Original Article

Efficacy and safety of tofacitinib in patients with alopecia areata

Shariqa Khan[1], Sumera Hanif [1], Aliza Hamadani [1], Ayesha Arshad Chattha[1], Rabia Shaukat[1], Iram Kausar[1], Fakiha Khan[1], Talat Akbar[1], Kiran Javaid[1], Zaryab Alam[1], Haroon Nabi[1]

[1]Department of Dermatology, Ghurki Trust Teaching Hospital/ Lahore Medical and Dental College, Lahore, Pakistan.

Abstract

Background Alopecia areata (AA) is an autoimmune disorder causing non-scarring hair loss with major quality-of-life impact. Tofacitinib, a Janus kinase inhibitor, has shown promise for AA, though long-term safety, sustained efficacy, and data from South Asian populations remain limited.

Objective To evaluate efficacy, safety, and relapse patterns of oral tofacitinib in alopecia areata.

Methods In this prospective quasi-experimental study, 59 patients aged 12-60 years with ≥30% scalp involvement or alopecia totalis/ universalis, refractory to first-line therapy, received tofacitinib 5 mg twice daily for 24 weeks. Primary endpoint was change in Severity of Alopecia Tool (SALT) score. Secondary endpoints included response rates (≥71% regrowth), safety, and relapse after discontinuation.

Results Mean SALT score improved significantly from 59.98±24.47 to 17.48±26.58 at week 24 (p<.001). Perfect response occurred in 45.1% of patients, good in 21.6%, moderate in 15.7%, weak in 9.8%, and none in 7.8%. Outcomes were best in ages 20-39 years and patchy AA, with 82.6% of perfect responders showing ≥90% regrowth. Adverse events were generally mild (headache 11.9%, upper respiratory infection 10.1%, acne 6.8%). Laboratory abnormalities were rare and reversible. Relapse occurred in 45.7% within 1-2 months, 38.9% within 4-6 months, and 9.6% by 10-12 months after discontinuation.

Conclusion Tofacitinib produced substantial regrowth with acceptable safety in AA patients. However, high relapse rates after withdrawal highlight the need for maintenance strategies. This study provides real-world evidence from an underrepresented South Asian population.

Keywords Alopecia areata; JAK inhibitors; Tofacitinib; Efficacy; Safety.

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Introduction

Alopecia Areata (AA) is a chronic inflammatory T-cell mediated disorder that disrupts hair follicle function culminating in noticeable hair loss.[1] The prevalence increases with increasing age, affecting 0.03% of children, 0.12% of adults and a lifetime prevalence of 0.10% in the general population across the globe.[2] AA is the second most common cause of hair loss,[3] with disease spectrum varying based on onset, disease duration, severity, location, and pattern.[4] The pathophysiology of AA involves a complex interaction between environmental and genetic factors leading to collapse of the hair follicle immune privilege. There is an upregulation of cytokines related to T-helper cells (Th1,Th2,Th17) particularly interferon gamma (IFN-γ) and IL-15 via the Janus kinase signal transducer and activator of transcription (JAK-STAT) signaling pathway.[5,6]

AA has a profound impact on the mental health of patients, emphasizing the need for effective management.[7] Different therapeutic options have been utilized based on the severity of AA. However,

Address for correspondence
Dr. Shariqa Khan, Department of Dermatology,
Ghurki Trust Teaching Hospital /Lahore Medical and Dental College, Lahore, Pakistan.
Ph: 03355075505; Email: shariqaafzalkhan@gmail.com

in cases of extensive AA, therapeutic response is often sub-optimal.[8] Oral and topical Janus Kinase (JAK) inhibitors are target-specific immunosuppressants, that have shown promising outcomes in AA with tofacitinib, a non-selective JAK inhibitor, which blocks the disease progression by modulating cytokines that act through the JAK-STAT pathway and affect IFN-γ gene expression.[9] Tofacitinib, widely used for other autoimmune conditions has demonstrated significant clinical improvement with minimal adverse effects such as increased risk of infection, thromboembolism, deranged lipid profile and liver function tests.[9,10]

Randomized trials have established the efficacy of baricitinib, ritlecitinib, and deuruxolitinib for severe alopecia areata.[11] However, this data largely arose from high-income, controlled settings and does not reflect effectiveness or affordability in routine clinical practice in South Asian population. This study evaluates the therapeutic response, safety, and relapse patterns of oral tofacitinib, widely available and commonly used off-label, in patients with alopecia areata in our setting.

Methods

This Quasi Experimental Study was conducted following approval from the institutional review board (LM&DC/510/2023 dated 13.01.2023). It continued from January 2023 to February 2025, at Outpatient Department of Dermatology, Ghurki Trust Teaching Hospital, Lahore. The sample size was calculated as 59 with a 90% confidence interval, 10% margin of error, and an assumed proportion of 32% of patients showing more than 50% improvement in their SALT score.[12] Data was collected using a detailed proforma including the demographic information, disease duration, sub-type of alopecia, family history, comorbidities and nail changes, through non-probability consecutive sampling. Patients aged 12-60 years of either gender with a current disease episode of more than 6 months were included. Eligible participants had ≥30% scalp hair loss, alopecia totalis (AT) defined as complete scalp hair loss (SALT=100%), or alopecia universalis (AU) defined as complete loss of scalp hair accompanied by complete or near-complete loss of body hair, were able to complete 6 months of treatment and follow-up and had refractory disease defined as failure of one or more first-line therapies (e.g; topical or oral corticosteroids, anthralin, diphenylcyclopropenone (DPCP) or phototherapy). Patients were excluded if they had other hair or scalp disorders such as telogen effluvium, trichotillomania, or tinea capitis, significant cardiovascular or thromboembolic disease, active or chronic infections (including tuberculosis or HIV), neurological, gastrointestinal, malignant, or psychiatric illnesses, systemic conditions causing hair loss such as thyroid, hepatic, renal disorders, or malnutrition. Those treated with anthralin, DPCP, systemic immunomodulators or biologics within 1 month prior to enrollment and oral, topical or intralesional steroids or any other hair growth promoting medications within 2 months before enrollment. Individuals with hypersensitivity to tofacitinib and pregnant or lactating women were also excluded.

Baseline laboratory investigations were performed, which included complete blood count (CBC), fasting lipid profile, liver function tests (LFTs), renal function tests (RFTs), Hepatitis B and C screening, and a QuantiFERON-TB Gold (IGRA) test. Informed consent was obtained from all participants. All subjects were administered oral tofacitinib 5 mg twice daily for 6 months with subsequent monitoring of hair regrowth and side effects. Follow-up evaluations were conducted at 4, 8, 12, 16, 20 and 24 weeks, during which areas of hair loss were photographed. Percentage of hair loss and efficacy were measured using the SALT score. Patients were classified as either perfect responders (SALT score improvement >90%), good responders (71-90%), moderate responders (51-70%), weak responders (25-50%) or non-responders (SALT<25%). The percentage of overall improvement was calculated using the formula: (Baseline SALT score- follow-up SALT score)/ baseline score. Safety was assessed via adverse effects reported spontaneously or through systematic solicitation (standardized

checklist, symptom diary, examination and vital monitoring) and laboratory evaluation at each follow-up visit. The patients were observed for relapse for 24 more weeks. Frequencies and percentages were used for qualitative variables such as gender and age. Mean and standard deviation were calculated for quantitative variables including SALT score and laboratory investigations.

Normality of data was checked using Shapiro-wilk test and after that, Repeated Measures ANOVA were applied to measure the difference in SALT scores while the chi-square test was applied to measure the association between variables considering $p \leq 0.05$ as significant.

Results

Of the 59 enrolled participants, 51 completed the trial; attrition was due to consent withdrawal, loss to follow-up, or discontinuation after an episode of asymptomatic severe hypertension that was effectively managed. The cohort was predominantly young adults (mean age 23.7 years) with a female preponderance (57.6%). Most patients had a total disease duration of 5-10 years (35.6%). Comorbidities were uncommon, nail changes were observed in 40% cases, and 20.3% reported a family history of AA. Detailed demographic and clinical characteristics are summarized in **Table 1**.

Safety assessments are summarized in **Tables 2** and **Table 3**. Laboratory monitoring showed only minor deviations: hemoglobin <11 g/dL in 2 patients (3.4%) (≤1g/dl reduction) that stabilized within 3 months without intervention, transient LFT (ALT/AST) abnormalities in 2(3.4%), and mildly deranged lipid profile in 3(5.1%), which was managed by life style modification and concomitant use of statins without treatment interruption according to the protocol. Renal function (urea/ creatinine) remained stable.

The mean SALT score decreased from 59.98±24.47 at baseline to 17.48±26.58 at week 24 **(Figure 1)**. Multivariate analysis confirmed a strong time effect

Table 1 Socio-demographic and Baseline Characteristics of Study Participants (n=59).

Category	*Frequency*	*Percent (%)*
Age groups (years)		
12-19 years	20	33.9
20-39 years	34	57.6
40- 60 years	5	8.5
Gender		
Male	25	42.4
Female	34	57.6
Marital Status		
Married	19	32.2
Unmarried	40	67.8
Education		
None	13	22.0
Matric	28	47.5
Graduation	16	27.1
Post-graduation	2	3.4
Occupation		
Student	31	52.5
Office worker	12	20.3
Manual worker	9	15.3
Housewife	7	11.9
Current Duration of Disease		
6 months - 2 years	41	69.5
2 - 5 years	18	30.5
Total Duration of Disease		
6 months - 2 years	14	23.7
2 - 5 years	16	27.1
5 - 10 years	21	35.6
>10 years	8	13.6
Nail changes		
No change	35	59.3
Pitting	8	13.6
Ridges	13	22.0
rough cuticle	3	5.1
Comorbidity		
No comorbidity	49	83.05
Vitiligo	1	1.7
Atopic dermatitis	1	1.7
Allergic rhinitis	5	8.5
Celiac disease	1	1.7
Asthma	1	1.7
Rheumatoid arthritis	1	1.7
Family History of Alopecia		
Yes	12	20.3

Table 2 Frequency Distribution of Laboratory Parameters Post-Treatment Assessment (n=59).

Variable	*Category*	*n (%)*
Hemoglobin	less than 11g/dl	2(3.4%)
LFT(ALT/AST)	Mildly deranged	2(3.4%)
Fasting lipid profile(cholesterol)	Mildly deranged	3(5.1%)

Table 3 Adverse Events (n=59).

Adverse Event	*n (%)*
Upper respiratory tract infection	6(10.1%)
Diarrhea	4 (6.8%)
Headache	7 (11.86%)
Fatigue	3 (5.1%)
Abdominal Pain	2 (3.4%)
Pruritus	2 (3.4%)
Cough	5 (8.47%)
Acne	4(6.8%)
Menstrual irregularity	2 (3.4%)
Herpes zoster	1 (1.7%)
Severe Hypertension (B.P≥180/120)	1 (1.7%)
weight gain (≥5%of baseline body weight)	1(1.7%)

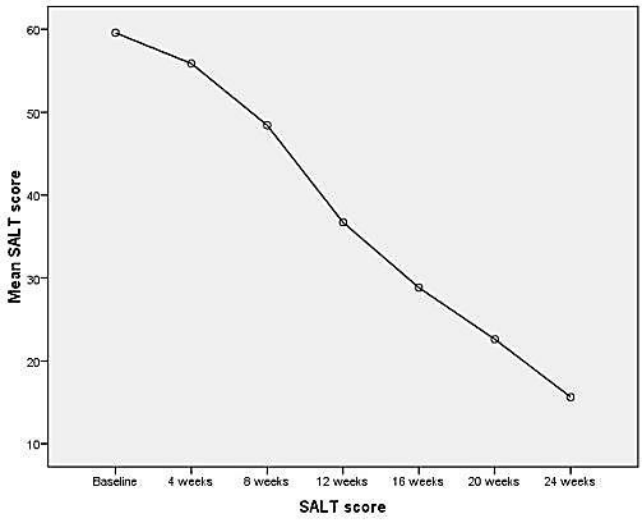

Figure 1 Comparison of SALT score from baseline till 24th week.

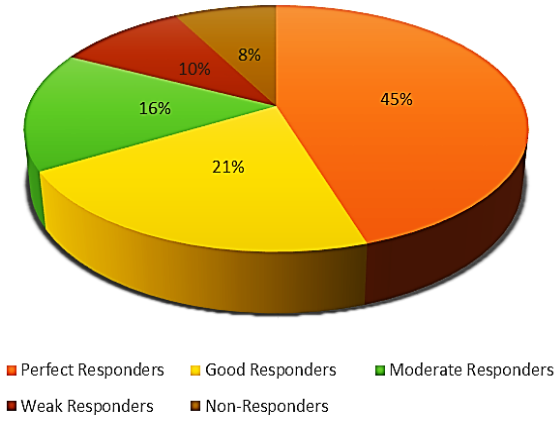

Figure 2 Distribution of efficacy of Tofacitinib.

on SALT score (Pillai's Trace=0.78, p<.001), explaining 78.1% of variance (Partial Eta Squared=0.78). The linear trend was highly significant (p<.001), suggesting consistent improvement. Mean hair regrowth was 75.3%±27.6%, and average time for initial regrowth was 7.92±3.45 weeks ranging from 4 to 20 weeks.

Among the 51 participants who completed the trial, 45.1% were perfect responders, 21.6% good, 15.7% moderate, 9.8% weak, and 7.8% were non-responders **(Figure 2)**. Response was not influenced by age, gender, comorbidity, or nail changes. Disease duration showed a marginal effect, with most perfect responders having a total disease duration of 5-10 years (34.8%) or current duration of 6 months-2 years (30.4%).

Subtype stratification showed the highest response in patchy AA, with 82.6% of perfect responders (≥90% improvement), although this did not reach statistical significance. Among AU cases, 17.4% achieved perfect response (Figures 3 and 4), while AT demonstrated variable outcomes. Rare phenotypes, including ophiasis and inverse ophiasis, were infrequently observed and clustered within specific response categories.

Following discontinuation at 6 months, relapse occurred in 45.7% within 1-2 months, 38.9% within 4-6 months, and 9.6% within 10-12 months.

Discussion

Despite the profound burden, the management of alopecia areata remains challenging due to its unpredictable clinical course.[13] While JAK inhibitors have shifted the treatment paradigm, current real world evidence for tofacitinib remains deficient and limited to retrospective studies. Our study bridges the gap through a prospective, standardized evaluation and longitudinal monitoring in a resource constrained setting. This structured approach yield demographic-specific insights and safety tracking that prior global cohorts frequently lack.

Comparative data from published research by Nasimi *et al*. demonstrated significant clinical improvement post treatment, affirming the efficacy of tofacitinib. However, they found a lower

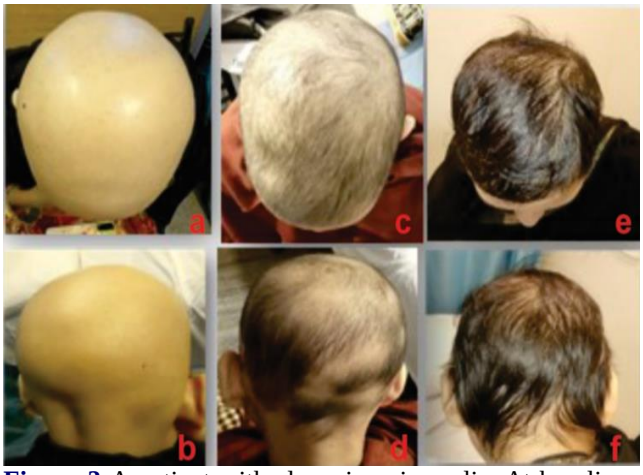

Figure 3 A patient with alopecia universalis. At baseline (a,b), 12 weeks (c,d) and 24 weeks (e,f) post treatment.

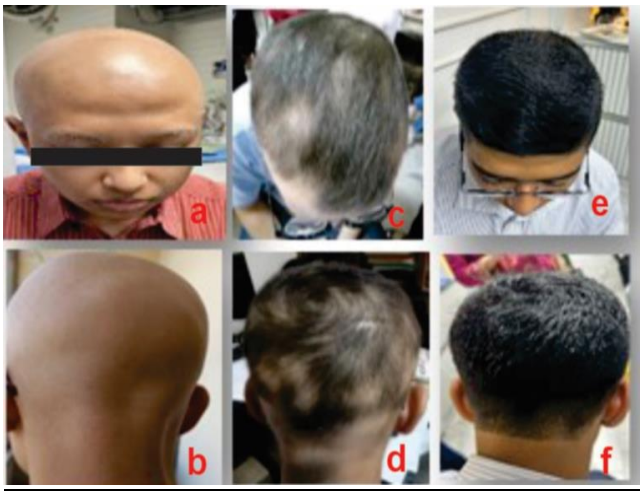

Figure 4 Other patient with alopecia universalis. At baseline (a,b), 12 weeks (c,d) and 24 weeks (e,f) post treatment.

proportion of perfect responders (44.3% vs. 45.1%), and a higher percentage of non-responders (20.6%) compared to our findings (7.8%). Mean SALT score percentage changes (67.74%) aligned with the trends in this study, emphasizing consistent findings across different populations.[14] This study offers compelling evidence of superior therapeutic outcomes relative to previous cohorts. Ibrahim *et al*. reported that hair regrowth rate ranged from 2% to 90% and mean hair regrowth was 44.3%±31.9%,[15] which is substantially lower than our study (75.32±27.60%). Differences in findings may be due to responder definitions, inclusion criteria, follow-up duration, patient demographics, disease chronicity, or variations in drug dosing strategies.

Similar to the findings of Liu *et al*; patients with patchy AA had a higher percentage change in SALT score in the current trial.[16] Chandrashekar *et al*. also found the most favorable therapeutic response in multifocal alopecia areata. Conversely, Alopecia universalis (AU) and Alopecia totalis (AT) displayed the poorest response rates in both cohorts.[17]

Gender based differences in treatment response remain an area of ongoing exploration in AA. In our study, female patients had a slightly higher proportion of perfect responders compared to males (*p*-value of .505). Similar findings were reported by Liu *et al*. but insignificant association was found between gender and SALT score (66.50% vs. 61.00%, p=0.25).[16] This could be due to a higher rate of consultations for hair loss concerns among women.[14]

A meta-analysis documented that use of tofacitinib in early-stage disease reduced the severity and spread of the condition, leading to faster and more sustained hair regrowth.[18] Similar to our findings, another meta-analysis revealed that during the early course of disease, the average time to initial hair growth was 2.2±6.7 months, while the average time to full hair regrowth was 6.7±2.2 months. On the other hand, delayed treatment even with JAK inhibitors lead to more extensive hair loss and a higher remission rate.[19]

Nail abnormalities, although frequently asymptomatic, can be cosmetically disfiguring and associated with reduced quality of life.[20] In our study, their frequency was lower than that reported by Shakoei *et al*.;[21] possibly reflecting a milder disease phenotype or a small sample size. However, no significant association was found with treatment efficacy. These disparities point to the value of standardized assessment of nail abnormalities as prognostic indicators in future research.

The adverse events recorded were mild and reversible in this study parallel to those in existing literature. Acne was less frequent than reported by Chandrashekar *et al*. (7.2%), though our cohort

showed higher rates of infections and menstrual irregularities.[17] However, no severe side effects such as thromboembolism or major adverse cardiovascular events (MACE) were reported, reaffirming the favorable safety profile of tofacitinib.

In our cohort, relapse after withdrawal of tofacitinib was frequent, broadly aligning with prior studies.[22] Earlier relapse was linked to higher baseline SALT scores and extensive disease, while later recurrence occurred in patchy AA and lower scores, indicating the need for long term therapy. Socioeconomic constraints further influenced outcomes, as relapse was largely prevented by continued therapy. Overall, relapse was nearly universal within 6 months, with timing shaped by disease phenotype and treatment accessibility, indicating critical implications for both patient counseling and policy development.

From a global perspective, low-dose tofacitinib emerges as a pragmatic therapeutic option where newer JAK inhibitors (baricitinib, ritlecitinib, deuruxolitinib) remain inaccessible with evidence showing that such dosing strategy can cut the cost by over half without compromising efficacy.[23] Our findings reinforce its value as an effective and comparatively accessible alternative for AA, with important implications for advancing treatment equity in resource-limited settings.

This study had some limitations. Alopecia areata has potential for spontaneous hair regrowth, therefore the clinical efficacy of JAK inhibitors might be overstated. Secondly, the absence of a control group in this study limits the strength of our findings. Furthermore, other areas with hair loss such as, eyelashes, beard, and eyebrows were not included, restricting the possibility of conducting subgroup analyses.

Conclusion

Based on our findings, tofacitinib exhibited both efficacy and a commendable safety profile in the study population. Nevertheless, large scale studies are essential to elucidate optimal treatment period, sustained clinical response, relapse rates, and long-term complications associated with JAK inhibitors. Incorporating clinical predictors, such as duration of illness, severity of scalp involvement, and associated nail abnormalities, may guide treatment stratification and improve patient outcomes. In addition, the inclusion of pediatric population in future research is crucial to establish age specific efficacy and safety benchmarks.

Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

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Conflict of interest No conflict of interest.

Author's contribution

SK,SH: Substantial contribution to study design, acquisition of data and manuscript writing.

AH: Substantial contribution to acquisition of data and critical review of the manuscript.

AAC: Substantial contribution to acquisition of data and manuscript writing.

KJ: Substantial contribution to acquisition of data and manuscript writing.

RS,IK,TA,BR,HN: Substantial contribution to interpretation and analysis of data, critical review of the manuscript.

Every author has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

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