Section: Dermatology

Original Research Article

# EFFICACY OF NOVEL PEDIATRIC ATOPIC DERMATITIS CREAMS CONTAINING TACROLIMUS AND HYDROCORTISONE IN THE TREATMENT OF PEDIATRIC ATOPIC DERMATITIS

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## Abstract

**Background:** Atopic dermatitis (AD) is a common chronic skin disorder affecting children, characterized by intense itchiness and eczema. Treatment options are limited, and there is a need for effective and safe therapies. This study aims to assess the efficacy and safety of a novel cream containing tacrolimus and hydrocortisone for treating pediatric AD. **Material and Methods:** A randomized, double-blind, placebo-controlled trial was conducted with 100 pediatric patients (age 3-16) with moderate to severe AD. Participants were randomly assigned to either the treatment group, receiving the novel cream, or the control group, receiving a placebo. The primary endpoints were the reduction in SCORAD (Scoring Atopic Dermatitis) and EASI (Eczema Area and Severity Index) scores after 12 weeks of treatment. Secondary outcomes included changes in the Dermatology Life Quality Index (DLQI) and the incidence of adverse effects. **Results:** The treatment group showed a significant reduction in SCORAD and EASI scores, with a 75% and 70% decrease respectively, compared to 20% and 15% in the control group ($p<0.001$). The DLQI score improved by 60% in the treatment group, significantly more than the 10% improvement in the control group ($p<0.001$). Mild side effects were reported, with a mild burning sensation being the most common. No serious adverse events were noted. **Conclusion:** The novel cream containing tacrolimus and hydrocortisone significantly improves the symptoms and quality of life in children with AD, with minimal side effects, suggesting it as an effective and safe treatment option.

## INTRODUCTION

Atopic dermatitis (AD), a chronic inflammatory skin condition, affects approximately 15-20% of children worldwide and is characterized by pruritus, erythema, and eczematous lesions.[1] The management of pediatric AD poses a considerable challenge due to its relapsing-remitting nature and the potential for long-term sequelae such as skin barrier dysfunction and impaired quality of life.[2]

Current treatment strategies for pediatric AD primarily involve topical corticosteroids and calcineurin inhibitors, which may be associated with adverse effects such as skin atrophy and systemic absorption concerns.[3,4] Therefore, there is a continuous quest for safer and more effective therapeutic options to alleviate the burden of AD in children.[5]

Tacrolimus, a calcineurin inhibitor, and hydrocortisone, a topical corticosteroid, have individually demonstrated efficacy in AD management.[6] Combining these agents in a novel cream formulation may offer synergistic benefits by targeting different aspects of AD pathogenesis, including inflammation and immune dysregulation, while minimizing the adverse effects associated with monotherapy.[7]

This study aims to evaluate the efficacy and safety of a novel cream containing tacrolimus and hydrocortisone in pediatric AD patients. The primary objective is to assess the reduction in disease severity measured by validated scoring


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systems such as the SCORAD (Scoring Atopic Dermatitis) index and the EASI (Eczema Area and Severity Index). Secondary endpoints include improvements in quality of life and the incidence of treatment-related adverse events.

## MATERIALS AND METHODS

**Study Design:** This study employed a randomized, double-blind, placebo-controlled trial design to assess the efficacy and safety of the novel cream containing tacrolimus and hydrocortisone in pediatric patients with atopic dermatitis.

**Study Setting:** The study was conducted at Gandhi Medical College, located in Secunderabad, India. The outpatient pediatric dermatology clinics served as the primary site for participant recruitment, intervention administration, and follow-up assessments.

**Study Period:** The study was conducted from January 2022 to December 2022, with a total duration of 12 months.

Participants:

**Inclusion Criteria:** Pediatric patients aged 3 to 16 years diagnosed with moderate to severe atopic dermatitis, as confirmed by clinical examination and meeting the criteria outlined in established guidelines.

**Exclusion Criteria:** Patients with known hypersensitivity or contraindications to tacrolimus, hydrocortisone, or any component of the study cream; those with uncontrolled systemic infections or other significant comorbidities; and those currently receiving systemic immunosuppressive therapy8,9.

**Sample Size Calculation:** The sample size was determined based on previous studies evaluating similar interventions and aiming for adequate power to detect clinically significant differences in primary outcome measures such as the reduction in SCORAD and EASI scores.

Randomization and Blinding: Participants were randomly assigned in a 1:1 ratio to either the treatment group or the control group using computer-generated randomization sequences. Both participants and investigators were blinded to treatment allocation throughout the study period to minimize bias.

**Interventions:**

**Treatment Group:** Participants in the treatment group received the novel cream containing tacrolimus and hydrocortisone, to be applied topically twice daily for 12 weeks.

**Control Group**: Participants in the control group received a placebo cream with identical packaging and application instructions.

**Outcome Measures:** The primary outcome measures included changes in SCORAD and EASI scores from baseline to week 12. Secondary outcome measures encompassed improvements in quality of life assessed by the Dermatology Life Quality Index (DLQI) and the incidence of treatment-related adverse events.

**Data Collection:** Baseline demographic and clinical data were collected at the initial visit. Participants underwent scheduled follow-up visits at weeks 4, 8, and 12 for clinical assessments, adverse event monitoring, and data collection. Compliance with treatment regimens was monitored through participant diaries and pill counts.

**Statistical Analysis:** Data were analyzed using appropriate statistical methods, including descriptive statistics for baseline characteristics and outcome measures. Continuous variables were expressed as means with standard deviations, while categorical variables were summarized as frequencies and percentages. Comparative analyses between treatment groups were performed using appropriate inferential statistical tests, with p-values $<0.05$ considered statistically significant. Additionally, intention-to-treat and per-protocol analyses were conducted to assess treatment efficacy and safety comprehensively.

**Ethical Considerations:** The study protocol was approved by the Institutional Ethics committee of Gandhi Medical College, and written informed consent was obtained from the legal guardians of all participants before enrollment.

## RESULTS

**Study Population:** Out of 100 enrolled participants, 50 were assigned to the treatment group (novel cream containing tacrolimus and hydrocortisone) and 50 to the control group (placebo cream). Participant adherence was high, with a 100% completion rate across both groups. The participants' mean age was 8 years, with a range of 3-16 years. The gender distribution was 52% male and 48% female. Baseline atopic dermatitis severity, measured by the Eczema Area and Severity Index (EASI), was similar across groups (mean EASI score of 22.5 in the treatment group and 23 in the control group).

**Efficacy:**

**SCORAD Index:** The treatment group experienced a significant mean reduction in SCORAD index by 75% (from a baseline of approximately 50 to 12.5) compared to a 20% reduction in the control group (from a baseline of approximately 50 to 40), with a p-value of $<0.001$.

**EASI Score:** The treatment group showed a mean reduction in EASI score by 70% (from 22.5 to 6.75) versus a 15% reduction in the control group (from 23 to 19.55), $p<0.001$.

**Quality of Life (QoL) Improvement:** Utilizing the Dermatology Life Quality Index (DLQI), the treatment group reported a mean improvement of 60% (from a baseline score of 10 to 4) compared to a 10% improvement in the control group (from a baseline score of 10 to 9), $p<0.001$.


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**Side Effects**

Treatment Group: 10% reported mild burning sensation, 5% reported transient itching, and 2% experienced localized erythema at the application site.

Control Group: 8% reported mild burning sensation, 4% experienced transient itching, and no cases of erythema were reported.

Serious Adverse Events (SAEs): No SAEs were reported in either group. The occurrence of side effects was monitored and recorded throughout the study, with no significant difference in the incidence rate of side effects between the two groups, confirming a favorable safety profile for the novel cream.

**Compliance and Satisfaction:**

Compliance Rate: High, with over 95% of participants in both groups reporting full adherence to the treatment regimen.

Satisfaction Rate: Based on a post-study survey, 85% of participants in the treatment group expressed satisfaction with the treatment outcome, compared to 30% in the control group.

**Table 1: Study Population Characteristics**

| Characteristic | Treatment Group | Control Group |
|---|---|---|
| Number of Participants | 50 | 50 |
| Mean Age (years) | 8 | 8 |
| Age Range (years) | 3-16 | 3-16 |
| Gender Distribution (%) | 52% Male; 48% Female | 52% Male; 48% Female |
| Baseline EASI Score (mean) | 22.5 | 23 |

**Table 2: Efficacy Outcomes**

| Outcome Measure | Treatment Group Change | Control Group Change | P-value |
|---|---|---|---|
| SCORAD Index Reduction (%) | 75% (from 50 to 12.5) | 20% (from 50 to 40) | <0.001 |
| EASI Score Reduction (%) | 70% (from 22.5 to 6.75) | 15% (from 23 to 19.55) | <0.001 |
| DLQI Improvement (%) | 60% (from 10 to 4) | 10% (from 10 to 9) | <0.001 |

**Table 3: Side Effects**

| Side Effect | Treatment Group (%) | Control Group (%) |
|---|---|---|
| Mild Burning Sensation | 10% | 8% |
| Transient Itching | 5% | 4% |
| Localized Erythema | 2% | 0% |
| Serious Adverse Events | 0% | 0% |

**Table 4: Compliance and Satisfaction**

| Measure | Treatment Group (%) | Control Group (%) |
|---|---|---|
| Compliance Rate | >95% | >95% |
| Satisfaction Rate | 85% | 30% |

## DISCUSSION

**Efficacy Findings:** The results of this study demonstrated a significant reduction in disease severity, as evidenced by substantial improvements in SCORAD and EASI scores among pediatric patients with atopic dermatitis who received the novel cream containing tacrolimus and hydrocortisone..[10] These findings are consistent with previous research highlighting the efficacy of both tacrolimus and hydrocortisone in managing atopic dermatitis. The observed reductions in SCORAD and EASI scores underscore the clinical relevance of the novel cream in effectively alleviating the signs and symptoms of pediatric AD over the 12-week treatment period.

**Comparison with Previous Studies:** Our study builds upon previous research by evaluating the combination of tacrolimus and hydrocortisone in a novel cream formulation specifically designed for pediatric patients with atopic dermatitis. While individual studies have assessed the efficacy of tacrolimus or hydrocortisone alone, few have investigated their combined use in a pediatric population.[11] By conducting a randomized controlled trial, we provide robust evidence supporting the efficacy of this novel combination therapy, thereby filling a critical gap in the literature.

**Safety Profile:** The safety profile of the novel cream was favorable, with only mild and transient side effects reported, such as mild burning sensation and transient itching. Importantly, no serious adverse events or systemic absorption-related complications were observed throughout the study period. These findings are consistent with the established safety profiles of tacrolimus and hydrocortisone when used topically in pediatric patients with AD.[12] The absence of severe adverse events further reinforces the safety of the novel cream, making it a viable treatment option for pediatric AD.

**Clinical Implications:** The findings of this study have significant clinical implications for the management of pediatric atopic dermatitis. The demonstrated efficacy and safety of the novel cream offer healthcare providers an additional therapeutic option for treating moderate to severe AD in children. Moreover, the combination of tacrolimus and hydrocortisone in a single formulation may


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provide synergistic benefits, allowing for improved disease control and better patient compliance.

Limitations and Future Directions: Despite the strengths of this study, including its randomized controlled design and comprehensive assessment of efficacy and safety outcomes, several limitations warrant consideration. The relatively short duration of follow-up may have limited our ability to assess long-term treatment effects and durability of response. Additionally, the study's single-center design may limit the generalizability of our findings to other populations and settings. Future research should aim to address these limitations by conducting longer-term, multicenter studies to further validate the efficacy and safety of the novel cream in diverse pediatric populations.

## CONCLUSION

The findings of this study support the efficacy and safety of the novel cream containing tacrolimus and hydrocortisone in pediatric patients with atopic dermatitis. The significant reductions in disease severity and favorable safety profile observed in our study highlight the potential of this combination therapy as a valuable treatment option for pediatric AD. Further research is warranted to confirm these findings and elucidate the long-term effects and real-world effectiveness of the novel cream in clinical practice.

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