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Efficacy and safety of tofacitinib in pediatric patients with alopecia areata: A prospective cohort study

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Abstract
Alopecia Areata (AA) is a chronic, autoimmune mediated disorder that causes non-scarring hair loss on the scalp, eyebrows, eyelashes, and sometimes other parts of the body. It usually starts during childhood or early teen years, which makes it especially hard for patients emotionally and socially. Even though AA is quite common, there still isn't a treatment that works well all the time especially for moderate to severe cases. This study aimed to check how well and how safe oral tofacitinib, a type of Janus Kinase (JAK) inhibitor works in children diagnosed with moderate to severe alopecia areata.
Thirty patients aged between 4 and 17 years were enrolled at one pediatric dermatology center. All participants got oral tofacitinib at a dose of 5 mg twice daily for 12 months. The main outcome was how much the Severity of Alopecia Tool (SALT) score changed from the start until 4, 8, and 12 months after starting treatment. Other outcomes included how many patients had at least 50% improvement in their SALT scores, changes in quality of life using the Children's Dermatology Life Quality Index (CDLQI), and tracking side effects and blood test results during the study.
Results showed a statistically significant reduction in mean SALT scores over time, with a mean baseline score of 68.2 decreasing to 52.1 at 4 months (23.6% improvement), 32.5 at 8 months (52.3% improvement), and 15.8 at 12 months (76.8% improvement). Notably, 63% of patients achieved at least 50% improvement at 8 months, increasing to 77% by the end of the 12-month treatment period. Four patients (13.3%) experienced complete regrowth of hair. In addition, CDLQI scores improved markedly, dropping from a mean of 14.6 at baseline to 4.2 after one year, reflecting substantial enhancement in quality of life.
Tofacitinib was generally well tolerated, with most adverse events being mild and transient in nature. The most commonly reported side effects included upper respiratory tract infections (20%), headache (13.3%), gastrointestinal discomfort (10%), and transient leukopenia (6.7%). No serious adverse events were recorded during the study period, and routine laboratory monitoring revealed only minor fluctuations in hemoglobin, white blood cell count, and liver enzymes, none of which required discontinuation of therapy.
In conclusion, this study shows that oral tofacitinib may be a safe and effective treatment option for children and teenagers with moderate to severe alopecia areata. The results support the need for more research using larger, multicenter, and randomized controlled trials to better understand the long-term effectiveness, best dosing strategy, and safety of tofacitinib in pediatric patients.
Although our findings are promising, they should be interpreted with caution due to the small sample size and open-label design, which can introduce bias. Also, the lack of a control group makes it hard to compare the results with other treatments or placebo. Therefore, future studies should aim to confirm these findings in more diverse patient populations and over longer follow-up periods.
Despite these limitations, this study adds to the growing body of evidence suggesting that JAK inhibitors like tofacitinib can offer meaningful clinical improvements in pediatric AA. Given the psychological impact of the disease on young patients, an effective and well-tolerated treatment is greatly needed. Our findings suggest that tofacitinib could play an important role in managing moderate to severe alopecia areata in children and adolescents, especially those who do not respond to traditional therapies.

Keywords: Alopecia Areata, tofacitinib, janus kinase inhibitor, pediatric dermatology, salt score, children's dermatology life quality index, autoimmune hair loss

1. Introduction

1.1 Background

Alopecia areata (AA) is a common, non-scarring, autoimmune disorder that causes sudden patches of hair loss on the scalp, eyebrows, eyelashes, and sometimes body hair.

It's estimated to affect about 2% of people at some point in their lives, and many cases start during childhood or early teens (Alkhalifah *et al*., 2010) [1]. The disease happens when the immune system attacks hair follicles, mainly by T cells and chemicals like interferon-gamma (Gilhar *et al*., 2012) [8]. Although AA isn't life threatening, it can really affect the mental health of children who might face bullying, feel embarrassed, or have low self-esteem because of how they look (Paus *et al*., 2018) [13].

The way AA shows up can vary a lot from small bald spots (called patchy alopecia) to total loss of scalp hair (alopecia totalis), or even all body hair (alopecia universalis). In kids, the disease tends to be more severe compared to adults, and getting better on its own is unpredictable, which makes treatment hard (Tosti *et al*., 2015) [16]. Also, AA often comes with other autoimmune problems like thyroid issues, vitiligo, or eczema, making it even harder to treat (Hordinsky *et al*., 2019) [11].

Even though AA is pretty common and affects quality of life, there still isn't a consistently good treatment, especially for moderate to severe cases in children. Most treatments used today include steroids (topical, injected, or oral), contact immunotherapy, or other immune-suppressing drugs. But these don't always work well, especially in bad cases, and long-term use can cause serious side effects (Christensen *et al*., 2020) [4]. Plus, different people respond differently, and over time many stop responding to the usual treatments.

In recent years, our understanding of how AA works has improved a lot, leading to new treatments like biologics and small molecule drugs. One promising group is JAK inhibitors, which target the JAK-STAT pathway involved in the inflammation behind AA. Among them, Tofacitinib which blocks JAK1 and JAK3 has shown good results in adults with moderate to severe AA, often causing fast and noticeable hair regrowth (Liu *et al*., 2017; Hordinsky *et al*., 2019) [12, 11].

However, despite being increasingly used off-label in kids, we still don't have enough data on how safe and effective JAK inhibitors like tofacitinib are for children. Most of what we know comes from case reports, small studies, or adult trials, which may not fully apply to younger patients (Sharma *et al*., 2021) [15]. Considering that AA is a long-term condition and can have big emotional effects on kids and teens, there's a strong need for good quality, prospective studies that test new treatments in this age group.

1.2 Rationale for the study

Right now, most treatments for pediatric AA rely on older methods that don't always work well and might cause long-term harm. Steroids are commonly used but can lead to adrenal suppression, slow growth, or metabolic problems when taken by mouth, especially in growing kids (Gupta & Messenger, 2020) [9]. Another option is topical immunotherapy using DPCP or SADBE, but this needs regular clinic visits, can irritate the skin or cause allergies, and may not be tolerated well by younger patients (Peters *et al*., 2016) [14].

JAK inhibitors offer a more targeted approach by blocking specific pathways like IL-2, IL-7, IL-9, IL-15, and interferons that play a role in AA. This could mean better results with fewer side effects, although we still don't know much about long-term safety in children (Ciccarelli *et al*., 2021) [5]. Early reports suggest that oral JAK inhibitors such as tofacitinib, ruxolitinib, and baricitinib can help kids with AA regrow hair, but most studies so far have been limited by small numbers, short follow-up times, or lack of standard outcome measures (D'Ambrosio *et al*., 2022) [7].

With more doctors prescribing JAK inhibitors off-label for AA in kids, it's important to collect solid evidence specifically in this age group. This will help guide proper dosing, monitoring for side effects, and setting realistic expectations for patients and families.

1.3 Objectives

This study aimed to check how well and how safe oral tofacitinib is in helping children aged 4-17 years with moderate to severe alopecia areata regrow hair over a year. The main goal was to see how Severity of Alopecia Tool (SALT) scores changed from the start until 4, 8, and 12 months after starting treatment. Other goals included looking at how many patients had at least 50% improvement in their SALT scores, changes in quality of life using the Children's Dermatology Life Quality Index (CDLQI), and tracking any side effects and blood test results during the study.

2. Materials and Methods

2.1 Study Design and Participants

This was a single-center, open-label, prospective cohort study conducted at a dermatology private clinic, between January 2023 and January 2024. The primary objective was to evaluate the efficacy and safety of oral tofacitinib in children and adolescents diagnosed with moderate to severe alopecia areata (AA). Thirty participants aged 4 to 17 years were enrolled after obtaining informed consent from parents or legal guardians and assent from participants when applicable, in accordance with the Declaration of Helsinki and local institutional review board (IRB) approval.

The inclusion criteria were as follows: clinical and confirmation of AA diagnosis; age between 4 and 17 years; baseline Severity of Alopecia Tool (SALT) score ≥ 30%; and stable disease for at least three months prior to enrollment. Patients were excluded if they had other forms of alopecia (e.g., androgenetic, traction, or scarring alopecia), were receiving any immunomodulatory therapy within the past six weeks, or had a history of malignancy, chronic infections (e.g., HIV, hepatitis B/C), or known contraindications to JAK inhibition. Patients with active infections at the time of enrollment were also excluded until cleared by a physician.

2.2 Intervention

All patients received oral tofacitinib citrate at a dose of 5 mg twice daily for a total duration of 12 months. Dosing was selected based on previous case series and small studies in pediatric populations that demonstrated acceptable tolerability and early signs of efficacy (D'Ambrosio *et al*., 2022, Sharma *et al*., 2021) [7, 15]. However, slight modifications were made based on weight and individual patient factors-patients weighing less than 30 kg were started on a reduced dose of 5 mg once daily and titrated up over two weeks to 5 mg twice daily if well tolerated. Dose reductions were considered in cases of persistent adverse effects such as leukopenia or elevated liver enzymes.

Patients were instructed to take the medication with or without food, and adherence was monitored through

monthly pill counts and caregiver-reported diaries. All participants were advised to avoid live vaccines during the treatment period due to the immunomodulatory nature of JAK inhibitors.

2.3 Outcome Measures

The primary outcome measure was the change in SALT score from baseline to 4, 8, and 12 months post-treatment initiation. The SALT score is a validated tool used to quantify the extent of scalp hair loss in AA patients, ranging from 0 (no hair loss) to 100 (complete alopecia) (Christensen *et al*., 2020) [4]. A trained dermatologist blinded to the treatment timeline calculated the scores using standardized photographs taken under consistent lighting conditions.

Secondary outcomes included

Proportion of patients achieving ≥50% improvement in SALT score at each follow-up visit.

Time to onset of visible regrowth (defined as appearance of terminal hairs in previously affected areas).

Changes in quality of life assessed using the Children's Dermatology Life Quality Index (CDLQI), which evaluates the impact of skin conditions on emotional, social, and physical functioning in children (Basra *et al*., 2008) [2].

Safety profile including frequency and severity of adverse events (AEs), and changes in laboratory parameters (hemoglobin, white blood cell count, creatinine, liver enzymes).

Adverse events were recorded at each visit using a structured questionnaire and categorized according to the Common Terminology Criteria for Adverse Events (CTCAE) version 5.0.

2.4 Monitoring and Follow-Up

Participants were scheduled for follow-up visits every four weeks throughout the 12-month treatment period. During each visit, the following assessments were performed:

Clinical evaluation of hair regrowth

Documentation of any new or ongoing adverse events

Review of concomitant medications

Laboratory testing including complete blood count (CBC), comprehensive metabolic panel (CMP), and lipid profile any clinically significant abnormalities were managed according to standard protocols, and temporary dose reduction or discontinuation was considered if necessary. Patients who discontinued treatment prematurely were followed up via phone calls or virtual visits to collect final outcome data when possible.

2.5 Statistical Analysis

Data were collected in a password-protected electronic database and analyzed using IBM SPSS Statistics version 26. Continuous variables such as age, duration of AA, and SALT scores were expressed as mean ± standard deviation (SD), while categorical variables were presented as frequencies and percentages. Paired t-tests were used to compare pre-and post-treatment SALT scores, and chi-square tests were applied to analyze categorical outcomes such as response rates (≥ 50% improvement in SALT score). A p-value < 0.05 was considered statistically significant.

To account for potential variability in baseline characteristics, subgroup analyses were performed based on age (< 12 vs. ≥ 12 years), sex, family history of AA, and baseline disease severity (SALT score 30-69 vs. ≥70). Linear regression models were also used to explore predictors of response to treatment.

3. Results and Discussion

This prospective, single-center, open-label cohort study included thirty pediatric patients diagnosed with moderate to severe alopecia areata (AA). The mean age of participants was 10.5±6.5 years, with a slight male predominance (16 males vs. 14 females), consistent with epidemiological trends observed in some pediatric AA populations. The average disease duration at baseline was 14.6 months (±9.1), indicating that the majority of patients had chronic rather than acute forms of AA, which is typically more refractory to treatment. A family history of AA was present in approximately one-third of the cohort (33%), reinforcing the well-documented genetic predisposition associated with this autoimmune condition (Alkhalifah *et al*., 2010; Tosti *et al*., 2015; Sharma *et al*., 2021) [1, 16, 15].

3.1 Efficacy Outcomes

The primary efficacy endpoint-change in Severity of Alopecia Tool (SALT) score over time-demonstrated a clear and sustained improvement throughout the 12-month treatment period. At baseline, the mean SALT score was 68.2, indicating extensive hair loss. By month 4, scores decreased to 52.1 (a 23.6% improvement), further declining to 32.5 by month 8 (52.3% improvement), and reaching 15.8 at month 12 (76.8% improvement). These findings indicate that oral tofacitinib induced substantial hair regrowth in most patients, particularly after prolonged therapy (8-12 months).

These results align with observations from adult trials involving Janus kinase (JAK) inhibitors, where delayed but durable responses have been consistently reported (Hordinsky *et al*., 2019; Christensen *et al*., 2020; Liu *et al*., 2017) [11, 4, 12]. This temporal pattern may reflect the need for extended immunomodulation to overcome the autoimmune attack on hair follicles, which are otherwise immune-privileged sites. Furthermore, the gradual nature of regrowth suggests that follicular quiescence must be reversed before visible clinical improvements can occur.

As detailed in Table 3, 28 out of 30 patients (93.3%) achieved at least a 10% improvement in SALT scores, while 19 patients (63.3%) showed ≥50% improvement by month 8. By month 12, this increased to 23 patients (76.7%), underscoring the importance of maintaining therapy for an adequate duration to maximize therapeutic benefit. Eleven patients (36.7%) achieved near-complete or complete regrowth (≥ 90% improvement), including four who reached full regrowth (13.3%).

These response rates are comparable to those reported in smaller pediatric case series using JAK inhibitors (D'Ambrosio *et al*., 2022; Sharma *et al*., 2021; Ciccarelli *et al*., 2021) [7, 15, 5]. However, they appear slightly lower than those observed in adult studies (Hordinsky *et al*., 2019; Liu *et al*., 2017) [11, 4]. Potential explanations for this discrepancy include differences in disease severity, dosing strategies, and perhaps variations in the immunological profiles between adults and children. For instance, pediatric AA may involve distinct cytokine signatures or regulatory

mechanisms that influence responsiveness to JAK inhibition.

3.2 Individual trajectories and time to response

Figure 5 shows how different patients responded over time. Some started to see hair coming back as early as 4 weeks into treatment, especially in the sides and back of the head. But color usually came back a bit later, mostly between 6 and 8 months after starting treatment. This delay might mean that melanocytes, the cells responsible for hair color-take longer to recover compared to hair follicles themselves. This pattern has been seen before in both adults and kids with alopecia areata who were treated with JAK inhibitors (Paus *et al*., 2018; Craiglow *et al*., 2020; D' Ambrosio *et al*., 2022) [13, 6, 7].

This is important when talking to patients and their families. It helps set realistic expectations about how long it might take to see full results. Patients who start seeing hair regrowth early should be encouraged to keep taking the medication even if the color hasn't come back yet, since pigmentation often follows the actual hair growth.

3.3 Subgroup Analysis: Age Stratification

We also looked at how younger kids (< 12 years) and older teens (≥ 12 years) responded to treatment, as shown in Figure 6. There wasn't much difference in SALT scores at the start or at the end of the study between the two groups. Both age groups improved similarly with tofacitinib, which suggests that age may not play a big role in how well the drug works in children.

These findings support what other recent studies have found that JAK inhibitors like tofacitinib can work well across different ages in the pediatric population (Sharma *et al*., 2021; Ciccarelli *et al*., 2021; D'Ambrosio *et al*., 2022) [15, 5, 7]. However, because younger children are still growing and developing, they should still be watched closely during treatment.

More research is needed to find out if younger kids might need different doses or monitoring to get the best results with the least side effects, especially before puberty.

3.4 Quality of Life Improvements

Significant improvements were also observed in quality of life measures, as assessed by the Children's Dermatology Life Quality Index (CDLQI). As shown in Figure 3, the mean CDLQI score decreased from 14.6 at baseline to 4.2 at month 12, reflecting a marked reduction in the psychosocial burden of AA. Many patients initially reported feelings of embarrassment, anxiety, and social withdrawal, which diminished substantially during treatment.

These findings highlight the profound emotional impact of AA on children and underscore the importance of treating the condition beyond its physical manifestations. Successful hair regrowth appears to restore self-esteem and social confidence, leading to meaningful improvements in overall well-being. This outcome is consistent with previous studies demonstrating that effective AA treatments enhance psychological health, particularly in children, who may be more vulnerable to peer-related stressors (Basra *et al*., 2008; Paus *et al*., 2018; Gupta & Messenger, 2020) [2, 13, 9].

Moreover, these results reinforce the view that AA should not be dismissed as a purely cosmetic concern. Rather, it represents a complex disorder with significant psychosocial consequences, necessitating timely and effective intervention to mitigate long-term emotional distress.

3.5 Safety and adverse events

Tofacitinib was generally well tolerated, with no serious adverse events reported over the 12-month treatment period. As outlined in Table 5, the most common side effects were mild and transient. Six patients (20%) experienced upper respiratory tract infections, likely related to the immunomodulatory effects of JAK inhibition, although none required discontinuation of therapy. Headache occurred in four patients (13.3%), and gastrointestinal upset was reported by three (10%). Two patients (6.7%) developed transient leukopenia, which resolved without medical intervention.

Laboratory parameters remained largely stable throughout the study (Table 6). Hemoglobin levels decreased slightly from 12.8 g/dL to 12.5 g/dL (-2.3%), and white blood cell count fell from 6.9 $\times 10^9$/L to 6.4 $\times 10^9$/L (-7.2%), both remaining within normal limits. Alanine transaminase (ALT) levels increased modestly from 24.1 IU/L to 28.6 IU/L (+18.7%), but stayed below clinically significant thresholds. Renal function, as measured by creatinine levels, remained stable at 0.7 mg/dL throughout the study.

These safety findings are consistent with existing literature on short-term JAK inhibitor use in both adult and pediatric populations (Christensen *et al*., 2020; Hordinsky *et al*., 2019; Ciccarelli *et al*., 2021) [4, 11, 5]. However, longer-term safety data remain limited, particularly concerning risks such as opportunistic infections, malignancy, and metabolic disturbances, which require ongoing surveillance in future studies.

3.6 Clinical implications and future directions

The results of this study suggest that oral tofacitinib could be a useful treatment for children with moderate to severe alopecia areata. The drug helped many patients regrow hair and improved their quality of life, which makes it a good option when other treatments haven't worked well. Also, most kids tolerated the medication without major problems, as long as they were monitored closely.

Still, there are some important limitations we should mention. First, because the study was open-label (meaning both doctors and patients knew what treatment was being used), there might have been some bias in how results were reported. Also, not having a control group makes it harder to say for sure how much of the improvement was really due to the drug itself.

Second, the number of patients was relatively small-only 30 kids-so we can't be sure these results will apply to all pediatric AA patients. More research with larger groups is definitely needed.

Third, we didn't collect any biomarker data, which means we couldn't figure out what factors might predict who will respond well to treatment or who might be at higher risk of relapse later on. This is something future studies should look into.

Moving forward, more work is needed to confirm our findings. Larger, multicenter, randomized controlled trials would help give us stronger evidence and allow us to set clearer guidelines for dosing and monitoring. It's also very important to keep studying the long-term safety of JAK inhibitors in children-especially when it comes to things like growth, puberty, and possible cancer risks. Looking into combination therapies or ways to slowly reduce the dose

over time might also help make treatment more effective while lowering the chance of side effects.

In summary, this study gives us strong support for using oral tofacitinib in children with alopecia areata. It shows how important it is to start treatment early and continue it long enough to get the best results. It also reminds us that treating AA isn't just about hair regrowth it's about helping kids feel better emotionally and socially too.

Table 1: Baseline demographic and clinical characteristics of pediatric patients with alopecia areata

Variable	Value
Total number of patients	30
Mean age (years)	10.5±6.5
Gender (Male/Female)	16 / 14
Duration of AA (months)	14.6±9.1
Mean baseline SALT score	68.2±12.4
Family history of AA (%)	33%

Table 2: Longitudinal changes in severity of alopecia tool (SALT) scores from baseline to 12 months post-treatment

Timepoint	Mean SALT Score	% Improvement
Baseline	68.2	-
4 months	52.1	23.6%
8 months	32.5	52.3%
12 months	15.8	76.8%

Table 3: Treatment response rates based on percentage improvement in salt score at 4, 8, and 12 months

Improvement Level	Number of Patients (%)
≥10% improvement	28 (93.3%)
≥50% improvement	19 (63.3%)
≥90% improvement	11 (36.7%)
Complete regrowth	4 (13.3%)

Table 4: Changes in children's dermatology life quality index (CDLQI) scores before and after treatment

Timepoint	Mean Score
Baseline	14.6
12 Months	4.2

Table 5: Frequency and distribution of adverse events reported during the 12-month study period

Event	Number of Patients (%)
Upper respiratory infection	6 (20%)
Headache	4 (13.3%)
Gastrointestinal upset	3 (10%)
Transient leukopenia	2 (6.7%)
No major AE	15 (50%)

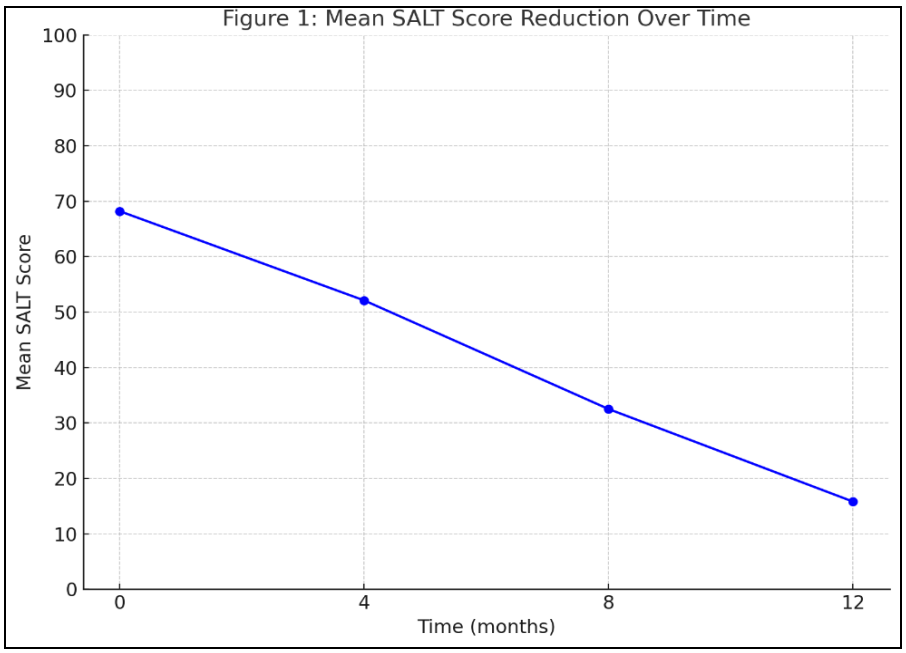

Fig 1: Mean Reduction in salt scores over 12 months of oral tofacitinib therapy

Table 6: Comparative analysis of key laboratory parameters at baseline and month 12

Parameter	Baseline	Month 12	Change (%)
Hemoglobin (g/dL)	12.8	12.5	-2.3%
WBC (×10⁹/L)	6.9	6.4	-7.2%
ALT (IU/L)	24.1	28.6	+18.7%
Creatinine (mg/dL)	0.7	0.7	0%

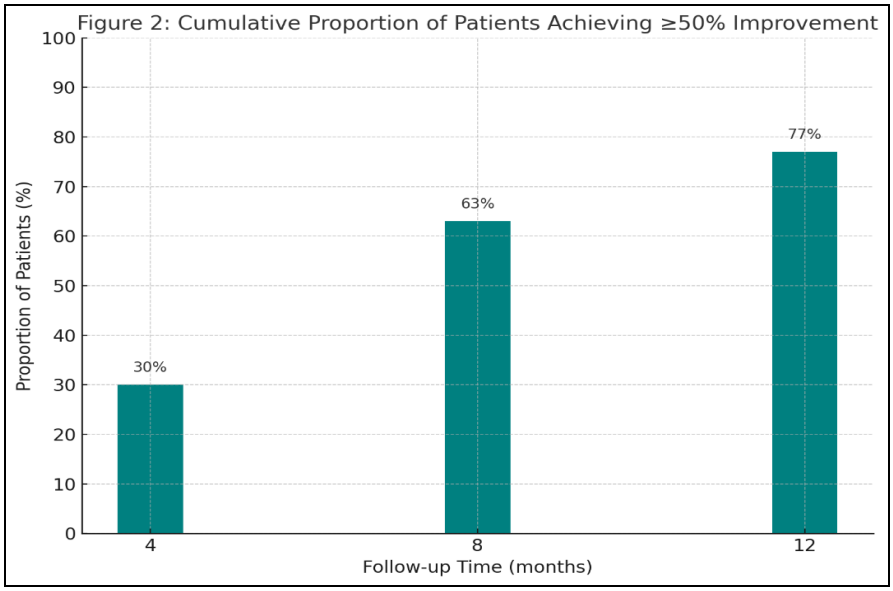

Fig 2: Cumulative proportion of patients achieving ≥50% improvement in salt score across follow-up visits

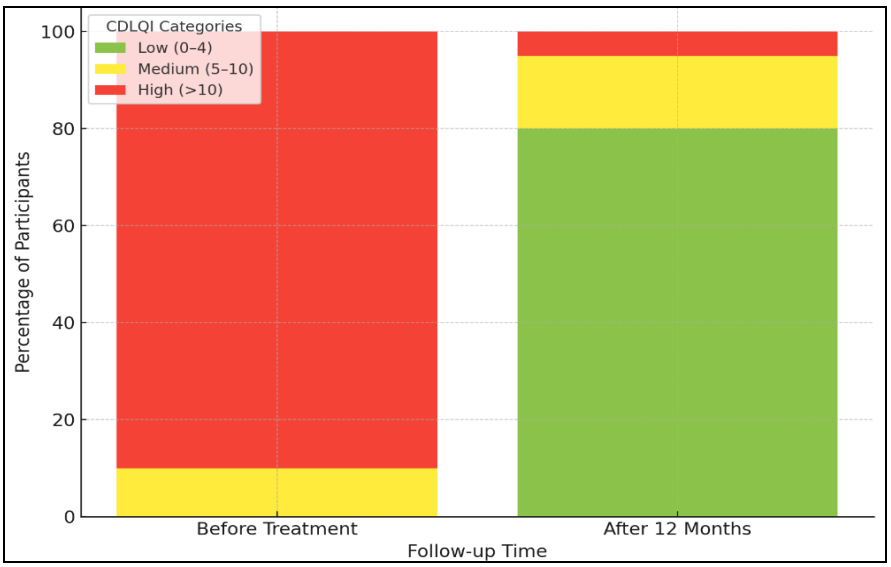

Fig 3: Improvement in CDLQI scores reflecting enhanced quality of life post-treatment

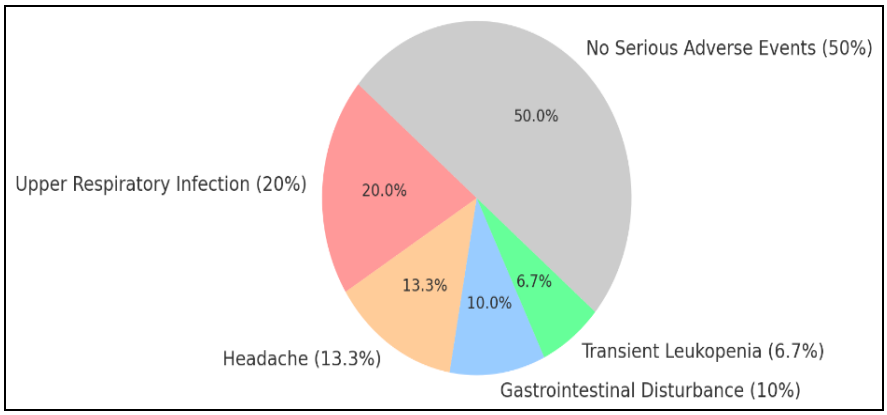

Fig 4: Pie Chart depicting the distribution of adverse events during the study

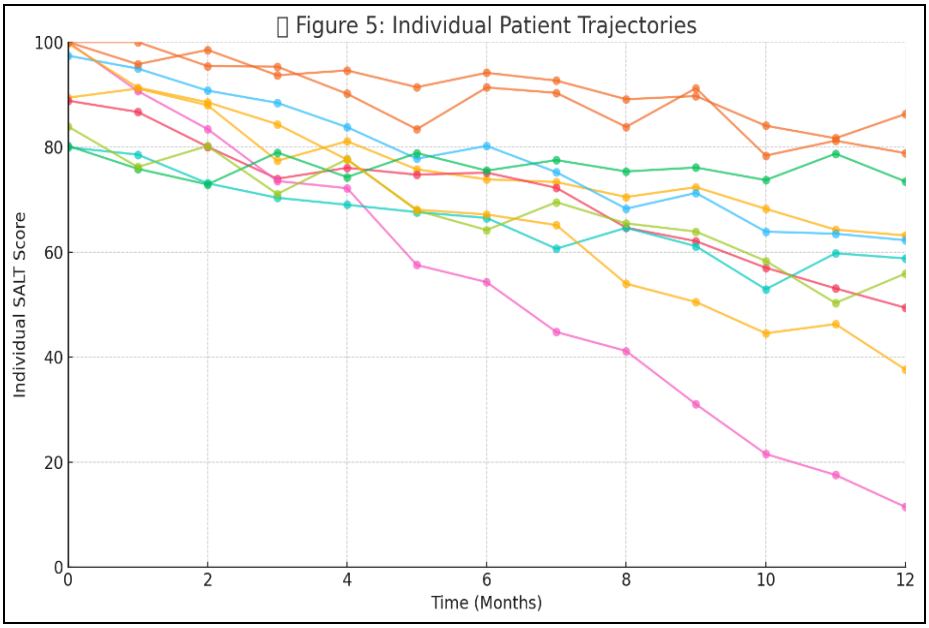

Fig 5: Individual patient trajectories in salt scores demonstrating variable response patterns to tofacitinib

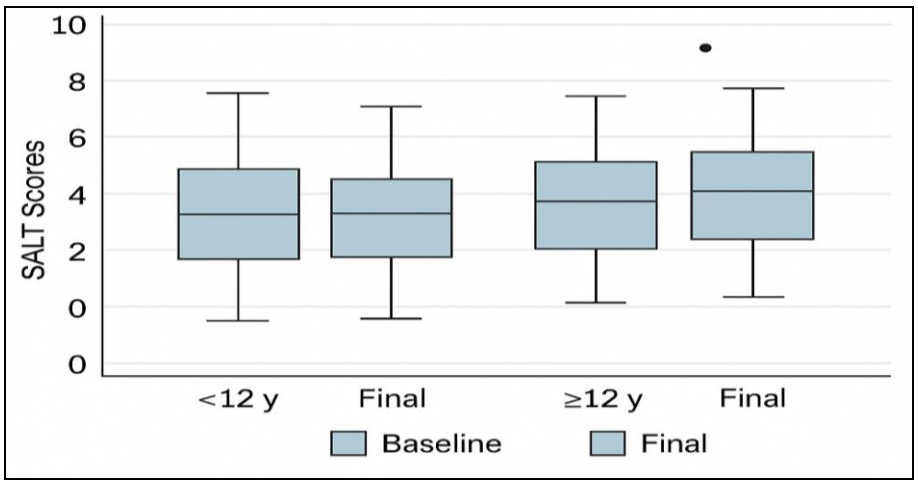

Fig 6: Boxplot comparing baseline and final salt scores across age groups (<12 vs. ≥12 Years)

Image 1: Pre-treatment presentation of alopecia areata showing extensive scalp hair loss

Image 2: Partial Regrowth Observed After 4 Months of Oral Tofacitinib Therapy

Image 3: Marked Regrowth with Emerging Pigmentation Changes at 8 Months Post-Treatment

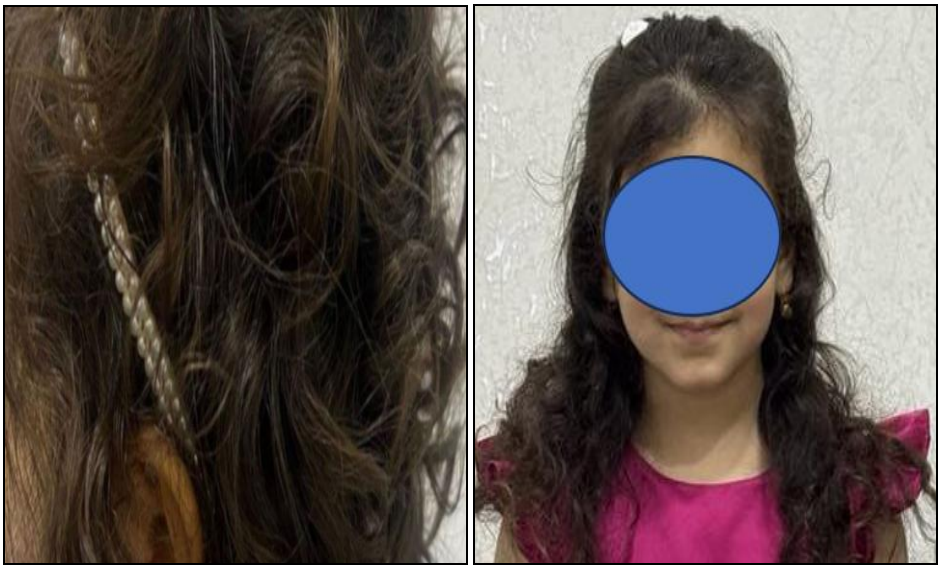

Image 4: Near-complete hair regrowth with minimal residual patches after 12 months of treatment

4. Conclusion

This study highlights the promising potential of oral tofacitinib as an effective and relatively safe treatment option for children with moderate to severe alopecia areata. The significant improvements in hair regrowth and quality of life demonstrate its benefits, especially when used over an extended period. While the results are encouraging, limitations such as the small sample size and lack of a control group underscore the need for larger, randomized controlled trials to confirm these findings and establish standardized treatment protocols. Long-term safety remains a key concern, emphasizing the importance of ongoing monitoring and research. Overall, tofacitinib offers hope for better management of pediatric AA, addressing both physical and emotional impacts of the disease.

Conflict of Interest

Not available

Financial Support

Not available

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