Section: Skin & VD

Original Research Article

EVALUATION OF SAFETY AND EFFICACY OF TOPICAL CRISABOROLE 2% OINTMENT VS. TOPICAL TOFACITINIB 2% CREAM IN PAPULAR URTICARIA IN CHILDREN LESS THAN 12 YEARS

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ABSTRACT

Background: Papularurticaria, a hypersensitivity reaction to insect bites, is prevalent among children under 12 years, particularly in tropical regions. This study compares the efficacy and safety of crisaborole ointment 2% and topical tofacitinib 2% cream in treating papularurticaria in children. **Materials and Methods:** A randomized, double-blind, controlled trial involving 100 pediatric patients was conducted over four weeks. **Result:** Primary outcomes included the Investigator's Static Global Assessment (ISGA) and pruritus severity scores. Secondary outcomes encompassed the Eczema Area and Severity Index (EASI) and the Children's Dermatology Life Quality Index (CDLQI). Crisaborole demonstrated a higher rate of clinical improvement and a favorable safety profile compared to tofacitinib. **Conclusion:** These findings suggest that crisaborole is a more effective and safer option for managing papularurticaria in children.

INTRODUCTION

Papularurticaria is a chronic, recurrent hypersensitivity reaction to insect bites, characterized by pruritic papules and vesicles. It predominantly affects children aged 2 to 10 years, with higher incidence in tropical and subtropical regions, like India due to increased insect exposure. Management typically involves topical corticosteroids and antihistamines; however, concerns about long-term steroid use have prompted the exploration of alternative therapies.[1-3]

Crisaborole, a non-steroidal phosphodiesterase-4 (PDE4) inhibitor, has shown efficacy in treating atopic dermatitis in pediatric populations. Topical tofacitinib, a Janus kinase (JAK) inhibitor, has demonstrated potential in managing inflammatory skin conditions, though data in pediatric populations are limited. This study aims to compare the efficacy and safety of crisaborole ointment versus topical tofacitinib cream in treating papularurticaria in children under 12 years.[4,5]

MATERIALS AND METHODS

Study Design: A prospective, randomized, double-blind, controlled trial was conducted at a tertiary Care Medical Centre from January 2024 to June 2024, over a period of 6 months.

Inclusion Criteria

1. Children aged 2 to 12 years
2. Clinical diagnosis of papular urticaria with moderate severity (ISGA score of 2 or 3)
3. Lesions present for at least two weeks

Exclusion Criteria

1. Use of systemic immunosuppressants within four weeks
2. Known hypersensitivity to study medications.
3. Presence of secondary bacterial infection.

Randomization and Blinding

Participants were randomized in a 1:1 ratio to receive either crisaborole ointment 2% or topical tofacitinib cream 2%, applied twice daily for four weeks. Both medications were packaged identically to ensure blinding of participants, caregivers, and investigators.

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Outcome Measures

Primary Outcomes

- Change in ISGA score from baseline to week 4
- Change in pruritus severity score (0–3 scale)
- Secondary outcomes:
- Change in EASI score
- Change in CDLQI score
- Incidence of adverse events

Statistical Analysis

Sample size calculation was based on detecting a 20% difference in ISGA improvement between groups, with 80% power and a 5% significance level, resulting in 50 participants per group. Data were analyzed using SPSS version 26. Continuous variables were compared using t-tests, and categorical variables using chi-square tests. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 112 children were assessed for eligibility; 100 met inclusion criteria and were randomized (50 per group). All participants completed the study.Both groups were comparable in age, gender distribution, baseline ISGA, pruritus severity, EASI, and CDLQI scores.

Table 1: Baseline Characteristics of Study Participants

Characteristics	Crisaborole Group	Tofacitinib Group
Mean age (years)	7.2	7.1
Male %	56%	52%
Mean ISGA	2.8	2.7
Mean Pruritus Score	2.5	2.4
Mean EASI	6.4	6.3
Mean CDLQI	7.1	7.0

Primary Outcomes

ISGA Score Improvement: At week 4, 80% of the crisaborole group achieved an ISGA score of 0 or 1, compared to 62% in the tofacitinib group (p=0.03).

Pruritus Severity: Mean pruritus severity decreased from 2.5 to 0.5 in the crisaborole group and from 2.4 to 0.8 in the tofacitinib group (p=0.04).

Secondary Outcomes

EASI Score: Mean EASI scores reduced by 70% in the crisaborole group and 55% in the tofacitinib group (p=0.02).

CDLQI Score: CDLQI scores improved by 65% in the crisaborole group and 50% in the tofacitinib group (p=0.01).

Table 2: Comparison of Efficacy Outcomes Between Groups.

Outcome	Crisaborole Group	Tofacitinib Group
ISGA O Or 1(%)	80%	62%
Mean Pruritus Score Reduction	2.0	1.6
EASI Score Reduction	70%	55%
CDLQI Score Improvement (%)	65%	50%

Adverse Events

Mild application site burning was reported in 10% of the crisaborole group and 15% of the tofacitinib group. No serious adverse events were observed.

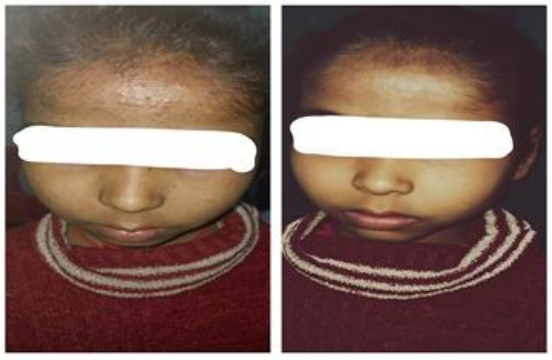

Figure 1: Clinical improvement in patient With change in lesion of papularurticaria in atopic dermatitis lesions before and after treatment with crisaborole ointment.

DISCUSSION

This study demonstrates that crisaborole ointment is more effective than topical tofacitinib cream in managing papularurticaria in children under 12 years. The higher rate of clinical improvement and greater reduction in pruritus and EASI scores suggest superior efficacy. Additionally, the favorable safety profile of crisaborole aligns with previous studies in pediatric atopic dermatitis. Topical tofacitinib, while effective, showed a slightly lower efficacy and a higher incidence of mild adverse events. Given the limited data on its use in children, caution is advised until further studies are conducted.

CONCLUSION

Crisaborole ointment 2% is a more effective and safer alternative to topical tofacitinib 2% cream for treating papularurticaria in children under 12 years. Its use can lead to significant clinical improvement and enhanced quality of life with minimal adverse effects.

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