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Dermatology

Therapeutic Outcomes of Terbinafine versus Voriconazole in Recalcitrant Dermatophysis

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Abstract **Original Research Article**

Background: Recalcitrant dermatophytosis, characterized by persistent or recurrent infections of the skin, hair, and nails, poses a growing clinical challenge due to increasing resistance to conventional antifungal therapies. Terbinafine, a widely used systemic antifungal, has moderate efficacy in resistant cases, whereas voriconazole, a broad-spectrum triazole, has demonstrated faster and higher cure rates with lower relapse. This study aimed to compare the efficacy and safety of oral terbinafine versus voriconazole in patients with recalcitrant dermatophytosis by evaluating clinical cure, symptom relief, overall treatment response, and adverse effects. ***Methods:*** This prospective comparative study was conducted from January to December 2023, enrolling 60 adult patients with clinically and mycologically confirmed recalcitrant dermatophytosis. Patients were randomly assigned to receive either oral terbinafine (250 mg twice daily, n = 30) or oral voriconazole (200 mg twice daily, n = 30) for 4 weeks. Outcomes assessed included clinical and mycological cure, time to symptom relief, recurrence, and adverse effects. Data were analyzed using SPSS v25, with $p < 0.05$ considered significant. ***Results:*** The study population was predominantly 31–45 years old, male, and from rural areas. Common clinical features included pruritus, erythema, and scaling, with 61.7% of patients having disease duration over 6 months. At 4 weeks, voriconazole achieved higher complete cure rates (76.7% vs. 63.3%) and faster symptom relief than terbinafine. Both drugs were well tolerated, with only mild and infrequent adverse effects reported. ***Conclusion:*** Voriconazole demonstrated superior efficacy and more rapid symptom improvement compared to terbinafine in recalcitrant dermatophytosis, while both medications were generally safe and well tolerated, supporting the use of voriconazole as an effective alternative in resistant cases.

Keywords: Terbinafine, Voriconazole, Recalcitrant Dermatophysis.

INTRODUCTION

Recalcitrant dermatophytosis, characterized by persistent or recurrent infections of the skin, hair, and nails, is a growing global concern due to rising resistance to conventional treatments and associated morbidity [1]. Dermatophytic infections result from fungi, host factors, and immune response, with fungal type and immunity driving relapses. Genera include *Trichophyton*, *Epidermophyton*, and *Microsporum*[2].

Terbinafine remains a key antifungal for dermatophytosis, but in recalcitrant cases, higher doses (e.g., 500 mg/day) and longer courses (>4 weeks), often combined with topical agents, are recommended to achieve cure [3]. Clinical studies show terbinafine can achieve about 80% cure in recalcitrant dermatophytosis, but combination therapy, such as with Voriconazole, yields higher cure rates, indicating limitations of terbinafine alone [4]. Terbinafine resistance, linked to SQLE gene mutations in *Trichophyton* species, leads to elevated MICs and treatment failure, often requiring alternative or adjunctive systemic antifungals with extended courses [5].

Voriconazole, a broad-spectrum triazole, has shown efficacy in recalcitrant dermatophytosis, achieving 90% clearance at 2 weeks and 75% at 6 weeks in resistant cases, with low recurrence and minimal adverse effects [6]. A Bangladeshi study reported that

oral voriconazole (200 mg twice daily for 4 weeks) achieved ~82% cure in recurrent, resistant dermatophytosis with manageable side effects [7].

Global research indicates that terbinafine monotherapy in recalcitrant dermatophytosis achieves approximately 80% cure, Voriconazole around 87%, and combination therapy up to 100%, highlighting the superior efficacy of combined systemic treatment in resistant cases [8]. In resistant dermatophytosis, oral voriconazole achieved an 82% cure rate compared to 64% with high-dose terbinafine, demonstrating its clearly superior effectiveness in difficult-to-treat cases [9].

A Bangladeshi study reported a 93% cure rate with oral voriconazole (200 mg twice daily for 4 weeks) in recalcitrant dermatophytosis, but lacked a control group and long-term follow-up, highlighting the need for randomized trials [10].

The study aims to compare the efficacy and safety of oral terbinafine versus oral voriconazole in patients with recalcitrant dermatophytosis by evaluating clinical cure rates, time to symptom improvement, overall treatment response, and adverse effects. The goal is to determine which systemic antifungal provides a faster, more effective, and safer therapeutic outcome in chronic and treatment-resistant dermatophyte infections.

METHODOLOGY

This prospective comparative study was conducted at the Upazilla Health Complex, Kapasia, Gazipur, Dhaka, Bangladesh, from January 2023 to December 2023, to evaluate the therapeutic outcomes of terbinafine versus voriconazole in patients with recalcitrant dermatophytosis.

Study Population and Sample Size:

Patients of both sexes aged 18 years and above with clinically and mycologically confirmed dermatophytosis unresponsive to at least 4 weeks of standard antifungal therapy were included. Patients with systemic illness, immunodeficiency, hepatic or renal dysfunction, pregnancy, or known hypersensitivity to the study drugs were excluded. A total of 60 patients were enrolled and randomly assigned into two equal groups: Group A (terbinafine, n = 30) and Group B (voriconazole, n = 30).

Intervention:

- **Group A:** Oral terbinafine administered at 250 mg twice daily for 4 weeks.
- **Group B:** Oral voriconazole administered at 200 mg twice daily for 4 weeks.

Outcome Measures:

The primary outcome was clinical and mycological cure, assessed at the end of therapy and at a 4-week follow-up. Secondary outcomes included time to symptom relief, recurrence rates, and adverse effects.

Data Collection:

Baseline demographic and clinical data, including age, sex, disease duration, lesion distribution, and previous antifungal therapy, were recorded. Clinical assessment of lesions included erythema, scaling, pruritus, and extent of involvement, while KOH mount and fungal culture were performed for mycological confirmation.

Statistical Analysis:

Data were analysed using SPSS version 25. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequency and percentage. Comparisons between the two groups were performed using Chi-square test or Fisher's exact test for categorical variables and independent t-test for continuous variables. A p-value < 0.05 was considered statistically significant.

RESULT

Table-1 shows nearly half of the participants were aged 31–45 years (48.3%), and a malepredominance was observed (58.3%). Most patients resided in rural areas (68.3%). The sociodemographic distribution was comparable between the terbinafine and voriconazole groups. Table-2 shows pruritus was present in all patients (100%), followed by erythema (91.7%) and scaling (85.0%). Annular lesions were noted in 71.7% of cases, while hyperpigmentation was observed in nearly half (46.7%). A majority of patients (61.7%) had disease duration exceeding six months, confirming the chronic and recalcitrant nature of dermatophytosis in the study population. Table-3 shows patients treated with voriconazole experienced earlier onset of pruritus relief and a higher proportion achieved ≥50% clinical improvement within 4 weeks compared to those receiving terbinafine. Near-complete lesion resolution at 4 weeks was also more frequent in the voriconazole group, indicating a faster and more pronounced therapeutic response during the treatment period. Table-4 shows adverse effects were infrequent and mild in both groups. Gastrointestinal upset and headache were the most commonly reported symptoms. A small number of patients in the voriconazole group experienced transient elevation of liver enzymes, skin rash, or visual disturbance. No serious adverse events or treatment discontinuations occurred, indicating good tolerability of both antifungal agents. Figure-I shows voriconazole achieved a higher complete clinical cure rate (76.7%) compared to terbinafine (63.3%) at 4 weeks. Partial improvement was more common in the terbinafine group, while non-response was lower among patients treated with voriconazole. Overall treatment response was higher with voriconazole (93.3%) than with terbinafine (86.7%), indicating superior short-term efficacy of voriconazole in recalcitrant dermatophytosis.

Table-1: Sociodemographic Characteristics of Study Participants (N = 60)

Variable	Category	Terbinafine (n = 30)	Voriconazole (n = 30)	Total n (%)
Age (years)	18–30	9	8	17 (28.3)
	31–45	14	15	29 (48.3)
	>45	7	7	14 (23.4)
Sex	Male	18	17	35 (58.3)
	Female	12	13	25 (41.7)
Residence	Rural	20	21	41 (68.3)
	Urban	10	9	19 (31.7)

Table -2: Baseline Clinical Characteristics of Dermatophytosis (N = 60)

Clinical Feature	Terbinafine (n = 30)	Voriconazole (n = 30)	Total n (%)
Pruritus	30	30	60 (100.0)
Erythema	27	28	55 (91.7)
Scaling	25	26	51 (85.0)
Annular lesions	21	22	43 (71.7)
Hyperpigmentation	13	15	28 (46.7)
Duration >6 months	18	19	37 (61.7)

Table-3: Time to Symptom Improvement During the 4-Week Treatment Period (N = 60)

Clinical Parameter	Terbinafine (n = 30)	Voriconazole (n = 30)
Mean time to onset of pruritus relief (weeks)	3.2 ± 0.8	2.4 ± 0.7
Patients achieving ≥50% reduction in pruritus by 4 weeks	22 (73.3%)	26 (86.7%)
Patients achieving ≥50% reduction in lesion size by 4 weeks	20 (66.7%)	25 (83.3%)
Patients with near-complete lesion resolution at 4 weeks	18 (60.0%)	23 (76.7%)

Table-4: Adverse Effects Observed During Treatment (N = 60)

Adverse Effect	Terbinafine (n = 30)	Voriconazole (n = 30)
Gastrointestinal upset	1 (3.3%)	2 (6.7%)
Headache	1 (3.3%)	1 (3.3%)
Mild elevation of liver enzymes	0 (0.0%)	1 (3.3%)
Skin rash	0 (0.0%)	1 (3.3%)
Visual disturbance	0 (0.0%)	1 (3.3%)
Any adverse effect	2 (6.7%)	3 (10.0%)

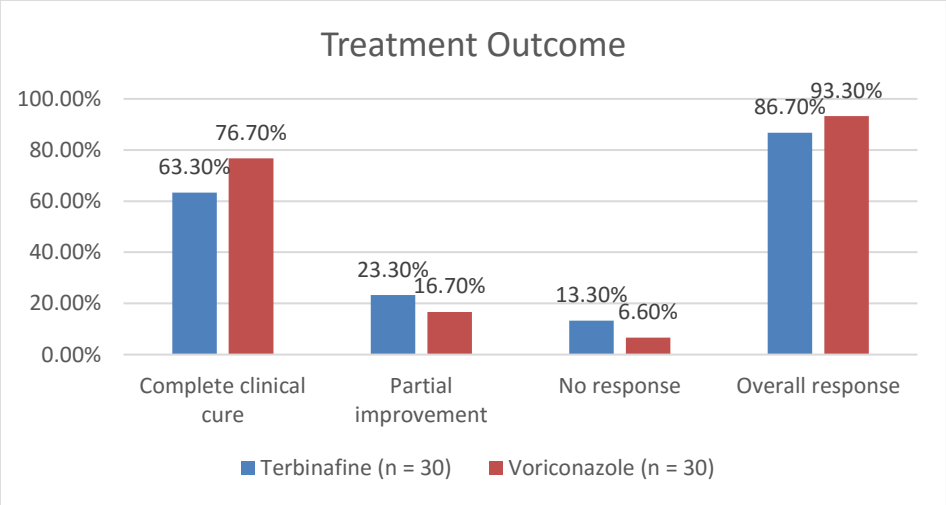

Figure 1: Clinical Response to Treatment at 4 Weeks (N = 60)

DISCUSSION

In this study of 60 patients with recalcitrant dermatophytosis treated with terbinafine or voriconazole, most patients were 31–45 years (48.3%), followed by 18–30 years (28.3%) and >45 years (23.4%). This aligns with previous studies showing peak

prevalence in young and middle-aged adults; for example, a multicentric Indian study reported most cases in the 18–40-year group (mean 36.6 ± 13.8 years) [11]. The sex distribution showed a slight male predominance (58.3% vs. 41.7%) in both treatment groups, consistent with prior studies; a 10-year retrospective study from Tehran reported 58.4% of cases in males and 41.6% in females, with tinea cruris and tinea pedis more common in men [12]. Most patients in both terbinafine and voriconazole groups were from rural areas (68.3%) versus urban centers (31.7%), consistent with studies reporting higher dermatophytosis prevalence in rural populations due to poorer hygiene and closer contact with animals; for example, 63.6% of cases in an Iraqi study were rural residents [13].

In this study, pruritus was present in all patients, followed by erythema in 91.7% and scaling in 85.0% of cases. These findings reflect classical clinical features of dermatophytosis, in which intensely pruritic, erythematous, and scaly plaques are hallmark signs. Previous epidemiological studies support this pattern: a multicentric Indian study reported itching in 99.0% and scaling in 89.1% of cases and erythema in 85.3% of cases [11]. Annular lesions were observed in 71.7% of our patients, reflecting classic ring-worm morphology, compared with 39.5% in a multicentric Indian study, highlighting variation in lesion presentation across populations [11]. Hyperpigmentation occurred in 46.7% of patients, consistent with reports of post-inflammatory hyperpigmentation in 40–60% of chronic inflammatory dermatoses [14]. Importantly, 61.7% of our patients had disease duration >6 months, highlighting the chronic and recalcitrant nature of dermatophytosis, compared with 29.4% reported in a large Indian case series, reflecting both the persistent nature of the disease and selective enrollment of recalcitrant case [15].

In our study, voriconazole achieved a higher complete cure rate (76.7%) than terbinafine (63.3%) at 4 weeks, with overall response also greater (93.3% vs. 86.7%), indicating superior short-term efficacy in recalcitrant dermatophytosis; previous studies report up to 90% clearance within 2 weeks with voriconazole and sustained responses at 6 weeks in refractory cases [6].

Symptomatic improvement occurred more rapidly in patients administered voriconazole than in those given terbinafine. These findings are consistent with prior clinical studies. For example, a case series of refractory dermatophytosis treated with voriconazole reported complete pruritus relief in 88% of patients within 2–3 weeks, with ≥50% lesion clearance achieved in 82% of cases by week 4[6]. In comparison, conventional terbinafine therapy in chronic dermatophytosis demonstrated partial improvement in 65–75% of patients by 4 weeks, with slower lesion resolution, reflecting the challenges of treating recalcitrant infections [16].

Adverse effects were infrequent and mild in both groups. In our study, gastrointestinal upset occurred in 3.3% of terbinafine patients and 6.7% of voriconazole patients, and headache in 3.3% in both groups. These findings are consistent with published data, where gastrointestinal complaints occurred in 4–5% and headache in 10–13% of terbinafine-treated patients, typically mild and transient [17]. In our voriconazole group, adverse effects were infrequent and mild. Mild, transient liver enzyme elevation occurred in 3.3% of patients, consistent with reports that azoles can cause asymptomatic increases in 10–23% of cases. Skin rash was also observed in 3.3%, aligning with previous studies reporting rash in 5–10% of systemic azole recipients. Additionally, visual disturbances occurred in 3.3% of patients, comparable to reports that 20–30% of voriconazole-treated individuals may experience transient visual symptoms such as blurred vision or altered color perception [18]. Overall, adverse effects were low (6.7% terbinafine, 10% voriconazole), mild, and did not cause treatment discontinuation, consistent with previous reports showing 5–15% overall adverse event rates for systemic antifungals, with serious events <1% [17].

Conclusion & Recommendation

In this study of recalcitrant dermatophytosis, oral voriconazole demonstrated superior short-term efficacy compared to terbinafine, with higher complete cure rates, faster pruritus relief, and more rapid lesion resolution within 4 weeks. Both antifungal agents were generally well tolerated, with infrequent and mild adverse effects. These findings suggest that voriconazole may be a valuable therapeutic option for patients with chronic or treatment-resistant dermatophytosis, particularly in cases where conventional therapy with terbinafine is insufficient. Further large-scale studies are warranted to confirm these results and establish long-term safety and effectiveness.

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