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Impact of tofacitinib on quality of life in patients of Alopecia Areata

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Keywords*Alopecia areata; Autoimmune disorder; Hair regrowth; Janus kinase inhibitors; Quality of life; SALT score; Tofacitinib; Trichoscopy***ABSTRACT**

Background: Alopecia areata (AA) is an autoimmune disorder that results in non-scarring hair loss and significant psychosocial repercussions. Tofacitinib, a Janus kinase inhibitor, has demonstrated potential in promoting hair regrowth; nevertheless, its effects on quality of life (QoL) necessitate additional assessment. **Aim:** To evaluate the clinical efficacy of oral tofacitinib and its impact on quality of life in individuals with moderate-to-severe alopecia areata. **Methodology:** A hospital-based, prospective, 18-month observational clinical study at MM Medical College, Solan, included 50 patients (aged over 16 years) with SALT scores exceeding 30%. All patients received oral tofacitinib (5 mg twice) and were assessed at baseline, 3, 6, 12, and 18 months. The SALT and AAPI ratings assessed disease severity, whereas the AA-QLI evaluated quality of life. Statistical analysis was conducted using paired t-tests. **Results:** The predominant demographic consisted of young to middle-aged males (70%) exhibiting patterned alopecia. Notable trichoscopic features comprised exclamation indicate hairs (96%) and black dots (74%). The mean SALT scores decreased from 45.3 at baseline to 2.4 at 18 months, reflecting a 94.7% improvement ($p < 0.001$), whilst the mean AAPI scores decreased from 32.4 to 3.9, indicating an 88% improvement ($p < 0.001$). Notable advantages were evident after six months. **Conclusion:** In conclusion, Tofacitinib significantly enhanced hair regeneration and quality of life in people with alopecia areata. Expanded multicenter trials with prolonged follow-up are necessary to validate long-term safety and efficacy.

1. INTRODUCTION:

Hair significantly impacts a person's identity, aesthetic appreciation, and self-esteem. Alopecia, defined as hair loss above the typical shedding of 50–100 hairs daily, is often distressing and affects individuals of all ages and genders¹. Alopecia Areata (AA) is a chronic, immune-mediated disorder characterized by distinct, non-scarring patches of hair loss, primarily impacting the scalp and face². The trajectory of AA is unpredictable, ranging from spontaneous recovery to persistent or progressive illness, hence significantly complicating its treatment³.

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AA has been recognized as an organ-specific autoimmune disorder, wherein genetically predisposed individuals elicit a T-cell-mediated inflammatory response targeting hair follicles, primarily triggered by cytotoxic CD8+ NKG2D+ T cells⁴. These immune cells produce interferon-gamma (IFN- γ) across activation by interleukin-15 (IL-15) signaling, resulting in follicular damage and hair loss⁵. The intricate pathophysiology, in addition to diverse clinical presentations such as alopecia totalis and alopecia universalis, complicates therapy⁶.

Recent progress in the immunopathogenesis of alopecia areata (AA) has resulted in the creation of targeted immunomodulators, with Janus kinase (JAK) inhibitors emerging as a distinctive and potential treatment alternative⁷. Tofacitinib citrate, a selective inhibitor of JAK1 and JAK3, has demonstrated positive outcomes in both preclinical and clinical investigations⁸.

In a significant open-label research, Craiglow and King (2014) documented effective hair regrowth in a patient with alopecia universalis treated with tofacitinib, underscoring its ability to reverse even severe types of alopecia areata⁹. However, Huang et al. (2023) conducted a retrospective review of 90 patients with moderate-to-severe alopecia areata, revealing that tofacitinib resulted in $\geq 50\%$ hair regrowth in 77% of cases over a median period of 4–6 months¹⁰.

Additionally, Morelli, et al., (2018) explored the immunological mechanisms in murine models and revealed that tofacitinib effectively suppresses IFN- γ and IL-15 pathways involved in follicular attack by CD8+ NKG2D+ T-cells, which are central to AA pathogenesis¹¹.

Although the clinical efficacy of tofacitinib in promoting hair restoration is progressively recognized, its influence on patient quality of life (QoL) remains not well recognized¹². Considering that AA impacts visible areas of the body and often manifests in younger individuals—particularly teenagers and young people experiencing pivotal phases of psychological development—its ramifications transcend mere physical appearance¹³. Patients frequently experience diminished self-esteem, emotional turmoil, social isolation, anxiety, and despair, all of which cumulatively compromise quality of life¹⁴.

Quality of Life (QoL) is a multifaceted concept that includes physical health, mental well-being, social connections, and individual views¹⁵. In dermatological conditions such as alopecia areata, when outward deformity is significant, impairments

in quality of life are very severe and sometimes disproportionate to clinical severity¹⁶. However, this case series seeks to assess the effects of tofacitinib on hair regrowth and quality of life (QoL) in patients with moderate-to-severe Alopecia Areata, considering the substantial psychological ramifications of the condition and the drug's promising therapeutic potential, in a tertiary care facility.

2. METHODS:

2.1. Case Selection Criteria:

This 18-month, hospital-based, cross-sectional research at MM Medical College, Solan, involved 50 patients aged over 16 years with moderate to severe alopecia areata (AA), who had been administered oral tofacitinib for a minimum of three months, with a SALT score over 30% and an increased AAPI. The exclusion criteria included past tofacitinib usage extending three months, comorbidities or mental illnesses that impact quality of life, and the presence of single-patch alopecia areata (AA).

2.2. Data Collection Methods:

Patients received clinical assessment, trichoscopy, and laboratory tests to verify alopecia areata and rule severe systemic disease. The severity of the disease was evaluated using SALT and AAPI scores, while quality of life was determined with the Persian version of the AA-QLI. All participants received oral tofacitinib at a dosage of 5 mg twice daily, with follow-up assessments conducted at 0, 3, 6, 12, and 18 months to evaluate alterations in SALT, AAPI, and AA-QLI scores.

2.3. Data analysis:

Data were analyzed utilizing SPSS 26.0v, with findings shown as mean \pm SD or frequencies. Paired t-tests evaluated alterations in SALT, AAPI, and AA-QLI; ethical approval and informed consent were obtained.

3. RESULTS:

3.1. Demographic Profile of the Study Population:

The baseline cohort characteristics ($n = 50$) indicated a significant prevalence of young to middle-aged males (58%; ages 21–40, 70% male), with housewives and farmers as the most impacted occupations. Alopecia exhibited a brief duration (≤ 6 months in 64%), with minor pruritus and scaling being the predominant manifestations (80%). Patterned alopecia (66%) was the predominant manifestation, with merely 10% exhibiting a positive familial history, and minimal autoimmune comorbidity was identified. The positive pull test (96%) and trichoscopic characteristics, including exclamation mark hairs (96%) and black dots (74%),

were the most reliable diagnostic indicators. The parietal and occipital regions were predominantly affected, with 2 to 6 patches being the most frequent manifestation in the majority of individuals. The data indicate that alopecia areata in this cohort primarily affected younger adolescents, who exhibited patterned focal disease, characteristic trichoscopic symptoms, and minimal correlations with systemic disease.

Table 1: Demographic characteristics of patients with hair loss

Parameter	Category	n (%)
Age Group	≤ 20 years	9 (18.0)
	21–30 years	15 (30.0)
	31–40 years	14 (28.0)
	> 40 years	12 (24.0)
Gender	Male	35 (70.0)
	Female	15 (30.0)
Occupation	Student	11 (22.0)
	Housewife	11 (22.0)
	Shopkeeper	2 (4.0)
	Farmer	15 (30.0)
	Labour	9 (18.0)
	Others	2 (4.0)
Hair Loss Duration	≤ 2 months	10 (20.0)
	3–6 months	22 (44.0)
	7–12 months	12 (24.0)
	> 12 months	6 (12.0)
Itching & Scaling	Not present	2 (4.0)
	Mild	40 (80.0)
	Moderate	8 (16.0)
Clinical Symptoms	Focal	11 (22.0)
	Patterned	33 (66.0)
	Diffuse	6 (12.0)
Preceding Illness	Not specified	—
Family History	Yes	5 (10.0)
	No	45 (90.0)
Autoimmune Diseases	Hypothyroidism	1 (2.0)
	DM type 2	1 (2.0)
	Not present	48 (96.0)
Drug History	Minoxidil + Finasteride + Biotin	1 (2.0)
	Home remedies only	1 (2.0)
	Unknown injection	1 (2.0)
	Thyronorm	1 (2.0)
	Momate lotion on scalp	1 (2.0)
	None	45 (90.0)
Hair Care Practices	Hair combing – 2 times/day	40 (80.0)
	Hair combing – 1 time/day	10 (20.0)
	Hair wash frequency – 2 times/week	20 (40.0)
	Hair wash – 3 times/week	4 (8.0)
	Hair wash – weekly	26 (52.0)
	Shampoo/Leave-on conditioners – Yes	27 (54.0)
	Shampoo/Conditioners – No	23 (46.0)
	Hairstyle practices – Yes	4 (8.0)
	Hairstyle – No	46 (92.0)
	Dyeing – Yes	2 (4.0)
	Dyeing – No	48 (96.0)
	Home care – Yes	5 (10.0)
	Home care – No	45 (90.0)
Hair Pull Test	Positive	48 (96.0)
	Negative	2 (4.0)
Trichoscopic	Exclamation mark hairs	48 (96.0)

Features	Black dots	37 (74.0)
	Yellow dots	15 (30.0)
	Erythema	2 (4.0)
	White spots	1 (2.0)
	Vellus hair	1 (2.0)
Site of Involvement	Parietal	40 (80.0)
	Occipital	37 (74.0)
	Frontal	30 (60.0)
	Beard	10 (20.0)
	Temporal	7 (14.0)
	Whole scalp	2 (4.0)
Hair Shaft Examination	Melanin granules present	37 (74.0)
	Melanin granules absent	13 (26.0)
Clinical Examination	2–4 patches	18 (36.0)
	4–6 patches	18 (36.0)
	> 6 patches	14 (28.0)
Additional Clinical Finding	Hypothyroidism	1 (2.0)
	Not present	49 (98.0)

3.2. Clinical characteristics:

The clinical profile of the responders indicated that the majority of patients appeared within the first six months (64%), with mild itching being the most prevalent symptom (80%). Patterned alopecia was the predominant manifestation (66%), but antecedent illnesses, autoimmune connections, and familial history were few. The majority of patients had not undergone prior therapy (90%), and the practices for hair maintenance indicated that 80% combed their hair twice daily and 52% washed their hair weekly, with minimal usage of damaging hairstyles or hair dye. The diagnostic evaluation revealed a positive pull test in 96% of patients and distinctive trichoscopic characteristics, predominantly exclamation mark hairs (96%) and black dots (74%). The parietal region was damaged in 80% of cases, while the occipital region was afflicted in 74%. Additionally, melanin granules were detected in 74% of hair shaft tests. The data indicates that alopecia areata is characterized by patterned hair loss, exhibiting distinct trichoscopic traits and few systemic connections.

Table 2: Illustration of Clinical Profile among respondents.

Parameter	Category	n (%)
Hair Loss Duration	≤ 2 months	10 (20.0)
	3–6 months	22 (44.0)
	7–12 months	12 (24.0)
	> 12 months	6 (12.0)
Itching Severity	Absent	2 (4.0)
	Mild	40 (80.0)
	Moderate	8 (16.0)
Pattern of Hair Loss	Focal	11 (22.0)
	Patterned	33 (66.0)
	Diffuse	6 (12.0)
Preceding Illness	Hypothyroidism	1 (2.0)
	None	49 (98.0)
Family History	Positive	5 (10.0)
	Negative	45 (90.0)
Autoimmune Diseases	Hypothyroidism	1 (2.0)
	Type 2 diabetes mellitus	1 (2.0)
	None	48 (96.0)
Drug History	None	45 (90.0)

	Minoxidil + finasteride	1 (2.0)
	Home remedies	1 (2.0)
	Unknown injection	1 (2.0)
	Thyronorm	1 (2.0)
	Mometasone lotion	1 (2.0)
Combing Frequency	Twice daily	40 (80.0)
	Once daily	10 (20.0)
Hair Wash Frequency	Twice a week	20 (40.0)
	Thrice a week	4 (8.0)
	Weekly	26 (52.0)
Shampoo/Conditioner Use	Yes	27 (54.0)
	No	23 (46.0)
Damaging Hairstyles	Yes	4 (8.0)
	No	46 (92.0)
Hair Dye Use	Yes	2 (4.0)
	No	48 (96.0)
Home Remedies	Yes	5 (10.0)
	No	45 (90.0)
Hair Pull Test	Positive	48 (96.0)
	Negative	2 (4.0)
Trichoscopy Findings	Exclamation mark hairs	48 (96.0)
	Black dots	37 (74.0)
	Yellow dots	15 (30.0)
	Erythema	2 (4.0)
	White spots	1 (2.0)
	Vellus hair	1 (2.0)
Sites of Involvement	Parietal	40 (80.0)
	Occipital	37 (74.0)

	Frontal	30 (60.0)
	Beard	10 (20.0)
	Temporal	7 (14.0)
	Whole scalp	2 (4.0)
Hair Examination Shaft	Melanin granules present	37 (74.0)
	Melanin granules absent	13 (26.0)

3.3. Disease severity and QoL improvement:

Respondents exhibited progressive enhancement in disease severity and quality of life during the follow-up period. The mean SALT score consistently declined from 45.3 at baseline to 2.4 at 18 months, reflecting a 94.7% reduction in illness severity, with statistically significant improvement observed from 6 months onward ($p < 0.001$). The mean AAPI score decreased from 32.4 at baseline to 3.9 at 18 months, indicating an 88.0% enhancement in quality of life as reported by patients, which remained statistically significant from 6 months onward ($p < 0.001$). The results indicate that continuous therapy and follow-up led to a significant reduction in the severity of alopecia areata and a corresponding enhancement in quality of life, providing evidence of both clinical and psychosocial benefits over time as shown in fig 1(a,b,c,d).

Table 3: Improvement in Disease Severity (SALT) and Quality of Life (AAPI) Over Time

Time Interval	SALT Score (Mean ± SD)	Change from Baseline (%)	p-value	AAPI Score (Mean ± SD)	Change from Baseline (%)	p-value
Baseline	45.3 ± 16.0	–	–	32.4 ± 15.8	–	–
3 months	34.4 ± 13.2	24.1%	–	13.1 ± 1.8	59.6%	–
6 months	22.4 ± 12.1	50.6%	<0.001	9.1 ± 1.2	71.9%	<0.001
12 months	11.3 ± 8.0	75.1%	<0.001	5.9 ± 0.83	81.8%	<0.001
18 months	2.4 ± 5.6	94.7%	<0.001	3.9 ± 0.55	88.0%	<0.001



Fig 1(a): Clinical photographs demonstrating progressive scalp hair changes in a patient with alopecia areata (Case 1,Case 2) at 3-month follow-up.



Fig 1(b): Clinical photographs demonstrating progressive scalp hair changes in a patient with alopecia areata (Case 2,Case 4) at 6-month follow-up.



Fig 1(c): Clinical photographs demonstrating progressive scalp hair changes in a patient with alopecia areata (Case 3, Case 5) at 12-month follow-up.



Fig 1(d): Clinical photographs demonstrating progressive scalp hair changes in a patient with alopecia areata (Case 3, Case 5) at 18-month follow-up.

4. DISCUSSION:

Alopecia areata, an unpredictable baldness condition, typically undermines the psychosocial well-being and quality of life of affected individuals¹⁷. Conventional treatments produce inconsistent outcomes, necessitating the pursuit of more effective alternatives. Tofacitinib, a Janus kinase (JAK) inhibitor, has exhibited promising outcomes via its targeted immunomodulation¹⁸. Besides promoting hair regeneration, its ability to enhance emotional and social well-being is a notable feature of its clinical utility¹⁹. The study situates the current results within the existing literature, emphasizing both therapeutic efficacy and the improvement of quality of life.

The current cohort predominantly consisted of males (70%) within the 21–40-year age range, corroborating the findings of Dandona et al. (2017), who identified male predominance and peak incidence of the disease in the second to fourth decades of life. However, our research diverges from that of Tzeng et al. (2023), who identified a minor female predominance in a Southeast Asian sample, suggesting geographical or hormonal influences²⁰. The occupational distribution in our cohort, with farmers and homemakers being the most frequently affected, aligns with the socioeconomic profile presented by Kumar et al. (2022), who identified a higher incidence of disease among outdoor workers and homemakers, likely due to increased exposure to environmental triggers and psychosocial stressors²¹.

The minimal disease duration at presentation in our cohort (≤ 6 months in 64%) aligns with Yim et al. (2019), who noted that presentation is often

triggered by concerns regarding appearance, particularly among younger individuals²². However, the modest prevalence of familial history (10%) in our population contrasts with the elevated rates (15–20%) reported by Moravvej et al. (2018), indicating possible ethnic or genetic differences in hereditary susceptibility²³. Furthermore, Gill et al., (2016) revealed that autoimmune comorbidity was infrequent (4% in our study), significantly lower than the 16–25% reported in European and North American cohorts, potentially due to variations in sample size, selection criteria, or geographic distribution of autoimmune prevalence²⁴.

Patterned alopecia was the predominant clinical manifestation (66%), succeeded by localized alopecia (22%) and diffuse alopecia (12%). This, highlighting that articulated by Jain et al. (2023), highlighting patterned AA as the predominant manifestation at tertiary centers²⁵. The low incidence of diffuse alopecia in our study mirrors its rarity reported in both pediatric and adult populations. Mild pruritus and scaling were observed in the majority (80%), paralleling the findings of Karla et al. (2021), who noted pruritus as a prevalent yet undervalued symptom²⁶.

In our survey, trichoscopy was identified as a standard diagnostic instrument, with exclamation mark hairs (96%) and black dots (74%) being the most prevalent characteristics. However, Rothschild et al., (2023) revealed that the characteristics have been extensively validated, wherein exclamation mark hairs are deemed pathognomonic of active disease²⁷. The identification of yellow spots (30%) in our survey occurred less frequently than the 45–60% observed in European case collections, potentially indicating variations in disease stage at presentation. Erythema and white spots were infrequently observed, aligning with the findings of Radziszewska et al. (2019), which indicated that these characteristics are more characteristic of chronic or cicatricial alopecias than of alopecia areata (AA)²⁸.

The distribution of our patient's scalp, with the parietal (80%) and occipital (74%) regions being the most affected, aligns with the preferences noted by Kumar et al. (2020) revealed that The prevalence of

beard involvement in 20% of our male subjects²⁹. These profiles demonstrate that AA frequently affects visually prominent regions, hence confirming its psychological implications. Similarly, Mubki et al., (2014) revealed that A positive hair pull test in 96% of patients further confirms current illness and aligns with the diagnostic significance³⁰.

Our research demonstrated a significant 94.7% reduction in SALT score (disease severity) and an 88% enhancement in QoL (AAPI score) at 18 months, corroborating the longitudinal findings of Koh et al. (2017), who noted analogous substantial regrowth and QoL improvement with sustained treatment adherence³¹. The temporal trend, characterized by significant improvement at 6 months, aligns with findings by Strazzulla et al. (2023), who emphasize the importance of prolonged therapy for optimal outcomes³². Psychosocial enhancement, indicated by elevated AAPI scores, aligns with the findings of Dixon et al. (2018), who noted improvements in self-esteem, social, and emotional well-being following clinical remission³³. The magnitude of improvement in our group surpasses that observed in shorter follow-up studies by Li et al., (2018), underscoring the importance of long-term evaluation and patient guidance for sustained therapeutic success³⁴.

However, the study confirms that alopecia areata predominantly affects young to middle-aged men, with patterned alopecia and distinctive trichoscopic features serving as the primary diagnostic indicators. Consistent therapy and monitoring led to significant clinical enhancement and improved quality of life. Our findings align with standard epidemiological profiles observed internationally, however they highlight regional disparities in comorbidities and treatment responses.

5. CONCLUSION:

In conclusion, the present study highlights that tofacitinib therapy substantially enhances the quality of life for individuals with alopecia areata, positioning it as a valuable treatment option for this psychologically and socially distressing condition. However, the findings are compromised by a limited sample size, short follow-up duration, and lack of long-term safety evaluation, hence constraining the generalizability of the results. Future research should focus on extensive, multicenter, randomized, controlled trials with extended follow-up to validate these findings, elucidate the long-term efficacy and safety of tofacitinib, and investigate optimal dose regimens.

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