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# ORIGINAL ARTICLE

## Effectiveness and safety of topical 1% terbinafine versus topical 2% sertaconazole inpatients with tinea cruris

Manish Soni

Assistant Professor, Department of Dermatology, Index Medical College Hospital & Research Center, Indore, Madhya Pradesh, India

***ABSTRACT:***

**Aim:** Effectiveness and safety of topical 1% terbinafine versus topical 2% sertaconazole in patients with tinea cruris. **Materials and methods:** Patients with secondary bacterial infections, diabetic, immunocompromised patients, and on other antifungals were excluded from the study. We excluded patients having drug history of hypersensitivity to azole as well as allylamine group and women with pregnancyand lactation. 80 treatment naive individuals with tinea cruris were randomized into two groups of 30 each of 1:1 ratio using computer random sequence generator to receive either topical terbinafine applied twice dailyor topical sertaconazole once daily for a period of 4 weeks. **Results:** 80 patients with tinea cruris fulfilling the inclusion criteria were analyzed in our study. At the baseline, composite score of all clinical symptoms was 5.11 ± 1.06 in the terbinafine group and 5.61 ± 1.15 in the sertaconazole group which was matched ($P$ = 0.85). At the end of treatment (4 weeks), total composite score was 0.09 ± 0.21 inthe terbinafine group and 0.04 ± 0.19 in the sertaconazole groupwhich showed statistical significance ($P$ < 0.001). Table 2 shows intragroup comparison of mean scores of two groups. **Conclusion:** Terbinafine was equal in efficacy and safety to newer azole sertaconazole in treating patients with tinea cruris. However, sertaconazole has showed a better response to therapy as compared to terbinafine. Mycological cure was achieved in all patients at the completion of therapy indicating no recurrence. Both the study drugs were well tolerated and no serious adverse reactions.

**Keywords:** terbinafine, sertaconazole, tinea cruris

**Corresponding author:** Manish Soni, Assistant Professor, Department of Dermatology, Index Medical College Hospital & Research Center, Indore, Madhya Pradesh, India

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## INTRODUCTION

One of the common varieties of tinea encountered is tinea cruris (12–27%). It is often seen at inguinal folds bilaterally and presents with erythematous plaque and pruritus. Dermatophytic infections can be treated by systemic as well as topical treatment. However, topical antifungals alone are usually sufficient for localized dermatophyte infections, avoid the systemic side effects, and can be easily applied[1]. Numerous studies have shown that allylamine like terbinafine is better to azoles in treating tinea infections and considered to have broad spectrum of antifungal activity[2]. However, sertaconazole one of the newer azoles with both fungicidal and fungistatic action, which is structurally unique with benzothiophene ring, which prolongs duration of action in stratum corneum approximately 48 h and this results in reduction in relapse rate and better mycological cure[3]. Furthermore, sertaconazole has additional anti-inflammatory, anti-pruritic actions and applied topically once a day[4,5]. Many topical antifungals of different groups are available for the treatment of dermatophytoses such as azole derivatives, allylamines, benzylamines, morpholine, etc., Systemic drugs, such as terbinafine and itraconazole, are currently used for the treatment of severe and chronic dermatophytosis[6]. Topical antifungal drugs are effective in localized infections. Topical antifungal therapy based on the use of imidazoles, such as clotrimazole, miconazole, and ketoconazole, is most commonly used[7]. Sertaconazole is a newer topical antifungal agent which belongs to the imidazole class of antifungals. Like other azoles, sertaconazole inhibits the synthesis of ergosterol, an essential component of fungal cell walls resulting in disruption of mycelial growth and replication. However, at higher concentrations, sertaconazole binds directly to non-sterol lipids in the fungal cell wall, which leads to increased permeability and subsequent lysis of the mycelium. Thus, depending on concentration, sertaconazole may exhibit both fungistatic and fungicidal activities[8]. Terbinafine hydrochloride is one of the fungicidal allylamine groups of drugs with broad spectrum of antifungal activity. It interferes with fungal sterol biosynthesis at an early stage. It also inhibits squalene epoxidation, leading to intracellular accumulation of toxic squalene responsible for fungal cell death[9]. There is paucity of clinical studies regarding the clinical efficacy of newer antifungal like sertaconazole in treatment of tinea corporis and tinea cruris. As per our knowledge, there is not a single study available at present comparing the clinical efficacy of topical terbinafine and sertaconazole cream in treatment of tinea corporis and tinea cruris. With this background the present trial was carried out to study and compare the efficacy of topical terbinafine hydrochloride 1%, a fungicidal agent and sertaconazole nitrate 2% cream, a

fungistatic agent in localized tinea corporis and tinea cruris and to study the adverse effects of these antifungal creams.

## MATERIALS AND METHODS

Patients aged 18–65 years with either gender who had localized tinea lesions limited to inguinal region, agreed to give written informed consent were included after taking clearance from the Institutional Ethics Committee. Patients with secondary bacterial infections, diabetic, immunocompromised patients, and on other antifungals were excluded from the study. We excluded patients having drug history of hypersensitivity to azole as well as allylamine group and women with pregnancyand lactation. 80 treatment naive individuals with tinea cruris were randomized into two groups of 30 each of 1:1 ratio using computer random sequence generator to receive either topical terbinafine applied twice dailyor topical sertaconazole once daily for a period of 4 weeks. The study pro forma included demographic details of patient, concomitant drugs taken, medical history, and physical and clinical examination which record vitals of patients, also regarding the prescription of drug given by the treating doctor was collected. Relevant investigations (potassium hydroxide [KOH] mount) were done at the first (baseline) visit and followed up at 2 and 4 weeks. It was possible to get sufficient scales at baseline and at the end of 1 week of treatment for mycological assessment but due to good treatment response there were hardly any scales to perform the mycological assessment at the end of 2nd and 3rd weeks. We performed the mycological assessment with whatever scales available at the end of 2nd and 3rd week. Mycological cure was defined as negative KOH and culture. Complete cure was defined as mycological cure with complete absence of clinical signs and symptoms. Statistical analysis was done using Students paired and unpaired *t*- tests from the data obtained.

## RESULTS

80 patients with tinea cruris fulfilling the inclusion criteria were analyzed in our study. The baseline parameters were matched betweentwo groups and presented in Table 1.

**Table 1: Baseline parameters**

| Parameters | Terbinafine cream | Sertaconazole cream | P value |
|---|---|---|---|
| Age in years | | | 0.86* |
| Mean (standard deviation) | 35.01 (12.61) | 34.63 (11.06) | |
| Gender – *n* (%) | | | 0.68** |
| Male | 31 (86.61%) | 32 (91%) | |
| Female | 9 (13.31%) | 8 (13%) | |
| Baseline mean score | 5.11 ± 1.06 | 5.61 ± 1.15 | 0.09* |

At the baseline, composite score of all clinical symptoms was 5.11 ± 1.06 in the terbinafine group and 5.61 ± 1.15 in the sertaconazole group which was matched ($P$ = 0.85). At the end of treatment (4 weeks), total composite score was 0.09 ± 0.21 inthe terbinafine group and 0.04 ± 0.19 in the sertaconazole groupwhich showed statistical significance ($P$ < 0.001). Table 2 shows intragroup comparison of mean scores of two groups.

**Table 2: Mean scores of primary efficacy parameters: Comparison of intragroup**

| Parameters | Baseline | 2nd week | 4th week | P value |
|---|---|---|---|---|
| Terbinafine | | | | |
| Pruritus | 3.01±0.51 | 0.89±0.45 | 0.09±0.29 | <0.001* |
| Erythema | 1.62±0.52 | 1±0.66 | 0±0.00 | <0.001* |
| Desquamation | 0.51±0.52 | 0.09±0.26 | 0±0.00 | <0.001* |
| Sertaconazole | | | | |
| Pruritus | 3.43±0.58 | 1±0.43 | 0±0.00 | <0.001* |
| Erythema | 1.55±0.59 | 0.88±0.59 | 0.05±0.19 | <0.001* |
| Desquamation | 0.72 ± 0.54 | 0.18 ± 0.39 | 0 ± 0.00 | <0.001* |

## DISCUSSION

Most common symptoms of fungal infection are vesicles, redness, pruritus, and desquamation. Higher recurrence rate is because of patients receiving inadequate therapy[1]. The main aim of the antifungal therapy is to reduce the morbidity associated with tineainfections. In our study, the efficacy and safety of terbinafine and sertaconazole applied topically in patients with mild-to- moderate tinea cruris was compared. There was improvementin clinical features by reduction of pruritus, redness, vesicles, and desquamation and 100% mycological cure in both the study groups from baseline to 4 weeks. Both the drugs were well tolerated.

The mean age of our enrolled patients was 34.03±11.60 years in the terbinafine group and 34.63±11.06 years in the sertaconazole group which was matched at baseline ($P$ = 0.83). Similar age representation was found in the study done by Jerjani *et al*[10]. with mean age of 36.45±14.70 in the

terbinafine group and 32.33±11.85 in azole group, as most commonly adults were encountered withtinea cruris. Males found to be higher affected with 86%in the terbinafine group and 89% in the sertaconazole group ($P$ = 0.68). Similar results in studies of Kumar *et al*[1]. and Borgohain *et al*[11]. where majority of the patients were male compared to females. This difference in gender distribution may be because of stigma associated with attending hospital. In a study done by Sharma *et al*[12]. on the efficacy and tolerability of sertaconazole nitrate 2% cream vs miconazole 1% cream in patients with cutaneous dermatophytosis, sertaconazole nitrate 2% cream was used twice daily for 2 weeks and they observed that 62.3% patients had a complete clinical cure. Sertaconazole was well tolerated without clinically significant side effects. In our study, complete cure rates of 73.33% at the end of 2nd week was seen. But we continued the treatment for another 1 week and observed complete cure rate (100%) at the end of the 3rd week. Esso *et al*[13]. in their study of sertaconazole in the treatment of paediatric patients with cutaneous dermatophyte infections used 2% sertaconazole once daily for a period of 2 weeks and observed that clinical cure was achieved in 75% and 100% patients after 2 and 4 weeks, respectively. No local adverse effects were observed in their study. In our study, complete cure rates of 73.33% at the end of 2nd week was seen with application of sertaconazole cream twice daily for 2 weeks. Esso *et al*[13]. achieved 75% cure rate with only once daily application of sertaconazole at the end of 2 weeks as compared to twice daily application in our study which could be explained on the basis that in paediatric age group percutaneous absorption is more due to thinner skin as compared to adults.

To the best of our knowledge, till date no study comparing the efficacy and safety of terbinafine hydrochloride 1% cream and sertaconazole nitrate 2% cream has been done.

Our study showed that the newer fungistatic drug sertaconazole nitrate 2% cream is as effective as terbinafine hydrochloride 1% cream which is one of the fungicidal drugs, though terbinafine hydrochloride 1% cream has higher rates of complete cure at the end of 2 weeks as compared to sertaconazole nitrate 2% cream. Both the drugs showed good tolerability with no adverse effects.

## CONCLUSION

Terbinafine was equal in efficacy and safety to newer azole sertaconazole in treating patients with tinea cruris. However, sertaconazole has showed a better response to therapy as compared to terbinafine. Mycological cure was achieved in all patients at the completion of therapy indicating no recurrence. Both the study drugs were well tolerated and no serious adverse reactions.

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