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COMPARISON OF FREQUENCY OF SUCCESSFUL TREATMENT IN PATIENTS OF BACTERIAL VAGINOSIS TREATED WITH INTRAVAGINAL METRONIDAZOLE VERSUS INTRAVAGINAL PROBIOTICS

Original Research

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ABSTRACT

Background: Bacterial vaginosis (BV) is a prevalent vaginal infection caused by an imbalance of lactobacillus-dominated flora and overgrowth of anaerobic bacteria such as Gardnerella vaginalis and Mycoplasma hominis. Standard treatment with intravaginal metronidazole often faces limitations such as recurrence, adverse effects, and poor compliance. Probiotics have emerged as a potential alternative by restoring vaginal microbiota without significant side effects. This study aimed to compare the efficacy of intravaginal probiotics and metronidazole for treating bacterial vaginosis.

Objective: To compare the frequency of successful treatment in patients with bacterial vaginosis treated with intravaginal metronidazole versus intravaginal probiotics.

Methods: This randomized controlled study was conducted over six months at the Department of Obstetrics & Gynecology, Sandeman Provincial Hospital, Quetta. A total of 66 women aged 18-35 years with BV (Nugent score ≥7) were randomly allocated into two groups. The BV-P group received intravaginal probiotics, while the BV-M group received intravaginal metronidazole. Treatment success was defined as the resolution of fishy odor and a Nugent score <4 at 30 days post-treatment. Baseline characteristics, follow-up Nugent scores, and treatment outcomes were recorded and analyzed using SPSS version 20.0.

Results: Participants had a mean age of 27.2 ± 5.3 years, with 37.9% aged 18-25 years and 62.1% aged 26-35 years. The mean disease duration was 12.8 ± 4.2 days. At baseline, both groups were comparable in age, disease duration, and Nugent scores ($p > 0.05$). At follow-up, the probiotics group demonstrated a significantly lower Nugent score (2.24 ± 1.50 vs. 3.79 ± 2.52, $p = 0.004$) and a higher success rate (90.9% vs. 60.6%, $p = 0.004$). Probiotics maintained superior outcomes across all subgroups.

Conclusion: Intravaginal probiotics showed significantly better efficacy than metronidazole in treating bacterial vaginosis, with improved Nugent scores and treatment success rates. Probiotics represent a viable alternative to traditional antibiotic therapy, providing better patient outcomes with minimal side effects.

Keywords: Bacterial Vaginosis, Lactobacillus, Metronidazole, Microbiota, Nugent Score, Probiotics, Randomized Controlled Trial

INTRODUCTION

Bacterial vaginosis (BV) is a prevalent cause of malodorous vaginal discharge among women of reproductive age, characterized as a polymicrobial syndrome with a reported prevalence of 29% (1). In Pakistan, the frequency of bacterial vaginosis has been documented at 29% among patients presenting with vaginal discharge at Holy Family Hospital, Rawalpindi, according to Arooj et al. (2), while another study reported a frequency of 17% (3). This condition arises when Lactobacillus bacteria, which normally dominate the vaginal microbiota and produce hydrogen peroxide to maintain vaginal health, are replaced by anaerobic bacteria such as Gardnerella vaginalis and Mycoplasma hominis (4,5). The imbalance in vaginal flora is not only associated with recurrence but also contributes to significant complications, including pelvic inflammatory disease, postoperative infections, increased susceptibility to sexually transmitted infections, HIV, and preterm labor in pregnant women (5).

The current first-line treatment for BV typically involves a seven-day regimen of oral or intravaginal metronidazole, achieving cure rates of 60%-70% within four weeks (4,6). However, the recurrence rate remains high, and adverse effects such as dizziness, headache, vaginal itching, burning, and discharge are frequently observed with intravaginal metronidazole. Prolonged or repeated use of this antibiotic can also predispose individuals to secondary vaginal yeast infections (9,10). As an alternative, the use of intravaginal probiotics has gained attention for their ability to restore a healthy vaginal microbiota. Probiotics, particularly lactobacilli, have demonstrated efficacy in normalizing vaginal flora and increasing lactobacillus scores in women with BV (7,8). Ling et al. (2013), in a randomized controlled trial involving 115 women, reported significantly higher treatment success rates with intravaginal probiotics (96%) compared to intravaginal metronidazole (70%) after a 30-day follow-up (9). Given the frequency of BV among women attending gynecological outpatient clinics in Pakistan (2,3) and the limited local and international data on comparative treatment efficacy, further research on this topic is crucial. The selection of an effective and safe treatment for BV is vital, as treatment outcomes may vary depending on the species and sensitivity patterns of the causative organisms. This study aims to provide evidence that can guide the selection of optimal therapeutic strategies, thereby improving clinical outcomes for patients with bacterial vaginosis in future medical practice.

METHODS

The study employed a randomized controlled trial design conducted in the Department of Obstetrics and Gynecology at Sandeman Provincial Hospital, Quetta. A total sample size of 66 patients, divided equally into two groups of 33, was calculated with a test power of 80% and a significance level of 95%. The calculation was based on an expected treatment success rate of 96.0% for intravaginal probiotics and 70.0% for intravaginal metronidazole in managing bacterial vaginosis (9). Female patients aged 18-35 years, newly diagnosed with bacterial vaginosis within the past 24 hours and with no prior history of the condition or its treatment, were included in the study. Patients with diabetes, those on steroids, individuals diagnosed with malignancy, patients undergoing chemotherapy, and those with a known allergy to metronidazole were excluded to minimize confounding factors. Informed consent was obtained from all participants before their inclusion in the study. Relevant demographic data, including age, duration of disease, and initial Nugent score, were recorded for each participant. Randomization was performed to allocate patients into two treatment groups. The BV-M group received 500 mg metronidazole gel administered intravaginally once daily at bedtime for seven days, while the BV-P group received an intravaginal probiotic containing Lactobacillus capsules, administered once daily at bedtime for ten days. Participants were instructed to adhere strictly to their prescribed treatment protocol and abstain from sexual intercourse during the treatment period.

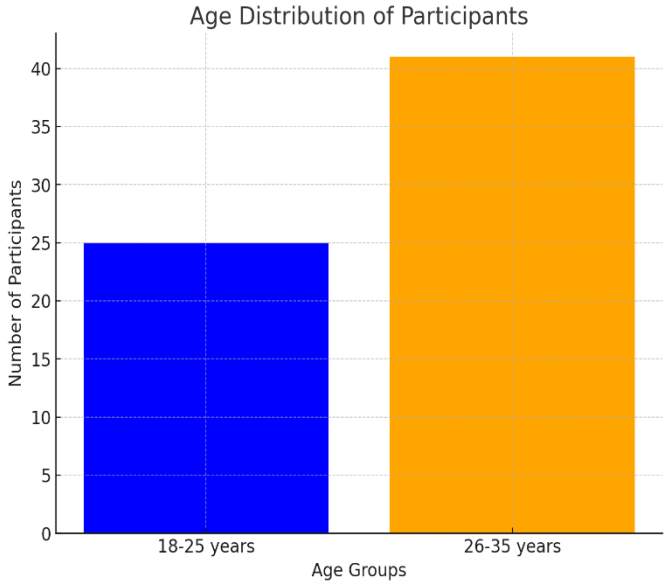
Follow-up assessments were conducted in the outpatient department four weeks after the initiation of therapy. Treatment success was evaluated based on an operational definition, with patients showing treatment failure managed according to departmental protocol. This involved an extended regimen of both oral and intravaginal metronidazole for 14 days. To minimize bias, all vaginal sampling procedures were performed by a single resident (the principal investigator) under the supervision of a consultant gynecologist. Microscopic evaluations of the samples were conducted by a single pathologist with over five years of experience. Efforts were made to control confounding variables through rigorous exclusion criteria. Data regarding demographic details, duration of disease, initial and follow-up Nugent scores, and treatment outcomes were meticulously recorded using a structured proforma. Statistical analysis was performed using SPSS version 20.0 to ensure the accuracy and reliability of results.

RESULTS

The study included a total of 66 participants, with a mean age of 27.2 ± 5.3 years. Of these, 37.9% (n=25) were aged between 18 and 25 years, while 62.1% (n=41) were aged between 26 and 35 years. The mean duration of symptoms was 12.8 ± 4.2 days, with 51.5% (n=34) experiencing symptoms for 7 to 13 days and 48.5% (n=32) for 14 to 20 days. The baseline Nugent score of participants had a mean value of 8.5 ± 1.1, with 40.9% (n=27) scoring between 7 and 8, and 59.1% (n=39) scoring between 9 and 10. Both groups were statistically comparable at baseline in terms of age, disease duration, and Nugent scores, as the observed differences were not significant

($p > 0.05$). At the four-week follow-up, participants in the probiotics group demonstrated significantly better outcomes compared to the metronidazole group. The mean follow-up Nugent score in the probiotics group was 2.24 ± 1.50, which was markedly lower than the mean score of 3.79 ± 2.52 observed in the metronidazole group ($p = 0.004$). Furthermore, the treatment success rate was significantly higher in the probiotics group, with 90.9% (n=30) achieving successful treatment compared to 60.6% (n=20) in the metronidazole group ($p = 0.004$). In contrast, treatment failure was observed in 9.1% (n=3) of the probiotics group and 39.4% (n=13) of the metronidazole group.

Stratification analysis further revealed that the probiotics group consistently outperformed the metronidazole group across various subgroups. Among participants aged 18 to 25 years, the treatment success rate was 92.3% in the probiotics group versus 58.3% in the metronidazole group ($p = 0.047$), while among those aged 26 to 35 years, the success rates were 90.0% and 61.9%, respectively ($p = 0.036$). Similarly, in participants with symptoms lasting 7 to 13 days, the success rate was 94.1% in the probiotics group compared to 64.7% in the metronidazole group ($p = 0.034$). For those with symptoms lasting 14 to 20 days, success rates were 87.5% versus 56.3%, respectively ($p = 0.049$). Stratification by baseline Nugent scores also maintained the superiority of the probiotics group, with treatment success rates of 92.3% for scores of 7 to 8 and 90.0% for scores of 9 to 10, compared to 57.1% and 63.2% in the metronidazole group, respectively ($p < 0.05$).



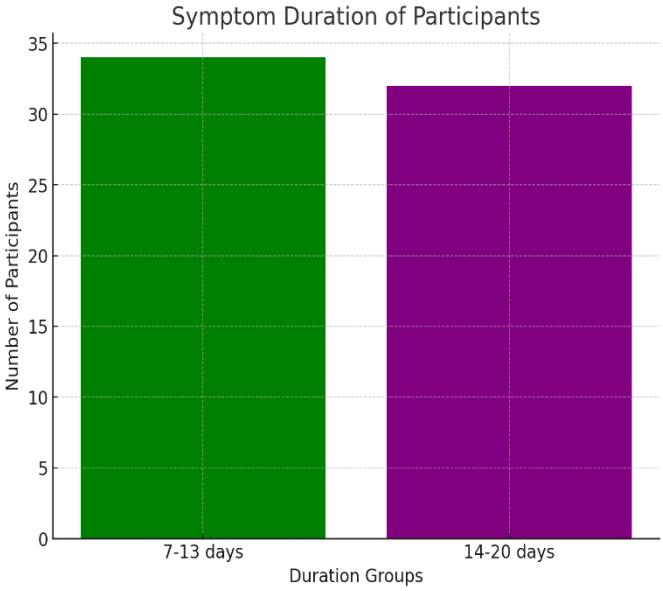


Table 1.0: Baseline Characteristics of Study Sample

Characteristics	Participants n=66
Age (years)	27.2±5.3
18-25 years	25 (37.9%)
26-35 years	41 (62.1%)
Duration (days)	12.8±4.2
7-13 days	34 (51.5%)
14-20 days	32 (48.5%)
Baseline Nugent Score	8.5±1.1
7-8	27 (40.9%)
9-10	39 (59.1%)

Table 2.0: Baseline Characteristics of Study Groups

Characteristics	Probiotics n=33	Metronidazole n=33	P-value
Age (years)	27.24±5.92	27.15±4.62	0.945
18-25 years	13 (39.4%)	12 (36.4%)	0.800
26-35 years	20 (60.6%)	21 (63.6%)	
Duration (days)	12.73±4.30	12.82±4.10	0.930
7-13 days	17 (51.5%)	17 (51.5%)	1.000
14-20 days	16 (48.5%)	16 (48.5%)	
Baseline Nugent Score	8.48±1.06	8.52±1.18	0.913
7-8	13 (39.4%)	14 (42.4%)	0.802
9-10	20 (60.6%)	19 (57.6%)	

Chi-square test and Independent sample t-test, observed difference was statistically insignificant

Table 3.0: Comparison of Nugent Score between the Groups

	Probiotics n=33	Metronidazole n=33	P-value
Baseline Nugent Score	8.48±1.06	8.52±1.18	0.913
Follow-up Nugent Score	2.24±1.50	3.79±2.52	0.004*

Independent sample t-test, * observed difference was statistically significant

Table 4.0: Comparison of Successful Treatment between the Groups

Successful Treatment	Probiotics n=33	Metronidazole n=33	P-value
Yes	30 (90.9%)	20 (60.6%)	0.004*
No	3 (9.1%)	13 (39.4%)	
Total	33 (100.0%)	33 (100.0%)	

Chi-square test, * observed difference was statistically significant

Table 5.0: Stratification of Successful Treatment between the Groups across Subgroups

Subgroups	Successful Treatment		P-value
	Probiotics n=33	Metronidazole n=33	
Age (years)			
18-25 years	12/13 (92.3%)	7/12 (58.3%)	0.047*
26-35 years	18/20 (90.0%)	13/21 (61.9%)	0.036*
Duration (days)			
7-13 days	16/17 (94.1%)	11/17 (64.7%)	0.034*
14-20 days	14/16 (87.5%)	9/16 (56.3%)	0.049*

Baseline Nugent Score			
7-8	12/13 (92.3%)	8/14 (57.1%)	0.037*
9-10	18/20 (90.0%)	12/19 (63.2%)	0.047*

Chi-square test, * observed difference was statistically significant

DISCUSSION

Bacterial vaginosis is a prevalent vaginal infection characterized by an imbalance in the normal lactobacillus-dominated flora, leading to the overgrowth of anaerobic bacteria such as Gardnerella vaginalis and Mycoplasma hominis. Intravaginal metronidazole has long been considered the standard treatment, but it is frequently associated with treatment failure, recurrence, and adverse effects that can hinder patient compliance. Recent studies have highlighted the potential of intravaginal probiotics as an alternative therapy, offering restoration of normal vaginal flora without the adverse effects associated with antibiotics. Despite these promising findings, local data comparing the efficacy of these treatment options remains scarce, underscoring the importance of the present study (10-12). The study revealed a mean patient age of 27.2 ± 5.3 years, comparable to findings reported in other populations, which strengthens the generalizability of the results. A majority of the patients were aged between 26 and 35 years, with a smaller proportion between 18 and 25 years. These findings align with global demographic trends for bacterial vaginosis, further validating the sample characteristics. The study also demonstrated a significantly higher frequency of successful treatment in the probiotics group compared to the metronidazole group, with success rates of 90.9% and 60.6%, respectively ($p = 0.004$). This superiority remained consistent across subgroups stratified by age, disease duration, and baseline Nugent scores, highlighting the robustness of probiotics as a treatment option (13-15).

The observed efficacy of probiotics is consistent with previously reported research, which demonstrated higher cure rates with probiotics compared to metronidazole. These studies reported success rates exceeding 90% for probiotics, in contrast to approximately 60%-70% for metronidazole, corroborating the present findings. The mechanism behind the superior efficacy of probiotics is likely related to their ability to restore and sustain a healthy vaginal microbiota, thereby reducing recurrence and improving patient outcomes. Additionally, probiotics are devoid of the side effects commonly associated with metronidazole, such as itching, burning, and secondary yeast infections, which improves patient adherence and compliance (16-18). The study's strengths lie in its randomized controlled design, strict exclusion criteria to minimize confounding variables, and consistent follow-up. The findings are particularly relevant as they provide local evidence supporting the use of probiotics, which has been underexplored in the region. However, the study has certain limitations. Recurrence of bacterial vaginosis was not assessed, which is a critical aspect of evaluating long-term treatment efficacy. Moreover, the study did not include data on adverse effects, which could further strengthen the comparative analysis of the two treatments. These limitations indicate the need for future studies to explore recurrence rates and adverse event profiles associated with these treatments, providing a more comprehensive understanding of their long-term efficacy and safety (19,20).

The findings of this study suggest that intravaginal probiotics are a highly effective and safer alternative to metronidazole for the treatment of bacterial vaginosis. Probiotics offer a superior treatment option, with higher success rates, minimal side effects, and improved patient compliance, making them a preferred choice for future clinical practice. Expanding research in this domain, particularly through long-term studies focusing on recurrence and resistance patterns, is imperative to establish more definitive treatment guidelines for bacterial vaginosis.

CONCLUSION

The study concluded that intravaginal probiotics provided a more effective treatment for bacterial vaginosis compared to metronidazole. Probiotics demonstrated consistent superiority across different patient subgroups, offering a promising alternative to conventional antibiotic therapy. By restoring the natural vaginal microbiota without the adverse effects commonly associated with antibiotics, probiotics present a safer and more patient-friendly option for managing this condition. These findings support the potential for probiotics to improve clinical outcomes and enhance treatment strategies for bacterial vaginosis in future practice.

Author	Contribution
Shazia Baloch	Prepared synopsis, conceived data, data analysis, write up & approval final draft
Sadia Ghilzai	Data entry & Data Analysis, Results, Discussion.
Farah Naz	Data entry & Data Analysis, Results, Discussion.
Kalsoom Noor	Data entry & Data Analysis, Results, Discussion.
Khadija Zahir	Data entry, Data analysis, Draft write up of Article

Sadia Ali	Data entry, Data analysis, Draft write up of Article

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