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Clinical Characteristics of Vaginitis and Effectiveness of Fenticonazole - An Observational Study from India

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Abstract

Objective: To characterise vaginitis among menstrual and menopausal women and to determine the effectiveness of Fenticonazole for the treatment of vaginitis.

Methods: A retrospective study was conducted on 86 women attending the gynecology clinic. The patients underwent screening for symptoms of vaginitis. The clinical and demographic characteristics were compared between menstrual and menopausal women.

Results: Based on the clinical examination, it was identified that 80 (93.02%) patients had symptoms of vaginal discharge (white discharge) and 51 (59.30%) of patients had a vaginal fungal infection. Mean age was 34.73 (10.13) years, and 52.04 (14.38) years and mean BMI 26.74 (3.31) and 29.32 (3.22) were significantly different among menstrual women and menopausal women respectively. Also, inflammatory smear and vaginitis both were found to be higher among menstrual women. It was identified that Fenticonazole was effective in the treatment of vaginitis.

Conclusion: In this observational study, vaginitis was identified in 51 (59.30%) patients, and Fenticonazole was found to be effective in treating vaginitis.

Introduction

Vaginitis is a common reproductive tract infection and remains a critical public health issue, seen in approximately 20-25% of women attending the gynaecology clinic[1-3]. Vaginitis is characterised by vaginal discharge, malodor, and vulvar itching/irritation. The most common causes of vaginitis are bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis[4,5]. Bacterial vaginosis is a common cause of vaginal dysbiosis among reproductive women and is associated with preterm delivery[6]. The prevalence of bacterial vaginosis in India varies from 20.5% to 48.5%[7-9]. Candida vulvovaginitis affects 75% of women at least once in their lifetime and is usually associated with severe

clinical outcomes[10-11]. Trichomonas vaginalis is a common curable sexually transmitted infection associated with infertility[12-13].

Abnormal vaginal discharge is polymicrobial. A combination of antibiotic with aerobic and anaerobic pathogens is used for treatment. As untreated vaginitis can lead to pelvic inflammatory disease, diagnosing and initiating treatment earlier is important. Fenticonazole is an imidazole derivative used to treat topical fungal infections and exerts a wide spectrum of antimycotic and antimicrobial activity[14-15]. Fenticonazole elicits anti-fungal activity by inhibiting the release of protease acid by *Candida albicans*, altering the critical component of fungal cell membrane synthesis, and blocking cytochrome oxidases and peroxidases[16-17]. This drug also exhibits antibacterial activity against Gram-positive bacteria and anti-parasitic activity against parasites like *Trichomonas vaginalis*[18]. Fenticonazole (600mg or 1 gram as a single dose or 200mg/day for three days) has been shown to be effective in treating Candida vulvovaginitis and mixed infections[19].

The present study was undertaken to characterise vaginitis in menstrual and menopausal women attending the outpatient clinic of Obstetrics and Gynaecology and to evaluate the efficacy of Fenticonazole in the treatment of vaginitis.

Methods

This observational study was conducted in the Department of Obstetrics and Gynaecology, India. A total of 86 patients attending the clinic from 2019-2020 who had a history of recurrent infection underwent screening for symptoms of vaginitis. The study included women with age between 20 and 72 years old. Pregnant, menstrual, and menopausal women were included in the study. A detailed physical examination was made for all the patients. From the lateral vaginal wall, vaginal material was collected with a cotton swab from all the patients. "KOH slide microscopy" was performed by placing a sample of vaginal discharge on a slide and mixed with potassium hydroxide solution. KOH kills bacteria and the cells of vagina and helps in the identification of yeast for fungal infection. Fungal culture and Pap Smear was also done on all the patients.

For the treatment of empirical candidiasis, fenticonazole nitrate vaginal capsules 600mg (alternate days for two days) was initiated to patients. During the follow-up visit, the response to fenticonazole was evaluated based on clinical examination.

Statistical analysis

Statistical analysis was done using R studio 2021.09.0 and Microsoft excel 2016. Continuous variables were represented as mean ± standard deviation. For categorical variables, number and percentages were used. Fischer exact test and t-test were used to evaluate the results. A p-value of less than 0.05 was considered statistically significant.

Results

A total of 86 patients were enrolled in the study, of which 27 (31.40%) were menopausal women and 59 (68.60%) were menstrual women.

Table 1: Demographic and Clinical Characteristics of Patients

Parameter	n (%)
Total Number of patients	86
Mean age	40.16 ± 14.09
Mean BMI	27.55 ± 3.48
Menstrual women Menopausal women	59 (68.60%) 27 (31.40%)
Mean Menarche age	13.31 ± 0.77
Obese women	29 (33.72%)
Number of pregnant women	2 (2.33%)
Status of GxPy G_0P_0 G_1P_0 G_1P_1 G_2P_2 G_3P_2 G_3P_3 G_4P_4	 2 (2.33%) 1 (1.16%) 10 (11.63%) 44 (51.16%) 1 (1.16%) 13 (15.12%) 15 (17.44%)
Presenting Complaints Itching vulva White discharge	 6 (6.98%) 80 (93.02%)
Anaemia	13 (15.12%)
Urine Culture UTI	 86 (100.00%)
STD Cervicitis	 35 (40.70%)
Pap Smear Cervicitis	 51 (59.30%)
Vaginal swab culture Vaginitis	 51 (59.30%)
Pelvic scan Fetus	 2 (2.33%)
Type of vaginal infection Fungal	 51 (59.30%)
Anti-fungal drugs used Candid CL Fenticonazole	 23 (26.74%) 63 (73.26%)

Most of the patients had complaints of white discharge (n=80, 93.02%). It was identified that 51 (59.30%) of the patients had a vaginal fungal infection. When performing a Pap smear, inflammatory smear was seen in 51 (59.30%) patients. Vaginal swab culture revealed vaginitis in 51 (59.30%) patients. The demographic characteristics of the patients in the study is given in table 1. Of all, 63 (73.26%) of the patients received Fenticonazole for treatment and 23 (26.74%) received other anti-fungal drugs. Upon clinical examination, Fenticanozole was found to be effective in treating vaginitis. The age-wise prescription pattern of Fenticonazole and other drugs received by the patients in the study are represented in figure 1. Upon performing a subgroup analysis comparing the demographic and clinical characteristics of menstrual and menopausal women, it was identified that the mean BMI was higher in menopausal women than in menstrual women (p=0.002). The mean hemoglobin levels were higher among menopausal women than the menstrual women (p=0.012). It was identified that both inflammatory smear and vaginitis were higher among menstrual women.

Figure 1: Age-wise prescription pattern of anti-fungal drugs used in the patients

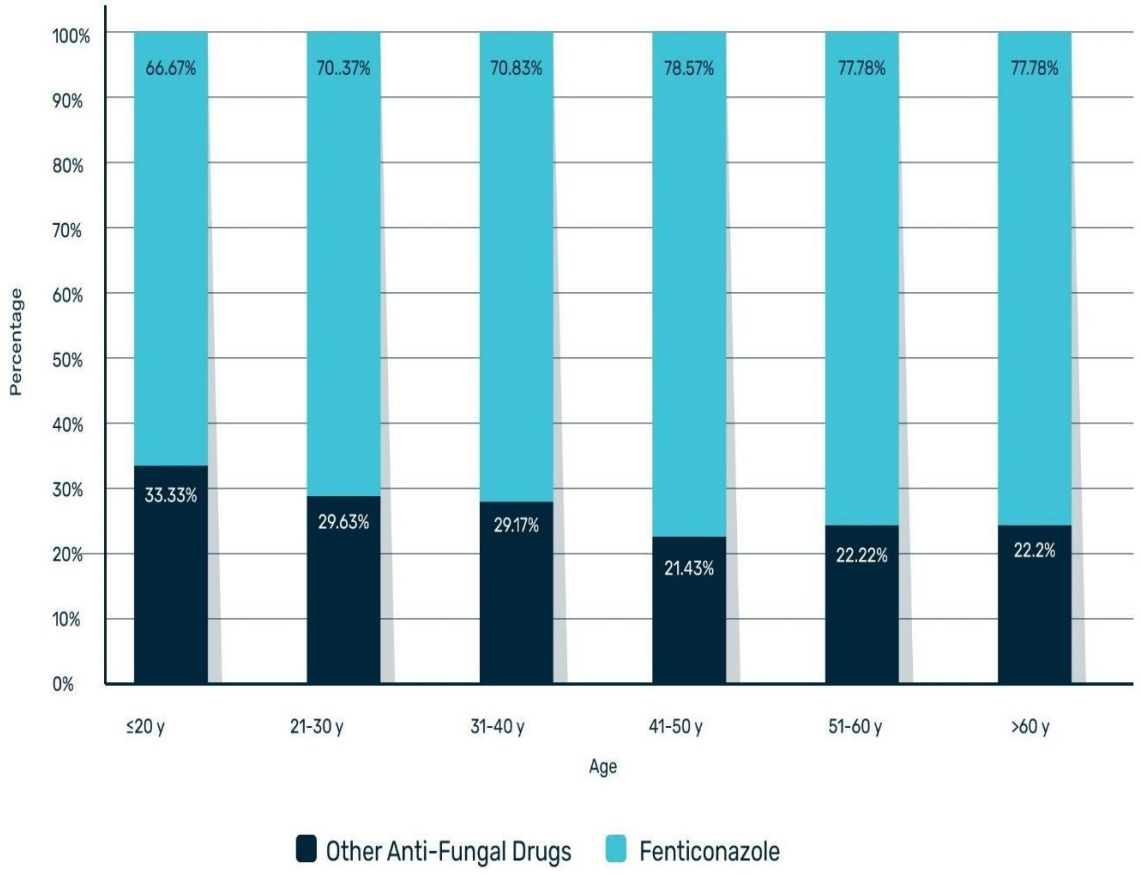

Table 2: Comparison of demographic and clinical characteristics in menstrual and menopausal women

Characteristics	Menstrual Women (n=59)	Menopausal women (n=27)	*p*-value
Presenting Complaints			
Itching Vulva	4 (6.77%)	2 (7.40%)	1.000
White Discharge	55 (93.22%)	25 (92.59%)	
Mean Age	34.73 ± 10.13	52.04 ± 14.38	<0.001
Mean BMI	26.74 ± 3.31	29.32 ± 3.22	0.002
Mean Menarche Age	13.34 ± 0.73	13.26 ± 0.86	0.807
Obesity	8 (13.56%)	21 (77.78%)	<0.001
G_0P_0	2 (3.39%)	0 (0.00%)	
G_1P_0	1 (1.69%)	0 (0.00%)	
G_1P_1	10 (16.95%)	0 (0.00%)	
G_2P_2	29 (49.15%)	15 (55.55%)	0.141
G_3P_2	1 (1.69%)	0 (0.00%)	
G_3P_3	6 (10.17%)	7 (25.93%)	
G_4P_4	10 (16.95%)	5 (18.52%)	
Mean Haemoglobin	11.77 ± 1.02	12.34 ± 0.81	0.012
Anaemia	13 (15.12%)	0 (0.00%)	0.009
Pap Smear finding			
Cervicitis	40 (67.80%)	11 (40.74%)	0.032
Vaginal Swab finding			
Vaginitis	40 (67.80%)	11 (40.74%)	0.032
Anti-fungal drug used			
Candid CL	19 (32.20%)	4 (14.81%)	0.153
Fenticonazole	40 (67.80%)	23 (85.19%	

Discussion

Approximately 20 lower genital-tract related infections have been identified so far, and these infections are caused by bacteria, fungi, mycoplasma, protozoa, and viruses[20]. Most of the female reproductive tract infections occur in the vagina and cervix. Vaginitis is a public health concern affecting millions of women every year. The causes of vaginitis can be infectious or inflammatory. Vulvovaginal candidiasis (20-25%) and bacterial vaginosis (40-50% of cases) are the most prevalent vaginitis[21]. Approximately 5-10% of vaginitis cases result from non-infectious causes like allergy,

atrophy, irritants, and inflammation[22]. Diagnosis of vaginosis is made through physical examination findings, a combination of symptoms, and laboratory testing.

The current study was conducted among 86 patients, and 51 (59.30%) of the patients had a vaginal fungal infection. Inflammatory smear was seen in 51 (59.30%) patients and vaginitis in 51 (59.30%) patients. Patients were treated with Fenticonazole, and it was found to be effective. Similarly, Lawrence et al. [23] in a study involving 417 women with vaginal candidiasis identified that Fenticonazole was associated with a significant reduction of the symptoms of vaginitis. Similarly, in a multicenter prospective, open- label study, Fenticonazole was effective in the treatment of mixed vulvovaginal infections[24]. Deka et al reported that in 705 clinically diagnosed patients with vaginitis, Dazel kit (fluconazole 150 mg, azithromycin 1 gm, secnidazole 1 g two tablets) was found to be effective in the treatment of vaginal symptoms[25]. In a Cochrane systematic review, it was found that there was no significant difference between oral and intra vaginal anti-fungal treatment for vulvovaginal candidiasis[26]. Thus, Fenticonazole has a broad-spectrum antimicrobial and antimycotic activity with a significant efficacy and tolerability profile[27].

A few studies conducted in India in which the prevalence of bacterial vaginosis was estimated. In a study conducted among women of the reproductive age group from Navi Mumbai, the prevalence of bacterial vaginosis was 17.3%.[28] Similarly, in a study conducted among women in Delhi, bacterial vaginosis was diagnosed in 32.8% of the patients.[29]

The limitations of the study need to be addressed. During the follow-up visit, the response to fenticonazole was evaluated based on clinical examination alone and no further microbial analysis was done to monitor if the infection was cleared. As this is a retrospective study, there is no proper data to reveal the time points during which patients were followed to determine the effectiveness of the drug.

Women attending the gynaecology clinic should be promptly tested for vaginitis based on the symptoms and should be appropriately treated earlier to avoid the risk of complications.

Conclusions

Vaginitis was seen in 51 (59.30%) of the patients, and Fenticonazole was found to be effective in treating vaginitis**.**

Ethical Approval: N/A

Conflict of Interest: Nil

Financial Disclosure: None

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