

## Efficacy of Topical 1% Oxiconazole Cream in the Treatment of Dermatophytosis

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Received: October 1, 2013 Accepted: April 2, 2014

### Abstract

**Background:** Dermatophytosis is a geographically widespread group of fungal infections. *Tinea corporis* and *tinea cruris* are the most common dermatophytoses in Bangladesh. Oxiconazole has recently been introduced in Bangladesh in the treatment of dermatophytoses. **Objective:** To evaluate the efficacy of topical 1% oxiconazole cream once daily in the treatment of *tinea corporis* and *tinea cruris*. **Materials and Methods:** A clinical trial was carried out in the department of Dermatology and Venereology, Jalalabad Ragib-Rabeya Medical College Hospital, Sylhet on 81 patients with *tinea corporis* and/or *tinea cruris*. The patients were instructed to apply 1% oxiconazole cream once daily for 2 weeks with clinical assessment made at weekly intervals during treatment period. **Results:** The mean age of the patients was  $32.5 \pm 10.5$  years, with *tinea corporis* in 47 (58.0%) patients and *tinea cruris* in 34 (42.0%). The mean clinical assessment score declined from  $6.6 \pm 1.3$  at baseline to  $3.9 \pm 1.2$  at week 1,  $0.9 \pm 1.3$  at week 2 and  $0.7 \pm 1.1$  at week 4. Reduction of clinical assessment score from baseline to end of the treatment period was statistically significant ( $p < 0.001$ ). The improvement of clinical score was from baseline to 41.6% at week 1, 89.3% at week 2 and 91.5% at week 4. Improvement of clinical score from baseline to end of the treatment period was statistically significant ( $p < 0.001$ ). Global response was clear in 55 (67.9%) patients, good in 25 (30.9%) patients and fair in 1(1.2%) patient. Clinical efficacy was cure in 55 (67.9%) patients, improvement in 25 (30.9%) and failure in 1(1.2%) patient. **Conclusion:** Once daily topical administration of oxiconazole cream is highly effective in the treatment of superficial fungal infections of the skin.

**Key words:** Dermatophytosis; Topical 1% oxiconazole cream; Clinical assessment score

J Enam Med Col 2014; 4(2): 89–93

### Introduction

Dermatophytosis is a geographically widespread group of fungal infections caused by dermatophytes.<sup>1,2</sup> Dermatophyte infections constitute a major public health problem in different countries.<sup>3-5</sup> The climate, overcrowding, poverty, malnutrition, poor hygienic environments, endogenous predis-

posing influences and ignorance are some of the contributory factors favourable for acquiring fungal infections in Bangladesh.<sup>6,7</sup> Although not life-threatening, they may produce significant symptoms which interfere with the quality of life. *Tinea cruris* and *corporis* are the commonest varieties and

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aetiologically, *T. rubrum* tops the list followed by *T. mentagrophytes* and *E. floccosum*, *T. verrucosum*, *M. canis* and *M. gypseum*.<sup>8-10</sup> Cutaneous dermatophytosis characteristically presents as scaly patches with central clearing and sharply demarcated, annular, erythematous, elevated, advancing margins.<sup>11</sup> Oxiconazole nitrate is an imidazole antifungal agent recommended as an effective therapy for superficial fungal infections of the skin.<sup>12</sup> It is fungistatic in action but may be fungicidal in high concentrations, presumably exerts its antifungal activity by altering cellular membranes, resulting in increased membrane permeability, secondary metabolic effects, and growth inhibition.<sup>13</sup> It appears that the antifungal activity of the drug results from interference with ergosterol synthesis, probably via inhibition of C-14 methylation of sterol intermediates.<sup>14</sup> Clinical study suggested that oxiconazole produced a clinical and mycologic cure within 2 to 4 weeks of initiating treatment.<sup>15</sup> In comparative clinical trials of various types of dermatophytoses, oxiconazole was shown to be more effective than miconazole, clotrimazole, and tolnaftate creams, and as effective as econazole and bifonazole creams.<sup>16</sup> Oxiconazole has recently been introduced in Bangladesh and no published data regarding the use of oxiconazole in the treatment of dermatophytosis in Bangladesh is yet available. So, this study was designed to evaluate the efficacy of once daily topical 1% oxiconazole cream in the treatment of tinea corporis and tinea cruris, the most common dermatophytosis.

## Materials and Methods

A clinical trial was carried out with the patients with dermatophytosis attending the department of Dermatology and Venereology, Jalalabad Ragib-Rabeya Medical College Hospital, Sylhet. Duration of the study was from January 2010 to October 2011. Patients of both sex aged 18 to 60 years, clinically diagnosed cases of tinea cruris and corporis infections and confirmed by a positive KOH reading were included. Patients with a history of hypersensitivity response to imidazole derivatives or any component of the formulation of oxiconazole cream, pregnant or lactating women, patients with renal or hepatic dysfunction, patients who received topical antifungal agents within the last week or received systemic antifungal agents within last four

weeks and patients who refused to give consent were excluded. Sampling technique was consecutive type of non-probability sampling. Pre-designed data collection sheet was used to gather information.

### Procedure of the study

Informed written consent was obtained from the patients after full explanation of the details of the disease process, options of treatment, ultimate outcome, possible side effects and complications and chances of recurrences and above all the purpose of the study. Eighty-one patients with tinea corporis and tinea cruris were selected according to the inclusion and exclusion criteria. Each and every patient was examined clinically as a diagnosed case of tinea corporis or cruris infections and confirmed by a positive 10% KOH reading. The data collection sheet was filled up with the information including age, sex, occupation and socio-economic status. All patients were advised to apply oxiconazole 1% cream once daily for 2 weeks with clinical assessment made at weekly intervals during treatment period. Clinical and mycological (10.0% KOH reading) assessment were done following a two-week of non-treatment follow-up period (i.e., at the end of 4 weeks). Patients were evaluated clinically and mycologically (10% KOH reading) at baseline and at 4<sup>th</sup> week. The severity of signs and symptoms of tinea cruris or tinea corporis such as pruritus, erythema and burning were graded on a scale ranging from 0–3 (0.0, absent; 1.0, mild; 2.0, moderate; 3.0, severe). Global evaluation responses of the clinical condition compared to baseline were assessed in accordance to the following criteria.<sup>15</sup>

- Cleared: 100% remission of clinical signs and symptoms except for residual manifestations
- Excellent: 90–99% improvement of clinical signs and symptoms from baseline
- Good: 50–89% improvement of clinical signs and symptoms from baseline
- Fair: 25–49% improvement of clinical signs and symptoms from baseline
- Poor:  $\leq$ 24% improvement of clinical signs and symptoms from baseline
- Worse: Clinical signs and symptoms deteriorated from baseline

Clinical efficacy was categorised in the following way.

- Cure (disappearance of all baseline signs and symptoms of infection; negative 10% KOH reading in conjunction with a global response as cleared or excellent)
- Improvement (partial disappearance of baseline signs and symptoms of infection)
- Failure (no change or worsening)
- Relapse (improvement or cure followed by reappearance or worsening)

*Statistical analysis*

Data were processed and analysed with the help of computer programme SPSS 16.0 version. Quantitative data were analysed using mean and standard deviation; qualitative data were analysed using rate, ratio and percentage. Repeated measure ANOVA was used for clinical assessment score and improvement of clinical score. A probability (p) value of <0.05 was considered statistically significant.

*Ethical consideration*

The protocol was approved by the Institutional Ethical Review Committee of Jalalabad Ragib-Rabeya Medical College & Hospital, Sylhet.

**Results**

This study was conducted on 81 patients with tinea corporis and tinea cruris who were instructed to apply oxiconazole 1% cream once daily for 2 weeks. The age of the patients ranged from 18 to 60 years with the mean age of 32.5 ± 10.5 years. The age of the male patients ranged from 18 to 60 years with the mean age of 33.4 ± 11.4 years while the age of the female patients ranged from 20 to 60 years with the mean age of 30.9 ± 8.7 years. The mean age of the female patients was significantly lower than that of male patients (Z=1.114; p<0.05) (Table I).

Table I: Distribution of the patients by age and sex

Sex	Age (years)		p value
	Range	Mean ±SD	
Male (n=52)	18–60	33.4 ± 11.4	<0.05*
Female (n=29)	20–60	30.9 ± 8.7	

\*Z test was employed to analyse the data

Fig 1 shows the distribution of the patients by clinical types of dermatophytosis. Among 81 patients, tinea corporis was found in 47 (58.0%) and tinea cruris in 34 (42.0%) patients.

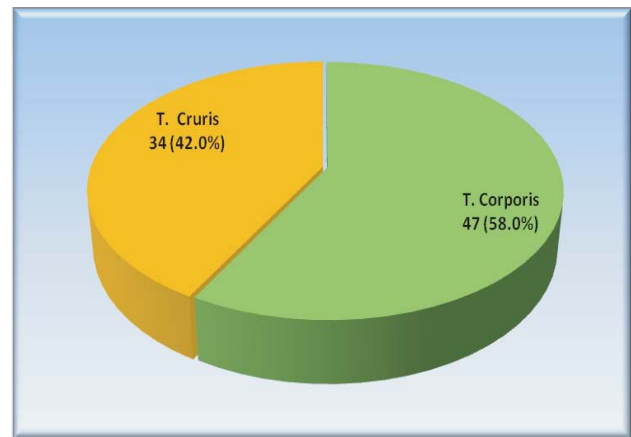


Fig 1. Distribution of the patients by clinical types of dermatophytosis (n=81)

Fig 2 shows the clinical assessment score at different intervals. The mean clinical assessment score declined from 6.6 ± 1.3 at baseline to 3.9 ± 1.2 at week 1, 0.9 ± 1.3 at week 2 and 0.7 ± 1.1 at week 4. Reduction of clinical assessment score from baseline to end of the treatment period was statistically significant (p<0.001). Repeated measure ANOVA was employed to analyse the data.



Fig 2. Clinical assessment score at different intervals (n=81)

Fig 3 shows the improvement at different time intervals. The improvement of clinical score was from baseline to 41.6% at week 1, 89.3% at week 2 and 91.5% at week 4. Improvement of clinical score from baseline to end of the treatment period was statistically significant (p<0.001). Repeated measure ANOVA was employed to analyse the data.

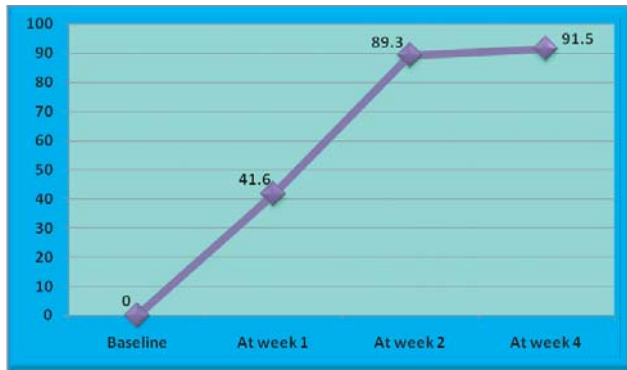


Fig 3. Improvement at different time intervals (n=81)

Distribution of patients by global response is shown in Fig 4. Global response was clear in 55 (67.9%) patients, good in 25 (30.9%) patients and fair in 1 (1.2%) patient. Distribution of patients by clinical efficacy is shown in Fig 5. Clinical efficacy was cure in 55 (67.9%) patients, improvement in 25 (30.9%) patients and failure in 1 (1.2%) patient.

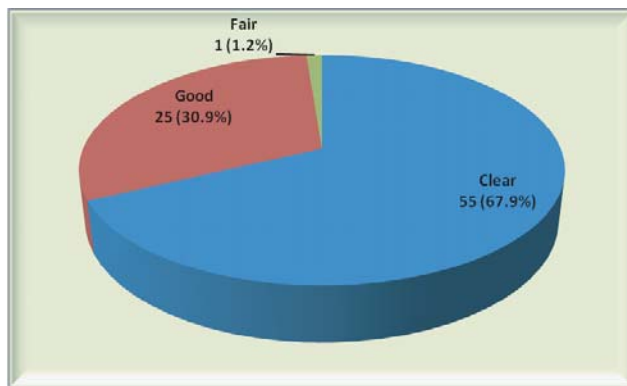


Fig 4. Distribution of patients by global response (n=81)

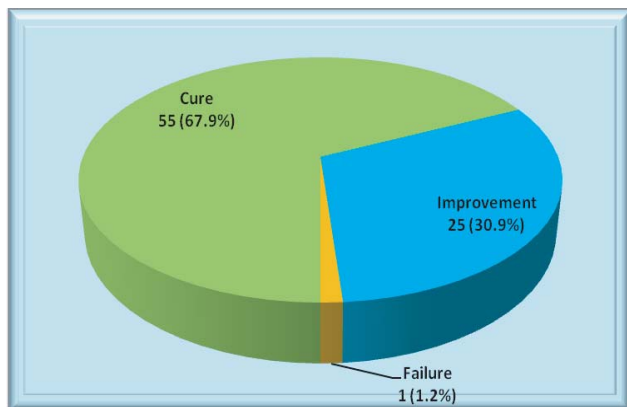


Fig 5. Distribution of patients by clinical efficacy (n=81)

## Discussion

In this study the age of the patients ranged from 18 to 60 years with the mean age of  $32.5 \pm 10.5$  years. This result was supported by Pakshir and Hashemi where mean age of the patients was 32 years.<sup>17</sup> This study also showed that there were highest number of patients (29, 35.8%) in the age group of 21–30 years and this result was in concordance with the study of Patel et al where 58 (29.30%) patients were in age group of 21–30 years.<sup>18</sup>

In the current study the mean clinical score declined from  $6.6 \pm 1.3$  at baseline to  $3.9 \pm 1.2$  at week 1,  $0.9 \pm 1.3$  at week 2 and  $0.7 \pm 1.1$  at week 4. Reduction of clinical assessment score from baseline to end of the treatment period was statistically significant ( $p < 0.001$ ). Jerajani et al found that statistically significant ( $p < 0.05$ ) decline was observed by the end of one week treatment in respect of each of the signs/symptoms.<sup>19</sup> The present study showed that improvement of clinical score was from baseline to end of the treatment period was statistically significant ( $p < 0.001$ ). In this study the global response was clear in 55 (67.9%) patients, good in 25 (30.9%) patients and fair in 1 (1.2%) patient. This result was supported by the study of Jerajani et al.<sup>19</sup>

In the current study the clinical efficacy was cure in 55 (67.9%) patients, improvement in 25 (30.9%) patients and failure in 1 (1.2%) patient. Jerajani et al reported that once daily application of oxiconazole showed 81% cure rate which was comparable to twice daily application.<sup>19</sup> Besides, the compliance with once daily application was found to be good.<sup>19</sup> Gugnani et al reported that in most cases, oxiconazole produced a clinical cure within 2 to 4 weeks of initiating treatment.<sup>20</sup>

From this study, it can be concluded that once daily topical administration of oxiconazole cream is highly effective in the treatment of superficial fungal infections of the skin. However, multi-centred controlled randomised trial with large sample size should be carried out to draw final conclusion.

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