Section: Pharmacology

Original Research Article

TO EVALUATE THE EFFICACY, SAFETY & PHARMACOECONOMICS OF ORAL ITRACONAZOLE & ORAL TERBINAFINE IN TREATING TINEA PATIENTS

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ABSTRACT

Background: Tinea is a prevalent superficial fungal infection with rising cases of resistance and relapse, necessitating evaluation of systemic therapies for efficacy, safety, and cost-effectiveness. **Aim & Objective:** To compare oral itraconazole and oral terbinafine in terms of clinical and mycological efficacy, adverse effects, and pharmacoeconomic profiles in patients with dermatophytosis. **Materials and Methods:** In this prospective, randomized, open-label study, 103 microscopically confirmed tinea patients were assigned to receive either itraconazole (100 mg twice daily) or terbinafine (250 mg once daily) for eight weeks. Clinical assessments (scaling, pruritus, erythema) were conducted at 2, 4, and 8 weeks. Mycological cure was determined via potassium hydroxide (KOH) microscopy. Adverse drug reactions (ADRs) and liver function tests were monitored, and drug costs were analyzed for pharmacoeconomic evaluation. **Results:** Both drugs achieved significant clinical improvement by week 8. Terbinafine showed faster symptomatic relief (e.g., 80.77% pruritus resolution vs. 45.10% with itraconazole; $p<0.01$), while itraconazole had a higher mycological cure rate (78.85% vs. 60.78%; $p=0.03$). ADRs were mild and comparable across groups, with dizziness and rash being most frequent. Terbinafine was more cost-effective per unit dose, whereas itraconazole offered sustained cure in potentially resistant cases. **Conclusion:** Both treatments are effective and well-tolerated. Terbinafine offers rapid symptom relief and lower cost, whereas itraconazole may be preferred in recurrent or resistant cases due to its sustained efficacy. Clinical choice should be individualized based on patient profile and local resistance patterns.

INTRODUCTION

Tinea, commonly referred to as dermatophytosis, is one of the most prevalent superficial fungal infections affecting humans worldwide. It is caused by dermatophytes, keratinophilic fungi that invade keratinized tissues such as skin, hair, and nails. These fungi belong predominantly to three genera: Trichophyton, Microsporum, and Epidermophyton, with nearly 30 species identified as pathogenic to humans.[1] Owing to their ability to utilize keratin as a nutrient source, dermatophytes establish persistent infections that often require prolonged treatment.

Dermatophytosis represents a significant global health burden, with an estimated 20–25% of the world's population affected at any given time.[2] The prevalence is notably higher in tropical and subtropical regions due to favorable climatic conditions such as heat and humidity, coupled with overcrowding, poor hygiene, and limited access to healthcare.[3] In India, dermatophytosis has emerged as a major public health concern, with an increasing number of chronic, recurrent, and treatment-resistant cases reported over the past decade.[4] Traditionally, Trichophyton rubrum has been the most common etiological agent; however, recent studies from India indicate a rising predominance of T. mentagrophytes/ T. interdigitale complex, which has been associated with more extensive disease and reduced responsiveness to standard antifungal therapy.[5]

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Clinically, tinea infections present with pruritic, erythematous, scaly, annular lesions and are classified based on anatomical involvement, including tinea corporis, tinea cruris, tinea pedis, and tinea capitis. Chronicity and recurrence are increasingly observed, often linked to irrational use of topical corticosteroid–antifungal combinations, poor treatment adherence, and host-related factors.[4] These infections significantly impair quality of life and impose a considerable socioeconomic burden.

Systemic antifungal therapy is indicated in extensive, recurrent, or refractory cases. Oral terbinafine, an allylamine antifungal, acts by inhibiting squalene epoxidase, leading to ergosterol depletion and fungal cell death, and has long been considered a first-line agent for dermatophytosis.[6] Oral itraconazole, a triazole antifungal, inhibits cytochrome P450-dependent ergosterol synthesis and demonstrates broad-spectrum activity against dermatophytes with favorable tissue penetration.[7] Both agents are widely prescribed in clinical practice; however, recent reports have highlighted variable treatment outcomes, concerns regarding safety, drug interactions, and rising antifungal resistance.[5,8] In addition to clinical efficacy and safety, the pharmacoeconomic impact of antifungal therapy is of growing importance, particularly in resource-limited settings where long treatment durations and relapse increase healthcare costs. Comparative evaluation of itraconazole and terbinafine with respect to efficacy, safety, and cost-effectiveness is therefore essential to guide rational drug selection and optimize management strategies for tinea infections.

Tinea is classified according to the site involved, such as tinea corporis (body), tinea cruris (groin), and tinea capitis (scalp), with intertriginous areas including the groins and toe webs being particularly susceptible due to moisture retention and an alkaline pH. Predisposing factors include warm and humid climates, poor personal hygiene, tight clothing, and occlusive footwear, while transmission occurs through direct contact or autoinfection. Clinically, tinea corporis typically presents as annular, pruritic, erythematous, scaly plaques with central clearing and active margins, and may be misdiagnosed as eczema, psoriasis, or seborrheic dermatitis. Accurate diagnosis depends on proper sampling, with skin scrapings obtained from the active lesion margin and transported in sterile black chart paper; a 10–20% potassium hydroxide preparation allows rapid bedside confirmation by demonstrating septate hyphae, although false-negative results can occur in up to 15% of cases. Treatment is guided by disease extent and severity, with topical antifungals being adequate for localized infections, while systemic therapy is indicated for extensive, recurrent, or treatment-resistant disease.[7] Terbinafine is considered first-line therapy owing to its high cure rates exceeding 90% and minimal drug interactions, acting through inhibition of squalene epoxidase to disrupt ergosterol synthesis, and is commonly administered at a dose of 250 mg daily for two weeks. Itraconazole serves as an effective alternative by inhibiting cytochrome P450–dependent ergosterol synthesis, with recommended regimens of 100 mg daily for two weeks or 200 mg daily for seven days, though its use may be associated with gastrointestinal discomfort, dizziness, gynecomastia, and occasional hepatotoxicity.[8]

Therefore, the present study was undertaken to evaluate and compare the efficacy, safety, and pharmacoeconomic profiles of oral itraconazole and oral terbinafine in patients with clinically and microscopically confirmed tinea infections. Clinical efficacy was assessed based on improvements in erythema, pruritus, and scaling over an eight-week treatment period, while mycological cure was determined using potassium hydroxide (KOH) microscopy at the end of therapy. Safety and tolerability were evaluated by monitoring adverse drug reactions during follow-up visits. Additionally, a comparative pharmacoeconomic analysis was performed considering drug costs and treatment outcomes, with the aim of providing evidence-based therapeutic guidance tailored to disease severity, recurrence, and local antifungal resistance patterns.

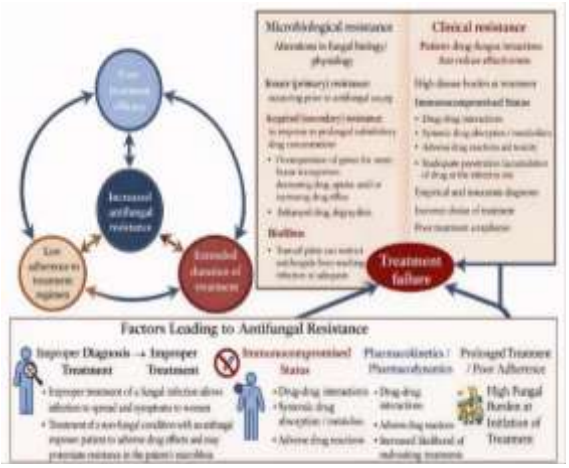

Figure 1: Schematic of antifungal resistance mechanisms and treatment failure in dermatophyte-osis.[24] Adapted from Gupta et al., 2024

MATERIALS AND METHODS

Research design

This prospective, randomized, open-label, comparative study was conducted in the Department of Pharmacology in collaboration with the Department of Dermatology at Maharani Laxmi Bai Medical College, Jhansi. A total of 128 clinically and microscopically confirmed patients of dermatophytosis were enrolled and allocated equally into two treatment groups. The study was carried out over a period of one and a half years following institutional ethics approval.

Inclusion Criteria

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- Clinically diagnosed and microscopically confirmed cases of tinea cruris, corporis, faciei, manus, pedis and unguium.
- Patients aged between 18-60 years of both genders.
- Patient who had provided their informed consent.

Exclusion Criteria

- Pregnant women or lactating mothers.
- Patient with a history of drug reaction or allergy to any drug.
- Patients missing at least two follow-ups at 2,4,8 weeks.
- Patients with medical illnesses like diabetes and hypertension.
- Patients who have not provided their informed consent.

Procedure

All enrolled cases underwent detailed history taking, including demographic information, assessment of presenting complaints, and evaluation of associated medical or surgical conditions, followed by a comprehensive clinical examination to assess the extent of lesions, associated symptoms, and to rule out systemic diseases. Patients meeting the inclusion criteria provided informed written consent and subsequently underwent sample collection for microbiological confirmation. Skin scrapings were obtained using a No. 15 scalpel blade or the edge of a glass slide, placed on a glass slide, treated with two drops of 10–20% potassium hydroxide, and examined immediately under a microscope by a microbiologist, with each smear assessed at baseline and at eight weeks. Diagnosis was initially clinical and confirmed microbiologically. Confirmed patients were randomly assigned to Group A (oral itraconazole 100 mg twice daily for eight weeks) or Group B (oral terbinafine 250 mg once daily for eight weeks). Follow-up assessments were conducted at two, four, and eight weeks, during which clinical evaluation was performed using a clinical severity score for dermatophytosis, assessing erythema, pruritus, and scaling (graded as absent, mild, moderate, or severe). Adverse drug reactions were recorded at each visit, liver function tests were repeated at the four-week visit, and patients missing at least two follow-ups or showing liver enzymes exceedingly twice the normal values at the third visit were excluded. Standardized clinical photographs were taken at each visit for comparative assessment. Treatment efficacy was defined as complete cure, comprising both clinical resolution and negative potassium hydroxide microscopy at eight weeks, while treatment failure referred to less than 50% clinical improvement after four weeks or the appearance of new or progressive lesions during therapy.

Plan for data analysis

All the available data were uploaded to a Microsoft Excel spreadsheet and analyzed by Statistical Package for Social Science (SPSS version 22) in Windows format. The continuous variables were represented as mean, standard deviation, and percentage. Categorical variables were calculated by the chi-square test, and values of p (<0.05) were considered significant.

Ethical considerations

The study was approved by the M.L.B. Medical College Institutional Review Board. Informed consent was obtained from each of the patients fulfilling the inclusion criteria before their enrolment in the study.

RESULTS

The study presents a detailed comparison of oral terbinafine and itraconazole across five key domains. Demographically, participants were mostly aged 30–44 years (48.54%) and predominantly male (65.05%). [Table 1] Clinical involvement was highest in the inner thighs (80.58%) and legs (78.64%), with nearly equal distribution between small (<5 cm) and medium (5–10 cm) lesion sizes. [Table 2] Symptomatically, itraconazole (Group A) showed more rapid clinical improvement in scaling, pruritus, and erythema across the 2nd and 3rd follow-ups, with statistically significant differences favoring terbinafine (Group B) only for scaling and erythema by week 8 (p<0.01 and p=0.002, respectively). [Table 3] Safety profiles were comparable, with dizziness and rash being the most reported adverse effects in both groups, and no serious adverse events were recorded. [Table 4] Notably, itraconazole achieved a higher mycological cure rate (78.85%) compared to terbinafine (60.78%), with statistical significance (p=0.03), highlighting itraconazole's superior long-term fungal clearance. [Table 5]

Table 1: Demographic Distribution of Study Participants

Paramters	Frequency	Percentage
Age (in years)		
18-29 years	41	39.81%
30-44 years	50	48.54%
45-59 years	8	7.77%
>60 years	4	3.88%
Gender distribution		
Male	67	65.05%
Female	36	34.95%

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Table 2: Clinical Characteristics of Affected Body Parts

Parameters	Frequency	Percentage
Body Parts		
Chest	12	11.65%
Hands	48	46.60%
Face	25	24.27%
Inner thighs	83	80.58%
Legs	81	78.64%
Trunk	63	61.17%
Size of affected body part		
< 5 cm	44	42.78%
5-10 cm	43	41.75%
>10 cm	16	15.53%

Table 3: Clinical Assessment of Symptoms (Scaling, Pruritus, Erythema) Over Follow-Up Periods

Parameters	Group A (n=52)		Group B (n=51)		Chi-square	p-value
	Frequency	Percentage	Frequency	Percentage		
SCALING						
1st Follow-up						
Mild	18	34.62%	20	39.22%	2.565	0.46
Moderate	26	50.00%	23	45.10%		
Severe	6	11.54%	8	15.69%		
Absent	2	3.85%	0	0.00%		
2nd Follow-up						
Mild	7	13.46%	16	31.37%	10.267	0.01
Moderate	15	28.85%	18	35.29%		
Severe	4	7.69%	6	11.76%		
Absent	26	50.00%	11	21.57%		
3rd Follow-up						
Mild	3	5.77%	12	23.53%	17.081	0.006
Moderate	8	15.38%	16	31.37%		
Severe	2	3.85%	5	9.80%		
Absent	39	75.00%	18	35.29%		
PRURITIS						
1st Follow-up						
Mild	24	46.15%	20	39.22%	0.507	0.47
Moderate	28	53.85%	31	60.78%		
Severe	0	0.00%	0	0.00%		
Absent	0	0.00%	0	0.00%		
2nd Follow-up						
Mild	8	15.38%	15	29.41%	13.601	0.003
Moderate	14	26.92%	19	37.25%		
Severe	0	0.00%	4	7.84%		
Absent	30	57.69%	13	25.49%		
3rd Follow-up						
Mild	3	5.77%	11	21.57%	15.026	0.001
Moderate	7	13.46%	15	29.41%		
Severe	0	0.00%	2	3.92%		
Absent	42	80.77%	23	45.10%		
ERYTHEMA						
1st Follow-up						
Mild	9	17.31%	15	29.41%	4.179	0.24
Moderate	27	51.92%	20	39.22%		
Severe	14	26.92%	11	21.57%		
Absent	2	3.85%	5	9.80%		
2nd Follow-up						
Mild	5	9.62%	13	25.49%	9.245	0.02
Moderate	14	26.92%	17	33.33%		
Severe	7	13.46%	9	17.65%		
Absent	26	50.00%	12	23.53%		
3rd Follow-up						
Mild	2	3.85%	8	15.69%	14.179	0.002
Moderate	6	11.54%	15	29.41%		
Severe	3	5.77%	6	11.76%		
Absent	41	78.85%	22	43.14%		

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Table 4: Incidence of Adverse Drug Reactions (ADRs) During Follow-Up

Safety (ADRs)	Group A (Post Treatment) (n=52)		Group B (Post Treatment) (n=51)	
	Frequency	Percentage	Frequency	Percentage
1st Follow-up				
Nausea	1	1.92%	1	1.96%
Abdominal pain	0	0.00%	0	0.00%
Diarrhea	4	7.69%	0	0.00%
Headache	5	9.62%	7	13.73%
Rash	5	9.62%	9	17.65%
Dizziness	8	15.38%	13	25.49%
2nd Follow-up				
Nausea	1	1.92%	1	1.96%
Abdominal pain	0	0.00%	0	0.00%
Diarrhea	0	0.00%	0	0.00%
Headache	4	7.69%	7	13.73%
Rash	5	9.62%	9	17.65%
Dizziness	8	15.38%	13	25.49%
3rd Follow-up				
Nausea	1	1.92%	1	1.96%
Abdominal pain	0	0.00%	0	0.00%
Diarrhea	0	0.00%	0	0.00%
Headache	4	7.69%	7	13.73%
Rash	5	9.62%	9	17.65%
Dizziness	8	15.38%	13	25.49%

Table 5: Mycological Cure Based on KOH Evaluation After 8 Weeks of Treatment

KOH Evaluation	Group A (n=52)		Group B (n=51)		Chi-square	p-value
	Frequency	Percentage	Frequency	Percentage		
Positive	11	21.15%	21	41.18%	4.514	0.03
Negative	41	78.85%	31	60.78%		

DISCUSSION

The present randomized, prospective, open-label comparative study evaluated the efficacy, safety, and pharmacoeconomics of oral itraconazole and oral terbinafine in the treatment of clinically and microscopically confirmed cases of tinea corporis, cruris, faciei, manus, pedis, and unguium. Both drugs demonstrated significant clinical improvement in lesion resolution, pruritus reduction, and pigmentation clearance by the end of eight weeks, with variable patterns of early response. These findings add to the growing body of evidence supporting systemic antifungal therapy amid changing epidemiological patterns, increasing resistance, and the need for cost-effective management strategies in dermatophytosis.[11,12]

In terms of efficacy, both itraconazole and terbinafine achieved high clinical and mycological cure rates by the end of therapy, although the temporal profile of improvement differed. Patients receiving terbinafine showed more rapid symptomatic relief within the first two to four weeks, consistent with its fungicidal action and rapid accumulation in the stratum corneum and sebum.[13] Itraconazole, which is primarily fungistatic against dermatophytes, demonstrated a slower but sustained response, attributable to its prolonged persistence in keratinized tissues.[14] Similar trends have been reported in comparative clinical studies, wherein early symptomatic improvement favored terbinafine, while final cure rates were comparable between the two agents.[15]

Our findings are consistent with Shah et al., who reported comparable cure rates with terbinafine (84.2%) and itraconazole (81.5%) without statistically significant differences.[16] Conversely, other studies have documented superior outcomes with itraconazole, particularly in chronic or recalcitrant dermatophytosis.[17,18] Such variability may be explained by differences in dosing regimens, treatment duration, local resistance patterns, and patient adherence. In the present study, standardized dosing minimized protocol-related bias.

Emerging antifungal resistance, particularly to terbinafine, has been increasingly reported from India and other regions. Several studies have identified terbinafine-resistant Trichophyton species, especially T. indotineae, associated with mutations in the squalene epoxidase gene.[19,20] While itraconazole resistance remains relatively uncommon, ongoing surveillance is essential. In our cohort, terbinafine maintained satisfactory efficacy, suggesting that resistance prevalence in our region may still be moderate.

Both drugs were generally well tolerated. Gastrointestinal symptoms were the most frequently reported adverse effects, while mild, transient elevations in liver enzymes were observed in a small number of patients without clinical sequelae. This safety profile is consistent with earlier reports describing low hepatotoxicity rates for terbinafine and a 1–5% incidence of asymptomatic transaminase elevation with itraconazole.[21,22]

Pharmacoeconomic analysis revealed that terbinafine was associated with a lower average daily treatment cost. However, itraconazole may

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offer superior cost-effectiveness in chronic or resistant cases by reducing relapse rates and repeated treatment courses.[18,23] These findings highlight the importance of tailoring therapy to local epidemiological and economic contexts.

CONCLUSION

Both itraconazole and terbinafine are effective, safe, and well-tolerated options for treating various forms of tinea. Terbinafine offers faster symptom relief and lower treatment costs, while itraconazole may provide better long-term outcomes in cases of resistance or recurrence. The optimal choice should be individualized based on clinical presentation, patient history, and cost-effectiveness.

Limitations: This study was limited by its single-center design and modest sample size, which may affect the generalizability of the findings to other populations. Fungal species identification and antifungal susceptibility testing were not performed, preventing precise evaluation of strain-specific resistance patterns. Follow-up was restricted to the treatment period, so long-term relapse rates could not be assessed. Adherence to medication and lifestyle modifications was based on patient reporting, which may introduce bias.

Suggestion

Terbinafine should be preferred for uncomplicated, acute tinea infections because of its rapid symptomatic relief and cost-effectiveness, whereas itraconazole is better suited for chronic, recurrent, or potentially resistant cases owing to its sustained antifungal activity and superior tissue retention. Liver function should be assessed before initiation and monitored during therapy, particularly with itraconazole or prolonged terbinafine use. Microbiological confirmation is essential prior to starting systemic antifungals to prevent inappropriate use and limit the development of antifungal resistance. In addition, patient education regarding strict treatment adherence, avoidance of steroid-containing topical preparations, and maintenance of proper personal hygiene is crucial to reduce treatment failure and relapse.

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