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Original Research Article

COMPARATIVE EFFICACY OF SINGLE ORAL DOSE OF FLUCONAZOLE VS A SINGLE ORAL DOSE OF ITRACONAZOLE IN PATIENTS WITH PITYRIASIS VERSICOLOR

ULLAH S, SALEEM S

Department of Dermatology, Combined Military Hospital, Nowshera, Pakistan
**Corresponding author email address: drsami152@gmail.com*

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ABSTRACT

Background: *Pityriasis versicolor is a common superficial fungal infection caused by Malassezia species, presenting with hypo- or hyperpigmented scaly patches. Although systemic antifungal agents such as fluconazole and itraconazole are widely used, evidence regarding their comparative single-dose efficacy remains limited.* ***Objective:*** *To compare the efficacy of a single oral dose of fluconazole versus a single oral dose of itraconazole in the treatment of pityriasis versicolor.* ***Study Design:*** *Randomized controlled trial.* ***Setting:*** *Combined Military Hospital (CMH), Nowshera, Pakistan.* ***Duration of Study:*** *From 11 December 2024 to 11 May 2025.* ***Methods:*** *A total of 92 patients with clinically and microscopically confirmed pityriasis versicolor were enrolled through non-probability consecutive sampling and randomly allocated into two equal groups. Group A received a single oral dose of fluconazole 400 mg, while Group B received a single oral dose of itraconazole 400 mg. Diagnosis was confirmed using a Wood's lamp examination and a 10% KOH mount, which showed the characteristic "spaghetti and meatball" appearance. Treatment efficacy was defined as the absence of fungal elements on repeat KOH mount at 4 weeks post-treatment. Data were analyzed using SPSS version 25.0, with a chi-square test applied for comparison; p-value <0.05 was considered significant.* ***Results:*** *The mean age of participants was 33.11 ± 8.75 years in Group A and 32.00 ± 7.79 years in Group B, with no significant difference between groups. Fluconazole demonstrated significantly higher efficacy, with 82.6% (n = 38) of patients achieving clearance, compared to 60.9% (n = 28) in the itraconazole group (p = 0.02).* ***Conclusion:*** *A single oral dose of fluconazole was significantly more effective than a single oral dose of itraconazole in treating pityriasis versicolor. These findings support fluconazole as a superior first-line systemic treatment option for this condition.*

Keywords: Pityriasis Versicolor, Fluconazole, Itraconazole, Mycological Cure

INTRODUCTION

Pityriasis versicolor (PV) indicates a common and non-threatening, superficial fungal dermatosis. Saprophytic, lipid-dependent yeasts from the genus Malassezia, referred to as Pityrosporum, are causative agents as well as components of normal skin flora (1-3). PV is distinct from other types of tinea infections as it is not categorized as a dermatophyte infection. Clinical characteristics include hyperpigmentation accompanied by fine overlying scales. The trunk, neck, and proximal extremities are the most commonly affected sites. PV is attributed to Malassezia, which constitutes a part of normal skin microbiota. Clinical disease arises when Malassezia shifts from its yeast form to mycelial form. Researchers have found 14 species of Malassezia (4). The main species involved in tinea versicolor include Malassezia furfur and Malassezia sympodialis, with M. globosa recognized as the most common (5-7). PV is prevalent worldwide, particularly in warm and humid climates. PV exhibits an incidence of 50% in tropical regions (8).

Fluconazole, as well as Itraconazole, are currently preferred systemic agents for medical care. Itraconazole is a synthetic triazole administered orally, whereas fluconazole is an oral synthetic bistrizole substance. Both actions hinder the cytochrome P450-dependent 14-alpha demethylation step in ergosterol synthesis, consequently impairing the functions of certain membrane-bound enzyme systems and ultimately hindering fungal growth (9, 10). Both drugs have been examined across various dosing regimens; however, the studies have produced inconsistent results on this subject. A standard drug and its corresponding dosage that guarantees a complete cure remain unavailable. A study demonstrated the efficacy of a single oral dose of fluconazole (83.33%) compared to a single oral dose of itraconazole (56.66%) among patients with PV 11.

Although both medications have been investigated under different dosage schedules, studies on this topic have produced varying findings. Currently, there is no typical medication or dosage that guarantees a total cure due to the paucity of literature on this subject locally. The goal of this study is to compare the efficacy of a single oral dose of fluconazole with that of a single oral dose of itraconazole in patients with pityriasis versicolor at our hospital. The findings of this study will help our medical professionals determine the optimal treatment course with a reasonable dosage schedule for Pityriasis Versicolor. By evaluating the efficacy of both treatments, this research aims to provide evidence-based recommendations for the optimal oral antifungal treatment strategy for pityriasis versicolor, ultimately enhancing patient outcomes and informing clinical practice.

METHODOLOGY

This randomized controlled trial was conducted in the Dermatology Department of the Combined Military Hospital, Nowshera, from December 11, 2024, to May 11, 2025, following approval from the hospital.

Ninety-two participants were enrolled, with 46 patients allocated to each treatment group using a consecutive non-probability sampling technique. The sample size was calculated using the WHO sample size calculator, with assumptions based on previously reported efficacy rates of 83.33% for fluconazole and 56.66% for itraconazole, 95% confidence level, and 80% power (12). Participants were adults aged 18 to 45 years who were presented with clinically and mycologically confirmed pityriasis versicolor. Diagnosis was established through clinical examination. Clinically, the condition was given as well-defined, scaly, hypo- or hyperpigmented lesions. The Diagnosis was confirmed through Wood's lamp examination, which revealed a

characteristic yellowish-green fluorescence and microscopic evaluation of skin scrapings using a 10% potassium hydroxide (KOH) mount. Under microscopy, the infection is identified by the presence of a spaghetti and meatball appearance. Individuals with hepatic, cardiac, or thyroid diseases, known hypersensitivity to the study drugs, malignancy, or those who were pregnant or lactating were excluded. Additionally, patients unwilling to attend follow-up visits were not enrolled.

Participants in Group A received a single 400 mg oral dose of fluconazole, while those in Group B received a single 400 mg oral dose of itraconazole. Efficacy was defined as the absence of fungal hyphae on KOH mount testing four weeks post-treatment. All clinical assessments were conducted under the supervision of an experienced dermatologist with a minimum of five years of practice. A structured proforma was used to record demographic and clinical data, including age, gender, body mass index (BMI), marital status, residence, socioeconomic status, educational status, and occupation.

SPSS 20 was used for data analysis. Age, BMI, height, and weight were presented as mean and SD. Gender, marital status, residence, socioeconomic status, educational status, efficacy, and occupation were evaluated in terms of frequency and percentages. Efficacy was compared between the two groups using the chi-square test with a significance level set at 5%. Demographics were stratified by efficacy in both groups using the Chi-Square test, with a significance level set at 5%.

RESULTS

The mean age of participants in Group A (fluconazole) was 33.11 ± 8.75 years, while in Group B (itraconazole) it was 32.00 ± 7.79 years. The mean BMI for Group A was 24.61 ± 1.35, and for Group B it was 24.88 ± 1.46. Both groups consisted of 46 participants.

Demographic analysis revealed that in Group A, 30 (65.2%) were male and 16 (34.8%) were female, whereas Group B had 27 (58.7%) males and 19 (41.3%) females. The remaining demographics of the patients are presented in Table 1.

Efficacy results demonstrated a significant difference between the two treatments. In Group A, 38 (82.6%) patients achieved efficacy, while in Group B, only 28 (60.9%) showed efficacy (P = 0.02) (Table 2). Table 3 presents the stratifications regarding the demographics.

Table 1: Demographics

Demographics		Groups			
		Group A (Fluconazole)		Group B (Itraconazole)	
		n	%	n	%
Gender	Male	30	65.2%	27	58.7%
	Female	16	34.8%	19	41.3%
Education	Educated	25	54.3%	20	43.5%
	Uneducated	21	45.7%	26	56.5%
Occupation status	Employed	22	47.8%	24	52.2%
	Unemployed	24	52.2%	22	47.8%
Residence	Urban	30	65.2%	24	52.2%
	Rural	16	34.8%	22	47.8%
Socioeconomic status	Lower class	13	28.3%	12	26.1%
	Middle class	25	54.3%	22	47.8%
	Upper class	8	17.4%	12	26.1%
Marital status	Married	21	45.7%	28	60.9%
	Unmarried	25	54.3%	18	39.1%

Table 2: Comparison of efficacy between both groups

Efficacy	Groups				P value
	Group A (Fluconazole)		Group B (Itraconazole)		
	n	%	n	%	
Yes	38	82.6%	28	60.9%	0.02
No	8	17.4%	18	39.1%	

Table 3: Stratification of comparison of efficacy between both groups with demographics

Demographics				Groups				P value
				Group A (Fluconazole)		Group B (Itraconazole)		
				n	%	n	%	
Gender	Male	Efficacy	Yes	25	83.3%	17	63.0%	0.08
			No	5	16.7%	10	37.0%	
	Female	Efficacy	Yes	13	81.2%	11	57.9%	0.13
			No	3	18.8%	8	42.1%	
Education	Educated	Efficacy	Yes	20	80.0%	12	60.0%	0.14
			No	5	20.0%	8	40.0%	
	Uneducated	Efficacy	Yes	18	85.7%	16	61.5%	0.06
			No	3	14.3%	10	38.5%	
Occupation status	Employed	Efficacy	Yes	18	81.8%	15	62.5%	0.14
			No	4	18.2%	9	37.5%	
	Unemployed	Efficacy	Yes	20	83.3%	13	59.1%	0.06
			No	4	16.7%	9	40.9%	
Residence	Urban	Efficacy	Yes	24	80.0%	14	58.3%	0.08
			No	6	20.0%	10	41.7%	
	Rural	Efficacy	Yes	14	87.5%	14	63.6%	0.09
			No	2	12.5%	8	36.4%	
Socioeconomic status	Lower class	Efficacy	Yes	8	61.5%	9	75.0%	0.47
			No	5	38.5%	3	25.0%	
	Middle class	Efficacy	Yes	24	96.0%	13	59.1%	0.002
			No	1	4.0%	9	40.9%	
	Upper class	Efficacy	Yes	6	75.0%	6	50.0%	0.26
			No	2	25.0%	6	50.0%	
Marital status	Married	Efficacy	Yes	18	85.7%	14	50.0%	0.009
			No	3	14.3%	14	50.0%	
	Unmarried	Efficacy	Yes	20	80.0%	14	77.8%	0.86
			No	5	20.0%	4	22.2%	

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Age distribution (Years)	18 to 30	Efficacy	Yes	13	81.2%	11	57.9%	0.13
			No	3	18.8%	8	42.1%	
	> 30	Efficacy	Yes	25	83.3%	17	63.0%	0.08
			No	5	16.7%	10	37.0%	
BMI (Kg/m2)	18 to 24.9	Efficacy	Yes	24	85.7%	15	65.2%	0.08
			No	4	14.3%	8	34.8%	
	> 24.9	Efficacy	Yes	14	77.8%	13	56.5%	0.15
			No	4	22.2%	10	43.5%	

DISCUSSION

The comparative efficacy of single oral doses of fluconazole and itraconazole in treating pityriasis versicolor has been extensively studied with varying results across different populations and settings. The demographic characteristics of our study participants, including age and gender distribution, were comparable to those reported in other studies. The mean age in our cohort was approximately 32–33 years, which is similar to the mean ages reported by Partap et al. (26 years in both groups) and Siddeshwara et al. (30 years in both groups) (10, 13).

Gender distribution in our study showed a slight male predominance (65.2% in Group A and 58.7% in Group B). Rizwan et al. also documented in a similar survey that the majority of their patients in both groups were male (11). A similar trend was also noted in the study by Khan et al., where males constituted 80% of the participants (14). These similarities in demographic profiles suggest that the condition is more frequently presented in males gender.

Our findings align with several previous studies, which demonstrate that fluconazole exhibits superior efficacy compared to itraconazole when administered as a single dose. In our research, fluconazole achieved an efficacy rate of 82.6%, whereas itraconazole showed a lower efficacy of 60.9% (P = 0.02). Rizwan et al. documented similar findings, noting that oral fluconazole (300 mg, administered as two 150 mg daily doses) had notably higher efficacy than itraconazole (11).

This trend is also consistent with the results reported by Nasir et al., who found that fluconazole (400 mg) yielded an efficacy of 83.3% compared to itraconazole (1000 mg), at 56.6%, further reinforcing the superiority of fluconazole in this context (12). Similarly, Siddeshwara et al. observed an 80% clinical cure rate with fluconazole, compared to 60% with itraconazole, corroborating our findings (13). Khan et al. also documented that a single dose of fluconazole was effective for treating pityriasis versicolor, although their study did not include a comparative arm (14).

Mycological cure assessed via KOH mount and Wood's lamp examination was a key outcome in our study. Partap et al. documented mycological cure rates of 65% for fluconazole and 20% for itraconazole (10). The stark difference in mycological efficacy between the two drugs may be attributed to fluconazole's unique pharmacokinetics, including its prolonged half-life and superior penetration into the stratum corneum, where it maintains therapeutic concentrations for extended periods (15). This property likely contributes to its consistent performance across multiple studies.

The safety profiles of both drugs have been well-documented, and they were comparable, with no serious adverse effects reported. Siddeshwara et al. observed similar tolerability for both drugs (13). Khan et al. reported no adverse effects with a single dose of fluconazole (14). The favorable safety profiles of fluconazole and itraconazole make them suitable for widespread use, though fluconazole's superior efficacy gives it an edge in clinical practice. Our findings, along with those of other studies, suggest that fluconazole should be considered the preferred treatment for pityriasis versicolor, particularly in cases requiring systemic therapy. Its higher efficacy, faster resolution of symptoms, and lower relapse rates, as reported by Pratap et al, make it a more reliable option than itraconazole (10). However, it is worth noting that individual patient factors such as comorbidities or drug interactions may influence the choice of treatment.

Future research could investigate the long-term outcomes of these treatments, including relapse rates over extended follow-up periods, to further refine clinical recommendations and inform future treatment strategies. Additionally, comparative studies incorporating larger and more diverse populations would help validate these findings across different demographic and geographic settings.

CONCLUSION

We conclude that the efficacy of a single oral dose of fluconazole was significantly better than that of a single oral dose of itraconazole in patients with pityriasis versicolor.

DECLARATIONS

Data Availability Statement

All data generated or analysed during the study are included in the manuscript.

Ethics approval and consent to participate

Approved by the department Concerned. (IRB)

Consent for publication

Approved

Funding

Not applicable

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

AUTHOR CONTRIBUTION

SAMI ULLAH (Postgraduate Resident)

Manuscript drafting, Data Collection, Review of manuscript, Manuscript revisions, Critical input, and Final approval of manuscript

SUMMAYA SALEEM (Assistant Professor).

Study Design, Critical Input, Supervision of entire process, Conception of Study, and Final approval of manuscript.

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