Original Article

Effectiveness and Safety Comparison Between Luliconazole (1%) Cream and Clotrimazole (1%) Cream in Treating Skin Tinea Infections

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Abstract

Background: The incidence of Tinea infections is on the rise in India, attributed to its tropical climate and prevailing low socio-economic conditions. Clotrimazole has been a longstanding treatment for these infections. However, Luliconazole, a more recent drug, is emerging as a superior option with enhanced effectiveness and tolerability, coupled with a shorter treatment duration. **Material and Methods:** Dermatology OPD attendees clinically diagnosed with tinea corporis or tinea cruris underwent screening, including medical history and medication details. Those with random blood sugar levels surpassing 200 mg/dl were excluded. Baseline clinical parameters erythema, scaling, pruritus, and papules were evaluated during the first visit, graded on a 4-point scale. Mycological evaluation was done by the Department of microbiology which involved the preparation of a KOH mount and microscopic examination. **Results:** Out of the total 84 cases studied in the study divided equally in to two groups. Group I luliconazole 1% and Group II clotrimazole 1% were determined baseline clinical parameters erythema, scaling, pruritus, and papules were evaluated during the first visit, graded on a 4-point scale. The same were evaluated at the end of 1 week, 2 weeks and 4 weeks. Both treatment regimens showed improvement in the clinical outcomes of Tinea infections over time. Group I treated with 1% Luliconazole achieved a higher rate of clinical cure at the first visit and a significantly higher rate of complete cure by the third visit compared to Group II treated with 1% Clotrimazole. **Conclusion:** The present study concludes that, topical luliconazole 1% demonstrated superiority over topical clotrimazole 1% in achieving complete clearance, achieving a faster clinical cure, and securing mycological cure. The proportion of cases achieving clinical cure was higher in luliconazole group.

Keywords: Luliconazole, Clotrimazole, Tinea Cruris, Tinea Corporis, Efficacy.

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INTRODUCTION

Dermatophytosis is a prevalent superficial fungal infection affecting the stratum corneum, hair, and nails rich in keratin.[1,2] The causative fungi, belonging to the genera Trichophyton, Microsporum, and Epidermophyton, commonly include Trichophyton mentagrophytes, Trichophyton rubrum, and Microsporum canis.[3-5] Globally, the prevalence of dermatophytosis is approximately 20-25%, and its incidence continues to rise.[6] In India, the prevalence varies, ranging from 36.6% to 78.4%.[7] Various factors such as age, sex, host conditions, immune status, environmental factors, and other epidemiological elements contribute to dermatophyte infections. Diagnosis typically involves direct microscopic examination using a potassium hydroxide (KOH) mount and fungal culture. KOH mount aids in detecting fungal hyphal elements, while culture helps identify the specific dermatophyte species.[8,9] The unique pathogenesis of dermatophytosis involves fungi not invading living tissues but forming colonies exclusively in keratin-containing host tissues. Despite this limited invasion, the presence of dermatophytes or their products triggers an allergic and inflammatory response in the host, varying in type and severity based on the infecting dermatophyte species. Dermatophytes rely on human or animal hosts for survival and dissemination.[10] Topical antifungal preparations are generally effective for Tinea corporis and Tinea cruris. Various groups of topical antifungal agents, including Imidazoles, Triazoles, and Allylamines, are available, although comparative efficacy is not extensively documented. Systemic antifungals such as fluconazole, itraconazole, and terbinafine are reserved for cases with extensive involvement. Clotrimazole, an Imidazole antifungal, and Luliconazole, a relatively newer agent, are among the topical treatments.[11] Clotrimazole necessitates twice-daily application for at least four weeks, while Luliconazole, with a more favorable efficacy and safety profile, requires only once-daily application for two weeks.[12] Both drugs inhibit the lanosterol 14-α-demethylase enzyme, crucial in

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ergosterol formation, a major component of the fungal plasma membrane. In recent years, several extended-spectrum topical antifungals, including Luliconazole, have entered the market. Luliconazole is said to have better efficacy, tolerability, and brief treatment duration. Luliconazole demonstrates higher lipophilic and reservoir properties in the stratum corneum compared to Clotrimazole, allowing for an extended duration of action.[13,14] Concerns regarding Clotrimazole resistance, linked to efflux pump overexpression, have raised questions about its efficacy.[15] Due to its favorable efficacy and safety profile, Luliconazole is rapidly gaining popularity in numerous countries worldwide. The current investigation aimed to assess and compare the effectiveness and safety of topical luliconazole with topical clotrimazole in the treatment of skin tinea infections.

Materials and Methods

This study was a Prospective observational study conducted in the Department of Dermatology in coordination with the Department of Pharmacology, Kakatiya Medical College and MGM Hospital, Warangal. Institutional Ethical approval was obtained for the study. Written consent was obtained from all the participants of the study after explaining the nature of the study in the vernacular language. Those voluntarily willing to participate were only included.

Inclusion criteria

1. Patients aged 15 and above
2. Males and Females
3. Patients diagnosed with tinea corporis or tinea cruris
4. Tinea lesions involved less than 20% of BSA.

Exclusion criteria

1. Pregnant and lactating females
2. Immunocompromised patients
3. Hypersensitivity to azole antifungals
4. Other types of tinea infections
5. Patients who received systemic antifungals 4 weeks prior to baseline visit
6. Patients with contact dermatitis, atopic dermatitis, psoriasis

Dermatology OPD attendees clinically diagnosed with tinea corporis or tinea cruris underwent screening, including medical history and medication details. Those with random blood sugar levels surpassing 200 mg/dl were excluded. Baseline clinical parameters erythema, scaling, pruritus, and papules were evaluated during the first visit, graded on a 4-point scale. Eligibility required a total score equal to or exceeding 5. Enrolment in the study included patients meeting the criteria, with recorded demographic details such as age and gender. Through computer-generated random tables, patients were allocated randomly to either Group 1 or Group 2 at a 1:1 ratio.

During the treatment phase, Group I applied 1% luliconazole cream topically, while Group II used 1% clotrimazole cream for tinea corporis or tinea cruris. Group 1's treatment spanned 2 weeks, compared to 4 weeks for Group 2. Group 1 patients applied luliconazole once daily for 2 weeks, covering the affected area and a 1-inch perimeter. Group 2 applied clotrimazole twice daily for 4 weeks in a similar manner. All patients were instructed to cleanse and dry the affected area before application. Baseline and follow-up assessments included direct microscopy and fungal culture. Weekly follow-ups tracked safety and efficacy.

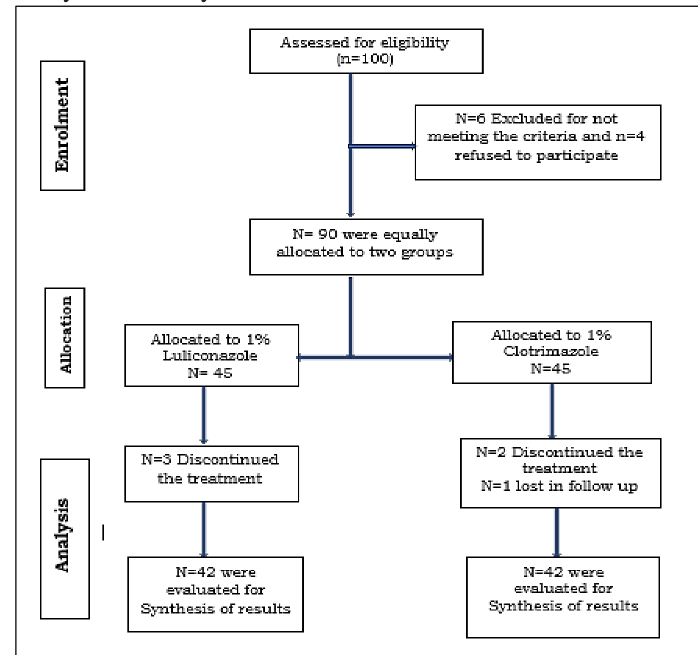

Figure 1: showing the blueprint of the study

Mycological evaluation was done by the Department of microbiology which involved the preparation of a KOH mount and microscopic examination. Infected areas were scraped from lesion edges using a size 15 scalpel blade, collecting scrapings on black paper or directly on slides. Ten percent Potassium hydroxide (KOH) solution (2-3 drops) was added to the scrapings, covered with a slip. Prepared slides were examined under direct microscopy, initially with low magnification (10X), followed by 40X, and finally under high resolution (100X) to confirm the presence of fungal hyphal elements. This process ensured a thorough examination of the specimens for mycological assessment. Specimens (scales) collected from each patient enrolled in the study were inoculated into the culture plates to culture preparation and identification.

Clinical evaluation occurred at every visit post-baseline, with both groups assessed for improvements in symptoms and signs (pruritus, erythema, scaling, papules). The investigator used a 4-point scale for scoring: 0=absent, 1=mild, 2=moderate, 3=severe. Global assessment scores were calculated by summing individual scores for erythema, scaling, pruritus, and papules at each follow-up visit. A 'Follow-up Phase' of 4 weeks post-treatment assessed potential relapse. Patients missing more than one week of medication were considered dropouts. Clinical cure, mycological cure, lesion clearance, and improvement from baseline were evaluated at each visit. Safety and tolerability were monitored, and mycological assessments were conducted at baseline, end of treatment, and end of follow-up.

Results

A total of 84 cases were included in the study as mentioned in the

figure 1. The mean age of the patients in Group I was 31.52 years, while the mean age in Group II was 33.54 years. The age distribution was relatively similar between the two groups, with the majority of patients falling within the 21-30 and 31-40 age groups. There was a slight male predominance in both groups, with approximately 54.76% of patients in Group I and 52.38% of patients in Group II being male. The most common type of Tinea infection in both groups was Tinea corporis, followed by Tinea cruris. The proportion of patients with each type of Tinea infection was relatively similar between the two groups [Table 1].

Table 1: Showing Demographic profile of the cases included in the study

Variable	Group I (N=42) 1% luliconazole	Group II (N=42) 1% clotrimazole
Age group in years		
15 – 20	5 (11.90%)	4 (9.52%)
21 – 30	12 (28.75 %)	14 (33.33%)
31 – 40	10 (23.8%)	8 (19.05%)
41 – 50	9 (21.42%)	10 (23.81%)
51 - 60	6 (14.28%)	6 (14.28%)
Mean ± SD	31. 52 ± 8.62	33.54 ± 7.5
Gender distribution of cases		
Male	23 (54.76%)	22 (52.38%)
Female	19 (45.23%)	20 (47.62%)
Type of Tinea infections		
Tinea corporis	24(57.14%)	25(59.52%)
Tinea cruris	18(42.85%)	17(40.48%)

Infection site: The average affected body area score was slightly higher in Group II (2.41) compared to Group I (2.15). The standard deviation had a larger variation in the affected body area scores in Group II. However, the p-value (0.552) is greater than 0.05, indicating no statistically significant difference in the affected body area between the two groups. Duration of Infection: The average duration of infection was comparable between Group I (3.32 months) and Group II (3.55 months). The standard deviation suggests a smaller variation in the duration of infection in Group I. Similar to infection site, the p-value (0.332). Mycology: All patients in both groups (100%) had positive KOH test results, confirming the presence of fungal elements. Additionally, all patients in both groups (100%) had positive fungal cultures, identifying the specific fungal species [Table 2].

Table 2: Showing the Baseline characteristics of the cases included in the study

Tinea Infections		Group I (N=42) 1% Luliconazole	Group II (N=42) 1% Clotrimazole	P value
Infection site		2.15 ± 1.02	2.41 ± 1.21	0.552
Duration of Infection in months		3.32 ± 4.25	3.55 ± 1.02	0.332
Mycology	KOH positive	42	42	1.00
	Culture positive	42	42	1.00

[Table 3] presents the frequency of various clinical symptoms observed in patients with Tinea infections upon enrollment in the study. It compares the two groups treated with 1% Luliconazole (Group I) and 1% Clotrimazole (Group II). The majority of patients in both groups (50-52%) experienced moderate intensity of itching. No statistically significant difference was observed in the distribution of itching severity between the two groups. Similar proportions of patients in both groups displayed faint erythema. The majority of patients exhibited bright erythema, with no significant difference between groups. Most patients had diffuse thick scaling, with no significant difference between groups. Most patients had papules at the borders of the lesions, with no significant difference between groups.

Table 3: Presenting features of the patients with tinea infection during recruitment (baseline values)

Parameters	Group I (N=42)	Group II (N=42)	P value
Pruritus			
Mild itching	3 (7.14%)	4 (9.52%)	0.254
Moderate itching	21 (50.00%)	22 (52.38%)	
Severe itching	18 (42.86%)	16 (38.09%)	
Erythema			
Faint Erythema	12 (28.57%)	12 (28.57%)	0.336
Bright Erythema	20 (47.62%)	21 (50.0%)	
Very bright Erythema	8 (19.04%)	9 (21.43%)	
Scaling			
Fine white scaling	9 (21.43%)	7 (16.67%)	0.414
Diffuse thick scaling	25 (59.52%)	28 (66.67%)	
Very thick scaling	8 (19.04%)	7 (16.67%)	
Papules			
No papules	12 (28.57%)	11 (26.19%)	0.223
Papules at border	23 (57.76%)	25 (59.52%)	
Papules partially covered	7 (16.67%)	6(14.28%)	

Overall, both groups presented with similar clinical features at baseline. Pruritus (itching) was the most common symptom, with moderate intensity being the most frequent. The majority of patients had bright erythema and diffuse thick scaling Papules were more commonly observed at the borders of the lesions. No statistically significant differences were observed between the two groups in the distribution of clinical features. This table suggests that the two groups were well-matched for baseline characteristics and provides a valuable reference point for evaluating the effectiveness of the different treatment regimens.

Table 4: The GAS scores in cases of study at the end of 2 weeks of treatment

Parameters	Group I (N=42)	Group II (N=42)	P value
Pruritus			
No Itching	6 (14.28 %)	7 (16.67%)	0.257
Mild itching	28 (66.67%)	26 (61.90%)	
Moderate itching	12 (28.57%)	9 (21.43%)	
Erythema			
No Erythema	14(33.33%)	10 (23.81%)	0.0212*
Faint Erythema	24(57.14%)	29 (69.04%)	
Bright Erythema	4(9.52%)	3 (7.14%)	
Scaling			
No scaling	14(33.33%)	9 (21.43%)	0.0414*
Fine white scaling	26(61.90%)	26 (61.90%)	
Diffuse thick scaling	2(4.76%)	7 (16.67%)	
Papules			
No papules	32(76.19%)	27(64.42%)	0.0125*
Papules at border	10(23.80%)	15(35.71%)	

* Significant

[Table 4] presents the Goal Attainment Scaling (GAS) scores for various clinical parameters in patients with Tinea infections after 2 weeks of treatment with either 1% Luliconazole (Group I) or 1% Clotrimazole (Group II). Both treatment regimens were effective in reducing the severity of Tinea infection symptoms after 2 weeks. Group I treated with 1% Luliconazole showed a statistically significant improvement in erythema, scaling, and papules compared to Group II treated with 1% Clotrimazole. However, both groups had similar outcomes in terms of itching and fine white scaling. These findings suggest that 1% Luliconazole might be a more effective treatment option for Tinea infections compared to 1% Clotrimazole, although further research with larger sample sizes is needed to confirm these results.

Table 5: The GAS scores in cases of study at the end of 4 weeks of treatment to determine relapse

Parameters	Group I (N=42)	Group II (N=42)	P value
Pruritus			
No Itching	36(85.71%)	21(50.0%)	0.0013*
Mild itching	5(11.90 %)	16(38.09%)	
Moderate itching	1(2.38%)	5(11.90%)	
Erythema			
No Erythema	37(88.09%)	20(47.61%)	0.002*
Faint Erythema	4(9.52%)	18(42.85%)	
Bright Erythema	1(2.38%)	4(9.52%)	
Scaling			
No scaling	38(90.47%)	22(52.38%)	0.0133*
Fine white scaling	3(7.14%)	17(40.47%)	
Diffuse thick scaling	1(2.38%)	3(7.14%)	
Papules			
No papules	40(95.23%)	39(92.86%)	0.521
Papules at border	2(4.76%)	3(7.14%)	
* Significant			

[Table 5] presents the Goal Attainment Scaling (GAS) scores for various clinical parameters in patients with Tinea infections after 4 weeks of treatment with either 1% Luliconazole (Group I) or 1% Clotrimazole (Group II). The table focuses on determining the rates of relapse in both groups.

Based on the GAS scores after 4 weeks of treatment, Group I treated with 1% Luliconazole showed a significantly lower relapse rate compared to Group II treated with 1% Clotrimazole. This suggests that 1% Luliconazole might be a more effective treatment option for preventing relapse of Tinea infections.

Table 6: Overall Clinical response of drug treatments at different intervals of follow up

Parameters	Group I	Group II	P value
First Visit			
Clinical cure	2 (4.76%)	0 (0.00%)	0.002*
Mycological cure	16 (38.09 %)	14 (33.33%)	
Complete cure	13 (30.95%)	8 (19.05%)	
No Response	11 (26.19 %)	20 (47.62%)	
Second visit			
Complete cure	33 (75.57%)	28 (66.67%)	0.041*
Lack of response to treatment	9 (21.42%)	14 (33.33%)	
Third visit			
Complete cure	36 (85.71%)	30 (71.43%)	0.003*
Lack of response to treatment	5 (11.90%)	7 (16.67%)	
Relapse	1 (2.38%)	5 (11.90%)	

[Table 6] presents the percentages of patients achieving various clinical outcomes at different follow-up visits after receiving either 1% Luliconazole (Group I) or 1% Clotrimazole (Group II) treatment for Tinea infections. Both treatment regimens showed improvement in the clinical outcomes of Tinea infections over time. Group I treated with 1% Luliconazole achieved a higher rate of clinical cure at the first visit and a significantly higher rate of complete cure by the third visit compared to Group II treated with 1% Clotrimazole. This suggests that 1% Luliconazole might be a more effective treatment option for Tinea infections compared to 1% Clotrimazole, especially in achieving faster and more complete clinical response.

Discussion

Dermatophytes, primarily aerobic fungi, are the predominant culprits, utilizing keratin for growth. These organisms thrive in the superficial epidermal layers, predominantly affecting keratin-rich body parts like hair, skin, and nails. Treatment options for dermatophytosis include oral and topical antifungals.[16] Despite all antifungals targeting ergosterol synthesis, a crucial fungal cell wall component, their efficacy varies due to distinct enzyme targets. Topical imidazole antifungals, inhibiting 14 alpha lanosterol demethylase enzyme, exemplify this. However, drawbacks from the conventional use of older imidazole antifungals, like clotrimazole, include resistance emergence, non-adherence due to extended treatment courses, and the need for twice-daily application, leading to frequent tinea infection recurrences.[17,18] In the Luliconazole and Clotrimazole treated groups, the mean ages were 31.52 ± 8.62 years and 33.54 ± 7.5 years, respectively. The majority of patients in both groups, comprising two-thirds, fell within the 18-44 years age range. This age distribution aligns with previous studies reporting dermatophytosis occurrences in similar age groups, both in terms of mean age and overall distribution.[19-21] This study revealed a male predominance, with the frequency of male patients being nearly double that of females in both treatment groups (54.76% vs. 45.23% for Luliconazole and 52.38% vs. 47.62% for Clotrimazole). The prevalence of Tinea corporis and Tinea cruris in males aligns with findings in previous studies.[7,12] This male predominance may be attributed to increased outdoor activity and the wearing of relatively tight-fitted clothing. Prolonged use of damp clothing due to sweating is identified as a risk factor for tinea infections, a trend supported by patient distribution based on occupation. In this study, the occurrence of Tinea corporis was slightly higher than that of Tinea cruris, with frequencies of 57.14% versus 42.85% in the Luliconazole treated group and 59.52% versus 40.48% in the Clotrimazole treated group. Lakshmi CP et al,[19] and Khan I,[22] observed nearly equal frequencies of Tinea corporis and Tinea cruris in their respective samples. The evaluation of clinical symptoms, including erythema, pruritus, scaling, papules, and global assessment scores, indicated that both groups were comparable at the initial assessment. However, by the end of the first week, the luliconazole group exhibited a more significant reduction in the mean scores of clinical symptoms compared to the clotrimazole group. Both the Luliconazole and Clotrimazole treated groups in this study showed a significant reduction in the Global Assessment Score (GAS). The mean GAS reduction was notably more pronounced in the Luliconazole group compared to the Clotrimazole group at the end of the first week of treatment (3.09 ± 1.10 vs. 2.91 ± 1.14, p=0.01) and at the third visit (0.95 ± 0.25 vs. 1.52 ± 0.67, p=0.032). Similar significant differences in mean reduction at the end of the first week, with no significant difference at the end of treatment, were also observed between the groups in the study.[7] In the Luliconazole group, complete cure was observed in 30.95% at the end of the first week, reaching 85.71% by the end of treatment. Prabha et al,[7] documented a 22.0% complete cure at the first week and 98.0% at the treatment's end. Group II displayed a slightly higher failure rate compared to Group I, consistent with previous studies.[7,8,12] This study found relapse in 2.38% of Luliconazole-treated patients and 11.90% of Clotrimazole-treated patients, aligning with another study's findings.[7]

Conclusion

The present study concludes that, topical luliconazole 1% demonstrated superiority over topical clotrimazole 1% in achieving complete clearance, achieving a faster clinical cure, and securing mycological cure. The proportion of cases achieving clinical cure was higher in luliconazole group. the luliconazole group had a shorter treatment duration (only 2

weeks). The relapse rate was lower in the luliconazole group. Both drugs were found to be safe and well-tolerated. Consequently, this study establishes the greater efficacy of 1% topical luliconazole compared to 1% clotrimazole in treating dermatophytosis.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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