

A Clinical Study to Compare the Terbinafine 1% and Butenafine 1% in Cream Base to Compare Their Efficacy in Treatment of Tinea Cruris

Manadavi¹, Shivangi Singh², Naresh Kumar³, Vikas Shankar⁴, Rani Indra Sinha⁵

¹Tutor, Department of Pharmacology, Patna Medical College and Hospital, Patna, Bihar, India

²Senior Resident, Department of Dermatology, Venereology and Leprosy, Patna Medical College and Hospital, Patna, Bihar, India

³Assistant Professor, Department of Pharmacology, Patna Medical College and Hospital, Patna, Bihar, India

⁴Assistant Professor, Department of Dermatology, Venereology and Leprosy, Patna Medical College and Hospital, Patna, Bihar, India

⁵Professor & HOD, Department of Pharmacology, Patna Medical College and Hospital, Patna, Bihar, India

Received: 15-09-2023 / Revised: 10-10-2023 / Accepted: 20-11-2023

Corresponding Author: Dr. Shivangi Singh

Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to compare the Terbinafine 1% and Butenafine 1% in cream base to compare their efficacy in treatment of Tinea cruris.

Methods: The study was conducted on 60 male patients between 18 and 61 years of age who visited department of Dermatology and department of Pharmacology, Venereology and Leprosy, Patna Medical College and Hospital. Duration of study was one year.

Results: Mycological cure was seen most with Regimen II (Butenafine) group than in the Regimen I (Terbinafine) group and this difference was statistically significant as early as day 7, ($P < 0.01$). The improvement in both the study groups increased steadily in the 2-week course of therapy and the 2-week post-treatment period. At the end of 42 days, the mycological cure rates were in 24 patients in Regimen II (Butenafine) group and 20 patients in the Regimen I (Terbinafine) group. Treatment with Butenafine 1% cream is considered as superior to treatment with Terbinafine 1% cream in treatment of Tinea cruris.

Conclusion: It was found that Butenafine produced the quickest result and primary efficacy end points were much higher with Butenafine cream than that of Terbinafine cream and this difference was statistically significant ($P < 0.01$).

Keywords: Tinea cruris, butenafine cream, terbinafine cream

This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.

Introduction

Tinea cruris is a dermatophyte infection of the groin and is more common in men than in women probably because males perspire more than females, greater areas of occlusive skin where the scrotum is in contact with the thigh and clothing difference. [1] Transmission of Tinea cruris may occur via physical contact with arthroconidia which are generated from dermatophyte filaments. Arthroconidia can survive for years embedded in scales of hair and skin, recurrent outbreaks of infection may occur particularly in individuals with a compromised immune system. [2] In the initiation and propagation of Tinea cruris, environmental factors like warm and humid climate are also important and these cause increased outbreak of Tinea cruris infection in

monsoon months in India.¹ In India, Tinea cruris infection is caused mainly by *Trichophyton rubrum* whereas in Western countries, *Epidermophyton floccosum* is the commonest dermatophyte. [1]

Till the 1940s, standard topical antifungal therapy was limited to Whitfield's ointment, Castellani's paint and Gentian violet. But today there are various modern topical antimycotics capable of eradicating human dermatomycoses. Several classes of antifungal agents available are imidazole, triazoles and allylamines. [2] Other topical antimycotics includes Ciclopirox olamine, Selenium sulphide and Tolnaftate.

Terbinafine is an allylamine which has a broad spectrum of antifungal activity. It interferes specially with fungal sterol biosynthesis at an early stage. [3] Butenafine is the only benzylamine class of antifungal agent with a structure and mode of action similar to allylamines. [4] Like the allylamines, Butenafine inhibits squalene epoxidation, blocking the biosynthesis of ergosterol, an essential lipid component of fungal cell membrane. The antifungal activity of both allylamine and benzylamine results from ergosterol deficiency and intracellular accumulation of squalene, which interferes with cell membrane function and synthesis. [3,4]

The aim of the present study was to compare the Terbinafine 1% and Butenafine 1% in cream base to compare their efficacy in treatment of Tinea cruris.

Materials and Methods

The study was conducted on 60 male patients between 18 and 61 years of age who visited department of Dermatology and department of Pharmacology, Venereology and Leprosy, Patna Medical College and Hospital. To qualify for enrollment, the subjects were required to have at least three signs and symptoms of Tinea cruris namely pruritus (symptom); polycyclic lesions, erythema, scaling, macerations, papules and vesiculation (signs). Patients with other disorders such as hypertension, diabetes mellitus and obesity were excluded from the study. Duration of study was one year.

The patients were divided into two groups as group with Regimen I (n 30) and group with Regimen II (n 30). None of the patients had received any previous therapy. Positive result on potassium hydroxide (KOH) examination for fungal elements was taken as the criteria for enrollment. Mycological culture for a fungal pathogen was also done.

Regimen I (n 30) patients were considered for Terbinafine cream (1%) and Regimen II (n 30) were considered for Butenafine (1%) cream. Patients were advised to apply the medication after bath to the affected sites and also to the areas surrounding the affected sites, once daily for 2 weeks. The patients were evaluated at the end of 7 days, 14 days (i.e. at the end of treatment period) and 42 days (i.e. at the end of follow-up period). Clinical evaluation and KOH examination were done to detect the presence of fungal elements. Clinical evaluation encompassed improvement of the appearance of the lesions and decreased severity of symptoms and signs of Tinea cruris (pruritus, erythema scaling, etc.)

The following variables were examined as primary efficacy end points: mycological cure (negative KOH and culture), overall cure (mycological cure and investigator's clinical assessment of "cleared" lesions) and effective treatment (mycological cure and investigator's clinical assessment of lesions as "cleared" or "excellent"). Secondary efficacy end points were effective clinical response, absence of total symptom and signs and patient's perception of improvement.

Results

Table 1: Primary efficacy end points

	Terbinafine Regimen I	Butenafine Regimen II	Z value	P value
Mycological cure				
Day 7	16	24	3.93	< 0.01
Day 14	18	27	3.60	< 0.01
Day 42	19	28	3.75	< 0.01
Overall cure				
Day 7	13	16	1.69	< 0.05
Day 14	19	22	1.41	< 0.05
Day 42	20	24	1.69	< 0.05
Effective treatment				
Day 7	19	23	1.41	< 0.05
Day 14	22	25	1.25	< 0.05
Day 42	24	27	1.55	< 0.05

Mycological cure was seen most with Regimen II (Butenafine) group than in the Regimen I (Terbinafine) group and this difference was statistically significant as early as day 7, ($P < 0.01$). The improvement in both the study groups increased steadily in the 2-week course of therapy and the 2-week post-treatment period. At the end of 42 days,

the mycological cure rates were in 24 patients in Regimen II (Butenafine) group and 20 patients in the Regimen I (Terbinafine) group. Treatment with Butenafine 1% cream is considered as superior to treatment with Terbinafine 1% cream in treatment of Tinea cruris.

Discussion

Tinea cruris, a pruritic superficial fungal infection of the groin and adjacent skin, is the second most common clinical presentation for dermatophytosis. It is an important clinical problem that may, at times, be a diagnostic as well as therapeutic challenge. [5] Tinea cruris has a worldwide distribution but is found more commonly in hot, humid climates and affects individual of all age and sex. [6,7] It is a contagious infection transmitted by fomites or by autoinoculation from a reservoir on the hands or feet (tinea magnum, tinea pedis and tinea unguium). The most common etiologic agents for tinea cruris include *Trichophyton rubrum* and *Epidermophyton floccosum*; less commonly *Trichophyton mentagrophytes* and *Trichophyton verrucosum* are involved. [5]

Mycological cure was seen most with Regimen II (Butenafine) group than in the Regimen I (Terbinafine) group and this difference was statistically significant as early as day 7, ($P < 0.01$). The improvement in both the study groups increased steadily in the 2-week course of therapy and the 2-week post-treatment period. At the end of 42 days, the mycological cure rates were in 24 patients in Regimen II (Butenafine) group and 20 patients in the Regimen I (Terbinafine) group. Treatment with Butenafine 1% cream is considered as superior to treatment with Terbinafine 1% cream in treatment of Tinea cruris. This finding was comparable with other studies. [8,9]

Tinea cruris is a dermatophyte infection of the groin and is more common in men than in women probably because males perspire more than females, greater areas of occlusive skin where the scrotum is in contact with the thigh and clothing difference. [10] One single study by Das et al¹¹ that compared these two drugs butenafine and terbinafine in the treatment of tinea cruris showed that at the end of 42 days, the overall cure rates were 79.49% in the Regimen II (butenafine) group and 62.16% in the Regimen I (terbinafine) group. The effective treatment rates after 2 weeks of post-treatment follow-up was 92.31% in Regimen II (butenafine) and 81.08% in Regimen I (terbinafine) study group which were all statistically significant ($p < 0.05$). The study concluded that treatment with butenafine 1% cream was considered superior to treatment with terbinafine 1% cream in case of tinea cruris. [11]

Conclusion

It was found that Butenafine produced the quickest result and primary efficacy end points were much

higher with Butenafine cream than that of Terbinafine cream and this difference was statistically significant ($P < 0.01$).

References

1. Valia AK, Dutta PK. IADVL Text book and Atlas of Dermatology. Edition... Mumbai: Bhalani Publishing House. 1996:500-86.
2. Piérard GE, Arrese JE, Piérard-Franchimont C. Treatment and prophylaxis of tinea infections. *Drugs*. 1996 Aug;52(2):209-24.
3. Ryder NS. Terbinafine: mode of action and properties of the squalene epoxidase inhibition. *Br J Dermatol*. 1992 Feb;126 Suppl 39:2-7.
4. Fukushiro R. Butenafine hydrochloride, a new antifungal agent; Clinical and experimental study. *Recent Progress in Antifungal Chemo therapy*. 1992.
5. Foster KW, Ghannoum MA, Elewski BE. Epidemiologic surveillance of cutaneous fungal infection in the United States from 1999 to 2002. *Journal of the American Academy of Dermatology* 2004; 50(5): 748–752.
6. Sadri MF, Farnaghi F, Danesh-Pazhooh M, Shokoohi A. The frequency of tinea pedis in patients with tinea cruris in Tehran, Iran. *Mycoses* 2000; 43(1-2): 41–44.
7. Yehia MA, El-Ammawi TS, Al-Mazidi KM, AbuEl-Ela MA, Al-Ajmi HS. The spectrum of fungal infections with a special reference to dermatophytosis in the capital area of Kuwait during 2000-2005: a retrospective analysis. *Mycopathologia* 2010; 169(4):241–246.
8. Rathi SK. Comparative efficacy of 1 terbinafine hydrochloride and 1 butenafine hydrochloride cream in the treatment of tinea cruris. *Indian Journal of Dermatology*. 1990 Oct 1;35(4):227-8.
9. Syed TA, Hadi SM, Qureshi ZA, Ali SM, Ahmad SA. Butenafine 1% versus terbinafine 1% in cream for the treatment of tinea pedis: a placebo-controlled, double-blind, comparative study. *Clinical Drug Investigation*. 2000 Jun; 19:393-7.
10. Kanwar A, Mamta CJ. Superficial fungal infections in: Valia RG Valia AR (eds). IADVL textbook and atlas of dermatology. 2nd edn. Mumbai: Bhalani Publishing House, 2001: 211–258.
11. Das S, Barbhuniya JN, Biswas I, Bhattacharya S, Kundu PK. Studies on comparison of the efficacy of terbinafine 1% cream and butenafine 1% cream for the treatment of Tinea cruris. *Indian Dermatol Online J* 2010; 1(1): 8–9.