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ORIGINAL ARTICLE

Comparative efficacy of oral and topical antifungals in recurrent vulvo-vaginal candidiasis

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ABSTRACT

Background: Vulvovaginal candidiasis (VVC) is a common gynaecological infection that significantly affects women's quality of life. Both oral and topical antifungal therapies are widely used; however, their comparative efficacy remains a subject of clinical interest.

Material and Methods: This quasi-experimental study was conducted in the Department of Gynaecology, Continental Medical College, Lahore (1st June to 30th November 2025). A total of 120 women with recurrent vulvovaginal candidiasis were included, who were divided into Group-A (oral fluconazole) and Group-B (topical clotrimazole). Both groups were treated for three months. After completion of therapy, patients were assessed for efficacy. Intergroup comparison of parameters was performed with Mann Whitney U-test and Fisher exact or chi-square test using SPSS v22.

Results: In this study, 120 patients were included and were divided into two groups. Median age was 29.00 (15.00) years. Median duration of discharge was 9.00 (6.00) days. There were 43 (35.80%) primiparous and 77 (64.20%) multiparous women. Among all women, 94 (78.30%) were premenopausal and 26 (21.70%) were menopausal. There were 71 (59.20%) women who were diabetic. In Group-A, efficacy/complete cure was achieved in 52 (86.67%) while in Group-B, it was achieved in 35 (58.33%) of the women, (p = 0.001).

Conclusion: In this study population, oral fluconazole demonstrated significantly better efficacy than topical clotrimazole for treating recurrent vulvovaginal candidiasis. However, given the study limitations, these findings should be considered preliminary and require confirmation through larger randomized controlled trials.

Keywords: Candidiasis, Clotrimazole, Fluconazole, Recurrent vulvovaginal candidiasis, Vulvovaginal.

BACKGROUND

Candida, often known as yeast, is a typical organism that inhabits the vagina, specifically the albicans type. Normally, the growth of Candida is inhibited by Lactobacilli, which are beneficial bacteria.[1] The majority of women are expected to encounter an occurrence of vaginal candidiasis at some point, primarily due to pregnancy, consumption of non-prescription antifungal medications, oral contraceptive pills and use of synthetic or non-breathable underwear.[2] Pregnancy is the most important risk factor for vulvovaginal candidiasis and according to a study, occurrence of vulvovaginal candidiasis in pregnant women has been reported to be as high as 35%.[3] However, pregnant women were excluded from the present study to avoid potential confounding effects of pregnancy-related hormonal and immunological changes on treatment outcomes, and to minimize any potential risk to the fetus. The reproductive hormones oestrogen and progesterone also play role in vaginal immunity.[4] Therapy directed against candida infection involving the lower female reproductive tract is the anti-fungal formulations.[5] These can be given either orally or by vaginal route.

In Pakistan, vulvovaginal candidiasis represents a substantial gynecological health burden, particularly among women of reproductive age. Several local studies have reported Candida species in approximately 25%–40% of women presenting with abnormal vaginal discharge, with Candida albicans being the predominant isolate. The prevalence is even higher among pregnant women and those with diabetes mellitus, both of which are common in the Pakistani population. VVC contributes significantly to outpatient gynecological visits, causing discomfort, impaired quality of life, increased healthcare utilization, and economic burden. Despite its high prevalence, there remains variability in treatment practices, and evidence comparing the

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effectiveness of oral and topical antifungal therapies in local populations is limited.

When it comes to comparison of these two different routes of administration of antifungal therapy, a study compared the efficacy of oral versus topical antifungals in women with vulvovaginal candidiasis and reported that oral antifungal therapy showed significantly better efficacy as compared to topical antifungal therapy in management of vulvovaginal candidiasis [79% versus 55%, respectively; p = 0.036].[6] Contrary to both the aforementioned studies, a study reported better efficacy of topical antifungal therapy as compared oral therapy for management of vulvovaginal candidiasis [78.3% versus 73.6%, respectively].[7]

Oral and topical antifungals are two different modes of treatment of vulvovaginal candidiasis but which amongst these two formulations should be preferred is still controversial, as evident from aforementioned studies with one showing oral antifungal therapy as better choice while the other one showing results in favour of topical therapy.[6,7] However, most of these studies have focused on uncomplicated or first-episode vulvovaginal candidiasis, with limited evidence regarding optimal treatment for recurrent vulvovaginal candidiasis (RVVC), defined as three or more episodes of symptomatic vulvovaginal candidiasis in the preceding 12 months.[8] Therefore, it is imperative to conduct further studies in this regard for which this study is conducted with the aim to compare efficacy of oral and topical antifungals in recurrent vulvovaginal candidiasis.

MATERIAL AND METHODS

This quasi-experimental study was conducted at Department of Obstetrics and Gynecology, Hayat Continental Medical College, Lahore from 1st June 2025 to 30th November 2025. The study protocol was approved from the Institutional Ethics Committee of Continental Medical College (Reference No: 54/IRB/CMC dated 24th February 2024) before commencement of the study. Calculation of the appropriate sample size calculation was done by using WHO sample size calculator by assuming 5% level of significance, 80% power and anticipated frequency of complete cure in oral and vaginal antifungal therapy in vulvovaginal candidiasis of 79% and 55%, respectively.[6] This yielded a sample size of 120 (60 in each group) which was selected by using non-probability consecutive sampling technique.

Women between 18 and 60 years of age and were diagnosed with recurrent vulvovaginal candidiasis (defined as three or more episodes of symptomatic vulvovaginal candidiasis in the preceding 12 months) were included. Diagnosis of vulvovaginal candidiasis was made by presence of curdy white vaginal discharge for five or more days which on direct microscopic examination using 10% KOH showed blastoconidia & pseudohyphae, and there was positive high vaginal swab yeast culture. Disease severity was assessed at baseline using the vulvovaginal candidiasis severity scoring system, which evaluates clinical signs and symptoms including pruritus, burning, erythema, edema, and discharge, with scores categorized as mild (≤3), moderate (4-7), or severe (8-10). Candida species identification was not performed separately due to resource constraints, which is acknowledged as a limitation of the study.[9] Women having history of hypersensitivity to either of study drugs, vaginal ulceration, prior anti-fungal therapy within the preceding 30 days, liver disease, immunosuppression, chemotherapy, and women who were pregnant were excluded.

Obtaining of informed consent in written form was made prerequisite before inclusion in the study. Baseline demographic and clinical information was collected for each patient, including age (in years), duration of discharge (in days), para (primiparous/ multiparous), socioeconomic status (upper/ middle/ lower), education status (no school education/ school education), area of residence (urban/ rural), menstrual status (premenopausal/ menopausal) and history of diabetes.

Once included, patients were divided into two groups by alternate allocation method (every alternate patient was allocated to Group-A). Participants and outcome assessors were not blinded to treatment allocation due to the nature of the intervention. Process of patient recruitment,

group allocation and outcome assessment was done by following STROBE checklist and guidelines.

Patients in Group-A (n = 60) were treated with oral fluconazole given on days one, three and seven followed by maintenance dose of 150 mg every week was given for six weeks and then 150 mg every two weeks till completion of three months. This extended regimen was employed for recurrent vulvovaginal candidiasis cases as recommended by the Infectious Diseases Society of America (IDSA) guidelines for maintenance suppressive therapy.[8] Patients in Group-B (n = 60) were treated with 100 mg clotrimazole vaginal tablets given once daily at night for fourteen days followed by twice weekly 100 mg of clotrimazole vaginal tablets till completion of three months. After completion of therapy, patients were assessed for efficacy. Efficacy was labelled based on achievement of complete cure at completion of three months of therapy. Complete cure was defined by absence of discharge and negative high vaginal swab yeast culture after completion of therapy. In case of failure of achievement of complete cure, alternative therapy as per advice of consultant gynaecologist was provided.

All the collected data was entered and analysed with SPSS version 22. Qualitative variables para, socioeconomic status, education status, area of residence, menstrual status, history of diabetes and efficacy were measured in terms of frequency and percentage. Quantitative variables like age and duration of discharge was measured in median interquartile range (IQR) since Shapiro-Wilk test showed the distribution as non-normal and intergroup comparison was performed with Mann Whittney U-test. To compare efficacy between groups, chi-square test was used. Efficacy was stratified by age, duration of discharge, para, menstrual status and history of diabetes to deal with effect modifiers. Post-stratification chi-square and fisher exact test was used. A p-value ≤ 0.05 was considered as significant.

RESULTS

One hundred and twenty patients were included in the study with a cumulative median age of 29.00 (15.00) years. Median duration of discharge was 9.00 (6.00) days. There were 43 (35.80%) primiparous and 77 (64.20%) multiparous women. There were 16 (13.30%) women in upper, 30 (25.00%) in middle and 74 (61.70%) in lower socioeconomic status. Seventy-one (59.2%) women did not receive any school education. A total of 56 (46.70%) women live in rural locality and 64 (53.30%) in urban locality. Among all women, 94 (78.30%) were premenopausal and 26 (21.70%) were menopausal. There were 71 (59.20%) women who were diabetic. Intergroup comparison of pre-treatment characteristics is given in Table-I. In Group-A, efficacy/complete cure was achieved in 52 (86.67%) of the women while in Group-B, it was achieved in 35 (58.33%) of the women, (p = 0.001). Intergroup efficacy comparison is given in Table-II. Stratification of efficacy by confounding variables including age, duration of discharge, para, menstrual status and history of diabetes is given in Table-III.

Table-I: Intergroup comparison of pre-treatment characteristics (n = 120)

Characteristic	Group-A (n = 60)	Group-B (n = 60)	p-value
Age	29.00 (15.00) years	29.00 (16.75) years	0.916*
Age group			
18-40 years	44 (73.33%)	40 (66.67%)	0.426†
41-60 years	16 (26.67%)	20 (33.33%)	
Duration of discharge	9.00 (6.00) days	9.00 (6.00) days	0.816*
Duration of discharge group			
< 10 days	33 (55.00%)	34 (56.57%)	0.854†
≥ 10 days	27 (45.00%)	26 (43.33%)	
Para			
Primiparous	25 (41.67%)	18 (30.00%)	0.183†
Multiparous	35 (58.33%)	42 (70.00%)	
SES			
Upper	8 (13.33%)	8 (13.33%)	

Middle	13 (21.67%)	17 (28.34%)	0.687†
Lower	39 (65.00%)	35 (58.33%)	
Education status			
No school education	43 (71.67%)	28 (46.67%)	0.005†
School education	17 (28.33%)	32 (53.33%)	
Area of residence			
Rural	29 (48.33%)	27 (45.00%)	0.714†
Urban	31 (51.67%)	33 (55.00%)	
Menstrual history			
Premenopausal	48 (80.00%)	46 (76.67%)	0.658†
Menopausal	12 (20.00%)	14 (23.33%)	
Diabetes status			
Diabetic	36 (60.00%)	35 (58.33%)	0.853†
Non-diabetic	24 (40.00%)	25 (41.67%)	
Severity Score			
Mild (≤3)	22 (36.67%)	20 (33.33%)	
Moderate (4-7)	28 (46.67%)	30 (50.00%)	0.789†
Severe (≥7)	10 (16.67%)	10 (16.67%)	

Mann Whitney U-test; † Chi-square test

Table-II: Intergroup efficacy comparison (n = 120)

Efficacy	Group-A (n = 60)	Group-B (n = 60)	p-value
Yes	52 (86.67%)	35 (58.33%)	0.001†
No	8 (13.33%)	25 (41.67%)	

† Chi-square test

Table-III: Stratification of efficacy by confounding variables (n = 120).

Stratification	Group	Efficacy	n (%)	p-value
Age stratification				
	Group-A	18-40 years (n=44)	38 (86.36%)	1.000Ω
		41-60 years (n=16)	14 (87.50%)	
	Group-B	18-40 years (n=40)	25 (62.50%)	0.355†
		41-60 years (n=20)	10 (50.00%)	
Duration of discharge stratification				
	Group-A	< 10 days (n=33)	29 (87.88%)	1.000Ω
		≥ 10 days (n=27)	23 (85.19%)	
	Group-B	< 10 days (n=34)	22 (64.71%)	0.252†
		≥ 10 days (n=26)	13 (50.00%)	
Stratification by para				
	Group-A	Primiparous (n=25)	23 (92.00%)	0.449Ω
		Multiparous (n=35)	29 (82.86%)	
	Group-B	Primiparous (n=18)	14 (77.78%)	0.046†
		Multiparous (n=42)	21 (50.00%)	
Stratification by menstrual status				
	Group-A	Premenopausal (n=48)	42 (87.50%)	0.655Ω
		Menopausal (n=12)	10 (83.33%)	
	Group-B	Premenopausal (n=46)	30 (65.22%)	0.050†
		Menopausal (n=14)	5 (35.71%)	
Stratification by history of diabetes				
	Group-A	Diabetic (n=36)	32 (88.89%)	0.702Ω
		Non-diabetic (n=24)	20 (83.33%)	
	Group-B	Diabetic (n=35)	20 (57.14%)	0.825†
		Non-diabetic (n=25)	15 (60.00%)	
Stratification by severity score				
	Group-A	Mild (n=22)	**20 (90.91%)**	
		Moderate (n=28)	**24 (85.71%)**	**0.823Ω**
		Severe (n=10)	**8 (80.00%)**	
	Group-B	Mild (n=20)	**13 (65.00%)**	
		Moderate (n=30)	**17 (56.67%)**	**0.718†**
		Severe (n=10)	**5 (50.00%)**	

† = Chi-square test, Ω = Fisher exact test

DISCUSSION

Candidal infections, like most of the fungal infections, are often considered to affect patients who have depressed immunity either due to a disorder of immune system itself or secondary to conditions that depress the immunity like diabetes.[9,10] These infections are very difficult to treat owing to widespread antifungal resistance globally and ability of these infections to recur.[11,12] Present study focused on the two different treatment modalities of a specific type of candida infection, i.e., recurrent vulvovaginal candidiasis. The extended three-month treatment regimen used in this study was specifically designed for recurrent vulvovaginal candidiasis, following the Infectious Diseases Society of America (IDSA) recommended maintenance suppressive therapy approach of fluconazole 150 mg weekly.[8] While single-dose fluconazole is standard for uncomplicated vulvovaginal candidiasis, recurrent cases typically require longer maintenance regimens to prevent recurrence.

In present study, median age of the women who were suffering from this condition was 29 years with majority of sufferers of this infection being multigravida and multiparous. This finding was similar to various previous studies showing this infection to be much more common in this particular set of women.[13,14] The reason behind higher chance of multiparous and multigravida to contract this infection is secondary to hormonal and epithelial changes in the vagina related to process of pregnancy and certain changes in the microbiota of the vaginal canal.[14] In addition, it was also found that majority of women who were sufferers of this infection belonged to lower socioeconomic status, who were not educated, premenopausal and diabetic. Similar to this, a study found that low socioeconomic status (SES) as well as illiteracy, can contribute to development of this infection.[15] In another study, it was found that owing to changes in the hormonal balance, particularly in premenopausal women, the chances of vulvovaginal candidiasis development was much high.[14] Similarly, diabetes has also been found to increase the propensity of this type of candida infection owing to its ability to cause immunosuppression.[16,17]

Upon intergroup comparison of the efficacy, it was observed that oral antifungal therapy was significantly more efficacious as compared to the topical antifungal therapy, ($p = 0.001$). Compared to this, a study was conducted by Kandil *et al.*[18] with the similar aim of comparing the two different routes of antifungal administration for vulvovaginal candidiasis in which it was found that there was no difference in the efficacy of these two routes of antifungal administration ($p = 0.72$). Notably, that study included patients with recurrent vulvovaginal candidiasis and also employed longer treatment durations, similar to our protocol. The discrepancy in findings may be related to differences in patient populations, treatment protocols, or outcome definitions. In another study, it was found that oral fluconazole therapy was much more efficacious as compared to topical clotrimazole in treating candida infection ($p = 0.03$), which was similar to present study, however, in this study the focus of candida infection was oral cavity rather than the vaginal infection.[19] Similarly, in another study which was a meta-analysis of fifty randomized clinical trials, it was observed that the efficacy of oral antifungals was better compared to the topical therapy.[20] However, it is important to note that these studies primarily focused on Candida albicans, and treatment outcomes may differ for non-albicans species, which were not specifically identified in our study.

Stratified analyses demonstrated that the superior efficacy of oral antifungal therapy was generally maintained across different age groups, symptom durations, menstrual statuses, and diabetes. Within the topical antifungal group, treatment efficacy was significantly higher among primiparous women than multiparous women ($P = 0.046$), while a borderline significant difference was observed between premenopausal and menopausal women ($P = 0.050$). These findings suggest that patient-specific factors may influence treatment response, particularly with topical therapy, and should be explored further in future studies.

Based on the results of present study, oral therapy appears to be more efficacious than topical therapy for treating recurrent vulvovaginal candidiasis. However, it is important to note that for uncomplicated vulvovaginal candidiasis, the Cochrane review found no statistically significant differences between oral and intra-vaginal antifungal treatment.[22]

However, the findings of the present study should be interpreted in light of certain limitations. First, the quasi-experimental design may have introduced selection bias and limits the ability to establish causal relationships. Second, the study was conducted at a

single center, which may limit the generalizability of the results to other populations and healthcare settings. Third, neither participants nor investigators were blinded to treatment allocation, creating the possibility of performance and assessment bias. Fourth, Candida species were not identified separately due to resource constraints, preventing evaluation of treatment efficacy according to species-specific susceptibility patterns. This is particularly relevant as Candida glabrata and other non-albicans species may exhibit reduced susceptibility to azoles.[23] Fifth, while the study specifically enrolled patients with recurrent vulvovaginal candidiasis, a validated severity scoring system was not systematically applied, which may limit the ability to correlate treatment response with baseline disease severity. Finally, the lack of categorization of first versus recurrent episodes is acknowledged as a limitation, although the study did focus exclusively on women with recurrent disease based on the inclusion criteria. Future multicenter randomized controlled trials with blinded outcome assessment and detailed fungal speciation are needed to further validate these findings and optimize treatment recommendations.

CONCLUSION

In conclusion, oral fluconazole demonstrated significantly higher efficacy than topical clotrimazole for treating recurrent vulvovaginal candidiasis in this study population. However, given the study limitations these findings should be considered preliminary and require confirmation through larger randomized controlled trials before definitive clinical recommendations can be made.

CONFLICT OF INTEREST

None

GRANT SUPPORT & FINANCIAL DISCLOSURE

Declared none

AUTHOR CONTRIBUTION

Sheeba Saifullah: Substantial contribution to study design and data acquisition, manuscript drafting and critical review, final approval of the version to be published

Iram Inam: Supervision of study design and methodology, critical manuscript review, final approval of the version to be published

Syeda Mishay Fatima: Analysis and interpretation of data, critical manuscript review, final approval of the version to be published.

Zunaira Anjum: Contribution to concept and study design, critical manuscript review, final approval of the version to be published

Hira Naeem: Data acquisition and management, manuscript drafting and review, final approval of the version to be published.

Mahnoor Ahmad: Data collection and preliminary analysis, manuscript drafting and review, final approval of the version to be published.

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