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Efficacy and Safety of Abrocitinib in an Elderly Chinese Population with Moderate-to-Severe Atopic Dermatitis: A Non-randomized Controlled Trial

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There is a paucity of data regarding the use of Janus kinase inhibitors in elderly patients with moderate-to-severe atopic dermatitis necessitating systemic therapy. This study aimed to evaluate the efficacy and safety of abrocitinib compared with dupilumab in atopic dermatitis patients aged 60 years or older. A single-centre, non-randomized controlled trial (ChiCTR2300077724) was conducted from December 2022 to March 2024, in which 58 patients were assigned to receive either abrocitinib (100 mg daily) or dupilumab (600 mg loading dose followed by 300 mg every 2 weeks). The primary endpoints were the proportion of patients achieving a ≥ 4 -point reduction in the Peak Pruritus Numerical Rating Scale (PP-NRS) at Week 2 and the proportion achieving Eczema Area and Severity Index (EASI)-75 at Week 12; EASI-90 response at Week 24 was a key secondary endpoint. Results showed that a higher proportion of patients receiving abrocitinib achieved a PP-NRS4 response at Week 2 (52% vs 26%; $p = 0.046$). At Week 12, EASI-75 response rates were similar between the 2 groups (45% for abrocitinib vs 44% for dupilumab; $p = 0.95$). By Week 24, the EASI-90 response rate was 52% in the abrocitinib group compared with 41% in the dupilumab group ($p = 0.4$). Adverse events in the abrocitinib group included colon tumour (3%), nausea (6%), folliculitis (6%), and headache (16%), while the dupilumab group reported T-cell prolymphocytic leukaemia (3%) and conjunctivitis (7%). In conclusion, abrocitinib provided more rapid relief from pruritus and demonstrated superior long-term efficacy compared with dupilumab in the elderly population.

Key words: atopic dermatitis in the elderly; atopic dermatitis; elderly; older patients; abrocitinib.

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Atopic dermatitis (AD) is a prevalent chronic inflammatory skin disorder characterized by recurrent eczematous lesions and persistent pruritus (1). Its clinical

SIGNIFICANCE

This study addresses a critical gap for elderly patients suffering from severe atopic dermatitis, a group often excluded from clinical trials. We directly compared 2 newer treatments – daily pill abrocitinib and bi-weekly injection of dupilumab – in patients over 60. The key finding is that abrocitinib provided faster relief from debilitating itching within just 2 weeks. While long-term skin clearance rates showed a positive trend for abrocitinib, both treatments had manageable side effects. This offers doctors valuable real-world evidence to personalize care for our growing elderly population, helping them choose treatments that quickly improve comfort and quality of life.

manifestations vary significantly across different age groups and geographic regions (2–4). A distinct subgroup, elderly-onset AD, is experiencing a rising incidence, primarily due to the global ageing population (3, 5). In elderly patients, AD often presents with atypical phenotypes such as prurigo nodularis, nummular eczema, and erythroderma, with xerosis being a more common feature (5–9). This condition significantly impacts the quality of life in older adults and may exacerbate existing comorbidities, adding complexity to their overall health management (3, 10, 11). Systemic treatment options for elderly patients with AD are often limited due to the presence of comorbidities (3), and many clinical trials exclude this population by imposing upper age limits (12, 13). Therapeutic strategies for managing AD include topical corticosteroids (TCS), topical calcineurin inhibitors (TCI), systemic corticosteroids (SCS), immunosuppressants, dupilumab, and Janus kinase (JAK) inhibitors. Among these, abrocitinib, a selective JAK1 inhibitor, and dupilumab, an injectable human monoclonal antibody targeting the interleukin (IL)-4 receptor alpha subunit, are approved treatments for moderate-to-severe AD in adolescents and adults (1, 14–17). Previous studies have demonstrated the efficacy and safety of dupilumab in adults aged ≥ 60 years with moderate-to-severe AD (11, 18–20). While JAK inhibitors, such as abrocitinib, provide a rapid onset of action and high efficacy, their use in elderly patients has been limited due to concerns about adverse events, including

infections and cardiovascular complications (18, 21–23). Clinical data on JAK inhibitors in elderly AD patients remain scarce. Piscazzi et al. reported a case series of 7 elderly patients with adult-onset moderate-to-severe AD treated with upadacitinib 15 mg, demonstrating its favourable safety and efficacy profile in this population (24). While abrocitinib has shown promising results in treating moderate-to-severe AD (25–29), evidence regarding its safety and efficacy in elderly patients is still limited. Therefore, this study aims to address this gap by evaluating the efficacy and safety of abrocitinib in elderly patients with moderate-to-severe AD.

METHOD

This was a non-randomized controlled trial approved by Wuhan No. 1 Hospital and conducted in accordance with the Declaration of Helsinki. All participants provided written informed consent prior to enrolment. The study followed the TREND (Transparent Reporting of Evaluations with Nonrandomized Designs) guidelines for reporting non-randomized studies.

Study population and inclusion/exclusion criteria

Participants were recruited from patients diagnosed with AD who visited Wuhan No. 1 Hospital between December 2022 and March 2024. Of the 58 patients who were enrolled, 56 patients completed 24 weeks of therapy. Demographic information was collected for all participants.

The inclusion criteria were as follows: (i) aged ≥ 60 years; (ii) diagnosis of moderate-to-severe AD based on standardized diagnostic criteria (Williams criteria or Chinese Diagnostic Criteria for Atopic Dermatitis), defined by: at baseline a score of at least 3 on the Investigator's

Global Assess (IGA; scored on a 5-point scale: 0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; and 4 = severe); a score of at least 7 on the Eczema Area and Severity Index (EASI; range 0–72); (iii) inadequate response to at least 4 consecutive weeks of treatment for AD within the past 6 months, or previous treatments (e.g., topical therapies, immunosuppressants, or biologics) were ineffective, necessitating systemic therapies for disease control; (iv) voluntary choice of treatment with either abrocitinib or dupilumab;

The exclusion criteria included: (i) inability to tolerate abrocitinib or dupilumab treatment; (iii) presence of severe infections, active tuberculosis, active hepatitis B or C, thrombosis, and history of malignancy within the past 5 years.

Study design and interventions

This non-randomized controlled trial evaluated the efficacy and safety of abrocitinib (100 mg once daily) and dupilumab (300 mg every 2 weeks following a 600 mg loading dose) in elderly patients (≥ 60 years). The study enrolled 58 patients, with 31 assigned to the abrocitinib group and 27 to the dupilumab group. Patients in the abrocitinib group received 100 mg orally once daily, while those in the dupilumab group received 300 mg subcutaneously every 2 weeks following an initial 600 mg loading dose. Concurrent use of topical therapies, including topical corticosteroids, calcineurin inhibitors, or phosphodiesterase-4 inhibitors, was permitted, with patients allowed to use more than 1 topical agent. The treatment period lasted 24 weeks, with assessments conducted at Week 2, Week 12, and Week 24. Following the 24-week treatment phase, patients were followed up for an additional 24 weeks (up to Week 48) to evaluate long-term outcomes and safety (**Fig. 1**).

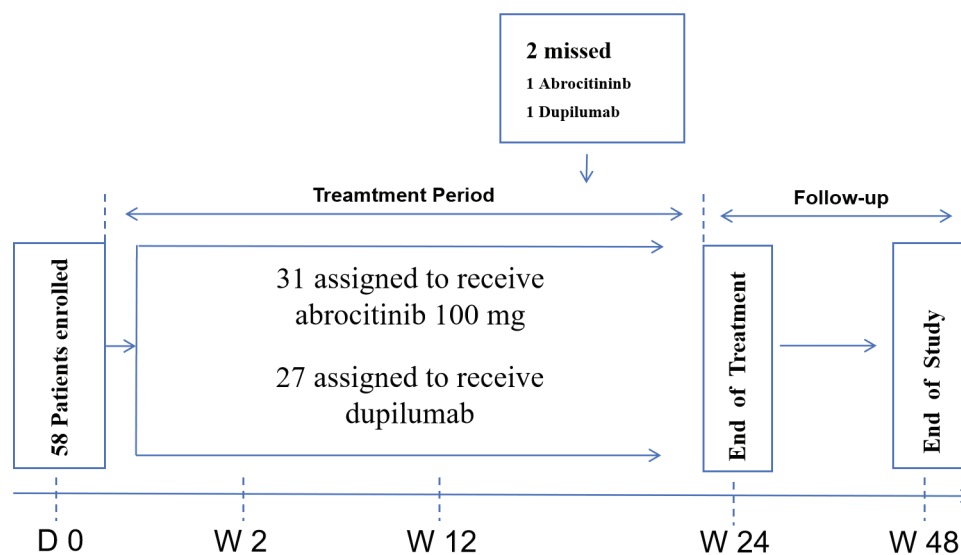


Fig. 1. Participant flow diagram.

End points

Primary efficacy endpoints. (i) Improvement in Pruritus: $A \geq 4$ -point improvement in the Peak Pruritus Numerical Rating Scale (PP-NRS4) at Week 2, which evaluates the intensity of itching as perceived by the patients. A reduction of ≥ 4 points is considered a clinically significant improvement in pruritus. (ii) EASI-75 Response: Achievement of a $\geq 75\%$ reduction in the Eczema Area and Severity Index (EASI-75) at Week 12, reflecting substantial improvement in both the severity and extent of skin lesions associated with AD.

Key secondary efficacy endpoints. EASI-90 response: Achievement of a $\geq 90\%$ reduction in the EASI score at Week 24, indicating near-complete resolution of skin lesions and demonstrating the sustained efficacy of the treatment.

Safety endpoints. (i) Adverse events (AEs): Monitoring the occurrence of adverse events, with special attention to serious adverse events (SAEs), defined as events that are life-threatening or result in death. (ii) Most common patient-reported adverse event: Identification of the most frequently reported adverse event by patients to provide insights into the overall safety and tolerability profile of the treatments.

Sample size calculation

The following formula was used: $n = (Z_{\alpha/2} + Z_{\beta})^2 \times [p_1(1-p_1) + p_2(1-p_2)] / (p_1 - p_2)^2$

Assuming the expected PP-NRS4 response rate of 48% for abrocitinib and 24% for dupilumab, with a 10% dropout rate, the estimated sample size per group was 66 (total = 132). However, only 58 patients were enrolled, with 56 completing follow-up. Although the sample size is small, the results still show certain trends, suggesting that the intervention may have a beneficial effect in elderly AD patients.

Statistical analysis

Descriptive statistics were used to summarize the demographic data. Continuous variables were reported as mean (SD), while categorical variables were analysed using proportional analysis to describe adverse event occurrences. For binary outcomes, a χ^2 test was the primary analysis. Risk differences (RD) with 95% CIs were calculated using the Newcombe–Wilson method with continuity correction to quantify clinical benefit magnitude. Statistical significance was defined as two-tailed $p < 0.05$.

The Full Analysis Set (FAS) was defined as all enrolled patients who received ≥ 1 dose of assigned treatment and had ≥ 1 post-baseline efficacy assessment. The FAS served as the primary dataset for efficacy analyses according to intention-to-treat (ITT) principles. A modified FAS (mFAS) excluding patients with major

protocol deviations was used in sensitivity analyses. For both approaches, missing data were handled using Last Observation Carried Forward for continuous variables. Statistical analyses were performed using GraphPad Prism version 10 (GraphPad Software; <https://www.graphpad.com/>).

RESULTS

Between December 2022 and July 2024, a total of 58 patients met the inclusion criteria and underwent eligibility assessment. Of 58 patients who completed the 12-week treatment phase (see Fig. 1), 56 patients received continuing follow-up to Week 24. Two patients in the abrocitinib group and 1 in the dupilumab group missed the Week 24 follow-up.

Baseline demographics and clinical characteristics were generally balanced between the 2 treatment groups (**Table I**). The majority of participants were male (64%), with a mean age of 68.5 years (SD 7.5). In the abrocitinib group, 64% (20 of 31) were male, with a mean age of 67 years (SD 6.2). Similarly, in the dupilumab group, 63% (17 of 27 patients) were male, with a mean age of 70.4 years (SD 8.5).

Of the 58 participants, 34 (59%) presented with moderate disease, while 22 (38%) had severe disease based on their Investigator Global Assessment (IGA) scores. The mean baseline EASI score was 20.1 (SD 10.6), with scores of 23.2 (SD 11.4) in the abrocitinib group and 16.7 (SD 8.6) in the dupilumab group. Both groups showed comparable IGA and PP-NRS scores. The median disease duration for all participants was 48 months, with 36 months in the abrocitinib group and 72 months in the dupilumab group.

Additionally, 8 patients (14%) had concurrent allergic conditions, 15 patients (26%) had elevated eosinophil levels, 20 patients (35%) had increased IgE levels, and 34 patients (60%) had other comorbidities. The majority of participants (39 of 58, 67%) had received prior systemic treatment for AD. Concomitant topical therapies were utilized by 17 of 31 patients (55%) in the abrocitinib group and 14 of 27 patients (52%) in the dupilumab group during the study period.

Efficacy

The proportion of patients achieving the primary endpoint of PP-NRS4 at week 2 was higher in the abrocitinib group compared with the dupilumab group (16/31 patients [52%] vs 7/27 patients [26%]). The risk difference was 26% (95% CI: -1.8% to 48.3% ; $p = 0.046$), indicating that 1 in 4 additional patients achieved rapid itch relief with abrocitinib.

For EASI-75 at week 12, a slightly higher proportion of patients in the abrocitinib group achieved this milestone (14/31 patients [45%]) compared with the dupilumab

Table I. Demographic and disease characteristics of the patients at baseline

Characteristic	Total (n = 58)	Abrocitinib, 100 mg once daily (n = 31)	Dupilumab, 300 mg every other week (n = 27)
Age, years, mean±SD	68.5±7.5	67±6.2	70.4±8.5
Male sex, n (%)	37 (64)	20 (64)	17 (63)
Duration of atopic dermatitis, years, mean±SD	48 (97)	36 (104)	72 (174)
IGA score, n (%)	3.3±0.5	3.3±0.6	3.3±0.4
0, clear	0	0	0
1, almost clear	0	0	0
2, mild	0	0	0
3, moderate	34	19	18
4, severe	22	13	9
EASI score (0–72), mean±SD	20.1±10.6	23.2±11.4	16.7±8.6
PP-NRS score (0–10), mean±SD	7.2±1.6	7.2±1.5	7.2±1.7
Coexisting medical, n (%)			
Allergic conditions ^a	8 (14)	6 (19)	2 (7)
Other comorbidities ^b			
Hypertension	26 (45)	16 (52)	10 (37)
Diabetes	6 (10)	4 (13)	2 (7)
Hyperlipidaemia	3 (5)	2 (6)	1 (3)
Proportion of increased eosinophils level, n (%)	15 (26)	5 (16)	10 (36)
proportion of increased IgE level, n (%)	20 (35)	7 (23)	13 (48)
Poor to previous treatments, n (%)	39 (67)	25 (81)	14 (52)
Concomitant topical therapies, n (%)	31	17 (55)	14 (52)

IGA: Investigator's Global Assessment.
Scores on the Eczema Area and Severity Index (EASI) range from 0 to 72, with higher scores indicating more severe disease.
Scores on the Peak Pruritus Numerical Rating Scale (PP-NRS) represent maximum itch severity in the previous 24 h and range from 0 to 10, with higher scores representing more severe itch.
^aAllergic conditions such as asthma, allergic conjunctivitis, allergic rhinitis, food allergy, and so on. ^bOther comorbidities such as hypertension, hyperlipidaemia, diabetes, heart disease, and so on.

group (12/27 patients [44%]). The risk difference was 0.7% (95% CI: –25.7% to 26.8%, *p*=0.95).

For the key secondary endpoint, at week 24, a greater proportion of patients in the abrocitinib group (16/31 patients [52%]) achieved the key secondary endpoint of EASI-90 compared with the dupilumab group (11/27 [41%]). The risk difference of 11% (95% CI: –16.3% to 36%) *p*=0.4) met the criteria for both non-inferiority and superiority, indicating that abrocitinib provided a significant and durable therapeutic benefit (Table II).

Safety

During the 48-week follow-up peirod, serious adverse events were reported in 1 patient (colon cancer) in the abrocitinib 100-mg group (3%) and 1 patient (T-cell prolymphocytic leukaemia) in the dupilumab group (3%). The most frequently reported adverse events in

the abrocitinib group were headache (5 patients [16%]), folliculitis (2 patients [6%]) and nausea (2 patients [6%]). In the dupilumab group, the most commonly reported adverse event was conjunctivitis (2 patients [7%]) (Table III).

DISCUSSION

It is a challenge to diagnose adult-onset AD in elderly patients because its symptoms often overlap with other skin conditions, such as cutaneous T-cell lymphoma and nummular eczema. A thorough clinical evaluation, sometimes including skin biopsy, is essential to confirm the diagnosis and avoid misclassification (8).

Elderly patients frequently present with comorbidities, such as hypertension, diabetes, and cardiovascular diseases, which influence treatment choices and outcomes.

Table II. Summary of efficacy end points

End point	Abrocitinib, 100 mg once daily (n = 31)	Dupilumab, 300 mg every other week (n = 27)
Primary end points		
Itch response at week 2 no./total no. (%)	16 (52)	7 (26)
Difference from placebo (95% CI)	26 (–1.8–48.3)	
<i>P</i> -value	0.046	
EASI-75 response at week 12 no./total no. (%)	14 (45)	12 (44)
<i>P</i> -value	0.95	
Difference from placebo (95% CI)	0.7 (–25.7–26.8)	
Key secondary end points		
EASI-90 response at week 24 no./total no. (%)	16 (52)	11 (41)
<i>P</i> -value	0.4	
Difference from placebo (95% CI)	11 (–16.3–36)	

Table III. Summary of adverse events

End point	Total (n = 58)	Abrocitinib, 100 mg once daily (n = 31) n (%)	Dupilumab, 300 mg every other week (n = 27) n (%)
Serious adverse event			
Death		0	0
Tumour	2 (3%)	1 (3%)	1 (4%)
Cardiovascular event		0	0
Thrombosis		0	0
Most common adverse event			
Thrombocytopenia		0	0
Nausea	2 (3%)	2 (6%)	0
Conjunctivitis	2 (3%)	0	2 (7%)
Upper respiratory tract infection		0	0
Headache	5 (9%)	5 (16%)	0
Acne		0	0
Zoster		0	0
Folliculitis	2 (3%)	2 (6%)	0

The differences in comorbidity patterns between populations thus restrict the generalizability of our findings (30).

Current treatment guidelines recommend dupilumab as the first-line biologic therapy for elderly patients with AD. JAK inhibitors, such as abrocitinib, are usually considered only when dupilumab fails and also require very careful patient selection. However, this population is frequently excluded from clinical trials (6). This real-world context also helps explain the observed baseline imbalance. Patients initiating abrocitinib in clinical practice tend to have higher disease activity at baseline. Moreover, the overall sample size for this specific subgroup is inherently limited (29).

Previous studies have demonstrated the efficacy of abrocitinib and dupilumab in treating moderate-to-severe AD in populations predominantly under the age of 65, with both treatments consistently achieving high EASI-75 scores by Week 12. Specifically, abrocitinib 200 mg has shown superior efficacy compared with 100 mg, although the higher dose was associated with an increased incidence of adverse events. Abrocitinib 100 mg has been reported as either slightly more effective or comparable to dupilumab (25, 28, 29, 31–34). In elderly patients, the efficacy of abrocitinib 100 mg was slightly reduced compared with that observed in younger populations. By Week 24 in this study, a higher proportion of elderly patients treated with abrocitinib 100 mg (52%) achieved EASI-90 compared with those treated with dupilumab (41%), consistent with findings from the JADE DARE trial (abrocitinib 100 mg vs dupilumab; 54% vs 42%) (29). Furthermore, abrocitinib demonstrated superior early response on the PP-NRS at Week 2 (52% vs 26% for dupilumab), highlighting its effectiveness in rapidly alleviating pruritus (35), a key symptom often more severe in elderly patients due to drier skin and higher comorbidity burdens.

Regarding adverse events, abrocitinib commonly caused side effects such as nausea and acne, while dupilumab was primarily associated with conjunctivitis (20, 25, 28, 29). In this study's elderly cohort, both treatments had similar adverse event profiles. In the abrocitinib group, a 72-year-old male was diagnosed with colon cancer 6 months after treatment initiation. In the dupilumab group, a 75-year-old female patient developed T-cell prolymphocytic leukaemia 3 months after treatment discontinuation. Both patients had no identifiable pre-malignant conditions or traditional risk factors at baseline evaluation. The temporal association between these treatments and cancer remains unclear. Elderly populations inherently face a higher cancer risk due to age and comorbid health conditions, highlighting the need for patient monitoring (36). Under careful screening and clear selection criteria, our real-world study did not find more adverse events linked to abrocitinib or dupilumab in these elderly patients. This finding aligns with recent reports from other clinical studies. Some studies

suggest that the use of JAK inhibitors or dupilumab is not associated with an increased risk of all-cause mortality, MACE, or VTE compared with placebo or active comparator groups in the short and long term (37–39). However, recent research has raised concerns about a potential association between dupilumab and the risk of cutaneous T-cell lymphoma (CTCL) in AD patients, possibly due to a shared Th2 inflammatory pathway in both conditions. While dupilumab may help alleviate itching in CTCL patients, there have been instances where it may be linked to the onset or progression of CTCL in some individuals, highlighting the need for caution in its use (40).

Limitations

Some limitations of this study should be acknowledged, including its non-randomized design, single-centre setting, the challenge of accurate diagnosis, differences in comorbidity patterns that restrict generalizability, and a relatively small sample size with insufficient follow-up. Consequently, large-scale trials are needed to further confirm the long-term efficacy and safety of abrocitinib in elderly patients with AD.

Conclusion

In this real-world comparative study, abrocitinib 100 mg once daily was demonstrated to be an effective and well-tolerated treatment option over 48 weeks in elderly patients with moderate-to-severe AD, provided that patient selection and dosing are appropriately managed. Compared with dupilumab, abrocitinib was associated with more rapid pruritus relief and numerically higher long-term efficacy rates. Larger trials in diverse populations are necessary to confirm the long-term efficacy and safety of abrocitinib.

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