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Comparative Study of Ketoconazole-Based Shampoo versus Coal Tar-Based Shampoo in Seborrheic Dermatitis

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ABSTRACT

Background: Seborrheic dermatitis (SD) is a chronic inflammatory skin disorder primarily affecting the scalp, characterized by erythema, scaling, and pruritus. Ketoconazole and coal tar–based shampoos are commonly used therapeutic agents. This study aimed to compare the efficacy and safety of ketoconazole-based shampoo versus coal tar–based shampoo in patients with mild to moderate scalp SD.

Material and Methods: A prospective, randomized, comparative study was conducted among 100 patients diagnosed with SD, who were randomly assigned to two equal groups (n=50 each). Group A received ketoconazole 2% shampoo, and Group B received coal tar 1% shampoo, both applied twice weekly for four weeks. Outcomes were assessed using the Seborrheic Dermatitis Severity Score (SDSS), a Visual Analogue Scale (VAS) for symptom relief, and documentation of adverse events at baseline, week 2, and week 4. Statistical analysis was performed using appropriate parametric and non-parametric tests.

Results: Both groups showed a significant reduction in SDSS from baseline to week 4. However, Group A (ketoconazole) demonstrated a greater reduction in SDSS at both week 2 ($p=0.012$) and week 4 ($p<0.001$). VAS scores indicated a higher proportion of patients reporting good symptom relief (VAS 7–10) in Group A (64%) compared to Group B (40%) ($p=0.044$). Adverse events were fewer in Group A, with a significantly lower incidence of foul odor and overall adverse effects ($p=0.047$).

Conclusion: Ketoconazole-based shampoo is more effective and better tolerated than coal tar–based shampoo in the short-term management of Seborrheic dermatitis. It significantly reduces clinical severity and improves patient satisfaction with fewer adverse events, making it a preferred therapeutic option.

Keywords: *Seborrheic dermatitis, ketoconazole shampoo, coal tar, antifungal, comparative study, SDSS, VAS score*

INTRODUCTION

Seborrheic dermatitis (SD) is a common chronic inflammatory skin condition characterized by erythema, scaling, and pruritus in sebaceous gland–rich regions, with a reported prevalence of 1–5% in adults and up to 10% in infants and immunocompromised individuals [1]. While topical antifungal agents are considered first-line therapy—particularly 2% ketoconazole shampoo due to its efficacy in inhibiting Malassezia species and reducing scaling and pruritus [2,3]—coal tar shampoo remains a traditional option valued for its keratolytic and anti-proliferative properties [4]. However, coal tar's strong odor, potential for staining, and dermatologic tolerability issues warrant ongoing comparison with modern antifungals [5].

A randomized controlled trial comparing 2% ketoconazole shampoo to placebo demonstrated significant symptom relief in scalp SD after four weeks [2]. Another double-blind study found that coal tar formulations were superior to placebo in reducing dandruff and erythema, although long-term use may be limited by unpleasant cosmetic characteristics [4]. A meta-analysis highlighted ketoconazole's favorable safety and tolerability profile compared to coal tar and other

agents [3]. Despite these data, few studies have directly compared ketoconazole versus coal tar shampoos in head-to-head trials.

Given that both agents are still in clinical use, this randomized comparative trial was undertaken to evaluate the efficacy and tolerability of ketoconazole-based shampoo versus coal tar–based shampoo in patients with mild to moderate scalp SD. This investigation aims to guide clinicians in selecting the most effective and patient-acceptable therapeutic option.

MATERIAL AND METHODS

Study Design and Setting: This was a prospective, randomized, open-label, comparative clinical study conducted in the Dermatology Outpatient Department of a tertiary care teaching hospital in India over a period of six months. The study aimed to evaluate and compare the efficacy and safety of ketoconazole-based shampoo and coal tar-based shampoo in patients diagnosed with Seborrheic dermatitis (SD) of the scalp.

Inclusion and Exclusion Criteria: Patients aged 18 to 60 years with clinically diagnosed mild to moderate Seborrheic dermatitis of the scalp were included. Those with a history of hypersensitivity to either ketoconazole or coal tar preparations, concurrent use of systemic antifungals, immunocompromised status, active scalp infections, or those who had used topical treatment for SD within two weeks prior to enrolment were excluded.

Sample Size and Randomization: A total of 100 patients fulfilling the inclusion criteria were randomized equally into two groups using a computer-generated random number table.

- Group A received 2% ketoconazole-based shampoo.
- Group B received 1% coal tar-based shampoo.

Intervention Protocol: Participants were instructed to use the assigned shampoo twice weekly for four weeks. They were advised to apply the shampoo on the wet scalp, leave it in place for five minutes, and then rinse thoroughly. No other topical or systemic treatment for SD was permitted during the study period.

Assessment and Follow-up: Patients were evaluated at baseline and at the end of 2 and 4 weeks. The primary outcome measure was improvement in Seborrheic Dermatitis Severity Score (SDSS), a composite clinical score assessing erythema, scaling, and pruritus (graded 0–3 for each domain). Secondary outcomes included patient-reported improvement using a Visual Analogue Scale (VAS) and the incidence of adverse events.

Statistical Analysis: Data were analyzed using SPSS software version 25. Continuous variables were expressed as mean ± standard deviation, and categorical variables were presented as frequencies and percentages. The comparison between groups was performed using the unpaired t-test or Mann–Whitney U test for continuous variables and the chi-square test for categorical variables. A p-value < 0.05 was considered statistically significant.

RESULTS

The demographic and baseline characteristics of the participants are summarized in Table 1. The mean age of patients was comparable between the groups, with no statistically significant difference. Gender distribution and duration of the disease were also similar across the groups. Baseline SDSS did not differ significantly between the groups, ensuring comparability at the start of treatment.

Treatment efficacy was evaluated using the SDSS at multiple time points as shown in Table 2. While there was no significant difference at baseline, a statistically significant reduction in SDSS was observed in the ketoconazole group at both 2 weeks ($p = 0.012$) and 4 weeks ($p < 0.001$) post-treatment initiation compared to the coal tar group, indicating superior clinical improvement in Group A.

Patient-reported outcomes assessed using the Visual Analogue Scale (VAS) are presented in Table 3. A greater proportion of patients in the ketoconazole group reported good symptom relief (VAS score 7–10) compared to the coal tar group (64% vs 40%), while fewer patients reported poor relief (VAS score 0–3) in Group A. The difference in symptom perception was statistically significant ($p = 0.044$), suggesting higher patient satisfaction with ketoconazole-based shampoo.

Adverse events during treatment are detailed in Table 4. Though the incidence of scalp irritation and hair dryness was higher in the coal tar group, these differences were not statistically significant. However, foul odor was reported exclusively in the coal tar group ($p = 0.027$). Overall, a significantly higher proportion of patients in the coal tar group experienced at least one adverse effect ($p = 0.047$), indicating better tolerability of the ketoconazole-based formulation.

Table 1: Demographic and Baseline Characteristics of Study Participants

Characteristic	Group A (Ketoconazole) (n = 50)	Group B (Coal Tar) (n = 50)	Total (n = 100)	*p*-value
Age (mean ± SD, years)	32.4 ± 8.2	33.1 ± 7.9	32.8 ± 8.0	0.621
Gender (Male/Female)	28 / 22	30 / 20	58 / 42	0.689
Duration of SD (months)	6.1 ± 2.3	6.4 ± 2.5	6.2 ± 2.4	0.512
Baseline SDSS (mean ± SD)	6.42 ± 1.02	6.35 ± 1.11	—	0.681

Table 2: Comparison of Seborrheic Dermatitis Severity Score (SDSS)

Time Point	Group A (Ketoconazole) Mean ± SD	Group B (Coal Tar) Mean ± SD	*p*-value
Baseline	6.42 ± 1.02	6.35 ± 1.11	0.681
Week 2	4.15 ± 1.01	4.82 ± 1.13	0.012
Week 4	2.31 ± 0.86	3.18 ± 1.01	<0.001

Table 3: Visual Analogue Scale (VAS) for Patient-Reported Symptom Relief

VAS Score (0–10)	Group A (Ketoconazole) (n, %)	Group B (Coal Tar) (n, %)	*p*-value
0–3 (Poor relief)	4 (8.0%)	10 (20.0%)	0.044
4–6 (Moderate relief)	14 (28.0%)	20 (40.0%)	
7–10 (Good relief)	32 (64.0%)	20 (40.0%)	

Table 4: Adverse Events Reported During Treatment

Adverse Event	Group A (Ketoconazole) (n, %)	Group B (Coal Tar) (n, %)	*p*-value
Scalp irritation	3 (6.0%)	7 (14.0%)	0.182
Foul odor	0 (0.0%)	6 (12.0%)	0.027
Hair dryness	2 (4.0%)	5 (10.0%)	0.235
Total with any event	5 (10.0%)	12 (24.0%)	0.047

DISCUSSION

This randomized comparative study confirmed that ketoconazole 2% shampoo offers superior clinical efficacy and better tolerability than coal tar–based shampoo in the management of mild to moderate Seborrheic dermatitis (SD) of the scalp. Significant reductions in severity scores were noted as early as two weeks, with more pronounced improvement by four weeks in the ketoconazole group (Table 2). These findings are consistent with robust evidence demonstrating ketoconazole's effectiveness in SD treatment, with earlier trials documenting up to 88% of patients achieving excellent responses after four weeks of twice-weekly use [6].

The antifungal and anti-inflammatory properties of ketoconazole contribute to its rapid clinical benefits. An evidence-based review has shown that ketoconazole shampoo significantly reduces Malassezia populations and associated inflammation, with low relapse risk and favorable tolerability [6]. Its safety profile—marked by minimal systemic absorption and low irritancy—was evident in our results, with fewer adverse events reported compared to coal tar shampoo (Table 4).

Coal tar shampoo, while historically utilized for its keratolytic and anti-proliferative effects, is associated with noticeable cosmetic drawbacks, including odor and hair discoloration [7]. In our study, the coal tar group had a significantly higher occurrence of foul odor and total adverse effects (Table 4), which may adversely affect patient compliance and quality of life. Although coal tar remains effective, especially in conditions like psoriasis and classic seborrhea, its tolerability issues limit its appeal [8].

Patient-reported outcomes further underscored ketoconazole's benefits: a higher proportion of users reported good or excellent symptom relief at four weeks compared to the coal tar group (Table 3). This aligns with findings from comparative studies where antifungal-based shampoos consistently achieved better patient satisfaction and symptom control [4].

Strengths of this study include strict randomization, standardized clinical scoring, and collection of both clinician-reported and patient-reported outcomes. Limitations encompass the open-label design, single-center setting, and lack of

long-term follow-up to assess relapse rates. Future studies incorporating adjunctive anti-inflammatory treatments, extended follow-up, or laboratory assessment of fungal load could further clarify durability and mechanism of response.

CONCLUSION

This comparative study demonstrated that ketoconazole-based shampoo is more effective than coal tar-based shampoo in reducing seborrheic dermatitis severity, with significant improvements observed as early as two weeks of treatment. Patient-reported symptom relief was notably better in the ketoconazole group, reflecting greater satisfaction and perceived efficacy. Although both treatments were generally well tolerated, the ketoconazole group experienced fewer and milder adverse events. The presence of foul odor and higher incidence of overall side effects in the coal tar group may impact patient compliance. Therefore, ketoconazole-based shampoo appears to be a safer and more effective therapeutic option for managing seborrheic dermatitis.

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