Original Article

Comparative Clinical Outcomes of Three Itraconazole Regimens in Tinea Corporis: A Prospective Non-randomized Real-World Observational Study from Bangladesh

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Abstract

Background Chronic and recurrent tinea corporis is increasingly difficult to manage in South Asia, and itraconazole regimens used in routine practice vary in dose, schedule, and formulation.

Objective To compare clinical cure and six-month relapse rates among three itraconazole-based treatment strategies.

Methods Patients aged 15-50 years with clinically diagnosed tinea corporis were enrolled. Tinea corporis was operationally defined as annular or polycyclic erythematous scaly plaque(s) on the trunk and/ or extremities with an active or advancing border, with or without pruritus. Seventy-two patients entered the study; 60 completed treatment (20/group). Group A received itraconazole capsules 200 mg twice daily for 2 weeks then 100 mg twice daily for 6 weeks; Group B received capsules 100 mg twice daily for 8 weeks; and Group C received tablets 200 mg once daily for 8 weeks. All groups received identical adjunctive topical therapy.

Results Clinical cure occurred in 19/20 (95%), 16/20 (80%), and 9/20 (45%) patients in Groups A, B, and C, respectively (*P*=.001). Among cured patients, relapse occurred in 2/19 (10.5%), 5/16 (31.3%), and 7/9 (77.8%), respectively (*P*=.002). Safety-related discontinuations included leg oedema (n=6), drug interactions (n=3), headache (n=2), and suspected cardiac toxicity (n=1).

Conclusion The induction–maintenance capsule strategy was associated with the highest clinical cure and lowest relapse. These exploratory findings require confirmation in adequately powered randomized trials with mycological confirmation.

Keywords Tinea corporis; Dermatophytosis; Itraconazole; Treatment outcome; Recurrence.

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Introduction

Dermatophytosis is an important clinical problem in South Asia, where chronic, recurrent and treatment-refractory infections are increasingly encountered. Changes in dermatophyte epidemiology, antifungal resistance, inappropriate use of topical corticosteroid containing combinations, reinfection, poor adherence and inadequate treatment duration may contribute to persistence and recurrence.[1-5]

Systemic antifungal treatment is often required for

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extensive, recurrent, chronic or treatment-resistant tinea corporis. Itraconazole is commonly used because of its broad antifungal activity and distribution into keratinized tissues. However, systemic exposure may vary with formulation, gastric acidity, food intake, gastrointestinal function, concomitant medicines and interpatient pharmacokinetic variability. Recent Pakistani studies have also documented the clinical importance of recalcitrant dermatophytosis and the use of itraconazole in tinea corporis.[6,7]

Comparative real-world evidence regarding commonly used itraconazole schedules remains limited. The objective of this study was to compare clinical cure and six-month relapse rates among three itraconazole-based treatment strategies used in routine dermatology practice in Bangladesh.

Methods

This was a prospective, non-randomized, comparative real-world observational study conducted in private dermatology practices in Dhaka and Mymensingh, Bangladesh, from January 2024 - December 2024. It was not a randomized clinical trial.

Operational definition: Tinea corporis was defined clinically as one or more annular or polycyclic erythematous scaly plaques on glabrous skin of the trunk and/or extremities with an active or advancing peripheral border, with or without central clearing and pruritus.

Inclusion criteria: Patients aged 15–50 years fulfilling the clinical definition of tinea corporis, treated with one of the three pre-specified itraconazole strategies, and available for treatment assessment and follow-up were included.

Exclusion/ withdrawal criteria: Patients were excluded from the per-protocol efficacy analysis if itraconazole was discontinued because of a clinically significant adverse event or clinically relevant drug interaction, or if adherence/ follow-up was inadequate for outcome assessment. During the study, the 12 post-enrolment exclusions were leg oedema (n=6), clinically relevant drug interactions (n=3), headache requiring discontinuation (n=2), and suspected cardiac toxicity (n=1).

This exploratory real-world study used a pragmatic consecutive sample rather than a formal hypothesis-driven sample-size calculation. Seventy-two eligible patients were enrolled during the study period. After 12 safety-related discontinuations, 60 patients completed the protocol and were included in the per-protocol efficacy analysis, with 20 patients in each group. The absence of an *a priori* power calculation is acknowledged as a study limitation.

Randomization was not used because the study objective was to observe and compare treatment strategies selected in routine clinical practice. Regimen selection was based on the treating physician's clinical judgment. This approach reflects real-world practice but permits selection bias and confounding by indication.

Group A received itraconazole capsules 200 mg twice daily for 2 weeks followed by 100 mg twice daily for 6 weeks. Group B received itraconazole capsules 100 mg twice daily for 8 weeks. Group C received itraconazole tablets 200 mg once daily for 8 weeks. All patients additionally received topical luliconazole once daily, a 6% salicylic acid preparation at night, and daily ciclopirox shampoo wash.

The primary outcome was clinical cure at completion of 8 weeks of treatment, defined as complete disappearance of erythema, scaling, pruritus and active/advancing lesion borders. The secondary outcome was clinical relapse during six months of follow-up among patients who achieved clinical cure. Relapse was defined as reappearance of clinically compatible active tinea lesions after documented clinical cure.

At follow-up visits, patients were questioned about new symptoms and examined for clinically apparent adverse effects. Concomitant medicines were reviewed for clinically important itraconazole interactions. Leg oedema and headache were recorded when newly reported or observed during treatment and considered clinically significant when discontinuation was required. Suspected cardiac toxicity was recorded when new cardiac or cardiopulmonary symptoms/ signs prompted discontinuation on clinical safety grounds. No formal adverse-drug-reaction causality scale, systematic echocardiography or therapeutic drug monitoring was used; therefore, cardiac toxicity is reported as suspected rather than confirmed.

Categorical variables were expressed as frequencies and percentages. Cure and relapse rates were compared using Pearson's chi-square test. Relapse denominators comprised only patients who had achieved clinical cure. A two-sided p value <0.05 was considered statistically significant. Statistical analyses were performed using computational statistical methods, with categorical comparisons conducted using Pearson's chi-square test. Ethical considerations: The study was conducted in accordance with the Declaration of Helsinki and was approved by the Institutional Ethics Committee of Nexus Hospital Mymensingh (Approval No. NCHRL/ERC/2026/D-068 dated 01.11.2023). Written informed consent was obtained for treatment, follow-up, clinical documentation and use of anonymized clinical data. For participants younger than 18 years, parental/legal-guardian consent and age-appropriate assent were obtained.

Result

A total of 72 patients were enrolled; 12 discontinued for safety-related reasons and 60 completed the protocol and were included in the per-protocol efficacy analysis. Each treatment group contained 20 patients. There were 30 males and 30 females, and the age range was 15–50 years.

Table 1 Clinical cure at completion of treatment.

Treatment group	*Clinically cured*	*Not cured*	*Cure rate*
Group A	19	1	95%
Group B	16	4	80%
Group C	9	11	45%

Table 2 Relapse during six-month follow-up among clinically cured patients.

Treatment group	*Clinically cured*	*Relapsing*	*Relapse rate*
Group A	19	2	10.5%
Group B	16	5	31.3%
Group C	9	7	77.8%

Clinical cure was achieved in different groups in shown in **Table 1**. The difference among groups was statistically significant (χ^2=13.47, df=2, *P*=.001).

Among patients who achieved clinical cure, relapse during six months of follow-up occurred is shown in **Table 2** (χ^2=12.74, df=2, *P*=.002).

Table 3 shows Safety-related discontinuations among the 72 enrolled patients comprised leg oedema in 6 (8.3%), clinically relevant drug interactions in 3 (4.2%), headache in 2 (2.8%), and suspected cardiac toxicity in 1 (1.4%). Drug interactions were classified as safety-related exclusions rather than adverse drug reactions.

Discussion

The principal finding of this prospective non-randomized study was that the induction-maintenance capsule strategy was associated with the highest clinical cure rate (95%) and the lowest six-month relapse rate (10.5%).

Table 3 Safety-related reasons for discontinuation among 72 enrolled patients.

Reason	*n*	*%age*
Leg oedema	6	8.3%
Clinically relevant drug interactions	3	4.2%
Headache	2	2.8%
Suspected cardiac toxicity	1	1.4%
Total	12	16.7%



Figure 1 Before and after treatment (Group- A- Female).



Figure 2 Before and after treatment (Group- A- Male).

The conventional 100 mg twice-daily capsule strategy produced intermediate outcomes, while the once-daily 200 mg tablet strategy showed the lowest cure and highest relapse. These differences should be interpreted as associations because treatment allocation was based on clinical judgment and baseline disease severity was not quantified.

A recent Pakistani randomized study by Hafeez compared itraconazole with terbinafine in tinea corporis and reported greater four-week efficacy with itraconazole (52% versus 24%).6 Although its design and outcome timing differed from the present study, it supports the continuing clinical role of itraconazole in tinea corporis in the regional setting. A Pakistani study from Karachi also documented recalcitrant tinea corporis/ cruris and demonstrated substantial mycological positivity, emphasizing the importance of laboratory confirmation in difficult cases.[7]

Khurana *et al*. compared different itraconazole doses in tinea corporis/ cruris and found that higher daily dosing could produce faster or greater initial cure, although relapse remained an important problem.[8] This is broadly consistent with the present observation that the regimen with greater initial itraconazole exposure had the best clinical outcome. However, direct comparison is limited because the present study was non-randomized and relied on clinical rather than mycological cure.

Formulation and bioavailability may also influence treatment response. Studies comparing conventional and super-bioavailable itraconazole formulations have shown that differences in exposure and clinical response can occur.[9,10] Therefore, the poorer outcome observed in Group C should not be interpreted as evidence that all tablet formulations are intrinsically inferior to capsules, particularly because product bioequivalence and serum itraconazole concentrations were not evaluated.

The safety observations require cautious interpretation. Leg oedema was the most frequent reason for discontinuation, and one patient had suspected cardiac toxicity. Itraconazole has recognized negative inotropic potential and important drug-interaction liability. In this study, events were detected clinically without a standardized causality instrument or systematic cardiac investigation, so they should be considered pragmatic safety observations rather than confirmed itraconazole-attributable incidence estimates.

Strengths of this study include its real-world design, comparison of three commonly used treatment strategies, and six-month follow-up for relapse. Limitations include the small pragmatic sample without formal power calculation, non-randomized allocation, per-protocol analysis, lack of validated baseline severity scoring, absence of routine KOH/ culture or susceptibility testing, lack of therapeutic drug monitoring, unmeasured adherence, and inability to separate the contribution of adjunctive topical therapy. Larger randomized studies using standardized formulations, objective mycological outcomes and intention-to-treat analysis are recommended.

Conclusion

The induction–maintenance itraconazole capsule strategy was associated with the highest clinical cure and lowest six-month relapse in this non-randomized cohort. The findings are hypothesis-generating and should be confirmed by adequately powered randomized studies with mycological confirmation and standardized formulations.

Declaration of patient consent Authors certify that they have obtained all appropriate patient consent.

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Conflict of interest No conflict of interest.

Author's contribution

MHR: Concept, literature search, figures, study design, data collection, data analysis, data interpretation, writing manuscript. Has given final approval of the manuscript version to be published and agreed to be accountable for all aspects of the work.

References

1. Verma S, Madhu R. The great Indian epidemic of superficial dermatophytosis: an appraisal. *Indian J Dermatol*. 2017;**62**:227-36.
2. Nenoff P, Verma SB, Vasani R, Burmester A, Hipler UC, Wittig F, *et al*. The current Indian epidemic of superficial dermatophytosis due to Trichophyton mentagrophytes: a molecular study. *Mycoses*. 2019;**62**:336-56.
3. Rajagopalan M, Inamadar A, Mittal A, Miskeen AK, Srinivas CR, Sardana K, *et al*. Expert consensus on the management of dermatophytosis in India. *BMC Dermatol*. 2018;**18(1)**:6.
4. Saunte DML, Hare RK, Jørgensen KM, Jørgensen R, Deleuran M, Zachariae CO, et al. Emerging terbinafine resistance in Trichophyton: clinical characteristics, squalene epoxidase gene mutations, and a reliable EUCAST method for detection. *Antimicrob Agents Chemother*. 2019;**63**:e01126-19.
5. Uhrlaß S, Verma SB, Gräser Y, Rezaei-Matehkolaei A, Hatami M, Schaller M, *et al*. Trichophyton indotineae-an emerging pathogen causing recalcitrant dermatophytoses in India and worldwide. *J Fungi (Basel)*. 2022;**8**:757.
6. Hafeez S. Efficacy of terbinafine versus itraconazole in the treatment of tinea corporis. *J Pak Assoc Dermatol*. 2025;**35**:99-104.
7. Sajid M, Asim SA, Sadia, Iqbal T, Najam-us-Saher, Shaikh SS. Isolation and identification of fungal species in patients of recalcitrant tinea corporis and/or tinea cruris attending tertiary care hospital in Karachi. *J Pak Assoc Dermatol*. 2023;**33**:929-34.
8. Khurana A, Agarwal A, Agrawal D, Panesar S, Ghadlinge M, Sardana K, *et al*. Effect of different itraconazole dosing regimens on cure rates, treatment duration, safety, and relapse rates in adult patients with tinea corporis/cruris: a randomized clinical trial. *JAMA Dermatol*. 2022;**158**:1269-78.
9. Shenoy M, Dhoot D, Mahajan H, Barkate H. An open-label, randomized, double-arm clinical trial to compare the effectiveness and safety of super bioavailable itraconazole capsules and itraconazole capsules in the management of dermatophytosis in India. *Clin Cosmet Investig Dermatol*. 2021;**14**:1367-76.
10. Tyagi H, Goel S, Puri A, Singla I, Rathore A. Comparative Efficacy of Three Oral Itraconazole Formulations in Superficial Dermatophytosis. *Mycoses*. 2025 Jun;**68(6)**:e70080.