RESEARCH
www.commprac.com
ISSN 1462 2815

TOPICAL TOFACITINIB 2 % SOLUTION IN THE TREATMENT OF ALOPECIA AREATA

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DOI: 10.5281/zenodo.11613720

Abstract

Introduction: Alopecia areata is an autoimmune disorder affecting hair follicles and causing sudden non-scarring hair loss. While multiple treatments exist, their variable efficacy and associated adverse effects have prompted exploration of novel targeted therapies such as tofacitinib, a Janus kinase (JAK) inhibitor in the treatment of this disorder. **Objective:** This study aimed to evaluate the efficacy of topical tofacitinib 2% solution in managing scalp and beard alopecia areata and document potential adverse effects. **Methodology:** A single-arm prospective interventional pilot study was conducted. Twelve participants with alopecia areata were treated with topical tofacitinib 2% solution once daily for a period of 4 weeks. Patients were followed-up every four weeks for a total of twelve weeks. Clinical and dermoscopic evaluation was carried out at each visit. Ethical considerations were upheld throughout. **Results:** Participants exhibited varying degrees of hair regrowth over 12 weeks. Notably, two patients experienced partial regrowth at four weeks, while three demonstrated significant regrowth by study conclusion. **Conclusion:** The study suggests promising outcomes for topical tofacitinib in treating scalp and beard alopecia areata, evidenced by positive hair regrowth.

Keywords: Alopecia Areata, Tofacitinib, JAK Inhibitor, Hair Regrowth.

INTRODUCTION

Alopecia areata is an autoimmune disorder, characterized by immune targeting of hair follicles, thereby leading to hair loss. Alopecia areata has an unpredictable onset and course. Within a year after the first occurrence of alopecia, 80% of patients experience spontaneous hair regrowth. However, recurrence or advancement to alopecia totalis or universalis may also occur[1,2] While alopecia areata has been characterised as a self-limiting condition because a high percentage of patients recover; however, can have a chronic course with a higher rate of recurrence[10].

While the precise aetiology of alopecia areata remains mostly unknown, immunology and genetics have been shown to be the primary factors contributing to the condition. There are currently no treatments available to prevent or treat alopecia areata. There are several immune-cell-targeting therapeutic options available for the illness, but the efficacy of these alternatives varies from person to person and depends on the length and stage of the disease at the time of treatment initiation.[5,6]

There is promise for more successful management of alopecia areata thanks to the investigation of innovative therapeutic approaches in recent years. One of these new treatments that has attracted interest is tofacitinib, a Janus kinase (JAK) inhibitor that has been effective in treating other autoimmune diseases. Tofacitinib was first identified for the treatment of rheumatoid arthritis by oral administration. However, due to its capacity to alter inflammatory pathways, studies have been conducted regarding its potential to treat alopecia areata.[7]

Objective:

The study was conducted with the objective to assess the effectiveness of topical tofacitinib 2% solution in the treatment of alopecia areata of the scalp and beard.

MATERIAL AND METHODOLOGY

Study design and setting: This was an interventional study without control conducted in the department of dermatology in a tertiary hospital during the time period of June 2022 to May 2023.

Study population:

Inclusion criteria:

- Male and female above eighteen years of age diagnosed with alopecia areata in at least two areas
- Deteriorating or stable illness for at least six months
- No illness treatment for a minimum of one month prior to enrollment
- Absence of signs of spontaneous hair growth

Exclusion criteria:

- Participants with a history of hypersensitivity or adverse reactions to tofacitinib or its components.
- Pregnant or breastfeeding individuals.
- Current use of systemic JAK inhibitors or immunosuppressants.
- History of malignancy within the last five years.
- Significant comorbidities including severe cardiovascular, hepatic, renal, or psychiatric disorders, immunosuppressive illness.

Sampling method: Purposive sampling was used.

Procedure:

Twelve patients diagnosed with alopecia areata of the scalp and beard were treated with topical tofacitinib 2% solution applied twice daily for four weeks. Patients were followed up every four weeks for twelve weeks and the efficacy was measured by hair regrowth using dermoscopic assessment and physical examination.

Ethical consideration:

Approval obtained from the Institutional Ethics Committee in compliance with local regulations and the Declaration of Helsinki. Informed consent obtained from all participants after explaining the study objectives, procedures, potential risks, and benefits in detail. Confidentiality and privacy of participants maintained throughout the study duration. Monitoring and reporting of adverse events promptly to ensure participant safety.

RESULTS

The mean age of the study participants was 35.25 ± 5.84 ranging from 26 to 44 years. The mean duration of disease was 9.17 ± 1.52 ranging from 7 to 11 years.

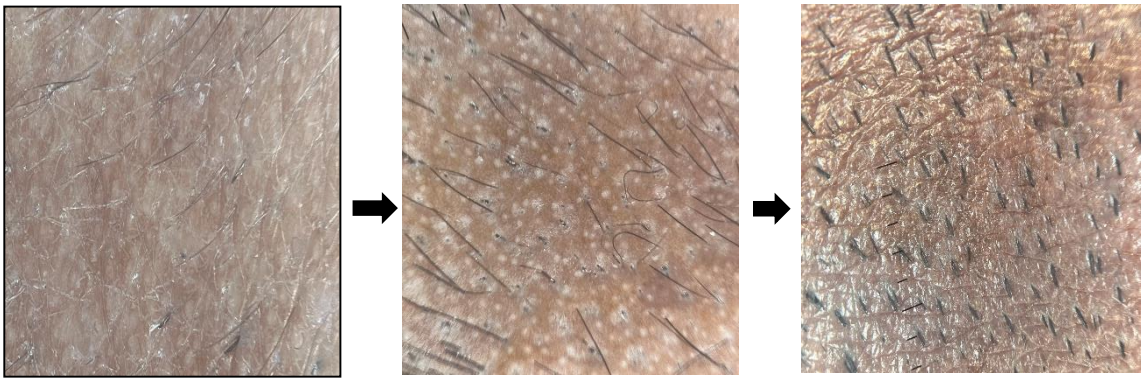
Table 1: Gender of the study participants

Gender	Frequency	Percentage
Male	4	33.3
Female	8	66.7

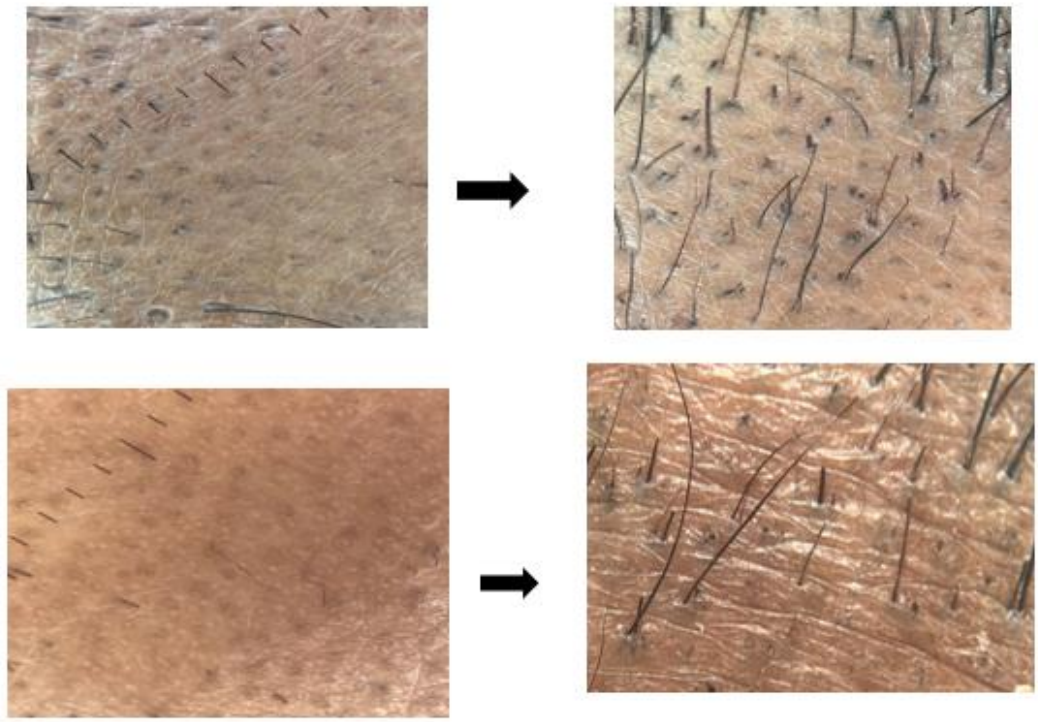
Two patients reported initial partial regrowth of hair after four weeks. Three patients had significant regrowth of hair after 12 weeks and 9 patients did not show any regrowth of hair.

None of the study participants experienced any side effects

Dermoscopic Images of Patients Showing Significant Regrowth of Hair



Dermoscopic Images of Patients Showing Partial Regrowth of Hair



Dermoscopic Images of Patients Showing No Regrowth of Hair

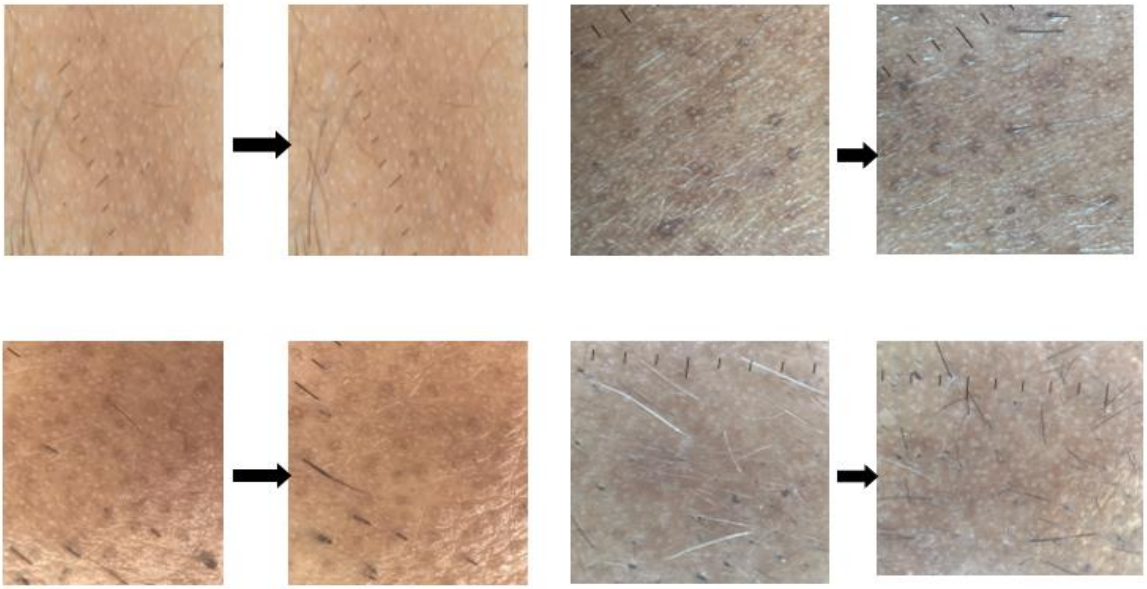


Table 3: Profile of the study participants who showed significant hair growth at 12 weeks

Responder	1	2	3
Week hair growth first observed	4	4	8
Duration of disease	9	10	9

DISCUSSION

The results of this research, which examined the effectiveness of 2% tofacitinib solution for treating alopecia areata on the scalp and beard, demonstrate promising outcomes. Despite the limited sample size, the 12-week study observed positive hair regrowth indicating a potential therapeutic benefit of topical tofacitinib. Particularly noteworthy is that two patients experienced partial regrowth after only four weeks, while three patients showed significant hair regrowth by the end of the study. This response highlights the potential effectiveness of topical tofacitinib in managing alopecia areata. The lack of negative side effects in our study also supports the safety data seen in trials of systemic JAK inhibitors, adding to the positive reputation of tofacitinib as a treatment for alopecia areata.

A recent study by Liu LY et al.[8] examined the effectiveness of topical tofacitinib treatment on hair regrowth in individuals with alopecia. Out of ten participants, three saw significant results with an average decrease of 34.6% in Severity of Alopecia Tool (SALT) scores, with a standard deviation of 23.2%. Notably, Patient 1 showed a dramatic 61% improvement from an initial SALT score of 100, while Patient 2 and 3 saw moderate improvements of 18% and 25% respectively, with starting scores of 17 and 40. Adverse effects, including 40% of participants reporting scalp skin irritation and 10% experiencing folliculitis, were observed but resolved without specific treatment. Interestingly, there were no significant reports of negative incidents. In a separate, unrestrained study, a remarkable 70% of the thirteen participants with AA, totalis, or universalis experienced complete hair regrowth. While there were some minor side effects noted, such as headaches, upper respiratory infections, and slightly elevated liver enzymes, there were no major adverse events reported.[9]

Although topical tofacitinib shows potential as a treatment for alopecia areata, the varying results among patients, including a significant number not experiencing hair regrowth, highlight the need for more research into individual responses to this approach. Further studies with longer follow-up periods and diverse patient groups are essential in determining the effectiveness, appropriate dosage, and long-term safety of topical tofacitinib for managing alopecia areata.

Limitations:

1) Limited sample size
2) No control group was included

CONCLUSION

The study's findings shed light on the promising potential and advantageous role of using topical tofacitinib 2% solution as a treatment for scalp and beard alopecia areata. In summary, while showing safety and promising results, ongoing investigations and extensive research are necessary to establish the position of topical tofacitinib as a viable therapeutic option for addressing alopecia areata and confirm its effectiveness, optimize dosages, and comprehend individual variations in response to the treatment.

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