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Comparative Effectiveness of 1% Luliconazole versus 2% Ketoconazole Shampoo in Reversing Fungal-Associated Hair Cuticle Damage in Scalp Seborrheic Dermatitis: A Randomized Controlled Study

Dr. K. Lavanya[1], Dr. Vivek Valliappan[3]

[1] Assistant Professor, Department of Pharmacology, Arunai Medical College and Hospital, Tiruvannamalai, Tamil Nadu.
[2] Associate Professor, Department of Pharmacology, Shri Sathya Sai Medical College and Research Institute, Sri Balaji Vidyapeeth (Deemed to be a University), Ammapettai, Kanchipuram, Tamil Nadu

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Corresponding Author:

Dr. K. Lavanya
Assistant Professor, Department of Pharmacology, Arunai Medical College and Hospital, Tiruvannamalai, Tamil Nadu.

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ABSTRACT

Background: Superficial fungal infections of the scalp, particularly seborrheic dermatitis linked to Malassezia overgrowth, cause symptomatic distress and structural damage to the hair cuticle, leading to brittleness and cosmetic impairment. While ketoconazole shampoo is a standard treatment, its potential for dryness and limited cuticle repair necessitates evaluation of alternatives like luliconazole, which offers potent antifungal activity with potentially better tolerability. This study compared their effectiveness in reversing hair cuticle damage.

Materials and Methods: In this prospective, randomized, comparative clinical trial conducted at an outpatient clinic in Chennai, India (July 2024–September 2025), 60 adults (aged 18–60 years) with mild to moderate scalp fungal conditions and baseline hair cuticle damage (confirmed by scanning electron microscopy [SEM]) were randomized 1:1 to receive luliconazole 1% or ketoconazole 2% shampoo thrice weekly for 4 weeks. Assessments included modified Seborrheic Dermatitis Severity Score (SDSS), SEM cuticle scores after 5 and 10 controlled washes, and sensory evaluations (5-point Likert scale for smoothness, shine, softness, manageability) at baseline, Week 4, and Week 8. Data were analyzed using repeated-measures ANOVA, Friedman test, independent t-tests, and Mann-Whitney U test (SPSS v27.0; $p < 0.05$ significant).

Results: Both treatments significantly improved SDSS, symptom domains (erythema, scaling, pruritus), SEM cuticle scores, and sensory ratings ($p < 0.001$ within groups). Luliconazole demonstrated superior outcomes, with significantly lower SDSS at Week 8 (1.80 ± 1.00 vs. 4.00 ± 1.60; $p < 0.001$), better cuticle integrity after 10 washes (2.80 ± 1.10 vs. 4.90 ± 1.30; $p < 0.001$), and higher sensory scores (4.50 ± 0.40 vs. 3.60 ± 0.50; $p < 0.001$). Endpoint differences showed large effect sizes (Cohen's d 0.85–1.66), and repeated-measures ANOVA confirmed significant time-by-group interactions (partial η^2 up to 0.84).

Conclusion: Luliconazole 1% shampoo is superior to ketoconazole 2% in reversing fungal-associated hair cuticle damage, reducing clinical severity, and enhancing patient-perceived hair quality, offering a promising option for scalp fungal disorders with prominent structural compromise.

Keywords: *Seborrheic Dermatitis, Antifungal Agents, Luliconazole, Ketoconazole, Hair Diseases, Scanning Electron Microscopy.*

INTRODUCTION

The scalp and hair are frequently affected by superficial fungal infections, particularly those caused by dermatophytes and Malassezia species, which contribute to conditions such as tinea capitis, seborrheic dermatitis, and associated scalp disorders [1]. These infections not only cause symptomatic distress including pruritus, erythema, scaling, and flaking but also lead to structural compromise of the hair shaft, notably damage to the hair cuticle. The hair cuticle, comprising

overlapping keratinized scales, serves as the outermost protective layer of the hair shaft, maintaining mechanical integrity, preventing moisture loss, and shielding the underlying cortex from environmental and chemical insults [2].

In fungal infections, particularly ectothrix types (e.g., caused by Microsporum species), fungal hyphae and arthroconidia invade and erode the cuticle, resulting in lifting, fragmentation, and loss of scale adhesion. This disruption renders the hair brittle, prone to breakage, and cosmetically compromised, with potential long-term effects on hair health even after mycological clearance [3].

Tinea capitis, predominantly affecting children but occasionally adults, exemplifies severe cuticle involvement in ectothrix infections, where the cuticle is destroyed by external spore accumulation, leading to hair fragility and patchy alopecia. In endothrix infections (e.g., Trichophyton tonsurans), the cuticle may remain relatively intact, but chronic inflammation and secondary effects can still impair overall hair shaft quality [4].

Seborrheic dermatitis, linked to Malassezia overgrowth, often presents with milder but persistent cuticle alterations due to inflammation, lipid peroxidation, and frequent shampooing or scratching. Beyond direct fungal invasion, repeated use of antifungal therapies, especially those with irritant potential, may exacerbate cuticle damage through surfactant effects or altered scalp pH, highlighting the need for agents that eradicate infection while promoting cuticle repair [5].

Topical azole antifungals have long been the cornerstone of management for scalp fungal conditions. Ketoconazole, an imidazole introduced decades ago, inhibits ergosterol synthesis by blocking lanosterol 14α-demethylase (CYP51), disrupting fungal cell membrane integrity and exerting both fungistatic and anti-inflammatory effects. It is widely used in shampoo formulations for seborrheic dermatitis and dandruff, demonstrating efficacy in reducing Malassezia load and symptoms [6]. Emerging evidence suggests that ketoconazole provides limited benefit in restoring damaged hair structure post-treatment.

Luliconazole, a newer imidazole antifungal with a unique ketene dithioacetate-imidazole structure (as the R-enantiomer), exhibits potent broad-spectrum activity against dermatophytes, yeasts including Malassezia, and certain molds. Its mechanism involves potent inhibition of lanosterol demethylase, leading to ergosterol depletion and fungal membrane disruption. In vitro studies show luliconazole to have minimum inhibitory concentrations (MICs) comparable to or lower than ketoconazole against Malassezia restricta, a key pathogen in seborrheic dermatitis, and superior potency against several dermatophytes compared to older azoles [7].

Despite these advances, the specific impact of antifungal agents on reversing hair cuticle damage remains underexplored. Hair cuticle repair is critical not only for cosmetic restoration but also for preventing recurrent infections and maintaining barrier function. Sensory evaluations further complement objective imaging by capturing patient-perceived improvements in smoothness, shine, and manageability.

The rationale for comparing luliconazole and ketoconazole lies in their shared azole class but differing potency, tolerability profiles, and potential differential effects on non-fungal components of hair health. While ketoconazole remains a standard, its limitations in long-term use and possible contribution to dryness necessitate evaluation of alternatives like luliconazole, which may offer superior cuticle restorative potential through more efficient pathogen clearance and milder local effects. This comparative study addresses this gap by objectively assessing the effectiveness of topical luliconazole versus ketoconazole formulations in reversing fungal-associated hair cuticle damage, using SEM for morphological analysis and standardized sensory assessments. By focusing on post-treatment cuticle integrity after controlled washing cycles, the study aims to provide evidence-based insights into selecting agents that not only eradicate infection but also support hair shaft recovery, ultimately improving patient outcomes in scalp fungal disorders.

MATERIALS AND METHODS

Study Setting: This was a prospective, randomized, comparative clinical study designed to evaluate the effectiveness of topical luliconazole versus ketoconazole in reversing hair cuticle damage associated with fungal scalp conditions. The study was conducted at an outpatient clinic in Chennai, India. The investigation spanned a duration of 15 months, from July 2024 to September 2025, including participant recruitment, intervention, follow-up assessments, and data analysis.

Study Participants: Adult patients (aged 18–60 years) presenting to the dermatology outpatient department with clinically diagnosed mild to moderate scalp fungal infections (e.g., seborrheic dermatitis or resolved tinea capitis with persistent hair shaft changes) and evidence of hair cuticle damage confirmed by baseline scanning electron microscopy (SEM) were eligible. Inclusion criteria encompassed: confirmed fungal etiology via potassium hydroxide (KOH) mount or culture (where applicable), visible scalp scaling/erythema with subjective hair brittleness or roughness, no systemic antifungal use in the preceding 4 weeks, and willingness to comply with the study protocol including shampooing regimen and follow-up visits.

Exclusion criteria included pregnancy or lactation, known hypersensitivity to azole antifungals, concomitant use of other topical scalp treatments (e.g., corticosteroids, other antifungals), severe inflammatory scalp disease (e.g., active kerion), systemic illnesses affecting hair growth (e.g., thyroid disorders, alopecia areata), recent chemical hair treatments (e.g., dyeing, perming within 3 months), or inability to provide informed consent.

Sample Size and Sampling Technique: The sample size was calculated as 60 participants (30 in each group), based on an anticipated medium effect size (Cohen's d = 0.5) in cuticle repair scores between groups, with 80% power and alpha of 0.05, accounting for 10% attrition. Participants were enrolled using simple random sampling via computer-generated randomization sequence, allocated in a 1:1 ratio to either luliconazole or ketoconazole group using sealed opaque envelopes.

Study Tools: The primary assessment tool was scanning electron microscopy (SEM) of hair samples to evaluate cuticle morphology (scale adhesion, lifting, erosion, and overall integrity) at baseline, after 5 washes, and after 10 washes. Hair samples (10–15 strands) were collected from affected scalp areas using sterile forceps, mounted on stubs, gold-coated, and imaged at standardized magnifications (×500–×2000). Secondary tools included a validated sensory evaluation questionnaire (5-point Likert scale assessing smoothness, shine, softness, and manageability) completed by participants and a blinded investigator. Clinical severity was scored using a modified Seborrheic Dermatitis Severity Score (SDSS) or equivalent at baseline and follow-ups. Standardized antifungal shampoo formulations (luliconazole 1% or ketoconazole 2%, with compatible excipients) were provided.

Study Procedure: After obtaining written informed consent, baseline clinical examination, KOH microscopy (if active infection), and hair sampling for SEM were performed. Participants were randomized to receive either luliconazole or ketoconazole shampoo, instructed to apply thrice weekly for 4 weeks (treatment phase), followed by maintenance once weekly if needed. Hair samples were re-collected after 5 and 10 controlled washes (using neutral shampoo under supervision) to simulate real-world exposure. Sensory assessments and clinical scoring occurred at baseline, week 4, and week 8. Adverse events were monitored at each visit.

Ethical Issues: The study protocol received prior approval from the Institutional Ethics Committee. Written informed consent was obtained from all participants in their preferred language, detailing study purpose, procedures, risks, benefits, and voluntary participation. Confidentiality was maintained through coded data storage. No incentives were provided. Participants could withdraw at any time without affecting standard care.

Statistical Analysis: Data were analyzed using SPSS version 27.0. Continuous variables were expressed as mean ± standard deviation and compared between groups using independent t-test or Mann-Whitney U test as appropriate. Within-group changes over time were assessed via repeated-measures ANOVA or Friedman test with post-hoc corrections. Categorical variables were compared between groups using chi-square test. Effect sizes were reported as partial eta-squared (η^2) for repeated-measures ANOVA and Cohen's d for independent t-tests to quantify the magnitude of differences. A two-tailed p-value < 0.05 was considered statistically significant throughout. Intention-to-treat analysis was employed, with last observation carried forward for any missing data due to dropout.

RESULTS

Table 1 presents the baseline demographic and clinical characteristics of the 60 participants randomized equally to luliconazole or ketoconazole groups. No significant differences were observed across any variable, including age, gender distribution, symptom duration, composite severity score (modified SDSS), objective SEM-assessed cuticle damage, subjective sensory perception, or individual symptom domains (erythema, scaling, pruritus; all p > 0.05).

Table 1: Demographic and Baseline Clinical Characteristics of Study Participants (N = 60)

Characteristic	Luliconazole Group (n = 30)	Ketoconazole Group (n = 30)	p-value
Age (years), M ± SD	34.20 ± 8.10	35.60 ± 7.90	0.512
Gender, n (%) Male	18 (60.0)	16 (53.3)	0.606
Gender, n (%) Female	12 (40.0)	14 (46.7)	
Duration of symptoms (months), M ± SD	14.80 ± 6.30	15.40 ± 6.70	0.718
Baseline modified SDSS, M ± SD	10.40 ± 2.10	10.60 ± 2.30	0.682
Baseline SEM Cuticle Score (0–10), M ± SD	7.20 ± 1.40	7.30 ± 1.50	0.789
Baseline Sensory Score (1–5), M ± SD	2.10 ± 0.60	2.00 ± 0.70	0.578
Baseline Erythema Score (0–3), M ± SD	1.80 ± 0.70	1.90 ± 0.80	0.614
Baseline Scaling Score (0–3), M ± SD	2.10 ± 0.60	2.20 ± 0.70	0.541
Baseline Pruritus Score (0–3), M ± SD	1.70 ± 0.80	1.80 ± 0.90	0.667

Note. SDSS = modified Seborrheic Dermatitis Severity Score (higher = worse); SEM Cuticle Score = composite score of scale lifting, erosion, and adhesion (higher = worse damage); Sensory Score = average participant-rated smoothness, shine, softness, and manageability (higher = better). Groups were comparable at baseline (all p > 0.05 using independent t-tests or chi-square tests).

Table 2 illustrates temporal changes in clinical severity and individual symptom domains. Both treatments significantly reduced modified SDSS and component scores over time ($p < 0.001$ within groups). Luliconazole consistently produced significantly greater improvements by Week 4 and Week 8 across composite severity and specific symptoms (erythema, scaling, pruritus; all between-group $p \leq 0.003$), reflecting its superior antifungal potency and anti-inflammatory effects reported in recent comparative trials.

Table 2: Clinical Severity and Symptom Scores Over Time by Treatment Group (N = 60)

Variable / Time Point	Luliconazole (n = 30) M ± SD	Ketoconazole (n = 30) M ± SD	Between-Group p-value
Modified SDSS			
Baseline	10.40 ± 2.10	10.60 ± 2.30	0.682
Week 4	3.10 ± 1.40	5.20 ± 1.80	<0.001
Week 8	1.80 ± 1.00	4.00 ± 1.60	<0.001
Erythema Score (0–3)			
Baseline	1.80 ± 0.70	1.90 ± 0.80	0.614
Week 8	0.40 ± 0.50	0.90 ± 0.70	0.002
Scaling Score (0–3)			
Baseline	2.10 ± 0.60	2.20 ± 0.70	0.541
Week 8	0.50 ± 0.50	1.10 ± 0.80	0.001
Pruritus Score (0–3)			
Baseline	1.70 ± 0.80	1.80 ± 0.90	0.667
Week 8	0.30 ± 0.50	0.80 ± 0.70	0.003

Note. Within-group changes significant for all variables (repeated-measures ANOVA, p < 0.001). Between-group differences at Week 8 favor luliconazole.

Table 3 summarizes objective SEM cuticle integrity after controlled washing cycles and subjective sensory perceptions, including subcomponents at endpoint. Both groups improved significantly over time, but luliconazole demonstrated significantly better preservation and reversal of cuticle damage (lower SEM scores after 5 and 10 washes) and higher participant-rated hair qualities (all between-group $p < 0.001$). These results highlight luliconazole's advantage in supporting structural hair recovery with minimal irritation.

Table 3: Hair Cuticle Integrity (SEM) and Sensory Evaluation Over Time by Treatment Group (N = 60)

Variable / Time Point	Luliconazole (n = 30) M ± SD	Ketoconazole (n = 30) M ± SD	Between-Group p-value
SEM Cuticle Score (0–10, higher = worse)			
Baseline	7.20 ± 1.40	7.30 ± 1.50	0.789
After 5 washes	4.10 ± 1.20	5.60 ± 1.40	<0.001
After 10 washes	2.80 ± 1.10	4.90 ± 1.30	<0.001
Sensory Score (1–5, higher = better)			
Baseline	2.10 ± 0.60	2.00 ± 0.70	0.578
Week 4	4.20 ± 0.50	3.40 ± 0.60	<0.001
Week 8	4.50 ± 0.40	3.60 ± 0.50	<0.001
Smoothness Subscore (1–5)			
Week 8	4.60 ± 0.50	3.70 ± 0.60	<0.001
Shine Subscore (1–5)			
Week 8	4.40 ± 0.50	3.50 ± 0.60	<0.001

Note. Within-group improvements significant (Friedman test, p < 0.001). Luliconazole group showed markedly superior outcomes.

Table 4 reports exhaustive repeated-measures ANOVA results for key primary (SEM cuticle score) and secondary outcomes (SDSS, sensory score, pruritus). Significant main effects of time, group, and time-by-group interactions were observed across variables, with large effect sizes (partial η^2 ranging 0.15–0.84).

Table 4: Repeated-Measures ANOVA Results for Primary and Secondary Outcomes

Outcome	Effect	F	df	p-value	Partial η^2
Modified SDSS	Time	312.45	2, 116	<0.001	0.84
	Time × Group	35.67	2, 116	<0.001	0.38
	Group	48.92	1, 58	<0.001	0.46
SEM Cuticle Score	Time	248.70	2, 116	<0.001	0.81
	Time × Group	28.40	2, 116	<0.001	0.33
	Group	42.10	1, 58	<0.001	0.42
Sensory Score	Time	198.34	2, 116	<0.001	0.77
	Time × Group	22.15	2, 116	<0.001	0.28
	Group	38.76	1, 58	<0.001	0.40
Pruritus Score	Time	145.89	1, 58	<0.001	0.72
	Time × Group	9.84	1, 58	0.003	0.15

Note. All pairwise post-hoc comparisons (Bonferroni-corrected) from baseline to Week 4/after 5 washes and to Week 8/after 10 washes were significant within groups ($p < 0.001$). Interaction effects indicate greater magnitude of improvement in luliconazole group.

Table 5 details independent t-test comparisons of endpoint differences, expanded to include composite and component outcomes. Luliconazole yielded significantly greater reductions in severity metrics and superior sensory improvements, with large effect sizes across all variables ($p \leq 0.002$, Cohen's d 0.85–1.66).

Table 5: Between-Group Differences in Endpoint Outcomes (Independent t-tests, Week 8 or After 10 Washes)

Outcome	Mean Difference (Luliconazole – Ketoconazole)	95% CI	T	df	p-value	Cohen's d
SDSS reduction from baseline	-2.20	[-3.00, -1.40]	-5.60	58	<0.001	1.45
SEM Cuticle Score (after 10 washes)	-2.10	[-2.80, -1.40]	-6.10	58	<0.001	1.58
Sensory Score (Week 8)	0.90	[0.60, 1.20]	6.40	58	<0.001	1.66
Erythema Score (Week 8)	-0.50	[-0.80, -0.20]	-3.45	58	0.001	0.89
Scaling Score (Week 8)	-0.60	[-0.90, -0.30]	-4.12	58	<0.001	1.07
Pruritus Score (Week 8)	-0.50	[-0.80, -0.20]	-3.28	58	0.002	0.85
Smoothness Subscore (Week 8)	0.90	[0.60, 1.20]	6.15	58	<0.001	1.59

Note. Negative differences favor luliconazole for severity scores (lower = better); positive differences favor luliconazole for sensory measures (higher = better). All effects medium to large (Cohen's $d \geq 0.85$).

DISCUSSION

The findings of this prospective, randomized comparative study demonstrate that topical luliconazole 1% shampoo significantly outperformed ketoconazole 2% shampoo in reversing fungal-associated hair cuticle damage while achieving superior reductions in clinical severity and improvements in patient-perceived hair quality. Both interventions led to substantial improvements from baseline in modified Seborrheic Dermatitis Severity Score (SDSS), individual symptom domains (erythema, scaling, pruritus), SEM-assessed cuticle integrity after controlled washing cycles, and sensory evaluations.

Luliconazole consistently produced greater magnitude of change, with statistically significant between-group differences across all key outcomes ($p \leq 0.003$ for clinical symptoms at Week 8; $p < 0.001$ for SEM scores after 5 and 10 washes and sensory scores at Weeks 4 and 8). Repeated-measures ANOVA confirmed robust main effects of time, group, and time-by-group interactions, with large effect sizes (partial η^2 up to 0.84 for SDSS), highlighting luliconazole's enhanced therapeutic profile. Endpoint independent t-tests revealed large Cohen's d values (0.85–1.66), affirming clinically meaningful superiority.

These results align with emerging evidence from comparative trials evaluating luliconazole-based formulations against ketoconazole in scalp seborrheic dermatitis. The LEAD study, a prospective, open-label, multi-center randomized trial in Indian adults with mild to moderate scalp seborrheic dermatitis, reported significantly greater improvements in seborrheic dermatitis severity scores, product tolerability, subjective cosmetic acceptability, and quality-of-life measures (Scalpdex-23) with a luliconazole 1% combination shampoo over four weeks compared to ketoconazole 2% [8].

Participants in the luliconazole arm exhibited more pronounced symptom resolution and better overall acceptability, attributed to luliconazole's potent in vitro antifungal activity against Malassezia species (often with lower or comparable minimum inhibitory concentrations) and favorable pharmacokinetic properties in skin penetration and retention [9]. Similar observations emerge from other investigations, where luliconazole-containing shampoos demonstrated significant effectiveness and tolerability in active and maintenance phases, with initial twice-weekly followed by once-weekly regimens yielding sustained benefits. In contrast, ketoconazole, while effective in reducing Malassezia load and inflammation, is frequently associated with limitations in long-term tolerability, including dryness, irritation, altered hair texture, and occasional discoloration—factors that may impede optimal cuticle recovery [10].

The superior reversal of hair cuticle damage observed in the luliconazole group, evidenced by lower SEM cuticle scores after 5 washes (4.10 ± 1.20 vs. 5.60 ± 1.40) and 10 washes (2.80 ± 1.10 vs. 4.90 ± 1.30), highlights a key differentiator. Scanning electron microscopy provides objective visualization of scale adhesion, lifting, and erosion, which are exacerbated in fungal scalp conditions through direct hyphal invasion (ectothrix types), inflammation-induced lipid peroxidation, and mechanical trauma from scratching or frequent washing [11]. Ketoconazole's known propensity for scalp and hair dryness, reported in postmarketing data and clinical reviews, likely contributes to persistent or residual cuticle compromise, as surfactants and pH alterations in formulations can strip natural lipids, further exposing the cortex [12].

Luliconazole, with its unique R-enantiomer structure and potent lanosterol demethylase inhibition, achieves efficient pathogen clearance with milder local effects, preserving or facilitating cuticle repair. This is corroborated by sensory subscores at Week 8, where luliconazole yielded higher ratings for smoothness (4.60 ± 0.50 vs. 3.70 ± 0.60) and shine (4.40 ± 0.50 vs. 3.50 ± 0.60), reflecting improved manageability and cosmetic perception—outcomes critical for patient adherence and satisfaction [13].

The study's focus on post-treatment cuticle integrity after simulated real-world exposure (controlled neutral shampoo washes) addresses an underexplored aspect of antifungal therapy. While prior research has documented SEM changes in chemically or environmentally damaged hair, few investigations have specifically examined reversal in fungal contexts. The controlled design, with hair sampling at baseline, after 5 washes (post-acute phase), and after 10 washes (maintenance simulation), strengthens the evidence that luliconazole not only eradicates infection but actively supports structural recovery. This is particularly relevant for patients with persistent hair brittleness or roughness despite mycological clearance, where suboptimal cuticle repair can predispose to recurrent infections or cosmetic concerns [14].

Limitations of the study include its single-center setting potentially limiting generalizability to diverse populations or climates, though the Indian cohort enhances relevance to regions with high seborrheic dermatitis prevalence. The sample size (n=60) was adequately powered for medium effect sizes, and randomization ensured baseline comparability, yet larger multicenter trials could confirm findings across ethnicities and hair types.

CONCLUSION

This study provides compelling evidence that luliconazole 1% shampoo offers superior efficacy over ketoconazole 2% in reversing fungal-associated hair cuticle damage, alongside greater clinical and sensory improvements. By combining potent broad-spectrum antifungal action with enhanced tolerability and hair health benefits, luliconazole represents a promising advancement for managing scalp fungal disorders. Clinicians may consider prioritizing luliconazole in patients with prominent hair shaft compromise or those at risk of ketoconazole-related dryness.

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