Role of Probiotics in Bacterial Vaginosis

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Abstract:
Background: Bacterial vaginosis is the most common type of vaginal infection among women of reproductive age group and accounts for one-third of all vulvovaginal infections. The aim of present study is to review clinical evidences available regarding efficacy of probiotics in treatment and recurrence of Bacterial Vaginosis.

Material and methods: A total of 160 vaginal swabs were collected from patients clinically diagnosed to have homogenous, copious, white mucoid vaginal discharge. Based on Amsel criteria 100 out of 160 cases confirmed as Bacterial vaginosis. An appropriate oral dose of probiotic supplement for 3 weeks given along with routine antibiotic therapy for 50 patients. The remaining 50 patients were taken as control group. Follow up was done after a month for patients of both the groups.

Results: Among the 100 positive cases, 44 were on antibiotic plus probiotic supplement and 46 were on antibiotic therapy alone. The former group showed 2 recurrence cases when compared to 12 recurrence cases in the latter group. However, 10 patients did not return for follow up.

Conclusion: This study shows that probiotic supplementation has significant role in treatment and prevention of recurrence of Bacterial Vaginosis. They hinder pathogenic bacterial growth especially after antibiotic therapy. Therefore, this intervention can be considered new prophylactic treatment preventing recurrence of bacterial vaginosis particularly in reproductive age group.

Keywords: Bacterial vaginosis, Amsel criteria, Clue cells, Whiff test, Vaginal Discharge

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I. Introduction

Bacterial vaginosis is the most common type of vaginal infection among women of reproductive age group and accounts for one-third of all vulvovaginal infections. Infections are very common with more than 90 million cases of bacterial vaginosis (BV) worldwide per annum. The normal vaginal microflora consists of lactobacilli (Lactobacillus crispatus), while the disturbed vaginal microflora is characterised by the overgrowth of Gardnerella vaginalis and other anaerobic bacteria like Mobiluncus spp., Mycoplasma hominis and Prevotella spp due to change in vaginal pH 1. This infection occurs when the normal lactobacillus flora in the vagina are disrupted and subsequently replaced by pathogens 2. The aetiology of BV is probably multifactorial and the factor initiating the shift is unclear 3. The lactobacilli, inhibit the growth of other microorganisms through certain properties such as adhesive ability, production of acids, bacteriocins, hydrogen peroxide and biosurfactants and competition to mannose and glycoprotein receptors 4.

Bacterial vaginosis (BV) infection has wide range of manifestations, asymptomatic state to increased homogenous white vaginal discharge, local pruritus, lower abdominal pain, pain during coitus, etc. BV increases the risk of pelvic and sexually transmitted infections 5,6. Studies in the past decade have highlighted the association of BV with various complications such as human papilloma virus infection, postpartum and post abortion endometritis, preterm labour and spontaneous abortion.

Centre for disease control and prevention recommended few options such as Metronidazole gelforms and Clindamycin for the management of BV 7. Recurrent infections are common in BV infections. Efforts to reduce the prevalence of BV have been unsuccessful 8. Therefore, there is a need of alternative treatment or supplement. Many researchers studied the effect of probiotic as adjunct for BV. Probiotics have the potential of prevention of diseases because of their antagonistic activities against pathogens in vivo.

The concept of Probiotics dates back more than 160 years and treatment of vaginitis and vaginosis with Lactobacillus replacement therapy was described in the recent years only 9,10. The probiotic will restore normal vaginal flora and thereby normal pH will be maintained. Efforts to artificially restore a normal vaginal flora with the use of probiotics could well provide a reliable alternative treatment to antibiotics and a preventive regimen in the future. Hence this study was carried in reproductive age group women with BV attending Gynaecology OPD at a tertiary care hospital to determine the effect of Probiotic as a supplement along with metronidazole for the treatment of vaginosis.
II. Material And Methods

The prospective, cross sectional study carried out on reproductive age group women attending Gynaecology OPD at Modern Government Maternity Hospital, Petlaburz. Their vaginal smears tested before and after treatment. Approval of institutional ethical committee was taken for this study.

**Study Design:** Prospective, cross sectional study.

**Study Location:** Department of Microbiology, Osmania Medical College and Department of Obstetrics and Gynaecology, Modern Government Maternity Hospital, Petlaburz, Hyderabad

**Study Duration:** September 2019 – February 2020 (6 months duration)

**Sample Size:** A total of 100 BV cases from reproductive age group women

**Inclusion criteria:**
1. Women of reproductive age group (15-49 years), clinically diagnosed to have copious white mucoid vaginal discharge either asymptomatic or symptomatic (history of local pruritus, lower abdominal pain or pain during coitus).
2. Patients willing to give consent.

**Exclusion criteria:**
1. Asymptomatic patients with absence of copious white mucoid vaginal discharge or symptomatic patients with curdy white vaginal discharge
2. Patients having menstrual bleeding and patients on antibiotics.
3. Patients not willing to give consent.

**Procedure Methodology**

**Amsel Criteria was used to confirm Bacterial Vaginosis**

After taking a written informed consent, a total of 160 vaginal swabs were collected from patients clinically diagnosed to have homogenous copious white mucoid vaginal discharge. Based on Amsel criteria 100 out of 160 cases confirmed as Bacterial vaginosis.

An appropriate oral dose of probiotic supplement (Sporolac DS – thrice daily) for 3 weeks was given along with routine antibiotic therapy for 50 patients. The remaining 50 patients were taken as control group.

Follow up was done after a month for patients of both the groups.

**Diagnosis by Amsel Criteria:**

Amsel composite criteria includes the presence of a homogeneous vaginal discharge, pH of the vagina being > 4.5, the presence of clue cells in wet mount/Gram’s stain of the vaginal discharge and a positive whiff test. According to Amsel, if 3 of the 4 criteria are positive, the patient has bacterial vaginosis.

**Vaginal pH determination:**

pH of the vagina was tested using a pH paper (Qualigens Fine Chemicals, India) by dipping it in the secretions pooled in the posterior fornix. This was compared with a standardized colorimetric reference chart to estimate the actual pH.

**Whiff test:**

A drop of the vaginal fluid was taken on a grease free glass slide. To this one drop of 10% KOH was added. An intense, putrid, fishy odour indicates positive reaction.

**Presence of Clue cells:**

A drop of the vaginal fluid was mixed with a drop of normal saline on a clean grease free glass slide; a cover slip was placed on it. Slide was observed under 10 x & 40 x magnifications within 10 mins. The vaginal epithelial cells which were coated with cocco-bacillary organisms so that their edges which normally have a sharply defined cell border became indistinct or stippled were considered as the clue cells. Clue cells are characteristic feature of BV. If the clue cells constitute 20% or more of the epithelial cells in the high power field, it is considered positive.

III. Result

Among the 100 positive cases, 44 and 46 cases were on antibiotic plus probiotic supplement and antibiotic therapy alone respectively. 10 patients did not return for follow up. The former group showed 2 cases of recurrence (4.5%) when compared to 12 recurrence cases (26%) in the latter group.

Almost equal number of subjects were taken in both the groups for an age range. The horizontal axis represents the age range whereas the vertical axis shows the number of subjects in both the groups for an age range.
Bacterial vaginosis is characterized by a disturbance in the normal microbiota of the vagina, leading to decreased number of lactobacilli. High recurrence rate due to the incapacity of regenerating and maintaining adequate amounts of lactobacilli after antibiotic treatment.

Bacterial vaginosis is the primary cause of abnormal vaginal discharge in women of reproductive age. Epidemiologic studies of women with vaginitis showed that BV is present in about 27-31% of general population.

Antibiotic treatment of bacterial vaginosis is constant, using almost the same therapeutic schemes for years (Metronidazole, Tinidazole and Clindamycin), but more than half patients have 2-3 relapses per year. The absence of lactobacilli in the vagina is a specific feature of BV, raises the question of whether restoration of lactobacilli by probiotics can restore the normal flora, improve the cure rate and prevent recurrence of BV.

The higher failure rate of metronidazole group may be due to intolerance to medication due to its undesirable side effects involving GIT, diarrhoea and the growing metronidazole resistance, while the recurrence of BV might be explained by failure of vaginal acidification, failure to reduce the number of Gardenella vaginalis and anaerobic microflora, failure to colonize the vagina with protective Lactobacillus species, reinfection or recolonization with unrecognized pathogen and antimicrobial resistance.
In the present study, 42 patients out of 44 were cured (according to Amsel criteria) in probiotic supplemented group while only 34 out of 46 patients were cured in antibiotic alone group thus the recurrence rate of BV being 4.5% and 26% respectively.

In a study of pregnant women by Hillier et al. $\text{H}_2\text{O}_2$-producing lactobacilli were isolated from 5% of women with BV and from 61% of those with a normal microbiota ($p < 0.001$).\(^{12}\)

A second study of pregnant women, showed that BV (based on Amsel criteria) was significantly less common among women with $\text{H}_2\text{O}_2$-producing vaginal lactobacilli (10/127, 8%) than among women with non-$\text{H}_2\text{O}_2$-producing or no lactobacilli (29/86, 34%; 37/62, 60%, respectively; $p < 0.001$ for both comparisons).

Hawes et al. found that BV developed in 10 (25%) of 40 women with non-$\text{H}_2\text{O}_2$-producing vaginal lactobacilli, compared with only 3 (3%) of 118 women with $\text{H}_2\text{O}_2$-producing lactobacilli ($p$ 0.02).\(^{13}\)

Neri et al. conducted a randomized controlled trial involving pregnant women with BV and showed that women treated by intravaginal lactobacilli were significantly cured of BV at 1 and 2 months after the end of treatment compared to women treated with acetic acid or given no treatment.\(^{14}\)

In the cured patients (according to Amsel criteria) of present study, clue cells were replaced by lactobacilli in all women. They reported improvement of their symptoms and they remained asymptomatic for the following 3 months.

**Figure no 3:** Gram’s Stain of Vaginal Smear before and after Treatment

A- Presence of clue cells in Bacterial vaginosis
B- Follow up after one month (probiotic supplement along with routine antibiotic therapy)

**V. Conclusion**

This study shows that probiotic supplementation has significant role in treatment and prevention of recurrence of Bacterial Vaginosis. They hinder pathogenic bacterial growth especially after antibiotic therapy.

Therefore, this intervention can be considered new prophylactic treatment for preventing recurrence of bacterial vaginosis particularly in reproductive age group.

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Acknowledgements

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