



COMPARATIVE STUDY OF COMBINED ANTIBIOTIC WITH PROBIOTIC THERAPY VERSUS ANTIBIOTIC THERAPY ALONE IN THE TREATMENT OF BACTERIAL VAGINOSIS

Obstetrics & Gynaecology

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ABSTRACT

Background: Bacterial vaginosis (BV) is a common vaginal infection in women of reproductive age, characterized by discharge and malodour due to an imbalance of vaginal flora. Recurrence rates after standard antibiotic treatment are high, prompting exploration of adjunct probiotic therapy to restore normal vaginal microbiota. **Objectives:** To compare the efficacy of combined antibiotic and probiotic therapy versus antibiotic therapy alone in the treatment of BV, in terms of cure rates and recurrence, and to determine if adding probiotics achieves higher cure rates, lower recurrence rates, and a healthier vaginal flora. **Methods:** A randomized controlled trial was conducted in the Department of Obstetrics and Gynaecology at a tertiary care centre. A total of 200 women aged 18–45 years diagnosed with BV by Amsel's criteria were randomly assigned to two groups. Group A received oral metronidazole (500 mg twice daily for 7 days) plus an oral probiotic supplement for 30 days, while Group B received oral metronidazole alone. Patients were followed at 1 week, 1 month, 2 months, and 6 months post-treatment, with repeat clinical examinations using Amsel's criteria to assess cure or recurrence. **Results:** Both groups had equivalent baseline characteristics. Initial cure rates at 1 month were 100% in both groups. However, by 6 months post-treatment, BV recurrence was significantly lower in the combined therapy group (6%) compared to the antibiotic-only group (24%, $p = 0.001$). Thus, adding probiotics did not affect short-term cure but significantly reduced long-term recurrence of BV. **Conclusion:** Combined antibiotic and probiotic therapy is more effective than antibiotic alone for long-term management of BV. While immediate cure rates are similar, adjunct probiotics markedly decrease the risk of BV recurrence by helping re-establish a normal vaginal flora. This combined approach represents a promising, natural strategy to improve BV treatment outcomes.

KEYWORDS

INTRODUCTION

Bacterial vaginosis, also known as BV, is one of the most frequent illnesses affecting the lower genital tract in women of reproductive age. It is also the most common cause of vaginal discharge and unpleasant odour [1]. More than 29 percent of women have been found to have bacterial vaginosis. [2]

Gardner and Dukes reported in 1955 that there was a high association between BV and the presence of *Gardnerella vaginalis*. This was the first time that BV had been identified. [3] However, in order to make any headway in determining the make-up of the vaginal microbiome, it was necessary to wait until new molecular techniques were developed. These findings implicated not one bacterial species but multiple bacteria in BV and expanded the understanding of the typical shift in the normal vaginal microbiota from a majority of protective lactobacilli to pathogenic anaerobic bacteria. This shift in the normal vaginal microbiota has been linked to the development of BV. [4] An overgrowth of vaginal anaerobes or Gram-negative bacteria, such as *Gardnerella vaginalis*, bacterial vaginosis-associated bacteria, *Megasphaera* species, *Atopobium* vaginae, *Mycoplasma hominis*, *Ureaplasma urealyticum*, *Prevotella*, *Mobiluncus* species, and *Peptostreptococcus* species, replaces the resident *Lactobacillus* species. [5] Furthermore, it has been demonstrated that bacteria associated with BV are responsible for the formation of a prolific polymicrobial biofilm that clings to the vaginal epithelium. The primary components of this biofilm were determined to be *G. vaginalis* and *A. vaginae*. [6]

Bacterial vaginosis can lead to a number of complications, including premature birth, premature rupture of membranes, chorioamnionitis, spontaneous abortion, infertility, and an increased chance of contracting HIV. Other complications include urinary tract infections. Vaginal douching, having several sexual partners, having a new sexual partner, smoking cigarettes, and using certain birth control methods are all factors that have been linked to this condition. [6] Gram stain

(Nugent) scoring and Amsel's criteria are utilized to arrive at a diagnosis of BV. There are several different approaches to treatment available for BV. The first is using antibiotics—most commonly metronidazole, a nitroimidazole antibiotic with widespread use in BV treatment. It can be administered orally or vaginally, in various regimens. *G. vaginalis* species, however, are showing a rising resistance to metronidazole. [7]

The use of probiotics is yet another method that can be utilized in the treatment of BV. "Live microorganisms that, when administered in suitable amounts, confer a health benefit to the host" is the scientific definition of probiotics. The use of probiotics in conjunction with antibiotics has the potential to boost the effectiveness of treatment. In one study, the combination of oral metronidazole therapy (500 mg twice daily for 7 days) and oral probiotic therapy (twice daily for 30 days, with a capsule containing *L. rhamnosus* GR-1 and *L. reuteri* RC-14) [9] showed significantly increased efficacy in comparison to oral metronidazole therapy alone; notably, that study was conducted on patients with gonorrhea. At the 30-day follow-up, 88% of women in the probiotic group had normal vaginal flora, but just 40% of women in the placebo group did. [7]

This study was conducted to know the efficacy of combined probiotic & antibiotic therapy vs antibiotic therapy alone in the treatment of BV.

MATERIALS AND METHODS

Study Area: The study was carried out in the Department of Obstetrics and Gynaecology at Alluri Sitaramaraju Academy of Medical Sciences (ASRAM Medical College), Eluru, Andhra Pradesh, India.

Study Population: All women attending the OBG outpatient department with complaints of white vaginal discharge were considered for the study.

Study Design: Randomised controlled trial.

Sample Size: 200 patients were included and divided into two equal groups.

- Group A: 100 patients (received Probiotic + Antibiotic therapy)
- Group B: 100 patients (received Antibiotic therapy alone)

Time Frame: April 2023 to March 2025.

All eligible women aged 18–45 years and diagnosed as having BV according to Amsel's criteria were enrolled and randomized into the two groups. Group A patients received standard antibiotic treatment (oral metronidazole 500 mg twice daily for 7 days) along with an adjuvant oral probiotic capsule daily for 30 days. Group B patients received the standard antibiotic treatment (oral metronidazole for 7 days) without probiotics. After completion of the treatment period, patients were followed up at 1 week, 1 month, 2 months, and 6 months. At each follow-up visit, a clinical evaluation including repeat Amsel's criteria was performed to determine if BV was cured or had recurred.

INCLUSION AND EXCLUSION CRITERIA

Inclusion Criteria: All women of reproductive age group (18–45 years) diagnosed as having BV according to Amsel's criteria.

Exclusion Criteria: Women with:

1. Age < 18 years or > 45 years
2. Unmarried status
3. Pregnant or menopausal women
4. Post-abortion or in puerperium
5. Premature menopause
6. Malignancy of the reproductive tract
7. Known allergies or immunocompromised states
8. Infections other than BV

RESULTS AND ANALYSIS

Table 1: Distribution of patients based on the age group.

Age Group (years)	Antibiotics (N = 100)	Antibiotics + Probiotics (N = 100)	Total (N = 200)
20–30	37 (37.0%)	33 (33.0%)	70 (35.0%)
31–40	32 (32.0%)	37 (37.0%)	69 (34.5%)
41–50	31 (31.0%)	30 (30.0%)	61 (30.5%)
Total	100 (100%)	100 (100%)	200 (100%)

Chi-square = 0.60, $p = 0.73$ (not significant)

The two groups were comparable in baseline characteristics. As shown in Table 1, the age distribution of patients was similar between Group A and Group B ($p = 0.73$). In both the antibiotics-only group and the antibiotics + probiotics group, 37% of patients were 20–30 years old, about one-third were 31–40, and around 30% were 41–50 years, with no significant difference between groups. The presenting symptoms were also comparable: in each group, 59% of patients had vaginal discharge, 23% had itching, and 18% had malodour of discharge, with no statistical difference. The duration of BV before treatment was <5 months in 83% and 6–10 months in 17% of patients in both groups, indicating no difference in chronicity. Laboratory findings were likewise similar across groups. On microscopic evaluation, 94% of patients in each group had a positive saline mount test for clue cells, and 94% in each group had a positive whiff test (KOH mount), with no significant inter-group differences. The vaginal pH distribution was also essentially identical between the two groups (pH 4 or 5 in ~70% and pH 6 in ~30% of patients in both groups). In summary, there were no statistically significant differences in baseline demographic or clinical characteristics between Group A and Group B ($p > 0.05$ for all comparisons).

All patients had BV at baseline (0 days) by Amsel's criteria in both groups. After treatment, at the 1-week follow-up, 92% of patients in each group showed no BV (i.e. cure), while 8% in each group still had BV. By the 1-month follow-up, 100% of patients in both Group A and Group B were free of BV (complete cure in both groups). At 2 months, 98% of patients in each group remained BV-free, with a 2% recurrence rate in both groups. However, by 6 months post-treatment, a marked divergence was observed: 24% of patients in the antibiotics-only group had recurrence of BV, whereas only 6% of patients in the antibiotics + probiotics group had BV recurrence. This difference in recurrence rates at 6 months was statistically significant ($p = 0.001$). Thus, although the initial cure rates were the same in both groups, the addition of probiotics significantly reduced the risk of BV returning in the long term.

DISCUSSION

In the present study, combined antibiotic and probiotic therapy demonstrated superior efficacy in the long-term management of BV compared to antibiotic therapy alone. While the short-term cure rates at 1 week and 1 month were identical for both groups, the probiotics-adjuvant group showed a significantly lower recurrence of BV by 6 months. This finding highlights that probiotics may not impact the immediate treatment success but play a crucial role in sustaining cure and preventing relapse over time.

The results of our trial are in agreement with several other studies in the literature. Marcone *et al.* reported that long-term vaginal administration of *Lactobacillus* probiotics after standard antibiotic treatment led to over 80% remission rates at 6 and 12 months, compared to lower remission rates in those who received antibiotic treatment alone. Similarly, Vujic *et al.* demonstrated that orally administered probiotic capsules significantly improved cure and reduced recurrence of BV in a randomized controlled trial. These studies, like ours, suggest that probiotics help maintain a protective vaginal flora after clearance of infection, thereby reducing the frequency of BV recurrence.

Our short-term findings concur with the observations of Tafazzoli-Harandi *et al.*, who found no significant difference in immediate cure rates when comparing metronidazole alone to metronidazole combined with probiotics in treating BV. In that study, as in ours, the probiotic effect was not evident in the first month of treatment; however, for those women who were initially cured, adjunct probiotic therapy significantly prolonged the time before relapse. This indicates that the primary benefit of probiotics lies in preventing the return of infection rather than enhancing initial cure. Other investigators have similarly noted that while probiotics may not markedly increase short-term cure rates, they are effective in sustaining normal vaginal flora and preventing recurrent BV episodes in the long run. Our finding of a significantly lower 6-month recurrence rate in the combined therapy group supports this concept.

Additionally, Arooj *et al.*^[7] reported significantly higher cure rates with combined probiotic and antibiotic therapy (83.3%) versus antibiotic alone (36.7%) in BV, corroborating the efficacy of probiotics as an adjunct treatment. Although the exact magnitude of benefit differed across studies, the overall trend favors the use of probiotics to improve long-term outcomes in BV. The variations in results among studies could be due to differences in probiotic strains, dosages, treatment durations, and population characteristics. Despite these differences, a common conclusion is that adjunct probiotics contribute to restoring the normal lactobacilli-dominant vaginal ecosystem, thereby offering protection against BV recurrence.

Bacterial vaginosis is notorious for its high recurrence rates and associated complications, and conventional antibiotic therapy alone often does not prevent relapse once treatment is stopped. The integration of probiotic therapy addresses this issue by re-establishing the indigenous vaginal microbiota. Probiotics such as *Lactobacillus rhamnosus* and *Lactobacillus reuteri* produce lactic acid and other substances that help maintain an acidic vaginal pH and inhibit the overgrowth of pathogenic bacteria. This mechanism explains the significant reduction in BV recurrence observed in our study's probiotic group. Furthermore, probiotic treatment is generally safe, well-tolerated, and free of serious side effects, making it a appealing adjunct strategy in managing BV.

In light of our findings and the supporting evidence from other studies, incorporating probiotics along with standard antibiotics could be considered a novel and effective approach to treat BV, especially for patients with recurrent disease. However, the sample size and follow-up duration of our study, while adequate to demonstrate a difference, still indicate that larger-scale studies are needed. Future research on a larger population and in different settings will help confirm the benefits of probiotics, determine the most effective strains and regimens, and establish guidelines for the routine use of probiotics in BV treatment and prevention of recurrence.

CONCLUSION

As a result of our research, we came to the conclusion that the treatment of BV with a combination of antibiotic therapy and probiotic therapy is more successful than antibiotic therapy alone. The use of probiotics as a form of treatment for BV is a novel and effective method

of treatment; nevertheless, additional research on a larger scale is required to corroborate our findings. The results of this study demonstrated that treatment with probiotics reduces the risk of recurrent BV.

REFERENCES

1. Yudin MH. Other Infectious conditions. James DK, Steer PJ, Weiner CP, Gonik B. High Risk Pregnancy: Management Options. 4th ed. Nottingham; 2011:521–42.
2. Macphée RA, Hummelen R, Bisanz JE, Miller WL, Reid G. Probiotic strategies for the treatment and prevention of bacterial vaginosis. *Expert OpinPharmacother*. 2010;11(18):2985–95.
3. Gardner HL, Dukes CD. *Haemophilus vaginalis* vaginitis: a newly defined specific infection previously classified non-specific vaginitis. *Am J Obstet Gynecol*. 1955;69(5):962–76.
4. Lamont RF, Sobel JD, Akins RA, et al. The vaginal microbiome: new information about genital tract flora using molecular based techniques. *BJOG*. 2011;118(5):533–49.
5. Fredricks DN, Fiedler TL, Marrazzo JM. Molecular identification of bacteria associated with bacterial vaginosis. *N Engl J Med*. 2005;353(18):1899–911.
6. Swidsinski A, Mendling W, Loening-Baucke V, et al. An adherent *Gardnerella vaginalis* biofilm persists on the vaginal epithelium after standard therapy of bacterial vaginosis. *J Clin Microbiol*. 2005;43(1):217–20.
7. Arooj A, Bano N, Nazir R, Chaudhri R. Comparison of Combined Probiotic and Antibiotic Therapy Versus Antibiotic Therapy Alone in Treatment of Bacterial Vaginosis. *J. Soc. Obstet. Gynaecol. Pak*. 2017;7(2):57–60.
8. Henry G, Susan S, Harold E, Berkovitz BKB. *Gray's Anatomy: The Anatomical Basis of Clinical Practice*. 39th ed. Edinburgh & New York: Elsevier Churchill Livingstone; 2005.
9. Kumar N, Behera B, Sagiri SS. Bacterial vaginosis: Etiology and modalities of treatment –A brief note. *J Pharm Bioallied Sci*. 2011;3(4):496–503.
10. Suresh A, Rajesh A, Bhat RM, Rai Y. Cytolytic vaginosis: A review. *Indian J Sex Transm Dis AIDS*. 2009;30(1):48–50.