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Original Research Article

Comparative Efficacy of Tacrolimus and Mometasone Furoate in Topical Treatment for Atopic Dermatitis: A Randomized Controlled Trial

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Abstract:

Background: Atopic dermatitis (AD) significantly impacts patients' quality of life due to symptoms like itchiness and skin inflammation. Tacrolimus and mometasone furoate are commonly used topical treatments for AD, each with unique benefits. While tacrolimus offers effective treatment without long-term steroid side effects, mometasone furoate provides potent anti-inflammatory effects. Comparative studies between these treatments aim to assess their efficacy and safety in managing AD.

Methods: This randomized controlled trial enrolled 70 adults aged 18-65 with moderate to severe AD. Participants were randomly assigned to receive either tacrolimus 0.1% ointment or mometasone furoate 0.1% cream topically twice daily. Outcome measures included AD severity, pruritus improvement, adverse events, and quality of life. Statistical analysis determined treatment effects.

Results: Both treatments significantly reduced AD severity and pruritus without significant differences between groups. Adverse events were mild and comparable. Quality of life improved similarly in both groups. Subgroup analyses showed no significant differences based on disease severity, age, or gender. Adherence to treatment was high, and both treatments were well-tolerated.

Conclusion: Both tacrolimus and mometasone furoate are effective and well-tolerated treatments for AD. Clinicians can consider individual patient factors when choosing between them. Further research could explore larger-scale studies with longer follow-up to confirm these findings.

Recommendations: Clinicians should consider tacrolimus and mometasone furoate as viable treatment options for AD, tailoring treatment choices to individual patient needs. Larger studies with longer follow-up could provide additional insights into treatment efficacy and safety.

Keywords: Atopic Dermatitis, Tacrolimus, Mometasone Furoate, Topical Treatment.

Introduction

Atopic dermatitis (AD), a chronic inflammatory skin condition, presents a significant burden to patients, affecting their quality of life due to persistent itchiness, dry skin, and a cycle of flare-ups and remissions. The management of AD involves moisturizers, systemic treatments, and topical therapies, among which tacrolimus and mometasone furoate have been widely studied for their efficacy and safety profiles.

Tacrolimus, a topical calcineurin inhibitor, has been recognized for its effectiveness in treating atopic dermatitis without the atrophogenic effects associated with long-term topical corticosteroid use. Studies have demonstrated that tacrolimus cream considerably improves the signs and symptoms of AD, offering a steroid-sparing alternative for patients, especially for sensitive skin areas like the face and neck [1]. Its mechanism involves the inhibition of T-cell activation and cytokine production, which are key components in the pathophysiology of AD.

On the other hand, mometasone furoate, a potent topical corticosteroid, has been a cornerstone in the topical treatment of AD due to its anti-inflammatory, antipruritic, and vasoconstrictive properties. Mometasone furoate has demonstrated high efficacy in reducing AD symptoms with a favorable safety profile, making it suitable for short-term and intermittent long-term therapy [2]. Its action mechanism involves the induction of phospholipase A2 inhibitory proteins, controlling

the release of arachidonic acid, a precursor of inflammatory mediators.

Comparative studies between tacrolimus and mometasone furoate have aimed to estimate their efficacy and safety in the management of AD. A meta-analysis suggested that while both treatments are effective, tacrolimus may offer advantages in long-term management due to its non-steroidal nature and lower risk of skin atrophy [3]. However, the choice between tacrolimus and mometasone furoate often depends on the severity of the condition, patient age, and specific treatment goals, including the minimization of side effects and maintenance of skin integrity.

Both tacrolimus and mometasone furoate play critical roles in the topical treatment landscape of atopic dermatitis. Their comparative efficacy and safety profiles highlight the importance of personalized treatment approaches, taking into account the individual patient's needs and the clinical characteristics of their disease.

The aim of the study is to compare the efficacy of Tacrolimus and Mometasone Furoate in topical treatment for atopic dermatitis through a randomized controlled trial.

Methodology

Study Design: The study adopted a randomized controlled trial (RCT) design to evaluate the efficacy of two topical therapies for atopic dermatitis. The trial adhered to established guidelines, ensuring robustness and validity in its findings.

Study Setting: The study was conducted at Darbhanga Medical College & Hospital, Skin OPD, between .August 2023 to January 2024.

Participants: 70 adult individuals were enrolled in the study. This study size was determined to provide sufficient statistical power to detect clinically meaningful differences between treatment groups.

Inclusion Criteria: Eligible participants were required to meet the following criteria: aged 18 to 65 years, diagnosed with moderate to severe atopic dermatitis, and willing to provide informed consent to take part in the study.

Exclusion Criteria: Participants were excluded from the study if they had known allergies to the study medications, were pregnant or lactating, or had other dermatological conditions that may confound the study results. These criteria were essential to ensure the safety and integrity of the trial outcomes.

Bias: To minimize bias, both participants and investigators were blinded to the treatment allocation throughout the duration of the study. This blinding strategy aimed to prevent any preconceived notions or expectations from influencing the assessment of treatment outcomes.

Variables: The study investigated the impact of two independent variables: the type of topical therapy (Tacrolimus 0.1% vs. Mometasone furoate 0.1%) on several dependent variables, including the severity of atopic dermatitis, improvement in pruritus, incidence and severity of adverse events, and patient-reported outcomes.

Data Collection: Data collection involved recording baseline demographic and clinical characteristics, assessing outcome measures at specified intervals during the treatment period, and documenting adherence to treatment protocols and any adverse events reported by participants.

Randomization: Participants were randomly appointed to treatment categories using computer-generated random numbers. Allocation concealment procedures were implemented to ensure that treatment assignments remained undisclosed until the time of intervention.

Intervention: Participants received either Tacrolimus 0.1% ointment (Category 1) or Mometasone furoate 0.1% cream (Category 2), which they applied topically two times daily to affected areas as per the assigned treatment group. Patient were asked to apply the ointment for 12 weeks, and evaluation was done at every 4 weeks interval.

Outcome Measurements: The primary outcome was the severity of atopic dermatitis, assessed using validated scoring systems such as the Eczema Area and Severity Index (EASI). Secondary outcomes included improvements in pruritus, incidence and severity of adverse events, and patient-reported outcomes related to quality of life.

Statistical Analysis: Statistical software (SPSS, ver. 24) was used for the analysis. Descriptive statistics summarized baseline characteristics, and statistical tests appropriate for the study design, such as t-tests or chi-square tests, were used for between-group comparisons.

Ethical Considerations: The study protocol was approved by the Ethics Committee and written informed consent was received from all the participants.

Result

Seventy participants were enrolled in the study, with an equal distribution between the Tacrolimus and the Mometasone furoate category. Baseline demographic and clinical characteristics, including age, gender, duration of atopic dermatitis, and baseline severity scores, were comparable between the two treatment categories, ensuring homogeneity at the outset of the study (Table 1).

Table 1: Characteristics of study population

Characteristic	Category I (N=35)	Category II (N=35)
Age (Mean ± SD)	38.5 ± 8.2	39.1 ± 7.5
Gender		
- Male	18	19
- Female	17	16
Duration of AD (months)	24.7 ± 6.3	25.1 ± 5.9
Baseline EASI Score	22.4 ± 4.6	23.0 ± 4.9
Time Point (Mean ± SD)		
- Baseline	22.4 ± 4.6	23.0 ± 4.9
- Week 4	15.8 ± 3.2	16.5 ± 3.4
- Week 8	10.2 ± 2.5	11.0 ± 2.7
- Week 12 (End)	6.5 ± 1.8	7.0 ± 1.9

Both categories demonstrated significant reductions in the severity of atopic dermatitis over the treatment period. Nevertheless, no statistically substantial difference was observed in the reduction of severity scores between the two treatment categories at the end of the study ($p > 0.05$).

Both treatment categories reported significant improvements in pruritus as assessed by a visual analog scale (VAS). The reduction in pruritus scores was comparable between the categories, with no significant difference observed ($p > 0.05$).

Adverse events were monitored throughout the study period, with the most commonly reported events being mild skin irritation and burning sensation at the application site. No substantial differences in the frequency or severity of adverse events involving the categories ($p > 0.05$).

Both treatment categories reported improvements in quality of life measures, including reductions in sleep disturbance and overall improvement in satisfaction with treatment. No statistically substantial differences were observed among the categories in terms of patient-reported outcomes ($p > 0.05$).

Subgroup analyses based on factors such as disease severity, age, and gender did not reveal any significant differences in treatment outcomes between the categories. Adherence to treatment was high in both categories, with the majority of participants completing the prescribed treatment regimen as per protocol.

Both categories were well-tolerated, with no serious adverse events reported during the study period. The overall safety profiles of the two treatments were similar, with no significant differences in the frequency or severity of adverse events.

Discussion

The study enrolled 70 participants, evenly distributed between the Tacrolimus and Mometasone furoate treatment groups, with comparable baseline characteristics ensuring homogeneity. Both treatment groups demonstrated significant reductions in atopic dermatitis severity and pruritus over the study period, with no statistically significant difference between them by the study's end.

Adverse events, primarily mild skin irritation and burning sensation, were similarly reported across both groups, with no significant differences in incidence or severity. Quality of life measures improved in both groups, without statistically significant differences between them. Subgroup analyses did not reveal significant treatment outcome differences based on disease severity, age, or gender.

Adherence to treatment was high in both groups, and both treatments were well-tolerated, indicating similar safety profiles. Overall, findings suggest that Tacrolimus 0.1% and Mometasone furoate 0.1% may offer comparable efficacy and safety in treating moderate to severe atopic dermatitis.

Several studies have explored the comparative efficacy of Tacrolimus and Mometasone Furoate in the treatment of atopic dermatitis, highlighting various aspects of their use. A study demonstrated that proactive treatment with Tacrolimus is superior in restoring the skin barrier compared to Mometasone Furoate, emphasizing the importance of treatment strategy in managing atopic dermatitis [1]. Another research focused on children with moderate to severe atopic dermatitis, assessing the ability for skin atrophy with the use of Mometasone Furoate 0.1% cream, indicating the need for careful monitoring in pediatric applications [2].

Further investigation into the sequential use of Mometasone Furoate cream and crisaborole for mild to moderate atopic dermatitis in children highlighted the benefits of combination therapy in reducing relapses and improving safety [3]. Comparative studies on the effects of Tacrolimus ointment and Mometasone Furoate cream on the epidermal barrier offer insights into their respective impacts on skin health, with Tacrolimus showing a positive influence on the skin barrier quality [4].

Additionally, a study conducted in Telangana, India, directly compared the topical applications of Mometasone and Tacrolimus, contributing to the localized understanding of treatment efficacy in the Indian context [5]. These studies collectively provide valuable information on the efficacy, safety, and application considerations of Tacrolimus and Mometasone Furoate in treating atopic dermatitis across different demographics and treatment settings. [6-8]

Conclusion

In conclusion, both Tacrolimus 0.1% and Mometasone furoate 0.1% demonstrated efficacy in the therapy of atopic dermatitis, with significant improvements in disease severity, pruritus, and quality of life measures. However, there were no statistically substantial differences between the two therapies in terms of efficacy or safety outcomes, suggesting that both therapies may be equally effective options for the management of moderate to severe atopic dermatitis.

Limitations:

The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population. Furthermore, the lack of comparison group also poses a limitation for this study's findings.

Recommendation:

Clinicians should consider tacrolimus and mometasone furoate as viable treatment options for AD, tailoring treatment choices to individual patient needs. Larger studies with longer follow-up could provide additional insights into treatment efficacy and safety.

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