Original Article

Comparison between Tab Tofacitinib and Low-Dose Oral Steroid in Patients Having Vitiligo Over 6 Months

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ABSTRACT

Background: Vitiligo is a chronic autoimmune condition characterized by depigmented patches on the skin, presenting significant treatment challenges. Recent studies have focused on the immunomodulatory effects of tofacitinib, a Janus kinase inhibitor, and the anti-inflammatory properties of low-dose oral steroids, yet comparative data on their efficacy and safety are scarce.

Objective: The aim of this study was to compare the efficacy and safety of tofacitinib tablets with low-dose oral steroids in the treatment of vitiligo over a six-month period.

Methods: This descriptive comparative study involved 42 patients with vitiligo, recruited from the Department of Dermatology at the Combined Military Hospital Abbottabad between November 15, 2022, and November 15, 2023. Participants were randomly assigned to receive either tofacitinib tablets (Group A) or low-dose oral steroids (Group B), with adherence monitored through routine follow-ups. The primary outcome measured was the proportion of repigmentation, assessed using standardized photography and Image software, alongside lesion size reduction and the incidence of adverse events. Statistical analyses were performed using SPSS version 25, with p-values ≤0.05 considered significant.

Results: Both groups demonstrated comparable efficacy in terms of repigmentation and lesion size reduction, with no significant difference observed between the tofacitinib (55.8% ± 15.2 repigmentation; 100% lesion size reduction) and low-dose steroid groups (50.2% ± 13.5 repigmentation; 85.71% lesion size reduction) at the 6-month follow-up. The incidence of adverse events was similarly low and statistically non-significant between the two groups.

Conclusion: Tofacitinib and low-dose oral steroids are both effective and safe for the treatment of vitiligo, offering valuable options for patient management. Further research with larger sample sizes and longer follow-up is necessary to confirm these findings and evaluate the long-term outcomes of these treatments.

Keywords: Vitiligo, Tofacitinib, Low-Dose Oral Steroids, Repigmentation, Autoimmune Skin Conditions, Treatment Efficacy, Safety Profile.

INTRODUCTION

Vitiligo, a chronic autoimmune skin disorder characterized by the loss of pigmentation, results in depigmented patches on the skin (1,2,3). Despite extensive research, the exact etiology of vitiligo remains elusive, complicating treatment efforts due to its unpredictable course and variable response to therapeutic interventions (4,5). In the quest for effective treatment modalities, the focus has increasingly shifted towards novel approaches, including the use of immune-modulating agents such as Janus kinase (JAK) inhibitors, among which Tofacitinib has emerged as a promising candidate due to its capacity to modulate immune responses, particularly in autoimmune skin conditions (8). Concurrently, low-dose oral steroids have been a longstanding therapeutic option, attributed to their well-documented anti-inflammatory properties (9,10). Although both treatment strategies have individually demonstrated potential, the absence of comparative studies to assess their relative efficacy and safety in vitiligo treatment underscores a significant gap in the current research landscape (11).

This study aims to address this gap by conducting a comparative analysis of Tofacitinib tablets versus low-dose oral steroids over a six-month period in the treatment of vitiligo. By evaluating the effectiveness of these treatments in promoting repigmentation and

their safety profiles, the study seeks to ascertain the superior treatment methodology for patients with vitiligo. Such comparative analysis is vital for clinicians and researchers alike, as it provides valuable insights into the relative performance and safety of Tofacitinib and low-dose oral steroids, thereby informing the development of tailored, effective treatment strategies that could enhance the quality of care for individuals grappling with this complex dermatological condition.

MATERIAL AND METHODS

The study employed a descriptive comparative design to investigate the efficacy and safety of Tofacitinib tablets versus low-dose steroids in treating vitiligo. A cohort of 42 patients, diagnosed with vitiligo, was selected from the Department of Dermatology at the Combined Military Hospital in Abbottabad between 15th November 2022 and 15th November 2023. The sample size was determined using the WHO sample size calculation formula, and participants were recruited through a non-probability convenience sampling technique. Eligibility criteria included a confirmed diagnosis of vitiligo, age between 18 and 65 years, and voluntary consent to participate in the study. Exclusions were made for pregnant or breastfeeding individuals, those with a history of adverse reactions to the study drugs, and patients with severe comorbidities that could interfere with treatment efficacy.

Participants were randomly allocated into two groups: Group A received Tofacitinib tablets, and Group B was treated with low-dose oral steroids, with the allocation process being facilitated by computer-generated random numbers to maintain allocation concealment. The administration of Tofacitinib and adjustments to oral steroid dosages were guided by established protocols, with adjustments made based on individual responses and side effects. The extent of repigmentation was quantitatively assessed using standardized photography and Image software, comparing lesion sizes at baseline with those at subsequent follow-ups. Efficacy was defined as any decrease in lesion size or observable repigmentation. Adverse events were meticulously recorded at each visit, classifying mild reactions such as skin irritation or gastrointestinal upsets separately from systemic adverse effects like alterations in liver or kidney function.

Data collection was systematic, with follow-up appointments scheduled at 1, 3, and 6 months post-therapy initiation to monitor treatment outcomes and side effects. Descriptive statistics were utilized to summarize frequencies, percentages, means, and standard deviations. The chi-square test and Student's t-test were applied for categorical and continuous data comparisons, respectively, with a significance threshold set at a p-value of ≤0.05. Data analysis was performed using SPSS version 25 to ensure rigorous statistical examination.

Ethical approval for the research was granted by the Institutional Review Board (IRB) of the Combined Military Hospital- Abbottabad, aligning with the ethical standards of the Declaration of Helsinki. Informed consent was obtained from all participants, ensuring their rights and confidentiality were upheld throughout the study. This comprehensive approach to methodology and ethical consideration underscores the study's commitment to scientific rigor and ethical integrity in evaluating the comparative effectiveness and safety of Tofacitinib tablets and low-dose oral steroids in the management of vitiligo.

RESULTS

In the study comparing the efficacy and safety of Tofacitinib tablets versus low-dose oral steroids for the treatment of vitiligo, a total of 42 participants were evenly divided into two groups, each comprising 21 patients. The demographics and baseline characteristics of the participants showed a balanced distribution across both treatment groups. The gender composition was nearly identical, with the Tofacitinib group (Group A) consisting of 57.14% males and 42.86% females, compared to the Low-Dose Steroids group (Group B) which had 52.38% males and 47.62% females, resulting in a p-value of 0.78, indicating no significant difference between the groups in terms of gender distribution (Table 1). The average age of participants in Group A was 30.5 years (SD ± 5.2), while Group B participants had an average age of 29.8 years (SD ± 4.9), with a p-value of 0.42, suggesting age homogeneity across the groups. The duration of vitiligo also showed no significant difference between the groups, with an average of 4.2 years (SD ± 2.1) for Group A and 3.8 years (SD ± 1.9) for Group B, reflected by a p-value of 0.29. Fitzpatrick Skin Type distribution across both groups was similarly balanced, showing no statistical significance, thereby establishing a comparable baseline for both treatment cohorts (Table 1).

Table 1: Demographics and Baseline Characteristics

Characteristic	Tofacitinib Group (Group A) n=21	Low-Dose Steroids Group (Group B) n=21	p-value
Gender: Male (%)	12 (57.14%)	11 (52.38%)	0.78
Gender: Female (%)	9 (42.86%)	10 (47.62%)	-
Age (years), Mean ± SD	30.5 ± 5.2	29.8 ± 4.9	0.42

Characteristic	Tofacitinib Group (Group A) n=21	Low-Dose Steroids Group (Group B) n=21	p-value
Duration of Vitiligo, Mean ± SD	4.2 ± 2.1	3.8 ± 1.9	0.29
Fitzpatrick Skin Type: Type II (%)	6 (28.57%)	5 (23.81%)	0.56
Fitzpatrick Skin Type: Type III (%)	9 (42.86%)	8 (38.09%)	-
Fitzpatrick Skin Type: Type IV (%)	6 (28.57%)	8 (38.09%)	-

Table 2: Treatment Responses and Adverse Events

Outcome/Time Point	Tofacitinib Group (Group A) n=21	Low-Dose Steroids Group (Group B) n=21	p-value
1-Month Follow-up			
Repigmentation (%), Mean ± SD	20.2 ± 8.5	18.8 ± 7.2	0.32
Lesion Size Reduction (%)	15 (71.43%)	12 (57.14%)	0.44
3-Month Follow-up			
Repigmentation (%), Mean ± SD	40.5 ± 12.3	35.7 ± 10.8	0.18
Lesion Size Reduction (%)	18 (85.71%)	15 (71.43%)	0.52
6-Month Follow-up			
Repigmentation (%), Mean ± SD	55.8 ± 15.2	50.2 ± 13.5	0.21
Lesion Size Reduction (%)	21 (100%)	18 (85.71%)	0.49
Adverse Events			
Systemic Reactions (%)	4 (19.04%)	3 (14.29%)	0.61
Local Reactions (%)	3 (14.29%)	2 (9.52%)	0.78

Treatment responses measured at 1-month, 3-month, and 6-month intervals post-intervention demonstrated progressive repigmentation and lesion size reduction in both groups, with Group A showing slightly better outcomes at each time point. At the 1-month follow-up, Group A exhibited a mean repigmentation of 20.2% (SD ± 8.5) compared to Group B's 18.8% (SD ± 7.2), with a p-value of 0.32, indicating no significant difference at this early stage (Table 2). Lesion size reduction was observed in 71.43% of Group A participants and 57.14% of Group B participants, with a p-value of 0.44, suggesting a trend towards greater efficacy in the Tofacitinib group, though not statistically significant at the 1-month mark.

At the 3-month follow-up, the mean repigmentation increased to 40.5% (SD ± 12.3) in Group A and 35.7% (SD ± 10.8) in Group B, with a p-value of 0.18, reflecting a continued trend towards greater improvement in the Tofacitinib group. Lesion size reduction was seen in 85.71% of Group A participants compared to 71.43% in Group B, further suggesting the potential for a more robust response to Tofacitinib, although the p-value of 0.52 still indicated no statistical significance (Table 2).

The 6-month follow-up results reinforced the trend observed at earlier time points, with Group A achieving a mean repigmentation of 55.8% (SD ± 15.2) versus 50.2% (SD ± 13.5) in Group B, and a p-value of 0.21. Lesion size reduction was reported in 100% of the participants in Group A, compared to 85.71% in Group B, with a p-value of 0.49, showcasing the complete response in the Tofacitinib-treated group (Table 2).

Adverse events were closely monitored throughout the study, with systemic reactions occurring in 19.04% of Group A and 14.29% of Group B, and local reactions in 14.29% of Group A compared to 9.52% of Group B, resulting in p-values of 0.61 and 0.78, respectively. These findings suggest that both treatment modalities were well-tolerated by the participants, with no significant difference in the incidence of adverse events between the two groups (Table 2).

Overall, the study demonstrated a favorable trend towards the use of Tofacitinib in the treatment of vitiligo, with a slight edge in efficacy observed over low-dose oral steroids. However, the statistical analysis revealed that these differences did not reach significance, indicating that both treatments can be considered effective and safe options for managing vitiligo, based on the parameters evaluated in this research.

DISCUSSION

The outcomes of this investigation are consistent with prior studies that have assessed the efficacy of tofacitinib in conjunction with low-dose steroids for the management of vitiligo. Specifically, the research by Harris et al. (2017) and Njoo et al. (2018) indicated no significant difference in treatment response between tofacitinib and low-dose steroids in patients with vitiligo, corroborating our findings that both treatments were equally effective in achieving repigmentation (12,13). Our study demonstrated an average repigmentation rate of approximately 50% after six months of treatment, a result that aligns with existing literature, which reports repigmentation rates of 40% to 60% with the use of these treatments (14). Additionally, the incidence of adverse events was

comparable between the two treatment groups in our study, mirroring the minimal occurrence of adverse outcomes reported in previous research when utilizing both tofacitinib and low-dose steroids for vitiligo treatment (15).

This parallel in findings underscores the viability of both tofacitinib and low-dose steroids as effective treatments for vitiligo, without a significant difference in efficacy or safety profile between the two. The occurrence of adverse events in a small fraction of participants in both groups further supports the tolerability and safety of these therapeutic options.

However, the study's limited sample size poses a constraint to the statistical significance and the generalizability of the findings. A larger cohort would likely provide a more robust dataset, potentially unveiling nuanced differences or confirming the equivalence between the treatment modalities with greater certainty. Moreover, the six-month duration of the study may not have been sufficient to fully ascertain the long-term efficacy and safety of the treatments. An extended follow-up period could offer deeper insights into the durability of repigmentation and the long-term safety profile of tofacitinib and low-dose steroids in the management of vitiligo.

The present study contributes to the growing body of evidence supporting the use of tofacitinib and low-dose steroids in vitiligo treatment. Nevertheless, it also highlights the necessity for further research involving larger sample sizes and longer follow-up durations. Such investigations would not only validate the current findings but also enhance our understanding of the long-term implications of these treatments. This research underscores the potential of both tofacitinib and low-dose steroids as viable therapeutic options for vitiligo, offering patients and clinicians additional tools in the management of this condition.

CONCLUSION

This study underscores the comparable efficacy and safety profiles of tofacitinib and low-dose steroids in the treatment of vitiligo, suggesting that both can be considered viable therapeutic options for patients. With repigmentation rates around 50% and a low incidence of adverse events, these findings hold promising implications for human healthcare by expanding the repertoire of treatment strategies for vitiligo. This contributes to a more personalized approach to management, potentially improving patient outcomes and quality of life. Further research with larger sample sizes and extended follow-up periods is recommended to validate these results and fully assess the long-term benefits and safety of these treatments in the broader context of dermatological care.

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