e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(6); 2294-2297

Original Research Article

Comparative Study of the Efficacy and Safety of Topical Antifungal Agents Clotrimazole versus Sertaconazole in the Treatment of Tinea Corporis/Cruris

Saurabh Krishna Misra[1], Hariom K Singh[2], Ravi Ranjan Singh[3], Richa Dokania[4]

[1]Assistant Professor, Department of Dermatology Venereology Leprosy, Autonomous State Medical College, Kaushambi, U.P., India

[2]Professor, Department of Pharmacology, Uttar Pradesh University of Medical Sciences, Saifai, Etawah U.P., India

[3]Assistant professor, Department of Pathology, Narayan Medical College and Hospital, Sasaram, Bihar, India

[4]Senior Lecturer, Department of Pedodontics and Preventive Dentistry, Kalka Dental College, Meerut, U.P., India

Received: 25-03-2024 / Revised: 23-04-2024 / Accepted: 26-05-2024

Corresponding Author: Dr. Saurabh Krishna Misra

Conflict of interest: Nil

Abstract:

Background: Tinea corporis and tinea cruris are common dermatophytic infections affecting the skin, causing significant discomfort and morbidity. Topical antifungal agents like clotrimazole and sertaconazole are widely used for treatment. This study aims to compare the efficacy and safety of clotrimazole versus sertaconazole in the treatment of tinea corporis and tinea cruris.

Materials and Methods: A total of 250 patients diagnosed with tinea corporis or tinea cruris were enrolled in this study conducted in Kaushambi, Uttar Pradesh, from July 2022 to December 2023. Patients were randomly divided into two groups: Group A received clotrimazole cream and Group B received sertaconazole cream. Both treatments were applied twice daily for four weeks. Efficacy was assessed based on clinical improvement, mycological cure rates, and patient-reported outcomes. Safety was evaluated by monitoring adverse events throughout the study period.

Results: Out of the 250 patients, 125 were treated with clotrimazole (Group A) and 125 with sertaconazole (Group B). By the end of the study, Group A showed a clinical improvement rate of 85%, with a mycological cure rate of 80%. Group B demonstrated a slightly higher clinical improvement rate of 88% and a mycological cure rate of 83%. Both groups reported minimal adverse events, with 5% in Group A and 4% in Group B experiencing mild skin irritation.

Conclusion: Both clotrimazole and sertaconazole are effective and safe for the treatment of tinea corporis and tinea cruris. Sertaconazole showed a marginally higher efficacy in clinical improvement and mycological cure rates compared to clotrimazole. However, the difference was not statistically significant. Both treatments were well-tolerated, with minimal adverse effects.

Keywords: Tinea corporis, Tinea cruris, Clotrimazole, Sertaconazole, Antifungal agents, Dermatophytic infections, Clinical efficacy, Mycological cure, Safety.

Introduction

Tinea corporis and tinea cruris are prevalent dermatophytic infections caused by various species of dermatophytes, primarily Trichophyton, Microsporum, and Epidermophyton. These infections predominantly affect the superficial layers of the skin, leading to circular, red, itchy, and scaly patches [1].

The global prevalence of dermatophytic infections is high, with an estimated lifetime risk of 10-20% in the general population [2]. Effective management of these infections is crucial to prevent complications and improve the quality of life for affected individuals. Topical antifungal agents are the mainstay of treatment for tinea infections due to their direct application to the affected area, reduced systemic side effects, and ease of use.

Clotrimazole, an imidazole antifungal, has been extensively used for decades and is known for its broad-spectrum activity against dermatophytes,

yeasts, and molds [3]. Sertaconazole, another imidazole antifungal, is a newer agent with similar broad-spectrum activity but also possesses additional anti-inflammatory properties; potentially offering enhanced therapeutic benefits [4]. Several studies have evaluated the efficacy and safety of clotrimazole and sertaconazole individually in the treatment of dermatophytic infections. Clotrimazole has been shown to achieve clinical cure rates of up to 80% in various studies [5]. Similarly, sertaconazole has demonstrated high clinical cure rates, with some studies suggesting superiority over older antifungal agents [6]. However, direct comparative studies between these two agents in the treatment of tinea corporis and tinea cruris are limited.

This study aims to fill this gap by conducting a comparative analysis of the efficacy and safety of clotrimazole versus sertaconazole in the treatment of tinea corporis and tinea cruris. The findings of this study could provide valuable insights for clinicians in selecting the most appropriate topical antifungal agent for these common dermatophytic infections.

Materials and Methods

Study Design and Setting: This was a randomized, controlled, parallel-group study conducted in Kaushambi, Uttar Pradesh, from July 2022 to December 2023. The study aimed to compare the efficacy and safety of clotrimazole versus sertaconazole in the treatment of tinea corporis and tinea cruris.

Study Population: A total of 250 patients, aged 18-60 years, diagnosed with tinea corporis or tinea cruris were enrolled. Inclusion criteria included patients with clinical and mycological confirmation of tinea corporis/cruris. Exclusion criteria were patients with systemic fungal infections, immunocompromised conditions, known hypersensitivity to azole antifungals, and those who had used any antifungal treatment within the past four weeks.

Randomization and Treatment: Patients were randomly assigned into two groups using a computer-generated randomization schedule. Group A (n=125) received clotrimazole cream, and Group B (n=125) received sertaconazole cream. Both groups were instructed to apply the respective cream to the affected area twice daily for four weeks.

Clinical and Mycological Assessment: Efficacy was assessed based on clinical improvement and mycological cure. Clinical improvement was evaluated using a 4-point scale (0 = no improvement, 1 = mild improvement, 2 = moderate improvement, 3 = complete improvement) at baseline, week 2, and week 4.

Mycological cure was determined by microscopic examination and culture of skin scrapings from the affected area at the same time points.

Safety Assessment: Safety was evaluated by recording adverse events throughout the study period. Patients were instructed to report any adverse reactions, which were categorized by severity (mild, moderate, severe) and possible relation to the study medication.

Statistical Analysis: Data were analyzed using SPSS software version 25.0. Clinical improvement and mycological cure rates between the two groups were compared using the Chi-square test. The incidence of adverse events was compared using Fisher's exact test. A p-value of <0.05 was considered statistically significant.

Results

A total of 250 patients were enrolled and completed the study. The baseline characteristics of the patients in both groups were comparable, as shown in Table 1.

Table 1: Baseline Characteristics of Study Participants

Characteristic	Group A (Clotrimazole)	Group B (Sertaconazole)
Number of Patients	125	125
Mean Age (years)	34.2 ± 10.3	33.8 ± 11.1
Male/Female Ratio	70/55	68/57
Duration of Infection (weeks)	4.5 ± 2.1	4.6 ± 2.0

Clinical Improvement: Clinical improvement was assessed at week 2 and week 4, as presented in Table 2.

Table 2: Clinical Improvement at Weeks 2 and 4

Clinical Improvement Score	Group A (Clotrimazole)	Group B (Sertaconazole)
Week 2		
No improvement (0)	20 (16%)	18 (14%)
Mild improvement (1)	35 (28%)	30 (24%)
Moderate improvement (2)	50 (40%)	55 (44%)
Complete improvement (3)	20 (16%)	22 (18%)
Week 4		

No improvement (0)	5 (4%)	4 (3%)
Mild improvement (1)	15 (12%)	10 (8%)
Moderate improvement (2)	40 (32%)	30 (24%)
Complete improvement (3)	65 (52%)	81 (65%)

Mycological Cure: Mycological cure rates were determined by microscopic examination and culture results at weeks 2 and 4, as shown in Table 3.

Table 3: Mycological Cure Rates at Weeks 2 and 4

Mycological Cure	Group A (Clotrimazole)	Group B (Sertaconazole)
Week 2		
Positive	85 (68%)	82 (66%)
Negative	40 (32%)	43 (34%)
Week 4		
Positive	25 (20%)	21 (17%)
Negative	100 (80%)	104 (83%)

Safety and Adverse Events: The incidence of adverse events was minimal and comparable between the two groups, as shown in Table 4.

Table 4: Incidence of Adverse Events

Adverse Events	Group A (Clotrimazole)	Group B (Sertaconazole)
Mild skin irritation	6 (5%)	5 (4%)
Moderate skin irritation	1 (0.8%)	1 (0.8%)
Severe skin irritation	0 (0%)	0 (0%)

Summary of Results

- Clinical improvement at week 4 was higher in the sertaconazole group (65% complete improvement) compared to the clotrimazole group (52% complete improvement).
- Mycological cure rates at week 4 were slightly higher in the sertaconazole group (83%) compared to the clotrimazole group (80%).
- Both treatments were well-tolerated, with minimal adverse events reported in both groups.

Discussion

This study compared the efficacy and safety of clotrimazole and sertaconazole in the treatment of tinea corporis and tinea cruris. The results demonstrated that both topical antifungal agents are effective, with sertaconazole showing a marginally higher clinical and mycological cure rate compared to clotrimazole.

The clinical improvement rates observed in our study are consistent with previous findings. Clotrimazole, a well-established antifungal agent, has been shown to achieve clinical improvement rates of up to 80% in various studies [1,2]. Our study found a 52% complete improvement rate at week 4, aligning with these reports. Similarly, sertaconazole has been reported to have high efficacy in treating dermatophytic infections, with some studies suggesting it may be superior to older azole antifungals [3-7]. Our study corroborates these findings, with a complete improvement rate of 65% at week 4. Mycological cure rates also followed a similar trend, with sertaconazole achieving a slightly higher cure rate (83%) compared to clotrimazole (80%) at week 4. These findings are in line with the reported broad-spectrum activity of sertaconazole, which not only targets dermatophytes but also possesses anti-inflammatory properties that may contribute to its efficacy [8,9]. Clotrimazole efficacy is well-documented, and our findings of an 80% mycological cure rate are consistent with prior studies [10-12].

Safety profiles for both agents were favorable, with minimal adverse events reported. Mild skin irritation was the most common adverse event, occurring in 5% of patients in the clotrimazole group and 4% in the sertaconazole group. This is comparable to other studies that have shown a low incidence of adverse effects with topical antifungal treatments [13]. The absence of severe adverse events underscores the safety of both clotrimazole and sertaconazole for topical use.

The marginally better outcomes with sertaconazole may be attributed to its unique pharmacological properties, including its higher affinity for ergosterol and its ability to inhibit fungal cytochrome P450 enzymes more effectively [14]. Additionally, sertaconazole's anti-inflammatory effects could help reduce local inflammation, potentially enhancing clinical outcomes [15]. Despite the slight edge of sertaconazole, the difference in efficacy between the two agents was not statistically significant. This suggests that both clotrimazole and sertaconazole are viable options for the treatment of tinea corporis and tinea cruris, and the choice of agent may depend on other factors such as patient preference, cost, and

availability. One limitation of this study is the short follow-up period of four weeks, which may not capture long-term recurrence rates. Future studies with longer follow-up periods are needed to assess the sustained efficacy and recurrence rates of these treatments. Additionally, a larger sample size might provide more definitive conclusions regarding the comparative efficacy of these antifungal agents.

Conclusion

In conclusion, both clotrimazole and sertaconazole are effective and safe for the treatment of tinea corporis and tinea cruris. Sertaconazole showed marginally better clinical and mycological outcomes, though the differences were not statistically significant. Both agents should be considered viable options in the clinical management of these common dermatophytic infections.

References

1. Crawford F, Hollis S. Topical treatments for fungal infections of the skin and nails of the foot. Cochrane Database Syst Rev. 2007;(3).
2. Gupta AK, Chaudhry M, Elewski B. Tinea corporis, tinea cruris, tinea nigra, and piedra. Dermatol Clin. 2003; 21(3):395-400.
3. Elewski BE, Ault KA, Popescu CM. Treatment of superficial fungal infections: focus on new topical antifungals. Ther Clin Risk Manag. 2014; 10:125-31.
4. Korting HC, Schöllmann C. Management of dermatophytosis and onychomycosis. Expert Opin Pharmacother. 2009; 10(14):2277-92.
5. Gupta AK, Cooper EA. Update in antifungal therapy of dermatophytosis. Mycopathologia. 2008; 166(5-6):353-67.
6. Hay RJ, Ashbee HR. Fungal infections. Medicine (Baltimore). 2019; 47(9):555-60.
7. Rangel-Gamboa L, Arenas R, Coronel-Martínez J, Domínguez-Cherit J, Vega-Memije ME. Sertaconazole in the treatment of dermatophytosis: a comparative study. J Eur Acad Dermatol Venereol. 2008; 22(5):578-82.
8. Elsayed MM, Abdallah OY, Naggar VF. Lipid vesicles for skin delivery of drugs: reviewing three decades of research. Int J Pharm. 2007; 332(1-2):1-16.
9. Draelos ZD. Therapeutic moisturizers. Dermatol Clin. 2000; 18(4):597-607.
10. Aly R, Maibach HI. Topical antifungal agents. Clin Dermatol. 1996; 14(1):111-9.
11. Yosipovitch G, Tang MB, Dawn AG, Chen SC, Goh CL. Study of psychological stress, sebum production and acne vulgaris in adolescents. Acta Derm Venereol. 2007; 87(2):135-9.
12. Arndt KA, Stern RS. Topical tretinoin therapy for acne vulgaris. J Am Acad Dermatol. 1989; 21(4 Pt 2):653-60.
13. Greer DL. Efficacy and safety of sertaconazole nitrate in the treatment of superficial cutaneous mycoses. Curr Med Res Opin. 2006; 22(5): 883-97.
14. Del Rosso JQ, Leyden JJ. The role of topical anti-inflammatory agents in the treatment of dermatologic disorders. J Clin Aesthet Dermatol. 2010; 3(3):24-39.
15. Gupta AK, Gupta MA, Summerbell RC, Cooper EA, Konnikov N, Albreski D. Tinea capitis: an overview with emphasis on the situation in the United States. Clin Microbiol Rev. 2001; 14(1):111-31.