Original Article
DOI: https://doi.org/10.70749/ijbr.v3i7.1855

INDUS JOURNAL OF BIOSCIENCE RESEARCH
https://ijbr.com.pk
ISSN: 2960-2793/ 2960-2807

Comparison of Efficacy of Sertaconazole Nitrate Cream 2 Percent vs Clotrimazole 1 Percent for the Treatment of Tinea Pedis

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ARTICLE INFO

Keywords: Tinea Pedis, Efficacy, Sertaconazole Nitrate, Clotrimazole.

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Declaration
Authors' Contribution: All authors equally contributed to the study and approved the final manuscript.

Conflict of Interest: No conflict of interest.

Funding: No funding received by the authors.

Article History
Received: 03-06-2025 Revised: 21-06-2025
Accepted: 07-07-2025 Published: 11-07-2025

ABSTRACT

Introduction: Tinea pedis is commonly referred to as athlete's foot. Tinea pedis is the consequence of superficial fungal infections on the foot skin brought on by dermatophytes. Among the most prevalent fungal infections of the foot worldwide, its frequency is rapidly rising. Topical imidazoles are effective ways for curing tinea pedis since they work well and have minimal side effects. In the study efficacy of topical Sertaconazole was compared with Clotrimazole on the lesions of Tinea pedis. **Objective:** To compare the Efficacy of Sertaconazole Nitrate Cream 2% Vs. Clotrimazole 1% for the Treatment of Tinea Pedis. **Methodology:** This randomized controlled trial study was carried out on OPD patients in the Department of Dermatology, Jinnah Postgraduate Medical Center (JPMC) Karachi, Pakistan. Patients of Tinea Pedis who met the selection criteria were enrolled in the study. Participants were randomly allocated in into two groups; patients of Group-A had used topical Sertaconazole 2% and patients in Group-B had used Clotrimazole 1%. Over four weeks, both creams were used topically twice daily. The patients were assessed at the final follow-up using all clinical investigations and a microscopic analysis. The effectiveness of the therapies was defined as a reduction in the overall composite score of at least two points with a negative KOH test following four weeks of therapy and the reporting of no adverse effects. All of the patients' adverse drugs events were observed. **Results:** Mean age was 30.39 years, with an SD of 8.56 years. Males represented 48% of patients in the Clotrimazole group and 50% of patients in the Sertaconazole group. Post-treatment signs and symptoms score showed, individuals received Sertaconazole, signs and symptoms reduced significantly. The study finding showed that the efficacy rate of Sertaconazole was higher than the patients in the clotrimazole group (86% vs. 66%; P-value <0.05). **Conclusions:** Topical sertaconazole 2% cream was found to be highly efficacious and superior to clotrimazole 1% cream in improvement of clinical parameters of tinea pedis.

INTRODUCTION

Tinea pedis is commonly referred to as athlete's foot. Tinea pedis is the consequence of superficial fungal infections on the foot skin brought on by dermatophytes such as Epidermophyton floccosum, Trichophyton rubrum, T mentagrophytes, and T interdigitale. (1) The sole, interdigital toe web, and dorsal surface of the foot are the main areas affected. In rare instances, some molds or yeasts cause it, but fungi that can break down keratin are the culprit. (2) Because it is recurring, infectious, and a major reservoir for dermatophytosis elsewhere in the body, tinea pedis is a public health problem. (3) It is estimated that between 6 and 52 percent of people with cutaneous dermatophytosis have tinea pedis. (4) The incidence of tinea pedis is thought to be around 3% worldwide. Lifetime risk can reach 70%. (5) It is considered to be the most prevalent fungal infection in the globe, with a frequency of 2-45% in the United States, 4-35% in Europe, 21% in Africa, and 15-31% in Asia. (6) In South Asia, the prevalence of tinea pedis has significantly increased over the last ten years, with rates varying by area from 6 to 61%. (3) According to earlier research, adults had a greater frequency than children. Between the ages of 16 and 45, incidence peaks. There are around three times as many men as women. Direct or indirect contact with a contaminated individual and their possessions can result in transmission. (2, 3)

Among the most prevalent fungal infections of the foot worldwide, its frequency is rapidly rising. The development of the disease is influenced by socioeconomic and traditions, occupations, contact with animals, climate, season, geographic location, demographics, male sex,

obesity, physical disability, low income, low education, and exposure to sweating, occlusive footwear, and contaminated floors in communal settings. (2, 4) In order to treat tinea pedis, clinicians typically use topical antifungals and recommend good foot cleanliness. Cellulitis, pyoderma, osteomyelitis, and lymphangitis are among the serious morbidities that can result from improperly treated tinea pedis, particularly in people with diabetes, peripheral vascular disease, or immune-compromised diseases. (2, 7)

Topical imidazoles are effective ways for curing tinea pedis since they work well and have minimal side effects. When topical treatment fails to work for a patient, systemic therapy is necessary. (8) Despite the safety and effectiveness of topical antifungal medications such terbinafine, tolfanate, miconazole nitrate, and clotrimazole, complete clinical cures are challenging to achieve due to relapses. (9, 10) Sertaconazole nitrate is a benzothiophene imidazole that has broad-spectrum in vitro action against bacteria, filamentous fungus, yeasts, and dermatophytes associated with cutaneous diseases. The extremely lipophilic benzothiophene fragment contained in the sertaconazole molecule is particularly significant in the treatment of tinea pedis because it optimizes drug penetration and long-term drug residence inside the horny layer of the epidermis. It is commonly known that it cures more rapidly and effectively than other azoles. (10, 11) The effectiveness of topical Sertaconazole and Clotrimazole on Tinea Corporis lesions was examined in the research. After three weeks, Sertaconazole significantly reduced erythema, scaling, and other symptoms as compared to Clotrimazole. It shown that Sertaconazole had superior antifungal efficacy. (12)

Treatment of tinea pedis, is still a widespread dermatological problem, but comparative research comparing the effectiveness of two topical antifungals often used in clinical practice, Sertaconazole nitrate and Clotrimazole, are conspicuously lacking. In the context of tinea pedis, sertaconazole nitrate, a relatively recent drug, has not been directly compared to clotrimazole despite its well-established efficacy. Due to the lack of comparison trials, clinicians are still unable to make firm recommendations about whether medicine offers superior patient results or tolerability. A competitive evaluation of these two therapies is required to bridge this gap since it will provide important details regarding their respective safety and effectiveness profiles. Eventually, by strengthening treatment protocols and promoting evidence-based clinical decisions, these data will enhance patient care and aid in more informed management of this prevalent fungal diseases.

MATERIAL AND METHODS

This randomized controlled trial study was carried out on OPD patients in the Department of Dermatology, Jinnah Postgraduate Medical Center (JPMC) Karachi, Pakistan, during February-May 2025. Institutional Ethical committee permission was obtained (Ref. No: No F2-81/2024-GENL/88/JPMC) and a clinical trial registration number (CTN-06869681) was obtained for the study. Written consent was obtained from all the study participants.

Open Epi sample size calculator was used, where taking efficacy in Clotrimazole group 30% and in Sertaconazole groups 96.7% (12), with 95% confidential interval and 90% power of the test. Total 100 confirmed cases of tinea pedis, 50 patients were included in each group.

All the patients of age 18-65years, having clinical manifestations of tinea pedis on one or both feet, confirmed by microscopic examination where skin scraping for KOH (Potassium hydroxide) mount test was positive (explained below)`. The following clinical assessment criteria for tinea pedis were used to evaluate the signs and symptoms as well as their severity.

Sign and Symptoms

Erythema: Change in skin colour (abnormal redness) from normal skin colour.

Itching: an irritating sensation that makes patients want to scratch your skin. Itching that affect daily activities and sleep.

Desquamation: peeling skin, it defined as the shedding of dead cells from the outermost layer of skin.

Vesicles: A vesicle, or blister, is a thin-walled sac filled with a fluid, usually clear and small.

Pustules: Pustules are small, inflamed, pus-filled, blister-like sores (lesions) on the skin surface.

KOH Examination

The active lesion border or vesicle roof skin scrapings were used for a KOH wet-mount test. On a slide, the material was mixed with a 10–20% KOH solution, either with or without dimethyl sulfoxide (DMSO). The squamous cells were broken down by mild heating, making the septate, branching hyphae and spores visible. Without heating, a 20–40% DMSO addition allows for faster analysis. This approach is fast, inexpensive, and easy to use; it usually yields results in two hours. (3)

On a scale of 0 to 3; 0 (absent), 1 (mild), 2 (moderate), and 3 (severe), each of these distinct signs and symptoms were assigned a score. Each sign and symptom's individual score was added up to determine the Total Composite Score (TCS) of the symptoms and indicators. Participants in the study were those who had a positive KOH test and a total composite score more than 6. (13)

Patients with secondary bacterial infection. Those who were using topical or taken any oral antifungal drug before the baseline visit. Diabetic, immune compromised patients. Women with pregnancy or lactating mothers. Patients allergic to the drugs were excluded. Patients of Tinea Pedis who met the selection criteria were enrolled following non probability consecutive sampling technique and educated regarding the study. Participants were randomly allocated in into two groups utilizing envelope method; patients of Group-A had used topical Sertaconazole 2% and patients in Group-B had use Clotrimazole 1%. Using a basic randomization plan, a computer generated a series of random numbers. A serial number was attached to an opaque envelope that was sealed around each randomization number. Once the patient's serial number was determined, they were notified of the assignment and opened the appropriate packet. Following cleansing of the diagnosed lesions, the patients used a cotton swab applicator to topically administer both creams. The application of the creams was

sufficient to create a thin layer of medicine covering the lesions. Over the course of four weeks, both creams were used topically twice daily.

Throughout the course of the four weeks of treatment, patients were monitored weekly for clinical improvement and therapeutic adverse effects. Following four weeks of therapy, the patients were assessed at the final follow-up using all clinical investigations and a microscopic analysis of a skin scraping from the lesion site using 10% potassium hydroxide. The effectiveness of the therapies was defined as a reduction in the overall composite score of at least two points with a negative KOH test following four weeks of therapy and the reporting of no adverse effects. (13)

All of the patients' adverse drugs events were observed. Photographs of the lesions obtained both before and after the research were used to evaluate the subjects' clinical progress. Detailed questionnaires followed regarding demographic and clinical characteristics like age, BMI, symptoms and co morbidities etc. Proper selection criteria used to control any biasness.

Data Analysis

Data Analysis was performed using SPSS version 20. Mean ± standard deviation (SD) was calculated for quantitative variable. Frequency and percentage (%) was calculated for categorical variables. Independent t-test was applied for quantitative variables (symptoms scores) and Chi- square test was applied for qualitative variables (Efficacy). P value ≤ 0.05 was considered as statistically significant.

RESULTS

One hundred patients with tinea pedis were recruited for this study and divided into two groups. The research participants' mean age was 30.39 years, with an SD of 8.56 years. Males represented 48% of patients in the Clotrimazole group and 50% of patients in the Sertaconazole group. 40% of patients in the sertaconazole group had tinea corporis, 46% had tinea curis, and 14% had both types of lesions. Of the patients in the Clotrimazole group, 42% had tinea corporis, 40% had tinea curis, and 18% had both types of lesions. The length of tinea pedis in the Sertaconazole group was 22.78+/-9.20 days, whereas it was 21.34+/-9.22 days in the Clotrimazole group. Within 20 days after the onset of the symptoms, the majority of patients arrived at the hospital. (Table-1)

All the patients' baseline KOH test results were positive. When comparing the baseline signs and symptoms score (Erythema, Itching, Desquamation, Vesicles, Pustules), there were no significant differences (P>0.05), and the severity of the illness symptoms was the same for both groups. In both groups, the post-treatment signs and symptoms score showed significant deviations from the baseline evaluations. Sertaconazole appears to have a greater effect in reducing the signs and symptoms of the condition than clotrimazole, even though there were substantial differences in itching and total composite score and that other i.e. Erythema, Desquamation, Vesicles, Pustules post-treatment scores were comparatively similar (P>0.05). In individuals receiving Sertaconazole, signs and symptoms reduced significantly. (Table-2)

Efficacy was also assessed on the basis of reduction of total composite score of more than 2 with negative KoH test. The study finding showed that the efficacy rate of Sertaconazole was higher than the patients in the clotrimazole group (86% vs. 66%; P-value <0.05). (Graph-1)

The research showed that while the success rates of the two therapies were similar in female patients (80% vs. 80.8%; P > 0.05), Sertaconazole was substantially more effective in male patients than in female patients (92% vs. 50%; P <0.05). Despite the lack of a statistically significant correlation between lesion type and treatment results, sertaconazole consistently outperformed Clotrimazole in all lesion categories. Different age groups and baseline sign and symptom ratings showed a similar pattern, with sertaconazole demonstrating higher effectiveness in each cohort. (Table-3) No serious side effects were recorded over the course of treatment, and both study medications were well tolerated.

Table 1

Descriptive Statistics of Patient Demographic Characteristics

Study variables		Groups: Sertaconazole (n=50)	Groups: Clotrimazole (n=50)	Total (n=100)
Age (in years)		29.12+/-8.62	31.66+/-8.39	30.39+/-8.56
Gender	Male	25(50%)	24(48%)	49(49%)
	Female	25(50%)	26(52%)	51(51%)
Lesion Type	Tinea Corporis	20(40%)	21(42%)	41(41%)
	Tinea Cruris	23(46%)	20(40%)	43(43%
	Both	7(14%)	9(18%)	16(16%)
Duration of disease (in days)		22.78+/-9.20	21.34+/-9.22	22.06+/-9.18

Table 2

Comparisons of Patient Signs & Symptoms Score between Groups

Post-Treatment Signs & Symptoms	Sertaconazole (n=50)	Clotrimazole (n=50)	P-value
Baseline			
Erythema	2.14+/-0.53	2.10+/-0.61	0.729
Itching	2.24+/-0.62	2.26+/-0.65	1.000
Desquamation	2.14+/-0.55	2.10+/-0.63	1.000
Vesicles	2.15+/-0.77	2.11+/-0.65	0.211
Pustules	1.94+/-0.68	2.16+/-0.65	0.102
Total Composite score	10.30+/-1.68	10.66+/-1.36	0.243
4th Week			
Erythema	0.92+/-0.92	1.20+/-0.81	0.110
Itching	0.78+/-0.76	1.34+/-0.77	0.0001*
Desquamation	0.44+/-0.54	0.64+/-0.56	0.073
Vesicles	0.90+/-0.68	1.08+/-0.67	0.183
Pustules	0.86+/-0.61	0.98+/-0.59	0.318
Total Composite score	3.90+/-2.18	5.24+/-2.32	0.004*

Graph 1

Comparisons of Efficacy between Groups

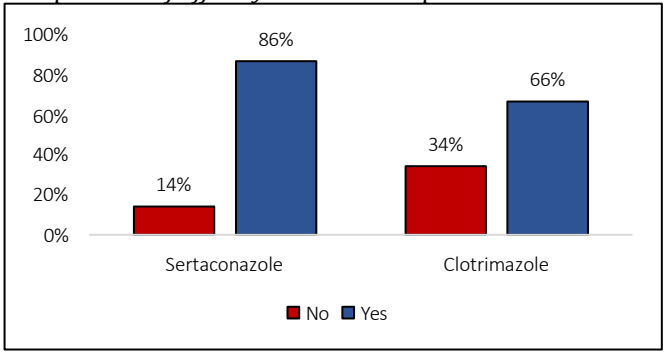

Table 3
Stratified Analysis

Study variables		Efficacy	Groups: Sertaconazole (n=50)	Groups: Clotrimazole (n=50)	Total	P-value
Gender	Male	No	2(8%)	12(50%)	14(28.6%)	0.001
		Yes	23(92%)	12(50%)	35(71.4%)	(Sig.)
	Female	No	5(20%)	5(19.2%)	10(19.6%)	0.945
		Yes	20(80%)	21(80.8%)	41(80.4%)	
Lesion Type	Tinea Corporis	No	3(15%)	7(33.3%)	10(24.4%)	0.172
		Yes	17(85%)	14(66.6%)	31(75.6%)	
	Tinea Cruris	No	3(13%)	6(30%)	9(20.9%)	0.173
		Yes	20(87%)	14(70%)	34(79.1%)	
	Both	No	1(14.3%)	4(44.4%)	5(31.3%)	0.197
		Yes	6(85.7%)	5(55.6%)	11(68.8%)	
Age groups	25 or less	No	4(17.4%)	3(25%)	7(20%)	0.593
		Yes	19(82.6%)	9(75%)	28(80%)	
	More than 25	No	3(11.1%)	14(36.8%)	17(26.2%)	0.02
		Yes	24(88.9%)	24(63.2%)	48(73.8%)	(Sig.)
BL score	10 or less	No	4(13.8%)	6(26.1%)	10(19.2%)	0.264
		Yes	25(86.2%)	17(73.9%)	42(80.8%)	
	More than 10	No	3(14.3%)	11(40.7%)	14(29.2%)	0.045
		Yes	18(85.7%)	16(59.3%)	34(70.8%)	(Sig.)

DISCUSSION

Tinea pedis known as the common fungal infection of the feet, which significantly reduces the quality of life. It can also cause painful blisters and nail infections in severe cases. To treat tinea pedis, antifungal drugs are frequently used topically or administered systemically. In order to treat tinea pedis, there has been a significant increase in interest in creating innovative drug delivery methods. These systems aim to improve antifungal therapy's safety and effectiveness by enhancing the drug's skin penetration and reducing the likelihood of systemic adverse effects. The two successful treatments for tinea pedis have been discussed in this study. Additionally, potential paths for therapy optimization and recurrence prevention of these serious fungal diseases have been highlighted. (14)

Monotherapy with topical antifungals is commonly used to treat tinea infections. Topical azoles are one of the most often utilized of them. Many commercial formulations of various azole compounds with varying concentrations are available today. The effectiveness and safety of these topical azoles have been demonstrated in several randomized controlled studies. Although there aren't many research comparing the effectiveness of topical azoles, all of them are shown to be rather effective when applied topically. The two widely used topical azoles, sertaconazole and clotrimazole, have not been recently compared for tinea pedis. Therefore, the purpose of this study was to find an improved topical azole for the treatment of tinea pedis. This research examined the effects of topical medications including 1% clotrimazole cream and 2% sertaconazole cream used twice daily for four weeks in individuals with tinea pedis. Both research groups showed a notable improvement in the main inflammatory signs and symptoms of tinea pedis (erythema, itching, desquamation, vesicles, and pustules) within a few weeks. At the completion of the "follow-up phase," patients treated with topical sertaconazole 2% cream showed noticeably superior improvement in erythema, itching, desquamation, vesicles, and pustules than those treated with clotrimazole 1% cream. No treatment-related adverse medication reactions were observed in this investigation.According to research by Shivamurthy et al. and Lakhani et al., topical sertaconazole has demonstrated a superior treatment response when compared to topical clotrimazole for different forms of tinea infections, including tinea corporis and curis. (12, 15) In this way, the findings of this study are rather comparable to those of other research on topical antifungal comparisons in various tinea infections.

In a research by Lakhani et al., both drugs were shown to be successful at the end of the follow-up period, with no recurrence or relapse of tinea cruris. Nonetheless, sertaconazole 2% cream demonstrated statistically significant quick reduction in terms of an improvement in clinical parameters such erythema when compared to clotrimazole 1% cream ($p<0.001$). (15) Sertaconazole was administered to patients in another research, and they were monitored for clinical improvement and medication therapy adverse effects. The study's conclusions aligned with the previously mentioned findings. (16) In order to examine the effectiveness and safety of sertaconazole, terbinafine, and luliconazole in patients with dermatophytoses, Jerajani et al. studied 83 individuals with tinea pedis infections. The mean total composite score (pruritus, erythema, vesicle, and desquamation) declined more in the sertaconazole group 97.1% than in the terbinafine 91.2% and luliconazole 92.9% groups. During the trial and follow-up period, they found that sertaconazole was more effective than terbinafine and luliconazole at minimizing signs and symptoms. (17)

To assess the sensitization potential of 2% sertaconazole cream in comparison to five other antifungal creams and controls, Romaguera et al. carried out a randomized double-blind experiment with 78 subjects. In two instances, only miconazole resulted in adverse reactions. Sertaconazole's remarkable safety for topical use was confirmed by the study's conclusion that it did not cause contact dermatitis. (18) Shivamurthy et al. examined 60 individuals with Tinea corporis to assess the efficacy of topical sertaconazole and clotrimazole. Sertaconazole substantially improved lesion margins (all $p<0.001$), scaling, itching, and erythema ($p<0.02$). Compared to the clotrimazole group (7.20 ± 1.69), the sertaconazole group had a higher mean overall score (8.80 ± 1.52). Sertaconazole had better clinical results over four weeks in treating Tinea pedis, which is in line with recent studies. (12) Furthermore, research indicates that topical sertaconazole has demonstrated a superior therapeutic response when compared to topical clotrimazole for all forms of tinea infections. (12, 16-18) According to the findings of another study, luliconazole is more cost-effective than sertaconazole, although sertaconazole was superior in reducing the signs and symptoms of dermatophytoses. Physicians can use this information to treat patients. Sertaconazole, which is more effective, may be provided to patients who can afford expensive therapy; for those who cannot, luliconazole cream may be used. (19)

This research assessed the safety and effectiveness of clotrimazole and sertaconazole in the treatment of tinea

pedis. Although both medications worked well, at week four, sertaconazole had a greater clinical and mycological cure rate (86%) than clotrimazole (66%). These findings are consistent with earlier research showing the proven efficacy of clotrimazole and the broad-spectrum action and anti-inflammatory advantages of sertaconazole. The safety of both therapies for topical application was confirmed by their good tolerance and the reports of very slight skin irritation. Sertaconazole's somewhat better efficacy could be the result of both its increased inhibition of fungal enzymes and its enhanced binding to ergosterol. (16, 20) Comparing sertaconazole with clotrimazole directly in terms of efficacy and safety was made possible by our study's equivalent demonstration of a considerable decrease in clinical symptoms. Even though it was a small sample size, open-label experiment, and only lasted four weeks, the results are nonetheless useful. However, bigger, double-blind trials with longer follow-up periods might yield more reliable information to properly evaluate recurrence rates and long-term results. Analyses incorporating direct, indirect, and additional costs might also be beneficial in assessing the cost-effectiveness of various interventions. One significant drawback of our study is its brief follow-up, which could not accurately represent the long-term durability of treatment effects. For a more thorough grasp of the relative advantages of various topical antifungal medications, future studies with a wider focus and longer observation times are advised.

CONCLUSION

In the treatment of tinea pedis, topical sertaconazole 2% cream outperformed clotrimazole 1% cream in terms of effectiveness and safety, improving clinical signs and symptoms significantly. Sertaconazole could be regarded as the recommended first-line topical treatment in considering these findings. To validate these findings and justify its general therapeutic usage, further comprehensive randomized controlled studies with longer follow-up are necessary.

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