Original Article:

A prospective Cross Sectional Cohort Study in South East Asia to Evaluate Comparative efficacy of highdose shortterm versus lowdose longterm itraconazole therapy for superficial dermatophyte infections

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Abstract

Background: Superficial dermatophyte infections are highly prevalent in tropical countries and are increasingly present as chronic, recalcitrant disease in South Asia. Itraconazole is widely used for tinea corporis and tinea cruris, but the optimal dosing regimen remains uncertain. **Objectives:** To compare a high-dose short-term versus low-dose long-term itraconazole regimen in patients with superficial dermatophyte infections. **Methods:** This prospective single-center cross-sectional comparative study assessed treatment efficacy for short term high dose vs. long term low dose itraconazol regimen (Group A: 200mg BID for 8 weeks vs. Group B: 100mg QD for 12 weeks). Demographic and clinical data, prior treatments and symptom duration were recorded. Clinical severity and patient satisfaction were assessed every 2 weeks; mycological response was evaluated by potassium hydroxide microscopy at end of therapy. **Results:** A total of 123 patients were recruited (54 and 69 patients in Group A and B, respectively). The Patients had more chronic and extensive disease, with longer symptom duration, universal skin-fold involvement and higher prior itraconazole and topical steroid use. Itraconazole 200mg BID for 8 weeks showed greater patients satisfaction (94.44%) compared to 4.35 % in Group B (100mg QD for 12 weeks). **Conclusions:** Resistance to oral antifungals is a growing problem globally, in particular in South Asian population. High dose short term regimen was favored to achieve complete clearance over long term low dose regimen with significant patients' satisfactions.

Key word: Dermatophyte infections, Itraconazole, Antifungal therapy, Chronic dermatophytosis, Steroid- modified tinea, Bangladesh

Introduction

Tinea is a global problem and a serious medical and economic burden in developing economies. They are commonly affect the skin, hair and nails, and are caused by Trichophyton, Microsporum and Epidermophyton species. South Asian region is densely populated, and its hot and humid climate further contributes to the spread of fungal infections. 1–3

Tinea corporis and tinea cruris account for most cases in these settings and are associated with pruritus, social stigma and impaired quality of life, especially in socioeconomically disadvantaged populations.1–3 Misuse of topical steroid combinations contributes to chronic, extensive and "steroid- modified" tinea, and recent data from Bangladesh highlight an increasing burden of recalcitrant disease. Moreover, steroid-related tinea incognito with a chronic course, and previous exposure to antifungals makes the management highly challenging.

Topical antifungals suffice for many localized infections, but extensive, severe, long- standing or recurrent disease requires systemic therapy.3–5 Itraconazole is a key oral agent, with broad antifungal activity, high tissue levels in

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keratinized structures and a long tissue half- life that supports flexible dosing schedules, including continuous and pulse regimens.4–6,8–10 itraconazole retains activity against many resistant isolates and remains first- line for tinea corporis and cruris in several regions yet emerging azole resistance in Trichophyton species raises concern.4–7

The optimal dose and duration of itraconazole in superficial dermatophytosis are unclear and likely depend on severity, extent and chronicity.4–6,8–10 Studies using daily doses of 100–400 mg and various pulse regimens report good short- term efficacy but similar relapse rates, suggesting that regimen choice must balance efficacy, safety and cost.6,8–10 Itraconazole is generally well tolerated, yet its hepatic metabolism and potential for drug–drug interactions and UV-related photosensitivity require attention, particularly with higher doses and prolonged courses in hot climate.3,4,8

Optimizing itraconazole regimens is a therapeutic concern in Bangladesh with growing rates of chronic and resistant dermatophytosis generally coupled with previous antifungal exposure and widespread abuse of topical corticosteroids. [3],[5] There are limited comparative data for continuous high-dose vs lower-dose prolonged regimens in such contexts. [6]–[8].

This study aimes to compare a high- dose short- term regimen (itraconazole 200 mg BID daily for 8 weeks) with a low- dose long- term regimen (100 mg QD daily for 12 weeks) in superficial dermatophyte infections, focusing on clinical severity, extent, mycological response and patient- reported satisfaction.

Materials and Method

Study design and setting

This prospective cross-sectional comparative cohort study was conducted at Bangladesh Medical College Hospital and Derma Care Clinic in Dhaka, Bangladesh, over 10 months (January–October 2024). The study protocol was approved by the Institutional Ethics Committee, and written informed consent was obtained from all participants.

Participants

Consecutive adult patients with potassium peroxide (KOH)-confirmed extensive tinea of the glabrous skin (more than 2 anatomical regions involved). Patients with known chronic liver disease, major systemic comorbidities requiring contraindicated medications, pregnancy or lactation, or recent systemic antifungal therapy beyond what was captured as prior exposure were excluded.

(I would add that patients lost to follow up were excluded and prepare a flow chart with the following numbers (total number of tinea of the glabrous skin patients, number of patients who agreed to particpate, number of patients excluded, number of patients lost to follow up for each group (A, B).

Treatment regimens

Participants were randomly assigned to one of two oral itraconazole regimens depending on routine local practices and physician's preferences:

· Group A: itraconazole 200 mg BID for 8 weeks (high-dose short- term regimen).

· Group B: itraconazole 100 mg BID for 12 weeks (low-dose long- term regimen).

Clinical and mycological assessment

At baseline, a structured case record form captured age, sex, previous episodes of dermatophytosis, prior antifungal and steroid treatments, duration of current symptoms and anatomical sites involved.

Follow up Visits

Patients were seen every 2 weeks till the prescribed course was finished. Clinical severity was regraded at each visit and adverse occurrences were documented. Microscopy of skin scrapings with potassium hydroxide (KOH) was examined after the end of therapy. Change in severity category was taken as clinical response and negative KOH mount in presence of clinical resolution or substantial improvement was taken as mycological cure. Treatment failure was defined as presence of lesions with positive KOH test at the conclusion of intended course.

Outcomes

Primary outcomes were clinical response, test of cure with KOH microscopy and patient- reported satisfaction. Satisfaction was rated on a 5- point scale (very satisfied, satisfied, neutral, dissatisfied, very dissatisfied) at the final visit. Secondary outcomes included anatomical extent (notably skin- fold involvement), and associations between prior therapies and baseline severity.

Statistical analysis

Data were analysed using SPSS version 26.0. Categorical variables were summarised as frequencies and percentages and compared between groups using chi-square or Fisher's exact test. Continuous variables were expressed as means ± standard deviations and compared using Student's t- test. A p- value < 0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 123 participants were included in the analysis, with 54 assigned to Group A (high- dose short- term regimen) and 69 to Group B (low- dose long- term regimen. Age and sex distributions were broadly comparable between the two groups, with no statistically significant difference in age distribution observed. Although Group A had a relatively higher proportion of participants in the 41–50-year age category, and Group B in the 31–40-year category, these variations did not reach statistical significance. The overall male predominance was similar in both groups, with no statistically significant difference in sex distribution.

Table 1: Distribution of baseline characteristics among the participants (N=123)

Baseline	Group A (n = 54)		Group B (n = 69)	
	n	%	n	%
Age				
≤30 yrs	9	16.67	18	26.09
31–40 yrs	9	16.67	24	
41–50 yrs	27	50	18	26.09
51–60 yrs	6	11.11	6	8.7
>60 yrs	3	5.56	3	4.35
Gender				
Male	30	55.56	36	52.17
Female	24	44.44	33	47.83

A previous history of superficial dermatophyte infection was more frequently reported in Group A than in Group B (44.44% vs 26.09%), although this difference did not reach statistical significance. By contrast, prior itraconazole exposure differed markedly between groups: 50.00% of Group A had a history of itraconazole use compared with none in Group B ($p < 0.001$), suggesting more chronic or recurrent disease in the high- dose group. A history of known allergy was numerically higher in Group A but not significantly different.

Table 2: Distribution of participants by previous relevant history (N=123)

Previous History	Group A (n = 54)		Group B (n = 69)		p-value
	n	%	n	%	
History of known allergy	15	27.78	12	17.39	0.425
Superficial dermatophyte infection	24	44.44	18	26.09	0.257
History of itraconazole use	27	50	0	0	<0.001

Topical steroid use was also substantially more common in Group A (83.33% vs 30.43%; $p = 0.001$), indicating greater steroid- modified disease. Prior use of other systemic antifungals, systemic steroids, antihistamines and voriconazole was less frequent and showed no statistically significant between- group differences.

Table 3: Distribution of participants by previous treatment history (N=123)

Previous treatment	Group A (n = 54)		Group B (n = 69)		p-value
	n	%	n	%	
Topical steroid	45	83.33	21	30.43	0.001
Systemic steroid	3	5.56	0	0	0.252
Antifungal medications	6	11.11	0	0	0.101
Itraconazole	18	33.33	0	0	0.003
Antihistamine	0	0	3	4.35	0.37
Voriconazole	12	22.22	3	4.35	0.083

Symptom duration and anatomical distribution

Duration of symptoms before presentation differed significantly between the two groups. In Group A, more than three quarters of patients reported symptoms lasting at least 2 months: 55.56% had symptoms for 2–3 months and 22.22% for more than 3 months, and no participant in this group presented within 1 month of symptom onset. In contrast, 56.52% of Group B reported symptom duration of 1 month or less, and only 4.35% reported symptoms persisting for more than 3 months (overall $p = 0.003$).

Table 4: Distribution of participants by duration of symptoms (N=123)

Duration of Symptoms	Group A (n = 54)		Group B (n = 69)		p-value
	n	%	n	%	
≤1 month	0	0	39	56.52	0.003
1–2 months	6	11.11	21	30.43	
2–3 months	30	55.56	6	8.7	
>3 months	12	22.22	3	4.35	

Involvement of skin folds was universal in Group A (100.00%) and also frequent in Group B (78.26%), with a statistically significant difference between groups (p = 0.035). Other anatomical sites, including face, abdomen, back, hands, legs, arms and chest, were variably involved in both groups, but the distribution across these sites did not differ significantly.

Table 5: Distribution of participants by location of skin folds (N=123)

Location of skin folds	Group A (n = 54)		Group B (n = 69)		p-value
	n	%	n	%	
Skin folds	54	100	54	78.26	0.035
Face	27	50	18	26.09	0.115
Abdomen	12	22.22	27	39.13	0.97
Back	12	22.22	6	8.7	0.224
Hands	6	11.11	3	4.35	0.409
Legs	12	22.22	9	13.04	0.438
Arms	3	5.56	3	4.35	0.859
Chest	6	11.11	0	0	0.101

Baseline severity and prior treatment profile

Baseline clinical severity differed strikingly between regimens. In Group A, the vast majority of patients (88.89%) were classified as having moderate infection, with only 5.56% each falling into mild or severe categories. In Group B, 73.91% had mild infection and 26.09% moderate infection; no severe cases were recorded (overall p < 0.001). This pattern of higher baseline severity in Group A is consistent with the longer symptom duration, more extensive skin- fold involvement and higher rates of prior topical steroid and itraconazole exposure described above.

Table 6: Distribution of participants by severity of infections (N=123)

Severity	Group A (n = 54)		Group B (n = 69)		p-value
	n	%	n	%	
Mild	3	5.56	51	73.91	<0.001
Moderate	48	88.89	18	26.09	
Severe	3	5.56	0	0	

The broader previous treatment profile is summarised in Table 6. In addition to the significantly higher use of topical steroids and itraconazole in Group A, prior exposure to systemic steroids, other antifungals, antihistamines and voriconazole was uncommon in both groups and did not differ significantly.

Treatment response and patient satisfaction

Patient- reported satisfaction at the end of therapy differed markedly between groups. In Group A, 33.33% of participants were very satisfied and 61.11% satisfied with treatment, so that 94.44% expressed a positive overall assessment. In contrast, only 4.35% of Group B participants reported being satisfied and none very satisfied. The majority of Group B described their experience as neutral (43.48%), dissatisfied (39.13%) or very dissatisfied (13.04%). The overall distribution of satisfaction levels differed significantly between groups (p < 0.001).

Table 7: Distribution of participants by previous treatment history (N=123)

Satisfaction level	Group A (n = 54)		Group B (n = 69)		p-value
	n	%	n	%	
Very satisfied	18	33.33	0	0	<0.001
Satisfied	33	61.11	3	4.35	
Neutral	0	0	30	43.48	
Dissatisfied	0	0	27	39.13	
Very dissatisfied	0	0	9	13.04	

Clinical assessments over the course of therapy demonstrated greater improvement in Group A, with a higher proportion of patients moving from moderate or severe categories towards minimal or no clinically detectable disease by the final visit.

Although detailed proportions of complete versus partial responders were not tabulated separately, the overall pattern of improvement corresponded with the satisfaction profile. Mycological assessment at end of treatment, as determined by potassium hydroxide microscopy, also favoured the high- dose regimen, with a higher proportion of KOH- negative results in Group A; however, long- term relapse after treatment cessation was not systematically recorded.

Discussion

This study compared two commonly used itraconazole regimens and found that a high- dose short- term schedule despite the high- dose group having more chronic, extensive and steroid- modified disease. [1–3]

The baseline profile of Group A—longer symptom duration, universal skin- fold involvement and greater prior itraconazole and topical steroid use—resembles cohorts with recalcitrant multi- site dermatophytosis in recent Indian trials, in which more intensive systemic or combination regimens were often required.[13–17] Our observation that high- dose itraconazole performed well in this more challenging group is consistent with studies suggesting that greater daily exposure can improve clearance without necessarily increasing relapse rates when appropriately monitored.[8–10,17] Although our study did not genotype isolates, the clinical profile of chronic, widespread tinea corporis/cruris with frequent prior terbinafine and azole exposure is highly compatible with the recalcitrant Trichophyton indotineae–driven dermatophytosis now reported across Asia, Europe and North America.[19,20] Reports from India, China and several European centres show that T. indotineae has rapidly become a dominant cause of difficult- to- treat tinea corporis and cruris, often associated with Dermatophyte infections have increasingly been observed with resistance to terbinafine , higher MICs and longer durations of disease .[19,20] In this context, some of the steroid-modified, multisite instances in our cohort may be Trichophyton indotineae or similar members of the T. mentagrophytes complex, although we did not have molecular confirmation.[19,20] The relatively low satisfaction in Group B, despite milder baseline condition, may indicate slower symptomatic relief and partial lesion clearance within a lower dose, longer duration regimen, highlighting the relevance of prompt clinical response for patient-perceived success.[17] In recent assessments of T. indotineae evidence, itraconazole regimens of roughly 200 mg/day seem to be more related with consistent clinical resolution, whereas lower dosages and lengthier inadequate courses are more frequently associated with treatment failure or relapse.[19]

Complementing this, an individual- patient- data meta-analysis of 81 T. indotineae patients reported a restricted mean time to initial improvement of approximately 11 weeks and a restricted mean time to complete clinical cure of around 11.5 weeks, highlighting that prolonged therapy is frequently required in this setting.[20] Our finding that a high- dose regimen of 200 mg twice daily for 8 weeks produced superior symptom control and satisfaction therefore sits within the 8–12- week treatment window now considered typical for recalcitrant disease in T. indotineae–endemic regions.[19,20]

Expert opinion on itraconazole “failure” in the era of T. indotineae suggests that many apparent failures are due to suboptimal dosing, inadequate treatment duration, or poor adherence rather than true azole resistance, with recommendations to avoid premature labeling of treatment failure in the first 6–8 weeks.[21] This is in line with our findings, where the lower dose regimen (100 mg bid for 12 weeks) was related with poorer patient satisfaction, highlighting the need for enough daily exposure in addition to sufficient treatment duration in chronic dermatophytosis.[20,21] Collectively, these data indicate a pragmatic approach for the treatment of moderate-to-severe or resistant tinea corporis and cruris in high-burden tropical settings using itraconazole regimens of ≥200 mg/day for several weeks and, in selected instances, up to 8–12 weeks.[19–21]

The main limitations of this study are the modest sample size, non- randomised design, single- country setting and absence of systematic long- term follow- up for relapse, which limit generalisability and prevent firm conclusions regarding sustained cure. Our study also did not include molecular identification of the causative species, which precludes definitive attribution of outcomes to T. indotineae or other specific dermatophytes. Nonetheless, the data provide pragmatic evidence from a high- burden tropical setting and, taken together with emerging T. indotineae literature, support tailoring itraconazole dose and duration to disease severity, chronicity, suspected resistance profile and prior treatment history.

Conclusion

In this Bangladeshi cohort with superficial dermatophytosis, a high- dose short- term itraconazole regimen (200 mg twice daily for 8 weeks) produced better clinical improvement and markedly higher patient satisfaction than a low- dose long-term regimen (100 mg twice daily for 12 weeks), despite more chronic and extensive baseline disease in the high-dose group. The results suggest a possible relevance of more intense itraconazole regimens for moderate to severe or resistant tinea corporis and tinea cruris, particularly in patients with skin-fold involvement, prolonged duration of disease, or prior exposure to steroids and antifungal drugs. In the context of increasing antifungal resistance, the use of longer-term, higher-dose itraconazole regimens may be considered as a pragmatic local approach. This needs to be confirmed in larger, preferably randomized studies with prolonged follow-up to determine efficacy, relapse, safety and the optimal dosing regimens in tropical resource-limited settings.

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Conflicts of Interest

None declared

Ethical approval

The study was approved by the Institutional Ethics Committee

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