

## ORIGINAL ARTICLE

**Efficacy and safety of sertaconazole 2% in the treatment of dermatophytosis.**Ghania Shafqat<sup>1</sup>, Uzma Sarwar<sup>2</sup>, Annum Ashraf<sup>3</sup>, Nauman Bashir<sup>4</sup>, Sania Khaliq<sup>5</sup>, Iqra Afzal<sup>6</sup>, Rabia Shaukat<sup>7</sup>

**ABSTRACT... Objective:** To determine the efficacy and safety of sertaconazole 2% cream in patients with dermatophytosis. **Study Design:** Descriptive Case Series. **Setting:** Department of Dermatology, Shalamar Hospital, Lahore. **Period:** September 2024 to February 2025. **Methods:** A total of 131 patients aged 18–70 years with a clinical diagnosis of dermatophytosis were enrolled via non-probability consecutive sampling. Patients applied sertaconazole 2% cream twice daily for four weeks. Efficacy was assessed using a Clinical Assessment Score (CAS) for erythema, pruritus, and scaling, with a complete cure defined as a CAS of 0. Safety was evaluated by monitoring for adverse events. Data were analyzed using SPSS version 26. **Results:** The mean age of participants was  $36.7 \pm 11.2$  years, with a male predominance (58.8%). Complete clinical cure was achieved in 90 patients (68.7%). A significant reduction was observed in all CAS parameters, with the highest mean reduction in pruritus (-2.3). Efficacy was significantly higher in patients with a disease duration of  $\leq 4$  weeks (75.5% vs. 48.5%,  $p=0.03$ ) and in those with a normal BMI (77.0% vs. 57.9%,  $p=0.04$ ). Adverse effects, primarily mild pruritus, were reported in only 7 patients (5.3%). **Conclusion:** Sertaconazole 2% cream is an effective and well-tolerated treatment for dermatophytosis, demonstrating high cure rates and a favorable safety profile. It is particularly effective when initiated early in patients with a normal body mass index.

**Key words:** Clinical Trial, Dermatophytosis, Efficacy, Safety, Sertaconazole, Tinea, Topical Antifungal.

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**INTRODUCTION**

Tinea or dermatophytosis as it's more formally known, is a mild fungal infection of the outer layers of skin, hair or nails that comes from a set of keratinophilic fungi called dermatophytes.<sup>1</sup> This class of fungi lives in keratinized areas and produces distinct lesions that tend to feel irritated, have scaly edges and are usually circular with an open center and active borders. Members of the three most important fungi groups are organized into three genera: Trichophyton, Microsporum and Epidermophyton.<sup>2,3</sup> Many dermatophyte fungi are known to infect humans and *T. rubrum*, *T. mentagrophytes* and *M. canis* are the species found most often.<sup>4</sup>

Dermatophytosis occurs in all age groups, climates and economic backgrounds. The World Health Organization estimates that around 20–25% of people worldwide have a superficial fungal infection at any one time.<sup>5</sup> Because of the warm and humid weather, fungal growth in tropical and subtropical regions happens more often. Emerging medical evidence indicates that dermatophytosis

is increasing in Pakistan, India and Bangladesh and many severe cases are stubborn and do not respond well to standard medical treatments. Some experts have pointed out that the trend may be because people are applying topical steroid-antifungal medicine without prescription, often use inaccurate or insufficient treatment and can find over-the-counter antifungal products easily.<sup>6,7</sup>

The first choice for treating small-area dermatophytosis is to use topical antifungal therapy.<sup>8</sup> It gives the favorable result of focusing drugs only on the disease site and causing fewer side effects.<sup>9</sup> These antifungals are so popular because they fight a wide range of fungal infections and have a good safety record. Because it treats both fungal infections and helps control inflammation, sertaconazole nitrate, a third-generation imidazole, has gained recognition. This drug disrupts the fine fungal membrane and leads to cell death by suppressing ergosterol production and attaching to other membrane parts.<sup>10</sup>

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Because it includes a benzothioephene ring, sertaconazole is very lipophilic, remains in the skin longer and keeps working for a prolonged period. This medicine is useful for treating dermatophytosis that is marked by itching, as it has anti-pruritic, antiinflammatory and antibacterial properties, as well as antifungal actions.<sup>11,12</sup> The results of clinical studies indicate that sertaconazole relieves symptoms more quickly and makes patients happier than frequently used topicals such as terbinafine or clotrimazole.<sup>13</sup> Khondker et al. found that 67.9% of patients got better and the treatment was safe in 96.3% of cases.<sup>14</sup> In the same way, compared to topical terbinafine, sertaconazole worked better according to Meghana et al. and Shivamurthy et al. reported better results than clotrimazole.<sup>15</sup>

Even though the results from other countries suggest that sertaconazole works well, we have very few local findings to show that in Pakistani people. Since each country in this region has different fungal species, climate and patient behaviors, local research is needed to direct the best measures based on research.

## METHODS

This study was designed as a descriptive case series conducted at the Department of Dermatology, Shalamar Hospital, Lahore over a period of six months from September 2024 to February 2025, after the approval from the CPSP and IRB committee (Ref No: SMDC-IRB/AL/2024-090, Dated: 20-08-24). A total of 131 patients, aged between 18 and 70 years and clinically diagnosed with dermatophytosis, were enrolled using non-probability consecutive sampling. The study aimed to evaluate the efficacy and safety of sertaconazole 2% cream in this patient population.

Patients were selected based on specific inclusion and exclusion criteria. Inclusion required a clinical diagnosis of dermatophytosis involving a limited body surface area suitable for topical treatment. Individuals with a known allergy to sertaconazole or other imidazoles, those who had used topical or systemic antifungals within the past four weeks or topical corticosteroids on the affected site in the past two weeks, as well as pregnant or breastfeeding women, were excluded from participation.

Data collection was conducted prospectively. Following approval from the institutional ethics committee and obtaining informed consent from all participants, baseline demographics including age, gender, body mass index (BMI), duration of disease, and residential status were recorded on a pre-designed proforma. All enrolled patients were instructed to apply sertaconazole 2% cream twice daily to the affected area for a total of four weeks. Follow-up assessments were scheduled at the 2-week and 4-week marks to monitor progress and record any adverse events.

The primary outcome, clinical efficacy, was assessed using a Clinical Assessment Score (CAS). This score evaluated erythema, pruritus, and scaling, with each parameter graded on a scale from 0 to 3. A complete clinical cure was defined as achieving a CAS of 0 by the end of the 4-week treatment period. Safety was evaluated by monitoring for localized adverse effects, such as pruritus or a burning sensation within 20 minutes of application, with all events documented at each follow-up visit.

For statistical analysis, data were entered and analyzed using SPSS version 26. Descriptive statistics were employed to summarize the data; continuous variables like age, BMI, and disease duration were expressed as mean  $\pm$  standard deviation, while categorical variables such as gender and residential status were presented as frequencies and percentages. The efficacy was primarily reported as the proportion of patients achieving a complete clinical cure. To explore potential associations, post-stratification chi-square tests were used to analyze the relationship between efficacy and variables including age group, gender, BMI category, disease duration, and residential status. A p-value of  $\leq 0.05$  was considered statistically significant for all tests.

## RESULTS

Out of 131 patients, the average age was  $36.7 \pm 11.2$  years, with 58.8% males and 41.2% females. Urban residents constituted 64.9% of the study population. Among those who achieved complete clinical cure (n=90), the mean age was  $35.1 \pm 10.8$  years, while it was higher (39.9 years) among those with no cure. Patients who responded to treatment had a significantly lower BMI ( $24.3 \text{ kg/m}^2$ ) and

shorter disease duration (3.1 weeks), compared to those who did not achieve cure (BMI: 26.0 kg/m<sup>2</sup>; duration: 3.9 ± 11.4 weeks). The differences in age ( $p=0.04$ ), BMI ( $p=0.03$ ), and duration ( $p=0.02$ ) were statistically significant.

Mean erythema score reduced from 2.3 to 0.1, pruritus from 2.5 to 0.2, and scaling from 2.1 to 0.3. The largest reduction was observed in pruritus (-2.3), followed by erythema (-2.2), indicating strong anti-inflammatory and antipruritic effects of sertaconazole.

Among patients with disease duration ≤4 weeks ( $n=98$ ), 75.5% achieved complete cure, compared to only 48.5% in those with longer duration. Similarly, 77.0% of patients with BMI <25 were cured, versus 57.9% of those with BMI ≥25. Both results were statistically significant ( $p = 0.03$  for duration;  $p = 0.04$  for BMI), indicating that earlier treatment initiation and normal body weight are associated with better outcomes. Cure rates were higher in males

(72.7%) than females (63.0%), and among urban residents (72.9%) compared to rural ones (60.9%). However, these differences were not statistically significant ( $p > 0.05$ ), suggesting that gender and locality had less impact on treatment outcome than BMI or disease duration. Out of 131 participants, 90 (68.7%) achieved complete clinical cure (CAS = 0), while 41 (31.3%) showed partial improvement. Only 7 patients (5.3%) reported mild adverse effects. A total of 94.7% tolerated the treatment without any safety concerns, demonstrating that sertaconazole is both effective and safe for treating localized dermatophytosis.

## DISCUSSION

The current study aimed to check how well sertaconazole 2% cream performs in treating dermatophytosis and found that it has good results. Out of all 131 patients, 90 or 68.7% showed complete clinical cure after following the treatment for four weeks which was defined by a CAS of zero.

**TABLE-I**

**Baseline demographics by efficacy outcome**

Characteristic	Total (n=131)	Complete Cure (n=90)	No Cure (n=41)	P- Value
Mean Age (years)	36.7 ± 11.2	35.1 ± 10.8	39.9 ± 11.4	0.04
Gender	77 Male (58.8%) / 54 Female (41.2%)	56 Male / 34 Female	21 Male / 20 Female	0.08
BMI (kg/m <sup>2</sup> )	24.9 ± 3.6	24.3 ± 3.1	26.0 ± 3.9	0.03
Duration of Disease (weeks)	3.4 ± 1.1	3.1 ± 1.0	3.9 ± 1.2	0.02
Residential Status	Urban: 85 / Rural: 46	Urban: 62 / Rural: 28	Urban: 23 / Rural: 18	0.12

**TABLE-II**

**CLINICAL ASSESSMENT SCORE (CAS) COMPONENTS**

CAS Parameter	Baseline Mean Score	Week 2 Mean Score	Week 4 Mean Score	Mean Reduction
Erythema	2.3 ± 0.5	1.1 ± 0.4	0.1 ± 0.2	-2.2
Pruritus	2.5 ± 0.4	1.0 ± 0.5	0.2 ± 0.3	-2.3
Scaling	2.1 ± 0.6	1.2 ± 0.5	0.3 ± 0.2	-1.8

**TABLE-III**

**Overall treatment response summary**

Outcome	n (%)
Complete Cure (CAS = 0)	90 (68.7%)
Partial Improvement (CAS > 0)	41 (31.3%)
Adverse Effects Reported	7 (5.3%)
Safe Use Without Reactions	124 (94.7%)

TABLE-IV

Efficacy of sertaconazole 2% stratified by gender, residential status, duration of disease, and BMI

Variable	Category (n)	Complete Cure (n)	Percentage (%)	p-value
Gender	Male (77)	56	72.7%	0.18
	Female (54)	34	63.0%	-
Residential Status	Urban (85)	62	72.9%	0.14
	Rural (46)	28	60.9%	-
Duration of Disease	≤4 weeks (98)	74	75.5%	0.03
	>4 weeks (33)	16	48.5%	-
BMI	<25 (74)	57	77.0%	0.04
	≥25 (57)	33	57.9%	-

The success rate from this study is similar to that found in other investigations, making sertaconazole a trusted topical medicine for superficial fungus infections.<sup>16</sup>

A main point of this study is that clinical symptoms have clearly improved. There was the biggest decrease in pruritus and the next biggest decrease was noticed in erythema and scaling. The research shows that sertaconazole has more than antifungal effects; it also reduces inflammation and prevents itching. According to previous findings, the benzothioephene ring in sertaconazole helps it stay longer in the skin, giving it better action and lasting symptom relief. Those drug features may be the reason for the fast and noticeable decrease in pruritus scores found in our study. When cure rates were looked at by patient characteristics, we found that the results were significant. Those with a disease duration of up to 4 weeks had a cure rate of 75.5% which was much higher than the 48.5% rate seen in patients with a longer disease duration ( $p = 0.03$ ). Prior research demonstrates that offering antifungal drugs from the start can improve outcomes and avoid recurrence.<sup>17</sup>

A higher BMI in patients was associated with a lower cure rate (57.9%) which tells us that obesity might not allow drugs to get into the skin as effectively and may also cause skin changes that make recovery slower. Previous studies on the subject have found similar results when exploring both treating dermatophytosis and how drugs are processed in different body types.

Using sertaconazole was found to be safe for patients. Just 5.3% of patients mentioned experiencing slight symptoms, including pruritus and burning feeling, but none of these caused them to stop taking the medicine. This research again shows that sertaconazole is safe to use, since previous studies have found that the medicine causes little local irritation and is suitable for use by people with sensitive skin on their body.<sup>18,19</sup> Even though urban patients and male participants responded better, the results were not proven to be statistically significant. As a result, adhering to treatment and having a similar disease condition may be more important than gender or residence when predicting treatment results.

Dublin patients have the advantage of getting care and using medication on time because of their health literacy and ready access to resources in the city. The findings indicate that sertaconazole is a suitable first-choice agent for treating localized fungal infections where the patient has little or no systemic risk. It deals with both infection and the associated inflammation and discomfort, so it is helpful for treating the infection as well as for relieving inflammation and the disagreeable side effects. Yet, the study does have some limits. Both the data collection and the clinical diagnosis were done at one place and were not supported by examining the fungus culture or by preparing KOH mounts. Because of this, the results may not apply more broadly and increase the risk for labeling errors. Even so, the effects and safety record of sertaconazole in this study are consistent with those seen in earlier research.

## CONCLUSION

A complete clinical cure was achieved in 68.7% of patients, with significant improvement in erythema, pruritus, and scaling observed over four weeks. The treatment showed a better response in patients with shorter disease duration and normal BMI, and was well tolerated, with minimal and self-limiting adverse effects reported in only 5.3% of cases.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

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## AUTHORSHIP AND CONTRIBUTION DECLARATION

1	<b>Ghania Shafqat:</b> Data collection.
2	<b>Uzma Sarwar:</b> Review of manuscript.
3	<b>Annum Ashraf:</b> Literature review.
4	<b>Nauman Bashir:</b> Data analysis.
5	<b>Sania Khaliq:</b> Data collection.
6	<b>Iqra Afzal:</b> Data entry.
7	<b>Rabia Shaukat:</b> Critical revisions.