Journal of Dermatological Treatment

ISSN: 0954-6634 (Print) 1471-1753 (Online) Journal homepage: www.tandfonline.com/journals/ijdt20

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To cite this article: Luigi Gargiulo, Luciano Ibba, Angela Alfano, Piergiorgio Malagoli, Fabrizio Amoruso, Anna Balato, Francesca Barei, Anna G. Burroni, Stefano Caccavale, Piergiacomo Calzavara-Pinton, Maria Esposito, Maria C. Fargnoli, Silvia M. Ferrucci, Caterina Foti, Giampiero Girolomoni, Massimo Gola, Mario B. Guanti, Carlotta Gurioli, Manfredi Magliulo, Martina Maurelli, Pietro Morrone, Maria L. Musumeci, Maddalena Napolitano, Michela Ortoncelli, Cataldo Patruno, Bianca M. Piraccini, Elena Pezzolo, Simone Ribero, Mariateresa Rossi, Paola Savoia, Claudio Sciarrone, Benedetta Tirone, Marco Vaccino, Federica Veronese, Antonio Costanzo & Alessandra Narcisi (2024) Short-term effectiveness and safety of abrocitinib in adults with moderate-to-severe atopic dermatitis: results from a 16-week real-world multicenter retrospective study – il AD (Italian landscape atopic dermatitis), Journal of Dermatological Treatment, 35:1, 2411855, DOI: 10.1080/09546634.2024.2411855

To link to this article: https://doi.org/10.1080/09546634.2024.2411855

Published online: 10 Oct 2024.

JOURNAL OF DERMATOLOGICAL TREATMENT
2024, VOL. 35, NO. 1, 2411855
https://doi.org/10.1080/09546634.2024.2411855

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BRIEF REPORT

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Short-term effectiveness and safety of abrocitinib in adults with moderate-to-severe atopic dermatitis: results from a 16-week real-world multicenter retrospective study – il AD (Italian landscape atopic dermatitis)

Luigi Gargiulo[a,b#], Luciano Ibba[a,b#], Angela Alfano[a,b], Piergiorgio Malagoli[c], Fabrizio Amoruso[d], Anna Balato[e], Francesca Barei[f], Anna G. Burroni[g], Stefano Caccavale[e], Piergiacomo Calzavara-Pinton[h], Maria Esposito[i], Maria C. Fargnoli[i], Silvia M. Ferrucci[f], Caterina Foti[j], Giampiero Girolomoni[k], Massimo Gola[l], Mario B. Guanti[m], Carlotta Gurioli[n,o], Manfredi Magliulo[l], Martina Maurelli[k], Pietro Morrone[d], Maria L. Musumeci[p], Maddalena Napolitano[q], Michela Ortoncelli[r], Cataldo Patruno[s], Bianca M. Piraccini[n,o], Elena Pezzolo[t], Simone Ribero[r], Mariateresa Rossi[h], Paola Savoia[u], Claudio Sciarrone[v], Benedetta Tirone[j], Marco Vaccino[p], Federica Veronese[v], Antonio Costanzo[a,b] and Alessandra Narcisi[a]

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ABSTRACT

Aim: Abrocitinib is a JAK-1 inhibitor approved for the treatment of moderate-to-severe atopic dermatitis (AD). We conducted a 16-week multicenter retrospective study to assess the short-term effectiveness and safety of abrocitinib in patients with moderate-to-severe AD.

Our retrospective study included 85 adult patients from 14 Italian Dermatology Units affected by moderate-to-severe AD treated with abrocitinib 100/200 mg.

Methods: Effectiveness of abrocitinib at weeks 4 and 16 was assessed by using the Eczema Area and Severity Index (EASI), the Investigator Global Assessment (IGA), the peak pruritus and sleep- Numerical Rating Scale (PP-NRS and S-NRS, respectively).

Results: At week 16, improvement of at least 90% in EASI (EASI90) and IGA 0/1 was observed in 49.4% and 61.2% of patients, respectively. A reduction of at least 4 points in PP-NRS and S-NRS compared with baseline was achieved by 70.6% of patients for both endpoints. No significant safety reports were observed during the study period. Naïve patients had better rates of EASI 90 compared to patients who previously failed dupilumab.

Conclusion: Our data confirm the effectiveness of abrocitinib in a real-world setting with better clinical responses at weeks 4 and 16, compared with Phase-III clinical trials. Longer analyses are required to further establish the safety profile of abrocitinib.

ARTICLE HISTORY
Received 29 July 2024
Accepted 13 September 2024

KEYWORDS
Abrocitinib;
atopic dermatitis;
JAK inhibitors

Introduction

The development of monoclonal antibodies and small molecules has revolutionized the treatment paradigm of moderate-to-severe atopic dermatitis (AD) [1]. In particular, Janus kinase (JAK) inhibitors represent a group of small molecules that target the signaling pathway activated by several pro-inflammatory cytokines involved in AD pathogenesis [2]. According to the European guidelines, three oral JAK inhibitors (abrocitinib, baricitinib and upadacitinib) are recommended in adults and/or adolescents suffering from moderate-to-severe AD [1]. Abrocitinib, in particular, is a selective JAK-1 inhibitor that has demonstrated efficacy and safety in

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several clinical trials, compared with both placebo and dupilumab [3–5]. Currently, limited data are available on the effectiveness and safety of abrocitinib in a real-life clinical setting [6].

We conducted a multicenter real-world study to evaluate the effectiveness and safety of abrocitinib in adult patients with moderate-to-severe AD who were all treated for at least 16 weeks.

Materials and methods

Eight-five patients treated with abrocitinib 100 or 200 mg from June 2023 to June 2024 were enrolled. Abrocitinib was prescribed according to EuroGuiDerm guidelines on AD and the Summary of Product Characteristics [1,3]. All patients had inadequate response/intolerance or contraindications to treatment with cyclosporine. Patients could apply topical treatment as needed during the study period, while none used other systemic therapies.

Patients' characteristics were retrospectively retrieved from the medical records of 14 Italian Dermatology Units.

The effectiveness of abrocitinib was evaluated in terms of improvement in Eczema Area and Severity Index (EASI), Investigator Global Assessment (IGA) and peak pruritus and sleep Numerical Rating Scale (NRS) at weeks 4 and 16, compared with baseline. In particular, we analyzed the percentage of patients who achieved a reduction of at least 75%, 90% and 100% in EASI score compared to the baseline (EASI 75, EASI 90 and EASI 100, respectively) and the percentage of patients who achieved absolute EASI score ≤ 7 and ≤ 3 was recorded. In addition, the percentage of patients who achieved an IGA score of 0 or 1 (clear or almost clear) at each time point was analyzed according to the endpoints of Phase-3 clinical trials [4,5]. Regarding patients' reported outcomes (PROs), the percentage of patients who achieved a reduction of at least 4 points in PP-NRS and S-NRS and the percentage of patients who reached a score of 0 or 1 in the aforementioned scores was recorded. Finally, the effectiveness of abrocitinib in patients who were naive to dupilumab and patients who had failed this treatment were compared.

Regarding safety, the occurrence of any adverse events (AEs) at weeks 4 and 16, focusing on severe AEs, AEs leading to discontinuation and AEs leading to dose reduction, was reported.

Continuous variables were reported using mean and standard deviation (SD), while categorical variables were expressed as absolute numbers and percentages. We used the Chi-squared test to assess the statistical differences between patients naïve and those who had previously failed dupilumab, and a p-value less than or equal to 0.05 was considered statistically significant.

The Institutional review board approval was exempted as the study protocol did not deviate from standard clinical practice. All patients provided written informed consent for the data collection during routine clinical practice (demographics, clinical scores). The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

Results

A total of 85 patients were included, with a mean age of 37.8 years (SD 15.10). Fifty-three patients were male (62.4%). At least one difficult-to-treat area (including face/neck, hands and genitalia) was involved in 67 patients (78.8%), and 40 patients (47.1%) had previously failed dupilumab. The mean EASI at baseline was 23.46 (9.40), while the mean peak pruritus-NRS (PP-NRS) and the mean sleep-NRS (S-NRS) were 7.15 (1.98) and 5.94 (2.42), respectively. At baseline, 73 patients (85.9%) were administered a daily dosage of 100 mg, whereas the remaining 12 (14.1%) received a daily dosage of 200 mg, according to disease severity. Complete patients' characteristics at baseline are shown in Table 1.

Table 1. Demographic characteristics of our cohort at baseline ($n = 85$).

	N (%) or Mean ± SD
Male	53 (62.4)
Classic phenotype	76 (89.4)
Atopic comorbidities	37 (43.5)
Involvement of Sensitive Areas	67 (78.8)
Face/neck	54 (63.5)
Hands	39 (45.9)
Genitalia	6 (7.1)
Previous failure to dupilumab	40 (47.1)
Dosage of 100 mg	73 (85.9)
IGA 4	44 (51.8)
Age, years	37.80 ± 15.10
BMI, Kg/m^2	24.47 ± 4.13
At least one CMD	10 (11.8)
EASI at baseline	23.46 ± 9.40
PP-NRS score at baseline	7.15 ± 1.98
S-NRS score at baseline	5.94 ± 2.42

IGA: Investigator Global Assessment; SD: Standard Deviation; BMI: Body Mass Index; EASI: Eczema Area and Severity Index; PP-NRS: Peak Pruritus-Numerical Rating Scale; S-NRS: Sleep-NRS; CMD (Cardiometabolic Comorbidity).

Effectiveness data are combined for the dosage of 100 and 200 mg. After 16 weeks of treatment, EASI 75, EASI 90 and EASI 100 were observed in 77.7% (66 patients), 49.4% (42) and 24.7% of patients (21), respectively. An absolute EASI ≤ 7 was reached by 82.4% of patients (70), while an EASI ≤ 3 by 63.5% (54). Fifty-two patients (61.2%) achieved an IGA of 0 or 1 at the same time point. Regarding PROs, a change of at least 4 points in PP-NRS and S-NRS was achieved by 70.6% of patients (60) for both endpoints. An absolute PP-NRS of 0 or 1 was reported in 51.8% of patients (44), and a S-NRS of 0/1 was observed in 72.9% (62). Complete effectiveness data of abrocitinib at weeks 4 and 16 are reported in Table 2.

We also compared the effectiveness of abrocitinib in terms of EASI 90, IGA 0/1 and a reduction of at least 4 points in PP-NRS in patients who had previously failed dupilumab and in patients who were naïve to this monoclonal antibody (Figure 1). At week 16, we observed that naïve patients had statistically significantly better rates of EASI 90 (60% vs. 37.5%, $p = 0.038$) and delta PP-NRS (80% vs. 60%, $p = 0.043$) compared to patients who previously failed treatment with dupilumab (Figure 1).

Eighteen patients (21.2%) reported at least one AE during the 16 weeks of follow-up (Table 3). The most commonly observed AEs were upper respiratory tract infections (6 patients), followed by blood count abnormalities (4) and hypercholesterolemia (3). Blood count abnormalities, including anemia and leukopenia, were transient and mild and did not lead to treatment discontinuation in any case. No severe AEs were reported, while one patient discontinued the treatment at week 16 because of recurrent urinary tract infections.

Discussion

Our study confirms the effectiveness of abrocitinib in a real-world clinical setting. Indeed, we observed better clinical responses at both week 4 and week 16, compared with those of the Phase-III clinical trials [4,5].

Compared with the JADE MONO-1 study, our patients experienced better rates of IGA 0/1, EASI 75 and EASI 90. In this study, after 12 weeks of treatment with abrocitinib 200 mg, 44% of

Table 2. Effectiveness outcomes of abrocitinib 100 mg/200 mg at week 4 and week 16.

	EASI 75	EASI 90	EASI 100	EASI ≤ 7	EASI ≤ 3	IGA 0/1	ΔPP-NRS≥ 4	ΔS-NRS≥ 4	PP-NRS 0/1	S-NRS 0/1
Week 4	49.4%	25.9%	15.3%	57.7%	32.9%	38.8%	60.0%	62.4%	35.3%	62.4%
Week 16	77.7%	49.4%	24.7%	82.4%	63.5%	61.2%	70.6%	70.6%	51.8%	72.9%

EASI: Eczema Area and Severity Index; IGA: Investigator Global Assessment; PP-NRS: Peak Pruritus-Numerical Rating Scale; S-NRS: Sleep-NRS.

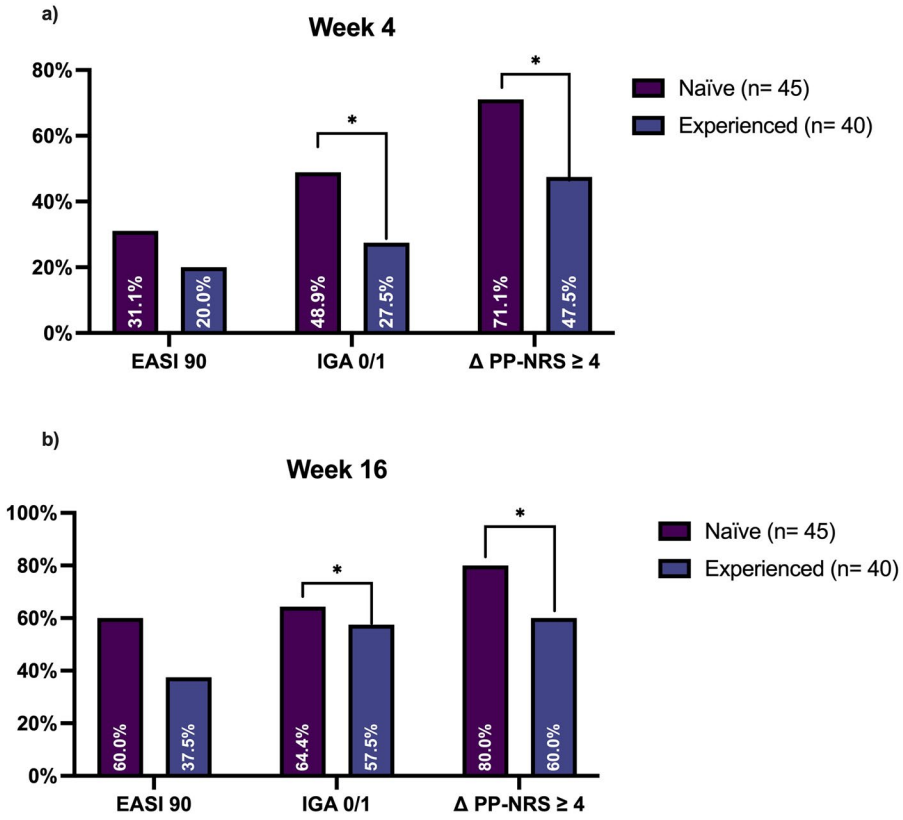

Figure 1. Effectiveness of abrocitinib according to the previous exposure to dupilumab at week 4 (Figure 1a) and week 16 (Figure 1b).
EASI: Eczema Area and Severity Index; IGA: Investigator Global Assessment; PP-NRS: Peak Pruritus- Numerical Rating Scale. *$p < 0.05$; **$p < 0.01$.

Table 3. Safety of abrocitinib throughout the study period.

AEs	*N* (% on total population)
Total	23 (27.1)
URTIs	6 (7.1)
Anemia	3 (3.5)
Hypercholesterolemia	3 (3.5)
Nausea	3 (3.5)
Headache	2 (2.4)
Papulopustular acne	2 (2.4)
Elevated liver enzymes	2 (2.4)
Lymphopenia	1 (1.2)
Urinary tract infection	1 (1.2)
AEs leading to discontinuation	1 (1.2)

AE: Adverse Event; URTIs: Upper Respiratory Tract Infections.

patients achieved IGA 0/1, 63% achieved EASI 75, and 39% achieved EASI 90 [4].

Despite limited evidence from real-world clinical practice on abrocitinib in AD [6], a few studies have been published on the effectiveness and safety of JAK inhibitors [7–9]. A recent consensus has highlighted the key role of these drugs in the management of severe AD in patients with high PP-NRS scores at baseline [10]. Our findings confirm the high effectiveness and rapidity of abrocitinib also in patients with previous exposure to other systemic treatments and with the involvement of difficult-to-treat areas.

Abrocitinib did not show significant new safety signals. Our results are consistent with a recent systematic review on the safety profile of another JAK-1 inhibitor in real-world clinical practice [11].

We recognize that the study has some limitations, represented by its retrospective design, limited follow-up, and multicentric nature, in which different clinicians evaluated patients. However, our study includes one of the largest cohorts of patients treated with JAK inhibitors for AD to date.

In conclusion, we highlight the rapid onset of action of abrocitinib in our population, as demonstrated by significant rates of complete skin clearance and resolution of symptoms after just one moth of treatment. Although limited by a short follow-up, our findings also confirm the safety profile of abrocitinib in the absence of severe AEs or new safety findings compared with clinical trials. Longer prospective studies should be conducted to investigate further the role of abrocitinib in the long-term management of severe AD.

Compliance with ethics guidelines

Institutional review board approval was exempted as the study protocol did not deviate from standard clinical practice. All patients received abrocitinib as in good clinical practice, in accordance with

European guidelines. All included patients had provided written consent for retrospective study of data collected during routine clinical practice (demographics, clinical scores). The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

Disclosure statement

L. Gargiulo has been a consultant and/or speaker and has participated to advisory boards for Abbvie, Almirall, Eli Lilly, Pfizer, Sanofi and UCB Pharma.

L. Ibba has been a consultant for Almirall.

P. Malagoli has been a speaker for AbbVie, Lilly, Novartis, Janssen-Cilag, Celgene, LeoPharma, and Almirall.

A. Balato has received honoraria for participation in advisory boards, meetings, or as speaker for AbbVie, Celgene, Janssen-Cilag, Eli Lilly, Novartis Pharma, Pfizer, Sanofi-Genzyme, and UCB Pharma.

F. Barei has been consultant or speaker for Leo Pharma and Almirall.

M. Esposito has served as a speaker/board member for Abbvie, Almirall, Biogen, Celgene, Eli Lilly, Janssen, Leo Pharma, and Novartis.

M. C. Fargnoli has served on advisory boards, received honoraria for lectures and/or research grants from AMGEN, Almirall, Abbvie, Boehringer-Ingelheim, BMS, Galderma, Kyowa Kyrin, Leo Pharma, Pierre Fabre, UCB, Lilly, Pfizer, Janssen, MSD, Novartis, Sanofi-Regeneron, Sunpharma.

S. M. Ferrucci has been principal investigator in clinical trials for AbbVie, Almirall, Galderma, Leo Pharma, Sanofi, Amgen, Novartis, Bayer and received honoraria for lectures for Novartis and Menarini.

C. Foti has been consultant or speaker for Abbvie, Pfizer, Sanofi, Novartis, Lilly and LeoPharma.

G. Girolomoni has received personal fees from AbbVie, Almirall, Amgen, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli-Lilly, Leo Pharma, Merck Serono, Novartis, Pfizer, Pierre Fabre, Samsung bioepis and Sanofi.

M. Gola has been consultant and/or speaker, has participated to advisory boards and has received personal fees from AbbVie, Almirall, Leo Pharma, Pfizer and Sanofi.

MB. Guanti has served as advisory board member and/or consultant and has received fees and speaker's honoraria or has participated for clinical studies for AbbVie, Leo Pharma, Sanofi Genzyme, Novartis, Cantabria, Menarini, Lilly.

M. L. Musumeci has previously served as advisory board member and consultant, and has received speaker's honoraria and fees for her participation to clinical trials for Abbvie, Almirall, Biogen, Eli-Lilly, Janssen Cilag, Leo Pharma, and Novartis.

M. Napolitano acted as speaker, consultant and/or advisory board member for Abbvie, Eli Lilly, Leo Pharma, Novartis, and Sanofi.

M. Ortoncelli has served as advisory board member and/or consultant and has received fees and speaker's honoraria or has participated for clinical studies for AbbVie, Leo Pharma, and Sanofi Genzyme.

C. Patruno has served as advisory board member and consultant, and has received speaker's honoraria and fees for her participation to clinical trials for Abbvie, Almirall, Eli-Lilly, Leo Pharma, and Novartis.

E. Pezzolo has been consultant and speaker for Sanofi Genzyme, AbbVie, Leo Pharma, Novartis, Janssen, Almirall, Pfizer, Galderma, and Boehringer Ingelheim.

S. Ribero has served as advisory board member and/or consultant and has received fees and speaker's honoraria or has participated for clinical studies for AbbVie, Almirall, Leo Pharma, Elli Lilly, Novartis, Pfizer and Sanofi Genzyme.

M. Rossi has received personal fee for advisory board meeting from Sanofi, Abbvie, Novartis, and Cantabria.

P. Savoia received speaker's honoraria and research grants from Novartis, Sanofi, Janssen, Kyowa Kirin, Almirall, Sunpharma, Ganassini, Idi.

A. Costanzo has served as an advisory board member, consultant and has received fees and speaker's honoraria or has participated in clinical trials for Abbvie, Almirall, Biogen, LEO Pharma, Lilly, Janssen, Novartis, Pfizer, Sanofi Genzyme, and UCB-Pharma.

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A. Alfano, F. Amoruso, A.G. Burroni, M. Magliulo, C. Gurioli, M. Maurelli, P. Morrone, BM. Piraccini, S. Caccavale, B. Tirone, M. Vaccino, P. Calzavara-Pinton, F. Veronese and C. Sciarrone have nothing to declare.

Funding

This work was partially supported by 'Ricerca Corrente' funding from Italian Ministry of Health to IRCCS Humanitas Research Hospital.

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Data availability statement

All the patients' data and information supporting the findings of the study are available from the corresponding author upon reasonable request.

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