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Original Research Article

Therapeutic potential of oral tofacitinib in alopecia areata: a retrospective study

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ABSTRACT

Background: Alopecia areata (AA), a prevalent autoimmune disorder, poses challenges in management, particularly in severe cases. Recent advancements highlight janus kinase (JAK) inhibitors-tofacitinib demonstrating promise. However, the literature reports conflicting information on its safety profile, especially at higher doses, necessitating a comprehensive evaluation.
Methods: This retrospective analysis investigates the long-term efficacy and safety of oral tofacitinib in AA patients from January 2017 to October 2022. The study included 69 patients diagnosed with patchy multifocal AA (mfAA), alopecia totalis (AT), alopecia universalis (AU) or alopecia sub-totalis (AS). Data analysis incorporated demographic details, treatment history, autoimmune comorbidities, tofacitinib dosages, prior investigations, recurrence rates, and adverse effects. Efficacy was assessed using severity of alopecia tool (SALT) scores, with a grading system for percentage of hair regrowth.
Results: The study comprising of 58% males and 42% females, exhibited varied alopecia types. Treatment response analyzed through percent change in SALT score revealed 46.5% showed very good response to tofacitinib treatment, while 4.3% had excellent response (100% change in SALT score). 44.9% of patients showed no recurrence. Adverse effects were minimal, including acneiform eruptions and upper respiratory tract infections. Pearson correlations revealed age negatively correlated with hair regrowth percentage, suggesting older individuals exhibited lower regrowth responses.
Conclusions: Our findings endorse tofacitinib as a promising therapeutic option for the management of AA, with no serious side effects observed even during longer treatment durations. It can be regarded as the primary choice of treatment modality for moderate to severe forms of AA.

Keywords: Alopecia areata, Oral tofacitinib, Janus kinase inhibitor, Multifocal alopecia areata, Alopecia totalis, Alopecia universalis, Alopecia sub-totalis

INTRODUCTION

Alopecia areata (AA) is an autoimmune disorder causing unpredictable patchy hair loss, affecting individuals of all age and with a lifetime risk of 1.7%.[1] Current medical interventions often prove inadequate, particularly in cases of severe disease.[2] Recent advancements in understanding AA pathogenesis have led to identifying janus kinase (JAK) inhibitors as a promising therapeutic approach. Tofacitinib, a JAK/STAT inhibitor, has demonstrated effectiveness in treating various dermatological conditions, including AA.[3-5]

Studies affirm the promising role of tofacitinib in AA treatment, with evidence supporting its efficacy in murine models and clinical settings.[4,5] Among various JAK inhibitors, tofacitinib has shown the lowest side effects and highest clinical response in resistant AA and alopecia universalis (AU) patients.[6] Notably, the literature reveals conflicting information on the safety profile of tofacitinib, particularly at higher doses.[7,8]

While some studies report increased incidence of severe side effects, others suggest that long-term continuation at lower doses, such as 10 mg/day, is sufficient to prevent recurrence with a lower side-effect profile. Economic considerations and the unknown long-term safety profile pose challenges to the use of tofacitinib, which is currently an off-label drug for AA.[3-5]

This retrospective analysis aims to evaluate the long-term efficacy and safety of oral tofacitinib. Secondary objectives include correlating alopecia areata types, assessing treatment duration, exploring dose adjustments, evaluating treatment success through severity of alopecia tool (SALT) scores, analyzing the adverse effects of tofacitinib usage and changes in laboratory parameters.

METHODS

Study design

This research employs a retrospective analysis approach to evaluate the long-term efficacy and safety of oral tofacitinib in patients with alopecia areata and its variants.

Study population, duration and place

The study includes patients with a clinical diagnosis of multifocal alopecia areata (mfAA), alopecia totalis (AT), AU or alopecia sub-totalis (AS) who presented to the outpatient department (OPD) from January 2017 to October 2022. The study was held at the CUTIS Academy of Cutaneous Sciences, Bangalore, Karnataka, India.

Inclusion and exclusion criteria

Inclusion criteria involved a clinical diagnosis of mfAA, AT, AS or AU, patients not on any treatment for one month before the study, and those treated with tofacitinib for at least four months.

Exclusion criteria were patients with other hair disorders (telogen effluvium, trichotillomania) and those on other systemic immunosuppressive therapy.

Patient records were analyzed, assessed the age, sex, the duration of disease, family history and results of investigations. Photographic data taken before and during treatment were analyzed for disease severity assessment. Efficacy was evaluated using the SALT score. Additionally, the study explored the correlation between different types of alopecia areata and their response to oral tofacitinib. The duration required to achieve disease stability and response was meticulously measured. The analysis extended to the assessment of dose adjustments and the likelihood of recurrence in cases of AA. Furthermore, the study scrutinized treatment success by comparing the initial and final SALT scores, alongside a thorough examination of adverse effects associated with the administration of tofacitinib.

Assessment of hair regrowth

The response to tofacitinib therapy was determined after calculating percentage change in SALT score. The latest change in SALT score of <25% change was taken as no response, 25–74% as moderate response, 75–99% as near complete response, and 100% as complete response.[9]

$$Percent\ change\ in\ SALT\ score = \frac{(100 \times [absolute\ change\ in\ SALT\ score\ between\ initiation\ and\ last\ evaluation\ during\ the\ treatment]}{initial\ SALT\ score} \times 100$$

Ethical concerns

Ethical clearance was obtained from the Institutional Ethics Committee before commencing the study. Confidentiality and privacy were maintained by assigning each case a reference number, with data stored securely on a password-protected computer accessible only to the investigators.

Statistical analysis

Statistical analysis was conducted using the statistical package for the social sciences (SPSS) software. The variables were expressed as mean. The independent variable of interest was compared with the dependent variables and analyzed using the Pearson correlation and Spearman correlation. A significance level of $p<0.05$ was considered.

RESULTS

The study included a total of 69 patients of both genders, with an average age of 23.6 years (range: 12 to 62 years). Among them, 58% (n=40) were male, and 42% (n=29) were female. The demographic details are outlined in Table 1.

Table 1: Demographical characteristics of patients with multifocal alopecia areata (mfAA), alopecia universalis (AU), alopecia totalis (AT) and alopecia sub-totalis (AS).

Variables	Frequency, N (%)
Age, years, average (range)	23.6 (12.0-62.0)
Gender	
Male	40 (58.0)
Female	29 (42.0)
Type of AA	
AU	32 (46.4)
mfAA	29 (42.0)
AT	7 (10.1)
AS	1 (1.4)
Duration of disease (years)	
Average (range)	12.6 (2.2-30.0)
Duration of current episode (years)	
Average (range)	3.7 (1.0-11.0)
Previous topical treatments	
Yes	50 (72.5)
No	19 (27.5)
Previous systemic treatments	
Yes	51 (73.9)
No	18 (26.1)
Other previous treatments-phototherapy/ILS	
Yes	30 (43.5)
No	39 (56.5)
Alternative medicines	
Yes	8 (11.6)
No	61 (88.4)
Autoimmune comorbidities	
Hypothyroid	9 (12.9)
Gilbert syndrome	1 (1.4)
20 nail dystrophy	1 (1.4)
None	58 (84.1)
Comorbidities	
Hypertension	1 (1.4)
Hypercholesterolemia	1 (1.4)
Aortic valve replacement on warfarin	1 (1.4)
None	66 (95.6)

The majority of patients had AU type (46.4%), followed by mfAA (42%), AT (10.1%), and AS (1.4%). The mean duration from the onset of the first episode was 12.6 years, ranging from 2.2 to 30.0 years, while the current episode had a mean duration of 3.7 years, ranging from 1.0 to 11.0 years.

Regarding treatment history, 72.5% patients had prior topical treatments (which included topical minoxidil, steroid lotion, tacrolimus lotion, peptide based serum, travoprost eye drops, methotrexate gel or calcipotriol lotion), 73.9% had previous systemic treatments (which included oral steroids, methotrexate, cyclosporine, azathioprine, apremilast or oral anti-oxidants) and 43.5% had other treatments (like intralesional steroid injections, platelet rich plasma, dermaroller with triamcinolone acetonide or phototherapy). Additionally, 11.6% patients opted for alternative medicines like ayurveda or homeopathic treatments. A total of 84.1% (n=58) patients did not have any associated autoimmune disorders, while a few presented with conditions such as hypothyroidism (n=9), Gilbert syndrome (n=1) and 20 nail dystrophy (n=1). Other comorbidities included one case each of hypertension, hypercholesterolemia and aortic valve replacement on warfarin.

Patients on tofacitinib were prescribed with varied starting doses, with the majority starting at 5 mg twice daily (79.7%) and few with 5 mg once daily (20.2%). In the disease control phase, 28 patients were continued with oral tofacitinib of 5 mg twice daily, and with 5 mg once daily in 3 patients, while 11 patients needed up dosing from 5 mg once daily to 5 mg twice daily and 27 patients needed up dosing from twice daily 5 mg dose to 10 mg twice daily, this up dosing was based on the absence of regrowth of hair at 4-6 months of treatment, or if the response was plateaued. Tapering was done when complete regrowth of hair was sustained for 3 months of treatment. Tapering dose involved adjustments to 5 mg once daily in 43 patients, 5 mg twice daily in 11 patients and 5 mg alternate days in 15 patients (Table 2). Adjuvant therapies like oral steroids was added in 24 patients (34.8%) who did not show any response with maximum dosage of tofacitinib or to those who showed minimal response or plateau response while on treatment with oral tofacitinib for at least 3 months of duration, of which most of them belonged to AU group (58.3%). Mini pulsed oral methylprednisolone was initiated in such patients. The time taken to notice the initial response (time from initiation of treatment to any signs of hair regrowth) for oral tofacitinib was averaged at 3.3 months, and it ranged from 1 to 17 months and the average duration to see maximum response was 5.7 months and ranged from 2 to 20 months (Table 3). The response was seen earlier in mfAA (4.9 months) when compared to AT (9.2 months) (Table 3). Figure 1 illustrates the treatment duration, maximum response time, and dose tapering details for each patient.

Recurrence of AA was observed at various stages of treatment, which included those on the maintenance dose (n=7), while tapering (n=14), or upon stopping tofacitinib (n=10) and only one patient developed a resistant patch (Table 2). Notably, in 44.9% (n=31) patients, AA did not recur until the last follow up, of which 26 patients were on maintenance dose and 5 patients on tapering doses. The treatment duration of tofacitinib ranged from 3 to 52.5 months, with an average treatment duration of 14.2 months. 72.5 % (n=50) of patients also were on adjuvant topical therapy (topical minoxidil or peptide lotions).

The treatment response was determined through a percent change in SALT score. Among the 69 patients, three patients (4.3%) had complete response (100% change in

SALT score), while 33 patients (47.8%) showed a near complete response to tofacitinib treatment. Additionally, 22 patients (31.8%) exhibited a moderate response and only 11 patients (15.9%) had no response after six months of the treatment (Figures 2-6).

Table 2: Clinical treatment characteristics of patients using oral tofacitinib.

Treatment	Frequency, n (%)
Starting dose	
5 mg OD	14 (20.2)
5 mg BID	55 (79.7)
Dose increased	38 (55.1)
From 5 mg OD to 5 mg BID	11 (28.9)
From 5 mg BID to 10 mg BID	27 (69.2)
Dose maintained	31 (44.9)
At 5 mg OD	3 (9.6)
At 5 mg BID	28 (90.3)
Dose tapered to	
5 mg alternate days	15 (21.7)
5 mg OD	43 (62.3)
5 mg BID	11 (15.9)
Added oral steroids	
Yes	24 (34.8)
mfAA	8 (11.5)
AT	2 (2.9)
AU	14 (20.3)
AS	0
No	45 (65.2)
Recurrence	
On continuation of same dose	7 (10.1)
On tapering	14 (20.3)
On stopping	10 (14.5)
Resistant patch	1 (1.4)
No recurrence	31 (44.9)
On continuation of same dose	26 (37.7)
On tapering	5 (7.2)
Loss of follow-up	6 (8.7)
Duration of treatment, months, average (range)	14.2 (3-52.5)
Adjuvant therapy	
Topicals	50 (72.5)

OD-Once daily; BID-twice daily

The correlation analyses revealed several associations among variables concerning the percent change in SALT score. Pearson correlations indicated that age had a significant negative correlation with % of hair regrowth (r= -0.211, p=0.082), suggesting that older individuals tended to have lower regrowth responses. Additionally, a marginal positive correlation was observed between gender and hair regrowth (r=0.206, p=0.089). However, the variables such as type of alopecia, dose, treatment duration, and addition of oral steroids did not exhibit significant correlations with regrowth of hair percentage.

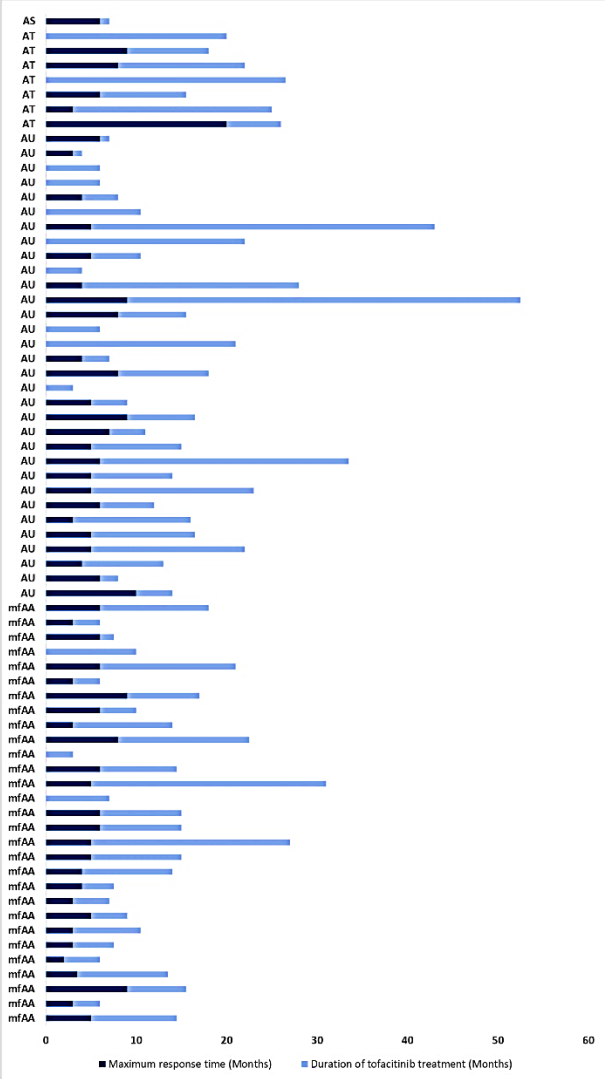

Figure 1: Illustration of each patient's treatment timeline- showing the variability in treatment duration and maximum response time across different AA patients.

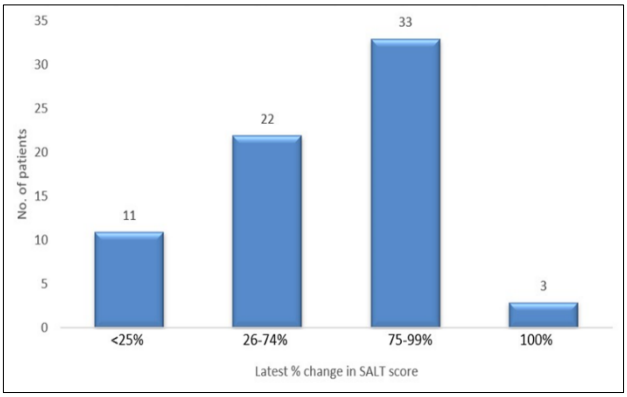

Figure 2: Latest percent change in SALT score (n=69).

SALT- Severity of alopecia tool

Spearman's rho correlations, a non-parametric measure, confirmed the significant negative association between age and regrowth of hair (ρ= -0.057, p=0.640). These findings suggest that age may play a role in predicting hair regrowth outcomes, emphasizing the importance of considering demographic factors in understanding treatment responses. The study found that the dose did not show a significant correlation with side effects (r= -0.036, p=0.772), or disease recurrence (r=0.018, p=0.884).

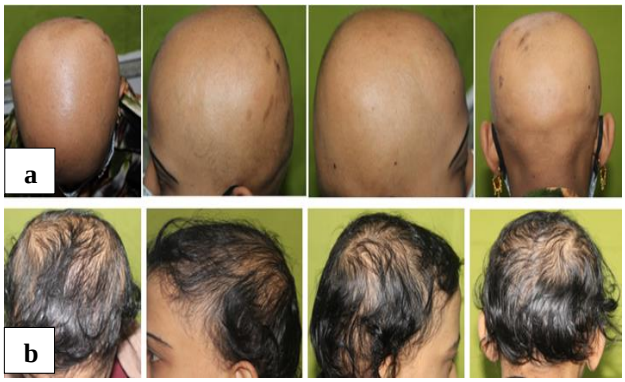

Figure 3: Excellent response with hair regrowth on scalp of an 18-year-old female patient with alopecia universalis following 12 months of oral tofacitinib treatment (a) baseline (SALT score-99); and (b) 12th month (SALT score-5).

Table 3: Clinical treatment response and side effects of oral tofacitinib.

Variables	Frequency, n (%)
Time taken to notice initial response, months, average (range)	3.3 (1- 17)
Max response time, months, average (range)	5.7 (2- 20)
Baseline blood investigations	
Deranged lipid profile	9 (13.0)
Deranged liver function tests	2 (2.9)
Within normal limits	50 (72.5)
Mantoux positive	5 (7.2)
Deranged thyroid profile	3 (4.3)
Repeat investigations	
Deranged lipid profile	17 (24.6)
Deranged liver function tests	9 (13.0)
Within normal limits	43 (62.3)
Side effects	
Acneiform eruptions	5 (7.2)
Infections	5 (7.2)
None	56 (81.2)
Renal stones	1 (1.4)
Menstrual irregularities	2 (2.9)

There were no serious adverse effects seen over 12 months of treatment duration. Few adverse events were noticed throughout the treatment course, including acneiform eruptions (5 patients), infections (5 patients- 4 had upper respiratory infection, 1 had flare in molluscum contagiosum), renal stones (1 patient who had a history of pre-existing renal calculi and was treated medically), and menstrual irregularities (2 patients- menorrhagia and amennorhea each). Notably, 81.2% (n=56) patients did not report any side effects (Table 3).

The baseline blood investigations identified deranged lipid profile in 9 patients, raised liver enzymes in 2 patients (which was less than 2 times the upper limit), a positive Mantoux test in 5 patients, and an abnormal thyroid profile in 3 patients (Table 3). Patients with Mantoux positive were further tested with TB Quantiferon test, which was also positive in all 5 patients. Physician opinion was obtained and they were initiated with oral isoniazid prophylactic therapy for 6 months. Tofacitinib was initiated after 2 months of initiation of isoniazid therapy.

Table 4: Type of alopecia areata with various treatment response parameters.

Parameters	mfAA (n=29)	AU (n=32)	AT (n=7)	AS (n=1)
Average duration of tofacitinib treatment (months)	12.7	15.5	21.9	7
Average duration to attain maximum response (months)	4.9	5.7	9.2	6
Average duration taken to taper tofacitinib (months)	9.6	9.6	17.0	-

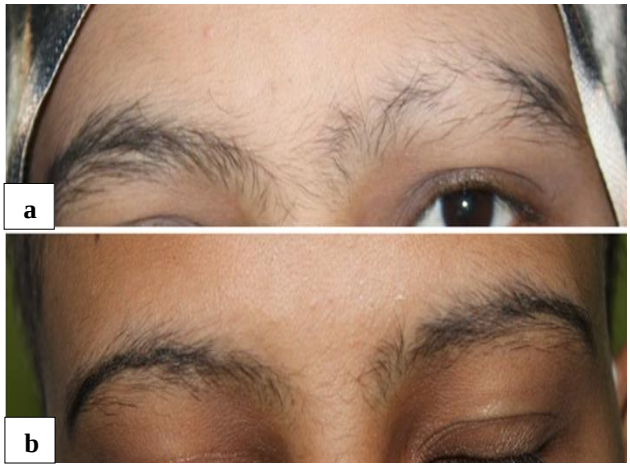

Figure 4: Significant hair regrowth in eyebrows of a 26-year-old female patient with alopecia universalis following 12 months of oral tofacitinib treatment (a) baseline; and (b) 12th month.

Figure 5: A case demonstrating excellent improvement in beard alopecia with oral tofacitinib treatment from (a) baseline to the (b) 9th month.

Blood tests were repeated in 1st month and then every 3 months once. During the treatment with tofacitinib, a follow-up blood investigation revealed 17 patients with a deranged lipid profile and 9 patients with elevated liver enzymes but less than twice the upper limit (Table 3). Mantoux test or TB quantiferon tests were repeated once in a year.

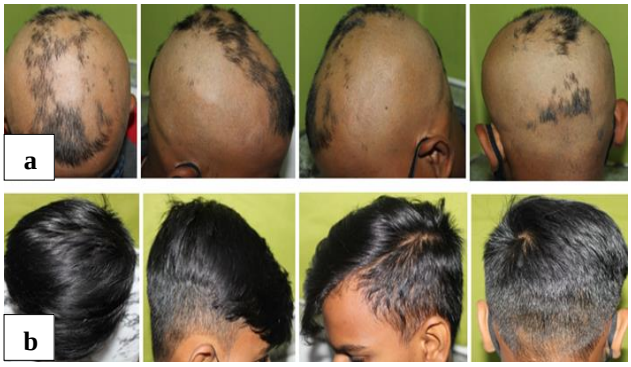

Figure 6: A 12-year-old male patient demonstrating excellent response to oral tofacitinib in alopecia subtotalis: (a) baseline (SALT score-80) and (b) after 2 years (SALT score-0).

DISCUSSION

The present study included 69 patients with a diverse demographic profile. The majority of patients had AU (32 patients), followed by mfAA (29 patients), AT and AS. The mean duration from the onset of the first episode and the current episode provided insight into the chronic nature of the condition. Patients had prior usage of various topical and systemic treatments.

In a clinical trial of 12 moderate to severe alopecia patients showed minimal adverse events, with eight patients achieving ≥50% hair regrowth with an initial dose of 5mg to 10mg twice daily dosing of tofacitinib.[10] In the largest retrospective study by Liu et al involving 90 patients with AA, AT, or AU, oral tofacitinib at doses of 5 mg or 10 mg twice daily demonstrated over 50% regrowth in 77% of patients.[11] Similarly, in our study, the majority of patients were started with the dose at 5 mg twice daily. Clinical efficacy of our study highlights an overall response rate of 80%, defining success as greater than 50% improvement in SALT scores, in the literature the reported success rates ranging from 32% to 66%.[10,12,13]

Concerns about relapse rates highlight the need for prolonged treatment.[3] In our study, recurrence of alopecia areata was observed at different stages of treatment, highlighting the need for prolonged and consistent therapy. The recurrence was more common in patients having long-standing disease duration, alopecia universalis type, those with other autoimmune diseases and when tofacitinib was tapered rapidly on observing disease stability. However, statistically no correlation between the dose and treatment outcome was observed. Various studies emphasize the importance of extended therapy with factors influencing recurrence rates including disease duration, initial SALT scores, and specific AA subtypes.[8,14] Various dosing strategies have been proposed, including a daily treatment dose of 20 mg to prevent relapse.[12,15] Serdaroglu et al reported that long-term continuation at low doses of 10 mg/day was sufficient to prevent recurrence and to provide a low side-effect profile.[16] Crispin et al studied the efficacy of oral tofacitinib (5 mg twice daily for 3 months) in 66 patients belonging to mfAA, AU and AT.[17] Results revealed 2% experienced 50% or greater improvement in SALT score with limited adverse effects and disease relapse observed within 8.5 weeks. In our study, the average maintenance dosage of 5 mg once daily or on alternate days of oral tofacitinib was followed (Table 2). This reduced dosage also reduced the risk of side effects. In other studies, the maintenance dosages varied i.e. 7 mg, 10 mg, 15 mg and 20 mg of tofacitinib.[12,18-21] However, the optimal dose in our study remains undefined and varies with individual patient and type of AA, which was similar to previous studies.[12,15] In our study, most of the patients (62.3%) maintained well with 5 mg once daily dosing without any relapse.

Some patients had adjuvant topical therapy and oral pulse steroids. Oral steroids were added as mini pulse in 24 patients, of which 58.0% of patients had AU, 33.3% had mfAA, and 8.3% had AT in our study. The need for oral steroids observed in our study was absence of regrowth of hair at 4-6 months of treatment with oral tofacitinib, no improvement seen when the dosage was increased, when new patches were observed and when the response was plateaued.

In a case series, the maximum cumulative tofacitinib treatment duration in AU or AA was found to be 28 months.[12] In this study, we investigated long-term efficacy and safety oral tofacitinib treatment in patients with alopecia areata. Twelve patients were on oral tofacitinib treatment for more than 2 years, with 4 individuals extending beyond 3 years. Among them, 7 patients had AU, 3 had AT, and 2 with mfAA (Table 4). Notably, none of the patients reported any serious adverse effects, underscoring the favourable safety profile of low-dose oral tofacitinib in the management of AA.

In terms of safety profile, approximately 80% of patients did not report any side effects throughout the treatment course while very few reported side effects such as acneiform eruptions, infections, renal stones, and menstrual irregularities were observed. The patient with renal stones did not have variation in renal function tests and it was unrelated to oral tofacitinib. Laboratory variables including lipid profile, liver enzymes and serum creatinine, remained generally stable over time. Though derangement was observed in lipid profile and liver enzymes (which was less than twice the upper limit of normal), it did not lead to tapering or stopping of oral tofacitinib. Patients with deranged lipid profile were advised lifestyle modification and were referred to physician in need for oral lipid lowering medications.

An increase in rate of occurrence of severe side effects such as herpes and similar viral infections, malignancy, tuberculosis activation, and gastrointestinal perforation, has been reported, especially with tofacitinib at higher doses and in patients with rheumatoid arthritis.[7,8] We did not observe such severe side effects in any of our patients even on 10 mg twice daily dosing, this could also be due to shorter treatment duration with such higher doses and tapering to the lowest possible dosage when the response was obtained. According to our study and a few other studies, the usage of tofacitinib in the treatment of AA is strongly recommended due to the absence of serious side effects.[11,21]

A retrospective case series examining paediatric patients treated with oral tofacitinib found a 72.7% hair regrowth rate, with minimal to no regrowth reported in 23.3% of cases and no serious adverse events recorded during the treatment period.[13] The overall evidence suggests that tofacitinib may be a valuable therapeutic option for various forms of alopecia areata of different age groups and diverse patient populations. However, our study exhibited a significant negative correlation with age and hair regrowth, suggesting older individuals tending to have lower regrowth responses. This could be attributed to long standing and recalcitrant disease. This also indicates the need for early initiation of treatment at younger age group.

Limitations

The limitations of our study was the absence of control arm to compare the efficacy with tofacitinib. There is a need for randomized controlled clinical trials comparing different treatment modalities and to determine the required dosage of oral tofacitinib for treatment with minimal side effects and in prevention of relapse. The response rates obtained from oral tofacitinib in this study suggests that JAKinbs are an effective modality in treatment of AA.

CONCLUSION

This retrospective analysis is one of its kind in Indian patients with respect to the duration of treatment and multiple variables taken into consideration in the treatment of severe recalcitrant alopecia areata subtypes with oral tofacitinib. Despite the observed correlations between age and regrowth outcomes, the overall positive treatment responses and the absence of serious side effects in patients with tofacitinib for over 2-4 years of treatment support the consideration of tofacitinib as a viable option for managing AA.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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