



# ORAL SINGLE DOSE FLUCONAZOLE 150 MG VERSUS INTRAVAGINAL CLOTRIMAZOLE TREATMENT OF ACUTE VULVOVAGINAL CANDIDIASIS

Priyanka Gupta, Jyoti Sharma

Dr. Priyanka Gupta (MS-OBG) Civil Hospital Bhawarna, Dr. Jyoti Sharma (MS-OBG) Regional Hospital  
Bilaspur

Corresponding author-Dr. Priyanka Gupta

## ABSTRACT

**Objective:** to check the safety the protection efficacy one hundred fifty mg single dose and intra-vaginal clotrimazole two hundred mg per day for 6 days and treatment of the acute episode of vulvovaginal moniliasis (VVC).

**Methods:** during a prospective study, fifty patients with acute clinical and mycological confirmed VVC were registered and divided every which way in 2 teams. Twenty-five patients received intra-vaginal pill (200 mg) daily for seven days, whereas twenty five patients received single dose oral fluconazole (150 mg). Second and third visits were in all of the patients seven days and one month after treatment and therefore the clinical and mycological outcomes evaluated. The analysis was performed with help of SPSS software.

**Results:** At the second visit, twenty one patients (84.00%) were cured clinically (inflammation and discharge) and twenty patients (80.00%) mycologically in fluconazole cluster and twenty patients (80.00%) were cured clinically and eighteen patients (72.00%) mycologically in clotrimazole cluster ( $P = \leq 0.05$ ). At the third visit, only 1 patient in fluconazole cluster and 4 patients in clotrimazole cluster had clinical sign of VVC ( $P = \text{zero}.001$ ).

**Conclusion:** Oral fluconazole single dose appears to be a sound and promising medical aid to cure acute signs and symptoms of VVC.

## ITRODUCTION

Vulvovaginal fungal infection (VVC) could be a lower genital tract disorder that happens in seventy fifth of girls a minimum of once in their lifespan with 40—50% of girls experiencing a second attack. [1]. Candida albicans is the species most frequently related to VVC, however, alternative yeasts can even cause this infection. VVC is treated with a range of anti-fungal medicine [2]. Frequent recurrences of symptomatic vulvovaginitis lead to sizable suffering and cost and have a markedly negative impact on sexual relations [3]. Diagnosis is made by vaginal secretions specimen, microscopic examination and culture [4]. Presently offered

choices for the treatment of this condition embody antifungal agents. There are various effective treatments that embody topical or oral antifungals. Topical azoles are used for one, three, seven, or maybe fourteen days, whereas oral medicines are suggested to be used for one, three or five days [5]. An ideal antifungal drug is ought to be simple to administer, effective in short medical care, with a broad spectrum of treatment, inflicting complete eradication, preventing repeated infections, bringing relief to patients, very low adverse or side effects, cheap and safe to administer during gestation [6]. A meta analysis study showed that there was no significant difference regarding the effectiveness between oral and topical treatment of uncomplicated VVC [5]. Though topical regimens are commonly used, oral treatment is most well-liked by patients thanks to the ease of administration and also the reduced duration of use [7]. Fluconazole is a triazole antifungal introduced within the early 1990s that encompasses a sensible safety profile and is the most generally used antifungal for VVC. The mechanism of action of the group of azole antifungals is that the inhibition of the fungal protein P450, which is an important part of the fungal cytoplasmic membrane. The susceptibility of fungus species to fluconazole, however, isn't uniform. *Candida albicans* is very susceptible to fluconazole [8,9]. The objective of our study was to assess the relative effectiveness of the oral versus intravaginal antifungal medications for the treatment of VVC. The aim was to check the clinical and microbiologic effectiveness and also the safety of a hundred and fifty mg oral fluconazole single dose and standard topical (intravaginal) clotrimazole for seven days within the treatment of acute VVC and particularly its efficacy in consecutive cure of it.

## METHODS

The study was performed between Sept 2021 and Feb 2022 at civil hospital Bhawarna (Distt. Kangra) and Regional hospital Bilaspur Himachal Pradesh. Study included fifty outpatients over 15 years of age with acute clinical and mycologically verified VVC. The exclusion criteria were pregnant ladies, diabetics, hormone replacement or contraception pill users (intervention of hormonal therapy), immune-suppressive drug users and immunocompromised patients. The diagnosis of VVC was confirmed with clinical symptoms and mycologically (i.e. positive microscopy for the yeast). The research worker interviewed all ladies individually. Written consent was obtained from all the patients. Patients listed within the study received either two hundred mg clotrimazole daily for seven days intravaginal regime (n = 25) or a hundred and fifty mg fluconazole as one oral dose (n = 25). All patients had second and third visits after seven days and one month after treatment was initiated and also the clinical and mycological outcomes were evaluated. Clinical cure was defined as the absence of the signs and symptoms and mycological cure was defined as the microscopic absence of yeast. Information was analyzed by SPSS fifteen.0 software package with unmatched t-test, and Mann-Whitney check, as acceptable.  $P < 0.05$  thought of statistically significant.

## RESULTS

64 patients with acute symptomatic VVC were listed, however fourteen patients failed to complete the study and were excluded. Therefore, fifty patients were included and completed the study. Patients listed within the study received either two hundred mg clotrimazole daily for seven days intravaginal regime (n = 70) or one hundred fifty mg fluconazole as one oral dose

**Table 1** Baseline demographic characteristics of study groups.

Characteristics	Oral fluconazole(N=25)	Intra-vaginal clotrimazole(N=25)	P value
Age in years (mean ± SD)	39. 5± 13.1	42. 4 ± 15.9	0.7
Marital status			0.6
Married	13 (52.00%)	14 (56.00%)	
Single	12(48.00%)	11 (44.00%)	
Separated (divorced or widowed)	0	0	
Post-menopausal			0.3
Yes	10 (40.00%)	12 (48.00%)	
Hormone replacement therapy			0.8
Yes	0 (0.00%)	1 (4.00%)	

  

Parameters	Oral fluconazole (N = 25)	Intra-vaginal clotrimazole (N = 25)	P value
Clinical cure (N (%))	21(84.00%)	20(80.00%)	0.001
Mycological cure (N (%))	20(80.00%)	18(72.00%)	0.01
Side effect (N (%))	1(04.00%)	0(00.00%)	0.4

Table one shows that there was no distinction within the demographic characteristics of each study groups. Table two shows that on the first visit candida was clinically treated in 21(84.00%) patients within the fluconazole group and 20(80.00%) within the clotrimazole group and microscopically eradicated (culture was negative) in 20(80.00%) of patients within the fluconazole group and in 18(72.00%) within the clotrimazole group (P = 0.001). There was no distinction in side effects in 2 teams (p = 0.4). The most important drug complication in fluconazole group was headache in one patient only. In Table three the return of VVC after one month of treatment is depicted. At the third visit (one month) fungus was present symptomatically in one patient within the fluconazole group and five patients in clotrimazole cluster (P = 0.001). Microscopical examination depicted candida in one patient within the fluconazole group and five patients in clotrimazole cluster at same time.

Parameters	Oral fluconazole (N = 25)	Intra-vaginal (N = 25)	P value
Relapse of clinical symptom (N(%))	1 (04.00%)	5 (20.00%)	0.001
Relapse of mycological symptom (N(%))	1 (04.00%)	5 (20.00%)	0.01

48(96.00%) patients enrolled in the study would prefer oral fluconazole treatment compared to topical clotrimazole. ( $P=0.001$ ).

## Discussion

Over the past 2 decades, the imidazoles group of drugs (miconazole, clotrimazole, ketoconazole, etc) have become the most widely used drugs for the effective treatment of VVC. With the exception of ketoconazole, all these agents can be used topically for treatment durations of one to seven days with almost similar success rates [10]. Local applications of these antifungal preparations are usually without side effects, but most patients still prefer the oral therapy only because of the ease of administration and the lower duration of use [7]. Also oral antifungal therapy of patients with vaginal/vulvovaginal candidiasis can decrease the candida population in the deep layers of vaginal tissues and rectum, which is an important pool of candida [11].

A new class of azole antifungal agents, the triazoles, are recently been introduced into clinical practice. These drugs appear to offer both microbiological and clinical advantages over the imidazoles and achieved high rates of microbiologic and/or clinical cure in a lot of studies, a finding that which is considered expected, because these agents are used through oral route for treatment durations of one to three days [9].

The aim of this study was to compare the clinical and microbiologic effectiveness and the safety of 150 mg oral fluconazole single dose and conventional topical (interavaginal) clotrimazole for seven days in the treatment of acute VVC. While the two drugs confirmed good overall clinical efficacy at both follow-up visits, the speed of symptom relief was remarkably better in fluconazole group. Also relapses after one month of clinical and microbiological symptoms were less in fluconazole group.

Although a metaanalysis by Watson et al. also showed that there was no significant difference regarding the effectiveness between oral and topical (intravaginal) treatment of uncomplicated VVC [5], in a current study Mohanty reported that since the majority of *C. albicans* isolates were susceptible to fluconazole, its use may be continued for empirical therapy of uncomplicated candidal vulvovaginitis in the community [10]. Maznejkova suggested that fluconazole is the choice drug for continuous treatment of vaginal candidia infection with the least toxicity [12]. The patients have expectedly more satisfaction with the oral treatment, because of good compliance and easy availability. This result was similar to the Watson study [5] and the Corić study [13].

## Conclusion

This study showed that single dose oral fluconazole is more effective than conventional topical clotrimazole for seven days in the treatment of acute VVC. Fluconazole tablet can more successfully and safely treat microbiological and clinical symptoms of VVC than clotrimazole pessary and can be more effective in reducing the relapse rate of the disease than the clotrimazole. A long term cure, however actually remains elusive in the scenario.

## Acknowledgement

Authors thank the Ob & Gy clinic nursing staff for their assistance.

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