

Role Of Probiotics In The Treatment Of Bacterial Vaginosis

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Abstract: Vaginosis is the most common infection in women of child bearing age. Infections are very common with more than 90 million cases of bacterial vaginosis (BV) worldwide per annum. This study was conducted to assess the efficacy of probiotics as a supplement along with metronidazole in treatment of vaginosis, A total of 50 rural women diagnosed as BV randomly categorized into two groups, Group A patients were treated with metronidazole and probiotic (*Lactobacillus rhamnosus* and *Lactobacillus reuteri*) whereas Group B were treated only with metronidazole for five days. Nugent score was recorded before and after the treatment. After initiation of the treatment, there was no change observed on the second and fourth day. On the seventh day symptoms such as itching, odour, discharge were suppressed in the two groups. There was a significant difference in the Nugent score before and after the treatment between group A and group B. ($p < 0.05$). The Nugent score for group A patient was reduced more than group B, because of the count of Lactobacilli was detected more among group B than group A. This study concluded that the treatment using probiotic along with metronidazole for Bacterial Vaginosis showed the successful effect.

Index Terms: Vaginosis, Probiotic, *Lactobacillus rhamnosus* and *Lactobacillus reuteri*.

1 INTRODUCTION:

Vaginosis is the most common infection in women of child bearing age. Infections are very common with more than 90 million cases of bacterial vaginosis (BV) worldwide per annum. The commonest organisms causing vaginosis are anaerobic gram-negative rods such as *Prevotella bivia*, *P. intermedia*, *Bacteroides* spp., anaerobic gram-positive rods like *Mobiluncus* morphotypes, anaerobic gram-positive cocci like *Peptostreptococcus* spp, facultative anaerobic bacteria like *Gardnerella vaginalis* and *Mycoplasmas*¹. This infection occurs when the normal lactobacillus flora in the vagina are disrupted and subsequently replaced by pathogens². The aetiology of BV is probably multifactorial and the factor initiating the shift is unclear³. 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 receptors⁴. Bacterial vaginosis (BV) infection 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, post partum and post abortion endometritis, preterm labour and spontaneous abortion. Centres for disease control and prevention in the United States recommended few options such as metronidazole gelforms and clindamycin for the management of BV⁷. Recurrent infections are common in BV infections. Efforts to reduce the prevalence of BV have been unsuccessful⁸. So there is a need of alternative treatment or supplement. Many researchers studied the effect of probiotic as adjunct for BV. Probiotic organisms are believed to 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 rural women with BV attending STD clinic at a tertiary care hospital to determine the effect of Probiotic as a supplement along with metronidazole for the treatment of vaginosis.

2. MATERIALS AND METHODS

Design of study: Vaginal smear examination of rural women attending STD clinic in a teaching hospital before and after treatment

Type of study: Prospective and follow-up study.

Setting: Department of Venerology and Dermatology and Department of Microbiology at a rural teaching hospital.

Period of study: June 2012 – July 2012.

Sample Size: A total of 50 rural women having BV who satisfied inclusion and exclusion criteria and living in villages, located in and around Mannachanallur Taluk, Trichy were enrrolled in the study.

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Inclusion criteria: Only rural women in reproductive age diagnosed with bacterial vaginosis.

Exclusion criteria: Rural women in reproductive age attending STD clinic with complications other than vaginosis.

Methods: After obtained a written consent, a vaginal swab was taken and a drop of vaginal fluid was smeared on a clean grease free microscope slide and mixed with a drop of normal saline and observed under a microscope for the presence of clue cells (epithelial cells coated with bacilli). Presence of over 20% clue cells suggests the diagnosis of bacterial vaginosis. The nature and consistency of the vaginal secretions were observed. pH of the vaginal mucosa was checked by a pH paper. Gram stain was performed and Nugent score was recorded. These 50 rural patients with BV (Nugent score ≥ 7) involved in the study were categorized into two groups. Group A (n=25) were treated with oral metronidazole and probiotic tablet containing freeze dried *Lactobacillus rhamnosus* and *Lactobacillus reuteri* and Group B (n=25) were treated with only oral metronidazole for 5 days. After initiation of treatment assessment of response were done on the second day and fourth day by subjective improvement of symptoms and on the seventh day Gram stain procedure was repeated and Nugent score was recorded. The project was approved by the institution ethical committee. Data were analysed by graph pad statistical software.

3. RESULT

Among 25 patients in group A, 2 patients did not returned for follow up after the baseline visit and in group B 22 patients were completed the study and three patients did not returned for the follow up study. Age details, use of contraceptive methods, menstrual cycle, symptoms and results of Amsel's criteria of the study group were given in table I. Nugent score evaluated before and after treatment for group A and group B was tabulated in table II. There was a significant difference in the Nugent score before and after the treatment between group A and Group B (Pearson's r hypothesis $p < 0.05$). In the follow up study there was no change observed on the second and fourth day after initiation of the treatment. In both the group A and B patients symptoms such as itching, odour, discharge were reduced after the completion of the treatment. The mean difference between the Nugent score before and after treatment for Group A and Group B was shown in FIG I.

4. DISCUSSION:

Bacterial vaginosis is the most common cause of vaginal discharge among women in reproductive age with a prevalence of 9-37% depending on the population studied. The prevalence ratio of bacterial vaginosis in peruvian women from socio-economically deprived population was 27% and it was significantly associated with sexually transmitted diseases (STDs)¹¹. These social, clinical and economic implications of adverse outcomes associated with BV have led to increased attention to diagnosis and treatment. The effect on the urogenital flora of antibiotic therapy for UTI was studied and concluded that probiotic protect the urogenital tract against infections^{12,13}. This present study supports the successful effect of probiotic

treatment along with an antibiotic, similar to other study¹⁴. In this study among 50 patients only 45(90%) patients completed the study. Gardiner et al., assessed the probiotic persistence of *L. rhamnosus* GR-1, *L. fermentum* RC-14 and *L. rhamnosus* GG in the human vagina and they concluded that strains RC-14, GR-1 may be more suited for vaginal colonization. Hence the same strains were given to group A patients along with metronidazole. The patients were followed for seven days which is concordance to other study report¹⁴ in which they reported the significant p value as $P = 0.016$ at day 6. Statistical analysis of the present study reveals that there was a significant difference ($p < 0.05$) in the Nugent score between the group A (antibiotic and probiotic) and group B (antibiotic). The Nugent score was improved by at least five after treating patients of BV with *L. casei rhamnosus* in other study¹⁵. In the follow up study, both the group A and B patients' symptoms such as itching, odour, discharge were suppressed after the completion of the treatment. The Nugent score for group A patient was reduced more than group B. This is because the count of Lactobacilli was detected more among group B than group A. This is accordance to other study⁸.

Gardiner et al,¹⁶ assessed the probiotic persistence of *L. rhamnosus* GR-1, *L. fermentum* RC-14 and *L. rhamnosus* GG in the human vagina and they concluded that strains RC-14, GR-1 may be more suited for vaginal colonization. It is concluded that strains RC-14, GR-1 may be more suited for vaginal colonization. According to Marcone et al.,² the safe and effective long-term vaginal administration of *Lactobacillus rhamnosus* appears to be a useful complementary approach in the management of bacterial vaginosis. This study was performed in a single centre and in short period became the limitations of this study.

CONCLUSION:

It is concluded that number of *Lactobacilli* flora was more among patients treated with probiotic and metronidazole than the patients treated only with metronidazole. In this study treatment using probiotic along with metronidazole for BV showed successful effect in the seven days. Future studies will be done to evaluate the long term usage of probiotics in prevention of recurrent BV infections.

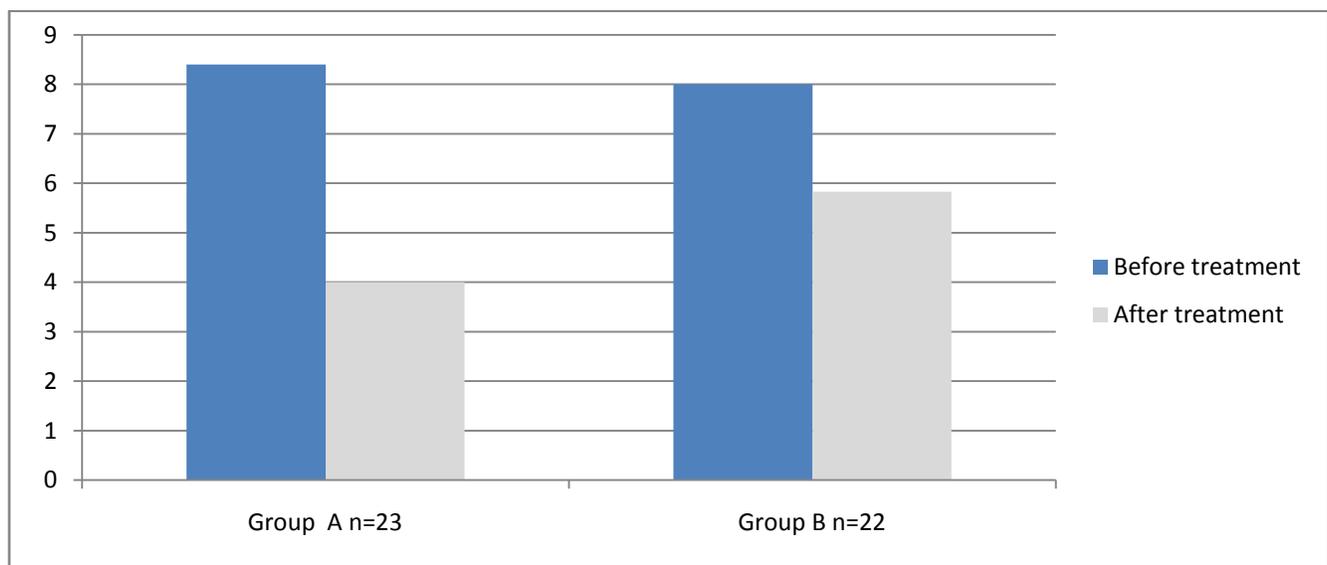
TABLE-1 Characteristics of study population

Observation	Group(n=23)	Group(n=22)
Mean age	30	32
Use of contraceptive methods	15	17
Regular menses	20	19
Recurrent BV	15	17
Symptoms	20	20
Positive Amsel criteria	25	25

TABLE II. Nugent score of Group A and Group B.

GroupA (Metronidazole+probiotic)	Nugent Score		GroupB (Memtronidazole)	Nugent score	
No. Of Patients(n=23)	Before treatment	After treatment	No.of. patients(n=22)	Before treatment	After treatment
8	7	3	6	7	5
4	8	4	2	7	6
2	8	3	1	8	6
6	9	4	10	9	6
3	10	6	3	10	8

p<0. 05

FIG. I. NUGENT SCORE STATUS**ACKNOWLEDGEMENT**

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