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Comparison Of Efficacy of Oral Fluconazole Versus Oral Itraconazole in the Treatment of Pityriasis Versicolor

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Abstract:
Objective: To compare the efficacy of oral fluconazole and oral itraconazole in patients having pityriasis versicolor. **Study Design**: Randomised controlled trial. **Duration and Place of Study:** Study was done from 5th April 2025 to 5th Nov 2025 at dermatology department of Khyber Teaching Hospital Peshawar. **Methodology:** Total 106 patients (n=106) were included and randomized into two groups, fluconazole (n=53) and itraconazole (n=53). Patients aged 18 to 50 years with confirmed pityriasis versicolor were enrolled. Diagnosis was confirmed by potassium hydroxide microscopy. Patient received treatment and followed till 8 weeks. Efficacy was assessed clinically and microscopically. Data analysed by SPSS. Mean ± standard deviation calculated for quantitative variables and frequencies percentages for qualitative variables. Chi-square test and Fisher exact test was applied and $p \leq 0.05$ was taken significant. **Results:** Mean age in fluconazole group was 31.26±7.29 years and in itraconazole group 33.02±6.70 years. Male patients were 33(62.3%) in fluconazole and 27(50.9%) in itraconazole group. Treatment efficacy was seen in 42(79.2%) patients in fluconazole group as compared to 29(54.7%) in itraconazole group showing significant difference (p=0.007). In age ≤35 years efficacy was higher with fluconazole 33(86.8%) versus itraconazole 20(60.6%) (p=0.011). Stratified analysis showed significantly higher efficacy with fluconazole among patients aged ≤35 years (p=0.011), males (p=0.013), rural residents (p=0.006), and those with poor socioeconomic status (p=0.005). **Conclusion:** Oral fluconazole show more better efficacy than itraconazole in treatment of pityriasis versicolor.

Keywords: Antifungal agents, Fluconazole, Itraconazole, Malassezia, Pityriasis versicolor

INTRODUCTION

Pityriasis versicolor is a common fungal infection affecting the skin surface and is caused by yeasts belonging to the genus Malassezia.[1] It is more frequently seen in young adults who reside in warm and humid climates. This condition is characterized by lesions which can be either hypopigmented or hyperpigmented, mainly found on the chest, back, neck, and upper arm regions.[2] Pruritus might accompany the lesion; however, many patients experience no symptoms at all. Though the condition does not pose any danger to life, it could generate cosmetic issues and emotional stress in some cases.[3]

Fluconazole is one of the commonly employed systemic antifungal drugs used in the management of pityriasis versicolor due to the high bioavailability of the medication and low side effects associated with it.[4]

The mode of action is inhibition of cytochrome P450 enzyme in fungi, which leads to disruption of ergosterol production.[5] The drug is usually taken once or in small doses and has been known to produce satisfactory clinical and mycological responses in most patients.[6]

The oral form of itraconazole represents another systemic antifungal that is frequently used in treating pityriasis versicolor.[7] Itraconazole possesses increased lipophilicity and keratinophilicity, making its ability to penetrate the skin and sebum more effective.[8] Just like any other azole, itraconazole acts by blocking ergosterol biosynthesis, but it is more potent and possesses a wider spectrum of action.[9] The treatment with itraconazole usually includes a course of administration in a pulsed manner and may last longer than other treatments. Nevertheless, it is more likely to interact with other drugs and cause hepatotoxicity than other antifungals.[10]

In a study carried out by Rizwan M et al, had reported that oral fluconazole efficacy was 77.8% while oral itraconazole was effective in 50% cases in the treatment of pityriasis versicolor.[11]

This research needs to be conducted in Peshawar due to the frequent occurrence of pityriasis versicolor in hot and humid weather, as well as the lack of comparative data on oral Fluconazole and Itraconazole in the area. The study's objective is to find an effective therapy and improve patient results. The objective of this study is to compare the efficacy of oral fluconazole versus oral itraconazole in the treatment of pityriasis versicolor.

Methodology:

This study was conducted at the Department of Dermatology Khyber Teaching Hospital from 05 April 2025 to 05 November 2025 and it was designed as a randomised controlled trial. Ethical approval was obtained from Institutional Research and Ethical Review Board with certificate No. 84/DME/KMC dated 23/01/2025 before start of study and the trial was also registered at ClinicalTrials.gov with registration number NCT06922344. The sample size was calculated as 106 patients (53 in each group) by using OpenEpi sample size calculator taking efficacy of oral Fluconazole as 77.8% and oral Itraconazole as 50%,[11] level of significance 5% and power of test 90%. Patients fulfilling the eligibility criteria were enrolled using consecutive non-probability sampling.

All patients of both genders aged 18 to 50 years having clinically suspected pityriasis versicolor were included in the study. The disease was considered present when there was superficial fungal infection with hyperpigmented or hypopigmented scaly patches mainly distributed over chest, back, shoulders and neck. Diagnosis was further confirmed by skin scraping from affected area using glass slide, and specimen was treated with 10% KOH solution and examined under microscope showing typical fungal elements.

Patients were excluded who had history of chronic renal disease, liver disease, malignancy, those receiving radiotherapy or chemotherapy, cardiac conduction abnormalities, patients who used any topical or systemic antifungal therapy within last 1 month, and pregnant or lactating females.

After taking written informed consent patients were enrolled through OPD of dermatology department. Demographic variables were recorded including age, gender, marital status, residence, socio economic status and education level. Detailed history was taken regarding duration and pattern of disease and full clinical examination was performed.

Participants were randomly allocated by block randomization into two equal groups. Group A (intervention group) received oral fluconazole 300 mg once weekly for two weeks, whereas Group B (control group) received the standard treatment with oral itraconazole 200 mg daily for five days. Patients were counselled regarding proper drug intake and were followed up at 2, 4, and 8 weeks. Treatment efficacy was assessed at the end of the 8-week follow-up and was considered successful when there was complete clinical clearance of scaling, absence of yellowish-golden fluorescence on Wood's lamp examination, and negative potassium hydroxide microscopy for fungal hyphae.

All data was entered and analysed using SPSS software. Quantitative variables like age and duration of disease were expressed as mean ± standard deviation (Prior to statistical analysis, normality of continuous variables (age and duration of disease) was assessed using the Shapiro–Wilk test. Both variables showed normal distribution in the two treatment groups (all p-values >0.05) therefore, they were summarized as mean ± standard deviation) while qualitative variables including gender, marital status, residence, socio economic status, education level and efficacy were expressed as frequencies and percentages. Efficacy was compared between two groups using chi-square test and p value ≤0.05 was taken as statistically significant. Stratification was done with effect modifiers including age, gender, marital status, residence, socio economic status, education level and duration of disease and post stratification chi-square test and Fisher's exact test was applied with p value ≤0.05 considered significant.

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RESULT

A total of 106 patients were enrolled and equally divided into two treatment groups, with 53 patients receiving oral fluconazole and 53 receiving oral itraconazole. The mean age of patients in the fluconazole group was 31.26 ± 7.29 years, whilst patients in the itraconazole group had a mean age of 33.02 ± 6.70 years. The mean duration of disease was 4.26 ± 1.23 months in the fluconazole group and 4.74 ± 1.56 months in the itraconazole group. Regarding gender distribution, males were more predominant in the fluconazole group, accounting for 33 patients (62.3%), as compared to 27 males (50.9%) in the itraconazole group. Females comprised 20 patients (37.7%) in the fluconazole group and 26 patients (49.1%) in the itraconazole group. (Table-I).

Table I: Patient Demographics in Both Groups n=106

Variables	Oral Fluconazole n=53	Oral Itraconazole n=53
	Mean ± SD	Mean ± SD
Age (years)	31.26 ± 7.29	33.02 ± 6.70
Duration of disease (months)	4.26 ± 1.23	4.74 ± 1.56
Gender	n (%)	n (%)
Male	33 (62.3%)	27 (50.9%)
Female	20 (37.7%)	26 (49.1%)
Marital Status		
Married	44 (83.0%)	49 (92.5%)
Unmarried	9 (17.0%)	4 (7.5%)
Residence		
Urban	23 (43.4%)	24 (45.3%)
Rural	30 (56.6%)	29 (54.7%)
Socioeconomic Status		
Poor	29 (54.7%)	20 (37.7%)
Middle	13 (24.5%)	21 (39.6%)
High	11 (20.8%)	12 (22.6%)
Educational Status		
Educated	27 (50.9%)	30 (56.6%)
Uneducated	26 (49.1%)	23 (43.4%)

In terms of treatment efficacy, oral fluconazole demonstrated significantly higher efficacy as compared to oral itraconazole. A total of 42 patients (79.2%) in the fluconazole group showed positive response, in contrast to only 29 patients (54.7%) in the itraconazole group, and this difference was found to be statistically significant (p=0.007) (Table-II).

Table II: Comparison of Efficacy Between the Two Groups n=106

Efficacy	Oral Fluconazole n=53 n (%)	Oral Itraconazole n=53 n (%)	p value
Yes	42 (79.2%)	29 (54.7%)	0.007*
No	11 (20.8%)	24 (45.3%)	
Total	53 (100%)	53 (100%)	

*Chi-Square test

When the efficacy was analysed against demographic variables, in patients aged ≤35 years, fluconazole showed treatment success in 33 patients (86.8%) compared to 20 (60.6%) with itraconazole (p=0.011). Among male patients, fluconazole was effective in 26 (78.8%) versus 13 (48.1%) with itraconazole (p=0.013). Among married patients, efficacy was observed in 34 (77.3%) with fluconazole compared to 26 (53.1%) with itraconazole (p=0.015). In rural residents, fluconazole showed success in 19 (63.3%) versus only 8 (27.6%) with itraconazole (p=0.006). Among patients of poor socioeconomic status, 19 (65.5%) responded to fluconazole versus 5 (25.0%) to itraconazole (p=0.005), and in the middle socioeconomic group, all 13 (100%) fluconazole patients showed efficacy compared to 12 (57.1%) with itraconazole (p=0.006). Among uneducated patients, fluconazole was effective in 15 (57.7%) as compared to only 3 (13.0%) with itraconazole (p=0.002). In patients with disease duration greater than 3 months, fluconazole showed efficacy in 35 (76.1%) versus 23 (48.9%) with itraconazole (p=0.007) (Table-III).

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Table III: Association of Efficacy with Demographic Variables

Demographic Variables	Subgroup	Group	Yes (n, %)	No (n, %)	p-value
Age (years)	≤35	Fluconazole	33 (86.8%)	5 (13.2%)	0.011*
		Itraconazole	20 (60.6%)	13 (39.4%)	
	>35	Fluconazole	9 (60.0%)	6 (40.0%)	0.380*
		Itraconazole	9 (45.0%)	11 (55.0%)	
Gender	Male	Fluconazole	26 (78.8%)	7 (21.2%)	0.013*
		Itraconazole	13 (48.1%)	14 (51.9%)	
	Female	Fluconazole	16 (80.0%)	4 (20.0%)	0.177*
		Itraconazole	16 (61.5%)	10 (38.5%)	
Marital Status	Married	Fluconazole	34 (77.3%)	10 (22.7%)	0.015*
		Itraconazole	26 (53.1%)	23 (46.9%)	
	Unmarried	Fluconazole	8 (88.9%)	1 (11.1%)	1.000**
		Itraconazole	3 (75.0%)	1 (25.0%)	
Residence	Urban	Fluconazole	23 (100.0%)	0 (0.0%)	0.234**
		Itraconazole	21 (87.5%)	3 (12.5%)	
	Rural	Fluconazole	19 (63.3%)	11 (36.7%)	0.006*
		Itraconazole	8 (27.6%)	21 (72.4%)	
Socioeconomic Status	Poor	Fluconazole	19 (65.5%)	10 (34.5%)	0.005*
		Itraconazole	5 (25.0%)	15 (75.0%)	
	Middle	Fluconazole	13 (100.0%)	0 (0.0%)	0.006**
		Itraconazole	12 (57.1%)	9 (42.9%)	
	High	Fluconazole	10 (90.9%)	1 (9.1%)	0.478**
		Itraconazole	12 (100.0%)	0 (0.0%)	
Educational Status	Educated	Fluconazole	27 (100.0%)	0 (0.0%)	0.114**
		Itraconazole	26 (86.7%)	4 (13.3%)	
	Uneducated	Fluconazole	15 (57.7%)	11 (42.3%)	0.002**
		Itraconazole	3 (13.0%)	20 (87.0%)	
Duration (months)	≤3	Fluconazole	7 (100.0%)	0 (0.0%)	N/A
		Itraconazole	6 (100.0%)	0 (0.0%)	
	>3	Fluconazole	35 (76.1%)	11 (23.9%)	0.007*
		Itraconazole	23 (48.9%)	24 (51.1%)	

*Chi-square-Test **Fischer Exact Test

DISCUSSION

The effectiveness of oral fluconazole was significantly better than that of itraconazole with 42 cases (79.2%) showing positive results as against 29 cases (54.7%), (p = 0.007). This might be due to the high bioavailability of fluconazole, about 90% along with increased concentrations in the stratum corneum through sweat, as the latter is the main area affected by Malassezia infection.4,6 On the other hand, itraconazole is a lipid-based molecule and has inconsistent absorption, which depends upon the stomach pH, leading to unpredictable concentrations in the skin.7,8 Oral fluconazole had significant better effectiveness among patients up to 35 years old in 33 cases (86.8%) as opposed to itraconazole in 20 cases (60.6%), (p = 0.011). Increased skin cell turnover rate and better immune reaction in young patients might result in faster elimination of Malassezia with an adequate concentration of drug.

The findings of present study showed that oral fluconazole was significantly more effective than oral itraconazole, with treatment success observed in 42 patients (79.2%) versus 29 patients (54.7%) respectively (p=0.007). These results agree with Siddeshwara MG et al. 12 who reported clinical cure of 80% with fluconazole versus 60% with itraconazole (p=0.029), and with Ullah S et al. 13 who found efficacy of 82.6% versus 60.9% (p=0.02) in favour of fluconazole. Similarly, Muhammad Rizwan et al. 11 reported efficacy of 77.8% with fluconazole versus 50% with itraconazole (p=0.014), and Smita Jha et al. 14 also reported better early response with fluconazole

at 2 weeks (78% vs 54%). The higher efficacy of fluconazole across these studies may be explained by its superior oral bioavailability of approximately 90% and its ability to achieve consistent drug concentrations in the stratum corneum via eccrine secretion, which is the primary site of Malassezia colonisation. Itraconazole, being highly lipophilic, requires acidic gastric environment for optimal absorption and its bioavailability remains more variable, which may account for its relatively lower treatment success rates.

However, not all studies was in agreement with these findings. Osman Kose et al. 15 found no statistically significant difference between fluconazole and itraconazole, with clinical response of 80% versus 74% and mycological cure of 88% versus 80% ($p>0.05$). Similarly, Ritu Jaswal et al.16 also reported no significant difference between both drugs ($p>0.05$), though fluconazole was preferred for its convenience and lower cost. These contrasting results may be due to differences in dosing regimens, follow-up periods, patient selection criteria, and the baseline severity of disease, all of which could have influenced the final efficacy outcomes.

In the present study, fluconazole showed better efficacy in younger patients aged ≤35 years, with 33 (86.8%) showing treatment success compared to 20 (60.6%) with itraconazole ($p=0.011$). Arun Kumar Das et al. 17 also reported slightly better clinical cure with fluconazole (66% vs 57%) with mean ages in both groups being around 30–31 years, which supports the observation that fluconazole may performs more consistently in younger age groups, possibly due to better immune responsiveness and more regular skin cell turnover that facilitates drug action at the site of infection.

Dian Anggraeni et al. 18 reported lower minimum inhibitory concentration (MIC) values for itraconazole compared to fluconazole against Malassezia furfur in vitro, suggesting stronger antifungal potency of itraconazole at laboratory level. This finding is in contrast to the clinical results of present study and several other clinical trials, which demonstrated better outcomes with fluconazole. This discrepancy between in vitro and clinical efficacy is not uncommon and may reflects the differences in drug pharmacokinetics, particularly the ability of fluconazole to penetrate skin layers effectively in vivo, which may not be captured in laboratory-based MIC studies.

Aditya K. Gupta et al. 19 highlighted that pityriasis versicolor carries relapse rates as high as 60% within one year and 80% within two years, which emphasises the importance of selecting a drug with not only good initial efficacy but also sustained action. The significantly higher treatment success observed with fluconazole in present study further supports its role as a more reliable first-line oral agent in the management of pityriasis versicolor, particularly in resource-limited settings where consistent drug absorption and patient compliance is of considerable importance.

This current study faces several weaknesses that need consideration. Being conducted within one centre or hospital only, it cannot be generalized to a larger group of people. The number of participants in this experiment was 106 individuals, a fairly small number that can limit the capacity of this research. Moreover, the follow-up period in this case was very short, while the disease often recurs due to its nature.

CONCLUSION

According to the findings of the current study, it can be concluded that oral fluconazole is more effective in treating pityriasis versicolor compared to oral itraconazole. This higher efficacy of fluconazole could be due to the high oral absorption property of the drug along with its ability to achieve steady-state concentrations in the stratum corneum. In addition to this, fluconazole showed better results in different age groups, males, rural people, and less educated participants.

Disclaimer: not any
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Conflict of Interest:
Author declare there is no any conflict of interests for this study.

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