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DAILY ORAL FLUCONAZOLE IN DERMATOPHYTOSIS: A PROSPECTIVE OBSERVATIONAL STUDY OF ADVERSE EFFECTS AND CLINICAL RESPONSE AT A TERTIARY CARE CENTRE

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ABSTRACT

Background: Daily oral fluconazole is increasingly used for recurrent and recalcitrant dermatophytosis in India, yet structured safety data for this dosing strategy remain limited. This study aimed to evaluate adverse effects, laboratory parameter changes, and clinical response associated with daily fluconazole therapy in patients attending a tertiary care dermatology centre.

Methods: A prospective, single-centre, open-label observational study was conducted at the Department of Dermatology, L.N. Medical College and J.K. Hospital, Bhopal, over 18 months. Patients diagnosed with dermatophytosis and initiated on oral fluconazole 150 mg once daily for eight weeks were enrolled consecutively. Clinical assessments and laboratory investigations—complete blood count (CBC), liver function tests (LFT), and renal function tests (RFT)—were performed at baseline, day 14, and day 56. Adverse effects were systematically documented at each follow-up visit.

Results: A total of 107 participants were enrolled; 86 completed full follow-up. The majority were male (63.55%) and in the 31–40 year age group (25.23%). Tinea corporis was the most frequent presentation (31.78%). Clinical response was observed in 87.21% of participants at day 56. Adverse effects were mild, with nausea the most common (9.35%), followed by headache (6.5%) and diarrhoea (4.67%). Mild asymptomatic elevation of liver enzymes occurred in 3.49%; one patient (1.16%) required drug discontinuation. All haematological and renal parameters remained statistically stable throughout follow-up ($p > 0.05$).

Conclusion: Daily oral fluconazole at 150 mg for eight weeks is well tolerated and clinically effective in patients with dermatophytosis. Laboratory monitoring revealed no significant organ toxicity in the majority of patients. Periodic biochemical surveillance remains advisable during prolonged therapy.

Keywords: *dermatophytosis, fluconazole, adverse effects, liver function tests, antifungal therapy, tinea*

INTRODUCTION

Dermatophytosis is one of the most prevalent superficial fungal infections worldwide, caused by keratinophilic fungi that invade the stratum corneum, hair, and nails.[1] Although it's rarely life-threatening, the disease carries considerable morbidity—persistent pruritus, disfigurement, and frequent recurrence impose a significant psychosocial and economic burden, particularly in tropical regions like India.[2] Over the past decade, dermatophytosis in India has evolved dramatically; clinicians are now seeing extensive, chronic, and treatment-resistant cases at an alarming rate.[3,4] Factors such as overcrowding, prolonged occlusive clothing, misuse of topical corticosteroid-antifungal combinations, and poor adherence to therapy are widely implicated.[5]

Systemic antifungal therapy is often necessary in moderate-to-severe or recurrent disease. Among the available agents—terbinafine, itraconazole, and fluconazole—the latter has gained considerable popularity, mainly because of its high oral bioavailability, predictable pharmacokinetics, and once-daily convenience.[7] Historically, fluconazole was prescribed as a weekly pulse (150 mg once weekly), but reports of incomplete responses and early relapse have prompted many clinicians to switch to daily administration.[8,9] Daily dosing theoretically maintains more consistent inhibitory drug concentrations within the stratum corneum, potentially improving outcomes in recalcitrant infections.

Despite this growing shift in prescribing practice, high-quality safety data specific to daily fluconazole dosing in dermatophytosis remain scarce. Most existing evidence is derived from short-term use, intermittent schedules, or systemic infections—populations that may not accurately represent the risk profile of otherwise healthy individuals receiving continuous daily therapy for a superficial condition.[10,11] Subclinical changes in hepatic enzymes, renal function, or haematological indices may develop before overt toxicity appears and go undetected without structured laboratory surveillance.[6] The widespread adoption of daily fluconazole in routine practice has thus outpaced the generation of robust real-world safety data. The present study was therefore designed to prospectively evaluate adverse effects, laboratory parameter changes, and clinical response in patients with dermatophytosis receiving daily oral fluconazole 150 mg for eight weeks at a tertiary care dermatology centre in central India.

Aim

To evaluate the adverse effects associated with daily oral fluconazole therapy in patients with dermatophytosis.

MATERIAL AND METHODS

Study Design

A single-centre, hospital-based, single-group, prospective, open-label observational study. The design allowed systematic observation of adverse effects and laboratory parameter changes associated with daily oral fluconazole therapy without altering routine clinical management.

Study Setting

The study was conducted in the Department of Dermatology at L.N. Medical College and Research Centre and its associated J.K. Hospital, Bhopal, Madhya Pradesh, India—a tertiary care centre serving a large, diverse outpatient dermatology population with access to routine laboratory facilities.

Study Duration

The study ran for 18 months, from April 2024 to September 2025, organised in three phases: an initial three-month planning and ethics-approval phase; a 12-month recruitment and follow-up phase; and a final three-month data-analysis and write-up phase. Each enrolled participant was followed for eight weeks after initiation of therapy, with assessments at baseline, day 14, and day 56.

Ethical Clearance

Ethics approval was obtained from the Institutional Ethics Committee of L.N. Medical College prior to study initiation (LNMC&RC/Dean/2024/Ethics/353, dated 10/5/2024). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants.

Study Outcomes

Primary outcomes: Occurrence and type of adverse effects during daily fluconazole therapy; changes in CBC, LFT, and RFT from baseline to day 56.

Secondary outcomes: Clinical response to treatment and improvement in presenting symptoms (pruritus, erythema, scaling) assessed at days 14, 28, and 56. Mycological response (KOH preparation) was also documented.

Measurement of Outcome

Adverse effects were captured by structured patient interview and clinical examination at each visit. Liver enzyme elevation was graded as mild (less than five times the upper limit of normal) or significant (five times or more). Clinical improvement was defined as reduction in lesion size and resolution or marked improvement in presenting symptoms. Mycological response was reported dichotomously (hyphae present or absent).

Study Participants

Patients attending the Dermatology Outpatient Department who were clinically diagnosed with dermatophytosis and initiated on daily oral fluconazole as part of routine care were considered for enrolment.

Inclusion Criteria

1. Patients willing to participate in the study.
2. Patients of all age groups and both sexes.
3. Patients commenced on daily fluconazole therapy for dermatophytosis.

Exclusion Criteria

1. Patients not willing to participate in the study.
2. Patients who had received any oral or topical antifungal therapy within 14 days prior to the baseline visit.
3. Patients with known hypersensitivity to fluconazole.
4. Pregnant and lactating women.
5. Patients with secondary infection or eczematized lesions.
6. Patients with any chronic systemic illness.
7. Patients with any pre-existing liver disease.

Sample Size

A formal sample size calculation was not performed given the observational, single-arm design. All eligible patients who attended the outpatient department during the recruitment phase and consented to participate were enrolled consecutively. This approach yielded a final sample of 107 participants, considered sufficient to provide meaningful preliminary estimates of adverse-effect frequencies for a pilot safety-surveillance study.

Sampling Methodology

Non-probability convenience sampling was used. Participants were enrolled consecutively as they presented to the outpatient department and fulfilled the selection criteria, ensuring the cohort reflected the real-world clinical caseload.

Data Sources

Demographic data (age, sex) were obtained by direct patient interview. Clinical data—diagnosis, site and extent of disease, presenting symptoms, and adverse effects—were captured by clinical examination and structured patient interview. Laboratory data (CBC, LFT, RFT) were obtained from institutional laboratory reports. Outcome data were collected at scheduled follow-up visits. Mycological status was assessed by KOH preparation of skin scrapings performed by the principal investigator.

Data Collection Procedure

Following clinical diagnosis and confirmation of eligibility, each participant provided written informed consent and was assigned a unique identification number. A structured close-ended proforma captured baseline demographic, clinical, and laboratory data. Blood samples were collected using standard aseptic technique and sent to the institutional laboratory. Skin scrapings were collected from the advancing margin of an active, untreated lesion, processed with 10% KOH, and examined under light microscopy. Fluconazole 150 mg once daily for eight weeks was prescribed as part of routine care. Follow-up visits were scheduled on days 14, 28, and 56; laboratory investigations were repeated on days 14 and 56. At each visit, participants were interviewed about adherence and new symptoms; focused clinical examination was performed, and all findings were entered contemporaneously into the proforma.

Statistical Analysis Plan

Data were entered into Microsoft Excel and analysed using Stata version 17.0. Categorical variables were summarised as frequencies and percentages. Continuous variables were expressed as mean with standard deviation (SD) or median with range as appropriate. Changes in laboratory parameters across time points were compared using repeated-measures analysis; statistical significance was defined as $p \leq 0.05$. Results are presented in tables with accompanying narrative descriptions.

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RESULTS

A total of 107 participants were enrolled; 21 (19.6%) were lost to follow-up by day 56 (all had attended the day 14 visit), leaving 86 patients available for final analysis.

Table 1: Characteristics of Participants (n = 107)

Variable	Frequency (n)	Percent (%)
Age Group (Years)		
21–30	19	17.76
31–40	27	25.23
41–50	25	23.36
51–60	26	24.30
61–70	10	9.35
Total	**107**	**100.00**
Sex Distribution		
Male	68	63.55
Female	39	36.45
Total	**107**	**100.00**
Site of Involvement		
Tinea corporis	34	31.78
Tinea cruris	29	27.10
Tinea pedis	25	23.36
Multiple site involvement	19	17.76
Total	**107**	**100.00**
Presenting Complaints at Baseline (multiple responses)		
Scaling	102	95.33
Pruritus	95	88.78
Erythema	74	69.16
Duration of Symptoms		
Less than 2 weeks	18	16.82
2–4 weeks	41	38.32
1–3 months	36	33.64
4–6 months	12	11.21
Total	**107**	**100.00**

Table 1 summarises the baseline characteristics of all 107 enrolled participants. The 31–40 year age group was most frequently represented (25.23%), followed by 51–60 years (24.30%) and 41–50 years (23.36%); participants aged 61–70 years were fewest (9.35%). Male participants outnumbered females, accounting for 63.55% of the cohort. Tinea corporis was the most common clinical presentation (31.78%), followed by tinea cruris (27.10%), tinea pedis (23.36%), and multiple site involvement (17.76%). At baseline, scaling was the most prevalent symptom (95.33%), with pruritus in 88.78% and erythema in 69.16% of participants. The majority had symptoms lasting 2–4 weeks (38.32%); a smaller proportion had suffered for 4–6 months (11.21%), reflecting the spectrum from early to established disease in this cohort.

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Table 2: Clinical Response at Day 56

Clinical Response	Frequency (n=86)	Percent (%)
Positive response (improvement)	75	87.21
No response	11	12.79
Total	86	100.00

Table 2 shows clinical response at the final follow-up visit. Of the 86 participants who completed the study, 75 (87.21%) demonstrated clinical improvement, while 11 (12.79%) showed no meaningful response to daily fluconazole therapy at eight weeks.

Table 3: Adverse Effects Recorded During Follow-up

Adverse Effect	Frequency (n=107)	Percent (%)
Nausea	10	9.35
Headache	7	6.54
Diarrhoea	5	4.67
Increased hair loss	4	3.74
Fatigue	4	3.74
Alterations in taste	4	3.74
Abdominal pain	1	0.93
Rash	0	0.00

Table 3 summarises adverse effects reported during follow-up. Nausea was most common (9.35%), followed by headache (6.54%) and diarrhoea (4.67%). Increased hair loss, fatigue, and taste alterations were each noted in 3.74% of participants. Abdominal pain was rare (0.93%), and no cases of rash were recorded.

Table 4: Severity of Liver Dysfunction During Follow-up

Severity Category	Frequency (n=86)	Percent (%)
No liver dysfunction	82	95.35
Mild asymptomatic ALT/AST elevation (<5× ULN)	3	3.49
Significant elevation requiring discontinuation (≥5× ULN)	1	1.16
Total	86	100.00

Table 4 details severity of liver dysfunction observed. The majority of participants (95.35%) had no liver dysfunction throughout follow-up. Mild asymptomatic transaminase elevation was found in three participants (3.49%); only one patient (1.16%) developed significant elevation necessitating drug discontinuation.

Table 5: Changes in Serum ALT, AST, and AST:ALT Ratio During Follow-up

Parameter	Baseline Mean (SD)	Day 28 Mean (SD)	Day 56 Mean (SD)	p-value
ALT (U/L)	30.9 (±10.0)	35.1 (±12.4)	35.0 (±11.0)	>0.05
AST (U/L)	25.2 (±7.8)	29.4 (±11.1)	28.4 (±10.4)	>0.05
AST:ALT Ratio	0.971 (±0.729)	0.985 (±0.668)	0.920 (±0.504)	>0.05

Table 5 shows changes in hepatic transaminase levels during the study. Mean ALT increased slightly from 30.9 (±10.0) U/L at baseline to 35.0 (±11.0) U/L at day 56, and mean AST from 25.2 (±7.8) to 28.4 (±10.4) U/L. Neither change was statistically significant ($p > 0.05$). The AST:ALT ratio remained stable and within normal range throughout.

DISCUSSION

The present study examined the safety and clinical effectiveness of daily oral fluconazole 150 mg over eight weeks in 107 patients with dermatophytosis at a tertiary care centre in central India. The overall findings suggest a favourable safety profile with good clinical response, broadly consistent with prior observational data from similar settings.

The distribution of age groups in the present study showed that middle-aged adults formed the bulk of the cohort; participants in the 31–40 years group were most frequent (25.23%), followed closely by 51–60 years (24.30%). A male predominance was evident, with 63.55% male participants, which aligns with several previous studies. Tadipudi et al. (2026) reported an even more pronounced male predominance of around 93% in a comparative study of terbinafine versus fluconazole in tinea corporis.[19]

Swaroop et al. (2024) similarly noted a higher male proportion (52%) in their comparative antifungal safety study, attributing this to occupational and lifestyle risk factors.[20] Tinea corporis was the most common clinical presentation (31.78%), followed by tinea cruris (27.10%) and tinea pedis (23.36%). Multiple site involvement was noted in 17.76% of participants. A similar predominance of tinea corporis has been reported by Mitra et al. (2024), who found it to be the most frequent clinical form in their comparative trial.[18] Shendge et al. (2022) also identified tinea corporis and tinea cruris as the most commonly reported forms across adult populations in their meta-analysis.[11]

A positive clinical response was observed in 87.21% of participants who completed follow-up. Saple et al. (2024) reported nearly complete resolution of all symptoms with mycological cure in 100% of patients at eight weeks in their open-label pilot study of daily fluconazole 150 mg.[17] The slightly lower response rate in the present study may reflect the more heterogeneous patient population in a routine clinical setting compared to a tightly controlled pilot study. Some comparative studies have reported itraconazole or terbinafine outperforming fluconazole as monotherapy. Amruthadevi et al. (2024) found itraconazole achieved higher clinical cure rates compared to fluconazole in superficial dermatophytosis.[16] Tadipudi et al. (2026) reported complete cure in all terbinafine-treated patients versus a lower proportion in the fluconazole group.[19] However, Shekhar et al. (2023) demonstrated that the combination of terbinafine plus daily fluconazole achieved significantly better outcomes than terbinafine alone, suggesting a possible synergistic benefit.[21] In the current epidemic of altered dermatophytosis in India, daily fluconazole remains a clinically viable option particularly where terbinafine efficacy may be compromised.

Adverse effects in the present study were mild and generally self-limiting. Nausea was the most frequent complaint (9.35%), followed by headache (6.54%) and diarrhoea (4.67%). These rates are comparable to those reported by Amruthadevi et al. (2024), who documented nausea/vomiting in 9.7%, headache in 6.5%, diarrhoea in 1.5%, reversible alopecia in 16%, and fatigue in 11.3% with fluconazole therapy.[16] The lower rate of alopecia in the present study (3.74%) compared to 16% in that report may reflect differences in follow-up duration, patient populations, or reporting methodology. No participant developed a severe cutaneous adverse reaction or serious systemic event other than the single case of significant transaminase elevation. The overall tolerability profile observed here supports findings from Saple et al. (2024), who reported only one case of mild, grade 1 ALT elevation requiring no intervention in their 100-patient pilot study.[17]

Hepatic parameters remained largely stable throughout the study. Mean ALT rose marginally from 30.9 to 35.0 U/L and AST from 25.2 to 28.4 U/L over eight weeks; neither change reached statistical significance ($p > 0.05$). This is consistent with the established literature describing fluconazole-associated hepatic enzyme changes as predominantly mild and reversible.[12,13] Shendge et al. (2022) similarly reported hepatic enzyme elevations with oral fluconazole are usually asymptomatic and self-limiting across various dosing regimens.[11] The small but present rise in transaminases observed here underscores the continued need for periodic liver enzyme monitoring during daily fluconazole therapy. All haematological indices—haemoglobin, total WBC count, lymphocyte percentage, neutrophil percentage, and platelet count—showed only negligible variation over the study period, with no statistically significant difference at any time point ($p > 0.05$). Renal function markers—serum urea, uric acid, and creatinine—and serum osmolality also remained stable throughout. These observations support a favourable short- to medium-term safety profile, consistent with prior reports that fluconazole-associated haematological and renal toxicity is uncommon in patients without pre-existing systemic illness.[14,15] The increasing prevalence of recalcitrant dermatophytosis in India has been attributed to misuse of topical corticosteroid combinations, antifungal resistance, and the emergence of Trichophyton indotineae—factors that complicate standard treatment and may reduce overall response rates. Given these challenges, the clinical improvement observed in over 87% of participants represents a meaningful outcome, and the acceptable safety profile supports the continued use of daily fluconazole in selected patients under monitored conditions.

CONCLUSION

Daily oral fluconazole at 150 mg for eight weeks is well tolerated and clinically effective in patients with dermatophytosis managed at a tertiary care centre. Adverse effects were predominantly mild and gastrointestinal; significant hepatotoxicity requiring drug discontinuation occurred in only 1.16% of participants. Haematological, hepatic, and renal laboratory parameters remained largely stable throughout follow-up without statistically significant changes. A positive clinical response was documented in 87.21% of patients completing the study period. Periodic biochemical monitoring remains advisable, particularly for liver enzymes, during prolonged daily therapy.

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Conflict of Interest: The authors declare no conflicts of interest in the design, implementation, or interpretation of this study.

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