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RESEARCH ARTICLE

A randomized comparative study to assess the efficacy of topical luliconazole versus topical clotrimazole in tinea corporis and tinea cruris

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ABSTRACT

Background: Dermatophytosis is a common cutaneous infection in India with prevalence varying from 36.6% to 78.4%. Topical azoles and allylamines are used to treat localized dermatophytosis but has disadvantages such as long duration of therapy, poor compliance, and high relapse rate. Luliconazole is a newer topical imidazole antifungal applied once daily with greater reservoir property in stratum corneum. **Aims and Objective:** The aim of the study was to compare the efficacy of topical luliconazole versus topical clotrimazole in tinea corporis and tinea cruris. **Materials and Methods:** An open-labeled randomized comparative study in the Dermatology Outpatient Department of Tirunelveli Medical College done from September 2015 to September 2016. Patients with tinea corporis/tinea cruris were randomized into two groups to receive topical luliconazole cream once daily for 2 weeks or topical clotrimazole cream twice daily for 4 weeks. Scrapings from lesion were taken for mycological assessment. Clinical and mycological cure was assessed at each visit. **Results:** Each group had 50 patients. At the end of 1st week, the mycological cure was 78% in luliconazole and 12% in clotrimazole ($P < 0.05$) and complete clearance was achieved in 11 patients (22%) in luliconazole group. By the end, 98% got cured in luliconazole group and 80% in the clotrimazole group ($P < 0.05$). Relapse occurred in 20% in clotrimazole group as against 4% in luliconazole group ($P < 0.05$). Both groups showed only mild application site reactions except one patient who developed hypersensitivity to clotrimazole. **Conclusion:** Topical luliconazole was better in achieving faster mycological and clinical cure with lower relapse.

KEY WORDS: Clotrimazole; Dermatophytosis; Efficacy; Luliconazole

INTRODUCTION

Dermatophytosis is a common superficial fungal infection of the stratum corneum of skin, hair, and nails which contain keratin.[1,2] The specific causative agents of tinea corporis and tinea cruris most commonly are *Trichophyton mentagrophytes*, *Trichophyton rubrum,* and *Microsporum canis*.[3] The prevalence of dermatophytosis is around 20–25% worldwide, and its incidence continues to rise.[4] In a country like India, with hot and humid climate conditions, recent epidemiological trends show an alarming increase in the prevalence of dermatophytosis ranging from 36.6% to 78.4%.[5] The development of dermatophytosis is not only dependent on climate but also is often as a result of a complex interaction between host factors such as age, sex, immunity, socioeconomic status, comorbidity, and poor sanitary conditions.[6,7] Direct microscopic examination with 10% potassium hydroxide (KOH) mount is the most simple and rapid cost-effective way to establish the diagnosis.[7]

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KOH mount aids in the detection of fungal hyphal elements while the culture aids in the identification of species of dermatophytes.[8,9] Topical therapy is sufficient for the treatment of uncomplicated and localized tinea infections due to their high efficacy and low potential to cause adverse reactions. Combination with systemic agents are needed when the area of involvement is large or when there is a secondary infection and also in immuno-compromised individuals.[3] Dermatophytosis though painless, poses a problem of recurrence and relapse if not treated adequately and adversely affects the quality of life of patients as it is contagious in nature.

At present, topical azoles and allylamines remain as the treatment of choice for localized dermatophytosis. The main disadvantage with these agents is the long duration of therapy, which results in poor compliance and a high rate of relapse.[10] The traditional imidazole antifungal agent clotrimazole is effective in the treatment of dermatophytosis with a cure rate of 60–100% on applying twice daily for 4 weeks.[11] Novel agents developed are focused toward shortening the frequency of application of antifungals and the duration of therapy to increase the patient compliance, to increase the cure rates, and to decrease the relapse rates. In the recent past, many newer topical agents have been introduced with potential benefits such as extended spectrum of activity, once-daily application, and short duration of therapy with better adherence.

Luliconazole is one among those topical antifungal agents, which offers a good efficacy and tolerability with a short duration of treatment.[13] 1% luliconazole cream was approved in Japan in the year 2005 for treating tinea infections, followed by food and drug administration approval in November 2013 for treating tinea pedis, tinea corporis, and tinea cruris.[12]

Azole antifungals are generally known to be fungistatic. The mechanism of action of luliconazole is same as that of clotrimazole, but luliconazole exhibits strong fungicidal activity in dermatophytosis against *Trichophyton species*. The potent antifungal activity is due to strong *in vitro* antifungal activity as well as favorable pharmacokinetic profile in the skin.[13] Luliconazole is topical imidazole antifungal agent which inhibits the ergosterol biosynthesis more effectively. It requires only once daily application because the reservoir property in the stratum corneum is greater for luliconazole.[14,15] Hence, the present study was done to compare the efficacy of topical luliconazole versus topical clotrimazole in localized tinea corporis and tinea cruris.

MATERIALS AND METHODS

This was an open-labeled prospective randomized comparative study conducted in the Dermatology Outpatient Department (OPD) of Tirunelveli Medical College from September 2015 to September 2016 after obtaining approval from the Institutional Ethics Committee. Written informed consent was obtained in the local vernacular language after explaining the purpose of the study, the role of the study participants and study procedures to all the patients before enrolling them for the study. The potential benefits and risks of participating in the study were explained fully before obtaining informed consent. The participation in the study was purely on a voluntary basis and the patients were allowed to withdraw from the study at any point of time. Confidentiality was maintained.

Inclusion Criteria

Patients aged >12 years of either sex clinically diagnosed with localized Tinea corporis or Tinea cruris were included in the study.

Exclusion Criteria

Immuno-compromised patients, patients with extensive dermatophytosis, other forms of tinea infections, superadded bacterial infection, contact dermatitis, atopic dermatitis, psoriasis, other skin diseases, and pregnant and lactating females were excluded from the study. Patients with a history of hypersensitivity to azole antifungals, patients who received topical antifungal within 1 week before baseline visit, and patients who received systemic antifungals within 4 weeks before baseline visit were also excluded from the study.

Study Procedure

Screening and recruitment

Patients diagnosed clinically with localized tinea corporis or tinea cruris were screened. Detailed medical and drug intake history were elicited. Random blood sugar estimation was done and patients with red blood cell (RBS) >200 mg/dl were excluded from the study.

Enrollment and randomization

Patients who satisfied the study criteria were enrolled for the study. The patients were randomly allotted to Group 1 or Group 2 by simple randomization using a computer-generated random table in the ratio 1:1.

Data collection

Demographic data such as age and sex were recorded. Baseline clinical parameters such as erythema, scaling, pruritis, and papules were noted during the first visit. Moreover, these clinical parameters were graded on a 4 point scale. Patients whose total score was ≥5 and whose KOH mount was positive were only eligible to participate in the study.

Treatment phase

The patients in Group 1 were advised to apply 1% luliconazole cream over the affected area and 1 inch surrounding that area

in a thin layer once daily for 2 weeks. The patients in Group 2 were advised to apply 1% clotrimazole cream over the affected area and 1 inch surrounding the affected area twice daily for 4 weeks. All the patients were advised to clean and dry the affected area before applying medications. Patients were given a week's supply of medication at each visit. The patients were followed up every week. Photographs of the lesion were taken for evidence of improvement.

Mycological assessment

Direct microscopy (KOH mount) was done at baseline and at each follow-up visit. Fungal culture was done at baseline and at the end of treatment.

Preparation of KOH mount and examination under microscope

The infected areas were scraped from the edge of the lesion using a scalpel blade of size 15. Scrapings were collected directly on the slide. Two to three drops of 10% KOH were added to the scrapings and the slide was covered by a coverslip. Prepared slides were mounted and examined initially under direct microscopy using low power of magnification (10X), then with 40X power and ultimately under the high resolution of 100X to confirm the presence of fungal hyphal elements.

Procedure for fungal culture

Specimens (scales) collected from each patient were carefully inoculated into the culture plates with Sabouraud dextrose agar medium and then incubated at room temperature. The culture media were examined weekly for the growth of dermatophytes. They were examined for at least 3 weeks for assessing the growth of fungi, before declaring the culture as negative.

Clinical assessment

At each visit after baseline, both the groups were evaluated for improvement in clinical parameters (pruritus, erythema, scaling, and papules). This improvement was assessed using a 4-point scale by the investigator: Score 0=absent, 1=mild, 2=moderate, and 3=severe. Global assessment score was calculated at each follow-up visit by summation of scores on all four parameters in a patient.

Follow-up phase

Follow-up was done for 4 weeks after the end of the treatment period. Patients were assessed clinically and mycologically for potential relapse. Patients who missed out more than 1 week of medications were treated as dropouts.

Operational Definitions

- Clinical cure: No signs or symptoms of tinea infection (erythema, scaling, pruritis, and papules) (Global assessment score ≤ 2).
- Mycological cure: Negative KOH microscopy.
- Complete clearance: Mycological cure with a complete absence of clinical signs and symptoms (GAS≤ 2).
- Relapse: Patients returning with clinical symptoms in the follow-up phase after completion of the treatment course and having positive KOH.

Primary Outcome

Comparison of efficacy of luliconazole and clotrimazole in terms of a number of patients achieving complete clearance.

Secondary Outcomes

Comparison of clinical cure achieved in both groups at the end of 1 week and at the end of the treatment period.

Comparison of mycological cure achieved in both groups at the end of 1 week and at the end of the treatment period.

Comparison of relapse at the end of the treatment period.

Statistical Analysis

The statistical analysis was done with SPSS version 17 (Statistical Package for the Social Sciences). The baseline demographic characteristics and lesion characteristics were analyzed with *t*-test. The efficacy of the individual drugs was analyzed with paired *t*-test. Comparison between groups was calculated using unpaired *t*-test. Mycological cure was analyzed using Fischer's exact test. $P < 0.05$ was considered as significant. All the analyses were carried out in the intention to treat (ITT) population. ITT group contained all the patients who were randomized, received treatment and had one baseline visit. Missing data were computed with the last observation carried forward method.

RESULTS

A total of 158 patients were screened out of which, 34 did not meet the inclusion criteria (KOH negative-11, age <12 years-7, RBS> 200 mg/dl-5, other reasons-11), 20 people were not willing to participate and hence 104 patients were recruited for the study [Figure 1]. Two patients were lost to follow-up in the luliconazole group and 8 patients were lost to follow-up in clotrimazole group. One patient discontinued treatment due to a hypersensitivity reaction to clotrimazole. Hence, a total of 48 patients completed the study in luliconazole group and 41 patients completed the study in clotrimazole group.

The mean age of patients in luliconazole and clotrimazole groups was 29.6 years and 31.98 years, respectively. In this clinical study, 70% of the patients presented with tinea corporis, while only 30% presented with tinea cruris. The time of presentation to the dermatologist was much earlier in both the groups, with 88% and 92% presenting to the OPD within

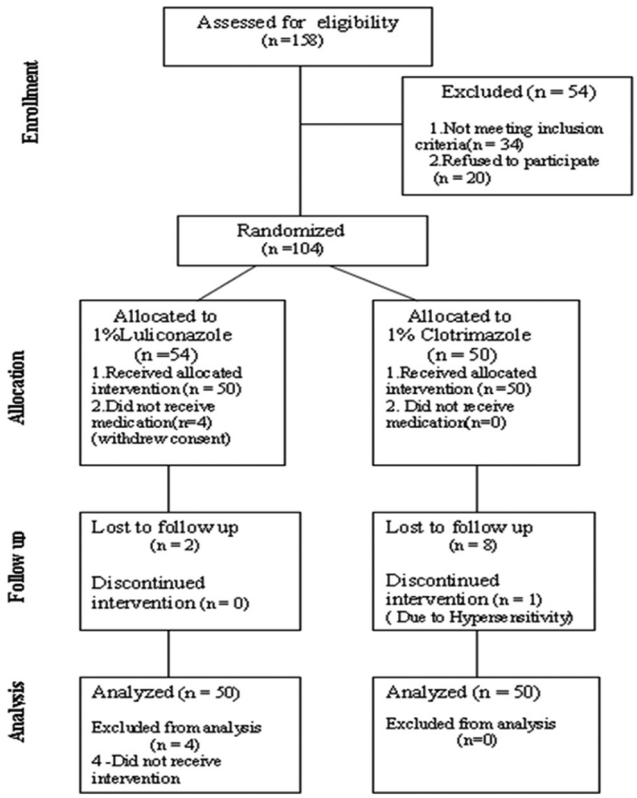

Figure 1: Study flow-chart

1 week of noticing the lesion in group 1 and 2, respectively. Clinical assessment for symptoms such as erythema, pruritis, scaling, papules, and global assessment scores with their mean scores revealed that both groups were similar at baseline [Table 1]. Only 38% of the study samples were positive in the fungal culture at baseline and the most common isolate was *T. rubrum* followed by *T. mentagrophytes*.

The reduction in the mean score of all the four clinical parameters at the end of 1 week in luliconazole group was greater than the clotrimazole group. This difference was statistically significant ($P < 0.05$) [Figure 2]. However, by the end of the treatment period (i.e. 2 weeks in luliconazole group and 4 weeks in clotrimazole group), the mean reduction in scores was the same in both the groups (*P* value not significant) [Figure 3]. The proportion of patients achieving complete clearance was higher in Group 1 when compared to Group 2 [Table 2].

In the present study, around 22% attained clinical cure by the end of 1 week in Group 1 while none attained clinical cure in Group 2. Clinical cure attained was 98% in Group 1 and 86% in Group 2 [Table 3]. Around 78% achieved mycological cure at the end of 1 week in luliconazole group while only 12% were mycologically cured in clotrimazole group. About 98%

Table 1: Baseline demographic and disease parameters

Baseline characters	Luliconazole group 1 (*n*=50)	Clotrimazole group 2 (*n*=50)	*P*-value
Age			
Mean±SD	29.6±13.90	31.98±13.39	0.385
Gender			
Male	24	23	0.84
Female	26	27	
Type			
Tinea corporis	34	36	0.28
Tinea cruris	16	14	
Number			
=1	36	34	0.82
≥2	14	16	
Duration			
<3 days	24	25	0.80
≥3 ≤7 days	20	21	
>7 days	6	4	
Mycology			
KOH mount positive	50	50	1
Symptoms (Mean±SD)			
Erythema	2.44±0.61	2.28±0.75	0.354
Scaling	2.38±0.56	2.32±0.55	0.568
Pruritis	2.54±0.57	2.64±0.48	0.451
Papules	2.12±0.71	2.36±0.63	0.055
Total score (GAS)	9.42±1.25	9.52±1.33	0.637

of patients achieved mycological cure in luliconazole group by the end of the treatment period (i.e., 2 weeks). However, it was only 80% by the end of treatment (i.e., 4 weeks) in clotrimazole group. In the present study, the relapse was higher with clotrimazole group (20%) while it was only 4% in luliconazole group [Figure 4].

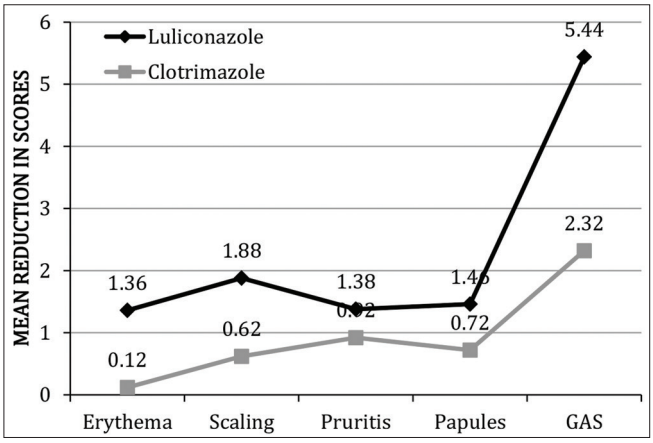

Figure 2: Comparison of mean reduction in scores from baseline to the end of 1 week (P<0.05)

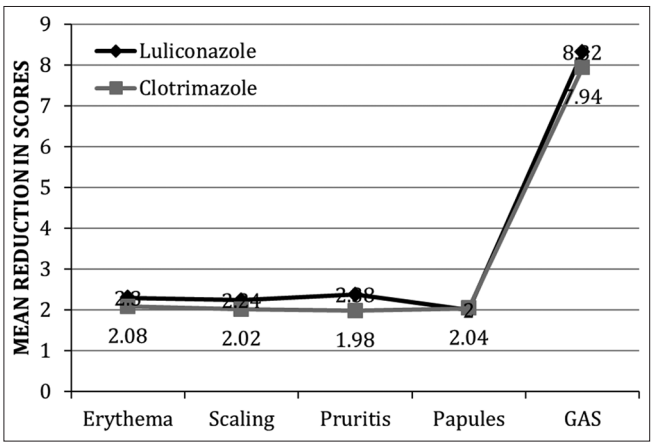

Figure 3: Comparison of mean reduction in scores from baseline to end of treatment

One female patient developed rashes, itching, and hypersensitivity reaction to topical clotrimazole application, and the treatment was discontinued in that patient. All other adverse effects reported were only mild and application site reactions in both the groups.

DISCUSSION

Superficial fungal infections are associated with an increase in morbidity, health-care expenditure, and poor quality of life.[16] Aerobic fungi like dermatophytes are the most common cause for superficial fungal infections. These dermatophytes digest keratin for their growth. They replicate in the superficial layers of the epidermis. As a result, clinically, the body parts rich in keratin such as the hair, skin, and nails are the most affected by dermatophytes. Prolonged survival of embedded arthroconidia in epidermis results in frequent recurrence/relapse.[15] Topical antifungals remain as the treatment of choice for patients presenting with localized tinea corporis or tinea cruris. All the available antifungals inhibit ergosterol synthesis, which is an essential component of the fungal cell wall, but the drugs act at different enzymes which make them vary in their efficacy. Luliconazole is a novel imidazole antifungal agent with the imidazole moiety incorporated into ketene dithioacetate and this unique feature leading to a massive increase in the antifungal property.[15]

The present study evaluated the efficacy of topical clotrimazole versus topical luliconazole in tinea corporis and tinea cruris. The mean age distribution in this study indicates that tinea infections are more common in the second and third decade. They contribute to the majority of the working population, which leads to an increase in outdoor activities, thus more prone for an increase in sweating which favors the growth of dermatophytes.[17,18] In this study, 72% of luliconazole group and 74% of clotrimazole group fall under the age group of 12–40 years. This may be due to the fact that the patients in the younger age group experience the greater impact of

Table 2: Comparisons of the number of patients achieving complete clearance in both groups

Duration	Group	Complete clearance		Chi-square	df	*P*-value
		Achieved	Not achieved			
1 week	Luliconazole	11	39	10.22	1	0.0014*
	Clotrimazole	0	50			
End of treatment	Luliconazole	49	1	11.294	1	0.0008*
	Clotrimazole	36	14			

Table 3: Comparison of the number of patients achieving clinical and mycological cure in both groups

Secondary outcomes	Duration	Luliconazole group 1 (n=50)	Clotrimazole group 2 (n=50)	*P*-value
Clinical cure	1 week	11	0	0.001*
	EOT	49	43	0.065
Mycological cure	1 week	39	6	<0.0001*
	EOT	49	40	0.01*

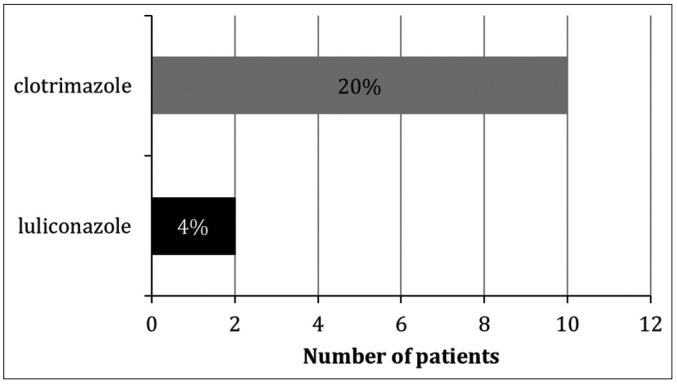

Figure 4: Comparison of relapse between two groups

the disease on their quality of life as tinea infections are contagious, spread readily, and produce itching which affects the daily activities and sleep. Hence, the people in this age group seek treatment earlier.

The number of males and females is found to be equal in contrast to other studies done by Nagaral *et al*. and Ramaraj *et al*. in India, where males were predominantly infected.[19,20] This may be due to the small sample size as well as the study criteria of the present study. Tinea corporis was the most common dermatophyte infection in this study followed by tinea cruris. This is similar to the results of a study published by Lakshmanan *et al*. in 2015and other recent studies in which tinea corporis was the most common clinical presentation.[19-21] Culture was positive only in 38% of the cases, as fungal culture lacks sensitivity. Moreover, fungal culture is strongly recommended only in recurrent or recalcitrant or multiple site dermatophytosis.[7] *T. rubrum* (74%) was the most common isolated species in a culture of dermatophytes while *T. mentagrophytes* was isolated in 26% of the samplesand none of the samples had *Epidermophyton* or *Microsporum* species. This is in correlation to a study result published by Lakshmanan *et al*.[21]

Complete clearance of the lesions was significantly higher in luliconazole group in the present study compared to clotrimazole group. This is similar to a study done by Jerajani *et al*.,[22] where the complete clearance was about 95% and comparable to study done by Lakshmi *et al*., in which the clinical cure and mycological cure were 100% at the end of 2 weeks on treating with 1% luliconazole with no relapse.[23] Furthermore, notably the short course of luliconazole (2 weeks) was more effective in achieving this outcome than the standard 4 weeks course of clotrimazole therapy in the present study.

A significant difference was observed in a number of patients achieving negative KOH at the end of 1 week in luliconazole group (78%) when compared to the clotrimazole group (12%). Mycological cure was attained in only 80% in the clotrimazole group at the end of 4 weeks. This is in contrast to a study done by Satish *et al*., where 100% mycological cure was attained at the end of 4 weeks with 1% clotrimazole.[24] The reason for a lower mycological cure by 4 weeks in the present study may be attributed to a high number of dropouts who did not turn up for follow-up in the clotrimazole group. Higher clinical cure and mycological cure in luliconazole group may be attributable to its novel structure having R-enantiomer in addition to one chiral center and higher retention in the stratum corneum. Luliconazole has the highest antifungal activity against *Trichophyton species* among the currently available topical antifungal drugs.[25,26] The onset of clinical and mycological cure was earlier in luliconazole group than in the clotrimazole group. This is because luliconazole is fungicidal whereas other azoles are fungistatic in nature.[15] Relapse was also considerably lower in luliconazole group (4%) due to its strong fungicidal activity.

A high proportion of patients completed the study in luliconazole group (96%) compared to clotrimazole group (86%) which might be attributed to the simple regimen of once daily application of the luliconazole for 2 weeks. Longer, the course of therapy led to poor compliance and greater loss to follow-up in clotrimazole group. In general, both the drugs were well tolerated with only mild application site reactions except one hypersensitivity reaction which occurred in the clotrimazole group.

Limitations of the Study

Although the present study had taken both clinical and mycological cure as end point, it was an open-labeled study with small sample size in a single center and did not include patients having other forms of dermatophytosis except tinea corporis and tinea cruris. Hence, future studies with large sample size and varied settings are needed.

CONCLUSION

Short course (2 weeks) once daily topical luliconazole cream regimen was more effective achieving complete clearance, faster clinical cure, and mycological cure than standard 4 weeks twice daily clotrimazole cream. However, the proportion achieving clinical cure was the same at the end of the treatment period in both the groups, but the duration of the treatment period was short (only 2 weeks) in luliconazole group. Relapse is lower in luliconazole group. Both the drugs were safe and well tolerated. Thus, the present study proves that 1% of topical luliconazole is more efficacious than 1% clotrimazole in localized tinea corporis and tinea cruris.

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