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Original Research Article

Comparative Evaluation of Efficacy and Safety of Topical Tacrolimus versus Topical Corticosteroid in the Management of Atopic Dermatitis: A Randomized Control Study

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Conflict of interest: Nil

Abstract

Background: Atopic dermatitis (AD) is a chronic inflammatory skin disorder requiring long-term topical therapy. While topical corticosteroids (TCS) remain the mainstay of treatment, their prolonged use is associated with adverse effects. Topical tacrolimus, a calcineurin inhibitor, offers a steroid-sparing alternative with a different safety profile.

Aim: To compare the efficacy and safety of topical tacrolimus versus topical corticosteroids in the management of atopic dermatitis.

Materials and Methods: A prospective, randomized, open-label, parallel-group study was conducted over one year in a tertiary care hospital. A total of 100 patients with mild to moderate AD were randomized into two groups: tacrolimus (Group A) and corticosteroids (Group B), with 50 patients each. Treatments were applied twice daily for 6 weeks. Disease severity was assessed using SCORAD score, along with pruritus score, adverse effects, and recurrence rates. Statistical analysis was performed using SPSS version 26.

Results: Both groups showed significant improvement in SCORAD and pruritus scores. However, corticosteroids demonstrated a significantly faster and greater reduction in disease severity at all follow-up intervals ($p<0.05$). Burning sensation was more common with tacrolimus (20%), whereas skin atrophy was observed only in the corticosteroid group (12%) ($p<0.05$). Recurrence rates were lower in the tacrolimus group (12%) compared to corticosteroids (28%).

Conclusion: Topical corticosteroids provide faster symptomatic relief in atopic dermatitis, making them suitable for acute flare management. However, tacrolimus offers comparable long-term efficacy with a superior safety profile and lower recurrence rates, making it a preferable option for maintenance therapy and use in sensitive skin areas.

Keywords: Atopic Dermatitis, Tacrolimus, Corticosteroids, SCORAD, Recurrence, Topical Therapy.

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Introduction

Atopic dermatitis (AD) is a chronic, relapsing inflammatory skin disorder characterized by intense pruritus, xerosis, and eczematous lesions, significantly impairing quality of life. It commonly begins in early childhood, with nearly 90% of cases presenting before the age of five years, and follows a course of exacerbations and remissions influenced by genetic, immunological, and environmental factors [1]. The pathogenesis of AD is complex and involves epidermal barrier dysfunction along with immune dysregulation, particularly a T-cell–mediated inflammatory response. This has led to the development of targeted therapies aimed at modulating immune pathways [2]. Topical therapy remains the cornerstone of AD management. Among available treatments, topical corticosteroids (TCS) have long been considered first-line agents due to their potent anti-inflammatory effects and ability to rapidly control disease flares. However, prolonged use of TCS is associated with well-recognized adverse effects such as skin atrophy, telangiectasia, striae,

and potential systemic absorption, especially when used on sensitive areas like the face and intertriginous regions [3]. To overcome these limitations, topical calcineurin inhibitors (TCIs), particularly tacrolimus, have emerged as effective non-steroidal alternatives. Tacrolimus acts by inhibiting calcineurin-dependent T-cell activation, thereby reducing the production of pro-inflammatory cytokines involved in AD pathogenesis [4]. Several randomized controlled trials and systematic reviews have demonstrated that topical tacrolimus has efficacy comparable to moderate- to potent-strength corticosteroids, with the added advantage of not causing skin atrophy, making it especially suitable for long-term use and application on delicate skin areas [5]. Additionally, recent studies suggest that tacrolimus may be more effective than mild corticosteroids such as hydrocortisone in reducing inflammatory markers and improving clinical outcomes in pediatric patients [6]. Despite its favorable efficacy profile, concerns regarding the long-term safety of tacrolimus, including a theoretical risk of malignancy, remain a topic of ongoing debate. Conversely, corticosteroids continue to be widely used due to their rapid action, accessibility, and established clinical experience [7]. Recent evidence from network meta-analyses indicates that both topical corticosteroids and tacrolimus rank among the most effective topical therapies for AD, though differences exist in their safety profiles and long-term tolerability [8].

Aims and Objectives: To compare the efficacy and safety of topical tacrolimus versus topical corticosteroids in the management of atopic dermatitis in a tertiary care hospital

Methodology: A prospective, randomized, open-label, parallel-group study carried out in the Department of Dermatology with the collaboration of Department of Pharmacology, at a tertiary care teaching hospital, central India, over a period of one year. Patients clinically diagnosed with atopic dermatitis attending the dermatology outpatient department. A total of 100 patients were included and randomly allocated into two groups (50 in each group).

Inclusion Criteria:

- Patients of either gender aged ≥2 years
- Clinically diagnosed cases of atopic dermatitis (based on standard criteria such as Hanifin and Rajka) [9].
- Mild to moderate disease severity
- Willingness to participate and provide informed consent

Exclusion Criteria:

- Severe atopic dermatitis requiring systemic therapy.
- Presence of active skin infections.
- Use of systemic immunosuppressive therapy within the last 4 weeks.
- Pregnant or lactating women.
- Known hypersensitivity to study drugs.

Randomization and Group Allocation:

Eligible patients were randomly assigned using a computer-generated randomization method into:

- **Group A:** Topical tacrolimus (0.03%/0.1% as per age and severity)
- **Group B:** Topical corticosteroid (e.g., hydrocortisone/ mometasone)

Medications were applied twice daily over affected areas for a duration of 6 weeks and all patients were advised regular use of emollients.

Outcome Measures:

1. Primary Outcome: Change in disease severity assessed by SCORAD/EASI score from baseline to end of treatment.
2. Secondary Outcomes: Reduction in pruritus score, Time to clinical improvement, Incidence of adverse effects (skin atrophy, burning sensation, irritation, etc.) and Recurrence during follow-up period.

Data Collection: Demographic details, clinical history, severity scores, and adverse events were recorded in a predesigned proforma. Patients were evaluated at baseline, 2 weeks, 4 weeks, and 6 weeks, with an additional follow-up at 8–12 weeks for recurrence assessment.

Statistical Analysis: Data were analyzed using statistical software IBM SPSS Ver.26. Continuous variables were expressed as mean ± standard deviation. Categorical variables were expressed as percentages. Student's t-test and Chi-square test were used for comparison between groups. A p-value <0.05 was considered statistically significant.

Results

The demographic profile of the study population was comparable between both groups. The mean age in the tacrolimus group was 18.6 ± 10.2 years, while in the corticosteroid group it was 19.3 ± 9.8 years, gender distribution was also similar. The mean duration of disease was 14.2 ± 6.5 months in Group A and 13.8 ± 7.1 months in Group B, showing no significant difference ($p > 0.05$). This indicates that both groups were well matched at baseline.

Table 1: Demographic Characteristics of Study Population (n = 100)

Variable	Group A (Tacrolimus) (n=50)	Group B (Corticosteroid) (n=50)	p-value
Mean Age (years)	18.6 ± 10.2	19.3 ± 9.8	>0.05
Gender (M/F)	28 / 22	30 / 20	>0.05
Mean Duration (months)	14.2 ± 6.5	13.8 ± 7.1	>0.05

At baseline, the mean SCORAD score was 48.5 ± 8.4 in the tacrolimus group and 47.9 ± 7.9 in the corticosteroid group. The difference was not statistically significant ($p > 0.05$).

Table 2: Baseline Disease Severity (SCORAD Score)

Parameter	Group A (Tacrolimus) (n=50)	Group B (Corticosteroid) (n=50)	p-value
Mean SCORAD Score	48.5 ± 8.4	47.9 ± 7.9	>0.05

Both treatment groups showed a progressive reduction in SCORAD scores over time. However, the corticosteroid group demonstrated a significantly greater reduction at all follow-up interval ($p<0.05$), this indicates that while both treatments were effective, corticosteroids produced a faster and more pronounced improvement in disease severity.

Table 3: Comparison of SCORAD Score Reduction

Time Interval	Group A (Tacrolimus)	Group B (Corticosteroid)	p-value
Baseline	48.5 ± 8.4	47.9 ± 7.9	>0.05
2 Weeks	35.2 ± 7.1	30.5 ± 6.8	<0.05
4 Weeks	22.8 ± 5.9	18.6 ± 5.5	<0.05
6 Weeks	14.3 ± 4.2	12.1 ± 3.9	<0.05

A similar trend was observed in pruritus reduction, with both groups showing improvement over time, but the corticosteroid group demonstrating superior results. Thus, corticosteroids provided faster relief from itching compared to tacrolimus.

Table 4: Comparison of Pruritus Score Reduction

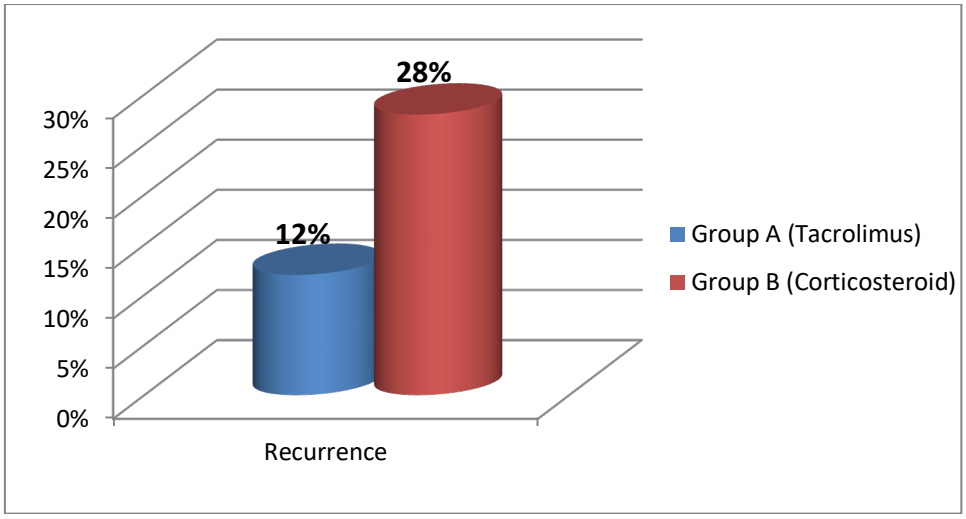
Time Interval	Group A (Tacrolimus)	Group B (Corticosteroid)	p-value
Baseline	8.2 ± 1.1	8.0 ± 1.2	>0.05
2 Weeks	5.6 ± 1.0	4.8 ± 1.1	<0.05
4 Weeks	3.2 ± 0.9	2.6 ± 0.8	<0.05
6 Weeks	1.8 ± 0.6	1.5 ± 0.5	<0.05

Burning sensation was more common in the tacrolimus group (20%) compared to the corticosteroid group (6%). Skin atrophy was observed only in the corticosteroid group (12%), which was statistically significant ($p<0.05$). Erythema/irritation occurred in 8% of the tacrolimus group and 10% of the corticosteroid group, with no significant difference ($p > 0.05$).

Table 5: Comparison of Adverse Effects Observed between the groups

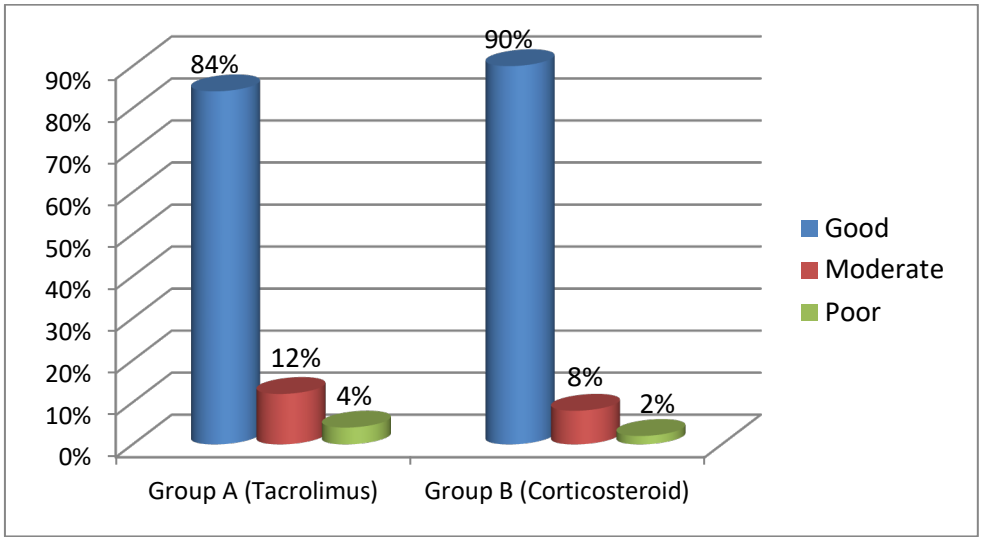
Adverse Effect	Group A (Tacrolimus)	Group B (Corticosteroid)	p-value
Burning Sensation	10 (20%)	3 (6%)	<0.05
Skin Atrophy	0 (0%)	6 (12%)	
Erythema/Irritation	4 (8%)	5 (10%)	

The recurrence rate during follow-up was lower in the tacrolimus group (12%) compared to the corticosteroid group (28%). This indicates that tacrolimus provides better sustained disease control and may be more effective in preventing relapse.



Graph 1: Comparison of Recurrence Rate at Follow-up

Patient compliance was generally good in both groups. However, slightly higher compliance was observed in the corticosteroid group.



Graph 2: Comparison of Patient Compliance

Discussion

The present study demonstrated that both topical tacrolimus and topical corticosteroids are effective in the management of atopic dermatitis, with significant reduction in SCORAD and pruritus scores in both groups. However, corticosteroids showed a faster onset of action and greater improvement at early follow-ups, whereas tacrolimus was associated with better long-term safety and lower recurrence rates. The baseline demographic and disease characteristics were comparable between the two groups, similar to findings reported by Sarkar et al [10] and Kumar P, et al [11], who also observed no significant baseline differences in Indian patients with atopic dermatitis. In the present study, corticosteroids demonstrated a more rapid reduction in SCORAD scores compared to tacrolimus. This is consistent with the study by Sarkar et al [10] and Patrizi A, et al [12], who reported that topical corticosteroids produce quicker symptomatic relief due to their strong anti-inflammatory action. However, the overall efficacy of tacrolimus was comparable over time, supporting findings from Dhar S et al [13], who concluded that tacrolimus is equally effective, particularly for maintenance therapy.

Pruritus reduction was significantly better in the corticosteroid group during early follow-up in our study. Similar observations were reported by Kumar P et al [11] and Verma SB, et al [14] where corticosteroids provided faster symptomatic relief, improving patient comfort and compliance. With regard to safety, tacrolimus was associated with a higher incidence of transient burning sensation, whereas corticosteroids showed a significant association with skin atrophy. These findings are in agreement with Indian studies by Mahajan R, et al [15] and Sarkar et al [10], which highlighted that topical calcineurin inhibitors avoid steroid-related

adverse effects, making them safer for long-term use, especially on sensitive skin areas.

An important finding of this study was the lower recurrence rate observed with tacrolimus compared to corticosteroids. This is consistent with findings from Dhar S et al [13] and Karthikeyan K, et al [16], who emphasized the role of tacrolimus in preventing disease relapse due to its immunomodulatory action. This suggests that tacrolimus may be more suitable for maintenance therapy, while corticosteroids are better suited for acute flare control.

Overall, the findings of this study align well with existing Indian literature, reinforcing that while topical corticosteroids remain the first-line therapy for rapid control, tacrolimus offers a safer alternative for long-term management and prevention of recurrence.

Conclusion

The present study concludes that both topical tacrolimus and topical corticosteroids are effective in the management of atopic dermatitis. Topical corticosteroids provide faster and greater symptomatic relief, particularly in the early phase of treatment. However, their use is associated with adverse effects such as skin atrophy. In contrast, topical tacrolimus demonstrates comparable efficacy over time with a superior safety profile, absence of steroid-related side effects, and significantly lower recurrence rates. Therefore, topical corticosteroids remain the preferred choice for acute flare management, while tacrolimus serves as a safer and more suitable option for long-term maintenance therapy and prevention of relapse, especially in sensitive skin areas.

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