Original Research Article

Efficacy of topical Luliconazole in management of tinea corporis and tinea cruris infections

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Abstract

Background: Superficial fungal infections of the skin, hair, and nails are common worldwide with a prevalence of 20–25%, of which dermatophytes are the most common causative agents.As dermatophytic infections of the hair mainly require systemic antifungal therapy, we will focus only on the topical therapy of dermatophytic infections of the skin and nails.Luliconazole is an imidazole antifungal agent that has been shown to have potent activity against a variety of fungi, especially dermatophytes.**Aim of the study:** To assess efficacy of topical Luliconazole in management of tineacorporis and tineacruris infections.**Materials and methods:** The present study was conducted in the Department of Dermatology of the medical institution. The ethical clearance for the study was approved from the ethical committee of the hospital. The present study was conducted on 60 patients with Dermatophytoses involving tineacorporis and tineacruris infections. All patients were informed regarding the study and written consent was obtained. General data such as name, age, gender etc. was recorded. A through clinical examination was done. Patients were instructed to apply luliconazole 1% cream once daily for two weeks. At the end of treatment phase, there was a 'Follow-up Phase' at end of two weeks, where the patients were assessed clinically and mycologically for relapse.**Results:** A total of 60 patients were included in the study. 32 patients were males and 28 were females. The mean age of the patients was 42.69 years. There was a significant reduction in the pruritis with application of Luliconazole topical for the treatment period. The results on comparison were found to be statistically significant. **Conclusion**: Within the limitations of the present study, it can be concluded that topical Luliconazole is highly effective for tineacorporis and tineacruris infections.

Key words: Luliconazole, tenia infection, fungal infection, skin infection

Introduction

Superficial fungal infections of the skin, hair, and nails are common worldwide with a prevalence of 20–25%, of which dermatophytes are the most common causative agents[1]. Dermatophytosis is defined as an infection of the hair, nails, or skin by the dermatophytes which include three genera i.e., Trichophyton spp., Microsporum spp., and Epidermophyton. As dermatophytic infections of the hair mainly require systemic antifungal therapy, we will focus only on the topical therapy of dermatophytic infections of the skin and nails. The most common clinical morphology is tineacorporis and cruris in most studies, and Trichophytonrubrum is the most commonly isolated species[1,2]. However, few studies have documented T. mentagrophytes as the most common isolate[1,3,4]. Treatment strategies to deal with fungal infections involve use of a systemic or topical antifungal agent. Ergosterol is an integral part of the fungal cell membrane. All the currently available antifungals interfere with the biosynthesis of ergosterol, an important component of the fungal cell wall, thus causing inhibition of fungal growth and

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replication. Luliconazole is an imidazole antifungal agent that has been shown to have potent activity against a variety of fungi, especially dermatophytes [5,6]. Hence, the present study was conducted to assess efficacy of topical Luliconazole in management of tineacorporis and tineacruris infections.

Materials and methods

The ethical clearance for the study was approved from the ethical committee of the hospital. The present study was conducted on 60 patients with Dermatophytoses involving tineacorporis and tineacruris infections. All patients were informed regarding the study and written consent was obtained. General data such as name, age, gender etc. was recorded. A through clinical examination was done. Patients were instructed to apply luliconazole 1% cream once daily for two weeks. At the end of treatment phase, there was a 'Follow-up Phase' at end of two weeks, where the patients were assessed clinically and mycologically for relapse. Results thus obtained were subjected to statistical analysis.The statistical analysis of the data was done using SPSS version 11.0 for windows. Chi-square and Student's t-test were used for checking the significance of the data. A p-value of 0.05 and lesser was defined to be statistically significant.

Results

Table 1 shows the demographics of the patients. A total of 60 patients were included in the study. 32 patients were males and 28 were females. The mean age of the patients was 42.69 years. Table 2 shows comparison of changes in proportion of patients with pruritus. At baseline, 5 patients had mild pruritis, 14 had mild pruritis, 22 had moderate pruritis and 19 had severe pruritis. At the end of the treatment, only one patient had severe pruritis, two had moderate pruritis, 39 had mild pruritis and 18 had no pruritis. There was a significant reduction in the pruritis with application of Luliconazole topical for the treatment period. The results on comparison were found to be statistically significant.

Table 1: Demographics of the patients

Demographic variables	Number of patients
Total patients	60
Male patients	32
Female patients	28
Mean age (years)	42.69

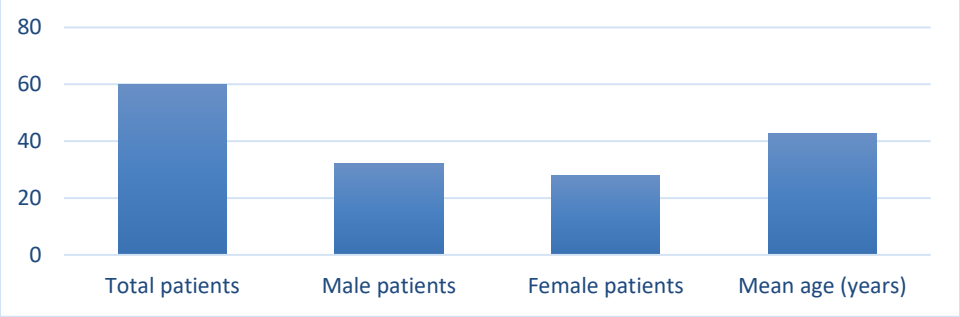

Fig 1: Demographic data

Table 2: Comparison of changes in proportion of patients with pruritus

Severity	At baseline	At end of treatment	p-value
None	5	18	0.02
Mild	14	39	
Moderate	22	2	
Severe	19	1	

Fig 2: Changes in proportion of patients with pruritis

Discussion

In the present study, we observed that there was significant reduction in the pruritis in the majority of patients over the treatment period with topical Luliconazole. The results were statistically significant. The results were compared with previous studies from the literature and were found to be consistent. Draelos ZD et al evaluated the efficacy and safety of luliconazole cream 1% applied once daily for 14 days in patients with interdigital tinea pedis. Three hundred twenty-two male and female patients ≥12 years of age diagnosed with interdigitaltineapedis. Complete clearance (i.e., clinical and mycological cure), effective treatment, and fungal culture and susceptibility.

Results

At study Day 42, complete clearance was obtained by a larger percentage of patients treated with luliconazole cream 1% compared with vehicle. Also at Day 42, more luliconazole-treated patients compared with vehicle-treated patients obtained effective treatment, clinical cure, and mycologic cure. Erythema, scaling, and pruritus scores were lower for the luliconazole cream 1% group compared with vehicle on Day 14, Day 28, and Day 42. For all species and the same isolates, the MIC50/90 for luliconazole cream 1% was 6- to 12-fold lower than for other agents tested. No patients discontinued treatment because of a treatment-emergent adverse event. They concluded that Luliconazole cream 1% was safe and well-tolerated and demonstrated significantly greater efficacy than vehicle cream in patients with interdigital tineapedis. Todokoro D et al investigated in vitro efficacy of luliconazole (LLCZ), a new imidazole antifungal, against FSSC and other filamentous fungi.A total of 18 Fusarium isolates and 7 others were grown on potato dextrose agar at 30 and 37°C. For Fusarium, species identification and phylogenetic tree analysis were performed based on elongation factor-1α (EF-1α) DNA sequencing. The broth microdilution method was used for antifungal susceptibility testing of 11 antifungal drugs including LLCZ.The 18 identified Fusarium isolates belonged to FSSC (n =13), Fusarium-oxysporum species complex (FOSC; n = 2), Fusariumchlamydosporum species complex (FCSC; n=1), Fusariumincarnatum-equiseti species complex (FIESC; n = 1), and Fusariumfujikuroi species complex (FFSC; n = 1). We further divided 13 FSSC isolates into 3 clades, FSSC5 (n = 8), FSSC3 + 4 (n = 4), and FSSC9-a (n =1), with 8 FSSC strains growing at 37°C. LLCZ showed lowest minimum inhibitory concentrations (MICs) against all tested filamentous fungi, with a MIC90 against the Fusarium species of 0.06 μg/mL, whereas MIC90 for NAT and VRCZ were 4 and 8 μg/mL, respectively. They concluded that LLCZ has the strongest in vitro antifungal activity among all drugs used against broad-range filamentous fungi including FSSC. LLCZ may potentially be a new medical treatment option for fungal keratitis[7,8]. Moslem M et al evaluated the efficacy of luliconazole in comparison to routine used antifungals on clinical and environmental isolates of Aspergillusflavus.Thirty eight isolates of A. flavus (18 environmental and 20 clinical isolates) were detected based on morphological and microscopic features and also PCR-sequencing of β-tubulin ribosomal DNA gene. All the isolates were tested against luliconazole, voriconazole, amphotericin B and caspofungin. Minimum inhibitory concentration (MIC), MIC50, MIC90 and MIC Geometric (GM) were calculated using CLSI M38-A2 protocol for both environmental and clinical isolates.Luliconazole with extremely low MIC range, 0.00049–0.00781 μg/mL and MICGM 0.00288 μg/mL showed very strong activity against both clinical and environmental A. flavus isolates. Moreover, voriconazole inhibited 100% of isolates at defined epidemiological cutoff values (ECV ≤ 2 μg/ml). 50% and 27.8% of clinical and environmental isolates of A. flavus, were resistant to

caspofungin, respectively. Whereas, all the isolates were found to be resistant to amphotericin B.The analysis of their data clearly indicated that luliconazole (with MICGM 0.00244 µg/ml for clinical and 0.00336 µg/ml for environmental isolates) had the highest in vitro activity against A. flavus strains.Jerajani H et al compared efficacy and safety of sertaconazole, terbinafine and luliconazole in patients with dermatophytoses.83 patients with tineacorporis and tineacruris infections were enrolled in this multicentre, randomized, open label parallel study. The initial 'Treatment Phase' involved three groups receiving either sertaconazole 2% cream applied topically twice daily for four weeks, terbinafine 1% cream once daily for two weeks, luliconazole 1% cream once daily for two weeks. At the end of treatment phase, there was a 'Follow-up Phase' at end of 2 weeks, where the patients were assessed clinically and mycologically for relapse. Of the 83 patients, 62 completed the study, sertaconazole (n = 20), terbinafine (n = 22) and luliconazole (n = 20). The primary efficacy variables including change in pruritus, erythema, vesicle, desquamation and mycological cure were significantly improved in all the three groups, as compared to baseline, in the Treatment and Follow-up phase. Greater proportion of patients in sertaconazole group (85%) showed resolution of pruritus as compared to terbinafine (54.6%); and luliconazole (70%), ($P < 0.05$ sertaconazolevsterbinafine). There was a greater reduction in mean total composite score (pruritus, erythema, vesicle and desquamation) in sertaconazole group (97.1%) as compared to terbinafine (91.2%) and luliconazole (92.9%). All groups showed equal negative mycological assessment without any relapses. All three study drugs were well tolerated. Only one patient in sertaconazole group withdrew from the study due to suspected allergic contact dermatitis. They concluded that Sertaconazole was better than terbinafine and luliconazole in relieving signs and symptoms during study and follow up period. At the end of 'Treatment Phase' and 'Follow-up' Phase, all patients showed negative mycological assessment in all three treatment groups suggesting no recurrence of the disease[9,10].

Conclusion

Within the limitations of the present study, it can be concluded that topical Luliconazole is highly effective for tinea corporis and tinea cruris infections.

Source of Support:Nil
Conflict of Interest: Nil

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