a rapid improvement in signs and PROMs compared with patients who received week in Week 12. The evaluation during Week 12 of our study and clinical trials is a strength not present in other real-world studies. The rate of EASI 75 responders is higher in our series (78.95% vs approximately 63% in the pivotal studies), which could reflect the absence of a washout period. However, our study's dropout rate is somewhat higher than clinical trials (18.42% vs. approximately 10%, respectively).^{7,8,11} Other real-world practice studies have also shown high discontinuation rates (31.1% and 41.5%^{7,8}). All these studies share a common feature of high prior exposure to other molecules. This could be because of the fewer alternative therapeutic options available when clinical trials were conducted and the greater exposure to previous advanced therapies. An important strength of this study in explaining real-world use behavior is the subanalysis of naïve and non-naïve populations to advanced therapy. Although the analysis of absolute variables does not reflect differences between naïve and non-naïve patients, a higher percentage of EASI 75 responders was found in naïve patients. None of the previous real-world studies have found these differences. The multicenter, prospective study design and a follow-up up to Week 24 of a large number of patients should be considered to validate our results. These data suggest that therapeutic positioning should be considered when assessing efficacy.

The limitations of our study are those inherent to real-world studies. On the one hand, the absence of a washout period in most patients could influence the maintenance of therapeutic effects of their previous AD treatment at the beginning,

especially those under biological treatments. However, the medium-term follow-up up to Week 24 counteracts this limitation. On the other hand, the absence of a control group and the allocation of 100 mg vs. 200 mg doses are limitations inherent in observational studies reflecting real-world daily practice.

In conclusion, our findings confirm that abrocitinib is an effective treatment for AD, including patients who had previous failures with biologics or JAK inhibitors. Our data also suggest that it is significantly more effective in patients naïve to previous therapy. The safety profile was favorable, with only three patients discontinuing abrocitinib due to AEs.

Patient consent

Before participation, all patients provided their written consent to the publication of their case details.

Data availability statement

The datasets generated during and/or analyzed during the current study are not publicly available due to privacy regulations embedded in national legislation, but they are available from the corresponding author on reasonable request.

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