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Review Article

Fluconazole for common tinea infection: An updated review of evidence and treatment guidance

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ABSTRACT

Dermatophytosis is the most common superficial fungal infection of the skin, hair, and nails. Tinea corporis, tinea cruris and tinea pedis are highly prevalent and frequently recur in India. Dermatologists and general physicians in India have been observing an increase in the prevalence of superficial fungal infections and find it clinically challenging to treat recalcitrant dermatophytosis due to new isolates, antifungal resistance, patient non-compliance, changing pathophysiology and symptoms. This review discusses the pharmacology, clinical efficacy, and safety of different dosage regimens of weekly oral fluconazole.

1. Introduction

Dermatophytosis is the most common superficial fungal infection of the skin or skin derivatives. It is caused by filamentous fungi called dermatophytes prone to attack and multiply in keratinized tissue such as skin, hair, and nails. Dermatophytosis is an umbrella term for tinea pedis, tinea corporis, tinea cruris, etc.[1] Data suggests that about 20-25% of the world population may be affected by dermatophytosis.[2] In India, the prevalence of dermatophytosis ranges from 36.6–78.4%.[1] Recalcitrant tinea infection referred to at least two episodes of recurrence within 6 weeks has caused dermatophytosis to become a chronic dermatological condition in India.[3] In one study, tinea corporis and tinea cruris accounted for 21.32% and 12.32% of the cases, while 11.84% cases of recalcitrant dermatophytosis were observed.[2,4,5] Dermatophytosis is one of the most common groups of skin diseases encountered by dermatologists in out-patient department (OPD).[3]

Symptoms include erythema, plaques, vesicles, small papules, and fissures. Diagnosis is difficult due to new and varying clinical presentation such as unusual large lesions, multiple site lesions, ring within ring lesions and corticosteroid modified lesions. Late diagnosis or negligence can cause dermatophytes to become invasive, leading to deeper and disseminated infection impacting overall quality of life. India‘s humid and warm climate, make it the ideal place for fungal infection. High usage of corticosteroids, more immunocompromised patients and agricultural infection, further contribute to the rising burden.[1]

The current scenario is characterized by changing pattern of the dermatophyte isolates, with Trichophyton mentagrophytes complex emerging as the major pathogen. Furthermore, few isolates are multidrug resistant.[6] Management of the disease has become clinically challenging in India due to changing pathophysiology and symptoms. With the rising trend of recalcitrant dermatophytosis, low mycological cure rate and antifungal

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resistance, this mycotic skin infection has turned into an alarming issue.[1]

Management of dermatophytosis with topical antifungals is becoming less clinically effective. First, due to recurrence and secondly, non-compliance towards topical antifungals has been observed due to its frequent need of application (two-three times a day).[7] Azoles, a category of antifungals is widely prescribed in India.[3] Ketoconazole is less frequently prescribed due to its hepatotoxic effects and use of griseofulvin is limited to tinea capitis.[8] Fluconazole, an oral antifungal is effective and safe for the management of dermatophytosis including recalcitrant cases. In India, majority of general physicians (GPs) prefer Fluconazole (150 mg weekly) as their first line oral antifungal drug for the treatment of dermatophytosis in both government and private sectors, according to a survey. This review would help dermatologists and general physicians in prescribing oral fluconazole based on clinical efficacy, safety, pharmacokinetics, and guideline recommendations.

2. Pharmacokinetic Properties

2.1. Absorption and distribution

Bioavailability of orally administered fluconazole is over 90% in healthy volunteers. Many of the clinical advantages ascribed to fluconazole relate to its pharmacokinetic profile which differs substantially from older azole antifungals. In humans, the volume of distribution approximates that of total body water (0.7-0.8 L/kg). Plasma protein binding of fluconazole is low (approximately 11%) compared to other azole antifungals which are highly bound. Thus, most fluconazole circulates as free drug.[9] Relevant pharmacokinetic parameters are summarized in Table 1.

The C_{max} and AUC data from a food-effect study indicated that exposure to fluconazole is not affected by food. Hence fluconazole may be taken without regard to meals.[10]

2.2. Metabolism and elimination

In normal volunteers, fluconazole is cleared primarily by renal excretion, with approximately 80% of the administered dose appearing in the urine as unchanged drug. About 11% of the dose is excreted in the urine as metabolites. In a special population, the elimination half-life ($t_{\frac{1}{2}}$) for fluconazole is 30 hours and is prolonged in patients with renal impairment.[10]

2.3. Special population

For renally impaired patients dose modification is required while administering oral fluconazole. In severe renally challenged cases hemodialysis or peritoneal dialysis is an alternative for drug elimination. During pregnancy fluconazole should be administered with precaution as it is known to cause adverse effects like teratogenicity or embryocidal effects on the foetus. Fluconazole has shown beneficial effects in children from 6 months to 13 years of age. Fluconazole should be avoided in infants less than 6 months.[10]

2.4. Drug interaction

Fluconazole is known to reduce the clearance of antipyrine. Though, fluconazole 50 mg daily had no effect on the metabolism of antipyrine in a study of 7 healthy volunteers however, few drug-drug interactions have been reported with fluconazole. Careful monitoring and dosage adjustment of phenytoin and possibly of oral anticoagulants, sulphonylureas and cyclosporin may be required, particularly if higher fluconazole dosages (about 200 mg/day) are used.[9] [Table 2]

3. Pharmacodynamics

Fluconazole is a highly selective inhibitor of fungal cytochrome P450 dependent enzyme lanosterol 14-α-demethylase. This enzyme functions to convert lanosterol to ergosterol. The subsequent loss of normal sterols correlates with the accumulation of 14-α-methyl sterols in fungi and may be responsible for the fungistatic activity of fluconazole. Mammalian cell demethylation is much less sensitive to fluconazole inhibition. Regarding invitro activity and in clinical Infections, fluconazole has been shown to be active against most strains of the following microorganisms – Candida albicans, Candida glabrata (Many strains are intermediately susceptible), Candida parapsilosis, Candida tropicalis and Cryptococcus neoformans.[10] The antifungal activity of any azole works by inhibiting sterol membrane synthesis by fungal cytochrome P450 enzyme. Ketoconazole also works by inhibiting cytochrome P450, while fluconazole has minimal effect on these enzymes implying to be free of adverse effects.[9] The nitrogen of the azole ring is thought to bind to the haem moiety of the fungal cytochrome P450 enzyme lanosterol 14α-demethylase, thereby halting conversion of lanosterol to ergosterol. [Figure 1]

4. Therapeutic Efficacy

Clinical efficacy and safety of oral fluconazole 150 has been well established in the management of tinea corporis, tinea cruris and tinea pedis.[Tables 3 and 4]

5. Tolerability

Fluconazole is generally well tolerated. In some patients, particularly those with serious underlying diseases such as AIDS and cancer, changes in renal and hematological function test results and hepatic abnormalities have been observed during treatment with fluconazole and

Table 1: Summary of fluconazole's pharmacokinetic parameters [9]

Dosage (per day)	N	Route	C_{min} (mg/L)	C_{max} (mg/L)	T_{max} (h)	AUC (mg/Lxh)	$t_{\frac{1}{2}}$ (h)	V_d (L/kg)
Healthy volunteers								
100 mg	20	IV		6.3		107[a]	36	0.71
200 mg	15	PO		10.1	1.5	170[b]	31	
400 mg	15	PO		18.9	1.5	350[b]	31	
Patients								
400	3	PO	21-23	30.6	3.3		37.2	

A 0-22 hours; b 0-24 hours

IV - intravenous; PO – oral; C_{min} – minimum plasma concentration prior to next dose; C_{max} – maximum plasma concentration; t_{max} – time to reach C_{max}; AUC – area under the plasma concentration-time curve; $t_{\frac{1}{2}}$ – elimination half-life; V_d = volume of distribution.

Table 2: Clinically relevant drug-drug interactions with fluconazole [6]

Drug level of fluconazole is decreased by	Fluconazole decreases level of these drugs	Fluconazole increases level of these drugs
Rifampicin	Oral contraceptives	Sulfonylurea, nifedipine, theophylline, NSAIDs, warfarin, cyclosporine

NSAID – Non-steroidal anti-inflammatory drugs

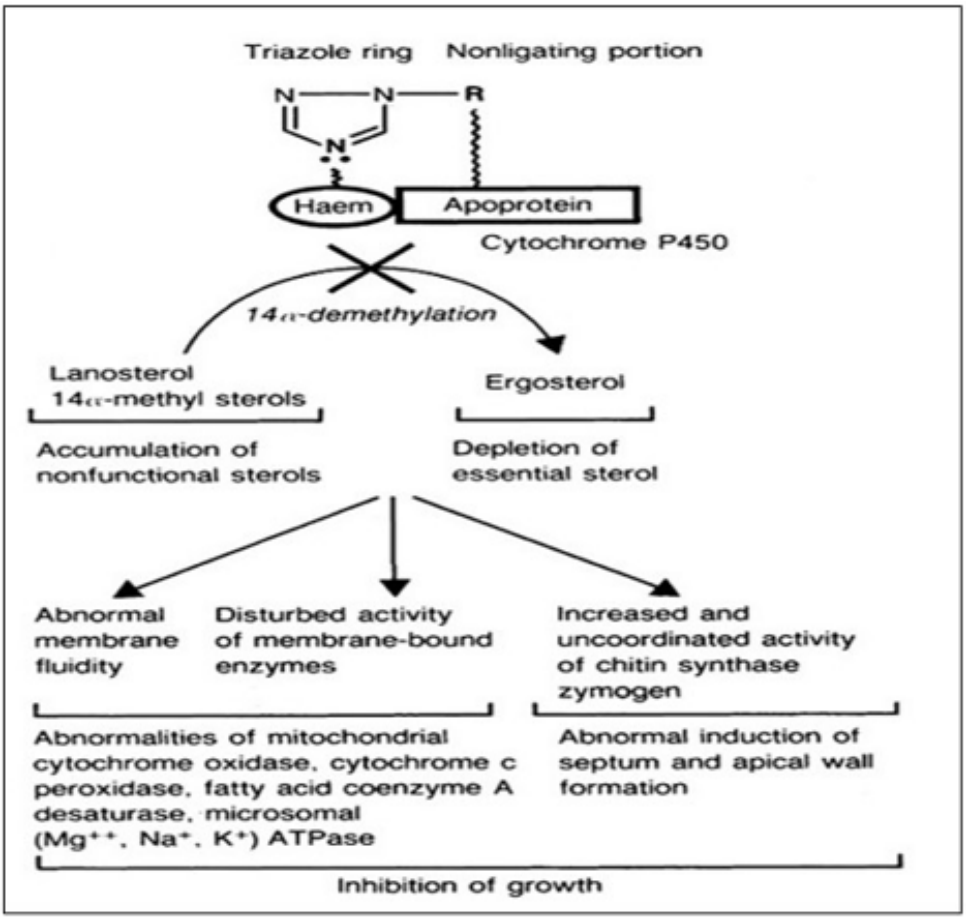

Fig. 1: Mechanism of fluconazole

Table 3: Non-comparative studies of oral fluconazole 150 mg

S. N o.	Trial design	N	Indication	Intervention and treatment duration	results of fluconazole primary	secondary	Ref.
1	Single arm study	70	Tinea pedis	Fluconazole 150 mg once in every 7-10 days. (4-5 doses in) 28 days-40 days	1.Mycological eradication at the end of study- 87% and at the follow-up was 78%. 2.Clinical eradication rate was 74% post treatment and 77% at the end of follow up.	1. Total pathogen eradication 86.7%. 2. Adverse events occurred in 5/70	[11]
2	multicentre open non comparative	95	Tinea corporis/cruris and cutaneous candidiasis	Fluconazole 150 mg / week (4-5 doses in) 28 days-40 days	1. mycological eradication was 99% post treatment and 89% after follow up. 2. clinical eradication 92% post treatment and 88% after follow-up. 3. Cure rate post treatment was 82%. 4. Total pathogen eradication 98.8%	dermatological effects (3), CNS (1), GI effect (1), Insomnia (1), moderate urticaria (1)	[12]
3	open, non-comparative study,	115	Tinea corporis and Tina cruris	Fluconazole 150 mg/week 2-4 weeks	1. Reduction in the total symptom severity score. 2. Overall clinical efficacy cure rate 1 week after last dose 41% and 3 weeks after last dose was 71%. 3. overall microscopic mycological cure rates in 40 patients, after 3 weeks last dose 55 patients cured	10 AE in 7/115 patients	[13]
4	open, non-comparative study	20	Tinea Corporis, Tinea Cruris, and Tinea Pedis	one dose of fluconazole 150mg in 7-10days 2-4 weeks	Fluconazole on Tinea Corporis/Cruris result: 1. Clinical cure rates 100% post treatment in 4^{th} dose and 95% long term follow up clinical cure rates 2. mycological eradication rates were 100% post treatment in 4 dose and 95% Follow up eradication	Fluconazole on Tinea Pedis result: 1. Clinical cure rates 42% post treatment in 4^{th} dose and 70% long term follow up clinical cure rates 2. mycological eradication rates were 75% post treatment in 4 dose and 75% follow up eradication rate	[14]
5	multicentre, open, noncomparative study	521	Tinea Corporis, Cruris or Pedis or Cutaneous candidiasis	Fluconazole 150 mg/week 2-6 weeks=avg 4.65 weeks	Clinical success rate: at the end of study=96%, follow-up=92%; Lesion cured= 68% (331/418), reduction in lesion=28% (136/418); After follow-up, improved after 1 week 36% and after 3 weeks 6%	1. good tolerability 2. 7 patients (1.3%) discontinued therapy	[15]

Table 4: Comparing Efficacy of Fluconazole versus other antifungals

S.No.	Trial design	N	Indication	Intervention and treatment duration	results of fluconazole		Ref
					Primary	Secondary	
1	Open label, comparative study	391	Tinea corporis, tinea cruris, tinea pedis or cutaneous candidiasis,	fluconazole 150mg /week or topical Clotrimazole 1% BD 2-4 weeks	1. Fluconazole with clinical response of 85%, 90%, 81%,100% post treatment and 93%, 78%, 82%, 100% during follow up in T. corpis, T. cruris, T.pedis and cutaneous candidiasis. 2. Mycological response of fluconazole was 75%, 90%, 79%, 100% post treatment and 83%, 72%, 69%, 100% during follow up in T. corpis, T. cruris, T.pedis and cutaneous candidiasis.	Fluconazole had 4% of AE observed (probably/ possibily) out of which 2.6%GI, 1% dermatitis/ urticaria 0.5% bronchospasm and 2.1% diarrhea, dyspepsia,etc.	[16]
2	double-blind, parallel comparative study	230	tinea corporis or tinea cruris.	fluconazole 150mg/ week or griseofulvin500 mg once daily 4-6 weeks	1. Clinical cured rates 74% and 62% in fluconazole and grisofulvin groups. on day 42-44. 2. improved clinical rates 18% and 22% in both groups. 3. mycological cured rates were 78% and 80% in fluconazole and grisofulvin group	7.5% and 12.5% patients in fluconazole and grisofulvin group had adverse effects.	[17]
3	single observer open comparative study	90	tinea corporis, tinea cruris, and tinea facie	A—Terbinafine 250 mg once daily for 2 weeks B—Terbinafine 250 mg twice daily for 1 week C—Fluconazole 150 mg weekly for 4 week	Non-significant difference in mycological and clinical cure rate in three groups Clinical cure rate: Group A – 80% Group B – 73.33% Group C – 63.3% Mycological cure rate at 4 weeks: Group A – 93.3% Group B – 86.7% Group C – 83.3%	Gastrointestinal side effects Group A+B – 16.7% Group C -20%	[18]
4	randomized double blind clinical trial	30	T. corporis and T .cruris	Fluconazole 150 mg weekly for 4 weeks or Terbinafine 250 mg daily for 2 weeks.	At the end of the treatment, 64.3% of the subjects in Fluconazole group developed clinical and laboratory responses, while the second group developed 75% clinical and 81.3% laboratory cure. One month later, 64.3% in the Fluconazole group were cured, while in the other group, 87.5% were cured		[19]

Table 5: Adverse events reported in post-marketing experience. [10]

System	Adverse event
Immunologic	In rare cases, anaphylaxis (including angioedema, face edema and pruritus) has been reported.
Body as a whole	Asthenia, fatigue, fever, malaise
Cardiovascular	QT prolongation, torsade de pointes.
Central nervous system	Seizures, dizziness.
Hematopoietic and lymphatic	Leukopenia, including neutropenia and agranulocytosis, thrombocytopenia.
Metabolic	Hypercholesterolemia, hypertriglyceridemia, hypokalemia
Gastrointestinal	Cholestasis, dry mouth, hepatocellular damage, dyspepsia, vomiting.
Other senses	Taste perversion.
Muscoskeletal	myalgia
Nervous system	Insomnia and somnolence both? tremor, vertigo.
Skin and appendages	Acute generalized exanthematous-pustulosis, drug eruption, increased sweating, exfoliative skin disorders including Stevens-Johnson syndrome and toxic epidermal necrolysis, alopecia.

Table 6: Recommendation of systemic treatment of tinea corporis, tinea cruris and teniapedis. [6,17,18]

Guideline	Condition	Fluconazole Dose Adults	Children	Minimum duration	Precautions
IADVL ITART 2020	Naïve tinea corporis and tinea cruris	50-100 mg/day		4 weeks	
		150-200 mg once weekly	3-6 mg/kg/day	8 weeks	hepatotoxicity
	CH/SMT/RCL tinea corporis and tinea cruris	100mg/day		6 weeks	
		150 mg/ thrice weekly *		8 weeks	
AFP guideline (2014)	Extensive disease, failed topical treatment, immunocompromised patients, or severe moccasin-type tinea pedis	6 mg/kg/ day 6 mg/kg once weekly	-	3-6 weeks	
Indian review article	Tinea corporis or Tinea Cruris	150-300 mg/week	-	3-4 weeks	
	Tinea pedis	150 mg/week		4 weeks	

IADVL - Experts from Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) Task Force against Recalcitrant Tinea –(ITART]; AFP – American Family Physician guidelines; CH – chronic; SMT – steroid modified tinea; RCL – recalcitrant *dosage in current practice and not evidence based.

Table 7: Special Patient Profiles for oral Fluconazole [6]

Patient characteristic	Choice of antifungal
Hepatic dysfunction	Oral fluconazole* or topical antifungals
Children under 2 years	Oral antifungal or topical antifungals with established safety
Children above 2 years	Oral fluconazole, terbinafine, itraconazole, and griseofulvin or topical antifungals with established safety
Lactating mother	Oral fluconazole or topical antifungals

* Fluconazole is recommended as a relatively safe option in patients with hepatic dysfunction, albeit with strict monitoring of liver function.

comparative agents, but the clinical significance and relationship to treatment is uncertain. The following treatment-related clinical adverse events occurred at an incidence of 1% or greater in 4048 patients receiving fluconazole for 7 or more days in clinical trials: nausea 3.7%, headache 1.9%, skin rash 1.8%, vomiting 1.7%, abdominal pain 1.7%, and diarrhea 1.5%. [10] In addition, the following adverse events have occurred during post-marketing experience. The most commonly reported events in children were vomiting (5%), abdominal pain (3%), nausea (2%), and diarrhea (2%). [10] [Table 5]

6. Dosage and Administration

1. As per Expert Consensus on The Management of Dermatophytosis in India (ECTODERM India), systemic antifungals like fluconazole (150mg-300mg/week) can be used, when other oral antifungals such as terbinafine or itraconazole have failed. [1]
2. According to the experts from Indian Association of Dermatologists, Venereologists and Leprologists (IADVL) Task Force against Recalcitrant Tinea (ITART), patients with the first episode, with no prior history of treatment may be prescribed tablet fluconazole 150 mg thrice weekly. [6]

3. Fluconazole in a dose of 150 mg thrice weekly for 8 weeks seem to lead to a good clinical outcome in patients with recalcitrant dermatophytosis.[20] [Table 6]

7. Place of Fluconazole in the Treatment of Dermatophytosis

Though, Itraconazole or Terbinafine is first line of treatment, Fluconazole is the alternative first choice of systemic drug when prolonged duration of treatment is required. According to the experts from the IADVL Task Force against Recalcitrant Tinea (ITART), fluconazole needs to be taken for a longer duration than Itraconazole or Terbinafine for the management of glabrous tinea.[6] Regarding treatment duration, antifungal agents should be prescribed for 2 more weeks post clinical cure, in accordance with current scenario of dermatophytosis in India.[1] According to American Family Physician (AFP) guidelines, oral fluconazole is acceptable treatment for tinea capitis, with shorter treatment courses than griseofulvin (Evidence rating A).[21] [Table 7]

8. Conclusion

India has been observing an increase in the prevalence of superficial fungal infections and it has become clinically challenging to treat recalcitrant dermatophytosis due to newer isolates, antifungal resistance, patient non-compliance, changing pathophysiology and symptoms. Compiled data on guideline recommendations, efficacy, safety, pharmacokinetic advantages will help dermatologists and general physicians in clinical decision making to prescribe oral fluconazole in the management of tinea corporis, tinea cruris and tinea pedis. Fluconazole offers better safety and can be prescribed for a longer duration in patients with recalcitrant dermatophytosis.

9. Conflict of Interest

None.

10. Source of Funding

None.

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