American Journal of Clinical Dermatology
https://doi.org/10.1007/s40257-026-01022-5

ORIGINAL RESEARCH ARTICLE

Ritlecitinib for Severe Alopecia Areata: A 24-Week, Multicentre, Real-World Study

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Received: 5 November 2025 / Accepted: 1 March 2026

Abstract

Background Ritlecitinib, an oral selective inhibitor of Janus kinase 3 and the TEC family of kinases, has recently been approved for the treatment of severe alopecia areata, but real-world data are still limited.

Objective The aim was to evaluate the effectiveness and tolerability of ritlecitinib 50 mg/day after 24 weeks in patients with severe alopecia areata in clinical practice.

Methods We performed an Italian observational, retrospective, multicentre study with 24 weeks of follow-up. Patients ≥ 12 years of age with severe alopecia areata (Severity of Alopecia Tool [SALT] ≥ 50) and a disease duration ≥ 6 months who were candidates for systemic therapy were enrolled. Ritlecitinib 50 mg/day was administered according to national guidelines. The primary endpoint was to evaluate the achievement of SALT ≤ 20 at week 24. Secondary endpoints included achievement of SALT ≤ 10; mean change in SALT; trichoscopic improvement; quality of life; psychological impact; efficacy in eyebrows, eyelashes, and nails; and safety profile.

Results A total of 102 patients were included. At week 24, 40.2% of patients achieved SALT ≤ 20, with a greater response in adolescents (48.6%) than in adults (21.9%). The mean SALT score decreased from 86.2 ± 18.5 to 40.8 ± 37.1. Significant improvements were observed in trichoscopic signs and quality of life. The treatment was also effective on eyebrows, eyelashes, and nails. Adverse events were mild (e.g., acne, headache). Ritlecitinib had to be discontinued in only one case of severe anaemia.

Conclusions In this multicentre real-world study, ritlecitinib 50 mg/day was an effective and well-tolerated treatment option for severe alopecia areata.

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Published online: 19 March 2026

Plain Language Summary

Alopecia areata is a common autoimmune disease that causes hair loss on the scalp and other parts of the body, such as eyebrows, eyelashes, and body hair. It affects people of any age, including adolescents, and often has a strong psycho-emotional impact, reducing quality of life. A new medication for severe alopecia areata, called ritlecitinib, was approved in 2023. Ritlecitinib is a Janus kinase inhibitor that modulates the immune response involved in the pathogenesis of the disease, promoting hair regrowth. However, data on its efficacy in everyday clinical practice have remained limited. To address this, we carried out a retrospective clinical study in Italy involving 20 university dermatology departments. We evaluated 102 adults and adolescents (≥ 12 years) with severe alopecia areata, treated with ritlecitinib 50 mg/day for 24 weeks. After 6 months of treatment, about 40% of patients had major hair regrowth on the scalp (with 80% of the scalp covered by hair). The treatment worked better in adolescents than in adults (48.6 vs 21.9%). Significant improvements were also noted in eyebrows, eyelashes, nail involvement, and quality of life parameters. Ritlecitinib was generally safe and well tolerated. Adverse effects were mild, and only one patient stopped treatment because of anaemia. Overall, our study showed that ritlecitinib was an effective and safe treatment for severe alopecia areata in real-world practice, particularly among adolescents.

Key Points

Ritlecitinib 50 mg/day showed clinical effectiveness in severe alopecia areata in real-world practice, particularly among adolescents, with 40% of patients achieving a Severity of Alopecia Tool (SALT) score of ≤ 20 at 24 weeks.

The treatment also improved trichoscopic signs, eyebrows, eyelashes, nails, and quality of life.

Ritlecitinib was well tolerated, with no serious adverse events, confirming its safety and effectiveness in the treatment of severe alopecia areata.

1 Introduction

The understanding of the inflammatory cytokine signalling pathways involved in the pathogenesis of alopecia areata (AA) has radically changed the treatment approach to severe forms of this condition, due to the development of targeted therapies, in particular oral Janus kinase (JAK) inhibitors [1]. These drugs have shown significant potential in promoting hair regrowth in patients with severe AA [2]. Baricitinib, a selective JAK1/2 inhibitor, was the first approved JAK inhibitor for severe AA in adults [3, 4]. Ritlecitinib, an oral selective inhibitor, characterized by its unique covalent inhibition of JAK3 and members of the TEC kinase family, received approval from the Food and Drug Administration in June 2023 and from the European Medicines Agency in September 2023 for the treatment of severe AA from 12 years of age [5]. The approval was based on the results of the ALLEGRO clinical trial, which demonstrated significant hair regrowth, with 23% of patients achieving a Severity of Alopecia Tool (SALT) score ≤ 20 at week 24 of treatment [6]. Furthermore, ritlecitinib has shown good tolerability up to 24 months of treatment. Mild to moderate adverse events (AEs) include headache, acne, nasopharyngitis, transient increases in liver enzymes, and alterations in haematological parameters [7, 8]. Similar to other JAK inhibitors, there is a theoretical risk of cardiovascular events and serious infections, although clinical studies have demonstrated no significant increase in these complications compared to placebo [9].

This multicentre retrospective study aims to evaluate the effectiveness and tolerability of daily ritlecitinib 50 mg at 24 weeks in Italian patients with severe AA, bridging the gap between clinical trials and real-world practice.

2 Material and Methods

2.1 Study Design and Population

We conducted a 24-week retrospective, observational, multicentre study to evaluate the effectiveness and safety of 50 mg daily of ritlecitinib in adolescents aged 12–17 years and adults aged ≥ 18 years with severe AA who started treatment between May 2024 and September 2024. Data were collected from patient records at 20 Italian centres, with the IRCCS *Azienda Ospedaliero-Universitaria Policlinico di Sant'Orsola* in Bologna serving as the coordinating centre, between January 1st, 2025, and March 31st, 2025. A flowchart illustrating the study design is provided in the electronic supplementary material (Fig. S1).

2.2 Inclusion and Exclusion Criteria

The patients, aged ≥ 12 years and of both sexes, had been diagnosed with severe AA, defined as a SALT score ≥ 50, including AA *totalis* and AA *universalis*. Eligibility criteria required a minimum duration of the current episode of 6 months, with diagnosis confirmed by clinical and

trichoscopic assessment. In addition, eligible individuals were patients who were candidates for systemic therapy and who had responded inadequately to, or were intolerant of, alternative therapeutic options, or for whom alternative therapeutic options were not appropriate, according to national regulatory provisions [3, 10, 11]. The exclusion criteria were concomitancy with other forms of alopecia, comorbidities incompatible with ritlecitinib, abnormal laboratory parameters (e.g. neutrophil count $\leq$ 1000 cells/mm^3, haemoglobin $\leq$ 8 g/dL), clinically significant depression, history of disseminated or recurrent herpes zoster or simplex, and pregnancy or lactation.

2.3 Treatment Protocol

Patients received oral ritlecitinib 50 mg daily according to national regulatory provisions [3, 10, 11].

2.4 Endpoints

The primary endpoint of this study was to evaluate the effectiveness of 50 mg ritlecitinib in patients with severe AA, as determined by the SALT score [12], by assessing the number and percentage of patients who achieved SALT $\leq$ 20 (i.e. achievement of a 20% or less scalp hair loss), similar to how it was performed in the phase 2b–3 trial [6]. Secondary endpoints were (1) to evaluate the percentage of patients achieving a SALT score $\leq$ 10 [6]; (2) to calculate the mean value change of SALT score; (3) to evaluate trichoscopic improvement [13, 14]; (4) to assess patients' quality of life and the psychological impact using Children's Dermatology Life Quality Index (CDLQI) [15] in patients under 16 of age, Skindex-16 AA [16], and Hospital Anxiety and Depression Scale anxiety/depression (HADS-A/D) [17] scores; and (5) to state the effectiveness of ritlecitinib on eyebrows and eyelashes through the Clinician-Reported Outcome (ClinRO EB/EL) measure and on nails through the ClinRO Nail Appearance measure [18].

2.5 Trichoscopic Evaluation

Trichoscopic monitoring was performed to document the course of AA and the therapeutic response [11, 19]. Acute exacerbation of AA is defined by trichoscopic signs that include black dots, exclamation point hairs, and dystrophic hairs, while chronic AA is associated with the exclusive presence of yellow dots and thin, non-pigmented hairs. The regrowth phase is characterized by the appearance of pointed upgrowing hairs [11, 20, 21].

2.6 Quality of Life and Psychological Assessments

The Skindex-16 and CDLQI were employed to measure quality of life, while HADS was used to assess the psychological impact. Skindex-16 measures three domains (symptoms, emotions, and functioning), whose scores are normalized from 0 (no effect) to 96 (maximum impact) [16]. The CDLQI is a questionnaire consisting of ten questions that quickly and easily assesses how much a skin condition affects a child's daily quality of life, exploring aspects such as symptoms, emotions, activities, school, and social relationships, with a score ranging from 0 to 30 [15]. HADS assesses anxiety (HADS-A) and depression (HADS-D) on a scale ranging from 0 to 21, with higher values reflecting more anxiety or depression. Patients with baseline HADS-A or HADS-D scores $\geq$ 8 were categorized as having borderline or abnormal anxiety or depression, while scores $<$ 8 were considered normal [17].

2.7 Clinician-Reported Outcome (ClinRO)

ClinRO EB/EL uses an ordinal scale of measurement, which ranges from 0 (= no visible hair loss) to 3 (= total loss of hair). ClinRO Nail Appearance uses an ordinal measurement scale, which ranges from 0 (= nails are not at all damaged) to 3 (= at least one nail is very damaged or the patient has lost at least one nail) [18]. The content validity, reliability, and accuracy of these tools have been validated in both adults and adolescents [22].

2.8 Study Visits

Primary and secondary endpoints were evaluated at baseline (T0) and after 4 weeks (T4w), 12 weeks (T12w), and 24 weeks (T24w). The reporting of AEs, and their grade of severity, was left to the investigator's clinical judgment. At each centre, SALT scores and trichoscopic findings were assessed by at least two experienced hair disorder dermatologists.

2.9 Statistical Analysis

Data were analysed using descriptive and inferential statistical methods. Continuous variables were expressed as mean $\pm$ standard deviation (SD). Categorical variables were reported as absolute frequencies and percentages. Comparisons of continuous variables over time were conducted using paired-sample *t* tests. For subgroup analyses, chi-square tests were employed to evaluate differences in categorical outcomes, such as severity level changes over time. Spearman's correlation coefficients (ρ) were calculated to assess associations between changes in scores. For the primary categorical

outcome analysis, treatment response was defined dichotomously as responder (SALT ≤ 20) or non-responder (SALT > 20) at each follow-up time point (4 weeks, 12 weeks, and 24 weeks) based on SALT score criteria. Responder rates were compared between adolescent and adult groups at each time point using the chi-square test of independence. When expected cell counts were less than five, Fisher's exact test was applied. Statistical significance was set at $p < 0.05$, and all tests were two-tailed.

2.10 Ethical Considerations

The study adheres to Good Clinical Practice guidelines, *Agenzia Italiana del Farmaco* (AIFA) regulations, and the Declaration of Helsinki. In addition, approval has been obtained from the ethics committee (245/2025/OssF/AOUBo).

3 Results

3.1 Patient Demographics and Baseline Characteristics

A total of 20 Italian university hospitals participated in this study, enrolling 102 patients with AA, comprising 55 males (53.9%) and 47 females (46.0%). Ten patients within the enrolled cohort had been previously included in a preceding study [23]. The mean age at enrolment was 23.9 ± 15.3 years, while the mean age at the first diagnosis of AA was 15.3 ± 13.0 years. Analysing the distribution by age group, 70 patients (68.6%) were adolescents aged 12–17 years, while 32 (31.4%) were adults aged ≥ 18 years.

The mean duration of the disease was 8.9 ± 8.9 years (5.8 ± 4.0 for adolescents and 14.9 ± 12.1 for adults), while the mean duration of the current episode was 49.3 ± 83.0 months (34.4 ± 31.9 for adolescents and 89.2 ± 121.0 for adults). Regarding the severity and type of AA using the SALT score, 45 participants (44.1%) had a severe form of AA (SALT 50–95), while 57 (55.9%) had a very severe form (SALT ≥ 95). At T0, the mean SALT score was 86.2 (84.7 in the adolescent cohort and 90.0 in the adult cohort).

Most of the patients had failed treatment with topical therapies before enrolment: 99 (97.1%) had used high-potency topical corticosteroids, 24 (33.3%) had been treated with topical immunotherapy, 29 (28.4%) with intralesional triamcinolone acetonide, and 15 (14.7%) with anthralin. As for systemic treatments, 68 patients (66.7%) had received systemic corticosteroids, 12 (11.8%) cyclosporin A, six (5.9%) previous JAK inhibitors, and four (3.9%) methotrexate. Familial occurrence of AA was observed in 22 patients (21.6%). Associated comorbidities are included in Table S1 (see the electronic supplementary material).

3.2 Improvement in SALT Score

Addressing the primary endpoint of this study, 40.2% of patients (41/102) achieved SALT ≤ 20 at T24w. Subdivided by age, this endpoint was reached by 48.6% of adolescents (34/70) and 21.9% of adults (7/32). Responder rates between adolescents and adults were compared using chi-square or Fisher's exact tests as appropriate. There was no significant difference in responder rates at T4w ($p = 0.75$) or T12w ($p = 0.61$). However, at T24w, adolescents demonstrated a significantly higher responder rate compared with adults (48.7 vs 29.2%, $\chi^2 = 4.01$, $p = 0.045$).

Concerning the secondary endpoints, 31.4% of patients (32/102) achieved SALT ≤ 10 by week 24. Subdivided by age, this endpoint was reached by 38.6% of adolescents (27/70) and 15.6% of adults (5/32) (Table 1).

The SALT score decreased from an average of 86.2 ± 18.5 at T0 to 81.4 ± 21.9 at T4w, 58.3 ± 33.9 at T12w, and 40.8 ± 37.1 at T24w, showing a statistically significant difference ($p < 0.001$). A statistically significant mean reduction of the SALT score at week 24 of treatment was observed both in patients with severe AA (68.8 at T0 vs 21.9 at T24w, $p < 0.001$) and in those with very severe AA (100.0 at T0 vs 56.3 at T24w, $p < 0.001$) (Table S2, see the electronic supplementary material). In patients previously treated with JAK inhibitors, the mean SALT score decreased from 86.4 at T0 to 53.5 at T24w.

In the subgroup of patients with SALT ≤ 20 at T24w, autoimmune comorbidities were reported in 16 patients (39.0%); in particular, thyroid disease was identified in six individuals (14.6%), atopy in nine (22.0%), and celiac disease in one (2.4%), whereas no cases of gastritis were detected. Among the 61 patients with SALT > 20, 22 individuals (36.1%) presented with at least one autoimmune comorbidity, including ten cases of thyroid disease, 12 of atopy, three of celiac disease, and two of gastritis.

3.3 Trichoscopic Evaluation

Trichoscopic signs observed throughout the study showed notable changes through time. The presence of yellow dots gradually declined from 94 patients (92.2%) at T0 to 68 patients (66.7%) at T24w. Black dots initially increased from 45 (44.1%) at T0 to 53 (52.0%) at T4w, before decreasing to 31 (30.4%) at T24w. Similarly, dystrophic hairs showed a progressive reduction, from 25 patients (24.5%) at T0 to 13 (12.7%) at T24w. Exclamation mark hairs also decreased over time, from 29 patients (28.4%) at T0 to 17 (16.7%) at T24w. In contrast, regrowing hairs, indicative of the disease regrowth phase, increased markedly during the study period, rising from

Table 1 Proportions achieving SALT ≤ 20 and SALT ≤ 10 by time point and age group

	SALT ≤ 20			SALT ≤ 10		
	Overall cohort[a] *n* (%)	Adolescent cohort[b] *n* (%)	Adult cohort[c] *n* (%)	Overall cohort[a] *n* (%)	Adolescent cohort[b] *n* (%)	Adult cohort[c] *n* (%)
T0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
T4w	2 (2.0%)	2 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
T12w	19 (18.6%)	17 (24.3%)	2 (6.3%)	12 (11.8%)	11 (15.7%)	1 (3.1%)
T24w	41 (40.2%)	34 (48.6%)	7 (21.9%)	32 (31.4%)	27 (38.6%)	5 (15.6%)

SALT Severity of Alopecia Tool, *T0* baseline, *T4w* after 4 weeks, *T12w* after 12 weeks, *T24w* after 24 weeks

[a] $N = 102$

[b] $N = 70$

[c] $N = 32$

14 patients (13.7%) at T0 to 86 patients (84.3%) at T24w (Table 2).

3.4 Quality of Life and Psychological Outcomes

Quality of life progressively improved throughout the study period. Skindex-16 mean score decreased from 48.4 ± 23.2 at T0 to 30.9 ± 20.0 at T24w, while the CDLQI mean value showed a consistent improvement, decreasing from 11.5 ± 6.7 at T0 to 5.4 ± 5.0 at T24w. Similarly, HADS scores showed a gradual reduction: mean depression scores decreased from 5.4 ± 4.6 to 3.4 ± 3.8, while anxiety scores decreased from 6.0 ± 3.8 to 4.5 ± 3.7 (Table S3, see the electronic supplementary material). The *t* test showed a statistically significant improvement in all items ($p < 0.001$) at T24w.

3.5 Eyebrow, Eyelash, and Nail Evaluation

Ritlecitinib treatment was also able to induce eyebrow and eyelash regrowth (Fig. 1 and Figs. S2 and S3 in the electronic supplementary material). The ClinRO EB score significantly decreased from a mean value of 1.9 ± 1.3 ($n = 89$) at T0 to 0.7 ± 1.0 ($n = 87$) at T24w ($p < 0.001$). Similarly, the ClinRO EL score decreased from 1.7 ± 1.3 ($n = 89$) to 0.7 ± 1.0 ($n = 87$) ($p < 0.001$). The ClinRO Nail Appearance score showed a statistically significant reduction ($p = 0.006$), from 0.3 ± 0.7 ($n = 72$) at baseline to 0.1 ± 0.4 ($n = 72$) at T24w. It should also be noted that nail involvement at T0 (ClinRO Nail Appearance 1–3) was present in only 14 patients. Performing an analysis in this subgroup, the mean ClinRO Nail Appearance score of 1.6 ± 0.8 at T0 dropped to 0.6 ± 0.8 at T24w ($p = 0.002$).

3.6 Laboratory Findings and Adverse Events

Laboratory evaluations during treatment revealed no major safety concerns (Table S4, see the electronic supplementary material). The most frequent laboratory abnormalities were hypertriglyceridaemia (6.9% at T12w) and hypercholesterolaemia (4.9% at T12w), followed by transient mild neutropenia (2.0% at T12w) and mild increases in creatine phosphokinase (CPK) (1.0% at T4w and T12w) or transaminases (2.0% at T12w), generally improving or stabilizing over time.

No significant increase in creatinine or gamma-GT levels was observed throughout the study. Anaemia was reported in two patients at T4w, two at T12w, and four at T24w. All cases were mild (haemoglobin > 11 g/dL), except for one patient at T24w, who experienced a decrease in haemoglobin, to 9.60 g/dL, leading to permanent treatment discontinuation.

AEs were mild, with no serious treatment-related complications reported during the study (Table 3). The

Table 2 Trichoscopic evaluation ($N = 102$)

	Yellow dots *n* (%)	Black dots *n* (%)	Dystrophic hairs *n* (%)	Exclamation mark hairs *n* (%)	Regrowing hairs *n* (%)
T0	94 (92.2%)	45 (44.1%)	25 (24.5%)	29 (28.4%)	14 (13.7%)
T4w	92 (90.2%)	53 (52.0%)	17 (16.7%)	21 (20.6%)	40 (39.2%)
T12w	89 (87.3%)	47 (46.0%)	16 (15.7%)	18 (17.6%)	84 (82.4%)
T24w	68 (66.7%)	31 (30.4%)	13 (12.7 %)	17 (16.7%)	86 (84.3%)

T0 baseline, *T4w* after 4 weeks, *T12w* after 12 weeks, *T24w* after 24 weeks

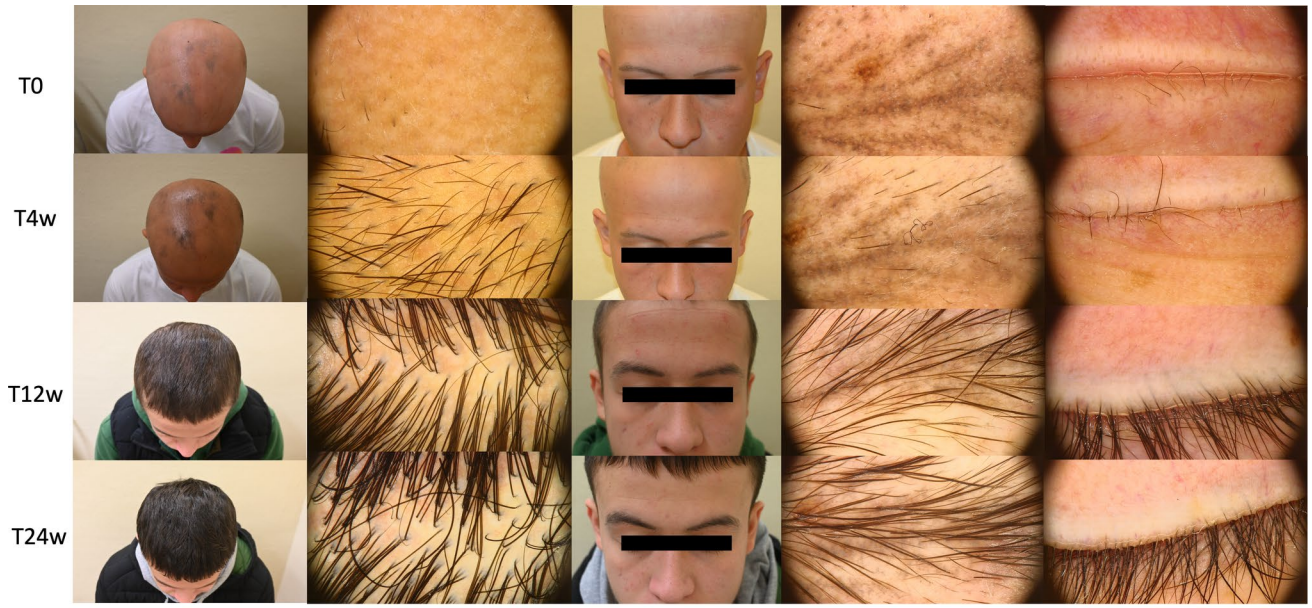

Fig. 1 Sixteen-year-old patient at T0, T4w, T12w, and T24w. Clinical picture (scalp and eyebrows) and trichoscopic evaluation with ×20 magnification (scalp, eyebrows, and eyelashes). The Severity of Alopecia Tool score decreased from 90 to 0, and trichoscopic evaluation showed a reduction in yellow dots, black dots, and exclamation mark hairs, with an increase in regrowing hair. *T0* baseline, *T4w* after 4 weeks, *T12w* after 12 weeks, *T24w* after 24 weeks

most frequent AEs were acne (4.9% at T12w and T24w), headache (3.9% at T4w), upper respiratory tract infections (2.9% at T4w), constipation (2.0% at T4w), fatigue (2.0% at T4w and T12w), and labial herpes simplex (2.0% at T12w). Isolated events such as nausea, fever, aphthoid lesions, vaginal candidiasis, and cystitis were also observed with low frequency. They were all managed by the patient's general physician. No cases of serious infections, thrombosis, or severe AEs were reported.

3.7 Treatment Discontinuation

No patients discontinued the drug at weeks T4w and T12w. One patient decided to discontinue treatment at T24w due to lack of efficacy (persistent SALT score of 100), and in another case, ritlecitinib was discontinued due to anaemia after the T24w visit, as previously described.

Table 3 Adverse events ($N = 102$)

	T4w	T12w	T24w
Acneiform rash	1	5	5
Aphthoid lesions	0	1	0
Constipation	2	1	1
Cystitis	0	1	0
Fatigue	2	0	2
Fever	1	0	0
Headache	4	1	1
Labial herpes simplex	1	2	1
Nausea	2	1	0
Upper respiratory tract infection	3	2	1
Vaginal candidiasis	0	0	1
Weight gain	1	0	0

T4w after 4 weeks, *T12w* after 12 weeks, *T24w* after 24 weeks

4 Discussion

Our real-world, Italian, multicentre study supports the effectiveness and safety profile of ritlecitinib 50 mg/day in adults and adolescents with severe AA over 24 weeks, supplementing the clinical trial data with information about real-world outcomes [6–9, 24–27].

In our cohort, 40.2% of patients reached SALT ≤ 20 at week 24, with response rates being higher in adolescents (48.6%) compared with adults (21.9%). These results are higher than those reported by King et al. in the ALLEGRO phase 2b/3 trial, where 23% of patients treated with ritlecitinib 50 mg achieved SALT ≤ 20 at T24w [6]. At T0, there were no significant differences between our cohort and ALLEGRO cohort in SALT scores, disease duration, or duration of the current episode [6]. It should be noted that

in our study the proportion of adolescents was much higher than in that of King et al. (69 vs 14%). So, it appears that the response to ritlecitinib is greater in adolescents than in adults. The higher response observed in our adolescent subgroup reflects findings from the Hordinsky et al. sub-analysis [8], in which up to 25% of adolescents reached SALT ≤ 20 at T24w. Similarly, the achievement of SALT < 10 in our cohort was higher (31.4% in the overall cohort, 38.6% in the adolescent cohort, and 15.6% in the adult cohort) than in the study by King et al. [6] (14% in the overall cohort) and in the Hordinsky et al. sub-analysis [8] (13% in the adolescent cohort). This difference may be partly explained by age-related factors, but also, in our cohort, adolescents showed a shorter mean disease duration and a substantially shorter duration of the current episode compared with adults, together with their greater follicular regenerative potential, and possibly better treatment adherence, which could enhance therapeutic outcomes [6, 28]. Furthermore, even patients who had failed previous JAK inhibitor therapy achieved a partial response.

Ritlecitinib demonstrated clinical efficacy in both the severe and very severe AA cohorts, as reflected by a comparable absolute reduction in SALT scores from T0 to T24w (46.9 in patients with baseline SALT 50–95 vs 43.7 in those with SALT ≥ 95). However, patients with severe AA achieved a lower absolute SALT score at T24w compared to those with very severe AA (21.9 vs 56.3).

There were no significant differences between patients who achieved SALT ≤ 20 and > 20 at T24w in terms of the percentage of associated autoimmune comorbidities.

The improvement of trichoscopic features, such as reduction of yellow dots and increase of regrowing hairs, confirms that these parameters may serve as early predictors of treatment response, as already proposed for other JAK inhibitors [4].

Patient-reported outcomes improved significantly. Skindex-16, HADS-A/D, and CDLQI scores all showed a progressive reduction, supporting the psychological and quality-of-life benefits of ritlecitinib, as also reported by Sinclair et al. using the Alopecia Areata Patient Priority Outcomes (AAPPO) instrument [26]. This is particularly relevant in adolescents, who are more vulnerable to the psychosocial burden of AA.

Moreover, the clinical benefit extended to eyebrows, eyelashes, and nails, areas often resistant to therapy and particularly relevant for patients' appearance and psychosocial well-being [8].

From a safety perspective, our data support the favourable profile of ritlecitinib, consistent with previous clinical trials and integrated safety analyses [8, 27]. The absence of severe AEs, together with only one discontinuation due to anaemia, supports its tolerability in real-world practice [9, 24]. Based on the available clinical information and considering the selective JAK3/TEC mechanism of action of ritlecitinib, which is not typically associated with anaemia, we consider this event more likely related to a concomitant condition rather than a direct drug-related effect.

Although promising, our study has some limitations, including its retrospective, uncontrolled design, lack of a control group, and relatively short duration. These aspects may introduce selection bias, as patients were recruited in tertiary centres and eligible for systemic therapy. Furthermore, the high proportion of adolescents may influence the generalizability of our findings.

We are continuing the study with a 52-week follow-up to evaluate long-term responders, analyse their trajectories, and assess whether they align with those reported in the literature. Since 24 weeks represent only a short-term evaluation, longer follow-up is needed to obtain a true picture of effectiveness and safety. Future directions include longer-term follow-up to assess the durability of response, evaluation of treatment discontinuation strategies, and head-to-head comparisons with other JAK inhibitors, such as baricitinib.

5 Conclusion

Our study demonstrated that ritlecitinib 50 mg/day was effective in the treatment of severe AA, particularly among adolescents, demonstrating consistent efficacy confirmed by trichoscopy, good tolerability, psychologically important benefits, and improvements in quality of life. This study provides real-world perspectives to further establish ritlecitinib as a cornerstone of treatment for AA and points to a future of personalized therapies, ultimately improving patient outcomes.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40257-026-01022-5.

Funding Open access funding provided by Alma Mater Studiorum - Università di Bologna within the CRUI-CARE Agreement. None.

Declarations

Conflict of interest Michela Starace reports personal fees for advisory board meetings and support for attending meetings from Almirall, Eli Lilly, Pierre Fabre, and L'Oréal, outside of the submitted work. Giampiero 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. Luigi Gargiulo has been a consultant and/or speaker and has participated on advisory boards for AbbVie, Almirall, Amgen, Bristol-Myers Squibb, Eli Lilly, Johnson & Johnson, LEO Pharma, Novartis, Pierre Fabre, Pfizer, Sanofi, and UCB Pharma. Alessandra Narcisi has served on advisory boards and received honoraria for lectures and research grants from Almirall, AbbVie, LEO Pharma, Celgene, Eli Lilly, Janssen, Novartis, Sanofi Genzyme, Amgen, and Boehringer Ingelheim. Francesca Ambrogio: Eli Lilly, Pfizer, AbbVie, Almirall, Sanofi, and Boehringer Ingelheim. Caterina Foti: Eli Lilly,

AbbVie, Almirall, Sanofi, Novartis, LEO Pharma, Pfizer, and Incyte; support for attending meetings and/or travel; advisory board member. Raffaele Dante Caposiena Caro has received honoraria for participation in speaker bureaus from Novartis, Eli Lilly, Sanofi, and Pfizer. Iris Zalaudek: data safety monitoring board (Philogen); payment or honoraria for lectures, presentations, speaker bureaus, manuscript writing, or educational events (Sanofi Genzyme, Sun Pharma, Novartis, MSD, Bristol-Myers Squibb, Philogen, Biogena, La Roche-Posay, Kyowa Kirin, Fotofinder, Mallinckrodt, Cieffe Derma, Pierre Fabre, Regeneron, Canova, Almirall, Beiersdorf); support for attending meetings and/or travel (Difa Cooper). Angelo Valerio Marzano reports consultancy/advisory board disease-relevant honoraria from AbbVie, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Incyte, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB. Andrea Sechi has received honoraria for speaker bureaus from Novartis, DS Laboratories, Cantabria Labs Difa Cooper, Eli Lilly, Pfizer, and Boehringer Ingelheim. Silvia Mariel Ferrucci: speaker, advisory board member, or principal investigator in clinical trials for AbbVie, Amgen, Almirall, LEO Pharma, Galderma, Novartis, Sanofi, Eli Lilly, Pfizer, Incyte, and Bayer. Laura Diluvio: Eli Lilly, Almirall, Sanofi, and Novartis. Luca Bianchi: AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Janssen, La Roche-Posay, LEO Pharma, Novartis, Pfizer, Pierre Fabre, Sanofi, and UCB. Mariateresa Cantelli: Sifarma, Dercos, Diego Dalla Palma, Eli Lilly, Infomedica, and Pfizer. Valeria Boccaletti: Sanofi, Eli Lilly, and La Roche-Posay. Elisabetta Fulgione has served as consultant and/or has received fees from AbbVie, Eli Lilly, Pfizer, L'Oréal, Shiseido, and Pierre Fabre. Anna Balato has served as consultant and/or has received fees from AbbVie, Amgen, Almirall, Boehringer Ingelheim, Bristol-Myers Squibb, Eli Lilly, Janssen, LEO Pharma, Novartis, Pfizer, Sanofi, and UCB. Federica Dall'Oglio: Eli Lilly and Pfizer (speaker). Giuseppe Micali: Eli Lilly (speaker). Elena Pezzolo: Pfizer, Eli Lilly, AbbVie, Galderma, Sanofi, Almirall, LEO Pharma, Novartis, Janssen, and Boehringer Ingelheim. Francesca Caroppo: LEO Pharma, Sanofi, Almirall, AbbVie, Unifarco, and Pfizer. Anna Belloni Fortina: Sanofi, LEO Pharma, Amgen, Novartis, AbbVie, Eli Lilly, Unifarco, Pfizer, and Almirall. Giacomo Caldarola has received consulting fees, honoraria, and support for attending meetings from AbbVie, Eli Lilly, Pfizer, Janssen, UCB, Novartis, and LEO Pharma, outside of the submitted work. Ketty Peris reports personal fees for advisory board meetings and support for attending meetings from AbbVie, Almirall, Galderma, Eli Lilly, LEO Pharma, Novartis, Pierre Fabre, Sanofi, Sun Pharma, Regeneron, and Janssen, outside of the submitted work. Riccardo Balestri: support for attending meetings and/or travel, advisory board member (Eli Lilly, AbbVie, Amgen, Novartis). Laura Atzori: advisory board, consultant, congress hospitality (AbbVie, Almirall, Amgen, Boehringer Ingelheim, Bristol-Myers Squibb, Johnson & Johnson, LEO Pharma, Novartis, Eli Lilly, Pfizer, Sanofi, UCB). Alfredo Rossi: Pfizer, Eli Lilly, Dercos, and AbbVie. Serena Lembo: Eli Lilly, AbbVie, Amgen, Novartis, Janssen, Almirall, Sanofi, LEO Pharma, and Boehringer Ingelheim; support for attending meetings and/or travel; advisory board member. Annunziata Raimondo: Eli Lilly, AbbVie, Amgen, Novartis, Janssen, Almirall, Sanofi, LEO Pharma, and Boehringer Ingelheim; support for attending meetings and/or travel; advisory board member. Flavia Manzo Margiotta: Eli Lilly, AbbVie, Almirall, Sanofi, LEO Pharma, and Pfizer. Valentina Dini: Eli Lilly, AbbVie, Convatec, Novartis, Janssen, Almirall, Sanofi, LEO Pharma, and UCB. Marco Romanelli: Eli Lilly, AbbVie, Novartis, Janssen, Almirall, Sanofi, LEO Pharma, UCB, and Urgo. Edoardo De Simoni reports speakers' fees from Eli Lilly. Oriana Simonetti: Sanofi, Celldex, MoonLake, Roche, and AbbVie. Francesca Satolli: speaker, advisory board member, or principal investigator in clinical trials for AbbVie, Almirall, LEO Pharma, Johnson & Johnson. Maria Beatrice de Felici del Giudice: Sanofi Regeneron, LEO Pharma, and AbbVie. Cesare Filippeschi: Sanofi and L'Oréal. Teresa Oranges: Abiogen, Novartis, Pfizer, MSD Animal Health, and Alexion. Greta Tronconi: Sanofi. Bianca Maria Piraccini has received consulting fees from Pierre Fabre-Ducray, Difa Cooper, Dercos-L'Oréal, Legacy Healthcare, Pfizer, and Eli Lilly. All the other authors have no relevant financial or non-financial interests to disclose.

Consent for publication Written informed consent for publication of clinical photographs and identifiable information was obtained from patients or their legal guardians, where applicable according to the Declaration of Helsinki principles.

Code availability Not applicable.

Consent to participate Informed consent to participate was obtained from all patients or their legal guardians.

Ethical approval The study adheres to Good Clinical Practice guidelines, AIFA regulations, and the Declaration of Helsinki. In addition, approval has been obtained from the ethics committee (245/2025/OssF/AOUBo).

Data availability statement The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

Author contributions MS, LR, FPampaloni, SC, FQ, FBruni, GMartelli, and BMP conceptualized and designed the study, conducted data collection and analysis, contributed to data interpretation, and wrote the initial draft of the manuscript. All authors conducted data collection, provided critical revisions, and read and approved the final manuscript.

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