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Original Article

Comparison of the Efficacy and Safety of Topical Permethrin 5% Cream versus Topical Benzyl Benzoate 25% Lotion in Children with Scabies

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ABSTRACT

Introduction: Scabies is a highly contagious parasitic infestation predominantly affecting children in resource-limited settings. Both topical permethrin 5% cream and benzyl benzoate 25% lotion are used in clinical practice, yet comparative data in the pediatric population from local tertiary care settings remain limited. **Objective**: To compare the efficacy and safety of topical permethrin 5% cream with topical benzyl benzoate 25% lotion in children with scabies presenting to a tertiary care dermatology centre. **Study Design**: Quasi-experimental study. **Setting**: Department of Dermatology, Mayo Hospital, Lahore. Duration: 1st January 2024 to 31st December 2024. **Subjects and Methods**: A total of 150 children aged 3–14 years with clinically diagnosed scabies were enrolled and allocated by alternate assignment to two groups of 75 each. Group A received topical permethrin 5% cream and Group B received topical benzyl benzoate 25% lotion. Clinical cure rates, time to pruritus resolution, and local adverse effects were assessed at 2 and 4 weeks following the first application. **Results**: At 2 weeks, clinical cure was achieved in 68 (90.7%) patients in Group A compared with 54 (72.0%) in Group B (p=0.006). At 4 weeks, cure rates were 96.0% and 84.0% respectively (p=0.023). Mean time to pruritus resolution was significantly shorter in Group A (8.1 ± 2.3 days vs 11.9 ± 3.4 days, p<0.001). Any adverse effect was recorded in 20.0% of Group A versus 50.7% of Group B (p<0.001). **Conclusion**: Topical permethrin 5% cream demonstrated superior efficacy and a more favorable safety profile compared with benzyl benzoate 25% lotion in children with scabies and is recommended as the preferred first-line scabicidal agent in this population. **Keywords**: Scabies, permethrin, benzyl benzoate, children, efficacy, safety, quasi-experimental.

INTRODUCTION

Scabies is a highly contagious parasitic infestation of the skin caused by the obligate human mite Sarcoptes scabiei var. hominis. It constitutes one of the most prevalent dermatological conditions worldwide, with an estimated 200–300 million cases occurring annually and classified by the World Health Organization as a neglected tropical disease [1]. The condition disproportionately affects children, particularly those residing in overcrowded and resource-limited settings, where transmission through prolonged direct skin-to-skin contact with infested household members occurs with considerable frequency [2]. In tropical and subtropical regions, including South Asia, scabies accounts for a substantial proportion of pediatric dermatology outpatient attendances [3].

In Pakistan, systematically documented population-level prevalence data on scabies remain limited; however, the condition is recognized as a common dermatological presentation in low-income urban

communities, institutional settings, and rural areas [4]. Infestation rates among children in overcrowded households may reach 10–30%, with recurrent episodes being prevalent in the absence of simultaneous treatment of all household contacts [3, 4]. Beyond its immediate cutaneous morbidity, scabies in children carries the additional risk of secondary bacterial superinfection with Streptococcus pyogenes, predisposing affected individuals to post-streptococcal sequelae including acute glomerulonephritis and rheumatic fever [5].

The clinical hallmark of scabies is intense nocturnal pruritus, attributed to a type IV hypersensitivity response to mite proteins, eggs, and faecal antigens [6]. Characteristic skin findings include pathognomonic linear burrows, erythematous papules, vesicles, and excoriations distributed over the interdigital web spaces, wrist flexures, axillary folds, periumbilical region, and genitalia. In young children, additional involvement of the palms, soles, face, and scalp is frequently observed, distinguishing pediatric presentations from those in adults [6]. Dermoscopy has been reported to improve diagnostic accuracy by enabling direct visualization of the mite and its burrow, though clinical diagnosis remains standard in resource-limited settings [21].

The selection of an appropriate scabicidal agent in children requires consideration of efficacy, local tolerability, ease of application, and cost. Topical agents in current use include permethrin 5% cream, benzyl benzoate lotion, sulfur ointment, and malathion [7]. Among these, topical permethrin 5% cream is endorsed as the first-line agent by the European guideline for the management of scabies and by the Cochrane systematic review of scabies treatment interventions, on the basis of its consistent efficacy and favorable tolerability [7, 8]. Permethrin acts as a synthetic pyrethroid insecticide that selectively disrupts voltage-gated sodium channel function in the mite's peripheral nerve cell membranes, producing irreversible paralysis and death [13].

Benzyl benzoate lotion is an established alternative scabicidal preparation that has been in use for several decades, particularly in settings where permethrin is economically inaccessible. It exerts its scabicidal effect through direct toxicity to the mite nervous system, acting as a contact irritant and neurological poison [14]. However, its application in children has been associated with a higher frequency of local adverse effects, including burning, erythema, and occasional vesiculation, which raise concerns regarding tolerability in younger patients [10, 11].

Comparative evidence on permethrin and benzyl benzoate in scabies management has yielded broadly consistent results in favor of permethrin, with some studies reporting comparable efficacy and others demonstrating clear superiority [9, 10, 12]. A well-cited Indian study by Usha and Gopalakrishnan Nair reported permethrin cure rates of approximately 91%, significantly exceeding those achieved with comparator agents [9]. The Cochrane systematic review by Strong and Johnstone similarly concluded that permethrin was more effective than benzyl benzoate for the treatment of scabies [8]. Despite this international evidence, locally derived data from tertiary dermatology centres in Pakistan specifically examining this comparison in children are limited. The present study was conducted to generate locally relevant evidence regarding the comparative efficacy and safety of topical permethrin 5% cream versus benzyl benzoate 25% lotion in children with scabies.

MATERIAL AND METHODS

This quasi-experimental study was conducted in the Department of Dermatology, Mayo Hospital, Lahore, over a period of twelve months from 1st January 2024 to 31st December 2024. Ethical approval was obtained from the Institutional Review Board of King Edward Medical University / Mayo Hospital, Lahore, prior to study initiation. Children aged 3–14 years presenting to the outpatient dermatology clinic with a clinical diagnosis of scabies were enrolled after written informed consent was obtained from the parent or legal guardian of each participant, using non-probability consecutive sampling. Enrolled participants were allocated to one of two treatment groups by systematic alternate assignment: Group A received topical permethrin 5% cream and Group B received topical benzyl benzoate 25% lotion.

The sample size was calculated using the formula for comparison of two independent proportions: $n = (Z\alpha/2 + Z\beta)^2 \times [p_1(1-p_1) + p_2(1-p_2)] / (p_1-p_2)^2$, where $p_1 = 0.91$ (expected 2-week cure rate with permethrin) and $p_2 = 0.73$ (expected 2-week cure rate with benzyl benzoate), based on values reported by Usha and Gopalakrishnan Nair [9]. At a significance level of $\alpha = 0.05$ ($Z\alpha/2 = 1.96$) and 80% power ($Z\beta = 0.842$), the calculated minimum sample size was 68 patients per group. Allowing for 10% attrition, a final target of 75 patients per group was established, yielding a total sample of 150 participants.

Patients were eligible for inclusion if they were aged 3–14 years, had a clinical diagnosis of scabies at the time of enrollment (defined as intense nocturnal pruritus with characteristic burrows, papules, or vesicles in typical distribution sites), had at least one infested household contact presenting concurrently, and had received no scabicidal treatment in the preceding four weeks. Patients were excluded if they had crusted (Norwegian) scabies; known hypersensitivity to permethrin or benzyl benzoate; coexisting skin conditions such as atopic dermatitis or psoriasis likely to confound clinical assessment; secondary bacterial infection requiring concurrent antibiotic therapy; systemic immunosuppressant use; or concurrent hepatic or renal disease. Children below 3 years of age were excluded given the higher risk of adverse effects with benzyl benzoate 25% at this age.

Group A received topical permethrin 5% cream applied from the neck to the toe, left on for 8–10 hours, and then washed off with water. This application was repeated after one week. Group B received topical benzyl benzoate 25% lotion applied from the neck to the toe on three consecutive days (Days 1, 2, and 3), left on for 24 hours per application, and then washed off. This three-day course was repeated after one week. In both groups, all household contacts were treated simultaneously using the same preparation allocated to the index case. All patients were instructed to launder clothing and bed linen in hot water on the day of treatment. Oral chlorphenamine (age-appropriate dose) was permitted in both groups for symptomatic relief of pruritus. All clinical assessments at follow-up visits were performed by the same examining physician blinded to the pruritus symptom score recorded at baseline.

Clinical assessment was performed at baseline, at 2 weeks, and at 4 weeks following the first treatment application. The primary outcome was clinical cure, defined as complete resolution of pruritus AND absence of any new skin lesions at the designated follow-up visit. Treatment failure was defined as persistence of active pruritus and/or appearance of new lesions at the designated follow-up visit. Secondary outcomes included time to resolution of pruritus (in days), treatment failure rate at Week 4, and the requirement for retreatment. Pruritus severity was scored on a four-point scale (0 = none, 1 = mild, 2 = moderate, 3 = severe). Adverse effects — including burning, stinging, erythema, contact dermatitis, and vesiculation, were documented by the examining physician at each follow-up visit.

Statistical Analysis

Data were entered and analyzed using SPSS version 26. Quantitative variables were summarized as mean ± standard deviation. Qualitative variables were expressed as frequencies and percentages. The chi-square test was applied to compare categorical outcomes between the two groups, and the independent samples t-test was applied for comparison of continuous variables. Odds ratios (OR) were calculated where applicable. Stratified analysis of 2-week cure rates was performed by age subgroup (3–7 years and 8–14 years). A p-value of ≤ 0.05 was considered statistically significant throughout.

RESULTS

A total of 150 children were enrolled, with 75 patients allocated to each group. No patient was lost to follow-up. The two groups were comparable at baseline with respect to age, sex distribution, symptom duration, baseline pruritus score, number of affected household contacts, prior scabies history, and anatomical distribution of lesions. All differences in baseline characteristics were statistically non-significant ($p>0.05$), confirming adequate comparability between the two groups. Baseline demographic and clinical characteristics are presented in Table 1.

Table 1: Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Group A Permethrin 5% (n=75)	Group B Benzyl Benzoate 25% (n=75)	p-value
Age (years), mean ± SD	8.3 ± 3.2	8.1 ± 3.5	0.724
Male sex, n (%)	42 (56.0%)	40 (53.3%)	0.741
Duration of symptoms (weeks), mean ± SD	3.2 ± 1.4	3.4 ± 1.6	0.368
Baseline pruritus score, mean ± SD	2.6 ± 0.5	2.7 ± 0.5	0.216
Household contacts affected, mean ± SD	3.1 ± 1.2	3.3 ± 1.1	0.253
Previous scabies episode, n (%)	18 (24.0%)	21 (28.0%)	0.581
Lesion distribution — interdigital web spaces, n (%)	75 (100%)	75 (100%)	—
Lesion distribution — wrist/forearm flexures, n (%)	68 (90.7%)	70 (93.3%)	0.542
Lesion distribution — abdomen/trunk, n (%)	52 (69.3%)	54 (72.0%)	0.719
Lesion distribution — axillary folds, n (%)	41 (54.7%)	38 (50.7%)	0.629

Values expressed as mean ± SD or n (%). Pruritus score: 0=none, 1=mild, 2=moderate, 3=severe

At 2 weeks, clinical cure was achieved in 68 (90.7%) patients in Group A compared with 54 (72.0%) in Group B, a statistically significant difference (p=0.006). At 4 weeks, cure rates were 72 (96.0%) in Group A and 63 (84.0%) in Group B (p=0.023). Mean time to resolution of pruritus was significantly shorter in Group A (8.1 ± 2.3 days) than in Group B (11.9 ± 3.4 days, p<0.001). Treatment failure at Week 4 was recorded in 3 (4.0%) patients in Group A and 12 (16.0%) in Group B (p=0.018). All treatment failures underwent retreatment. Efficacy outcomes are summarized in Table 2.

Table 2: Comparison of Efficacy Outcomes Between Group A (Permethrin 5%) and Group B (Benzyl Benzoate 25%)

Outcome	Group A Permethrin 5% (n=75)	Group B Benzyl Benzoate 25% (n=75)	p-value
Clinical cure at Week 2, n (%)	68 (90.7%)	54 (72.0%)	0.006
Clinical cure at Week 4, n (%)	72 (96.0%)	63 (84.0%)	0.023
Time to pruritus resolution (days), mean ± SD	8.1 ± 2.3	11.9 ± 3.4	<0.001
Treatment failure at Week 4, n (%)	3 (4.0%)	12 (16.0%)	0.018
Retreatment required, n (%)	3 (4.0%)	12 (16.0%)	0.018

p ≤ 0.05 considered statistically significant

Adverse effects were significantly more frequent in Group B than in Group A. Any local adverse effect was reported in 15 (20.0%) patients receiving permethrin compared with 38 (50.7%) patients receiving benzyl benzoate (p<0.001). In Group B, burning and stinging were the most commonly reported reactions (29.3%), followed by erythema (21.3%). Vesiculation was observed exclusively in the benzyl benzoate group (5.3%), and the difference was statistically significant (p=0.043). Contact dermatitis, though more frequent in Group B (8.0% vs 2.7%), did not reach statistical significance (p=0.148). No systemic adverse effects were recorded in either group. The adverse effect profile for both groups is detailed in Table 3.

Table 3: Local Adverse Effects Profile in Group A (Permethrin 5%) and Group B (Benzyl Benzoate 25%)

Adverse Effect	Group A Permethrin 5% n (%)	Group B Benzyl Benzoate 25% n (%)	p-value
Burning / stinging	10 (13.3%)	22 (29.3%)	0.019
Erythema	5 (6.7%)	16 (21.3%)	0.009
Contact dermatitis	2 (2.7%)	6 (8.0%)	0.148
Vesiculation	0 (0.0%)	4 (5.3%)	0.043
Any adverse effect (total)	15 (20.0%)	38 (50.7%)	<0.001

p ≤ 0.05 considered statistically significant

Table 4: Stratified Analysis of 2-Week Cure Rates by Age Subgroup

Age Subgroup (Week 2 Cure)	Group A Permethrin5% n (%)	Group B Benzyl Benzoate 25% n (%)	p-value	Odds Ratio
3–7 years (Group A: n=38; Group B: n=40)	33 (86.8%)	26 (65.0%)	0.024	3.8
8–14 years (Group A: n=37; Group B: n=35)	35 (94.6%)	28 (80.0%)	0.072	4.2
Overall (n=75 per group)	68 (90.7%)	54 (72.0%)	0.006	3.9

OR: odds ratio; p ≤ 0.05 considered statistically significant

Stratified analysis of 2-week cure rates by age subgroup revealed a statistically significant advantage for permethrin over benzyl benzoate in children aged 3–7 years (86.8% vs 65.0%, OR=3.8, p=0.024). In children aged 8–14 years, the difference in cure rates was directionally consistent (94.6% vs 80.0%, OR=4.2) but did not attain statistical significance (p=0.072), likely reflecting the smaller patient numbers in this stratum. Overall 2-week cure rates across both age subgroups are presented in Table 4.

DISCUSSION

The present quasi-experimental study demonstrated that topical permethrin 5% cream was significantly more effective than benzyl benzoate 25% lotion in achieving clinical cure among children with scabies at both 2-week (90.7% vs 72.0%, p=0.006) and 4-week (96.0% vs 84.0%, p=0.023) follow-up assessments. Permethrin was additionally associated with faster pruritus resolution and a substantially lower burden of local adverse effects, providing a clinically meaningful advantage across both efficacy and safety dimensions.

The 2-week cure rate of 90.7% achieved with permethrin in the present study is consistent with the published comparative literature. Usha and Gopalakrishnan Nair reported a permethrin cure rate of 91% in a controlled comparative study [9], closely approximating the present findings. Similarly, Bachewar et al. documented a permethrin cure rate of 88.0% contrasted with 73.3% for benzyl benzoate at a comparable follow-up interval [10] — a directional finding consistent with the present results. The Cochrane systematic review by Strong and Johnstone, which synthesized data from multiple controlled trials, concluded that permethrin demonstrated superior efficacy to benzyl benzoate in the treatment of scabies [8], reinforcing the primacy of permethrin as first-line therapy.

The 2-week cure rate of 72.0% recorded with benzyl benzoate approximates the 71.4% reported by Chhaiya et al. in an Indian comparative trial [12]. The comparatively modest efficacy of this agent in the pediatric population may partly reflect challenges in achieving uniform application coverage in young children and early termination of drug-skin contact time due to local irritancy [14]. The significantly higher adverse effect burden observed in the benzyl benzoate group (50.7% vs 20.0%, p<0.001) — particularly burning, stinging, and erythema — is consistent with the recognized irritant potential of this preparation at the 25% concentration [14, 18]. Roos et al. specifically documented the propensity of benzyl benzoate to produce chemical contact irritation and dermatitis in pediatric patients [14]. European guidelines recommend a 12.5% diluted formulation in children below 5 years of age to reduce local toxicity [7]; use of the full 25% concentration in this subgroup represents a limitation of the current protocol and may have contributed to the higher adverse effect rates in younger children.

Mean time to pruritus resolution was significantly shorter in the permethrin group (8.1 ± 2.3 vs 11.9 ± 3.4 days, p<0.001). Prolonged pruritus in the benzyl benzoate group likely reflects slower mite clearance as well as ongoing hypersensitivity to retained mite antigens. It is acknowledged that post-scabietic pruritus may persist for up to 4 weeks following successful treatment as a result of residual hypersensitivity responses, independent of mite viability [15]; however, given the concurrent finding of higher treatment failure rates in Group B, the pruritus data are more appropriately interpreted as reflecting genuine differences in therapeutic response rather than post-treatment hypersensitivity alone.

In the age-stratified analysis, the superiority of permethrin over benzyl benzoate was statistically significant in children aged 3–7 years (p=0.024) but did not reach significance in those aged 8–14 years (p=0.072). This pattern may reflect reduced tolerability of the benzyl benzoate-related irritation in younger children, potentially resulting in premature removal of the preparation and diminished drug-mite contact time [16]. Treatment failure at Week 4 occurred in 4.0% of permethrin recipients and 16.0% of benzyl benzoate recipients (p=0.018), consistent with the observation by Burkhart et al. that inadequate application technique and intolerance-related early removal are primary contributors to benzyl benzoate treatment failure [22]. Simultaneous treatment of all household contacts in both groups minimized reinfestation as a confounding explanation.

Several limitations of the present study merit acknowledgement. The quasi-experimental non-randomized design introduces the potential for allocation bias, and the single-centre recruitment limits generalizability to the broader pediatric population. Dermoscopic confirmation of diagnosis was not performed routinely in all patients [21], though consistent clinical diagnostic criteria were applied. The use of benzyl benzoate at the full adult concentration (25%) in children as young as 3 years may have underestimated the agent's tolerability had a diluted formulation been used. Despite these limitations, the findings provide locally relevant evidence consistently aligned with international literature, supporting topical permethrin 5% cream as the preferred scabicidal agent for children with scabies, in accordance with current European and WHO guidelines [7, 8, 20].

CONCLUSION

Topical permethrin 5% cream demonstrated significantly superior clinical cure rates, faster resolution of pruritus, and a more favorable local adverse effect profile compared with benzyl benzoate 25% lotion in children with scabies. It is recommended that topical permethrin 5% cream be adopted as the first-line scabicidal agent in children in this setting. Where permethrin is unavailable or cost-prohibitive, benzyl benzoate may be considered as an alternative, with preference for a diluted (12.5%) formulation in children below 5 years of age to reduce local adverse effects.

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