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A REAL-WORLD EFFECTIVENESS AND SAFETY OF TOFACITINIB OINTMENT IN ADULT PATIENTS WITH ATOPIC DERMATITIS (TOP STUDY)

Dermatology

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ABSTRACT

Background: Atopic dermatitis (AD) is chronic inflammatory skin condition presenting with severe pruritus. AD has significant prevalence among children (15–30%) and adults (2–10%), affecting quality of life. The primary objective of the study is to evaluate the effectiveness of Tofacitinib ointment in improving clinical outcomes in patients with AD, measured by change in Eczema Area and Severity Index (EASI) score from baseline to 4 weeks. **Methodology:** The present study is retrospective, multicentre, observational OPD-based study that included dermatology patients from various centres in India. Patients who fulfilled the following eligibility criteria were included: Adults aged ≥18 years with AD; patients who were treated with tofacitinib ointment during study period and assessment of EASI score before and after application of treatment. The difference in outcome measures (EASI scores) at 4 weeks relative to baseline was determined using paired t-tests, and percentage improvement in efficacy was calculated based on mean differences. A significance level of $p<0.05$ for two-sided test was employed for statistical analysis. **Results:** The study enrolled 4,921 patients with mean age of 39.97 ± 13.07 years; male prevalence was slightly higher than females (53.5% vs. 46.5%). Most patients had moderate AD (49.5%), while 38.7% and 11.8% had mild and severe disease, respectively. Maximum patients received tofacitinib ointment twice daily (60.1%), while 39.9% used it once daily. There was remarkable improvement in level of disease severity among the subjects. The average EASI score dropped from 30.64 ± 28.05 to 17.04 ± 20.72, which represents a 44.4% decrease after 4 weeks. Most patients tolerated the treatment well. **Conclusion:** The present study shows Tofacitinib as an effective therapeutic option for the management of AD. Owing to its widespread availability, cost-effectiveness, demonstrated clinical efficacy, and manageable safety profile, it may serve as a valuable treatment alternative for adults with moderate-to-severe AD.

KEYWORDS

Atopic Dermatitis, Tofacitinib, Eczema Area Severity Index (EASI) Score

INTRODUCTION

Atopic dermatitis (AD) is a chronic inflammatory skin condition presenting with severe pruritus. AD has a significant prevalence among children (15–30%) and adults (2–10%), affecting their quality of life (1). Limited epidemiologic data exist on the AD in India (2). Due to an underlying complex aetiology, AD is attributed to the TH2 polarization associated with the release of cytokines such as IL-31, IL-13, IL-5, IL-4, IL-17, and IL-22. Additionally, in chronic lesions, TH1 cells are released (3).

Moderate to severe AD exhibits resistance to treatment modalities; however, the crucial treatment options include topical calcineurin inhibitors, emollients, phototherapy, and topical corticosteroids (4). Several immunomodulatory drugs, such as azathioprine, cyclosporine, and methotrexate, have demonstrated varied effectiveness in refractory AD. Newer targeted therapies have been introduced following the appropriate understanding of AD pathogenesis (5).

Personalized medical intervention is required to manage AD and achieve desirable outcomes (6). One such medication is Tofacitinib, a pan-Janus kinase (JAK) inhibitor that specifically inhibits JAK/1 and JAK/3 pathways, resulting in the suppression of Th1, Th2, Th17, and Th22 cell lines. Tofacitinib has shown beneficial effects in various inflammatory dermatoses. Topical tofacitinib (2% ointment) has gained approval in India for mild to moderate AD (7), but its application is limited to smaller body areas, which restricts its use in moderate and severe AD cases (7).

Several randomized clinical trials have reported the effectiveness and safety of Tofacitinib ointment in the management of AD. Most of the existing studies were limited by a smaller sample size, the inclusion of the patient population that does not completely represent the real-world clinical scenario, and shorter follow-up periods (8). Hence, the present study aims to assess the real-world effectiveness and safety profile of Tofacitinib ointment in AD patients. This will provide novel insights to clinicians and dermatologists to address the gap in knowledge by assessing the real-world implications of the use of Tofacitinib ointment effectiveness and safety profile in AD patients.

METHODOLOGY

The present study is a retrospective, multicenter, observational OPD-based study that included dermatology patients from various centres in India.

Study Population

Data was gathered from various centres across India, including clinics, hospitals, and healthcare institutions. Data was collected retrospectively by the dermatologists using a case report form. Appropriate ethical approval was taken from the ethics committee (EC) as per ICMR guidelines for ethical guidelines for biomedical research on human participants. As this is a retrospective study involving de-identified participants who cannot be contacted, a waiver of consent was sought from the ethics committee. Patient identities and personal data remained confidential and accessible only to the investigator's authorized personnel, IEC, and relevant regulatory authorities, as applicable.

Patients who fulfilled the following eligibility criteria were included: Adults aged ≥18 years diagnosed with AD; patients who were treated with tofacitinib ointment during the study period; and assessment of the Eczema Area and Severity Index (EASI) score before and after application of treatment.

Patients were excluded if they had dermatological conditions or any other systemic conditions that may interfere with the treatment outcomes, such as skin disorders or active infections; those who had undergone treatment with Tofacitinib ointment for less than 4 weeks; and those with incomplete medical records around the effectiveness or safety of topical Tofacitinib ointment.

Study Objective

The primary objective of the study is to evaluate the effectiveness of Tofacitinib ointment in improving clinical outcomes in patients with atopic dermatitis, measured by the change in EASI score from baseline to 4 weeks.

The secondary objective of the study is to evaluate the safety profile of Tofacitinib ointment in AD patients. Additionally, assess treatment duration, adherence, patient-reported outcomes, and factors influencing the effectiveness and safety of Tofacitinib ointment.

The Eczema Area Severity Index (EASI) score was used to assess the severity and extent of AD (9). The score ranges from 0- 72. Score 0 denotes clear or no eczema; Score 0.1 to 1 denotes almost clear; 1.1-7 denotes mild AD; 7.1 – 21 denotes moderate AD; 21.1-50 denotes severe AD, and > 51 denotes excessively severe disease

Data Collection

Data was recorded from each center as per the protocol and proforma. Demographic data included age and gender. Clinical assessment included reporting the severity of AD, any other skin conditions, frequency, and duration of application, effectiveness, and safety of tofacitinib ointment application, measured as a change in EASI score.

Statistical Analysis

Statistical analysis was done through the use of SPSS software. Descriptive statistics were employed to provide summary information on baseline characteristics, clinical data, and treatments. Age, weight, disease duration, and Eczema Area and Severity Index (EASI) scores were analyzed as continuous variables, thus presented as mean ± standard deviation (SD). Categorical variables were reported in terms of frequency and percentage.

The difference in the outcome measures (EASI scores) at 4 weeks relative to baseline was determined using paired t-tests, and the percentage improvement in efficacy was calculated based on mean differences. A significance level of $p<0.05$ for a two-sided test was employed for statistical analysis. The correlation between categorical variables (severity, skin types, and areas affected) and the clinicians' evaluation of the outcomes (efficacy and safety) was measured using Pearson Chi-square tests, as well as likelihood ratios where appropriate. The confidence interval for all statistical analyses was set at 95%.

RESULTS

The study included 4921 subjects. The mean age of the studied population was 39.97 ± 13.07 years old. Slight male prevalence can be noted as well, with 53.5% male patients and 46.5% being female (Table 1). Mean body weight was 65.99 ± 13.69 kg and mean duration of the disease was 7.28 ± 3.83 months.

The predominant form of the disease among all patients in our cohort was a condition characterized by dry skin (54.3%), whereas combination skin is second on the list (23.8%) (Table 2). Majority of patients in our sample did not experience any change related to seasonality (84.4%), yet, among patients that did experience seasonal changes, it occurred during summer (6.7%) and winter (6.6%).

As far as disease severity is concerned, most prevalent were moderate cases (49.5%), with 38.7% having mild cases and 11.8% having a severe form. As for the disease localization, face (17.0%) and neck (15.7%) areas prevailed. Symptoms that have been described by most patients were itching (58.6%), redness (52.9%), and dry skin (51.0%).

The topical application of tofacitinib ointment was prescribed twice daily in 60.1% of the study subjects, and the remaining 39.9% of the study participants were on once-daily topical application of the medication (Table 3).

There was a remarkable improvement in the level of disease severity among the subjects. The average EASI score dropped from 30.64 ± 28.05 to 17.04 ± 20.72, which represents a 44.4% decrease after 4 weeks (Table 4). The result indicates a considerable efficacy of the therapy, $p < 0.001$.

The treatment resulted in positive patient outcomes in most of the study subjects. For instance, 50.6% of the study population had "good" patient outcomes, while 44.4% had "excellent" results. On the other hand, very few patients experienced "fair" (4.7%) and "poor" (0.3%) treatment outcomes (Table 5).

The medication was safe, with 48.8% reporting "excellent" treatment tolerance, and 47.1% reported "good". Additionally, only 0.2% of the patients reported "poor" medication safety (Table 6). None of the study subjects reported adverse effects. Instead, 99.8% of the subjects had no adverse effects during the treatment process (Table 7).

There is evidence of an interaction between the level of efficacy of the treatment and disease severity, skin type, and anatomical distribution of lesions ($p < 0.001$ for all) (Table 8). This may suggest that certain clinical factors could impact therapeutic efficacy. It was noted that more severe cases resulted in comparatively greater numbers of patients experiencing “excellent” results, while those suffering from moderately severe conditions often experienced “good” results. Such observations could imply that the severity of disease affects treatment outcomes. In addition, the skin type of the patient affected the outcome; patients with dry skin showed comparatively better results, implying the effect of skin-related properties on therapy efficacy. Finally, there is evidence that the anatomical distribution of lesions influenced the efficacy of the treatments. Certain areas, such as the face, back, and chest, resulted in comparatively greater numbers of excellent outcomes.

There is statistical significance in the relationships between safety results and disease severity, skin type, and body locations involved ($p < 0.001$ for all) (Table 9). This implies that patient and disease factors may determine the safety of the treatment process. Those patients who had severe conditions had better safety rates than those with other severities, meaning the treatment process might not be the same for other severity types. Skin type was also found to affect the safety rate, where dry skin and sensitive skin were among those with good safety ratings, showing that skin type may have contributed to the treatment process. Safety ratings were quite good regardless of body location, with certain locations like the face, back, and chest having better rates compared to others.

Table 1. Demographic and Baseline Characteristics

Variable	Value
N	4921
Age (years)	39.97 ± 13.07
Gender	
Female, n (%)	2286 (46.5)
Male, n (%)	2635 (53.5)
Weight (kg)	65.99 ± 13.69
Duration of disease (months)	7.28 ± 3.83

Table 2. Clinical Characteristics of Atopic Dermatitis

Domain	Category	Frequency (n)	Percentage (%)
Skin Type	Combination	1170	23.8
	Dry	2671	54.3
	Oily	771	15.7
	Sensitive	309	6.3
Seasonal Variation	No variation	4151	84.4
	Autumn exacerbation	13	0.3
	Monsoon exacerbation	101	2.1
	Summer exacerbation	332	6.7
	Winter exacerbation	324	6.6
Severity of Condition	Mild	1904	38.7
	Moderate	2438	49.5
	Severe	579	11.8
Areas Affected	Face	839	17.0
	Neck	775	15.7
	Legs	638	13.0
	Arms	612	12.4
	Back	601	12.2
	Chest	557	11.3
	Scalp	443	9.0
	Abdomen	375	7.6
	Genital	78	1.6
	Other	3	0.1
Presenting Complaints	Itching	2886	58.6
	Redness	2605	52.9
	Dry skin	2509	51.0
	Rash	2245	45.6
	Inflammation	1613	32.8
	Scaling / Flaking	927	18.8
	Lichenification	162	3.3

Table 3. Treatment Regimen (Tofacitinib Ointment Usage)

Frequency of Application	n (%)
Once daily	1964 (39.9)
Twice daily	2957 (60.1)

Table 4. Change in Eczema Area and Severity Index (EASI) Scores (Baseline vs After 4 Weeks)

Parameter	Mean ± SD	% Reduction	p-value
Baseline EASI score	30.64 ± 28.05	—	—
EASI score at 4 weeks	17.04 ± 20.72	44.4%	<0.001*

* p value significant at 95% using paired t test

Table 5. Clinician's Global Assessment – Effectiveness

Category	n (%)

Excellent	2184 (44.4)
Good	2490 (50.6)
Fair	231 (4.7)
Poor	16 (0.3)

Table 6. Clinician's Global Assessment – Safety

Category	n (%)
Excellent	2403 (48.8)
Good	2318 (47.1)
Fair	190 (3.9)
Poor	10 (0.2)

Table 7. Adverse Events

Category	n (%)
No adverse events	4910 (99.8)
Yes	11 (0.2)

Table 8. Factors Influencing Treatment Effectiveness (Clinician's Global Assessment – Effectiveness)

Domain	Category	Excellent n (%)	Good n (%)	Fair n (%)	Poor n (%)	Total	p-value
Severity	Mild	882 (46.3)	972 (51.1)	49 (2.6)	1 (0.1)	1904	<0.001*
	Moderate	949 (38.9)	1340 (55.0)	139 (5.7)	10 (0.4)	2438	
	Severe	353 (61.0)	178 (30.7)	43 (7.4)	5 (0.9)	579	
Skin Type	Combination	410 (35.0)	670 (57.3)	84 (7.2)	6 (0.5)	1170	<0.001*
	Dry	1324 (49.6)	1263 (47.3)	79 (3.0)	5 (0.2)	2671	
	Oily	302 (39.2)	410 (53.2)	54 (7.0)	5 (0.6)	771	
	Sensitive	148 (47.9)	147 (47.6)	14 (4.5)	0 (0.0)	309	
Areas Affected	Abdomen	160 (42.7)	184 (49.1)	27 (7.2)	4 (1.1)	375	<0.001*
	Arms	216 (35.3)	367 (60.0)	28 (4.6)	1 (0.2)	612	
	Back	325 (54.1)	248 (41.3)	27 (4.5)	1 (0.2)	601	
	Chest	287 (51.5)	235 (42.2)	33 (5.9)	2 (0.4)	557	
	Face	416 (49.6)	400 (47.7)	21 (2.5)	2 (0.2)	839	
	Genital	27 (34.6)	47 (60.3)	2 (2.6)	2 (2.6)	78	
	Legs	250 (39.2)	365 (57.2)	22 (3.4)	1 (0.2)	638	
	Neck	324 (41.8)	409 (52.8)	41 (5.3)	1 (0.1)	775	
	Other	0 (0.0)	3 (100)	0 (0.0)	0 (0.0)	3	
	Scalp	179 (40.4)	232 (52.4)	30 (6.8)	2 (0.5)	443	

* p-values is considered significant at 95% CI and represent overall association between each domain and treatment effectiveness through Pearson's Chi-square test.

Table 9. Factors Influencing Safety (Clinician's Global Assessment – Safety)

Domain	Category	Excellent n (%)	Good n (%)	Fair n (%)	Poor n (%)	Total	p-value
Severity	Mild	940 (49.4)	921 (48.4)	40 (2.1)	3 (0.2)	1904	<0.001*
	Moderate	1095 (44.9)	1226 (50.3)	112 (4.6)	5 (0.2)	2438	
	Severe	368 (63.6)	171 (29.5)	38 (6.6)	2 (0.3)	579	
Skin Type	Combination	452 (38.6)	643 (55.0)	70 (6.0)	5 (0.4)	1170	<0.001*
	Dry	1448 (54.2)	1167 (43.7)	54 (2.0)	2 (0.1)	2671	
	Oily	334 (43.3)	384 (49.8)	50 (6.5)	3 (0.4)	771	
	Sensitive	169 (54.7)	124 (40.1)	16 (5.2)	0 (0.0)	309	
Areas Affected	Abdomen	165 (44.0)	185 (49.3)	25 (6.7)	0 (0.0)	375	<0.001*
	Arms	259 (42.3)	337 (55.1)	16 (2.6)	0 (0.0)	612	
	Back	330 (54.9)	245 (40.8)	23 (3.8)	3 (0.5)	601	
	Chest	299 (53.7)	226 (40.6)	29 (5.2)	3 (0.5)	557	
	Face	476 (56.7)	339 (40.4)	23 (2.7)	1 (0.1)	839	
	Genital	33 (42.3)	42 (53.8)	3 (3.8)	0 (0.0)	78	
	Legs	274 (42.9)	347 (54.4)	17 (2.7)	0 (0.0)	638	
	Neck	367 (47.4)	377 (48.6)	29 (3.7)	2 (0.3)	775	
	Other	3 (100)	0 (0.0)	0 (0.0)	0 (0.0)	3	
	Scalp	197 (44.5)	220 (49.7)	25 (5.6)	1 (0.2)	443	

* p-values is considered significant at 95% CI and represent overall association between each domain and treatment effectiveness through Pearson's Chi-square test.

DISCUSSION

The present study demonstrates the effectiveness and safety of tofacitinib ointment in the treatment of AD. The demographic predominantly consisted of middle-aged individuals with a slight male preponderance. Clinical characteristics of AD showed that the majority of the patients had dry skin type, followed by combination skin type, and most of them did not experience any change related to seasonality, with moderate to mild severity of AD.

Most AD patients were prescribed tofacitinib ointment twice daily, with the remaining patients receiving the medication once daily via topical application. A statistically significant association was reported between treatment efficacy and disease severity, skin type, and the anatomical distribution of lesions ($p < 0.001$ for all comparisons). Severe AD cases resulted in comparatively greater numbers of patients experiencing "excellent" results, while those suffering from moderately severe AD conditions often experienced "good" results, denoting that the severity of disease affects treatment outcomes. Patients with dry skin showed comparatively better results, implying the effect of skin-related properties on therapy efficacy. The effectiveness of the treatments was impacted by the anatomical distribution of lesions. Certain regions, like the chest, back, and face, showed relatively excellent results compared to other affected areas. Similarly, a statistically significant association was reported between safety results and disease severity, skin type, and body locations involved ($p < 0.001$ for all). Patients with severe AD types reported superior safety outcomes compared to other types of AD. Patients with dry and sensitive skin demonstrated favorable safety outcomes, suggesting that skin type potentially affects treatment tolerability.

In the present study, AD disease severity levels improved significantly after 4 weeks of tofacitinib ointment application; the average EASI score decreased by 44.4%, indicating significant efficacy of the therapy ($p < 0.001$). The clinician's overall assessment of the treatment's efficacy revealed excellent and good patient outcomes with a tolerable and safe profile. Similarly, in another study (10), eyebrows and eyelashes were the most commonly affected areas in AD patients, with symptoms including allergic rhinitis and eczema. In this study, patients had previously received systemic corticosteroid therapy; however, treatment was subsequently discontinued due to disease recurrence and corticosteroid-associated adverse effects. The duration of tofacitinib administration varied across several studies. For example, in a study, a significant improvement in AD symptoms was reported with a reduction of ~66.67% from baseline (10).

Management of AD has posed several challenges for many dermatologists. Systemic immunomodulators (azathioprine, cyclosporine, and methotrexate) are recommended by Indian

guidelines for patients with severe or resistant AD (4). The effectiveness of topical tofacitinib has been investigated in the literature. A randomized controlled trial (RCT) found that 69 adult patients with mild to moderate AD who used topical tofacitinib ointment (2%) for 4-weeks showed a significant improvement in EASI score (11). The reduction in EASI score from the baseline in the placebo group (vehicle ointment) versus in patients with topical tofacitinib was 29.9% and 81.7%, respectively. This highlights the suitability and safe tolerability of the ointment in AD patients (11). In another study (8), topical tofacitinib application twice daily for 4 weeks resulted in complete AD remission, highlighting that the medication was effective in the treatment of refractory eczema. Another study (1) found that topical tofacitinib application twice daily for 6 months showed significant improvement in EASI score (reduced by 62.5% from baseline), clinical symptoms in AD patients. Similarly, another study found that in AD patients who were resistant to multiple systemic agents, administration of 5-10 mg of tofacitinib over 8 weeks helped to attain an EASI score of 90% (7). Most of the existing studies investigated the role of tofacitinib in alleviating pruritus from baseline to six months.

In the present study, the face and neck were the most commonly affected areas, with patients reporting itching, redness, and dry skin as the predominant presenting complaints. Similarly, in another study, the most prevalent symptoms in AD patients were pruritus. Tofacitinib overcomes pruritus as it mitigates the overexpression of IL-13 and IL-4 by targeting JAK signalling (12).

The present study demonstrates that patients suffering from mild to moderate AD reported that tofacitinib ointment helped alleviate their symptoms. Currently available treatment options, including topical calcineurin inhibitors (TCIs) and topical corticosteroids (TCSs) are often unsuitable for application on sensitive anatomical sites such as the face, genital areas, and groin, thereby limiting effective symptom management in these regions (4,13). Tofacitinib offers a promising therapeutic alternative by enabling targeted and potentially safer application to these challenging areas.

The underlying etiology and pathogenesis of AD are multifactorial, involving a complex interplay of environmental, genetic, and immunological factors (14,15). AD initiation is dependent on the release of several cytokines such as IL-4, IL-13, and IL—31 (14). Cytokines and several growth factors use the activator of transcription (STAT) and JAK signal transducer pathway for signal transduction (15). Tofacitinib effectively inhibits cytokines, leading to the diminution of JAK–STAT signalling in keratinocytes (16).

Although several JAK inhibitors, including abrocitinib, ruxolitinib, and upadacitinib, have been investigated for the management of AD, direct head-to-head comparative data among these agents, particularly involving tofacitinib, remain limited. Consequently, there is insufficient evidence to guide clinicians in selecting the most appropriate JAK inhibitor for the treatment of AD (17). While JAKi are effective and cost-effective, further trials within the class and with existing systemic agents are required. Aside from a promising efficacy profile, tofacitinib offers a safe and well-tolerated option in mild to moderate AD patients over the course of 4 weeks (18).

The present study had several strengths. The retrospective study provides real-world evidence on the effectiveness and safety profile of tofacitinib ointment in AD patients. A large sample size (n=4921) offers meaningful insights to comprehensively assess the association of clinically relevant parameters, including disease severity, skin type, and anatomical distribution of lesions, and treatment outcome with the medication. Furthermore, clinician-reported global assessments strengthened the clinical relevance and applicability of the study findings. The findings demonstrate the effectiveness and tolerability of therapy in sensitive and commonly affected areas, especially in all skin types of AD patients, which has been lacking in previous studies.

Certain limitations of the study need to be acknowledged. Firstly, a relatively short follow-up duration (4 weeks) limits the assessment of long-term effectiveness and sustained safety outcomes of tofacitinib ointment in AD patients. Secondly, the majority of the patients had mild-to-moderate AD, thereby limiting the generalizability of the findings to severe or refractory cases. Thirdly, a lack of assessment of potential confounding factors, including prior treatments, environmental influences, and skincare practices, affects the overall findings of the treatment response with tofacitinib. Further, larger multicentric RCTs with longer follow-up periods are required to validate the effectiveness and safety response in AD patients.

CONCLUSION

The present study shows tofacitinib to be an effective therapeutic option for the management of AD. Owing to its widespread availability, cost-effectiveness, demonstrated clinical efficacy, and manageable safety profile, it may serve as a valuable treatment alternative for adults with moderate-to-severe AD, particularly in patients where dupilumab or cyclosporine are contraindicated, ineffective, or inaccessible. Nevertheless, larger prospective, long-term RCTs are warranted to further establish its efficacy and long-term safety profile.

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