

## CLINICAL EVALUATION OF 1% OXICONAZOLE CREAM FOR DERMATOPHYTOSIS: EFFICACY AND TOLERABILITY

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### ABSTRACT

**Background:** Dermatophytosis, also known as ring worm is a common fungal infection that affects a significant portion of the global population. In Pakistan, Tinea corporis, Tinea cruris, Tinea Pedis are most common fungal infections. Oxiconazole has recently been introduced in Pakistan for treatment of dermatophytosis.

**Objectives:** To evaluate clinical efficacy of 1% oxiconazole cream once daily for treatment of tinea corporis, tinea cruris and tinea pedis and to estimate its side effects.

**Methods:** A clinical trial was carried out in the outpatient department of Dermatology, Akhtar Saeed Trust Hospital, EME, Lahore. 110 patients of Dermatophytosis were selected and were instructed to apply 1% oxiconazole cream once daily for 6 weeks with clinical assessment made fortnightly during treatment period.

**Results:** The mean age of patients were 40.5 years. Numbers of male patients were 48 and female patients were 62. Among 110 patients, tinea corporis were found in 58 (52.7%), tinea cruris in 29 (26.3%) and tinea pedis in 23 (20.9%) patients. Mean clinical assessment score declined from  $8.2 \pm 1.5$  at baseline to  $4.1 \pm 1.2$  at week 2,  $1.5 \pm 1.3$  at week 4 and  $0.6 \pm 1.1$  at week 6. Reduction of clinical assessment from baseline at end of the treatment period was statically significant ( $p < 0.001$ ). Improvement of clinical score from baseline was 50.1% at week 2, 92.6% at week 4, 95.2% at week 6. Global response was clear in 77(70%), good in 32(29%) patients and fair in 1 (1%). Side effects like pruritus, erythema and burning were not reported in any patient.

**Conclusion:** Once daily application of 1% oxiconazole cream is highly effective, affordable and tolerable treatment for dermatophytosis.

**Key words:** oxiconazole cream, dermatophytosis, clinical assessment score

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### INTRODUCTION

Dermatophytosis, also known as ring worm is a common fungal infection that affects a significant portion of the global population. It's estimated that more than 20% to 25% of the world's population is affected by this condition, making it one of the most common fungal diseases in humans.<sup>1</sup> Dermatophytosis is a significant public health concern in Pakistan with a considerable prevalence rate of about 31%.<sup>2</sup> Risk factors contributing to their spread are low socioeconomic status, poor hygiene and sanitation, contact with

infected animals, high humid environmental conditions, age and immune system and lack of awareness.<sup>3</sup> While not critical, these conditions can cause considerable symptoms that affect daily life and diminish overall quality of life. Dermatophytosis are caused by fungi belonging to genera of Trichophyton, Microsporum and Epidermophyton, (4,5). *T.rubrum* account for 60-80% of dermatophyte infection whereas *M. canis* is responsible for 10-20% of cases.<sup>6</sup> Dermatophytosis of skin characteristically presents with annular lesions marked by scaly surfaces, central clearing and sharply demarcated erythematous raised borders.<sup>7</sup> Oxiconazole nitrate is an imidazole antifungal agent effective against various dermatophytes.<sup>8</sup> Oxiconazole nitrate's mechanism of action involves inhibiting fungal cell membrane ergosterol synthesis, essential for cell integrity and function.<sup>9</sup> Studies evaluating oxiconazole against miconazole and clotrimazole in dermatophytosis treatment showed oxiconazole's improved clinical outcomes.<sup>10</sup>

The introduction of oxiconazole in Pakistan is recent and consequently there is dearth of published data on its clinical outcomes in treating dermatophytosis in Pakistan patients. This study was designed to evaluate the clinical efficacy and side effects estimation of once daily topical 1% oxiconazole cream in the treatment of dermatophytosis.

## METHODS

An interventional study was carried out with patients of dermatophytosis attending outpatient department of Akhtar Saeed Trust hospital, EME, Lahore. Duration of study was from April 2025 to June 2025. Patients of both genders between the ages of 16 to 65 years were selected. Clinically diagnosed cases of tinea corporis, tinea cruris and tinea pedis and in selective cases confirmed by positive KOH reading were included. Patients with tinea incognito, those who were previously taking oral antifungal for last 4 weeks or currently using topical antifungal agents in last week, pregnant /lactating females, children under 15 years of age, patients with renal/hepatic dysfunction or those allergic to imidazole agents were excluded from study. Sampling technique was consecutive non-probability. Pre designed data collection proforma was used to gather information.

## PROCEDURE

Informed consent was obtained from patients. 110 patients with tinea corporis, tinea cruris and tinea pedis were selected according to inclusion and exclusion criteria. Each and every patient was examined clinically as a diagnosed case of tinea corporis or cruris or pedis

infections and in selective cases confirmed by positive 10% KOH reading. Pre designed proforma was filled up with information including age, sex, occupation and socio-economic status. All patients were advised to apply 1% oxiconazole cream once daily (preferably at night) for 6 weeks with clinical assessment made at 2 weeks interval during treatment period. Clinical assessment was done at 2 weekly intervals. The severity of signs and symptoms of tinea cruris, pedis and corporis like pruritus, burning and erythema were graded on an ascale ranging from 0-3 (0: absent, 1: mild, 2: moderate, 3: severe). Global evaluation responses of the clinical condition compared to baseline were assessed in accordance to following criteria: (11)

**cleared:** 100% remission of clinical signs and symptoms

**excellent:** 90-99% improvement of clinical signs and symptoms

**good:** 50-89% improvement of clinical signs and symptoms

**fair:** 25-49% improvement of clinical signs and symptoms

**poor:** < 24% improvement of clinical signs and symptoms

**worse:** clinical signs and symptoms deteriorated from baseline

Clinical efficacy was categorized as follows:

**Cure:** disappearance of all baseline signs and symptoms of infection, with global response as cleared or excellent

**Improvement:** partial disappearance of baseline signs and symptoms of fungal infection

**Failure:** no change/ worsening

**Relapse:** improvement/ cure followed by reappearance/ worsening. Side effects estimation like burning, erythema, pruritus after application of cream were done according to scale. 0: absent 1: mild 2: moderate 3: severe

## STATISTICAL ANALYSIS

Data was processed and analyzed with help of spss 16 version. Quantitative data were analyzed using mean and standard deviation. Chi-square test was used for clinical assessment score and improvement of clinical score. A probability value of < 0.05 was considered statically significant.

## RESULTS

This study was conducted on 110 patients with tinea corporis, tinea cruris and tinea pedis who were instructed to apply 1% oxiconazole cream once daily (preferably at night) for 6 weeks. The age of patients ranged from 16 to 65 years with mean age of 40.5 years. Number of male patients were 48 and number of female patients were 62.

Among 110 patients, tinea corporis were found in 58 (52.7%), tinea cruris in 29 (26.3%) and tinea pedis in 23

(20.9%) patients. Mean clinical assessment score declined from 8.2+ 1.5 at baseline to 4.1+1.2 at week 2, 1.5+ 1.3 at week 4 and 0.6 +1.1 at week 6. Reduction of clinical assessment from baseline to end of the treatment period was statically significant ( $p < 0.001$ ).

Improvement of clinical score from baseline was 50.1% at week 2, 92.6% at week 4, 95.2% at week 6. Improvement was statistically significant ( $p < 0.001$ ).

Global response was clear in 77(70%), good in 32(29%) patients and fair in 1(1%). Clinical efficacy was cure in 77, improvement in 32 and failure in 1 patient.

## DISCUSSION

In this study the age of the patients ranged from 16 to 65 years with mean age of 40.5 years. This result was supported by md. Tawhidul Islam, Shamim Akhter where mean age of patients were 32.5 years.<sup>11</sup>

In the current study the mean clinical score declined from 8.2+1.5 at baseline to 4.1 +1.2 at 2 weeks to 1.5+1.3 at 4 weeks to 0.6+1.1 at 6 weeks. Reduction of clinical assessment score from baseline to end of treatment period was statically significant ( $p < 0.001$ ). Farzana afroz et al found statistically significant reduction in clinical score with comparison of ketoconazole for treatment of dermatophytosis (12). The present study showed that improvement of clinical score was from baseline to 50.1% at 2 weeks, 92.6% at 4 weeks and 95.2 % at 6 weeks. Improvement of clinical score from baseline to end of treatment period was statically significant ( $p < 0.001$ ). In this study the global response was clear in 77 patients, good in 32 and fair in 1 patient. This result was supported by the study of Md Tawhidul Islam.<sup>11</sup>

In this study the clinical efficacy was cure in 77 (70%) patients, improvement in 32(29%) and failure in 1 (1%) patient. Gandhi GR reported that oxiconazole cream is efficacious in treatment of dermatophyte infection.<sup>13</sup> once daily application of oxiconazole cream was found to be good.<sup>14</sup>

HR jerajani et al reported that in most cases oxiconazole produced clinical cure within 2 to 4 weeks of initiating treatment.<sup>15</sup>

## CONCLUSION

From this study, it is concluded that once daily topical application of oxiconazole cream is highly efficacious for treatment of superficial fungal infections of the skin. As it is novel and affordable treatment option in Pakistan, large multi-centered trials should be carried out to further support the study specially in current conditions of resistant dermatophyte infection.

## ETHICAL APPROVAL

Ethical approval of article was granted by the Institutional Ethical Review Board of Akhter Saeed Medical & Dental College vide reference No CMH M-25/228 dated 15 April, 2025.

## CONFLICT OF INTEREST

Authors declare no conflict of interest.

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## AUTHOR'S CONTRIBUTIONS

**RA:** Concept, design of study, manuscript writing, supervision

**RS:** Data collection, statistical analysis, Critical Review of the manuscript

**WN:** Literature review, references

**NC:** data interpretation, critical review of the manuscript

**MS:** Methodology design, proof reading

**ZM:** Data collection, data analysis

**All Authors:** Approval of the final version of the manuscript to be published

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