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Comparative assessment of the efficacy and safety of sertaconazole (2%) cream versus terbinafine cream (1%) versus luliconazole (1%) cream in patients with dermatophytoses: A pilot study

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 Login to access the email ID**DOI:** 10.4103/0019-5154.105284➤ **Abstract**

Background : Sertaconazole is a new, broad spectrum, fungicidal and fungistatic imidazole with added antipruritic and anti-inflammatory activity that would provide greater symptomatic relief and hence would be beneficial in improving the quality of life for the patient with dermatophytoses. **Aims and Objectives :** To compare efficacy and safety of sertaconazole, terbinafine and luliconazole in patients with dermatophytoses. **Materials and Methods :** 83 patients with *tinea corporis* and *tinea cruris* 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. **Results :** 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%), ($P < 0.05$ sertaconazole vs terbinafine). 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. **Conclusion :** 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

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assessment in all three treatment groups suggesting no recurrence of the disease.

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What was known?

Dermatophytoses is characterized by inflammatory lesions. Concomitant pruritus often affects patients' Quality of Life. Optimal compliance to therapy ensures high success rates preventing relapse or recurrences.

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Superficial mycotic infections such as 'Dermatophytoses' is an extremely common infection occurring throughout the world with a reported incidence of 20% in USA. [1] The disease is caused by dermatophytes belonging to genera of Trichophyton, Microsporum and Epidermatophyton. The fungal infections of the skin and its appendages are more common in tropical countries like India due to environmental factors like heat (summer) and humidity (monsoon). The risk factors include socio-economic conditions like overcrowding and poverty leading to poor personal hygiene. The type and frequency of dermatophytoses may change with time, due to changes in living standards and application of preventive measures like personal hygiene. However in India, the most commonly occurring clinical type of dermatophytoses for adults includes, tinea corporis (36-59%) and tinea cruris (12-27%). [2],[3]

Though classically dermatophytoses is characterized by the presence of 'ringed lesions' with central healing, concomitant presence of inflammatory symptoms including pruritus is noted in these patients. Pruritus often leads to intense urge to itch affecting the quality of life of the patient. Secondly, intense itching of the lesion increases the chances of secondary bacterial infections and eczematization. Misuse of topical steroids result in unclear morphology of fungal infections (tinea incognita)

Imidazoles, allylamines and triazoles are most effective agents for dermatophytoses. Topical daily antifungal therapy usually involves imidazoles (namely, *Luliconazole* and *Sertaconazole*) and allylamines (*Terbinafine*). Terbinafine is a broad spectrum lipophilic antifungal agent showing excellent activity in patients with tinea corporis or tinea cruris. Luliconazole, an imidazole antifungal agent is active against dermatophytes and highly active against candida albicans but it is inactive against zygomycetes. However the antifungal therapy is often fraught with several clinical challenges including high relapse rates and recurrences that often occur after treatment stoppage or discontinuation. Also untreated and improperly treated infections may become chronic, causing significant disability and morbidity. To manage this growing pathogenicity of superficial fungal infections, development of newer broad spectrum antifungals like sertaconazole have opened up new treatment options.

Sertaconazole is a new benzothioephene imidazole derivative that is being used worldwide for varied indications including dermatophytosis, candidiasis, pityriasis versicolor, seborrheic dermatitis of scalp. Sertaconazole has both fungistatic and fungicidal activity against *Dermatophytes*, *Candida spp.* and *Cryptococcus* fungal infections. It is also effective against *Aspergillus* fungi and Gram-positive bacteria (*Staphylococcus* and *Streptococcus* genera), that are likely to cause secondary infections. [4],[5] This action is attributable to its indirect inhibition of ergosterol synthesis and direct inhibition of nonsterol component of fungal cell membrane leading to rapid leakage of key intracellular components and immediate cell death. Additionally, the unique benzothioephene ring in the chemical structure offers higher lipophilicity and greater retention of drug in the stratum corneum for up to 48 hrs, leads to greater mycological cure rates and lesser chance of relapse. [6] The anti-inflammatory and anti-pruritic actions of Sertaconazole leads to symptomatic relief and is considered to be beneficial to patients. [7],[8],[9] These ancillary properties of sertaconazole are likely to make an impact on the concomitant symptom control and therefore improve quality of life of these patients with dermatophytoses. Drug resistance is a common problem with most of the antifungal agents; however the data for sertaconazole is quite limited. According to resistance testing conducted in European settings, 4% strains were resistant to sertaconazole compared to 48.8%

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with triazoles (fluconazole). [10] Sertaconazole has excellent safety record, with the reported adverse event being cutaneous related including contact dermatitis, dryness, burning, eczema, itching and skin tenderness. However the frequency of these side effects was comparable to placebo. [11]

Clinical efficacy and safety of these three topical antifungals has not been studied in Indian population and therefore the present study was undertaken to compare the efficacy and safety of sertaconazole 2% cream with terbinafine 1% and luliconazole 1% for the treatment of superficial mycoses.

Materials and Methods



A prospective, randomized, multicentric, open-labeled, parallel study was undertaken in 83 patients with Dermatophytoses involving *tinea corporis* and *tinea cruris* infections. The study protocol, case record form, patient consent form and patient information sheet was approved by the Ethics Committee and the study was conducted as per ICH-GCP guidelines.

Adults between the age of 18 and 70 years, with clinical diagnosis and mycological confirmation (positive KOH test) for *tinea corporis* and *tinea cruris* infections, were included in the study. Patients were excluded from the study, if they had clinical diagnosis of *tinea pedis/manum*, received topical or oral antimycotics either one or four weeks prior to the initiation of the study respectively, history of hypersensitivity to study drugs, immunocompromised status, superadded bacterial infection or pregnant or lactating women.

Patients fulfilling selection criteria were randomized to receive trial drugs supplied by Sponsor as per randomization schedule in 1:1:1 ratio involving three study groups. 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 two weeks, where the patients were assessed clinically and mycologically for relapse.

Primary efficacy was based on clinical and mycologic assessment of *tinea lesion* at baseline, end of 'Treatment Phase' and end of Follow-up Phase (2 weeks following completion of the treatment). *Clinical assessment* was based on the proportion of patients with symptoms and signs of *tinea lesions namely* pruritus, erythema, vesicle and desquamation, and graded as none (0), mild (1), moderate (2) and severe (3) depending on intensity. *Mycologic assessment* was based on KOH mounting for dermatophytes.

Secondary efficacy was a 'Composite Score' of all clinical symptoms (*pruritus, erythema, vesicle and desquamation*); and 'Physician Global Assessment' based on three criteria; successful treatment outcome (*clinical cure + negative mycology*), clinical success (*symptomatic relief + clinical cure*) and clinical failure (*no clinical and mycological improvement*), at end of 'Treatment Phase' and 'Follow-up Phase'.

Safety and tolerability was assessed by monitoring treatment related adverse events at each visit.

Patients who failed to follow up for two consecutive visits were considered as being lost to follow up and treated as drop outs.

Statistical methods

All randomized patients who received study medication and completed the study were included for analysis. The difference in change in clinical assessment of pruritus, erythema, vesicle and desquamation. Mycological assessment by scraping of skin scales and examination in 10% KOH mount and physician global assessment, within and between the groups were analyzed using Chi-square test. Baseline demographic data and laboratory investigations were analyzed using ANOVA.

Results



Of the 83 patients who were enrolled, 62 patients completed the study. In sertaconazole group, 6 patients were lost to follow up and 1 withdrew due to suspected contact dermatitis. In the Terbinafine and luliconazole group, 7 patients each were lost to follow up. Baseline demographic data including age, weight and height in all the three treatment groups were comparable, as shown in [Table 1].

Parameters	Sertaconazole	Terbinafine	Luliconazole
No. of patients	27	25	27
Male/Female	15/12	17/8	15/12
Age (years)	27.45 (11.12)	26.6 (10.43)	22.59 (7.35)
Weight (kg)	49.5 (11.52)	47.22 (11.66)	43.37 (8.54)
Height (cm)	171.8 (12.54)	167.44 (10.18)	167.76 (8.11)

Table 1: Baseline demographics

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Primary efficacy results

Change in pruritus

At the end of treatment phase, the resolution of pruritus was seen in higher proportion of patients in sertaconazole group (85%) as compared to terbinafine (54.6%); and luliconazole group (70%). The percentage of patients with change in pruritus was significantly more in sertaconazole group as compared to terbinafine. During the 'Follow-up Phase', 100% of patients in sertaconazole and luliconazole group and 95.5% of the patients in terbinafine group showed absence of pruritus [Table 2].

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

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Change in erythema

At the end of treatment phase, the resolution of erythema was seen in higher proportion of patients in sertaconazole group (95%) as compared to terbinafine (90.9%); and luliconazole group (85%). During the 'Follow-up Phase', all the patients showed absence of erythema in all treatment groups [Table 3].

Table 3: Comparison of changes in proportion of patients with erythema

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Change in vesicle and desquamation

At baseline, 40 to 45.5% of patients had vesicles in all treatment groups. At end of 'Treatment Phase' and 'Follow-up' Phase, all patients showed absence of vesicles that was significant from the baseline.

At baseline, 70 to 100% of total study cases had desquamation in all treatment groups of which 55 to 77.3% of cases had moderate to severe desquamation. At the end of 'Treatment Phase', desquamation was absent in all patients in sertaconazole group (100%) as compared to terbinafine (90.9%) and luliconazole group (95%). At the 'Follow-up' Phase, all patients showed absence of desquamation in all three groups.

Mycologic assessment

At baseline all patients had positive KOH test for Dermatophytes. At end of 'Treatment Phase' and 'Follow-up' Phase, all patients showed negative mycological assessment (negative KOH test).

Secondary efficacy results

Change in composite score

At baseline, the 'Composite Score' of all clinical symptoms and signs of *Tinea* infection (*pruritus*, *erythema*, *vesicle* and *desquamation*) was 6.80 in sertaconazole group, 6.73 in terbinafine group and 7.05 in luliconazole group. At the end of 'Treatment Phase', there was a greater reduction in mean total composite score in sertaconazole group (97.1%) as compared to terbinafine (91.2%) and luliconazole group (92.9%). At the end of 'Follow-up Phase', the mean total composite score was zero in sertaconazole and luliconazole group and 0.05 in terbinafine group [Table 4].

Table 4: Comparison of changes in proportion of patients with composite score

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The improvement in the total composite score was well reflected clinically in a patient with tinea corporis in the abdomen as shown in [Figure 1]a, b.



Figure 1: (b) Improvement in tinea corporis lesion with topical sertaconazole 2% applied for two weeks (After)

Figure 1: (a) Improvement in tinea corporis lesion with topical sertaconazole 2% applied for two weeks (Before)

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Physician global assessment

Physician Global Assessment at end of 'Treatment Phase', the 'Successful Treatment Outcome' was 100% in

sertaconazole group as compared to terbinafine (86.4%) and luliconazole (95%).

Safety assessment

All three study drugs were well tolerated. Only one patient in sertaconazole group withdrew from the study due to suspected allergic contact dermatitis.

Discussion



Dermatophytoses is one of the most earliest known fungal infections and affects the quality of life of patients due to the concomitant inflammatory symptoms involving pruritus. Recurrence of tinea infections is common due to inadequate treatment or reinfections especially of the intertriginous areas.

In the present analysis based on data of 62 evaluable patients, all the three study drugs showed significant reduction in signs and symptoms (*pruritus, erythema, vesicles and desquamation*) of tinea infections as compared to baseline. At end of 'Treatment Phase' greater proportion of patients in sertaconazole group had absence of pruritus (85%) and erythema (95%) as compared to terbinafine and luliconazole.

This substantiates the antipruritic and anti-inflammatory action of sertaconazole over other antifungals that would ensure better adherence to treatment and improved quality of life. This antipruritic and anti-inflammatory property of sertaconazole is due to its ability to reduce histamine release and several other proinflammatory cytokines including PGE2. The clinical implication of this is significant since for most patients with tinea infections topical imidazoles are usually advocated where sertaconazole shows highest antimycotic potency compared to other antifungal agents especially against *candida albicans* that are also likely to be involved or concomitantly present in a patient of tinea cruris. [\[9\],\[12\]](#)

Significant improvement in vesiculation and desquamation was observed in all three groups compared to baseline.

At the end of 'Treatment Phase' and 'Follow-up' Phase, all patients showed negative mycological assessment in all three treatment groups, suggesting of no recurrence of the disease.

As per physician global assessment, all patients in Sertaconazole group (100%) had successful treatment outcome (clinical and mycological cure) as compared to terbinafine (95%) and luliconazole (86.4%).

In the present study, all three treatments were well tolerated and found to be safe. One patient in the sertaconazole group had complained of burning sensation on application. This could be attributed to the pharmacological property of any topical antifungal drug or hypersensitivity to the study drug, that could not be assessed since the patient was lost to follow-up. [\[13\]](#)

The results of this study are likely to be confounded by the study design since the therapy duration was different for all the treatment drugs. However since most the clinical trials conducted with sertaconazole employed a four week study design, our pilot study also employed similar duration of therapy for sertaconazole while comparing its efficacy and safety with standardized regimen of terbinafine and luliconazole (2 weeks) for the first time in patients with tinea cruris or corporis.

Conclusion



The results of the present study indicate that sertaconazole was better than terbinafine and luliconazole in relieving signs and symptoms of dermatophytoses especially pruritus thereby improving patients' quality of life. The mycological cure was similar in all the three drugs at the end of treatment and follow up period. The mean percentage reduction in total composite score was 97.1%, 91.2% and 92.9% for sertaconazole, terbinafine and luliconazole group respectively, suggesting comparable efficacy of the studied anti-fungal agents at the end of follow-up phase. Only one patient reported suspected contact dermatitis suggesting excellent safety and tolerability of sertaconazole, luliconazole and terbinafine.

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What is new?

Imidazoles, Allylamines and Triazoles are the most effective agents for Dermatophytoses. Sertaconazole has additional 'anti-inflammatory' & 'antipruritic' actions. Comparative clinical study highlights better antipruritic results for Sertaconazole in Superficial mycotic infections.

Figures

[\[Figure 1\]](#)

Tables

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