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COMPARATIVE STUDY OF SAFETY AND EFFICACY OF ORAL ITRACONAZOLE VERSUS FLUCONAZOLE IN THE TREATMENT OF SUPERFICIAL DERMATOPHYTOSIS

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Abstract:

Background:

With increasing resistance to antifungals in India, evaluating the effectiveness of current treatments is crucial. This study compared the efficacy and safety of oral itraconazole and fluconazole in superficial dermatophytosis, a common fungal skin infection.

Materials and Methods:

A prospective observational study was conducted with 200 newly diagnosed dermatophytosis patients. Group I (100 patients) received itraconazole 200 mg daily, and Group II (100 patients) received fluconazole 150 mg every alternate day, both for 4 weeks. Baseline parameters were measured. Follow-up evaluations were conducted at 2 and 4 weeks. Clinical improvement assessed via the Dermatophytosis Severity Score (DSS) and percentage improvement of erythema, pruritus, scaling, and raised borders, were measured. Safety was evaluated by adverse drug reactions (ADRs).

Results:

Group I showed significantly better results compared to Group II. By the 2nd follow-up, 84% of patients in Group I achieved complete clinical cure, compared to 62% in Group II ($p = 0.008$). Group I also showed greater improvement in erythema (78% vs. 64%, $p = 0.012$), raised borders (72% vs. 51%, $p = 0.001$), and scaling (74% vs. 63%, $p = 0.001$). Pruritus resolved in 79% of Group I versus 65% in Group II ($p = 0.032$). Both treatments were well-tolerated, with minimal ADRs.

Conclusion:

Itraconazole proved to be more effective and faster than fluconazole in treating dermatophytosis. Both drugs were safe, but itraconazole is recommended for faster and more comprehensive resolution of symptoms.

Keywords: Dermatophytosis Severity Score (DSS), Itraconazole, Fluconazole, Efficacy, Safety, Antifungal Therapy.

Fungal infections, also known as mycoses, are caused by fungi, which are microorganisms found in the environment. These infections can affect various parts of the body, including the skin, nails, hair, and internal organs. Fungi thrive in warm, moist environments, making areas such as skin folds and the feet particularly susceptible. Superficial fungal infections, such

as dermatophytosis (commonly referred to as ringworm), tinea, and candidiasis, primarily affect the skin, nails, and mucous membranes.
Dermatophytosis is caused by Dermatophytes. They are highly specialized Keratinophillic filamentous fungi and are the most common pathogenic agents of skin, nail and hair mycoses. They include three genera of fungi, *Trichophyton*, *Epidermophyton* and *Microsporum* (1-3).

Though there have been many studies on superficial dermatophytosis, it is difficult to calculate the exact incidence and prevalence owing to a paucity of community based surveys. Superficial dermatophytosis affects 20%-25% of the world population and is a common infective dermatoses in clinical practice.
The current reported prevalence in India falls in a very wide range (6.09% - 61.5%). A prevalence of 6.09% to 27.6% has been reported in studies from south India, while a high prevalence of 61.5% has been recorded in North India (4).

The Epidemiology and clinical presentations of superficial dermatopytosis in India have undergone a sea change. This importantly includes the rather abrupt change from *Trichophyton rubrum* to *Trichophyton mentagrophytes* as the predominant species in less than a decade. The disease now spreads at an unprecedentedly high rate among family members and intimate contacts, regardless of climate variations, age, sex, education, or socioeconomic level. Individual lesions undergo morphological changes with various degrees of inflammation, and a sizable portion of patients have steroid-modified Dermatophytosis (4).
This phase of Dermatophytosis may be the result of a complicated and intriguing interaction between the host, the fungus, the medication, and the environment. This interaction may have been influenced by a number of factors, including more humid and warmer climate, the absurd use of topical corticosteroid based combinations, the increased use of broad spectrum antibiotics, the increasing burden of immune compromised population, the wide spread use of antifungals in the agricultural industry, and the questionable role of antifungal resistance (5).

Due to this evolving phase, the majority of dermatologists in India are relying on several experience-based treatment options, including prescribing systemic antifungal medications, longer treatment durations, and larger doses of antifungals. Because of this changing nature of dermatophytosis in India, there is a compelling need to examine the efficacy and safety of the existing antifungals in greater detail.

Itraconazole and fluconazole have revolutionized the treatment in tinea versicolor both in single and divided doses. Itraconazole is an oral synthetic triazole compound which acts by inhibiting the cytochrome-P450 dependent 14-alpha-demethylation step in the formation of ergosterol and lead to accumulation of 14-alpha-methylsterols, these methylsterols may disrupt the close packing acyl chains of phospholipids, impairing the functions of certain membrane bound enzyme systems, thus inhibiting the growth of fungi (6). Fluconazole is an oral synthetic bis-triazole compound that functions in the same way as Itraconazole.

Although safety and efficacy of Itraconazole and Fluconazole, which are the most common drugs used, have been established in long term clinical trials (7-9). However, the effectiveness and safety in the current Indian scenario has to be evaluated. It is important that dermatologist follow proper guidelines on the management of dermatophytosis, which is evidence based & experience driven practical approach.

Materials and Methods

This was a prospective, observational study conducted at the Department of Pharmacology and Dermatology of Gandhi Medical College and Hamidia Hospital, Bhopal. The study followed the

ICMR National Ethical Guidelines (2017). All participants provided written informed consent after receiving detailed explanations of the study. The study protocol was approved by the Institutional Ethics Committee of Gandhi Medical College. The study spanned from April 2023 to September 2024, with a 15-month case collection period, followed by 3 months for data analysis and interpretation.

The aim of the study was to evaluate and compare the safety and efficacy of oral itraconazole and fluconazole in the treatment of superficial dermatophytosis. A total of 200 patients, newly diagnosed with superficial dermatophytosis, were enrolled in the study. The sample size for this study was calculated based on the prevalence of superficial dermatophytosis in India, obtained from a recent study (4). Using this prevalence data, we applied a standard formula for sample size determination in clinical studies, accounting for a 95% confidence level, a 5% margin of error, and an estimated 10% attrition rate. This resulted in a required sample size of 200 patients to ensure sufficient power for detecting statistically significant differences between treatment groups. The participants were divided into two groups: Group 1 consisted of 100 patients who received oral itraconazole 200 mg once daily for 4 weeks, while Group 2 included 100 patients who received oral fluconazole 150 mg every alternate day for 4 weeks.

Patients were included in the study if they were aged between 18 and 60 years, had a new diagnosis of superficial dermatophytosis, and were willing to participate. Additionally, participants had not received any systemic or topical antifungal treatment within the previous 4 weeks and were suffering from moderate to severe dermatophytosis.

The exclusion criteria were as follows: patients with comorbidities such as renal or hepatic impairments, diabetes mellitus, or systemic mycoses; those receiving immunosuppressants, corticosteroids, or other antifungal drugs; pregnant or lactating women; and patients with a history of alcohol or drug dependency within the last 6 months. Furthermore, individuals who were unable to give informed consent or comply with the study procedures were also excluded from participation.

The diagnosis of superficial dermatophytosis was made based on clinical evaluation by the dermatologist. Participants were assigned to one of the two treatment groups through simple random sampling, where cases diagnosed in the OPD were randomly given either of the two drugs without the use of a computer-generated sequence. The availability of drugs was ensured through the hospital's dispensary.

Clinical improvement was systematically assessed at three time points: baseline (prior to treatment initiation), at 2 weeks, and at 4 weeks post-treatment, using the Dermatophytosis Severity Score (DSS) (10,11). This scoring system evaluated key clinical parameters including erythema, pruritus, scaling, and raised borders, which were considered indicators of the severity of infection. Each of these symptoms was graded on a scale from 0 to 3, where 0 represented the absence of the symptom and 3 indicated severe manifestation. At each visit, the treating dermatologist performed a thorough clinical examination to assess these parameters. The assessment focused on clinical improvement rather than mycological cure.

The primary endpoint of the study was defined as complete clinical cure, which was achieved when all symptoms (erythema, pruritus, scaling, and raised borders) were graded as 0, indicating total resolution of visible signs of infection. The secondary endpoint was the documentation of partial improvement, where patients demonstrated reduced severity scores in one or more parameters but had not yet achieved a full cure.

In addition to absolute DSS scores, the percentage change in clinical parameters—erythema, pruritus, scaling, and raised borders—was calculated to provide a more precise measure of improvement over time. The percentage change was determined by comparing the baseline scores to those recorded at 2 and 4 weeks post-treatment. This approach allowed for a clearer assessment of the relative reduction in symptom severity between the two treatment groups.

The percentage change for each clinical parameter was computed using the formula:

$$\text{Percentage Change} = \frac{\text{Baseline Score} - \text{Follow- up score}}{\text{Baseline score}/100}$$

This calculation was performed for each patient and each clinical parameter, at both the 2-week and 4-week follow-up visits. The average percentage change for each group was then analyzed and compared to determine the effectiveness of each treatment.

In addition to clinical efficacy, safety was rigorously monitored throughout the study. At each visit, participants were asked to report any adverse events, including but not limited to gastrointestinal disturbances (nausea, diarrhea), dizziness, headaches, or any skin reactions such as rashes. A comparison between the two treatment groups was made to assess if there were any significant differences in safety profiles.

Data were entered into Microsoft Excel and analyzed using EPI INFO 1.0 software. For statistical analysis, baseline characteristics were compared between groups using descriptive statistics. Continuous variables like DSS scores were expressed as means ± standard deviations, and categorical variables like adverse effects were presented as percentages. Chi-square tests were used for categorical comparisons, while paired t-tests or Wilcoxon signed-rank tests (inferential statistics) (depending on the data distribution) were employed to analyze changes in DSS scores from baseline to follow-up visits. A p-value of <0.05 was considered statistically significant for all analyses.

Results

A total of 200 patients were enrolled in the study and divided equally into two groups: Group I and Group II, each consisting of 100 participants. The baseline demographic and clinical characteristics between these two groups were well-matched, ensuring comparability. The mean age of participants in Group II was 37.23 ± 6.78 years, while the mean age in Group I was 38.63 ± 5.25 years, with no statistically significant difference between the two groups ($p = 0.382$). The sex distribution was also comparable, with Group II having a male-to-female ratio of 35:65 and Group I having a ratio of 48:52, again without any statistically significant difference ($p = 0.162$). Furthermore, the types of lesions, including tinea corporis, tinea cruris, and mixed presentations (tinea corporis with cruris or faciei), were evenly distributed across both groups ($p = 0.762$), demonstrating a balanced clinical profile between the groups.

Table 1: Comparison basic demographic parameters and clinical profile of the study groups

Variables	Group		
	Fluconazole	Itraconazole	P value
Age; Mean±SD	37.23±6.78	38.63±5.25	0.382
Sex (male/female)	35/65	48/52	0.162
Lesion type			
Tinea corporis	54	52	0.762
Tinea cruris	40	43	
Tinea corporis + tinea cruris	5	3	
Tinea corporis + tinea cruris + tinea faciei	1	2	

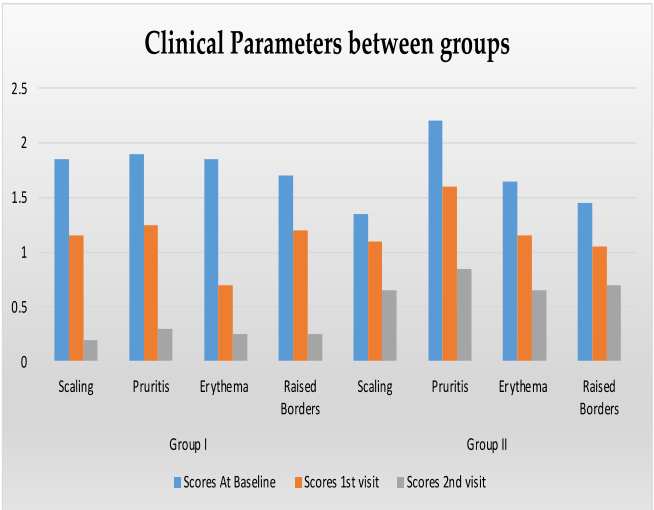
The clinical outcomes at the 2nd follow-up visit revealed significant differences between the two groups in terms of overall efficacy. Group I demonstrated a notably higher clinical cure rate, with 84% of participants achieving complete resolution of all symptoms compared to 62% in Group II, a difference that was statistically significant (p = 0.008). When examining the individual symptoms, Group I consistently outperformed Group II across all major clinical parameters. Specifically, 78% of participants in Group I showed complete resolution of erythema (Grade 0) compared to 64% in Group II (p = 0.012). Similarly, the proportion of participants with no raised borders (Grade 0) was significantly higher in Group I at 72%, compared to 51% in Group II (p = 0.001). The absence of scaling (Grade 0) was also more frequent in Group I (74%) than in Group II (63%), with a highly significant p-value of 0.001. Moreover, pruritus, one of the most bothersome symptoms of dermatophytosis, was resolved in 79% of participants in Group I compared to 65% in Group II, a difference that was also statistically significant (p = 0.032). Thus, Group I demonstrated superior effectiveness in reducing all major clinical symptoms.

Table 2: Clinical Cure performance of the study medication at 2nd follow-up visit

Variables	Group I (%)	Group II (%)	P value
Complete cure (Grade 0 for all the symptoms)	84	62	0.008
Erythema Grade 0	78	64	0.012
Raised boarders Grade 0	72	51	0.001
Scaling Grade 0	74	63	0.001
Pruritus Grade 0	79	65	0.032
Clinical failure (topical drug withdrawn)	1	8	0.011
Some improvement (topical drug continued)	6	18	0.001

In terms of treatment failure and the need to discontinue topical medication, Group II experienced a higher rate of clinical failure (8%) than Group I (1%), with a significant p-value of 0.011. Additionally, some participants in both groups showed partial improvement and continued the use of topical medication beyond the 2nd follow-up visit. This partial improvement was more common in Group II (18%) compared to Group I (6%), with the difference being statistically significant (p = 0.001).

The visit-wise complete cure rates showed a consistent pattern of better performance by Group I. At the first follow-up visit, 48% of Group I participants had achieved complete cure compared to only 32% in Group II, with the difference being statistically significant (p = 0.021). By the second follow-up visit, the complete cure rate for Group I remained higher at 84%, while Group II improved to 62%, with a highly significant p-value of 0.008.



Further evaluation of clinical parameters such as scaling, pruritus, erythema, and raised borders confirmed the superior efficacy of Group I. For scaling, there was a significant reduction in mean scores from first to the second visit in Group I, with a decrease from 1.15 ± 0.40 to 0.20 ± 0.50, while Group II showed a less pronounced reduction from 1.10 ± 0.60 to 0.65 ± 1.00. The p-values for scaling were highly significant ($p = 0.04$ and $p = 0.002$, respectively). Similar trends were observed for pruritus and erythema, with Group I showing a more substantial reduction in symptoms across visits. For pruritus, the mean score in Group I dropped from 1.90 ± 0.70 at baseline to 0.30 ± 0.80 by the second visit, while Group II saw a smaller decrease. For erythema, Group I's mean score declined from 1.25 ± 0.60 at baseline to 0.25 ± 0.70 at the second visit, which was significantly better than Group II's reduction from 1.65 ± 0.60 to 0.65 ± 1.10 ($p < 0.05$). Raised borders followed a similar pattern, with Group I consistently showing greater improvement compared to Group II.

Table 3: Percentage Change in Clinical Parameters in Both Groups

Parameters	Group I (n=100)	Group II (n=100)	P values between groups
Pruritus			
Baseline to 1st visit	24.5 ± 26.0	22.0 ± 30.8	0.625
1st visit to 2nd visit	34.5 ± 25.0	33.0 ± 32.5	0.230
Baseline to 2nd visit	54.0 ± 31.0	51.0 ± 46.5	0.875
Scaling			
Baseline to 1st visit	12.8 ± 4.8	7.0 ± 1.0	<0.001
1st visit to 2nd visit	32.5 ± 10.0	20.0 ± 11.5	<0.001
Baseline to 2nd visit	33.0 ± 13.0	21.0 ± 12.0	0.011
Erythema			
Baseline to 1st visit	23.5 ± 12.5	17.0 ± 32.0	0.001
1st visit to 2nd visit	27.0 ± 11.5	18.5 ± 24.0	0.022
Baseline to 2nd visit	44.0 ± 8.0	35.0 ± 39.5	0.012
Raised Borders			
Baseline to 1st visit	17.0 ± 13.5	10.0 ± 25.5	0.008
1st visit to 2nd visit	28.5 ± 14.5	22.0 ± 30.0	0.015
Baseline to 2nd visit	38.0 ± 15.0	32.0 ± 37.0	0.015

Percentage changes in clinical parameters from baseline to subsequent visits also showed that Group I had a more significant reduction in symptoms. For scaling, Group I demonstrated a remarkable 12.8 ± 4.8% improvement from baseline to the second visit, compared to only 7.0 ± 1.0% in Group II ($p < 0.001$). Similarly, from the second to the third visit, Group I showed a 32.5 ± 10.0% improvement compared to 20.0 ± 11.5% in Group II ($p < 0.001$). Overall, from baseline to the third visit, Group I exhibited a significant 33.0 ± 13.0% improvement in scaling, whereas Group II improved by only 21.0 ± 12.0% ($p = 0.011$). A similar pattern was observed for erythema, raised borders, and pruritus, with Group I consistently showing greater improvements across visits.

Regarding the incidence of adverse drug reactions (ADRs), there was no statistically significant difference between the two groups at either the first or second follow-up visits. Common ADRs included abdominal pain, sleep disturbances, hair loss, headache, nausea, dizziness, anorexia, and loose stools. For instance, at the second follow-up visit, 3% of participants in Group II and 2% in Group I experienced headaches, while 2% in Group II and 1% in Group I reported hair loss. Despite these minor variations, the incidence of ADRs remained low, and no significant differences were observed between the groups, with p-values of 0.624 for the first follow-up visit and 0.588 for the second follow-up visit. This suggests that both treatments were well-tolerated with no major safety concerns.

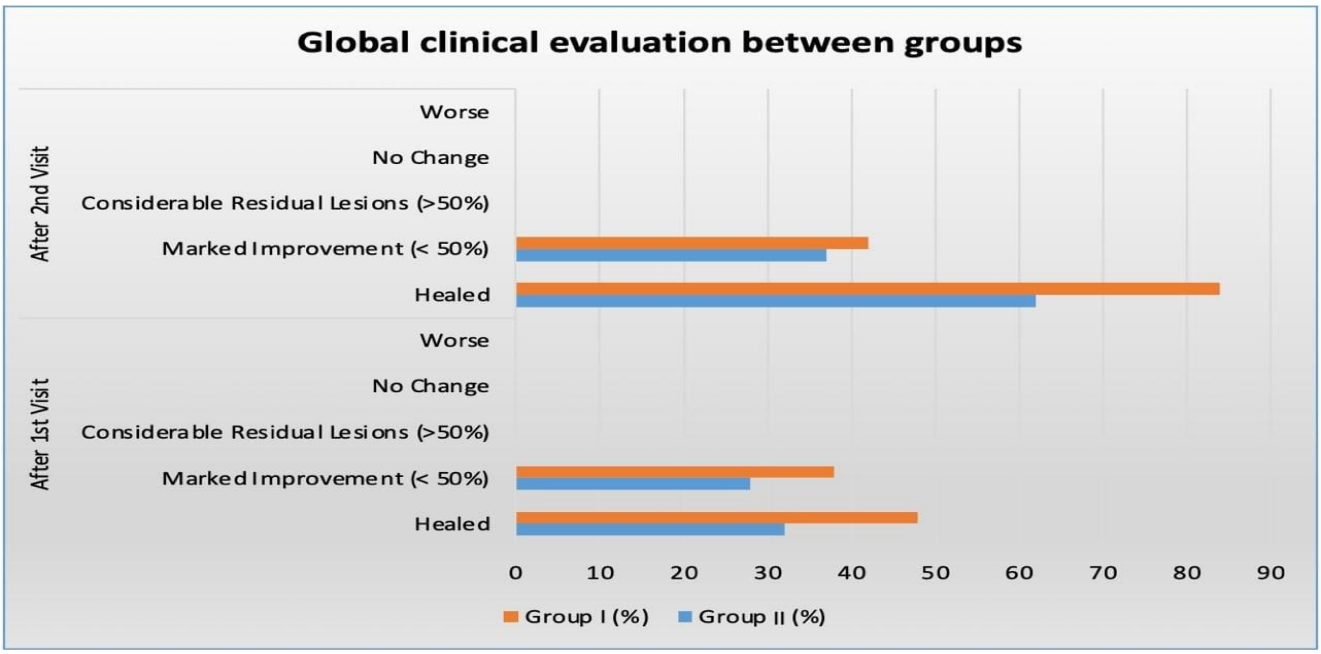
Discussion

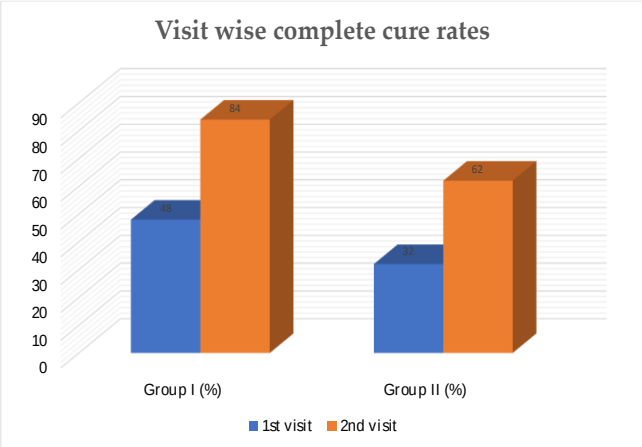
In recent years, the medical community in India has noted a rise in the prevalence of dermatophytosis, along with growing resistance to conventional antifungal drug dosages. This shift in the clinical landscape, marked by more frequent treatment failures, has sparked the search for an effective first-line treatment strategy that ensures rapid and complete clearance of the infection. While initial studies and guidelines suggest that topical antifungals should be the first choice for managing dermatophytosis, current clinical practice in India indicates that topical therapy alone is often inadequate for patients with large or multiple lesions. In such cases, systemic therapy is frequently recommended to avoid treatment failures and relapses.

Systemic anti-fungal agents such as fluconazole, and itraconazole have been known to be active against dermatophytes. A few strains of dermatophytes show primary resistance to azoles, but many treatment failures are due to insufficient bioavailability of antifungal agents, particularly itraconazole, often caused by the use of generic formulations or drug interactions, such as with antacids. Experts recommend longer or more intensive itraconazole therapy for recalcitrant dermatophytosis, with maintenance doses to prevent relapses. Additionally, it is important to implement holistic measures, such as treating family members and maintaining hygiene, to prevent reinfection and ensure treatment success (12).

In the past two decades, several genes and mutations which increase resistance to fluconazole in clinical isolates, primarily in *C. albicans*, have been elucidated (13). According to the Expert Consensus on the Management of Dermatophytosis in India (ECTODERM India), fluconazole (150 mg–300 mg/week) can be used when other oral antifungals, such as terbinafine or itraconazole, have failed. Additionally, the Indian Association of Dermatologists, Venereologists, and Leprologists (IADVL) Task Force against Recalcitrant Tinea (ITART) recommends fluconazole 150 mg thrice weekly for patients with no prior treatment history, with an 8-week course showing good clinical outcomes in cases of recalcitrant dermatophytosis (14).

In the present study, patients in Group I received itraconazole 200 mg daily for 4 weeks, while those in Group II were treated with fluconazole 150 mg every alternate day for 4 weeks. Group I, with its treatment regimen, seemed to offer a more favorable therapeutic response compared to Group II, potentially leading to better overall management of dermatophytosis and improvement in symptoms like erythema, pruritus, scaling, and raised borders.





The higher complete clinical cure rate in Group I (84%) compared to Group II (62%) aligns with the findings of previous studies such as that of Difonzo *et al.(*15), who reported cure rates of 88.2% and 72.2% for itraconazole and fluconazole, respectively. While the cure rates in the current study are slightly lower, this may be attributable to the shorter follow-up period.
Rajak *et al.* (16) reported a 91% reduction in dermatophytosis with itraconazole, slightly higher than the 84% clinical cure rate observed in the present study. However, Dhoot *et al.* (17) reported a lower complete cure rate of 76.31% in the itraconazole group,
which is below the results seen in this study. These differences highlight the variability in itraconazole efficacy, possibly due to differences in patient populations, dosing regimens, and study design.

In terms of fluconazole, Someshwar *et al.* (18) reported a clinical cure rate of 63.3%, similar to the 62% cure rate observed in this study. In contrast, Kumar *et al.* (19) reported an 82.00% clinical response rate, although this did not represent complete cure, indicating fluconazole's variable performance. Suchil *et al.* (20) reported a significantly higher clinical cure rate of 92%, much higher than the cure rate observed in the present study, suggesting differences in patient populations or study conditions.
The significant difference in symptom resolution rates between the two groups can be attributed to the emerging resistance to certain antifungal agents, which may have impacted the efficacy of fluconazole in particular. This growing resistance, especially in chronic or recurrent cases, underscores the importance of selecting an appropriate treatment regimen. Group I's treatment may have had a faster onset of action and longer-lasting therapeutic effects, as evidenced by the higher proportion of participants achieving complete clinical cure early in the study. This suggests that Group I's medication not only works effectively over a shorter duration but also leads to better long-term outcomes compared to Group II.
The comparable incidence of ADRs between the two groups is an encouraging finding, indicating that both treatments are well-tolerated with minimal risk of side effects. This is particularly important in the management of dermatophytosis, where patient adherence to treatment can be affected by the occurrence of side effects. The low incidence of ADRs, combined with the high efficacy observed in Group I, suggests that this treatment option may offer a more favorable risk-benefit profile. Chang *et al.* (21) also reported that all oral antifungal treatment regimens for dermatophytosis were associated with minimal adverse drug reactions, further supporting the safety profile of these medications.
The findings of this study are highly relevant to clinical practice in India, given that the sample was drawn from a diverse population representing various age groups, lesion types, and severities of superficial dermatophytosis. As the study used commonly prescribed oral antifungal agents (itraconazole and fluconazole), the results are applicable to a wide range of dermatophytosis cases in outpatient settings. However, the generalisability may be limited to similar clinical settings with

comparable patient demographics and fungal resistance patterns. Further studies are needed to confirm these findings in different geographical regions, including rural populations and settings with higher antifungal resistance.

One limitation of this study is that it focused solely on clinical cure, defined by the resolution of visible symptoms, without assessing mycological cure through laboratory tests. While clinical cure is important, complete eradication of dermatophytosis typically requires both clinical and mycological confirmation, as residual fungal elements may persist even after symptom resolution.

Conclusion

In conclusion, this study has shown that Group I achieved significantly better clinical outcomes than Group II in the treatment of dermatophytosis, particularly in terms of clinical cure and symptom resolution. The treatment in Group I was more effective in reducing erythema, scaling, raised borders, and pruritus, and led to higher clinical cure rates earlier in the treatment course. The safety profiles of both treatments were comparable, with no significant difference in the incidence of adverse events. These findings suggest that the treatment used in Group I may be a more effective and safe option for managing dermatophytosis, particularly for patients seeking faster relief from symptoms. Future studies could explore the long-term outcomes of this treatment and its efficacy in different subtypes of dermatophytosis or patient populations with comorbidities.

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