Original Article

Comparing the Efficacy of Oral 200 Milligram Voriconazole Once a Day Vs Twice a Day in the Treatment of Resistant Dermatophyte Infections (Tinea Corporis and Tinea Cruris)

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Abstract

Background: Treatment of dermatophyte infection in our country is becoming difficult due to the developing resistance to traditional antifungal agents. Assessing the effectiveness and feasibility of a newer antifungal drug like voriconazole is the need of the hour in resistant cases.

Objective: To compare the efficacy of oral 200 milligram voriconazole once a day vs twice a day in the treatment of resistant dermatophyte infections (tinea corporis and cruris).

Methods: This Randomized Controlled Trial (registration number NCT06680544.) was carried out in Outpatient Dermatology Department, Sheikh Zayed Hospital Rahim Yar Khan, Pakistan. Total 106 patients were divided into two groups, Group A and Group B, each consisting of 53 patients. Group A was given oral voriconazole 200mg once a day and Group B was given twice a day for a maximum of 28 days. Efficacy was assessed at day 14 and day 28, and relapse was noted at the 2-month follow-up visit. Data was recorded on a preformed Proforma for each patient and analyzed using SPSS 24. A p-value of less than 0.05 was considered statistically significant.

Results: In Group A, complete clinical cure/efficacy was noted in 28.3% and 94.7% patients at day 14 and 28, respectively. In Group B, complete clinical cure/efficacy was noted in 34.0% and 94.4% patients at day 14 p= 0.338) and 28 (p=0.817), respectively. Over all 22 patients (20.7%) showed relapse. Visual disturbance in the form of altered perception of light after first dose was the most common side effect noted.

Conclusion: Oral voriconazole at a dosage of 200 mg once daily is comparable in efficacy and safety to 200 mg twice daily regimen but is more cost effective in treatment of resistant tinea corporis and tinea cruris.

Key Words: Tinea, Voriconazole; Dermatomycoses; Drug Resistance; Fungal; Antifungal Agents.

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Introduction

Infectious diseases rank as the second leading cause of mortality worldwide.[1] While viruses and bacteria are typically the primary agents responsible for these infections, there has been a notable increase in the prevalence of human fungal infections on a global scale.[1] This emerging issue is gaining significant attention due to the rising incidence of persistent and recurrent fungal infections. Fungal infections in humans are traditionally classified into three categories: superficial, subcutaneous, and systemic.[2] Among these, superficial infections are the most prevalent.[2] Superficial fungal skin infections can be further divided into several categories, including those caused by dermatophytes, non-invasive candidiasis, and tinea versicolor.[2] Dermatophytes are a specific group of fungi that thrive on keratinized tissues, such as

skin, hair, and nails.[3] These organisms primarily belong to the family Arthrodermataceae, which encompasses nearly 40 species categorized into three genera: Epidermophyton, Microsporum, and Tricho-phyton.[4] The worldwide prevalence of dermatophyte infections is estimated to be around 25%.[5]

Patients diagnosed with tinea corporis and tinea cruris typically exhibit distinct clinical manifestations characterized by the development of ring-shaped, red, scaly, and itchy skin lesions on the trunk and groin, respectively.[6] These lesions can expand outward, often extending several centimeters from their original site. Following successful treatment, the lesions generally start to heal from the center, which may result in residual pigmentation or a return to normal skin texture, typically without scarring.[6]

In our country, the KOH mount procedure is a widely utilized method for diagnosing dermatophyte infections due to its cost-effectiveness and rapid results.[7] While this technique is highly beneficial, its sensitivity can vary significantly, ranging from 44% to 100%.[7] In contrast, fungal culture offers greater sensitivity than the KOH mount; however, it tends to be more expensive and is often unnecessary, as conditions such as tinea cruris and tinea corporis can typically be diagnosed through clinical evaluation alone.[8]

In our country, the oral antifungal medications available for treating dermatophyte infections include terbinafine and a range of azoles, such as fluconazole, itraconazole, and voriconazole.[9] However, there is an increasing concern regarding resistance to commonly prescribed oral antifungals, particularly terbinafine, fluconazole, and itraconazole.[10] A case of tinea corporis or tinea cruris is defined clinically resistant when patients do not achieve complete clearance of lesions after receiving the standard dosage of oral terbinafine (5 mg/kg per day for four weeks) or itraconazole (5 mg/kg per day for four weeks).[9] Resistance may develop either naturally or over time as dermatophytes are exposed to antifungal agents.[10] While further research is needed to ascertain the exact prevalence of terbinafine and itraconazole resistance in our country, existing studies indicate a growing concern regarding antifungal resistance in dermatophyte infections.[11,12,13] Several factors contribute to the development of this resistance, including prolonged fungal infections, irregular treatment regimens, and the inappropriate use of antifungal medications and corticosteroids.[11,12]

Voriconazole, a newly introduced antifungal agent in our country, is recognized for its broad-spectrum antifungal properties. It functions by inhibiting fungal cytochrome P450-mediated 14-alpha lanosterol demethylation, which ultimately disrupts and damages the fungal cell membrane.[9] Reported adverse effects of voriconazole include liver function abnormalities, nausea, vomiting, and visual disturbances, such as blurred vision, altered light perception, and visual hallucinations.[14] Recently, a few studies have been conducted to evaluate the efficacy of voriconazole in treating dermatophyte infections. These studies, however, are uncontrolled trials that have utilized high doses of voriconazole (200 mg twice daily).[9] One of the main challenges associated with administering high doses of the drug in our country is its relatively high cost (almost 200 rupees per tablet). In this study, we aim to compare the effectiveness of a low dose (200 mg once daily) with a high dose of voriconazole in the treatment of dermatophyte infections. Our objective was to identify the most cost-effective dosage as well as the optimal duration of voriconazole therapy for treating these infections.

Methods

This Randomized Controlled Trial was conducted in the Outpatient Dermatology Department of Sheikh Zayed Hospital in Rahim Yar Khan, spanning from November 15, 2024, to February 15, 2025 after approval from the hospital's ethical review committee, reference number 825/IRB/SZMC/SZH. This trial was registered on ClinicalTrials.gov under the registration number NCT 06680544.

Inclusion Criteria Included:

- Age: 18-60 year.

- Gender: Both.
- Resistant cases of tinea corporis or cruris: A case of tinea corporis or cruris is defined clinically resistant in a patient who does not show complete clearance of lesions after receiving the standard dosage of oral terbinafine or itraconazole for standard duration (oral terbinafine 5mg/kg per day for 4 weeks or oral itraconazole 5mg/kg per day for 4 weeks).[9]
- Skin area: Groin and trunk.
- Total diameter of the lesions: 5cm to 80 cm.

Exclusion Criteria Included:

- History of hypersensitivity to azoles.
- All those individuals having immunocompromised state (malignancy, tuberculosis, AIDS, history of organ transplant and history of immunosuppressive drug treatment etc.).
- Patients of diabetes, liver or kidney disease.
- Lactating mother.
- Pregnant female.

The sample size for this study was calculated using the World Health Organization (WHO) calculator, with a significance level set at 5% and a test power of 80%. The anticipated population proportion for the first group was 34% based on a pilot study, while the second group's anticipated population proportion was 58%.[9] After ensuring that all participants met the eligibility criteria and providing informed consent, a total of 120 patients diagnosed with tinea corporis and tinea cruris were enrolled in the study through a non-probability consecutive sampling technique. 14 patients were lost to follow-up. Ultimately, 106 patients were randomly assigned to two groups (Group A and Group B) using a drawing method, with each group comprising 53 patients. Group A received oral voriconazole at a dosage of 200 mg once daily for a maximum of 28 days, while Group B was administered the same medication at a dosage of 200 mg twice daily for the same duration. Additionally, all patients in both groups were instructed to apply topical clotrimazole lotion to the affected areas twice daily for the same treatment period.

The patients were assessed for efficacy and side effects and data was recorded on days 14 and 28, as well as two months after the initiation of treatment. The outcomes of the treatment (efficacy/cure) were classified into the following clinical subgroups:

- *Complete Cure at Day 14:* Patients showed a total clearance of skin lesions, resulting in either pigmentation or normal skin by day 14.
- *Complete Cure at Day 28:* Patients showed a total clearance of skin lesions, with either pigmentation or normal skin recorded by day 28.
- *Partial Cure at Day 14:* Patients showed incomplete clearance of the disease at day 14.
- *Resistant Cases / Non-responders:* Patients showed incomplete clearance of the disease at day 28.
- *Relapse Cases for Patients Cured by Day 14:* Patients who were completely cured clinically by day 14 experienced a recurrence of the disease within the last follow-up.
- *Relapse Cases for Patients Cured by Day 28:* Patients who achieved complete cure by day 28 clinically, experienced a recurrence of the disease within the last follow-up.

Patients who achieved complete clinical clearance of lesions during any of the follow-up visits (on days 14 or 28) were recommended to discontinue treatment and instructed to return if any recurrence occurred. Each patient was closely monitored for side effects at every visit. Compliance to the prescribed drugs was closely monitored for all patients, with data meticulously recorded on a preformed proforma for each patient. The collected data was analyzed using SPSS version 24. Quantitative variables, such as age, were analyzed using an independent samples t-test, while qualitative variables, including gender and percentages, were analyzed using a chi-square test. A p-value of less than 0.05 was considered statistically significant.

Results

The mean age of the patients in this study was 34.27 ± 10.906 years. Group A had a mean age of 32.42 ± 9.744 years, while Group B had a mean age of 36.13 ± 11.756 years. Out of a total of 106 patients, 57 were male (53.7%) and 49 were female (46.2%). Among these patients, 59 were diagnosed with tinea cruris (55.6%), and 47 were diagnosed with tinea corporis (44.3%). In Group A, which consisted of 53 patients, there were 27 males (47.4%) and 26 females (53.1%). Within this group, 33 cases were diagnosed as tinea cruris (62.2%), while 20 cases were diagnosed as tinea corporis (37.7%). Group B, also comprising 53 patients, included 30 males (52.6%) and 23 females (46.9%). In this group, 26 cases were diagnosed with tinea cruris (55.6%), and 47 were diagnosed with tinea corporis (44.3%). In Group A, which consisted of 53 patients, there were 27 males (47.4%) and 26 females (53.1%). Within this group, 33 cases were diagnosed as tinea cruris (62.2%), while 20 cases were diagnosed as tinea corporis (37.7%). Group B, also comprising 53 patients, included 30 males (52.6%) and 23 females (46.9%). In this group, 26 cases were diagnosed with tinea cruris (49.0%), and 27 cases were diagnosed with tinea corporis (50.9%) (Table 1).

Table 1: *Demographic Data and Diagnosis wise Distribution.*

Variables	Group A	Group B	Total
Mean Age	32.42±9.744	36.13±11.756	34.27±10.906
Males	27 (47.4%)	30 (52.6%)	57 (100.0%)
Females	26 (53.1%)	23 (46.9%)	49 (100.0%)
Tinea Corporis cases	20 (37.7%)	27 (50.9%)	47 (44.3%)
Tinea Cruris cases	33 (62.2%)	26 (49.0%)	59 (55.6%)

In Group A, complete cure was recorded in 15 patients (28.3%) at day 14 and in 36 patients (94.7%) at day 28. Group B demonstrated complete cure rates in 18 patients (34.0%) at day 14 and in 33 patients (94.3%) at day 28. After a full 28 days of treatment, four cases of resistance (5.5%) were documented clinically in the study, with two cases occurring in each group (p-value = 0.817). The most

Table 2: *Comparison of Efficacy/cure at Day-14 and Day 28 and Side effects between once daily and twice daily regime of voriconazole 200 mg.*

Cure (Efficacy) & Side effects			Treatment Group		Total	P-value
			Group A	Group B		
Cure at day 14	Partial Cure	Count	38	35	73	0.338
		% within Treatment Group	71.7%	66.0%	68.9%	
	Complete Cure	Count	15	18	33	
		% within Treatment Group	28.3%	34.0%	31.1%	
	Total	Count	53	53	106	
		% within Treatment Group	100.0%	100.0%	100.0%	
Cure at day 28	Resistant cases	Count	2	2	4	0.817
		% within Treatment Group	5.3%	5.7%	5.5%	
	Complete Cure	Count	36	33	69	
		% within Treatment Group	94.7%	94.3%	94.5%	
	Total	Count	38	35	73	
		% within Treatment Group	100.0%	100.0%	100.0%	
Side effects	Transient visual disturbance	Count	10	14	24	0.394
		% within Treatment Group	18.8%	26.41%	22.6%	
	Nausea	Count	5	8	13	
		% within Treatment Group	9.4%	15.0%	12.2%	
	Constipation	Count	1	0	1	
		% within Treatment Group	1.8%	0%	0.9%	
	Urinary frequency	Count	0	1	1	
		% within Treatment Group	0%	1.8%	0.9%	

frequently reported side effect was visual disturbances in the form of perception of flashes of light occurring 1-2 hours after the administration of the first dose. This side effect was noted in 10 patients (18.9%) from Group A and 14 patients (26.4%) from Group B. Nausea was the second most common side effect reported, affecting 5 patients (9.4%) in Group A and 8 patients (15%) in Group B (p-value = 0.307) (Table 2).

Table 3: *Comparison of Relapsed Cases.*

Relapsed Cases	Count % within Group	P - value
Who completely cured at day 14	12 (54.5%)	
Who completely cured at day 28	10 (45.4%)	0.434
Total	22 (100%)	

Overall, relapse was seen in 22 cases (20.7%) in the study. Among these, 12 cases (54.5%) recorded in individuals who had achieved complete recovery by day 14, while 10 cases (45.5%) were recorded in those who were fully cured by day 28. (P-value 0.434) (Table 3).

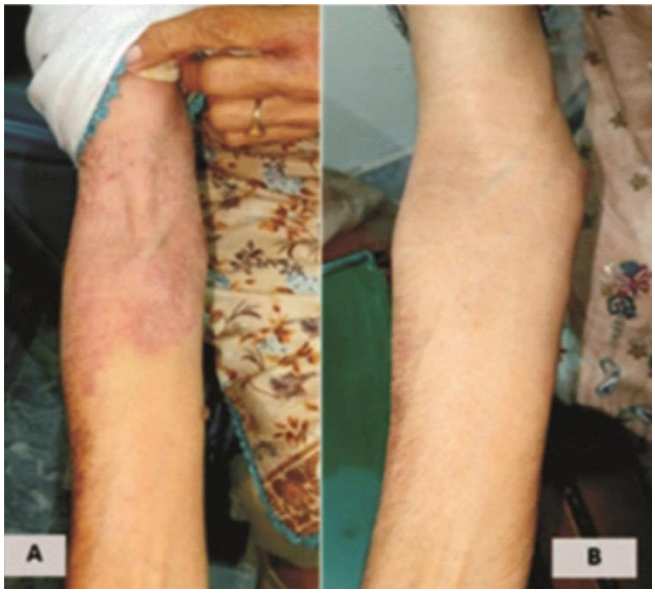

Figure 1: *Tinea Corporis lesion at day zero (A) and complete cure at day 14 (B).*

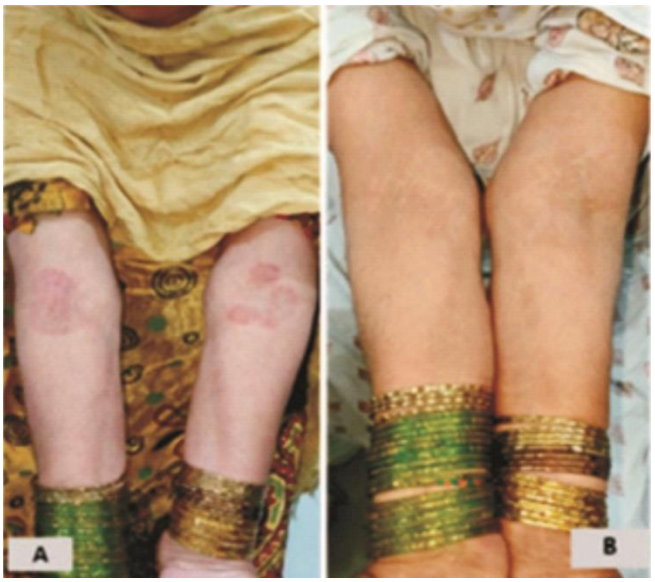

Figure 2: *Tinea corporis lesion at day zero (A) and complete cure at day 28(B).*

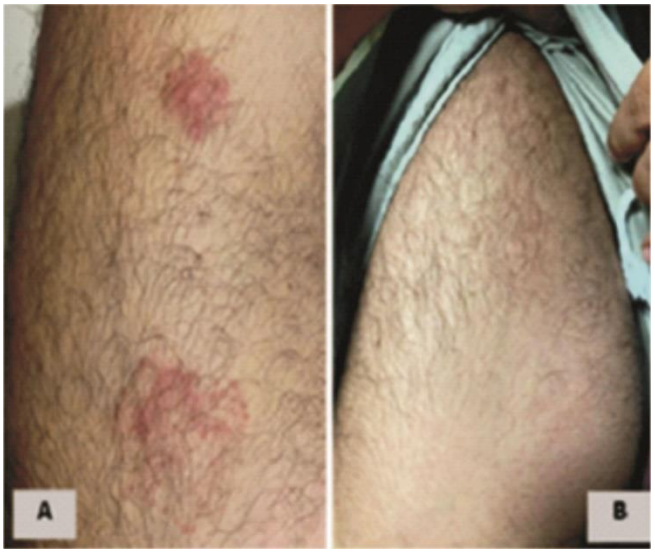

Figure 3: *Tinea cruris lesions at day zero (A) and complete cure at day 28 (B).*

Discussion

There has been a significant rise in the global incidence of human fungal infections.[1] Current estimates indicate that the worldwide prevalence of dermatophyte infections stands at approximately 25%.[5] Notably, the prevalence of tinea infections is relatively consistent across various countries in the Asian subcontinent, influenced by a range of ecological factors.[15,16,17] A study conducted by Kashif et al, highlights a concerning trend: the

prevalence of dermatophyte infections in Pakistan is steadily increasing.[15] Over recent years, there has been a marked rise in resistant and recurrent cases of these infections on a global scale.[16,17] Many patients suffering from dermatophyte infections are showing inadequate responses to the maximum dosages of conventional antifungal medications, such as terbinafine and itraconazole.[18,19] This growing resistance underscores the urgent need for enhanced treatment strategies and further research in the field of mycology.

Voriconazole, a newer antifungal medication, has been studied for the treatment of resistant dermatophyte infections in our country.[9] Historically, this drug has primarily been utilized for invasive fungal infections.[20,21,22] However, one of the significant challenges associated with voriconazole is its relatively high cost compared to other antifungal agents. Previous studies have employed high doses of voriconazole, typically 400 mg per day or more in the treatment of tinea corporis and cruris.[9] In our research, we aimed to compare the efficacy of high-dose versus low-dose voriconazole in treating dermatophyte infections.

In our study, we documented a higher prevalence of male participants compared to females, although this difference was not statistically significant (p-value = 0.131). This finding contrasts with a study conducted by Noor T et al, which reported a higher prevalence of females (66.1%) in similar cases.[23] The discrepancy may be attributed to variations in local weather and occupational conditions.

Furthermore, a study by Preethi P et al, indicated that tinea corporis (31.30%) was more prevalent than tinea cruris (16%). In contrast, our findings revealed that tinea cruris (55.7%) was more common than tinea corporis (44.3%), although this difference was also not statistically significant (p-value = 0.125).[24] This variation may be influenced by differing ecological conditions in our region.

A study conducted by Chandrashekar B.S. et al, investigated the use of a high-dose regimen of voriconazole for the treatment of resistant dermatophyte infections.[25] The treatment protocol involved a two-week course of oral voriconazole, starting with an initial dose of 800 mg on day one, followed by 200 mg administered twice daily for the subsequent 13 days. Their findings revealed complete clearance of the infection in 90% of patients by week 2 and 75% by week 6. Whereas our study reported a complete cure rate of 34% at 2 weeks and 94.4% at 4 weeks. Notably, the efficacy observed in our study at the 4-week mark aligns closely with the results from Chandrashekar et al, at 6 weeks. The disparity in efficacy at the 2-week interval may be attributed to the significantly higher loading dose of voriconazole utilized in their research.

In their study, Shahzad MK et al, administered a twice-daily dosage of 200 mg of voriconazole for the treatment of dermatophyte infections over a period of two weeks.[9] They reported an efficacy rate of 58%. In contrast, our findings indicated a lower efficacy rate of 34% after the same two-week duration with the identical dosage. Additionally, a study conducted by Ahmad SS et al, demonstrated an efficacy rate of 82% with a twice-daily regimen of 200 mg voriconazole after four weeks of treatment. [26] This result aligns more closely with our study's findings, highlighting the variability in treatment outcomes.

In our study, the most frequently reported side effect among patients was visual disturbance, characterized by the perception of flashes of light occurring 1 to 2 hours after the administration of the first dose. The second most prevalent side effect was nausea. Notably, there was no statistically significant difference in the incidence of these side effects between the two treatment groups, with p-values of 0.273 for visual disturbances and 0.307 for nausea. Consistent with our findings, Ahmad SS et al, also identified visual disturbances, specifically altered perception of light, as the most common side effect in their research.[26]

Several uncontrolled trials have been conducted to assess the efficacy of high doses of oral voriconazole in treating dermatophyte infections. However, no studies have yet compared the outcomes of a single 200 mg dose versus a twice-daily regimen of oral voriconazole for resistant dermatophyte infections. Given the relatively high cost

of this medication, our research aimed to evaluate the efficacy of a single daily dose compared to a twice-daily dose, thereby identifying a more cost-effective treatment regimen. In our study, we found that the efficacy of a single 200 mg dose of voriconazole was comparable to that of a double dose at both 14 and 28-days post-treatment, with p-values of 0.137 and 0.471, respectively. Additionally, there was no statistically significant difference in relapse rates between patients who were completely cured at day 14 and those who achieved complete cure by day 28 (p-value 0.434). The results of our study indicate that a single daily dose of oral voriconazole 200 mg is effective in treating resistant dermatophyte infections. This dosing regimen not only demonstrates comparable efficacy and side effect profiles to the twice-daily dose but also offers a more cost-effective treatment option.

All the cases included in the study were diagnosed on the basis of KOH mounting, but this method has low sensitivity for diagnosing superficial fungal infections. The gold standard test for diagnosing such cases is fungal culture. Resistance cases were determined on basis of clinical response to antifungal treatment, but it is better to define resistance based on culture and sensitivity. The high cost and the time required to obtain the results of the fungal culture test were the two main hurdles for not performing this test.

Conclusion

In our study population, the oral administration of voriconazole at a dosage of 200 mg once daily demonstrates comparable efficacy, relapse rates, and side effect profiles to the twice-daily regimen, while also proving to be more cost-effective.

Ethical Approval: The hospital's ethical committee of Sheikh Zayed Hospital in Rahim Yar Khan approved this study vide reference number 825/IRB/SZMC/SZH.

Conflict of Interest: There was no conflict of interest to be declared by any author.

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Author's Contribution:

MKS: Conception & design, acquisition of data, drafting of article, final approval of the version to be published.

TH: Conception & design, acquisition of data, analysis & interpretation, analysis & interpretation, critical revision of the article.

RT: Conception & design, acquisition of data, analysis & interpretation, analysis & interpretation, critical revision of the article.

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