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Abrocitinib: 1-Year Real-Life Experience From the French OMCCI Registry

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ABSTRACT

Abrocitinib is a selective inhibitor of Janus kinase 1 approved to treat moderate-to-severe atopic dermatitis (AD). Phase 3 clinical trials have demonstrated the efficacy and safety of abrocitinib; nevertheless, there is a need for real-world patient data. This study aimed to assess the efficacy and safety of abrocitinib in patients with AD in the real-world setting. In this prospective, observational, multicentre study, all patients with AD enrolled in the French registry Observatory of Chronic Inflammatory Skin Diseases ('Observatoire Maladies Cutanées Chroniques Inflammatoires'; OMCCI) who received abrocitinib were included. Effectiveness was evaluated using outcome measures provided by clinicians and patients, including quality-of-life scores. Adverse events (AEs) were also assessed. Sixty-five patients were included, 45 with 1 year of follow-up. Abrocitinib treatment resulted in a significant decrease in disease severity at 12 months. After 1 year, median (interquartile range; IQR) Eczema Area and Severity Index Score decreased from 16.00 (9.10, 19.00) to 2.10 (0.80, 6.40), median (IQR) Dermatology Life Quality Index improved from 10.00 (6.00, 13.00) to 1.00 (0.00, 7.00), median (IQR) Mental Component Score and Physical Component Score increased from 48.14 (44.60, 56.82) to 57.21 (48.97, 60.12) and from 30.84 (28.13, 34.93) to 34.85 (30.74, 39.39), respectively, indicating improvement; all changes from baseline were significant ($p < 0.001$). The most frequently reported AEs included 13 (23.2%) cases of acne and 11 (19.6%) cases of gastrointestinal symptoms. Eleven patients discontinued abrocitinib treatment due to ineffectiveness (8 [17.8%]) or AEs (3 [6.7%]). Abrocitinib can be an effective and safe treatment for patients with moderate-to-severe AD in daily clinical practice.

1 | Introduction

Atopic dermatitis (AD) is a chronic inflammatory skin disease mainly characterized by a relapsing/resolving course with repeated flare-ups and inflammatory eczematous skin lesions associated with intense itch [1]. From an epidemiological point of view, AD is one of the most common skin disorders, affecting up to 4.9% of the adult population worldwide [2]. AD has a very negative impact on patient quality of life (QoL) that then confers a substantial economic burden to healthcare systems and society [3, 4].

Thanks to remarkable advances in research over the past decades, the therapeutic armamentarium of AD is now reasonably

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broad and well-structured, encompassing several topical and systemic therapeutic agents that have demonstrated efficacy in controlling this disease [5].

Currently, three biologics, dupilumab, lebrikizumab, and tralokinumab, are available for treating moderate-to-severe AD. These drugs target the alpha chain of the interleukin (IL)-4 receptor (dupilumab) or the IL-13 cytokine (lebrikizumab and tralokinumab) [6–8]. However, despite their superior efficacy and better tolerance compared to traditional systemic treatments, response rates may vary considerably, and a proportion of patients is still resistant or intolerant, highlighting an ongoing unmet need in the treatment of AD [9]. Recent advancements in understanding AD pathophysiology have led to the emergence of Janus kinase (JAK) inhibitors. However, attention has recently been paid to the risk of serious side effects associated with JAK inhibitors used to treat chronic inflammatory disorders, such as cardiovascular conditions, blood clots, cancer, and infections [10]. Data from real-life studies assessing the possible risk of adverse events (AEs) in patients with AD treated with JAK inhibitors are still lacking.

Abrocitinib, an oral, once-daily, JAK1-selective inhibitor, was approved by the US Food and Drug Administration in 2022 for the treatment of moderate-to-severe AD. The efficacy and safety of abrocitinib as monotherapy have been demonstrated in multiple Phase 3 clinical trials, where significant improvements in disease activity and patient-reported outcome measures (PROMs) have been shown in patients with moderate-to-severe AD [11–15]. Real-life data on abrocitinib are limited, with only a few reports currently available [16–22]. To address this gap and evaluate the effectiveness and safety of abrocitinib in patients with moderate-to-severe AD in a real-world setting, we analyzed data from the French Observatory of Chronic Inflammatory Skin Diseases ('Observatoire Maladies Cutanées Chroniques Inflammatoires'; OMCCI) registry [23, 24].

2 | Materials and Methods

2.1 | Study Design

The OMCCI registry is currently ongoing and has been initiated to prospectively determine the long-term impairment caused by the four most common chronic inflammatory diseases (CIDs; psoriasis, AD, hidradenitis suppurativa, and chronic urticaria) that impact several aspects of patients' lives. It is driven by RESO-Dermatology [24], a French national network involved in CID management at 49 dermatology centres (university/public/military/private hospitals and private practices) distributed all over France. Patients are included in the OMCCI at the initiation or modification of a conventional, biological, or JAK inhibitor systemic therapy.

In this study we included adult patients (≥ 18 years of age) with moderate-to-severe AD (Eczema Area and Severity Index [EASI] ≥ 7) enrolled in the OMCCI registry and treated with abrocitinib. All included patients who gave oral informed consent to the publication of their case details in line with revised French Research Standard MR003 were selected for analysis. Patients who did not speak French, who were subject to a legal protection measure, or who were unable to express their consent, as well as patients participating in an interventional study, were excluded.

The study was approved by the Ethics Committee of the French National Data Protection Commission and the Committee for the Protection of Individuals, Ile-de-France (Protocol Number 62-2020).

2.2 | Data Collection

The following patient information was collected: gender, age at AD diagnosis (including identification of patients with adult-onset AD, defined as patients with a diagnosis of AD made at 18 years of age or later) [25], age at baseline, level of education, socioeconomic status, and body site involvement. The EASI [26] score, the proportion of patients with an EASI score of ≤ 7, and the proportion of patients with EASI-50/75/90 (≥ 50%, ≥ 75%, or ≥ 90% EASI improvement) after 1 year of treatment were evaluated.

QoL-related PROMs assessed included: Dermatology Life Quality Index (DLQI; 10 questions; range: 0–30) [27]; the 12-item Short-Form health survey (SF-12), with the Mental Component Score (MCS-12) and the Physical Component Score (PCS-12) derived from the SF-12 [28, 29]; and the impact of AD on sleep in the previous 7 days (evaluated as often, occasionally, rarely/never), evaluated at 6 and 12 months. Atopic history and comorbidities were not available.

Data on previous medication received in the 2 years before starting abrocitinib were also recorded. Finally, causes of abrocitinib discontinuation and any AEs reported in abrocitinib recipients were collected. Data concerning the incidence and severity of AEs were obtained from patient records and were defined by the dermatologist who had prescribed the therapy and followed the patient over time. The severity of AEs was classified according to the Common Terminology Criteria for AEs (CTCAE) and according to whether or not they led to discontinuation. Grade 1 (mild) AEs were not recorded because only AEs that needed medical intervention were registered. Drug survival and retention rate (DRR) at 6 and 12 months was assessed. Although laboratory data were not directly included in the registry, laboratory exams (blood count, liver and renal functions, and lipid profile) were performed for all patients after 1 month of treatment and every 6 months and were considered by dermatologists to establish the presence of relevant AEs.

2.3 | Statistical Analysis

Descriptive statistics were generated with absolute frequencies and percentages calculated for the qualitative variables and mean and standard deviation (SD), 95% confidence intervals (CI), or median and interquartile range (IQR) calculated for the quantitative variables. Comparison of outcomes at drug induction and 1 year was assessed with the Wilcoxon test in the case of a score or with the McNemar test for qualitative variables. Per protocol and intention-to-treat (ITT) analyses were performed. In the ITT analysis, missing 1-year EASI values for patients who discontinued treatment or had only baseline assessment were handled using the last observation carried forward, while all remaining patients had complete follow-up up to 1 year. The Kruskal–Wallis test was performed to independently compare DLQI, MCS-12, and PCS-12 between the three time points (baseline, 6 months, and 1 year). When the Kruskal–Wallis test result was significant, post hoc analysis was performed with multiple Mann–Whitney tests and the false discovery rate as p value correction. A Spearman correlation test was performed to compare EASI and DLQI with MCS-12 and PCS-12. DRRs at 6 and 12 months were examined using a Kaplan–Meier survival

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analysis considering: (i) any reason for discontinuation (overall DRR) and (ii) only 'loss of effectiveness'. A p-value < 0.05 was considered statistically significant. All analyses were carried out with R version 4.3.1.

3 | Results

Sixty-five patients with AD treated with abrocitinib from May 2022 to November 2023 were enrolled in eight French OMCCI centres. Baseline characteristics are summarized in Table 1. The population were mostly women (44 [67.7%]), with a mean (SD) age at baseline of 34.98 (12.92) years. The mean (SD) age at diagnosis was 11.51 (15.79) years; adult-onset AD occurred in 13 (20%) patients. Data at 1 year were available in 45 patients, and data at 6 months were available in 56 patients; in the remaining 9 patients, only baseline was present.

Table 2 details all treatments performed and the reasons for discontinuation during the 2 years before abrocitinib initiation. Topical treatments were received by 90.7% of patients in the 2 years before abrocitinib initiation, and most of these patients were still receiving those treatments when they started abrocitinib. Overall, 42.3% of subjects were previously treated with cyclosporin, followed by dupilumab (27.6%), baricitinib (21.5%), and methotrexate (18.4%). Most patients who previously received biological therapies (such as dupilumab or tralokinumab) or JAK inhibitors (such as baricitinib or upadacitinib) did not go on to discontinue abrocitinib treatment due to ineffectiveness defined by doctors or an AE (Table 2). Among the 11 patients who discontinued abrocitinib therapy, 2 transitioned to baricitinib, 3 to upadacitinib, and 6 to dupilumab.

3.1 | EASI

The median (IQR) EASI score at baseline of the entire cohort of 65 patients was 16.00 (7.50, 19.00). In total, 45 (69%) of patients were followed up over 1 year (Table 3). A per-protocol analysis considering this subgroup showed a significant decrease of EASI score over time, with a mean (SD) percentage change from baseline of 73.8 (28.09%). After 1 year, 82.2% of patients had an EASI score ≤ 7, and 38 (86.4%), 28 (63.6%), and 16 (36.4%) achieved an EASI 50/75/90, respectively (Table 3). The ITT analysis of the entire cohort of 65 patients showed a median EASI score at 1 year of 3 (IQR 1, 7.1) with 63.1%, 61.5%, 44.6%, and 24.6% of patients achieving EASI ≤ 7/50/75/90, respectively.

Concerning body involvement at baseline, the most involved areas were represented by the upper extremities, followed by hands, face and neck, and the scalp (Table 3). After 1 year of treatment with abrocitinib, a statistically significant decrease in involvement of all sub-areas was reported, including upper extremities, scalp, face and neck, hands, thorax and abdomen, and genital area (Table 3).

3.2 | QoL

Details of DLQI, MCS-12, and PCS-12 assessed at baseline and 1 year are summarized in Table 3. The median DLQI score improved significantly after 1 year ($p \leq 0.001$) (Table 3), and reductions in median DLQI were also seen at 6 months ($p \leq 0.001$) (Figure 1(a)). The mean (SD) DLQI score improved from 10.93 (5.48) at baseline to 3.53 (4.49) after 1 year ($p < 0.001$). The mean percentage change after 1 year was ~64%, with a decrease of ≥ 4 points from baseline observed in two-thirds of patients (Table 3). Overall, 32 (71.1%) patients reached a DLQI score ≤ 5 after 1 year (Table 3).

Regarding the MCS-12 and PCS-12 questionnaires, a significant ($P < 0.01$) improvement over time was observed (Table 3, Figures 1(b), 1(c)). Finally, 53.3% of patients reported that the disease 'often' impacted sleep, whereas after 1 year of treatment, this percentage decreased to 2.2% (Table 3).

3.3 | Correlation of EASI, QoL Scores, and Baseline Factors

The achievement of EASI-50/75/90 and an EASI score of ≤ 7 were not associated with age at diagnosis, adult-onset AD, or baseline involvement of a specific body area. A DLQI decrease of ≥ 4 points from baseline and a DLQI score ≤ 5 after 1 year were not associated with age at diagnosis, involvement of specific body sites, or DLQI, MCS-12, or PCS-12 score at baseline. Baseline DLQI, MCS-12, and PCS-12 were not associated with the achievement of EASI-50/75/90, EASI score ≤ 7, age at diagnosis, or baseline involvement of a specific body area. However, EASI and DLQI at baseline (EASI: r: −0.42, $p < 0.001$; DLQI: r: −0.45, $p < 0.001$) and after 1 year (EASI: r: −0.49, $p < 0.001$; DLQI r: −0.51 $p < 0.001$) had a moderate correlation with the baseline PCS-12 score.

3.4 | DRR

The Kaplan–Meier survival curves considering any reason for discontinuation (overall DRR) and only for loss of effectiveness, respectively, are shown in Figure 2. Eleven patients discontinued the treatment: 8 for loss of effectiveness and 3 for AEs (2 cases of headache and 1 case of infectious pneumonia); 45 were ongoing at 12 months. The overall abrocitinib DRRs at 6 and 12 months were 93.7% and 77.1%, respectively. When considering only loss of effectiveness as a discontinuation reason, DRRs at 6 and 12 months were 100% and 82.2%, respectively.

Twenty-eight AEs not leading to discontinuation, classified as grade 2 (moderate) CTCAE developed in 22 out of 56 patients. Specifically, 13 (23.2%) cases of acne, 7 (12.5%) cases of nausea, 4 (7.1%) cases of abdominal pain, 3 (5.3%) cases of herpes simplex virus (HSV) infection, and 1 (1.7%) case of herpes zoster virus infection. Among these, 2 patients had concomitant acne and nausea, and 4 had nausea and abdominal pain. Overall, no deaths, major cardiovascular AEs, thromboembolic events, or malignant neoplasms occurred, and only one grade 3 CTCAE AE (severe infectious pneumonia) was recorded.

3.5 | Dosing Regimens

Overall, 28 (43.1%) patients were treated with 100 mg abrocitinib and 37 (56.9%) patients with 200 mg. In 11 cases, the treatment dosage was adjusted: in 6 cases it was increased from 100 to 200 mg, and in the remaining 5 cases it was decreased from 200 to 100 mg. No differences were observed in terms of EASI, DLQI, MCS-12, PCS-12, and body surface area affected between abrocitinib 100 and 200 mg after 1 year. Concerning AEs not leading to discontinuation, 12 of the 28 AEs occurred in patients receiving abrocitinib 100 mg (4 acne, 3 HSV infections, 3 nausea, and 2 abdominal pain), and 16 AEs occurred in patients receiving 200 mg (9 acne, 4 nausea, 2 abdominal pain, and 1 HSV infection). Of the 8 patients who had loss of effectiveness, 7 were receiving abrocitinib 200 mg, and 1 was receiving abrocitinib 100 mg.

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TABLE 1 | Clinical and demographic characteristics of the study population at baseline.

Characteristics	Overall ($N = 65$)
Age at baseline, mean (SD) (years)	34.98 (12.92)
Female, *n* (%)	44 (67.7)
Age at diagnosis, mean (SD) (years)	11.51 (15.79)
Adult-onset AD, *n* (%)	13 (20.0)
BMI, median (range) (kg/m^2)	24.9 (17–34)
Cardiovascular risk factors, *n* (%)	32 (49.2)
Hypertension, *n* (%)	1 (1.5)
Diabetes, *n* (%)	0
High-density lipoprotein < 40 mg/dL, *n* (%)	6 (9.2)
Tobacco use ($N = 32$)	
Current, *n* (%)	9 (28.1)
Past, *n* (%)	6 (18.8)
Never, *n* (%)	17 (53.1)
Marital status	
Single, *n* (%)	23 (35.4)
Married, *n* (%)	36 (55.4)
Divorced/separated, *n* (%)	4 (6.1)
Widowed, *n* (%)	2 (3.1)
Family members in the household, median (IQR) number	3 00 (2.00, 3.00)
Highest achieved education level	
Without diploma, *n* (%)	3 (4.6)
Primary school, *n* (%)	2 (3.1)
Secondary school, *n* (%)	17 (26.2)
University, *n* (%)	23 (35.4)
PhD, *n* (%)	9 (13.8)
Other, *n* (%)	1 (1.5)
Employment status	
Employed or off sick, *n* (%)	44 (67.7)
In search of a job, *n* (%)	6 (9.2)
Retired, *n* (%)	3 (4.6)
Unemployed, *n* (%)	12 (18.5)
Employment type	
Farmer, *n* (%)	1 (2.3)
Craftsman, *n* (%)	6 (13.6)
Manager, *n* (%)	15 (34.1)
Intermediate profession, *n* (%)	9 (20.5)
Employee, *n* (%)	13 (29 5)
EASI at baseline, median (IQR)	16.00 (7.50, 9.00)
DLQI at baseline, median (IQR)	10.00 (6.00, 13.00)

Abbreviations: AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IQR, interquartile range; PhD, Doctor of Philosophy; SD, standard deviation.

TABLE 2 | Overview of treatments performed and reasons for discontinuation during the 2 years before abrocitinib initiation and abrocitinib treatment course for the overall population.

	Overall ($N = 65$)	Discontinued treatment, *n* (%)				Under treatment, *n* (%)	Abrocitinib, *n* (%)		
		Voluntary interruption	Ineffectiveness	AE	Other reasons[†]		Discontinued due to ineffectiveness	Discontinued due to AE	Under treatment
Topical treatments[‡], *n* (%)	59 (90.7)	1 (1.6)	0	0	0	58 (89.2)	8 (13.5)	2 (3.3)	49 (83)
Triamcinolone acetonide, *n* (%)	2 (3)	0	1 (50)	0	1 (50)	0	0	0	2 (100)
Alitretinoin, *n* (%)	2 (3)	0	2 (100)	0	0	0	1 (50)	0	1 (50)
Systemic antihistamine, *n* (%)	3 (5)	0	0	0	1 (33.3)	2 (3)	0	0	3 (100)
Phototherapy, *n* (%)	1 (1.6)	0	1 (100)	0	0	0	0	0	1 (100)
Cyclosporine, *n* (%)	25 (42.3)	1 (4)	1 (4)	6 (24)	17 (68)	0	3 (12)	1 (4)	21 (84)
Methotrexate, *n* (%)	12 (18.4)	0	6 (50)	4 (33.3)	2 (16.6)	0	2 (16.6)	2 (16.6)	8 (66.6)
Dupilumab, *n* (%)	18 (27.6)	3 (16.6)	12 (66.6)	3 (16.6)	0	0	0	0	18 (100)
Tralokinumab, *n* (%)	10 (6.5)	0	7 (70)	3 (30)	0	0	1 (10)	1 (10)	8 (80)
Baricitinib, *n* (%)	14 (21.5)	0	14 (100)	0	0	0	3 (21.4)	2 (14.2)	9 (64.2)
Upadacitinib, *n* (%)	3 (5)	0	2 (66.6)	1 (33.3)	0	0	0	0	3 (100)

Abbreviation: AE, adverse events.
[†]For cyclosporin, this corresponds to an induction protocol for a short period of a few weeks, before switching to abrocitinib.
[‡]Topical treatments including topical corticosteroids and topical calcineurin inhibitor.

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TABLE 3 | Disease severity reported as EASI, DLQI, SF-12, body site involvement, and impact on sleep at baseline and after 1 year of treatment in 45 patients with 1 year of follow-up.

Variables	Baseline	1 year	*p* value
EASI			
EASI, median (IQR)	16.00 (9.10, 19.00)	2.10 (0.80, 6.40)	< 0.001
Mean (SD) percentage change in EASI	—	73.8 (28.09)	—
EASI-90 response, *n* (%)	—	16 (36.4)	—
EASI-75 response, *n* (%)	—	28 (63.6)	—
EASI-50 response, *n* (%)	—	38 (86.4)	—
EASI ≤ 7, *n* (%)	—	37 (82.2)	—
DLQI			
DLQI, median (IQR)	10.00 (8.00, 13.00)	1.00 (0.00, 7.00)	< 0.001
Mean (SD) percentage change in DLQI	—	63.78 (44.22)	—
≥ 4-point reduction of DLQI, *n* (%)	—	31 (68.9)	—
DLQI ≤ 5, *n* (%)	—	32 (71.1)	—
SF-12			
PCS-12, median (IQR)	48.14 (44.60, 56.82)	57.21 (48.97, 60.12)	< 0.001
MCS-12, median (IQR)	30.84 (28.13, 34.93)	34.85 (30.74, 39.39)	< 0.001
Body site involvement			
Scalp, *n* (%)	33 (73.3)	9 (20.0)	< 0.001
Face, neck and ears, *n* (%)	34 (75.6)	12 (26.7)	< 0.001
Arms and armpits, *n* (%)	36 (80.0)	18 (40.0)	< 0.001
Hands, fingers, and fingernails, *n* (%)	35 (77.8)	14 (31.1)	< 0.001
Thorax and abdomen, *n* (%)	19 (42.2)	7 (15.6)	0.001
Back and shoulders, *n* (%)	16 (35.6)	8 (17.8)	0.027
Genital area, *n* (%)	18 (40.0)	7 (15.6)	0.002
Buttocks and thighs, *n* (%)	24 (53.3)	11 (24.4)	0.003
Knees, lower legs, and ankles, *n* (%)	26 (57.8)	15 (33.3)	0.010
Feet, toes and toenails, *n* (%)	14 (31.1)	5 (11.1)	0.016
Impact of AD on sleep			< 0.001
Rare/never, *n* (%)	5 (11.1)	33 (73.3)	—
Sometimes, *n* (%)	16 (35.6)	11 (24.4)	—
Often, *n* (%)	24 (53.3)	1 (2.2)	—

Note: MCS-12, Mental Component Score; PCS-12, Physical Component Score; SF-12, 12-item short-form health survey.
Abbreviations: AD, atopic dermatitis; DLQI, Dermatology Life Quality Index; EASI, Eczema Area and Severity Index; IQR, interquartile range; SD, standard deviation.

4 | Discussion

Our study shows the real-world effectiveness and safety of abrocitinib in a group of patients with AD from the OMCCI registry who were followed for 1 year—a longer follow-up than previously published real-life studies that had a median follow-up time of 12 weeks [18, 20] or 28 weeks [16, 17].

Interestingly, we found that 90.7% of patients received topical treatments in the 2 years before abrocitinib initiation, and most of these patients were still receiving those treatments when they started abrocitinib. The four most administered therapies prior to abrocitinib were cyclosporin, followed by dupilumab, baricitinib, and methotrexate. Considering the group of patients who received prior biological therapies or other JAK inhibitors, the majority did not discontinue abrocitinib because of ineffectiveness or AE.

When considering the 45 patients with a follow-up of 1 year, the effectiveness of abrocitinib was better than that previously reported in real-life studies with a median follow-up of 28 weeks. EASI-50/75/90 was achieved by a higher proportion of patients (86.4%, 63.6%, and 36.4%) in our study compared to 81.8%, 57.6%, and 18.2% [17], and 41.5%, 31.7%, and 29.6% [16], respectively. However, the ITT analysis that included all the patients showed closer results, with 61.5%, 44.6%, and 24.6% of patients achieving EASI 50/75/90 at 1 year, respectively.

Comparison of the results of the present study with pivotal studies is difficult because these mainly focus on short-term results. The JADE DARE (NCT04345367) [14, 30], JADE MONO-1 (NCT03349060) [11], JADE MONO-2 (NCT03575871) [15], and JADE COMPARE (NCT03720470) [12] pivotal studies evaluated the efficacy and safety of abrocitinib 100 or 200 mg at 12–26 weeks. JADE EXTEND (NCT03422822), an extension of the previous studies with data at 48 weeks, found slightly higher

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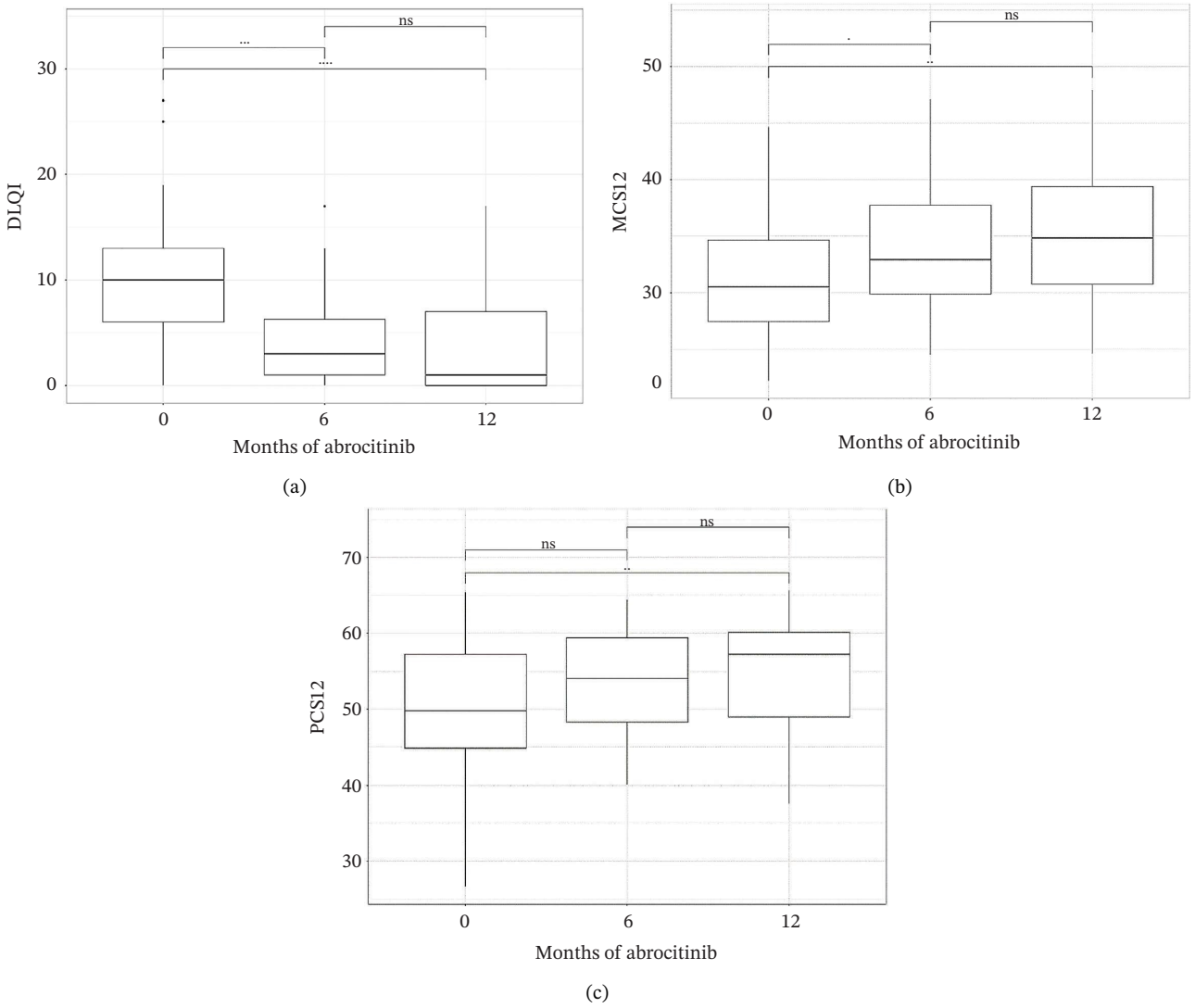


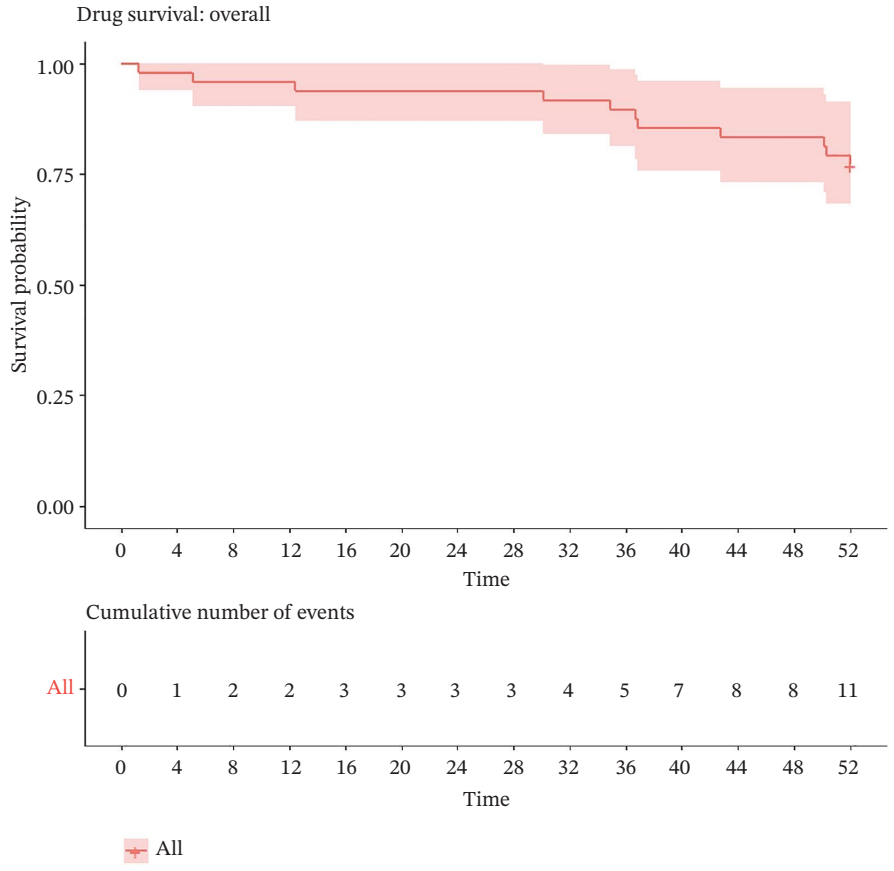
FIGURE 1 | Patient-reported outcomes measures. (a) Median DLQI score assessed in abrocitinib-treated patients at baseline, 6 months, and 1 year. (b) Median MCS-12 score assessed in abrocitinib-treated patients at baseline, 6 months, and 1 year. (c) Median PCS-12 score assessed in abrocitinib-treated patients at baseline, 6 months, and 1 year. Plots show the minimum (lower whisker), first quartile (lower box), median (middle box), third quartile (upper box), and maximum values (upper whisker), with any outliers indicated as dots. DLQI, Dermatology Life Quality Index; MCS-12, mental component score; ns, not significant; PCS-12, physical component score.

EASI75 rates (82% and 67% of patients taking abrocitinib 200 and 100 mg, respectively, at week 48) compared to our study (63.6% at 1 year) [13]. As already shown in a previous real-life study, there could have been an underestimation of the effect of abrocitinib on the outcome measures in our study due to possibly lower EASI scores at baseline compared to clinical trials [16]. In clinical trials, patients who use systemic immunosuppressive treatment at baseline are excluded due to the washout period, whereas in real life many patients still use concomitant immunosuppressive drugs at baseline. In this setting, it is relevant to observe that absolute values of EASI dramatically decreased at 1 year in our study, with an EASI score ≤ 7 achieved by a large majority of our population (82.2% at 1 year), similar to the 83.8% reported in the study of Kamphuis et al. at 16 weeks [17], but greater than the rates reported in other real-world studies with a median follow-up of 28 weeks (53.7% at last review) [16]. Interestingly, efficacy at 1 year was independent from treatment dosage in our study.

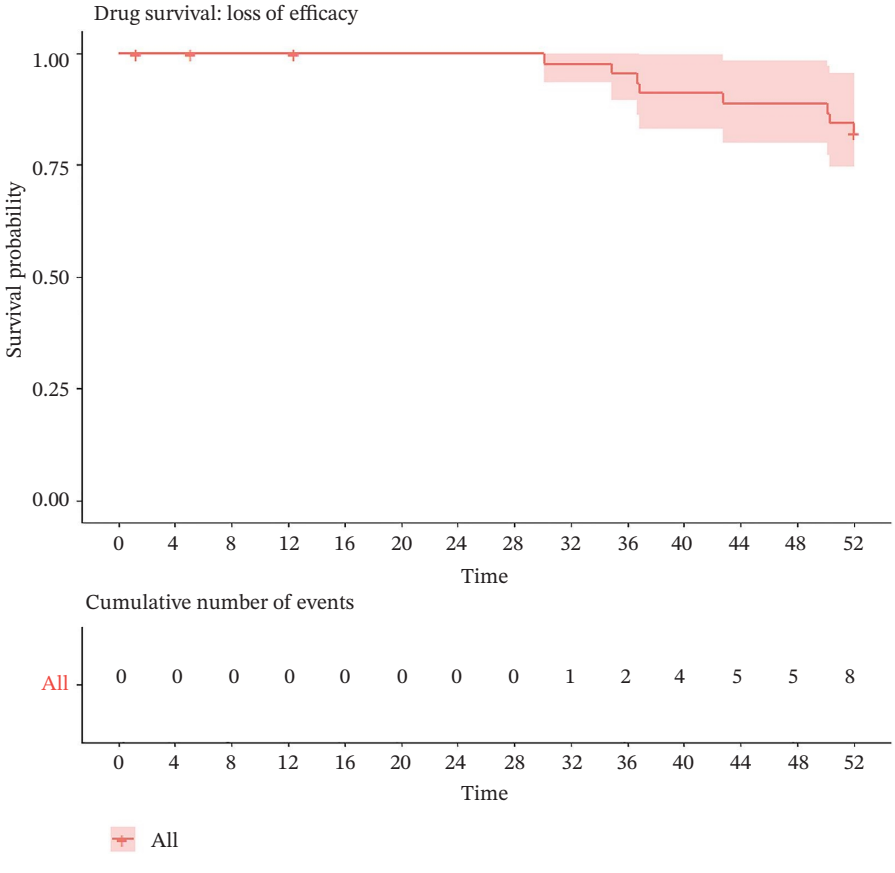
Our study considered many PROMs to evaluate the impact on patient QoL. Several studies involving patients with AD have used SF-12 and DLQI to assess QoL [31, 32]. Nevertheless, data on the QoL of patients with AD treated with abrocitinib are still limited. In our study, in addition to DLQI, SF-12 (including MCS-12 and PCS-12) was also used, and impact on sleep was evaluated after 6 months and 1 year.

In our population, the mean DLQI score improved significantly, from 10.93 at baseline to 3.53 after 1 year. Kamphuis et al. reported a decrease from a mean (95% CI) DLQI of 12.8 (10.7–14.9) to 7.6 (5.6–9.7) at 16 weeks [17]. Overall, 32 (71.1%) patients in our study reached a DLQI score ≤ 5 after 1 year, compared to 54.9% at 16 weeks in the study by Kamphuis et al. [17]. Interestingly, we found that DLQI was not associated with EASI (DLQI was independent of EASI-50/75/90 and EASI ≤ 7; DLQI decreased ≥ 4 points, and DLQI scores ≤ 5 were independent of the EASI score) indicating that disease burden could be viewed

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(a)



(b)

FIGURE 2 | Kaplan–Meier survival curves for (a) any reason for discontinuation (overall DRR) and (b) discontinuation for loss of effectiveness only.

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differently by patients and physicians. We did not find any association between different body areas affected or age at diagnosis and outcome in terms of EASI (EASI-50/75/90 and EASI ≤ 7) or DLQI, which could predict treatment response.

The MCS-12 and PCS-12 showed an impaired QoL, both in the MCS and the PCS, before starting abrocitinib and a significant improvement at 1 year of treatment. These two scores, calculated from the SF-12 [29, 30] are not specific for skin conditions—unlike the DLQI—and are used to evaluate the impact of different diseases on QoL. Interestingly, the baseline MCS-12 and PCS-12 scores confirmed that AD can have an impact on QoL similar to other noncutaneous diseases, but the lack of association of these scores with DLQI confirmed that they are assessing different areas of QoL. We could only find a moderate correlation between EASI and DLQI and PCS-12, indicating that EASI and DLQI are more related to the physical component of the SF-12. Unfortunately, we could not find any data on SF-12 in other AD studies with abrocitinib.

Notably, we found that treatment with abrocitinib also had a positive impact on AD-related sleep disturbance, with 53.3% of patients at baseline declaring that AD often impacted sleep, whereas after 1 year of treatment, few patients had this complaint (2.2%).

AEs were as expected from previous pivotal studies [32]. No deaths, major adverse cardiovascular events, thromboembolic events, or malignant neoplasms occurred, and only one severe AE of infectious pneumonia was recorded. AEs leading to discontinuation occurred in 5.3% (one case of pneumonia and two cases of headache), and 39.2% of patients had AEs that did not lead to discontinuation. Acne (23.2%) and nausea (12.5%) were the most common AEs. Acne was slightly more frequent, and nausea was similar in this study versus the rates reported in other pivotal studies (acne: 2.9%–6.6% in JADE COMPARE, 13% in JADE DARE, and no cases reported in JADE MONO-1; nausea: 4.2%–11.1% in JADE COMPARE, 19% in JADE DARE, 9%–20% in JADE MONO-1, and 7.6%–14.2% in JADE MONO-2) [11, 12, 14, 15]. Notably, our study showed headaches can be severe and lead to treatment discontinuation, as reported in other studies [14]. In contrast to previous studies, nasopharyngitis and upper respiratory tract infection [16] and conjunctivitis [12, 30] were not reported. Unlike clinical trials where patients are under close medical supervision, mild respiratory infections are usually not reported by the patients in the real-world setting because they are not considered to be associated with the treatment. Although we could not find any significant differences in terms of efficacy and AEs with the two available dosages of abrocitinib at 1 year, the OMCCI register did not record the reason for dosage adjustment during treatment that could be related to infectiveness and AEs.

The strengths of our study are the prospective design, the long follow-up over 1 year and the evaluation of many PROMs. The main limitation is the lack of short-term and intermediate effectiveness data with physician-reported scores. Moreover, the Investigator's Global Assessment 0/1 (clear/almost clear) was not reported. Although a specific score for itch, which is a major symptom of AD, such as Numeric Rating Scale (NRS: 0–10) or Peak Pruritus NRS, commonly used in AD studies, was not evaluated (which limited the evaluation of symptom relief), many PROMs indirectly related to itch were included, such as SF-12, DLQI, and the impact of AD on sleep. Concerning safety, laboratory findings were not available in the OMCCI registry because it would be extremely time-consuming to register single analysis results differently from registration trials with centralized laboratory results.

In conclusion, the JAK1 inhibitor abrocitinib has lived up to expectations derived from clinical trial studies. Our data confirmed the clinical effectiveness and the safety and tolerability of abrocitinib. Moreover, our study showed a substantial improvement in QoL, as reported by the PROMs. Further studies that include pruritus-specific scales that are missing in the OMCCI registry will provide additional insight into this emerging therapy.

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Ethics Statement

The study was approved by the Ethics Committee of the French National Data Protection Commission and the Committee for the Protection of Individuals, Ile-de-France (Protocol Number 62-2020). Patients whose data were included in this manuscript gave oral informed consent for the publication of their case details in line with revised French Research Standard MR003.

Conflicts of Interest

Elisa Cinotti: Speaker for Pfizer; Anne Claire Fougerousse: Speaker and Investigator for Pfizer. The remaining authors declare no conflicts of interest.

Data Availability Statement

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

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