Comparative Efficacy and Safety of Super Bioavailable Itraconazole versus Conventional Itraconazole in the Treatment of Cutaneous Fungal Infections: A Study in A Tertiary Care Hospital, Cumilla, Bangladesh

Tahmina Sultana[1*], Ayesha Akter[2], Gazi Md Matiur Rahman[3]

ARTICLE INFO

Received: 13 July 2026
Accepted: 23 July 2026
Published Online: 27 July 2026

DOI: 10.5281/zenodo.21778200

Volume: 10, Number: 1, Page: 26-30

e-ISSN: 2789-5912
ISSN: 2617-0817

*Corresponding author

ABSTRACT

Background: Itraconazole is a widely used triazole antifungal agent for the treatment of superficial and systemic fungal infections. However, conventional itraconazole (C-ITZ) exhibits variable and often unpredictable oral bioavailability due to its dependence on gastric acidity, food intake and formulation characteristics. These limitations may result in subtherapeutic drug levels and treatment failure. SUBA-itraconazole (Super BioAvailable itraconazole; S-ITZ) is a novel formulation developed to enhance absorption and achieve more consistent plasma concentrations, independent of gastric pH. **Objective:** To compare the clinical efficacy, mycological cure rates, safety and tolerability of SUBA-itraconazole with conventional itraconazole in routine clinical practice. **Methods & Materials:** This prospective, open-label, comparative study was conducted in the Department of Dermatology and Venereology at Cumilla Medical College Hospital, Cumilla, Bangladesh, over a 12-month period from January 2024 to December 2024. A total of 100 adult patients with clinically and mycologically confirmed fungal infections were enrolled. Patients were equally divided into two groups: Group A received SUBA-itraconazole 65 mg twice daily, while Group B received conventional itraconazole 100 mg twice daily. Patients were evaluated at baseline and followed up at 4, 6, and 8 weeks. Clinical cure, mycological cure, time to symptom resolution, adverse events and liver and renal function parameters were assessed at each follow-up visit. **Results:** The SUBA-itraconazole group demonstrated a significantly higher complete clinical cure rate (88% vs. 68%) and mycological cure (86% vs. 66%). Patients treated with SUBA-itraconazole experienced faster symptom resolution (12.4 ± 3.1 days) compared to conventional itraconazole (18.7 ± 4.6 days). Adverse events were mild and comparable between groups. **Conclusion:** SUBA-itraconazole demonstrated superior clinical and mycological efficacy with faster symptom relief and a safety profile comparable to conventional itraconazole. Its improved and predictable bioavailability makes it a preferable therapeutic option for the management of fungal infections in routine clinical practice.

Keywords: *SUBA-Itraconazole, Conventional Itraconazole, Antifungal Therapy, Dermatophytosis, Fungal Infections, Bioavailability, Clinical Efficacy, Mycological Cure (KOH Microscopy) Safety and Tolera*bility.

1. *Associate Professor (Skin and VD), Cumilla Medical College, Cumilla, Bangladesh (ORCID: 0009-0007-2656-8648)*
2. *Associate Professor (Skin and VD), Cumilla Medical College, Cumilla, Bangladesh (ORCID: 0009-0001-4508-7360)*
3. *Associate Professor (Skin and VD), Cumilla Medical College, Cumilla, Bangladesh (ORCID: 0009-0004-0965-9722)*

INTRODUCTION

Fungal infections represent a significant and growing public health problem worldwide, affecting both immunocompetent and immunocompromised individuals. Superficial mycoses such as dermatophytosis are highly prevalent in tropical and subtropical regions, while systemic and invasive fungal infections contribute substantially to morbidity and mortality, particularly among patients with diabetes, malignancy or those receiving immunosuppressive therapy.[1] Effective antifungal therapy therefore remains a cornerstone of clinical management. Itraconazole a second-generation triazole antifungal agent, has been extensively used for the treatment of a broad spectrum of fungal infections, including dermatophytosis, candidiasis, aspergillosis and histoplasmosis. [2] Its mechanism of action involves inhibition of fungal cytochrome P450-dependent 14-α-demethylase, leading to impaired ergosterol synthesis and disruption of fungal cell membrane integrity. [3] Despite its broad antifungal coverage, the clinical use of conventional itraconazole (C-ITZ) has been limited by its erratic and highly variable oral bioavailability. The absorption of conventional itraconazole capsules depends on gastric acidity, food intake and formulation characteristics. Reduced gastric acidity, concomitant use of proton pump inhibitors and gastrointestinal disorders can significantly decrease itraconazole absorption resulting in subtherapeutic plasma concentrations and clinical failure. [4] Even itraconazole oral solution, although better absorbed than capsules, is associated with gastrointestinal intolerance and poor patient compliance. [5] These limitations have prompted the development of improved formulations with enhanced and more predictable bioavailability. SUBA-itraconazole (Super BioAvailable itraconazole) is a novel formulation utilizing a solid dispersion technology that enhances dissolution and absorption in the gastrointestinal tract, independent of gastric pH and food intake. [6] Pharmacokinetic studies have demonstrated that SUBA-itraconazole achieves higher and more consistent plasma concentrations compared with conventional itraconazole at equivalent doses. [7] Improved bioavailability may translate into better clinical outcomes, reduced inter-patient variability and potentially lower rates of treatment failure.Although pharmacokinetic advantages of SUBA-itraconazole are well documented, real-world clinical data comparing its effectiveness and safety with conventional itraconazole remain limited, particularly in routine clinical practice settings. Comparative clinical studies are essential to determine whether improved bioavailability results in meaningful clinical benefits. The present study was therefore undertaken to compare SUBA-itraconazole and conventional itraconazole in terms of clinical efficacy, mycological cure rates, safety profile and tolerability among 100 patients with fungal infections managed in everyday clinical practice.

METHODS & MATERIALS

Study Design and Setting

This prospective, open-label, comparative study was conducted in the Department of Dermatology and Venereology at Cumilla

Medical College Hospital, Cumilla, Bangladesh, over a 12-month period from January 2024 to December 2024.

Study Population
A total of 100 patients aged 18–65 years with clinically and KOH microscopy confirmed fungal infections were enrolled. Informed consent was obtained from all participants. Patients were divided into two equal groups of 50 each.

Inclusion Criteria
- Confirmed diagnosis of cutaneous fungal infection
- Willingness to provide informed consent and comply with study protocol

Exclusion Criteria
- Severe hepatic or renal impairment
- Pregnant or lactating women
- Known hypersensitivity to itraconazole
- Concurrent use of drugs with major interactions with itraconazole

Intervention
- **Group A (SUBA-Itraconazole):** Received SUBA-itraconazole 65 mg twice daily
- **Group B (Conventional Itraconazole):** Received conventional itraconazole 100 mg twice daily

Treatment duration ranged from 4 to 8 weeks depending on clinical indication.

Outcome Measures
Primary outcome was clinical cure, defined as complete resolution of signs and symptoms. Secondary outcomes included mycological cure (defined as negative KOH microscopy), time to symptom resolution and incidence of adverse events.

Follow-up and Assessment
- Patients were evaluated at baseline, 4 weeks, 6 weeks, and 8 weeks for clinical progress and KOH microscopy.
- Liver function tests and renal function tests were performed at baseline and at every follow-up visit to monitor safety.

Statistical Analysis
Data were analyzed using descriptive statistics. Categorical variables were compared using chi-square test, with $p < 0.05$ considered statistically significant.

Ethical Considerations
Ethical approval was obtained from the Institutional Ethics Committee (IEC) of Cumilla Medical College, Cumilla, Bangladesh, before the commencement of the study. Written informed consent was obtained from all participants. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Participant confidentiality and privacy were strictly maintained, and all collected data were used solely for research purposes.

RESULTS

Baseline Characteristics
A total of 100 patients with clinically and mycologically confirmed cutaneous fungal infections were enrolled and equally allocated to the SUBA-itraconazole and conventional itraconazole groups (n = 50 each). The age distribution was comparable between the two groups. The majority of participants (33%) were aged 31–40 years, followed by 18–30 years (27%), 41–50 years (23%), and >50 years (17%) (*Table I*).

Table I
Age Distribution of Patients.

Age Group (years)	SUBA-ITZ (n=50)	Conventional ITZ (n=50)	Total (n=100)
18–30	14 (28%)	13 (26%)	27 (27%)
31–40	16 (32%)	17 (34%)	33 (33%)
41–50	12 (24%)	11 (22%)	23 (23%)
>50	8 (16%)	9 (18%)	17 (17%)

Male participants predominated in both treatment groups. Overall, 61% of the study population were male and 39% were female with similar gender distribution between the SUBA-itraconazole and conventional itraconazole groups indicating comparable baseline characteristics (*Table II*).

Table II
Gender Distribution.

Gender	SUBA-ITZ	Conventional ITZ	Total
Male	31 (62%)	30 (60%)	61 (61%)
Female	19 (38%)	20 (40%)	39 (39%)

Dermatophytosis was the predominant diagnosis among all enrolled patients. Tinea corporis was the most common clinical presentation (45%), followed by tinea cruris (31%) and tinea faciei (24%). The distribution of fungal infections was comparable between the two treatment groups (*Table III*).

Table III
Type of Fungal Infection.

Diagnosis	SUBA-ITZ (n=50)	Conventional ITZ (n=50)	Total
Tinea corporis	23(46%)	22 (44%)	45 (45%)
Tinea cruris	16 (32%)	15 (30%)	31 (31%)
Tinea faciei	11(22%)	13 (26%)	24 (24%)

Clinical Outcomes
Patients receiving SUBA-itraconazole achieved a significantly higher complete clinical cure rate (88%) than those treated with conventional itraconazole (68%). Partial clinical improvement occurred in 8% of patients receiving SUBA-itraconazole compared with 20% in the conventional itraconazole group, whereas treatment failure was lower in the SUBA group (4% vs. 12%) (*Table IV*, *Figure 1*).

Table IV
Overall Clinical Response.

Response	SUBA-ITZ	Conventional ITZ
Complete cure	44 (88%)	34 (68%)
Partial improvement	4 (8%)	10 (20%)
No response	2 (4%)	6 (12%)

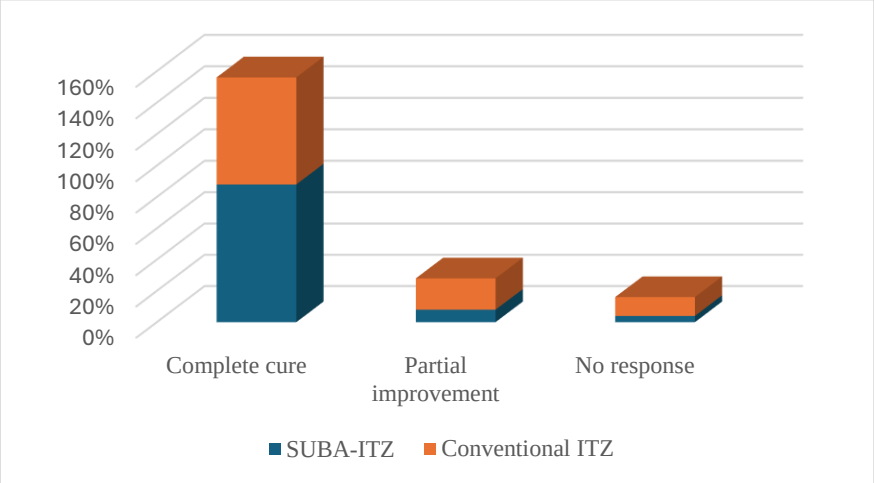

Figure 1 Distribution of Clinical Response Between SUBA Itraconazole and Conventional Itraconazole.

When analyzed according to the type of fungal infection, SUBA-itraconazole consistently demonstrated higher clinical cure rates across all diagnostic categories. Cure rates were highest in patients with tinea cruris (92%), followed by tinea corporis (89%) and tinea faciei (83%), whereas the corresponding cure rates in the conventional itraconazole group were 73%, 71%, and 67%, respectively (*Table V*).

Table V
Clinical Cure by Diagnosis.

Diagnosis	SUBA-ITZ Cure (%)	Conventional ITZ Cure (%)
Tinea corporis	89	71
Tinea cruris	92	73
Tinea faciei	83	67

Patients treated with SUBA-itraconazole experienced significantly faster symptom resolution than those receiving conventional itraconazole. The mean time to complete symptom relief was 12.4 ± 3.1 days in the SUBA-itraconazole group compared with 18.7 ± 4.6 days in the conventional itraconazole group (*Table VI*).

Table VI
Mean Time to Symptom Resolution.

Group	Mean ± SD (days)
SUBA-ITZ	12.4 ± 3.1
Conventional ITZ	18.7 ± 4.6

Mycological cure, confirmed by negative KOH microscopy, was achieved in 86% of patients receiving SUBA-itraconazole compared with 66% of those treated with conventional itraconazole. Persistent fungal positivity remained substantially lower in the SUBA-itraconazole group indicating superior mycological efficacy (*Table VII*).

Table VII
Mycological Cure Rates.

Outcome	SUBA-ITZ	Conventional ITZ
Negative microscopy	43 (86%)	33 (66%)
Persistent positivity	7 (14%)	17 (34%)

Safety Profile
Both treatment regimens were generally well tolerated. Adverse events were mild and self-limiting in both groups. Nausea and abdominal discomfort were the most frequently reported adverse events. Mild elevation of liver enzymes occurred in one patient (2%) in the SUBA-itraconazole group and two patients (4%) in the conventional itraconazole group. No abnormalities in renal function were observed and no serious adverse events or treatment discontinuations occurred during the study period (*Table VIII*).

Table VIII
Adverse Events Profile.

Adverse Event	SUBA-ITZ (n=50)	Conventional ITZ (n=50)
Nausea	3 (6%)	5 (10%)
Abdominal discomfort	2 (4%)	4 (8%)
Headache	2 (4%)	3 (6%)
Elevated liver enzymes	1 (2%)	2 (4%)
Abnormal renal function	0 (0%)	0 (0%)

DISCUSSION

Superficial fungal infections remain a major public health concern, particularly in tropical and subtropical regions, due to their chronicity, high recurrence rates, and increasing resistance to conventional antifungal therapies. The present comparative study demonstrates that SUBA-itraconazole provides superior clinical and mycological outcomes compared with conventional itraconazole in routine clinical practice. Itraconazole has long been a cornerstone in the systemic management of dermatophytosis; however, variable bioavailability and erratic absorption have limited its clinical effectiveness in real-world settings. The present study evaluated the clinical efficacy, mycological outcomes and safety profile of super bioavailable itraconazole (SUBA ITZ) in comparison with conventional itraconazole formulations. The demographic characteristics of the study population were comparable between both treatment arms with the majority of patients belonging to the 31–40-year age group and a male predominance. This demographic pattern is consistent with previous epidemiological studies, which have shown higher prevalence of dermatophytosis among young and middle-aged adults, possibly due to increased physical activity, occupational exposure and excessive sweating.[4] Dermatophytosis constituted the majority of fungal infections in the present study, with tinea corporis and tinea cruris being the most common clinical presentations. This distribution aligns with recent reports from India and other tropical regions, where these clinical types predominate due to favorable climatic conditions and widespread topical steroid misuse. [5] A key finding of this study was the significantly higher rate of complete clinical cure observed with SUBA itraconazole (88%) compared to conventional itraconazole (68%). Additionally, lower rates of partial response and treatment failure were noted in the SUBA ITZ group. These findings support the premise that enhanced and predictable bioavailability of SUBA itraconazole translates into superior clinical outcomes. Conventional itraconazole capsules are highly dependent on gastric acidity and food intake for absorption, leading to interpatient variability, whereas SUBA itraconazole employs a solid dispersion technology that improves solubility and systemic exposure.[6] Across all diagnostic subgroups, SUBA itraconazole demonstrated consistently higher cure rates, including in difficult-to-treat infections such as tinea unguium. Nail infections often require prolonged therapy and higher drug concentrations at the site of infection. Improved tissue penetration and sustained plasma levels achieved with SUBA itraconazole may account for its enhanced efficacy in these cases. [7] The mean time to symptom resolution was significantly shorter in patients receiving SUBA itraconazole, suggesting a faster onset of action. Early symptom relief is clinically important as it improves patient compliance, reduces disease transmission and minimizes inappropriate use of topical corticosteroids. Similar findings of faster clinical response with SUBA itraconazole have been reported in earlier pharmacokinetic and clinical studies. [8-12] Mycological cure rates further substantiated the clinical findings, with 86% of patients in the SUBA itraconazole group achieving negative KOH microscopy results, compared to 66% in the conventional group. Mycological clearance, confirmed by negative microscopy is essential to prevent relapse and chronicity, which have become increasingly common in dermatophytosis. The higher mycological cure rates observed with SUBA itraconazole may help address the growing problem of recalcitrant fungal infections. [13] Both formulations were well tolerated, with only mild adverse events reported. Gastrointestinal symptoms were the most common side effects, and mild elevations in liver enzymes were infrequent and transient. No significant renal impairment or hypertensive complications were observed during the treatment period, further establishing the tolerability of both formulations. Importantly, no serious adverse events or treatment discontinuations occurred, confirming the favorable safety profile of SUBA itraconazole. These findings are consistent with previously published safety data. [14,15] Limitations of the study include the relatively small sample size and open-label design. Larger randomized controlled trials with therapeutic drug monitoring would further strengthen the evidence base.

CONCLUSION

SUBA-itraconazole demonstrated superior clinical efficacy, faster symptom resolution, and higher mycological cure rates compared with conventional itraconazole. The safety profile remained comparable, with no adverse impact on liver or renal functions noted across the follow-up periods. Its improved and predictable bioavailability, combined with a robust safety monitoring protocol makes it a valuable advancement in antifungal therapy for routine clinical practice.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this study.

SOURCE OF FUNDING

This research received no external funding and was conducted with institutional support only.

ACKNOWLEDGMENT

The authors gratefully acknowledge the support of the Department of Dermatology and Venereology, Cumilla Medical College, the participating patients and all physicians, nursing staff and laboratory personnel who contributed to patient management, data collection and laboratory investigations throughout the study.

REFERENCES

1. World Health Organization. WHO fungal priority pathogens list to guide research, development and public health action. Geneva: WHO; 2022.
2. Gupta AK, Cooper EA. Itraconazole: pharmacokinetics, mechanism of action, and clinical applications. J Am Acad Dermatol. 2008;58(5):805–816.
3. Odds FC, Brown AJP, Gow NAR. Antifungal agents: mechanisms of action. Trends Microbiol. 2003;11(6):272–279.
4. Barone JA, Moskovitz BL, Guarnieri J, et al. Enhanced bioavailability of itraconazole in hydroxypropyl-β-cyclodextrin solution versus capsules in healthy volunteers. Antimicrob Agents Chemother. 1998;42(7):1862–1865.
5. Hardin TC, Graybill JR, Fetchick R, et al. Pharmacokinetics of itraconazole following oral administration to normal volunteers. Antimicrob Agents Chemother. 1988;32(9):1310–1313.
6. Hossain MA, Ahmad S, Haseeb A. Development and evaluation of super bioavailable itraconazole

(SUBA-itraconazole). Drug Dev Ind Pharm. 2017;43(9):1524–1532.
7. Gupta AK, Daigle D. Comparative pharmacokinetics of SUBA-itraconazole and conventional itraconazole capsules. Mycoses. 2018;61(7):485–492.
8. Hay RJ, Ashbee HR. Fungal infections. BMJ. 2017;356: j128.
9. Nenoff P, Verma SB, Ebert A, et al. Recalcitrant dermatophytosis: causes, challenges, and management strategies. Clin Dermatol. 2021;39(3):389–399.
10. Lewis RE. Current concepts in antifungal pharmacology. Mayo Clin Proc. 2011;86(8):805–817.
11. Korting HC, Ollert M, Abeck D. Results of oral antifungal therapy in dermatophytosis. Mycoses. 1995;38(5–6):189–195.
12. Verma S, Madhu R. The great Indian epidemic of superficial dermatophytosis. Indian J Dermatol. 2017;62(3):227–236.
13. Ryder NS. Activity of itraconazole against dermatophytes. J Med Vet Mycol. 1993;31(S1):147–150.
14. Katz HI, Gupta AK. Itraconazole in the treatment of tinea corporis and tinea cruris. Int J Dermatol. 1995;34(4):256–260.
15. Perea S, Patterson TF. Antifungal resistance in dermatophytes and clinical implications. Clin Infect Dis. 2002;35(11):1387–1391.