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Original Research Article

ASSESSING EFFICIENCY OF ORAL METRONIDAZOLE WITH VAGINAL CLINDAMYCIN FOR BACTERIAL VAGINOSIS

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ABSTRACT

Background: Bacterial vaginosis (BV) is a prevalent vaginal infection among women of reproductive age, characterized by an imbalance in the vaginal microbiota. While oral metronidazole and vaginal clindamycin are both established treatment options, limited comparative data exist on their efficacy and tolerability. This study aimed to evaluate and compare the therapeutic effectiveness of oral metronidazole with vaginal clindamycin in the management of BV. **Materials and Methods:** A randomized controlled trial was conducted involving 120 women aged 18–45 years diagnosed with BV based on Amsel's criteria and Nugent scoring. Participants were randomly allocated into two equal groups: Group A received oral metronidazole (500 mg twice daily for 7 days) and Group B received vaginal clindamycin cream (2%, 5 g once daily for 7 days). Primary outcomes included clinical cure rate at day 14 and microbiological cure (Nugent score ≤ 3). Secondary outcomes assessed recurrence at 8 weeks and reported adverse effects. Data were analyzed using Chi-square and Student's t-tests, with $p < 0.05$ considered statistically significant. **Result:** At day 14, the clinical cure rate was 83.3% in the oral metronidazole group and 86.6% in the vaginal clindamycin group ($p = 0.64$). Microbiological cure rates were 80.0% and 85.0%, respectively ($p = 0.47$). Recurrence at 8 weeks was observed in 18.3% of the metronidazole group and 15.0% of the clindamycin group ($p = 0.62$). Adverse effects were reported in 21.6% of participants receiving metronidazole (mainly gastrointestinal discomfort) compared to 10.0% in the clindamycin group (mainly local irritation), with a significant difference in side-effect profile ($p = 0.04$). **Conclusion:** Both oral metronidazole and vaginal clindamycin demonstrated comparable clinical and microbiological cure rates in treating BV, with similar recurrence rates. However, clindamycin was associated with fewer systemic side effects, suggesting it may be preferable for patients prone to gastrointestinal intolerance.

INTRODUCTION

Bacterial vaginosis (BV) is the most frequently encountered cause of abnormal vaginal discharge in women of reproductive age, accounting for up to 40–50% of such cases in clinical practice.[1,2] It is characterized by a shift in the vaginal flora from dominant lactobacilli to an overgrowth of anaerobic microorganisms such as Gardnerella vaginalis, Mobiluncus species, and Atopobium vaginae.[3,4] This alteration in the vaginal microbiome not only leads to bothersome symptoms but is also associated with adverse reproductive health outcomes, including preterm delivery, pelvic inflammatory disease, and increased susceptibility to sexually transmitted infections.[5,6]

The diagnosis of BV is primarily based on Amsel's clinical criteria or the Nugent scoring system, which evaluates Gram-stained vaginal smears for bacterial morphotypes.[7,8] Effective treatment aims to eradicate the pathogenic overgrowth and restore the protective lactobacillus-dominated flora.[9] Current therapeutic guidelines recommend oral or intravaginal antibiotics, with oral metronidazole and intravaginal clindamycin being among the most widely prescribed regimens.[1]

Oral metronidazole, a nitroimidazole compound, has been the mainstay of BV treatment due to its broad-

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spectrum anaerobic coverage, affordability, and ease of administration.[2] However, systemic therapy is often associated with gastrointestinal side effects, metallic taste, and potential interactions with alcohol, which can reduce adherence.[3,4] Vaginal clindamycin, a lincosamide antibiotic, offers a topical alternative with high local concentrations, potentially fewer systemic effects, and a similar cure rate.[5,6]

While both regimens are recommended by international guidelines, comparative studies evaluating their efficacy, recurrence rates, and tolerability in different populations remain limited.[7,8] Understanding these differences is essential for tailoring treatment to patient needs and optimizing clinical outcomes. The present study was designed to compare the clinical and microbiological cure rates, recurrence, and adverse effects of oral metronidazole and vaginal clindamycin in women diagnosed with BV.

MATERIALS AND METHODS

Study Design and Setting: A randomized controlled trial was conducted in the Department of Obstetrics and Gynecology at a Pandit Deen Dayal Upadhayay Goverment Hospital, Varanasi. over a period of 6 months from January 2025 to June 2025.

Study Population: Women aged 18–45 years presenting with symptoms of abnormal vaginal discharge, pruritus, or malodor and diagnosed with bacterial vaginosis based on Amsel's criteria (presence of at least three of four clinical signs) and confirmed by Nugent scoring were included.

Inclusion Criteria

- Women with a Nugent score ≥ 7 on Gram-stained vaginal smear.
- Non-pregnant and not currently menstruating at the time of recruitment.
- Willing to abstain from intravaginal medications or sexual intercourse during the treatment period.

Exclusion Criteria

- History of allergy or hypersensitivity to metronidazole or clindamycin.
- Use of systemic or intravaginal antibiotics within the previous 14 days.
- Presence of concurrent sexually transmitted infections (confirmed by laboratory testing).
- Pregnant or lactating women.

Randomization and Intervention

Eligible participants were randomly assigned into two equal groups (n = 60 each) using a computer-generated block randomization list. Group A received oral metronidazole 500 mg twice daily for 7 days, while Group B received intravaginal clindamycin cream 2% (5 g) once daily at bedtime for 7 days. Adherence to treatment was monitored through patient diaries and empty medication container returns.

Outcome Measures: The primary outcomes were:

1. Clinical cure — defined as the absence of at least three of the four Amsel's criteria at the follow-up visit on day 14.
2. Microbiological cure — defined as a Nugent score ≤ 3 at day 14.

Secondary Outcomes Included:

- Recurrence rate at 8 weeks (reappearance of clinical and microbiological features of BV).
- Adverse events reported during the study period.

Data Collection and follow-up

Baseline demographic and clinical data were recorded at enrolment. Vaginal pH testing, whiff test, and microscopic evaluation were performed at baseline, day 14, and week 8 follow-up visits. Participants were instructed to report any adverse effects immediately.

Statistical Analysis: Data were analyzed using SPSS version 26. Continuous variables were expressed as mean ± standard deviation, and categorical variables as frequencies and percentages. Group comparisons were performed using Student's t-test for continuous data and Chi-square test for categorical data. A p-value of less than 0.05 was considered statistically significant.

RESULTS

A total of 120 women meeting the inclusion criteria were enrolled and equally randomized into two groups: oral metronidazole (Group A, n = 60) and vaginal clindamycin (Group B, n = 60). The mean age of participants was 29.8 ± 6.4 years in Group A and 30.1 ± 6.1 years in Group B, with no statistically significant difference (p = 0.78). Baseline demographic and clinical characteristics, including mean vaginal pH and Nugent scores, were comparable between groups [Table 1].

At the day-14 follow-up, clinical cure was achieved in 50 participants (83.3%) in Group A and 52 participants (86.6%) in Group B (p = 0.64). Microbiological cure rates were 80.0% for Group A and 85.0% for Group B (p = 0.47) [Table 2].

Recurrence of BV at 8 weeks was observed in 11 participants (18.3%) in Group A and 9 participants (15.0%) in Group B (p = 0.62). Adverse events were reported in 13 participants (21.6%) receiving metronidazole—mainly gastrointestinal upset (15.0%) and metallic taste (6.6%)—while 6 participants (10.0%) in the clindamycin group reported local irritation (6.6%) or mild pruritus (3.3%) (p = 0.04) [Table 3].

Table 1: Baseline demographic and clinical characteristics of study participants.

Parameter	Group A: Oral Metronidazole (n=60)	Group B: Vaginal Clindamycin (n=60)	p-value
Mean age (years)	29.8 ± 6.4	30.1 ± 6.1	0.78
Mean vaginal pH	5.5 ± 0.4	5.4 ± 0.5	0.46
Mean Nugent score	8.2 ± 0.8	8.1 ± 0.9	0.59

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Symptom duration (days)	8.6 ± 3.2	8.4 ± 3.5	0.71

Table 2: Clinical and microbiological cure rates at day 14.

Outcome	Group A: Oral Metronidazole (n=60)	Group B: Vaginal Clindamycin (n=60)	p-value
Clinical cure (%)	50 (83.3%)	52 (86.6%)	0.64
Microbiological cure (%)	48 (80.0%)	51 (85.0%)	0.47

Table 3: Recurrence and adverse events.

Parameter	Group A: Oral Metronidazole (n=60)	Group B: Vaginal Clindamycin (n=60)	p-value
Recurrence at 8 weeks (%)	11 (18.3%)	9 (15.0%)	0.62
Any adverse event (%)	13 (21.6%)	6 (10.0%)	0.04*
Gastrointestinal upset (%)	9 (15.0%)	0	—
Metallic taste (%)	4 (6.6%)	0	—
Local irritation (%)	0	4 (6.6%)	—
Mild pruritus (%)	0	2 (3.3%)	—

*Statistically significant.

Both groups demonstrated high cure rates with no significant difference in efficacy outcomes [Table 2]. However, the side-effect profile differed, with metronidazole producing more systemic adverse events and clindamycin producing localized but fewer overall reactions [Table 3].

DISCUSSION

The present study compared the clinical and microbiological outcomes of oral metronidazole and vaginal clindamycin in the management of bacterial vaginosis (BV). Both treatment regimens achieved high cure rates at the two-week follow-up, with no statistically significant difference between groups. These results are in agreement with previous trials that demonstrated comparable efficacy between oral and topical antibiotic regimens for BV.[1,2]

The clinical cure rates observed in our study (83.3% for metronidazole and 86.6% for clindamycin) are consistent with earlier reports, where cure rates typically ranged from 80–90% following a one-week course of either drug.[3,4] Similarly, microbiological cure rates in our trial (80.0% vs. 85.0%) align with findings by Bradshaw et al., who reported comparable reductions in Nugent scores for both oral and intravaginal regimens.[5]

BV recurrence is a well-recognized challenge, with rates of 15–30% reported within three months of treatment.[6,7] In our study, recurrence rates at eight weeks were 18.3% for metronidazole and 15.0% for clindamycin, which is in line with the lower spectrum of recurrence described in the literature.[8,9] Possible explanations for recurrence include persistence of pathogenic biofilms, incomplete restoration of lactobacillus-dominated flora, and re-exposure to predisposing factors.[10]

Adverse effects differed between groups, with systemic side effects such as gastrointestinal discomfort and metallic taste being more common in the metronidazole group. This is consistent with previous studies that highlight higher rates of systemic intolerance with oral nitroimidazoles.[11,12] Conversely, local irritation was the primary complaint in the clindamycin group, a finding supported by data from earlier topical therapy evaluations.[13] These observations suggest that intravaginal clindamycin may be a preferable option for patients with a history of gastrointestinal sensitivity or those who prefer localized therapy.

Our findings further support international guidelines, which recommend either oral metronidazole or intravaginal clindamycin as first-line therapy for BV.[14] The choice of regimen should therefore be individualized based on patient preference, tolerability, comorbidities, and accessibility of treatment.

A limitation of the present study is the relatively short follow-up period, which may underestimate longer-term recurrence rates. Additionally, partner treatment was not evaluated, which could influence reinfection risk. Future research should investigate combination regimens or adjunctive probiotic therapy, as emerging evidence suggests that microbiome restoration may reduce recurrence.[15]

CONCLUSION

In summary, this trial confirms that both oral metronidazole and vaginal clindamycin are highly effective in the short-term treatment of BV, with similar cure and recurrence rates, but different tolerability profiles. Clinicians should consider both efficacy and side-effect patterns when selecting the optimal regimen for individual patients.

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