Studies on comparison of the efficacy of terbinafine 1% cream and butenafine 1% cream for the treatment of Tinea cruris

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ABSTRACT

Background: In this study, 76 male patients aged between 18 and 61 years affected with Tinea cruris attending the outpatient department of NRS Medical College during a 1-year period were selected. **Materials and Methods:** The patients were divided into two groups as Regimen I (n 37) and Regimen II (n 39) who were treated with Terbinafine (gr I) cream and Butenafine (gr II) cream, respectively. **Results:** The predominant pathogen was found to be *Trichophyton rubrum* in 99% of cases. Mycological cure, overall cure and effective treatment were evaluated on 7, 14 and 42 days. **Conclusions:** From the study, 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 ($P < 0.01$).

Key words: Tinea cruris, butenafine cream, terbinafine cream

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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 imidazoles, triazoles and allylamines.[2] Other topical antimycotics includes Ciclopirox olamine, Selenium sulphide and Tolnaftate.[2]

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 dermatophytes responsible for Tinea cruris have been shown to be susceptible to both Terbinafine and Butenafine. Because Tinea cruris is a common presentation in dermatology clinics which often recurs and relapses, we undertook this trial using 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 76 male patients between 18 and 61 years of age who visited dermatology outdoor during a period of 1 year from June 2005 to May 2006. 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.

The patients were divided into two groups as group with Regimen I (n 37) and group with Regimen II (n 39). 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 37) patients were considered for Terbinafine cream (1%) and Regimen II (n 39) 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

In this study consisting of 76 male patients, most belonged to the age group of 30–45 years accounting for 67% of the study group. The youngest patient was 18 years and the oldest patient was 61 years. Nearly half the patients (46%) had duration of illness less than 6 months. *Trichophyton rubrum* was the predominant pathogen isolated (75/76, 98.68%) and one case was that of Trichophyton mentagrophytes (1/76, 1.31%).

Primary efficacy end points are shown in the Table 1.

Table 1: Primary efficacy end points

	Terbinafine Regimen I	Butenafine Regimen II	Z value	*P* value
Mycological cure				
Day 7	20/37 (54.05)	31/39 (79.49)	3.93	< 0.01
Day 14	22/37 (59.46)	36/39 (92.31)	3.60	< 0.01
Day 42	23/37 (62.16)	37/39 (94.87)	3.75	< 0.01
Overall cure				
Day 7	12/37 (32.43)	20/39 (51.28)	1.69	< 0.05
Day 14	23/37 (62.16)	30/39 (76.92)	1.41	< 0.05
Day 42	23/37 (62.16)	31/39 (79.49)	1.69	< 0.05
Effective treatment				
Day 7	23/37 (62.16)	30/39 (76.92)	1.41	< 0.05
Day 14	27/37 (72.97)	33/39 (84.62)	1.25	< 0.05
Day 42	30/37 (81.08)	36/39 (92.31)	1.55	< 0.05

Figures in parentheses are in percentage

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). This finding is comparable with other studies.[5,6]

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 94.87% in the Regimen II (Butenafine) group and 62.16% in the Regimen I (Terbinafine) group. The overall cure rates were 79.49% and 62.16% in Regimen II and Regimen I groups, respectively at the end of 42-day period. The effective treatment rates after 2 weeks of post-treatment follow-up was 92.31% in Regimen II and 81.08% in Regimen I study group which were all statistically significant P < 0.05. Treatment with Butenafine 1% cream is considered as superior to treatment with Terbinafine 1% cream in treatment of Tinea cruris.

REFERENCES

1. Kanwar AJ, Mamta, Chander J. Superficial fungal infection. In: Valia RG, Valia AR, Siddappa K, editors. Textboob and Atlas of Dermatology. 2nd ed. Mumbai, India: Bhalani Publishing House; 2001. p. 215-58.
2. Pierard GE, Arrese JE, Pierard-Franchimont C. Treatment and prophylaxis of tinea infections. Drugs 1996;52:209-24.
3. Ryder NS. Terbinafine: mode of action and properties of the squalene epoxidase inhibition. Br J Dermatol 1992;126:2-7.
4. Fukushiro R, Urabe H, Kagawa S. Butenafine hydrochloride, a new antifungal agent: clinical and experimental study. In: Yamaguchi H, Kobayashi GS, Takahashi H, editors. Recent progress in antifungal therapy. New York: Marcel Dekker; 1992. p. 147-57.
5. Rathi SK. Comparative efficacy of 1% terbinafine hydrochloride and 1% butenafine hydrochloride cream in the treatment of tinea cruris. Indian J Dermatol 2001;46:227-8.
6. Syed TA, Hadi SM, Qreshi ZA. Butenafine 1% versus terbinafine 1% in cream for the treatment of tinea pedis. A placebo-controlled, double blind, comparative study. Clinical Drug Investigation 2000;19:393-97.

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