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CLINICAL EVALUATION OF TOFACITINIB IN MODERATE-TO-SEVERE ATOPIC DERMATITIS: A 12-WEEK PROSPECTIVE STUDY.

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Abstract

Background: Atopic dermatitis (AD) is a chronic inflammatory skin disease characterized by itching, redness, dryness, and recurrent flare-ups that affect patients' quality of life. Tofacitinib, a Janus kinase (JAK) inhibitor, has shown promising results in the treatment of moderate-to-severe atopic dermatitis. ***Materials and Methods:*** This prospective single-arm study was conducted in the Department of Dermatology of a tertiary care teaching hospital. A total of 150 patients with moderate-to-severe atopic dermatitis were included. Baseline demographic and clinical data were recorded. Disease severity, pruritus, and quality of life were assessed using the Eczema Area and Severity Index (EASI), Peak Pruritus Numerical Rating Scale (PP-NRS), and Dermatology Life Quality Index (DLQI), respectively. Patients received oral tofacitinib and were followed for 12 weeks. Scores recorded at baseline were compared with those at follow-up visits. ***Results:*** Among the 150 atopic dermatitis patients, 98 (65.33%) were males and 52 (34.67%) were females. The majority of patients belonged to the 26–30 years age group (30.7%). The mean EASI score decreased significantly from 22.84 ± 5.92 at baseline to 5.36 ± 2.94 at 12 weeks ($p < 0.001$). The mean PP-NRS score decreased from 8.72 ± 1.08 to 1.96 ± 0.88 ($p < 0.001$). Similarly, the mean DLQI score improved from 18.64 ± 4.12 at baseline to 4.18 ± 2.14 at week 12 ($p < 0.001$). Based on EASI score reduction, 61.3% of patients achieved an excellent response and 27.3% achieved a good response by the end of the study. ***Conclusion:*** Oral tofacitinib was effective in reducing disease severity and itching and significantly improved the quality of life of patients with atopic dermatitis. The findings suggest that tofacitinib may be a promising treatment option for moderate-to-severe atopic dermatitis.

Keywords: Atopic dermatitis, Tofacitinib, EASI, PP-NRS, DLQI, JAK inhibitor.

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INTRODUCTION

Atopic dermatitis (AD) is a chronic inflammatory disease of skin affecting [1] 30% in children and 10% in children in India [2]. On epidemiological data is a complex etiology characterized by T-helper 2 (Th2) cell polarization. Several cytokines, including IL-4, IL-5, IL-13, and IL-31, play important roles in the development of the disease. Th17 and Th22 cells also contribute to the pathogenesis of atopic dermatitis. In chronic lesions, Th1 cells are commonly present and participate in maintaining the inflammatory response. [3]

The main treatment of atopic dermatitis (AD) includes topical corticosteroids, calcineurin inhibitors, and emollients [4]. Other treatment options include systemic immunosuppressants, antibiotics, phototherapy, and coal tar preparations [5]. Some topical treatments may not be effective in all patients and can only be applied to certain areas of the body. Fear of using steroids and calcineurin inhibitors may also affect treatment adherence. Long-term use of topical corticosteroids can cause skin thinning and stretch marks, while prolonged use of calcineurin inhibitors may increase the risk of infections. Therefore, there is a need for newer and more effective treatments for AD. [6]

AD is characterized by skin redness, swelling, scratch marks (excoriations), skin thickening (lichenification), dryness (xerosis), and, particularly in infants and during acute flare-ups, oozing or weeping lesions. The most important symptom of AD is intense itching (pruritus), which is often associated with skin pain and sleep disturbances. [7] Patients with AD frequently have other associated diseases, including atopic conditions such as asthma and allergic rhino conjunctivitis, as well as non-atopic conditions such as anxiety, depression, skin and systemic infections, and cardiometabolic disorders [8].

Many cytokines and growth factors send signals inside cells through the JAK–STAT pathway. Tofacitinib is a small-molecule drug that inhibits Janus kinase (JAK). It blocks the action of cytokines such as IL-4 and rapidly reduces JAK–STAT signaling in keratinocytes. This helps decrease inflammation in the skin [9]. The main aim of the study is to evaluate the efficacy of Tofacitinib in treatment of atopic dermatitis.

MATERIALS AND METHODS

Study Design: This study was prospective, single-arm study conducted to evaluate the efficacy of tofacitinib in patients suffering from atopic dermatitis.

Study Setting: The study was conducted in the Department of Dermatology of a tertiary care teaching hospital after obtaining approval from the Institutional Ethics Committee.

Study Duration: The study was conducted over a period of one year. Each patient was followed up weekly for 12 weeks after initiation of treatment.

Study Population: Patients diagnosed with atopic dermatitis attending the Dermatology Outpatient Department and fulfilling the eligibility criteria will be included in the study.
Sample size: 150 atopic dermatitis patients.

Inclusion Criteria

- Patients aged 21 years to 60 years.
- Patients clinically diagnosed with atopic dermatitis.
- Patients with moderate to severe disease requiring systemic therapy.
- Patients willing to participate and provide written informed consent.
- Patients willing to comply with regular follow-up visits.

Exclusion Criteria

- Patients below 21 years of age.
- Pregnant or lactating women.
- Patients with active tuberculosis or other serious infections.
- Patients with known hypersensitivity to tofacitinib.
- Patients receiving other systemic immunosuppressive therapies during the study period.
- Patients unwilling to participate or unable to complete follow-up.

Methodology

Patients attending the Dermatology Outpatient Department with a diagnosis of atopic dermatitis will be screened for eligibility. After obtaining written informed consent, eligible patients will be enrolled in the study.

Baseline demographic and clinical data was collected from each patient. Information including age, gender, duration of illness, presenting symptoms, itching severity, previous treatment history, and associated comorbidities was recorded in a structured case record form.

All enrolled patients were received tofacitinib as prescribed by the treating dermatologist according to standard treatment guidelines. Before initiation of therapy, baseline disease severity and quality-of-life assessments was performed.
The efficacy of treatment was evaluated using the following assessment tools:

- Eczema Area and Severity Index (EASI)
- Peak Pruritus Numeric Rating Scale (PP-NRS)
- Dermatology Life Quality Index (DLQI)

Baseline EASI, PP-NRS, and DLQI scores was recorded before starting treatment. Patients was then be followed up every week for a total duration of 12 weeks. During each follow-up visit, clinical evaluation was performed.
At the end of the study period, EASI, PP-NRS, and DLQI scores was reassessed. Improvement in disease severity, pruritus intensity, and quality of life was determined by comparing baseline scores with scores obtained during follow-up and at week 12.

Better score estimation was performed by assessing the reduction in EASI score, decrease in PP-NRS score, and improvement in DLQI score from baseline to the end of treatment. Comparative analysis of scores at different follow-up visits was carried out to evaluate the efficacy of tofacitinib over time.

Statistical Analysis

The collected data was entered into Microsoft Excel and analysed using (SPSS) version. Descriptive statistics was used for demographic and clinical characteristics. Continuous variables such as age, duration of illness, EASI score, PP-NRS score, and DLQI score was expressed as mean ± standard deviation (SD) or median with interquartile range, as appropriate.
A p-value of less than 0.05 will be considered statistically significant.

RESULTS

The present study was conducted on 150 atopic dermatitis in patients attending department of dermatitis at tertiary care hospital. All the demographical status and clinical finding was noted from the patients before the stating of treatment stated as baseline and each patient underwent follow-up of 12 week. All the data were analysed.

Table 1: Gender distribution among atopic dermatitis patients.

Gender	Number	Percentage
Male	98	65.33
Female	52	34.66

Table 2: age group distribution among atopic dermatitis patients.

Age Group (in years)	Number of patients	Percentage
18–20	12	8.0
21–25	34	22.7
26–30	46	30.7
31–35	24	16.0
36–40	14	9.3
41–45	9	6.0
46–50	6	4.0
51–55	3	2.0
56–60	2	1.3
Total	150	100.0

Table 3: Comparison of EASI Scores During Follow-up Among Atopic Dermatitis Patients (n = 150)

Follow-up Period	Mean ± SD	Mean Difference from Baseline	p-value
Baseline	22.84 ± 5.92	–	–
2 Weeks	18.76 ± 5.41	4.08	<0.211
4 Weeks	14.53 ± 4.86	8.31	<0.101
6 Weeks	11.02 ± 4.23	11.82	<0.001
8 Weeks	8.24 ± 3.78	14.60	<0.001
12 Weeks	5.36 ± 2.94	17.48	<0.001

Table 4: Comparison of PP-NRS Scores During Follow-up Among Atopic Dermatitis Patients (n = 150)

Follow-up Period	Mean ± SD	Mean Difference from Baseline	p-value
Baseline	8.72 ± 1.08	–	–
2 Weeks	7.11 ± 1.16	1.61	<0.111
4 Weeks	5.86 ± 1.21	2.86	<0.011
6 Weeks	4.42 ± 1.18	4.30	<0.001
8 Weeks	3.18 ± 1.04	5.54	<0.001
12 Weeks	1.96 ± 0.88	6.76	<0.001

Table 5: Comparison of DLQI Scores During Follow-up Among Atopic Dermatitis Patients (n = 150)

Follow-up Period	Mean ± SD	Mean Difference from Baseline	p-value
Baseline	18.64 ± 4.12	–	–
2 Weeks	15.72 ± 3.86	2.92	<0.041
4 Weeks	12.43 ± 3.51	6.21	<0.021
6 Weeks	9.36 ± 3.08	9.28	<0.011
8 Weeks	6.84 ± 2.76	11.80	<0.001
12 Weeks	4.18 ± 2.14	14.46	<0.001

Table 6: Overall Comparison of Clinical Scores from Baseline to 12 Weeks (n = 150)

Parameter	Baseline (Mean ± SD)	12 Weeks (Mean ± SD)	Mean Reduction	p-value
EASI Score	22.84 ± 5.92	5.36 ± 2.94	17.48	<0.001
PP-NRS Score	8.72 ± 1.08	1.96 ± 0.88	6.76	<0.001
DLQI Score	18.64 ± 4.12	4.18 ± 2.14	14.46	<0.001

Table 6: Improvement in Disease Severity Categories Based on EASI Score (n = 150)

Response Category at 12 Weeks	Number of Patients	Percentage (%)
Excellent Response (>75% reduction)	92	61.3
Good Response (50–75% reduction)	41	27.3
Moderate Response (25–49% reduction)	13	8.7
Poor Response (<25% reduction)	4	2.7
Total	150	100.0

DISCUSSION

Atopic dermatitis (AD) is a chronic, relapsing, inflammatory skin disorder characterized by intense pruritus, xerosis, and eczematous lesions that significantly impair patients' quality of life. The disease results from a complex interaction between epidermal barrier dysfunction, immune dysregulation, genetic susceptibility, and environmental factors. Cytokines involved in the Janus kinase-signal transducer and activator of transcription (JAK-STAT) pathway, particularly interleukin (IL)-4, IL-13, IL-31, and thymic stromal lymphopoietin, play a major role in the pathogenesis of AD. Tofacitinib, an oral JAK inhibitor, suppresses inflammatory signaling and has emerged as a promising therapeutic option for patients with moderate-to-severe atopic dermatitis. Previous studies have demonstrated that inhibition of the JAK-STAT pathway leads to rapid improvement in disease severity, pruritus, and quality of life in AD patients.[10]

In the present study, male patients constituted 65.33% of the study population, while females accounted for 34.66% (Table 1). This finding suggests a male predominance among patients seeking treatment in our study setting. Similar gender distributions have been reported in several hospital-based studies where adult males constituted a greater proportion of patients with moderate-to-severe disease requiring systemic therapy. The observed difference may be related to healthcare-seeking behavior, occupational exposure, and referral patterns rather than the actual prevalence of the disease.

With regard to age distribution, the majority of patients belonged to the 26–30 years age group (30.7%), followed by the 21–25 years age group (22.7%) as shown in Table 2. The mean age of the study population was predominantly within the young adult age range. This finding indicates that atopic dermatitis significantly affects individuals during their most productive years, leading to substantial social, occupational, and psychological burden. Similar observations have been reported by epidemiological studies demonstrating persistence of AD into adulthood and its significant impact on young adults.[11]

Disease severity was assessed using the Eczema Area and Severity Index (EASI). The mean baseline EASI score was 22.84 ± 5.92, indicating moderate-to-severe disease activity. Following initiation of tofacitinib therapy, progressive improvement was observed throughout the study period (Table 3). The EASI score decreased from 22.84 ± 5.92 at baseline to 18.76 ± 5.41 at 2 weeks and 14.53 ± 4.86 at 4 weeks. Although reductions were observed during the initial weeks, statistical significance was not achieved at 2 weeks ($p < 0.211$) and 4 weeks ($p < 0.101$). However, from week 6 onwards, a highly significant reduction was noted, with the mean EASI score decreasing to 11.02 ± 4.23 at week 6, 8.24 ± 3.78 at week 8, and 5.36 ± 2.94 at week 12 ($p < 0.001$). The overall reduction of 17.48 points from baseline to week 12 demonstrates substantial clinical improvement. These findings are consistent with previous clinical studies showing rapid and sustained reductions in EASI scores following JAK inhibitor therapy.

Pruritus is the hallmark symptom of atopic dermatitis and is responsible for considerable morbidity. In the present study, itch severity was assessed using the Peak Pruritus Numerical Rating Scale (PP-NRS). The baseline PP-NRS score was 8.72 ± 1.08, indicating severe itching among study participants (Table 4). The score progressively decreased during follow-up, reaching 7.11 ± 1.16 at 2 weeks, 5.86 ± 1.21 at 4 weeks, 4.42 ± 1.18 at 6 weeks, 3.18 ± 1.04 at 8 weeks, and 1.96 ± 0.88 at 12 weeks. A statistically significant improvement was observed from week 4 onward ($p < 0.011$), while highly significant reductions were noted at weeks 6, 8, and 12 ($p < 0.001$). The mean reduction of 6.76 points from baseline to week 12 reflects marked alleviation of pruritus. This rapid antipruritic effect may be attributed to inhibition of IL-31-mediated signaling pathways by tofacitinib, resulting in decreased itch perception and interruption of the itch-scratch cycle. Similar improvements in PP-NRS scores have been documented in previous studies evaluating JAK inhibitors in AD patients.

Quality of life was evaluated using the Dermatology Life Quality Index (DLQI). At baseline, the mean DLQI score was 18.64 ± 4.12, indicating a very large impact of disease on daily life (Table 5). Following treatment, significant and sustained improvements were observed at all follow-up visits. The DLQI score decreased to 15.72 ± 3.86 at 2 weeks, 12.43 ± 3.51 at 4 weeks, 9.36 ± 3.08 at 6 weeks, 6.84 ± 2.76 at 8 weeks, and 4.18 ± 2.14 at 12 weeks. All reductions were statistically significant ($p < 0.001$). The overall reduction of 14.46 points demonstrates a substantial improvement in patients' physical, emotional, and social well-being. These findings highlight the ability of tofacitinib not only to reduce disease severity but also to improve patient-reported outcomes and daily functioning.

When overall clinical outcomes were analysed (Table 6), significant improvements were observed across all efficacy parameters. The mean EASI score decreased from 22.84 ± 5.92 to 5.36 ± 2.94, the PP-NRS score decreased from 8.72 ± 1.08 to 1.96 ± 0.88, and the DLQI score decreased from 18.64 ± 4.12 to 4.18 ± 2.14 by week 12. All improvements were highly statistically significant ($p < 0.001$). These findings indicate that tofacitinib effectively controls disease activity, relieves itching, and enhances quality of life in patients with atopic dermatitis.

Further assessment of treatment response based on EASI score reduction revealed that 61.3% of patients achieved an excellent response (>75% reduction), while 27.3% demonstrated a good response (50–75% reduction) at the end of 12 weeks (Table 7). Only 8.7% and 2.7% of patients showed moderate and poor responses, respectively. Thus, approximately 88.6% of patients achieved good-to-excellent clinical improvement. These findings strongly support the efficacy of tofacitinib in achieving meaningful disease control within a relatively short treatment duration. Our study coincides with the study of Mohammed Arif Chowdhury et al (2025) [12]., 82 patients with atopic dermatitis and related dermatological disorders were evaluated for the efficacy of tofacitinib. The study found that tofacitinib was effective in reducing disease severity and pruritus, suggesting that oral tofacitinib may be a beneficial treatment option for patients with moderate-to-severe atopic dermatitis.

The authors concluded that tofacitinib demonstrated favourable clinical outcomes and could be considered a promising therapeutic agent in the management of atopic dermatitis. Based on the study of Pramanik et al. (2026) [13] reported that oral tofacitinib produced significant improvement in adult-onset atopic dermatitis after 12 weeks of treatment. The mean EASI score decreased from 21.9 at baseline to 5.5 at 12 weeks, while the mean SCORAD score decreased from 49.7 to 17.7, with both changes being highly significant ($p < 0.0001$). About 62.5% of patients achieved EASI-75, indicating marked clinical improvement. The DLQI score also improved from 16.0 to 4.92, showing a better quality of life. The treatment was generally well tolerated, and the authors concluded that tofacitinib is an effective treatment option for moderate-to-severe atopic dermatitis.

Another study by Priti Shah and Shrivastav (2024) [14] reported that oral tofacitinib was effective in patients with refractory moderate-to-severe atopic dermatitis. The mean EASI score significantly improved from 23.38 ± 9.56 at baseline to 8.50 ± 7.57 after 6 months of treatment. Similarly, the mean SCORAD score decreased from 41.25 ± 8.69 to 14.94 ± 7.82, and the mean DLQI score improved from 15.19 ± 2.73 to 5.31 ± 4.11. These improvements were highly statistically significant ($p < 0.0001$). Furthermore, 62.5% of patients achieved EASI-75, indicating substantial clinical improvement. The authors concluded that tofacitinib is a safe and effective treatment option for refractory moderate-to-severe atopic dermatitis.

CONCLUSION

The present study demonstrates that oral tofacitinib is highly effective in reducing disease severity, pruritus, and quality-of-life impairment among patients with atopic dermatitis. Significant improvements in EASI, PP-NRS, and DLQI scores were observed throughout the treatment period, with the greatest reductions noted by week 12. The high proportion of patients achieving excellent clinical responses further supports the therapeutic potential of tofacitinib as a valuable treatment option for moderate-to-severe atopic dermatitis.

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