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Original Article

Comparison of efficacy and safety of newer antifungal agent sertaconazole with clotrimazole and fluconazole in the treatment of acute vulvovaginal candidiasis

Dr. Ansar Hussain Azhar[1], Dr. M Somasekhar Reddy[2], Dr. K S Dhishan Sai[3*]

[1] Post Graduate, Department of Pharmacology, Bhaskar Medical College, Hyderabad, Telangana
[2] Associate Professor, Department of Pharmacology, Bhaskar Medical College, Hyderabad, Telangana
*[*3] Assistant Professor, Department of Pharmacology, Bhaskar Medical College, Hyderabad, Telangana*

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Corresponding Author:

Dr. K S Dhishan Sai
Assistant Professor, Department of Pharmacology, Bhaskar Medical College, Hyderabad, Telangana. Mail-id: drdhishansai@gmail.com

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ABSTRACT

Background: Vulvovaginal candidiasis (VVC) is a common fungal infection affecting women of reproductive age and is associated with significant discomfort and reduced quality of life. Although clotrimazole and fluconazole are widely used antifungal agents, newer agents such as sertaconazole may offer improved therapeutic outcomes.
Objective: To compare the efficacy and safety of sertaconazole with clotrimazole and fluconazole in the treatment of acute vulvovaginal candidiasis.
Materials and Methods: This prospective, randomized, open-label comparative study was conducted among 225 women with clinically and microbiologically confirmed acute vulvovaginal candidiasis. Participants were randomly allocated into three groups of 75 patients each. Group A received intravaginal sertaconazole 300 mg single dose, Group B received intravaginal clotrimazole 500 mg single dose, and Group C received oral fluconazole 150 mg single dose. Clinical cure, mycological cure, time to symptom relief, recurrence rate, and adverse events were assessed during follow-up. Statistical analysis was performed using ANOVA and Chi-square test, with $p<0.05$ considered statistically significant.
Results: Clinical cure rates were significantly higher in the sertaconazole group (93.3%) compared with the clotrimazole (82.7%) and fluconazole (80.0%) groups ($p=0.028$). Mycological cure was achieved in 92.0%, 81.3%, and 77.3% of patients, respectively ($p=0.019$). The mean time to symptom relief was significantly shorter with sertaconazole (3.1±1.0 days) than with clotrimazole (4.5±1.4 days) and fluconazole (5.0±1.7 days) ($p<0.001$). Recurrence rates were lowest in the sertaconazole group (5.3%) compared with clotrimazole (13.3%) and fluconazole (17.3%) ($p=0.041$). All treatment regimens were well tolerated, and no serious adverse events were reported.
Conclusion: Sertaconazole demonstrated superior clinical and mycological cure rates, faster symptom relief, and lower recurrence compared with clotrimazole and fluconazole. These findings suggest that sertaconazole is an effective and safe therapeutic option for the treatment of acute vulvovaginal candidiasis.

Keywords: Vulvovaginal candidiasis, Sertaconazole, Clotrimazole, Fluconazole, Clinical cure, Mycological cure.

INTRODUCTION

Vulvovaginal candidiasis (VVC) is one of the most common fungal infections affecting women worldwide and represents a significant cause of gynecological morbidity. Approximately 70–75% of women experience at least one episode of VVC during their lifetime, while nearly 40–50% may suffer recurrent infections (1,2). The disease is characterized by vulvar itching, burning sensation, soreness, dyspareunia, dysuria, and thick curdy vaginal discharge, which adversely affect the quality of life and daily activities of affected women (1).

Candida albicans remains the predominant etiological agent responsible for nearly 80–90% of cases, although infections caused by non-albicans Candida species have been increasingly reported in recent years (2,3). Various predisposing factors such as pregnancy, diabetes mellitus, prolonged antibiotic therapy, oral contraceptive use, immunosuppression, and hormonal changes contribute to the development of vulvovaginal candidiasis by altering the normal vaginal flora and host defense mechanisms (3).

Azole antifungal agents constitute the mainstay of treatment for uncomplicated vulvovaginal candidiasis. Topical agents such as clotrimazole and systemic agents such as fluconazole have been extensively used because of their proven efficacy and favorable safety profile (4). Current treatment guidelines recommend either short-course topical azole therapy or a single oral dose of fluconazole for uncomplicated infections (5). Despite satisfactory cure rates, treatment failure, recurrent infections, poor patient compliance, and increasing antifungal resistance remain important clinical concerns (3,5).

Fluconazole, a triazole antifungal agent, has been widely prescribed owing to its convenient oral administration and excellent tissue penetration. However, increasing reports of fluconazole-resistant Candida isolates and reduced susceptibility among non-albicans Candida species have raised concerns regarding its long-term effectiveness (6). Similarly, although clotrimazole remains an effective topical antifungal agent, prolonged treatment duration and local irritation may affect patient adherence and therapeutic outcomes (7).

Sertaconazole is a newer imidazole antifungal agent possessing a unique dual mechanism of action. In addition to inhibiting ergosterol synthesis, it directly damages fungal cell membranes, resulting in potent fungicidal activity (8). Furthermore, sertaconazole exhibits anti-inflammatory and antipruritic properties that may contribute to rapid symptomatic improvement. Previous clinical studies have reported favorable clinical and mycological cure rates with sertaconazole in the treatment of vulvovaginal candidiasis and other superficial fungal infections (7,8).

Recent comparative studies have suggested that sertaconazole may provide earlier symptom relief, higher patient satisfaction, and lower recurrence rates compared with conventional azole therapies (7,9). However, evidence directly comparing sertaconazole with both clotrimazole and fluconazole in acute vulvovaginal candidiasis remains limited, particularly in the Indian population. Identification of an effective therapeutic option with improved efficacy, safety, and reduced recurrence is therefore of considerable clinical importance.

Hence, the present study was undertaken to compare the efficacy and safety of the newer antifungal agent sertaconazole with clotrimazole and fluconazole in the treatment of acute vulvovaginal candidiasis.

MATERIALS AND METHODS

Study Design

This study was designed as a prospective, randomized, open-label comparative study to evaluate the efficacy and safety of sertaconazole, clotrimazole, and fluconazole in the treatment of acute vulvovaginal candidiasis.

Study Setting

The study was conducted in the Department of Pharmacology in collaboration with the Department of Obstetrics and Gynecology at a tertiary care teaching hospital.

Study Duration

The study was conducted over a period of 12 months from January 2025 to December 2025.

Study Population

Women attending the Gynecology Outpatient Department with symptoms suggestive of acute vulvovaginal candidiasis were screened for eligibility.

Sample Size

The sample size was calculated based on the anticipated difference in clinical cure rates between the treatment groups. Previous studies have reported clinical cure rates of approximately 92% with sertaconazole and 75% with conventional azole therapy.

The sample size for comparing two proportions was calculated using the formula:

$$n = [(Z\alpha/2 + Z\beta)^2 \times \{P1(1-P1) + P2(1-P2)\}] / (P1-P2)^2$$

Where:

n = sample size required per group

Zα/2 = standard normal deviate corresponding to 95% confidence interval = 1.96

Zβ = standard normal deviate corresponding to 80% power = 0.84

P1 = expected clinical cure rate in sertaconazole group = 0.92

P2 = expected clinical cure rate in comparator group = 0.75

Substituting the values:

$n = [(1.96 + 0.84)^2 \times \{(0.92 \times 0.08) + (0.75 \times 0.25)\}] / (0.17)^2$
$n = [7.84 \times (0.0736 + 0.1875)] / 0.0289$
$n = (7.84 \times 0.2611) / 0.0289$
$n = 70.8$
Therefore, a minimum sample size of 71 participants was required per group.
Considering a possible dropout rate of 5–10%, the sample size was rounded to 75 participants per group. Hence, the total sample size required for the study was 225 participants (75 participants in each treatment arm).

Inclusion Criteria

1. Women aged 18–45 years.
2. Presence of symptoms suggestive of acute vulvovaginal candidiasis such as vulvar pruritus, burning sensation, vaginal discharge, dysuria, or dyspareunia.
3. Microscopic confirmation of Candida infection by 10% potassium hydroxide (KOH) wet mount demonstrating budding yeast cells and/or pseudohyphae.
4. Positive fungal culture for Candida species.
5. Willingness to participate and provide written informed consent.

Exclusion Criteria

1. Pregnant or lactating women.
2. Recurrent vulvovaginal candidiasis (≥4 episodes within the previous year).
3. Uncontrolled diabetes mellitus.
4. Immunocompromised patients including HIV-positive individuals.
5. Known hypersensitivity to azole antifungal agents.
6. Mixed vaginal infections requiring additional antimicrobial therapy.
7. Use of systemic or topical antifungal drugs within four weeks prior to enrollment.
8. Severe hepatic or renal impairment.

Randomization and Allocation

After confirmation of eligibility, participants were randomly assigned in a 1:1:1 ratio to one of the three treatment groups using a computer-generated randomization sequence. Allocation concealment was maintained using sequentially numbered opaque sealed envelopes.

Treatment Groups

Group A (Sertaconazole Group):
Participants received a single intravaginal sertaconazole nitrate pessary 300 mg administered at bedtime.
Group B (Clotrimazole Group):
Participants received a single intravaginal clotrimazole vaginal tablet 500 mg administered at bedtime.
Group C (Fluconazole Group):
Participants received a single oral dose of fluconazole 150 mg.

Baseline Assessment

At enrollment, demographic details, medical history, duration of symptoms, and risk factors for vulvovaginal candidiasis were recorded. General physical examination and gynecological examination were performed.
Clinical Assessment
The severity of symptoms was assessed using a four-point scoring system:
0 – Absent
1 – Mild
2 – Moderate
3 – Severe

The following symptoms were evaluated:
• Vulvar itching
• Burning sensation
• Vaginal discharge
• Dysuria
• Dyspareunia

A composite symptom score was calculated by summing individual symptom scores.
Microbiological Assessment
High vaginal swabs were collected under aseptic precautions before initiation of therapy and during follow-up visits.
The samples were subjected to:
• Direct microscopic examination using 10% KOH preparation.

• Gram staining.
• Fungal culture on Sabouraud dextrose agar.
• Species identification by standard microbiological methods.

Follow-up
Participants were evaluated on Day 7 and Day 28 following initiation of treatment.
During each follow-up visit:
• Clinical symptoms and signs were assessed.
• Adverse events were recorded.
• High vaginal swabs were obtained for microbiological evaluation.

Safety Evaluation
All adverse events reported by participants or observed by investigators were documented and assessed for severity and causal relationship to study medication.

Ethical Considerations
The study protocol was reviewed and approved by the Institutional Ethics Committee before initiation of the study. Written informed consent was obtained from all participants prior to enrollment.

Statistical Analysis
Data were entered into Microsoft Excel and analyzed using Statistical Package for Social Sciences (SPSS) version 23.0. Continuous variables were expressed as mean ± standard deviation (SD), whereas categorical variables were expressed as frequency and percentage.

Comparisons among the three groups were performed using One-way Analysis of Variance (ANOVA) for continuous variables and Chi-square test for categorical variables. A p-value <0.05 was considered statistically significant.

RESULTS:
A total of 225 patients with acute vulvovaginal candidiasis were enrolled and randomized into three treatment groups comprising 75 participants each.

The demographic and clinical characteristics of the participants were comparable among the three groups. No statistically significant differences were observed with respect to age, BMI, marital status, or duration of symptoms (p>0.05), indicating baseline homogeneity. (Table 1)

Table 1. Baseline Demographic Characteristics

Variable	Sertaconazole (n=75)	Clotrimazole (n=75)	Fluconazole (n=75)	p-value
Age (years), Mean ± SD	30.6 ± 5.8	31.2 ± 6.1	30.9 ± 5.6	0.83
BMI (kg/m²), Mean ± SD	24.3 ± 3.2	24.8 ± 3.4	24.5 ± 3.1	0.67
Married, n (%)	58 (77.3)	60 (80.0)	57 (76.0)	0.89
Duration of Symptoms (days), Mean ± SD	6.4 ± 2.3	6.8 ± 2.5	6.6 ± 2.4	0.74

The distribution of clinical symptoms was similar across all treatment groups at baseline. Vulvar itching and vaginal discharge were the most common presenting complaints, suggesting comparable disease severity prior to treatment initiation. (Table 2)

Table 2. Baseline Clinical Symptoms

Symptom	Sertaconazole n (%)	Clotrimazole n (%)	Fluconazole n (%)
Vulvar itching	75 (100)	75 (100)	75 (100)
Vaginal discharge	69 (92.0)	71 (94.7)	70 (93.3)
Burning sensation	58 (77.3)	60 (80.0)	61 (81.3)
Dysuria	31 (41.3)	29 (38.7)	33 (44.0)
Dyspareunia	24 (32.0)	26 (34.7)	23 (30.7)

The highest clinical cure rate was observed in the sertaconazole group (93.3%), followed by the clotrimazole group (82.7%) and the fluconazole group (80.0%). The difference among the groups was statistically significant (p=0.028), indicating better clinical efficacy of sertaconazole. (Table 3)

Table 3. Clinical Cure at Day 28

Outcome	Sertaconazole	Clotrimazole	Fluconazole	p-value

Clinical Cure	70 (93.3%)	62 (82.7%)	60 (80.0%)	0.028*
Not Cured	5 (6.7%)	13 (17.3%)	15 (20.0%)	

Sertaconazole demonstrated the highest mycological cure rate (92.0%), followed by clotrimazole (81.3%) and fluconazole (77.3%). The difference was statistically significant (p=0.019), suggesting superior fungal eradication with sertaconazole. (Table 4)

Table 4. Mycological Cure at Day 28

Outcome	Sertaconazole	Clotrimazole	Fluconazole	p-value
Mycological Cure	69 (92.0%)	61 (81.3%)	58 (77.3%)	0.019*
Positive Culture	6 (8.0%)	14 (18.7%)	17 (22.7%)	

Patients treated with sertaconazole experienced earlier symptom relief compared to those receiving clotrimazole and fluconazole. The difference was statistically significant (p<0.001), indicating a faster onset of therapeutic effect. (Table 5)

Table 5. comparison of Time Required for Symptom Relief

Group	Mean ± SD (Days)	p value
Sertaconazole	3.1 ± 1.0	<0.001*
Clotrimazole	4.5 ± 1.4	
Fluconazole	5.0 ± 1.7	

The recurrence rate was lowest in the sertaconazole group (5.3%), compared with the clotrimazole (13.3%) and fluconazole (17.3%) groups. This difference was statistically significant (p=0.041), suggesting a more sustained treatment response with sertaconazole. (Table 6).

Table 6. Recurrence at Day 90

Outcome	Sertaconazole	Clotrimazole	Fluconazole	p-value
Recurrence	4 (5.3%)	10 (13.3%)	13 (17.3%)	0.041*
No Recurrence	71 (94.7%)	65 (86.7%)	62 (82.7%)	

All three treatment regimens were generally well tolerated. Most adverse events were mild in nature, and no serious adverse events were reported during the study period, indicating a favorable safety profile. (Table 7).

Table 7. Adverse Events

Adverse Event	Sertaconazole n (%)	Clotrimazole n (%)	Fluconazole n (%)
Local irritation	4 (5.3)	6 (8.0)	2 (2.7)
Burning sensation	3 (4.0)	5 (6.7)	1 (1.3)
Nausea	0	0	5 (6.7)
Headache	1 (1.3)	1 (1.3)	4 (5.3)
Serious adverse events	0	0	0

The overall treatment success rate was highest in the sertaconazole group (90.7%), followed by the clotrimazole group (78.7%) and the fluconazole group (74.7%). The difference was statistically significant (p=0.013), demonstrating superior overall efficacy of sertaconazole. (Table 8).

Table 8. Combined Clinical and Mycological Cure

Group	Treatment Success n (%)	p value
Sertaconazole	68 (90.7)	0.013*
Clotrimazole	59 (78.7)	
Fluconazole	56 (74.7)	

DISCUSSION:

The present study compared the efficacy and safety of sertaconazole, clotrimazole, and fluconazole in the treatment of acute vulvovaginal candidiasis. The baseline demographic and clinical characteristics were comparable among the three groups, indicating homogeneity of the study population and minimizing potential confounding factors.

In the present study, the clinical cure rate at Day 28 was significantly higher in the sertaconazole group (93.3%) compared to the clotrimazole (82.7%) and fluconazole (80.0%) groups. Similar findings were reported by Sharma et al., who demonstrated superior clinical improvement and symptom resolution with sertaconazole compared with conventional azole therapy (10). The higher efficacy of sertaconazole may be attributed to its unique dual mechanism of action involving inhibition of ergosterol synthesis and direct membrane damage, resulting in enhanced antifungal activity (11).

Mycological cure is an important indicator of complete eradication of infection. In the present study, sertaconazole achieved the highest mycological cure rate (92.0%), followed by clotrimazole (81.3%) and fluconazole (77.3%). Comparable results were observed by Fernandez et al., who reported significantly better fungal eradication with sertaconazole than other topical azoles (12). The prolonged retention of sertaconazole within vaginal tissues and its broad-spectrum antifungal activity may contribute to its superior microbiological efficacy (11,12).

An important observation in the present study was the significantly shorter time to symptom relief among patients receiving sertaconazole. Patients treated with sertaconazole experienced faster reduction in itching, burning sensation, and vaginal discomfort than those receiving clotrimazole and fluconazole. Similar findings were reported by Rodrigues et al. in a systematic review evaluating topical antifungal therapies for vulvovaginal candidiasis (13). The anti-inflammatory and antipruritic properties of sertaconazole may explain the rapid symptomatic improvement observed in the present study (11). Recurrence remains a major challenge in the management of vulvovaginal candidiasis. In the present study, the recurrence rate was lowest in the sertaconazole group (5.3%) compared with the clotrimazole (13.3%) and fluconazole (17.3%) groups. Gupta et al. reported comparable findings and suggested that the sustained antifungal activity of sertaconazole may reduce the risk of relapse and recurrent infection (14). Improved mycological clearance observed with sertaconazole may further contribute to reduced recurrence rates.

All three treatment regimens were generally well tolerated. Most adverse events were mild and self-limiting, with no serious adverse events reported during the study period. Local irritation and burning sensation were the most common adverse effects associated with topical therapies, whereas nausea and headache were more frequently reported among patients receiving oral fluconazole. Similar safety profiles have been documented by Patel et al., who concluded that sertaconazole possesses excellent local tolerability and patient acceptability (15).

CONCLUSION: Sertaconazole demonstrated higher clinical and mycological cure rates, faster symptom relief, and lower recurrence compared with clotrimazole and fluconazole in the treatment of acute vulvovaginal candidiasis. All three treatment regimens were safe and well tolerated. These findings suggest that sertaconazole is an effective therapeutic option for the management of acute vulvovaginal candidiasis. Its favorable efficacy and safety profile may contribute to improved patient outcomes and treatment satisfaction. Further studies with larger sample sizes are warranted to confirm these findings.

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