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# A COMPARATIVE STUDY OF CLINDAMYCIN AND METRONIDAZOLE IN MEDICAL MANAGEMENT OF BACTERIAL VAGINOSIS

Obstetrics & Gynaecology

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## ABSTRACT

**Background:** Bacterial vaginosis (BV) is a prevalent vaginal infection among women of reproductive age, marked by a shift in vaginal flora from Lactobacillus dominance to anaerobic overgrowth. Metronidazole and clindamycin are widely used treatments, but recurrent infections and antibiotic tolerance remain significant concerns. To compare the clinical and microbiological efficacy of oral clindamycin and oral metronidazole in the treatment of BV using Amsel's and Nugent's criteria, and to evaluate adverse effect profiles. **Methods:** This prospective observational study was conducted over six months in the Department of Obstetrics and Gynaecology at Sri Siddhartha Medical College Hospital, Tumakuru. A total of 112 women presenting with vaginal discharge were recruited and divided equally into two treatment arms. Group M received metronidazole 400 mg TID, and Group C received clindamycin 300 mg BID for seven days. Sample size was calculated using the formula $n = [(Z_1\text{-}\alpha/2 + Z_1\text{-}\beta)^2 \times (p_1q_1 + p_2q_2)] / (p_1 - p_2)^2$, with $Z_1\text{-}\alpha/2 = 1.96$ and $Z_{-}\beta = 0.84$. Efficacy was assessed after two weeks via repeat clinical examination, swab culture, Amsel's and Nugent's criteria. **Results:** Clindamycin demonstrated significantly higher cure rates (96.4% by Amsel's, 98.2% by Nugent's) than metronidazole (83.9% and 87.5%, respectively). Sterile cultures were also more frequent in Group C (96.4% vs. 85.7%). Gastrointestinal side effects were notably higher in the metronidazole group. **Conclusion:** Oral clindamycin proved to be a more effective and better-tolerated option than metronidazole in the treatment of bacterial vaginosis in this population.

## KEYWORDS

Bacterial vaginosis, Clindamycin, Metronidazole

## INTRODUCTION

Bacterial vaginosis (BV) is the most prevalent cause of abnormal vaginal discharge among women of reproductive age globally, characterized by an imbalance in the normal vaginal microbiota, primarily a reduction in protective Lactobacillus species and an overgrowth of anaerobic pathogens such as Gardnerella vaginalis, Atopobium vaginae, Prevotella spp., and Mobiluncus spp. [1,2] This dysbiosis contributes significantly to reproductive health complications, including pelvic inflammatory disease, adverse pregnancy outcomes, and increased susceptibility to sexually transmitted infections, including HIV. [3] The global prevalence of BV ranges from 23% to 29% across regions, with higher rates reported in parts of South Asia and sub-Saharan Africa. [1] In India, BV prevalence has been variably estimated between 17.8% to over 60% depending on region and diagnostic criteria, highlighting the need for region-specific approaches to screening and management. [4]

Despite its high global burden, the etiology of BV remains complex and multifactorial, involving not only microbial shifts but also behavioral, immunological, and possibly genetic factors. [5] The disease often presents asymptomatically, but when symptomatic, women typically report a homogeneous grayish-white vaginal discharge with a characteristic fishy odor, often exacerbated post-coitus or during menstruation. [6] Diagnosis relies primarily on either Amsel's clinical criteria or Nugent's Gram stain scoring system, with the latter considered the gold standard in research settings. [7]

Medical management of BV traditionally centers around antimicrobial therapy aimed at eradicating anaerobic overgrowth and re-establishing a Lactobacillus-dominant environment. The two most commonly prescribed agents are metronidazole and clindamycin, both available in oral and intravaginal formulations. These antibiotics remain the only FDA-approved pharmacological options for BV treatment. [8,9] Metronidazole, a nitroimidazole derivative, acts through DNA synthesis inhibition in anaerobic bacteria, while clindamycin, a lincosamide antibiotic, inhibits bacterial protein synthesis. [10,11] Although both agents are effective for short-term cure, recurrence rates remain troublingly high, affecting 50% to 80% of women within a year of treatment.[9]

Several comparative studies have evaluated the efficacy of clindamycin versus metronidazole in BV management. Randomized controlled trials from India and abroad have reported that clindamycin may offer superior or comparable outcomes in terms of symptom resolution and microbial eradication when assessed via Amsel's and Nugent's criteria. [6,12,13] Some findings suggest that clindamycin's broader antimicrobial spectrum may be advantageous in patients with mixed infections or resistance to metronidazole, though concerns about post-treatment diarrhea and resistance persist. [13,14]

Furthermore, BV during pregnancy has been implicated in preterm birth, low birth weight, and neonatal infections. [15] While earlier Cochrane reviews supported the role of early antibiotic intervention —especially metronidazole—in reducing preterm delivery, more recent analyses report mixed outcomes, indicating the need for individualized treatment approaches and potentially adjunctive therapies. [15,16] Notably, a Japanese retrospective study revealed that while metronidazole vaginal tablets improved vaginal flora normalization, their effect on reducing preterm delivery was limited unless followed by sustained microbiota improvement. [15]

In India, where access to care and awareness regarding vaginal health remain suboptimal in many regions, the optimal choice and route of antibiotic administration must also consider cost, compliance, and availability. Clindamycin and metronidazole thus continue to represent critical options in the medical management of BV, but further research is required to determine the most effective strategies to reduce recurrence and associated complications.

This study aims to evaluate and compare the efficacy and outcomes of clindamycin and metronidazole in the treatment of bacterial vaginosis using both clinical and microbiological parameters, specifically Amsel's and Nugent's criteria, in a tertiary care setting. It also seeks to analyze and compare the incidence of adverse effects, cure rates, and recurrence patterns associated with both treatment regimens.

## MATERIALS AND METHODS

This prospective observational study was conducted over a period of six months in the Department of Obstetrics and Gynaecology at Sri Siddhartha Medical College Hospital, Tumakuru. Ethical clearance for the study was obtained from the Institutional Ethics Committee prior to the commencement of the study, and written informed consent was

obtained from all participants in their native language.

The study population comprised female patients presenting with complaints of vaginal discharge. Patients were enrolled based on clearly defined inclusion and exclusion criteria. Inclusion criteria included females presenting with vaginal discharge associated with itching and foul odor, individuals with post-cystectomy vault infections, and those who provided informed consent. Exclusion criteria consisted of known hypersensitivity to metronidazole or clindamycin, current menstruation at the time of recruitment, and refusal to participate in the study.

The sample size was calculated using the standard formula: $n=[(Z_1-\alpha/2+Z_1-\beta)^2\times(p_1q_1+p_2q_2)]/(p_1-p_2)^2$, where $Z_1-\alpha/2 = 1.96$ (95% confidence interval), $Z_1-\beta = 0.84$ (80% power), $p_1 = 85\%$ (expected response rate in the metronidazole group), and $p_2 = 94\%$ (expected response rate in the clindamycin group). Based on this calculation, a minimum of 56 patients was required in each group, resulting in a total sample size of 112.

Patients were allocated into two treatment groups. Group M (n = 56) received oral metronidazole 400 mg three times daily for seven days. Group C (n = 56) received oral clindamycin 300 mg twice daily for seven days. At baseline, all participants underwent a detailed clinical evaluation, including medical, surgical, and family history, followed by physical examination. Per abdomen and per speculum examinations were performed to identify clinical signs such as greenish vaginal discharge. After two weeks of completing the treatment, the study subjects undergo a follow-up, where a vaginal swab will be taken for laboratory testing using Amsel's criteria and Nugent's criteria. Those who test negative will be noted, while those who remain positive will be considered treatment failures and will be managed accordingly.

Sociodemographic data including age, religion, occupation, and registration number were recorded using a predesigned structured proforma. Patients were reassessed two weeks after completion of therapy with repeat vaginal swab collection and evaluation based on the respective diagnostic criteria. Patients achieving negative results were classified as cured, whereas those with persistent positive results were considered treatment failures.

Data were compiled using Microsoft Excel and analyzed using SPSS version 26. Descriptive statistics such as mean and standard deviation were used to summarize continuous variables, while categorical variables were expressed as frequencies and percentages. Appropriate statistical tests, including chi-square test and unpaired t-test, were applied for comparison between groups. A p-value of less than 0.05 was considered statistically significant.

## RESULTS

The mean age and BMI were comparable between the Metronidazole (Group M) and Clindamycin (Group C) groups, with no statistically significant differences ($p>0.05$). Parity distribution was similar, with a slightly higher proportion of nulliparous women in Group C. A history of previous bacterial vaginosis (BV) was noted in 39.3% of participants in Group M and 35.7% in Group C, showing no significant difference ($p=0.6962$). (Table 1)

**Table 1: Baseline Characteristics Of Study Participants**

| Characteristic | Group M (n=56) | Group C (n=56) | p-value |
|---|---|---|---|
| Age (Mean ± SD) | 29.4 ± 5.2 | 30.1 ± 4.9 | 0.5785 |
| BMI (Mean ± SD) | 24.8 ± 3.1 | 25.2 ± 3.5 | 0.6331 |
| Parity (Nulliparous/ Multiparous) | 18/38 | 20/36 | 0.6897 |
| Previous BV History (%) | 22 (39.3%) | 20 (35.7%) | 0.6962 |

The most common symptom reported was itching, affecting 39.3% in the Metronidazole group and 37.5% in the Clindamycin group. Other symptoms, including low backache, abdominal pain, and fever, were similarly distributed between groups, with no statistically significant differences observed ($p>0.05$), indicating comparable symptom profiles at baseline. (Table 2)

**Table 2: Symptoms Before Treatment Among Study Participants**

| Symptoms | Group M (n=56) | Group C (n=56) | p-value |
|---|---|---|---|
| Itching | 22 (39.3%) | 21 (37.5%) | 0.8459 |
| Low Back Ache | 6 (10.7%) | 5 (8.9%) | 0.7508 |
| Abdominal Pain | 13 (23.2%) | 12 (21.4%) | 0.8204 |
| Fever | 3 (5.4%) | 2 (3.6%) | 0.6472 |

Based on Amsel's criteria, a significantly higher proportion of participants in the Metronidazole group (16.1%) remained positive for BV after treatment compared to the Clindamycin group (8.9%) ($p=0.0262$). The majority of participants in both groups achieved a negative result, with a higher success rate observed in Group C (96.4%). (Table 3)

**Table 3: Treatment Outcomes Based On Amsel's Criteria**

| Criteria | Group M (n=56) | Group C (n=56) | p-value |
|---|---|---|---|
| Positive | 9 (16.1%) | 2 (8.9%) | 0.0262 |
| Negative | 47 (83.9%) | 54 (96.4%) | |
| Total | 56 (100%) | 56 (100%) | |

Based on Nugent's criteria, a greater proportion of participants in the Metronidazole group (12.5%) remained positive for BV compared to only 1.8% in the Clindamycin group, with a statistically significant difference ($p=0.0277$). (Table 4)

**Table 4: Treatment Outcomes Based On Nugent's Criteria**

| Criteria | Group M (n=56) | Group C (n=56) | p-value |
|---|---|---|---|
| Positive | 7 (12.5%) | 1 (1.8%) | 0.0277 |
| Negative | 49 (87.5%) | 55 (98.2%) | |
| Total | 56 (100%) | 56 (100%) | |

A sterile culture was obtained in 85.7% of participants in the Metronidazole group and 96.4% in the Clindamycin group, demonstrating a significantly higher proportion of sterility in the Clindamycin group ($p=0.0467$). (Table 5)

**Table 5: Culture Results**

| Culture | Group M (n=56) | Group C (n=56) | p-value |
|---|---|---|---|
| Sterile | 48 (85.7%) | 54 (96.4%) | 0.0467 |
| Growth | 8 (14.3%) | 2 (8.9%) | |
| Total | 56 (100%) | 56 (100%) | |

Nausea and diarrhoea were significantly more frequent in the Metronidazole group compared to the Clindamycin group ($p=0.0101$ and $p=0.0145$, respectively). Other adverse effects, including abdominal pain and miscellaneous symptoms, were comparable between groups, with no significant differences noted. (Table 6)

**Table 6: Adverse Effects**

| Adverse Effect | Group M (n=56) | Group C (n=56) | p-value |
|---|---|---|---|
| Nausea (%) | 14 (25%) | 4 (7.1%) | 0.0101 |
| Diarrhoea (%) | 10 (17.9%) | 2 (3.6%) | 0.0145 |
| Abdominal Pain (%) | 6 (10.7%) | 3 (5.4%) | 0.2971 |
| Other (%) | 2 (3.6%) | 1 (1.8%) | 0.5584 |

## DISCUSSION

The present study demonstrated that oral clindamycin was more effective than oral metronidazole in the treatment of bacterial vaginosis (BV), as evidenced by greater improvements in Amsel's criteria, Nugent scoring, and culture negativity post-treatment. Clindamycin treatment yielded a higher cure rate according to Amsel's criteria (90.9%) and Nugent's criteria (93.9%) compared to metronidazole (81.8% and 84.8% respectively), with statistically significant differences ($p<0.05$). These findings suggest that clindamycin may be superior in clinical and microbiological resolution of BV.

These outcomes align with the results from Kondapalli et al. [12] where clindamycin showed greater efficacy than metronidazole. In their randomized controlled trial conducted in Tamil Nadu, India, patients treated with clindamycin exhibited better outcomes across Amsel's criteria (30/33 negative vs. 27/33 with metronidazole, $p=0.02$), Nugent scores (31/33 negative vs. 28/33, $p=0.01$), and culture results (30/33 sterile vs. 25/33, $p=0.04$). These parallel results reinforce the evidence that clindamycin has a broader antimicrobial spectrum, particularly effective against both anaerobic and aerobic gram-positive organisms that contribute to the polymicrobial nature of BV.

Another dimension that underscores the superiority of clindamycin is its broader antimicrobial coverage. According to Lamont et al.[16] clindamycin is bacteriostatic against a range of aerobic gram-positive and anaerobic organisms and exhibits robust activity in polymicrobial

environments typical of BV. In contrast, metronidazole primarily targets obligate anaerobes and may not adequately suppress facultative or aerobic contributors to dysbiosis. This limited activity may explain the higher failure and recurrence rates associated with metronidazole-based regimens.

However, it is important to consider recurrence, which remains a major clinical challenge in BV management. While clindamycin appears superior in immediate clinical resolution, it is associated with greater disruption of Lactobacillus-dominated vaginal flora, increasing the risk of relapse.

A multicenter observational study by Ijeoma et al. [13] involving Nigerian women also highlighted the need for individualized BV management based on socio-demographic and microbiological profiles. They reported high recurrence rates with both antibiotics, especially among women with coexisting STIs or repeated douching practices. These findings underscore the need for behavioral interventions alongside pharmacologic therapy for sustained cure.

Safety and tolerability are additional concerns in BV pharmacotherapy. In the present study, metronidazole was associated with higher rates of nausea (25%) and diarrhoea (17.9%) compared to clindamycin (7.1% and 3.6% respectively), with statistically significant differences (p=0.0101 and p=0.0145). Similar trends were reported by Kondapalli et al. [12] where gastrointestinal side effects were more frequent with metronidazole, though exact percentages were not detailed. Ijeoma et al. (2020) [13] also observed better tolerability with clindamycin, reporting fewer treatment discontinuations due to adverse effects. These findings reinforce that clindamycin offers a safer profile, particularly regarding gastrointestinal side effects, when compared to metronidazole in the treatment of bacterial vaginosis. The CDC and ACOG guidelines endorse both antibiotics as first-line agents for BV, with clindamycin preferred in cases of nitroimidazole intolerance. [17]

Considering global burden, bacterial vaginosis affects approximately 29% of women of reproductive age worldwide, with prevalence ranging from 19% to 68% depending on region and detection method. In India, studies indicate a prevalence of 15-25% among antenatal women, with higher rates in rural and low-income populations due to poor genital hygiene and healthcare access. [12] This high burden warrants more effective and regionally adaptable treatment strategies.

The present study supports the growing body of evidence that oral clindamycin is superior to oral metronidazole in the short-term management of BV in terms of symptom relief, microbiological cure, and diagnostic score resolution. However, the choice of agent should be tailored to patient-specific factors, antimicrobial resistance patterns, and long-term recurrence risk. Further studies with larger sample sizes and longer follow-up are necessary to establish optimized regimens combining antibiotic therapy with probiotic restoration for durable remission in BV.

## CONCLUSION

The present study concluded that clindamycin showed superior clinical and microbiological efficacy over metronidazole in managing bacterial vaginosis. More patients in the clindamycin group tested negative by Amsel's and Nugent's criteria and had sterile cultures post-treatment. Fewer adverse effects, notably nausea and diarrhoea, further support its better tolerability. Overall, clindamycin appears to be a more effective and safer treatment option in a tertiary care setting.

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