

**Original article:**

## **To Compare Effectiveness of Topical Sertaconazole with Terbinafine in Localized Dermatophytosis: An Institutional Based Study**

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### **Abstract**

**Background:** Dermatophytosis is a superficial fungal infection of keratinized tissue, caused by keratinophilic fungi called dermatophytes. Sertaconazole is a new benzothiazole imidazole derivative that indirectly inhibits ergosterol synthesis and directly inhibits the non-sterol component of the fungal cell membrane as well. Terbinafine is the only orally administered allylamine that is available commercially. Hence; the present study was undertaken for comparing the effectiveness of topical sertaconazole with terbinafine in localized dermatophytosis.

**Materials & Methods:** A total of 40 patients within the age group of 20 to 60 years, of either gender or presenting with localized tinea lesions were enrolled in the present study. Diagnosis of localized dermatophytosis was confirmed by identification of fungal hyphae in scrapings under potassium hydroxide smear microscopy. All the patients were divided into two study groups with 20 patients in each group; Group A: Patients receiving topical sertaconazole, and Group B: Patients receiving terbinafine. Clinical assessment of erythema, pruritus and scaling was done. Follow-up details were recorded.

**Results:** In group A, significant improvement of lesion occurred in 25 percent of the patients. In group B, significant improvement of lesion occurred in 10 percent of the patients. Non-significant results were obtained while comparing the improvement in lesion among the two study groups. In group A, complete resolution of lesion occurred in 70 percent of the patients. In group B, complete resolution of lesion occurred in 80 percent of the patients. Non-significant results were obtained while comparing complete resolution among the two study groups. In 5 percent of the patients of group A and 10 percent of the patients of group B, the drug was withdrawn due to adverse effects.

**Conclusion:** Both the topical agents can be used with equal effectiveness in patients with localized dermatophytosis.

**Key words:** Dermatophytosis, Eczema, Pruritus.

### **INTRODUCTION**

Dermatophytosis is a superficial fungal infection of keratinized tissue, caused by keratinophilic fungi called dermatophytes. Dermatophytosis is commonly called as tinea. Tinea corporis and tinea cruris is the dermatophytosis of glabrous skin and groin, respectively.<sup>1</sup> "Tinea" refers to scaly fungal infections of the epidermis and skin appendages caused by a group of keratinophilic fungi known as "dermatophytes" which

includes three genera, namely, Epidermophyton, Microsporum, and Trichophyton. Trichophyton rubrum is implicated as the most common causative agent of dermatophytosis in India.<sup>2,3</sup>

Traditionally, azole antifungals such as Itraconazole, when present in therapeutic concentrations, interrupt the functions of ergosterol that is present in the fungal membranes and disrupt both the structure of the membrane as well as its functions (nutrient transport and chitin synthesis). Sertaconazole, on the other hand, is a relatively new benzothiazole imidazole derivative that indirectly inhibits ergosterol synthesis and directly inhibits the non-sterol component of the fungal cell membrane as well. Its collective action results in leakage of intracellular components and results in rapid cell death. In addition, the lipophilic property of the benzothiazole ring enables prolonged dermal retention that permits just once-daily application of 2% sertaconazole cream. 4 Terbinafine is the only orally administered allylamine that is available commercially.<sup>4-6</sup> Hence; the present study was undertaken for comparing the effectiveness of topical sertaconazole with terbinafine in localized dermatophytosis.

## **MATERIALS & METHODS**

The present study was undertaken for comparing the effectiveness of topical sertaconazole with terbinafine in localized dermatophytosis. A total of 40 patients within the age group of 20 to 60 years, of either gender or presenting with localized tinea lesions were enrolled in the present study. Only those patients were included which have not applied any topical or taken any oral antifungal drug before the baseline visit.

Exclusion criteria for present study included:

- Diabetic patients,
- Hypertensive patients,
- Patients with presence of immuno-compromised state
- Pregnant subjects

Ethical approval was obtained before the starting of the study and written consent was obtained from all the patients after explaining in detail the entire research protocol. Diagnosis of localized dermatophytosis was confirmed by identification of fungal hyphae in scrapings under potassium hydroxide smear microscopy. All the patients were divided into two study groups with 20 patients in each group; Group A: Patients receiving topical sertaconazole, and Group B: Patients receiving terbinafine. Clinical assessment of erythema, pruritus and scaling was done. Follow-up details were recorded. All the results were recorded and analysed by SPSS software.

## **RESULTS**

Mean age of the patients of group A and group B was 42.3 years and 44.8 years respectively. Majority of the patients of both the study groups belonged to the age group of 31 to 45 years. 65 percent of the patients of group A and 60 percent of the patients of group B were males while the remaining were females. In group A, significant improvement of lesion occurred in 25 percent of the patients. In group B, significant improvement of lesion occurred in 10 percent of the patients. Non-significant results were obtained while comparing the improvement in lesion among the two study groups.

In group A, complete resolution of lesion occurred in 70 percent of the patients. In group B, complete resolution of lesion occurred in 80 percent of the patients. Non-significant results were obtained while comparing complete resolution among the two study groups. In 5 percent of the patients of group A and 10 percent of the patients of group B, the drug was withdrawn due to adverse effects.

**Table 1: Age-wise distribution**

Age group (years)	Group A		Group B	
	N	%	n	%
Less than 30	5	25	6	30
31 to 45	8	40	8	40
More than 45	7	35	6	30

**Table 2: Gender-wise distribution**

Gender	Group A		Group B	
	N	%	n	%
Males	13	65	12	60
Females	7	35	8	40

**Table 3: Comparison of clinical improvement after 3 weeks follow-up**

Variable	Group A	Group B	p- value
Significant improvement of lesion (% of patients)	25	10	0.124
Complete resolution of lesion (% of patients)	70	80	0.521
Withdrawal of drug due to adverse effect	5	10	0.274

## DISCUSSION

Superficial mycosis is estimated to be one of the most prevalence infections, affecting roughly quarter of the world's population. Among the various classes of cutaneous mycoses, dermatophytes are the most common causative agents. Generally referred to as ringworm or tinea, this specific group of dermatophytes include the genera *Microsporum*, *Trichophyton* and *Epidermophyton*. Many topical antifungals of different groups are available for the treatment of dermatophytosis 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.<sup>6-9</sup> In the present study, mean age of the patients of group A and group B was 42.3 years and 44.8 years respectively. In group A, significant improvement of lesion occurred in 25 percent of the patients. In group B, significant improvement of lesion occurred in 10 percent of the patients. Non-significant results were obtained while comparing the improvement in lesion among the two study groups. Chatterjee D et al compared of the effectiveness of the once-daily topical azole, sertaconazole, with terbinafine in these infections. Overall 88 patients on sertaconazole and 91 on terbinafine were analyzed. At 2 weeks, the clinical cure rates were comparable at 77.27% for sertaconazole and 73.63% for terbinafine. Fourteen patients in either group improved and on further treatment showed complete healing by another 2 weeks. They suggested that once-daily topical sertaconazole is as effective as terbinafine in localized tinea infections.<sup>9</sup>

In the present study, in group A, complete resolution of lesion occurred in 70 percent of the patients. In group B, complete resolution of lesion occurred in 80 percent of the patients. Non-significant results were obtained while comparing complete resolution among the two study groups. In 5 percent of the patients of group A and 10 percent of the patients of group B, the drug was withdrawn due to adverse effects. Choudhary S et al compared the efficacy of topical terbinafine hydrochloride 1% cream and sertaconazole nitrate 2% cream in localized tinea corporis and tinea cruris and to know the adverse effects of these antifungal creams. Patients in group A and B were treated with twice daily topical 1% terbinafine hydrochloride and 2% sertaconazole nitrate cream

respectively for a total duration of three weeks. The newer fungistatic drug sertaconazole nitrate 2% cream was 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.<sup>7</sup> Sumitha A et al compared the efficacy and safety of topical antifungal agents, terbinafine versus sertaconazole in the treatment of tinea corporis. A total of 60 (n=60) patients were included and divided into two groups of 30 patients each in the study. 1st group - received topical 1% terbinafine hydrochloride and 2nd group - received 2% sertaconazole cream. They concluded that 2% sertaconazole cream was as effective as 1% terbinafine cream, though 1% terbinafine had higher rates of complete cure at the end of 2 weeks as compared to sertaconazole.<sup>10</sup>

## CONCLUSION

From the above results, the authors concluded that both the topical agents can be used with equal effectiveness in patients with localized dermatophytosis.

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