



Original Research Article

A Comparative Study of Antifungal Activity of Topical Per Vaginal Application of Tablet Sertaconazole and Clotrimazole in Cases of Vulvovaginal Candidiasis

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ABSTRACT

Aims: The purpose of the study was to compare the efficacy and tolerability of topical per vaginal application of tablet sertaconazole 500 mg and topical per vaginal application of tablet clotrimazole 200 mg in cases of vulvovaginal candidiasis.

Methods: A randomized prospective study was conducted on 150 cases coming to OPD aged 18 years or more with complaint of vaginal pruritus, burning sensation or thick curdy white discharge in S P Medical College, Bikaner, Rajasthan, India.

Results: On comparison of symptomatic relief in both groups after 10-14 days follow up, favorable clinical response was found in 94.7% of sertaconazole group and 89.3% of clotrimazole group. P value was 0.001 and this difference was statistically significant. Similarly mycological cure /improvement was seen in 80% of sertaconazole group and 74.7% of clotrimazole group after 10-14 days of follow up.

Conclusions: Sertaconazole is a better drug than clotrimazole for candidiasis. It has rapid onset of clinical response and also mycological and clinical cure is obtained more rapidly than clotrimazole.

Keywords: Clotrimazole; Sertaconazole; Vulvovaginal Candidiasis.

INTRODUCTION

The vaginal candidiasis represents the second most frequent cause of vaginal infection. It is estimated that around 50% of the women of reproductive age suffer from an episode of vulvovaginal candidiasis during their life and 5% of these patient have recurrence of disease. ^[1] Candida vaginitis is most commonly caused by Candida albicans. ^[2,3]

The incidence of vulvovaginal candidiasis has increased dramatically in the past decades. Up to 75% of women experience vaginal candidiasis in their life time and it accounts for 20-30% of gynecological diseases. It is generally found in women of reproductive age group mainly in between 25 to 35 years of age. ^[4]

Sertaconazole is a fungicidal imidazole derivative particularly active on candida species including those with a low

sensitivity and resistance to other imidazoles. [5,6]

It has broad spectrum antifungal activity and also has a good safety profile, sustained retention and low systemic absorption all of which make it ideal for topical application. There is no need of separate drug, single dose is effective. [7]

In view of above reference, this study was conducted to compare the effectiveness of topical per vaginal application of sertaconazole and topical per vaginal application of clotrimazole in cases of vaginal candidiasis.

MATERIALS AND METHODS

The present study was conducted in the Department of Obstetrics and Gynecology, P.B.M. & A.G. Hospitals, S.P. Medical College, Bikaner (Raj).

It was a randomized prospective study and was conducted on 150 cases attending the OPD of Department of Obstetrics and Gynecology during 2009-2010. All these patients were aged 18 years or more with complaints of vaginal pruritus, burning sensation or thick curdy discharge. Informed consent was taken from all patients who were included in the study.

Pregnant and lactating women were excluded from study. Women with non-specific vaginitis or using other antifungal treatment and who were known to be sensitive to azole containing drugs were excluded. Patients with impaired hepatic or renal infection also not included in this study. All these patients were examined per vaginally for any inflammation or discharge and high vaginal swab was taken and transported dry to the Microbiology Department. After examining the patients, those patients who were showing candida species in the culture were divided in two groups. Group A included every alternate patients 1,3,5..149 and they received tablet Sertaconazole 500 mg per vaginally and

group B included other alternate patients 2,4,6..150 and they were given tablet Clotrimazole 200mg per vaginally for three consecutive days and response to both of these drugs were compared by doing follow up of these patients after 10-14 days and again high vaginal swab was sent for direct microscopic examination and culture. Data were analyzed using SPSS version 17 for descriptive statistics. The Percentage and Chi- Square test were applied to test the significance wherever indicated. The statistical significance was set at 0.05.

RESULTS

TABLE I. Demographic variability of age of subjects under study

Age of Women (In Years)	Group A	Group B	Total Patients
18-25	27(36.0%)	28(37.3%)	55(36.7%)
26-35	30(40.0%)	29(38.7%)	59(39.3%)
36-45	15(20.0%)	14(18.7%)	29(19.3%)
>45	03(4.0%)	04(5.3%)	07(4.7%)
Total	75	75	150
Mean	30.41	30.54	30.48
S.D.	7.95	7.41	7.66

S.D. – Standard Deviation

The mean age of patients in group A was 30.41 and in group B was 30.54 years. So both groups were comparable and there was no statistical difference in distribution of patients in two groups.

TABLE II. Chief Complaints and per speculum examination in patients.

Chief complaints	Group A	Group B	P-Value
White discharge	75(100%)	75(100%)	0.28 (Non-significant)
Pruritus vulva	70(99.3%)	62(82.7%)	
Dysuria	33(44%)	32(42.7%)	
Dyspareunia	26(34.7%)	18(24%)	
Per speculum examination			
Mild Vaginitis (Only redness)	22(29.3%)	23(30.7%)	
Moderate Vaginitis (Vaginitis with swollen inflamed vulva)	37(49.3%)	38(50.7%)	
Severe Vaginitis	16(21.3%)	14(18.7%)	

The mean duration of onset of group A was 1.17 and 1.91 in group B.

TABLE III. Comparison of onset of relief of clinical symptoms in group A and group B

Onset of relief (In days)	Group A	Group B	P-Value
0-1	54(72%)	08(10.7%)	0.002 (Significant)
2-7	17(22.7%)	59(78.7%)	
8-14	01(1.3%)	0(0%)	
No response	03(4%)	08(10.7%)	
Mean	1.17	1.91	

Patients who showed mycological cure in group A and group B were 80% and

74.7% respectively. While failure was seen in 20% and 25.3% patients of group A and B. 94.6% patients in group A showed complete clinical cure while 89.3% patients in group B showed complete cure. 5.3% patients in group A not responded to treatment and 10.7% patients in group B not responded to treatment.

TABLE IV. Comparison of mycological cure and complete clinical cure after 10-14 days of follow up

Follow up after 10-14 days	Group A (75)	Group B (75)	P Value
Mycological cure/Improvement	60(80%)	56(74.7%)	0.018 (Significant)
Mycological Failure	15(20%)	19(25.3%)	
Patient completely cured	71(94.6%)	67(89.3%)	0.01 (Significant)
Patient clinically not cured	4(5.3%)	8(10.7%)	

TABLE V. Showing side effects of both the drugs

Side effects	Group A	Group B	P Value
Pruritus	2(2.6%)	3(4%)	0.0001 (Significant)
Perineal pain	1(1.3%)	1(1.3%)	
Pain abdomen	-	-	
Diarrhea	-	2(2.6%)	
Irritation	-	1(1.3%)	
Fatigue	-	1(1.3%)	
Vaginal bleeding	-	-	
Thirst	-	-	
Total	3(4%)	8(10.6%)	

Side effects in Sertaconazole group were few and better tolerated than Clotrimazole group. So comparatively Sertaconazole is well tolerated and safer than Clotrimazole.

DISCUSSION

In our study the maximum number of patients in both groups belongs to age group 26-35 year (40% & 38.7% in group A and group B respectively). This finding is supported by a study by Sobel J. D. [8] 80% & 74.7% patients in group A and group B respectively showed mycological cure or improvement, while 20% & 25.3% patients in group A and group B respectively showed failure or no response. It was supported by Dellenbach et al., 2000, [7] according to which 80.6% of Sertaconazole group and 72.3% of Clotrimazole group showed mycological cure after 14 days of follow up.

In our study patients were also asked about complete relief from symptoms in both groups. 94.6% patients in group A and 89.3% patients in group B showed complete clinical cure. While 5.3% patients in group A and 10.7% patients in group B not responded to treatment. This difference is statistically significant.

The mean days for complete relief of symptoms in group A was 1.95 & for group B was 2.79. It was supported by study conducted by Palacin et al., 1992, 2001. [9,10] The median time of onset of symptomatic relief was 1 day and 2 days for Sertaconazole group and Clotrimazole group respectively and the corresponding time for complete relief was 2 days and 3 days respectively in group A & group B. [11] Patients were also asked about the side effects after drug administration. It was found that in group A pruritus was reported in 2.6% of patients and perineal pain was reported by 1.3% patients. Overall only 4% cases in group A showed minor side effects. In group B 4% patients reported pruritus, 2.6% reported diarrhea and perineal pain. While vaginal irritation and fatigue complained by 1.3% patients. Overall 10.6% patients in Clotrimazole group showed side effects. On statistical analysis it was found

that this difference was significant. ($P < 0.05$). In a study it was found that side effects in Sertaconazole treated patients were approximately 3-5% and these were mild and well tolerated. Compared to alternative drugs, there appears to be a certain tendency towards fewer local adverse events and better patient acceptance with Sertaconazole in study by Wang et al., 2006 [12] and similar result found in study by Croxtall JD et al., 2009. [13]

SUMMARY AND CONCLUSION

The present prospective study was conducted on 150 patients of diagnosed vulvovaginal candidiasis. These cases were divided into two groups. Group A patients were given per vaginal tablet of Sertaconazole 500mg and group B were given tablet Clotrimazole 200mg for intra vaginal use for three consecutive nights.

Mycological cure /improvement was seen in 80% of Sertaconazole group and 74.7% of Clotrimazole group after 10-14 days of follow up. It was found that in Sertaconazole group maximum number of patients (72%) showed onset of clinical response within 24 hours. While in Clotrimazole group clinical response was seen in between 2-7 days. Maximum number of patients in both groups showed complete relief in between 2-7 days. Only 4% patients in Sertaconazole group and 10.6% patients in Clotrimazole group showed side effects. Although side effects were mild and well tolerated in both groups but they were few in number and better tolerated in Sertaconazole group. Thus it is safer than Clotrimazole.

Our study concluded that Sertaconazole is a better drug than Clotrimazole for candidiasis. It has rapid onset of clinical response and also mycological and clinical cure is obtained more rapidly than Clotrimazole.

The main advantage of Sertaconazole over Clotrimazole is single dose application, sustained retention and low systemic absorption. It also has good safety profile, less side effects and better patient compliance.

Conflict of Interest: No

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