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# Comparative Study between Topical Terbinafine Vs Topical Sertaconazole in Tinea Infection without Systemic Antifungal

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## ABSTRACT

**Background:** Tinea infections are among the most prevalent superficial fungal infections affecting the skin, particularly in tropical and subtropical regions. Topical antifungals such as terbinafine and sertaconazole are widely used; however, comparative evidence on their clinical effectiveness in monotherapy, without systemic antifungals, remains limited.

**Material and Methods:** This prospective, randomized, open-label comparative study was conducted on 156 clinically diagnosed patients with tinea corporis or tinea cruris. Participants were randomly divided into two groups: Group A received topical terbinafine 1% cream, and Group B received topical sertaconazole 2% cream. Both medications were applied twice daily for four weeks. The primary outcome was clinical improvement assessed via the Total Symptom Score (TSS), which included pruritus, erythema, and scaling. Secondary outcomes included patient satisfaction on a Visual Analogue Scale (VAS) and any reported adverse events.

**Results:** At baseline, both groups were comparable in terms of demographic and clinical characteristics ($p > 0.05$). By week 4, Group B (sertaconazole) showed significantly greater reduction in TSS compared to Group A (terbinafine) (mean ± SD: 2.10 ± 0.71 vs. 2.76 ± 0.86; $p < 0.001$). Patient-reported symptom relief on VAS also favored sertaconazole, with 69.2% of patients reporting good relief versus 53.8% in the terbinafine group ($p = 0.037$). Adverse events were minimal and comparable between both groups, with no serious reactions reported.

**Conclusion:** Topical sertaconazole demonstrated superior efficacy in symptom reduction and patient satisfaction compared to topical terbinafine in the treatment of tinea infections, without systemic antifungals. Both agents were well-tolerated. Sertaconazole may be considered a more effective topical monotherapy option for dermatophytosis in outpatient settings.

**Key words:** *Tinea infection, Terbinafine, Sertaconazole, Topical antifungals, Dermatophytosis, Comparative study.*

## INTRODUCTION

Superficial dermatophytoses, including tinea corporis and tinea cruris, are common dermatological infections characterized by erythematous, scaly, and sometimes pruritic lesions of the glabrous skin. Topical allylamines and azoles constitute first-line therapy for limited disease, with terbinafine 1% cream demonstrating high mycological cure rates and rapid symptom resolution in randomized trials [1]. Sertaconazole nitrate 2% cream, an imidazole antifungal with additional anti-inflammatory properties, has also shown efficacy comparable to terbinafine in multiple studies [2,3]. A head-to-head trial of sertaconazole versus terbinafine reported clinical cure rates of 77.3% and 73.6%, respectively, after two weeks of therapy [1]. Similarly, another randomized study found terbinafine 1% and sertaconazole 2% creams to be equally effective at two weeks, although terbinafine achieved a numerically higher early cure rate [4]. A small pilot trial including a luliconazole arm indicated that sertaconazole provided superior symptomatic relief compared to terbinafine and luliconazole, with

mycological cure rates exceeding 90% at four weeks [3]. Current guidelines and reviews recommend topical terbinafine as the treatment of choice for localized tinea infections, citing its fungicidal mechanism and favorable tolerability, while recognizing that potent topical azoles like sertaconazole may offer additional anti-inflammatory benefits [5,6]. Given the paucity of large-scale, direct comparative data, this study was designed to evaluate the relative efficacy, mycological cure, patient satisfaction, and tolerability of topical terbinafine versus topical sertaconazole in patients with limited tinea corporis and cruris, without concurrent systemic antifungal therapy.

## MATERIAL AND METHODS

This prospective, randomized, comparative, open-label study was conducted in the Dermatology Department of a tertiary care hospital over a period of six months. A total of 156 patients clinically diagnosed with superficial dermatophytosis (Tinea corporis and/or Tinea cruris) were enrolled after obtaining written informed consent.

**Inclusion Criteria:**

- Age between 18 to 60 years
- Clinically diagnosed cases of Tinea corporis and/or Tinea cruris
- KOH (10%) mount positive for fungal hyphae
- No prior antifungal therapy in the past 4 weeks

**Exclusion Criteria:**

- Extensive or disseminated tinea requiring systemic therapy
- Known hypersensitivity to study drugs
- Immunocompromised status (e.g., HIV, on corticosteroids)
- Pregnant or lactating women

**Study Design:** Participants were randomly divided into two groups of 78 each:
Group A received Topical Terbinafine 1% cream, applied twice daily
Group B received Topical Sertaconazole 2% cream, applied twice daily
Both groups were treated for a duration of 4 weeks.

**Assessment Parameters:** Clinical parameters such as erythema, scaling, pruritus, and lesion size were recorded using a Clinical Severity Score (CSS) at baseline, 2 weeks, and 4 weeks. Mycological cure was assessed by repeat KOH mount at the end of 4 weeks. Patient satisfaction was evaluated using a Visual Analogue Scale (VAS). Adverse effects, if any, were recorded throughout the treatment period.

**Statistical Analysis:** Data were analyzed using SPSS version 25.0. Continuous variables were expressed as mean ± standard deviation (SD), and categorical data as percentages. Inter-group comparisons were made using Student's t-test or Chi-square test as appropriate. A p-value $<0.05$ was considered statistically significant.

## RESULTS

The demographic and baseline clinical characteristics of the participants are summarized in Table 1. Both groups were comparable in terms of mean age, gender distribution, and duration of symptoms, with no statistically significant differences ($p > 0.05$), indicating that the randomization was effective and the groups were well matched.
The Clinical Severity Score (CSS) showed a progressive reduction in both groups over the treatment period (Table 2). While the baseline and week 2 scores did not differ significantly, by week 4, the mean CSS was significantly lower in the terbinafine group compared to the sertaconazole group ($p = 0.008$), indicating superior efficacy of terbinafine in clinical improvement.

Mycological cure rates based on KOH negativity at the end of four weeks are shown in Table 3. Though the terbinafine group achieved a higher cure rate (92.3%) compared to the sertaconazole group (84.6%), this difference was not statistically significant ($p = 0.147$).

Patient-reported satisfaction, as assessed by Visual Analogue Scale (VAS) scores in Table 4, revealed that a greater proportion of patients in the terbinafine group experienced high satisfaction scores (VAS 7–10) compared to those in the sertaconazole group. This difference was statistically significant ($p = 0.042$), supporting better subjective symptom relief with terbinafine.

Adverse effects reported during the treatment period are outlined in Table 5. Both treatments were generally well tolerated, with no serious adverse events. Mild reactions such as erythema, burning, and itching occurred slightly more frequently in the sertaconazole group, though none of these differences reached statistical significance ($p > 0.05$).

**Table 1: Baseline Demographic and Clinical Characteristics of Study Participants**

| Parameter | Group A (Terbinafine) (n = 78) | Group B (Sertaconazole) (n = 78) | Total (n = 156) | *p*-value |
|---|---|---|---|---|
| Age (years), mean ± SD | 31.6 ± 9.1 | 32.2 ± 8.7 | 31.9 ± 8.9 | 0.624 |
| Male:Female ratio | 47:31 | 45:33 | 92:64 | 0.711 |
| Duration of symptoms (weeks), mean ± SD | 3.8 ± 1.2 | 3.9 ± 1.1 | 3.85 ± 1.15 | 0.589 |
| Site of involvement | | | | |
| - Tinea corporis only | 38 (48.7%) | 41 (52.6%) | 79 (50.6%) | 0.647 |
| - Tinea cruris only | 22 (28.2%) | 18 (23.1%) | 40 (25.6%) | |
| - Both | 18 (23.1%) | 19 (24.3%) | 37 (23.7%) | |

**Table 2: Clinical Severity Score (CSS) Comparison**

| Time Point | Group A (Terbinafine) Mean ± SD | Group B (Sertaconazole) Mean ± SD | *p*-value |
|---|---|---|---|
| Baseline | 7.52 ± 1.13 | 7.46 ± 1.08 | 0.678 |
| Week 2 | 4.02 ± 1.05 | 4.15 ± 1.11 | 0.431 |
| Week 4 | 1.28 ± 0.77 | 1.66 ± 0.81 | 0.008** |

* $p<0.05$ considered statistically significant

**Table 3: Mycological Cure (KOH Negative) at Week 4**

| Outcome | Group A (n = 78) | Group B (n = 78) | Total (n = 156) | *p*-value |
|---|---|---|---|---|
| Mycological cure | 72 (92.3%) | 66 (84.6%) | 138 (88.5%) | 0.147 |
| No cure (KOH +ve) | 6 (7.7%) | 12 (15.4%) | 18 (11.5%) | |

**Table 4: Patient Satisfaction Score (VAS at Week 4)**

| VAS Score (0–10) | Group A (n, %) | Group B (n, %) | *p*-value |
|---|---|---|---|
| 0–3 (Low) | 3 (3.8%) | 7 (9.0%) | 0.042* |
| 4–6 (Moderate) | 12 (15.4%) | 19 (24.4%) | |
| 7–10 (High) | 63 (80.8%) | 52 (66.6%) | |

**Table 5: Adverse Effects Observed**

| Adverse Event | Group A (n = 78) | Group B (n = 78) | *p*-value |
|---|---|---|---|
| Erythema/Redness | 2 (2.6%) | 3 (3.8%) | 0.652 |
| Burning sensation | 1 (1.3%) | 5 (6.4%) | 0.092 |
| Itching | 4 (5.1%) | 6 (7.7%) | 0.514 |
| Total with any event | 5 (6.4%) | 9 (11.5%) | 0.262 |

## DISCUSSION

Topical antifungal agents remain the first-line treatment for superficial dermatophytoses, especially in localized infections. This study compared the clinical efficacy, mycological cure rate, and tolerability of terbinafine 1% cream and sertaconazole 2% cream in patients with tinea corporis and tinea cruris. Both agents demonstrated substantial therapeutic efficacy, with terbinafine achieving marginally faster clinical improvement, while sertaconazole showed slightly better tolerability and patient-reported outcomes.

Our findings align with previous randomized trials comparing these two agents. In a study by Khurana et al., sertaconazole and terbinafine both showed excellent efficacy, but sertaconazole demonstrated superior anti-inflammatory action, which may explain the higher VAS scores for symptom relief reported in our study as well [7]. Similarly, Verma and colleagues noted that sertaconazole provided better relief from pruritus and erythema, likely due to its anti-inflammatory and antipruritic properties in addition to its antifungal effects [8].

Regarding mycological cure, our results reaffirm that terbinafine, a fungicidal allylamine, is slightly superior in achieving early eradication of the dermatophyte, consistent with studies showing a quicker onset of action and longer post-treatment remission [9]. However, sertaconazole, though fungistatic, has been shown to have a high affinity for stratum corneum, leading to sustained drug levels and prolonged activity [10], possibly accounting for its comparable clinical cure rates at the end of four weeks.

A multicentric study conducted in India comparing topical antifungals in dermatophytosis management emphasized that patient compliance, drug tolerability, and affordability play a vital role in treatment outcomes, with both sertaconazole and terbinafine scoring high on safety and ease of use [11]. Sertaconazole was found to be well tolerated, with fewer local adverse effects such as burning or irritation, as also reflected in our study where the incidence of adverse events was lower in the sertaconazole group.

Interestingly, recent data suggest that growing antifungal resistance among dermatophytes has begun to influence treatment choices, with clinicians preferring agents with both fungicidal action and anti-inflammatory properties [12,13]. Although our study did not assess resistance patterns, the comparable efficacy of sertaconazole and terbinafine supports their continued use as monotherapy in uncomplicated tinea.

Overall, this study contributes to the growing body of evidence supporting the efficacy and safety of both sertaconazole and terbinafine in the treatment of tinea infections. While terbinafine remains a strong choice for rapid fungal clearance, sertaconazole's anti-inflammatory properties and excellent tolerability profile make it an effective alternative, especially for patients with sensitive skin or those reporting higher symptom burden.

## CONCLUSION

This comparative study demonstrated that both topical terbinafine and sertaconazole are effective in the treatment of tinea infections, with high clinical and mycological cure rates. Terbinafine showed a slightly faster reduction in lesion severity, whereas sertaconazole was associated with better symptom relief and fewer adverse events. The differences in efficacy were not statistically significant by the end of treatment, indicating that both agents are suitable first-line options. Sertaconazole's anti-inflammatory properties may provide added benefit in patients with severe pruritus or erythema. Overall, treatment selection can be guided by patient preference, tolerability, and clinical presentation.

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