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COMPARISON OF EFFICACY OF TOPICAL BETAMETHASONE LOTION VERSUS TOPICAL KETOCONAZOLE 2% W/V LOTION IN THE TREATMENT OF SEBORRHEIC DERMATITIS

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Abstract

Background: *Seborrheic dermatitis (SD) has a multifactorial etiology, is a chronic inflammatory dermatosis and is characteristically found in sebum-rich skin areas. Direct comparative evidence of the efficacy of both topical corticosteroids and antifungals in mild to moderate SD is lacking.*

Objective: *Comparison of safety and efficacy of betamethasone dipropionate 0.05% w/v lotion with ketoconazole 2% w/v lotion in mild to moderate seborrheic dermatitis by Seborrheic Dermatitis Area and Severity Index (SDASI) and Visual Analog Scale (VAS) scores.*

Methods: *This 6-month prospective observational cohort study was carried out at Dermatology Department, CMH Abbottabad on 120 clinically diagnosed mild to moderate SD adults (SDASI ≤12), who were enrolled and divided equally into two groups. Group A was treated with betamethasone lotion, whereas Group B was treated with ketoconazole lotion, both applied once a day for 4 weeks. SDASI and VAS scores (pruritus, erythema, and scaling) were documented at baseline and Weeks 1, 2, and 4. Adverse events and recurrence at 6-week follow-up were also noted. Data were analyzed using SPSS v26.*

Results: *116 patients (58 in each group) completed the study. Mean SDASI decrease at Week 4 was significantly higher in the betamethasone group (5.2 ± 1.7) than in the ketoconazole group (4.3 ± 1.6; p = 0.003). VAS scores for all symptoms improved significantly in both groups with quicker and more relief in the betamethasone group. Median time to ≥50% SDASI decrease was 12 days vs. 16 days (p = 0.009). Both treatments were well tolerated with no difference in adverse effects. Recurrence at 6-week follow-up was slightly higher in the ketoconazole group (22.4% vs. 15.5%; p = 0.32).*

Conclusion: *Topical betamethasone dipropionate 0.05% lotion is more effective in the short-term compared to ketoconazole 2% lotion in the treatment of mild to moderate seborrheic dermatitis, with similar safety. This supports its application in the relief of symptoms quickly, with ketoconazole still being useful for ongoing use. Randomized controlled trials are recommended for long-term outcomes.*

INTRODUCTION

Seborrheic dermatitis is a chronic, relapsing inflammatory skin disease with pruritus, erythema, and scaling, involving predominantly sebum-rich areas like the scalp, face, and upper trunk. It involves a worldwide population of about 5–10% of adults, with increased prevalence in men and the age group of 18–65 years, especially those with conditions predisposing them like stress, immunosuppression, or neurological illness [1,2]. Pathogenesis is a multifactorial interplay of sebum secretion, colonization by Malassezia yeast, and immune-mediated inflammation, for which antifungals and anti-inflammatory drugs are cornerstones of treatment [3].

Topical corticosteroids like betamethasone are frequently used for their strong anti-inflammatory effect, quickly suppressing erythema and pruritus in seborrheic dermatitis. Long-term use, however, carries risks like skin atrophy and telangiectasia, and requires careful use [4]. Alternatively, topical antifungals like ketoconazole 2% w/v lotion act on Malassezia species, against a relevant etiological agent, and are preferred because of their good safety profile and efficacy in maintenance therapy [5]. Despite widespread use, very few prospective studies have directly compared their efficacy and safety in a controlled clinical environment, especially in South Asian populations where environmental and genetic factors might affect responses to treatment [6]. Few studies, including a local Pakistani study, have examined their individual efficacy, but strong, prospective cohort comparisons with standardized scoring systems are lacking [7].

The Seborrheic Dermatitis Area and Severity Index (SDASI) is a validated objective tool of disease severity, such as lesion area, erythema, and scaling in a numerical score [8]. The Visual Analog Scale (VAS) is also a valid and simple method of measuring subjective symptoms such as pruritus and erythema longitudinally [9].

The Combined Military Hospital (CMH) Abbottabad, Pakistan, has a mixed patient population, and hence a good environment in which to compare these treatments in adults with mild to moderate seborrheic dermatitis. The aim of this study is to bridge the gap of comparative data by comparing the safety and efficacy of topical betamethasone lotion with ketoconazole 2% w/v lotion for 6 months from September 21, 2024, to March 21, 2025. We hypothesize that betamethasone will bring about quicker relief from symptoms due to its anti-inflammatory action, whereas ketoconazole will yield more sustained control with fewer side effects due to its antifungal action.

Study Objectives

1. To compare the efficacy of topical betamethasone lotion versus topical ketoconazole 2% w/v lotion in reducing the Seborrheic Dermatitis Area and Severity Index (SDASI) score in adults with mild to moderate seborrheic dermatitis over 4 weeks.
2. To evaluate patient-reported symptom relief (itching, erythema, and scaling) using a visual analog scale (VAS) in both treatment groups.
3. To assess the time to achieve a 50% reduction in SDASI score between the two treatment groups.
4. To determine the incidence of adverse events associated with topical betamethasone and ketoconazole lotions.
5. To compare the recurrence rates of seborrheic dermatitis at a 6-week follow-up in both treatment groups.

Materials and Methods

Study Design

This is a prospective observational cohort study to compare the safety and efficacy of betamethasone dipropionate USP 0.05% w/v lotion with topical ketoconazole 2% w/v lotion for the treatment of mild to moderate seborrheic dermatitis.

Study Setting

The study was carried out at the Combined Military Hospital (CMH) Abbottabad, Pakistan, Dermatology Department, which is a tertiary care center with a wide variety of patients from Khyber Pakhtunkhwa's urban and rural areas.

Study Duration

The study lasted six months between September 21, 2024, and March 21, 2025, including participant recruitment, 4-week treatment, and a 6-week post-treatment follow-up.

Study Population

Inclusion Criteria

Adults aged 18-65 years with a clinical diagnosis of mild to moderate seborrheic dermatitis, as certified by a dermatologist using Seborrheic Dermatitis Area and Severity Index (SDASI) score (range: 0 to 12 for mild to moderate severity) [10], were recruited. Other inclusion criteria were willingness to give written informed consent and the ability to comply with the study protocol, including once-daily application of the lotion they were prescribed and follow-up appointments.

Exclusion Criteria

Patients were excluded in the presence of severe seborrheic dermatitis (SDASI score >12), coexistent bacterial, viral, or fungal skin infections needing systemic therapy, or hypersensitivity to betamethasone, ketoconazole, or any component of the lotion. Other exclusion criteria included the use of systemic corticosteroids or antifungals within the 4 weeks before enrollment, pregnancy or lactation, history of immunosuppressive or neurological conditions (e.g., Parkinson's disease, HIV) that could mask treatment effect [2]. Previous enrollment in another clinical trial within the previous 3 months was also an exclusion criterion.

Sample size

Sample size was calculated to detect a 20% difference in mean SDASI score reduction between the two treatment groups, with a standard deviation of 2.5, two-tailed alpha of 0.05, and 80% power. The estimate gave a minimum of 54 participants per group. To provide for 10% loss to follow-up, the target sample size was 120 participants, 60 participants per treatment condition [11].

Sampling Technique:

A consecutive non-probability sampling technique was used. Patients who were eligible and were attending the dermatology outpatient clinic were consecutively recruited following informed consent until the desired sample size was attained. They were classified into two groups using non-random allocation method, depending on the lotion they received.

Intervention Protocol

Participants in Group A (Betamethasone Group) received topical betamethasone dipropionate USP 0.05% w/v lotion, which was administered once a day to the affected areas, e.g., the scalp, face, or trunk, for 4 weeks. Participants in Group B (Ketoconazole Group) received topical ketoconazole 2% w/v lotion, which was administered once a day to the affected areas for 4 weeks.

Data Collection Procedure

Baseline Assessment

Demographic information at baseline such as gender and age, duration of disease, and baseline Seborrheic Dermatitis Area and Severity Index (SDASI) were collected. Patient self-reported symptoms of erythema, itching, and scaling were measured on a 10-point visual analog scale (VAS).

Treatment Phase

Participants applied the given lotion once a day for 4 weeks. Follow-up consultations at weeks 1, 2 and 4 consisted of blinded dermatologist SDASI scoring and patient-administered VAS. Side effects of burning, irritation, and skin atrophy were noted on a standardized checklist.

Follow-Up Phase

A final follow-up was also done at 6 weeks after treatment (week 10) to determine recurrence rates and late-onset side effects.

Outcome Measures

Primary Outcome

Change in SDASI score from baseline to week 4, indicating improvement in erythema, scaling, and lesion size [12].

Secondary Outcomes

Patient-reported improvement on itching, erythema, and scaling was measured on visual analog scale (VAS) at weeks 1, 2, and 4 [9]. Time to 50% improvement in Seborrheic Dermatitis Area and Severity Index (SDASI) score was measured. Number and intensity of adverse effects within the 4-week treatment period were captured. Recurrence rate of seborrheic dermatitis was measured on follow-up at 6 weeks after treatmentb. All follow-up measurements

were carried out by the same dermatologist to reduce inter-observer variability.

Data Analysis Process

Data were entered and processed using SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Continuous data like SDASI and VAS scores were presented as mean ± standard deviation (SD). Based on whether data were normally distributed or not, independent samples t-test or Mann–Whitney U test was used to compare the outcome between the two groups. Repeated-measures ANOVA was used for trend analysis of VAS scores over time and Kaplan–Meier analysis was used to compare time to achieve a ≥50% reduction in SDASI scores. Categorical variables like adverse events and recurrence rates were analyzed by the Chi-square test or Fisher's exact test, if necessary. A p-value of < 0.05 was used as statistically significant.

Ethical Implications

The study protocol was approved by the Institutional Review Board (IRB) of CMH Abbottabad. Informed written consent was taken from all the participants. The study was performed as per the Declaration of Helsinki (2013 revision) and in line with applicable Good Clinical Practice (GCP) guidelines [13].

Results

Participant Flow and Baseline Characteristics

138 patients were screened. 120 patients were enrolled based on the inclusion criteria, with 60 patients in each group. Four participants (2 in each group) were lost to follow-up, with an end evaluable sample of 116 patients (58 in each group). Table 1 summarizes the baseline demographic and clinical characteristics. The groups were comparable regarding age, gender distribution, baseline SDASI score, and disease duration.

Table 1. Baseline Characteristics of Study Participants

Variable	Betamethasone Group (n = 58)	Ketoconazole Group (n = 58)	*p*-value
Mean Age (years) ± SD	34.1 ± 10.6	33.5 ± 11.2	0.72
Male: Female Ratio	33:25	30:28	0.58
Mean Baseline SDASI ± SD	8.1 ± 2.1	8.4 ± 2.0	0.46
Duration of SD (months) ± SD	11.4 ± 3.8	11.7 ± 4.2	0.67

No statistically significant difference at baseline was observed between the two groups.

Primary Outcome

Reduction in SDASI Score

At Week 4, mean SDASI score in the betamethasone group fell from 8.1 ± 2.1 to 2.9 ± 1.5, and in the ketoconazole group from 8.4 ± 2.0 to 4.1 ± 1.7. Decrease of mean SDASI was significantly higher in the betamethasone group (5.2 ± 1.7) than in the ketoconazole group (4.3 ± 1.6, p = 0.003) (Figure. 1).

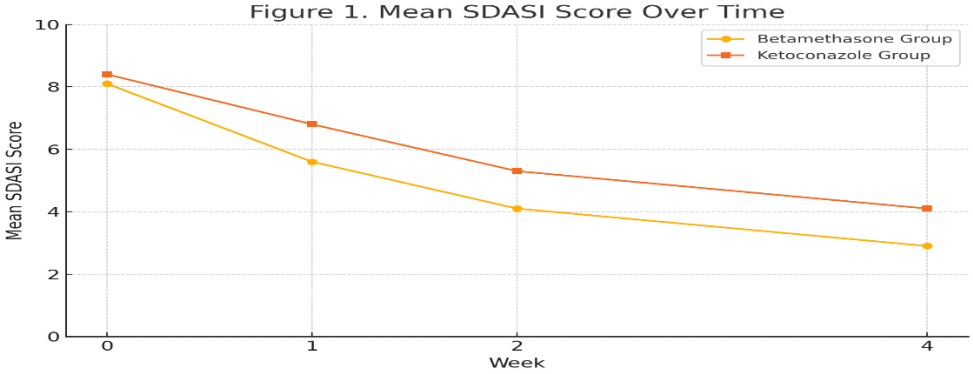

Figure 1. Line Graph Showing Mean SDASI Score Over Time

Secondary Outcomes

VAS Scores for Symptoms

VAS scores (0–10 scale) for erythema, scaling, and pruritus at Weeks 1, 2, and 4 were measured. Symptom improvement was evident in both groups with time, but betamethasone group experienced faster and more marked relief of all symptoms (Table. 2).

Table 2. Mean VAS Scores Over Time

Symptom	Time Point	Betamethasone (Mean ± SD)	Ketoconazole (Mean ± SD)	*p*-value
Pruritus	Week 1	4.2 ± 1.2	5.1 ± 1.3	0.005
	Week 4	1.8 ± 1.0	2.6 ± 1.2	0.002
Erythema	Week 4	2.1 ± 1.0	3.0 ± 1.2	0.004
Scaling	Week 4	2.4 ± 1.1	3.3 ± 1.3	0.006

Time to 50% Reduction of SDASI

The median time to reach ≥50% decrease in SDASI score was 12 days in the betamethasone group and 16 days in the ketoconazole group, and it was significant (log-rank test, p = 0.009) (Figure. 2).

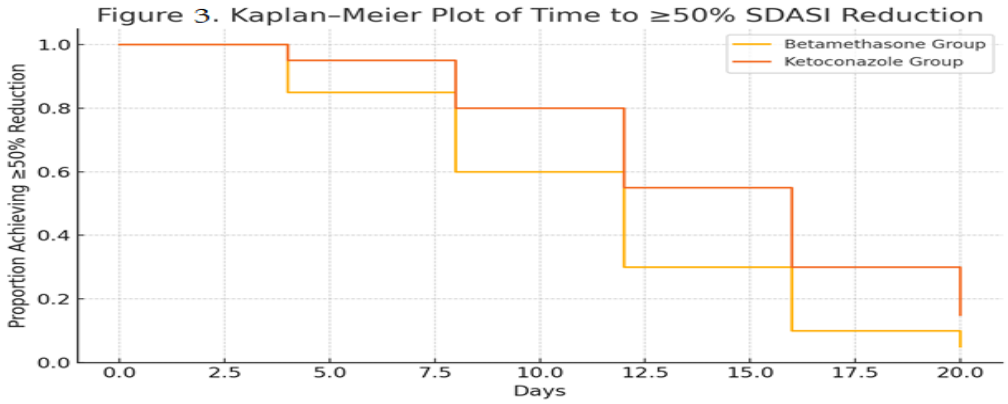

Figure 2. Kaplan–Meier Plot of Time to 50% SDASI Reduction

Adverse Events

Adverse events were mild and self-limiting in both groups. There was no statistically significant difference in the total incidence, (Table. 3).

Table 3. Adverse Events

Adverse Event	Betamethasone (n = 58)	Ketoconazole (n = 58)	*p*-value
Skin irritation	4 (6.9%)	5 (8.6%)	0.73
Burning sensation	3 (5.2%)	4 (6.9%)	0.69
Dryness/flaking	2 (3.4%)	6 (10.3%)	0.14

Recurrence Rate at 6-Week Follow-Up

At Week 10 (six weeks after therapy withdrawal), recurrence in 9 patients (15.5%) was observed in the betamethasone group and in 13 patients (22.4%) in the ketoconazole group, but the difference was not statistically significant (p = 0.32).

Betamethasone dipropionate lotion 0.05% worked significantly better to decrease SDASI scores at Week 4. Symptom improvement, as noted by VAS, was quicker and more significant in the betamethasone group. Side effects were negligible and similar in both groups, and recurrence rates were not

significantly dissimilar between groups at 6-week follow-up.

Discussion.

This prospective observational cohort study contrasted the efficacy and safety of topical betamethasone dipropionate 0.05% w/v lotion and topical ketoconazole 2% w/v lotion in the treatment of mild to moderate seborrheic dermatitis (SD) for 4 weeks, with a 6-week post-treatment follow-up. The findings indicate that both medications were effective for the relief of SD severity; however, betamethasone showed significantly better and faster clinical improvement, particularly in SDASI scores and symptom relief via VAS.

During 4 weeks, the betamethasone-treated group produced significantly more improvement in SDASI scores compared to ketoconazole-treated patients ($p = 0.003$). This can be expected from the potent anti-inflammatory effects of corticosteroids with rapid action to diminish erythema and scaling, the primary components of SDASI. The sooner relief of symptoms in the betamethasone group in all VAS parameters bears witness to its effectiveness in the short term, especially in flares or an acute exacerbation [14].

Ketoconazole 2%, an imidazole broad-spectrum antifungal, also decreased the severity of the disease significantly but with delayed action. This is to be expected from its antifungal action, which is mostly against Malassezia species and not against inflammation directly. Its effectiveness in SD treatment has been proven in earlier research but with its comparative inferiority in quick control of symptoms [15].

The Kaplan–Meier estimate also pointed towards the more rapid clinical improvement in the betamethasone group with median time to ≥50% SDASI improvement of 12 days versus 16 days in the ketoconazole arm ($p = 0.009$). However, such a difference, even though statistically significant, should be considered against the clinical backdrop of balancing efficacy versus safety in the long term.

Of particular interest, the two treatments were very well tolerated with minimal, transient side effects in both groups. No serious adverse events or treatment discontinuations occurred. This is consistent with earlier reports that short-term topical corticosteroid treatment, used judiciously, is safe for the treatment of SD of limited duration [16].

In respect to recurrence, although slightly greater relapse rate was observed at 6 weeks follow-up in the ketoconazole group, the difference was not statistically significant. This could be due to the antifungal effect of ketoconazole potentially causing longer-term suppression of Malassezia-related colonization even after discontinuation [17].

The results of this study are in agreement with Ravikumar et al., who also demonstrated superior short-term efficacy of betamethasone compared to ketoconazole in SD of the scalp [18]. It is, however, not in agreement with other research that recommends antifungals as first-line treatment owing to their good long-term relapse patterns [19]. Such discrepancies can be attributed to variations in disease presentation, study duration, and outcome measures.

Strengths and Limitations

One of the key strengths of this research is the use of validated disease measuring tools—SDASI and VAS—to determine the objective and subjective dimensions of improvement in disease. Additionally, the prospective design, routine follow-up schedule, and treatment administration in real-world clinical practice contribute to the external validity of results.

However, several limitations should be noted. Firstly, the non-random assignment carries a potential risk of selection bias. Secondly, the study was conducted in one tertiary care center, which may limit external validity. Thirdly, follow-up duration may be too brief to clearly establish long-term relapse rates or corticosteroid-related side effects.

Clinical Implications

Based on these observations, topical betamethasone dipropionate may be preferred for immediate symptomatic relief in the case of mild to moderate SD, particularly in acute flares. Ketoconazole, yet, may remain an option for maintenance over the long term or in steroid-sparing situations. Stepwise or rotational therapy may be optimal to address efficacy and safety aspects.

Conclusion

Betamethasone dipropionate 0.05% lotion was superior short-term to ketoconazole 2% lotion in decreasing severity of seborrheic dermatitis. The treatments were well tolerated. These results are consistent with the use of corticosteroids for quick relief of flares, with antifungals still useful for long-term management. More randomized controlled trials are needed to define optimal treatment regimens.

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