



EFFICACY OF PROBIOTICS IN THE MANAGEMENT OF BACTERIAL VAGINOSIS

Medical Science

Dr.T.Vanathi Senior Assistant Professor of DVL, M.D.D.V.L Institute of Dermatology Venereology Leprosy, Madras Medical College/RGGGH, Chennai.

Dr. S. Kalaivani* D.D.V Director And Professor of DVL, Institute of Dermatology Venereology Leprosy Madras Medical College/RGGGH, Chennai. *Corresponding Author

ABSTRACT

Bacterial vaginosis is a poly microbial syndrome involving replacement of normal vaginal lactobacilli by a variety of anaerobic bacteria. Probiotics are live microorganisms, which when administered in adequate amounts confers a health benefit on the host.

AIM & OBJECTIVE: To analyze social and demographic factors associated with bacterial vaginosis and to determine the efficacy of probiotics in the treatment of bacterial vaginosis.

MATERIALS AND METHODS: 100 women diagnosed with Bacterial vaginosis were enrolled in the study. They were given probiotics containing lactobacillus rhamnosus and lactobacillus reuteri twice daily for one month followed by once daily for next month. Patients were followed up in the first week, first month and second month and response were analyzed based on Amsel's criteria and Nugent's scoring system for Bacterial vaginosis.

RESULTS: Probiotics demonstrated comparable therapeutic benefits at two months follow up period based on Amsel's criteria and at first month and second month follow up based on Nugent's scoring system.

CONCLUSION: Administration of probiotics aid in recovery from infection, restoring and maintaining a healthy vaginal ecosystem thus improving female reproductive and sexual health.

KEYWORDS

Bacterial vaginosis, probiotics, Amsel's criteria, Nugent score

INTRODUCTION

Bacterial vaginosis [BV] is one of the most common causes of vaginal discharge syndrome seen among the women of the child bearing age group.^[1] BV is a polymicrobial condition resulting from the replacement of the normal vaginal flora [lactobacillus] with large proportions of the anaerobic bacteria [Prevotella sp. and Mobilincus sp.], Gardnerella vaginalis, Ureaplasma, Mycoplasma and numerous fastidious anaerobes.^[2] Presence of BV increases the risk of acquisition of sexually transmitted infections [STIs]^[3,4] and HIV infection.^[5]

The function of lactobacillus is to sustain a vaginal microbial environment by production of lactic acid, which creates an acidic vaginal milieu and hydrogen peroxide, both of which are inhibitory to the growth of pathogenic microorganisms^[6,7]

AIMS AND OBJECTIVES:

To analyze the social and demographic factors associated with the bacterial vaginosis, to determine the efficacy of the probiotics in the treatment of bacterial vaginosis and to assess the safety and the compliance of probiotics in the study population.

All the women aged 18 years and above who were fulfilling the Amsel's and Nugent's criteria, those who gave consent to participate in the study & those who were willing for HIV testing after pretest counseling were recruited in the study.

Study design:

Prospective interventional study with approval of the Institutional Ethical Committee.

MATERIALS AND METHODS:

100 females with bacterial vaginosis who attended the Sexually transmitted diseases outpatient of Institute of DVL, Madras Medical College, Chennai from August 2017 – September 2018 were included in the study. A thorough history taking followed by systemic and genital examination using Cusco's bivalve self - retaining vaginal speculum was done. For unmarried females speculum examination was not done. Smears were made from the genital discharge taken from the posterior fourchette in unmarried patients and from the posterior blade of the vaginal speculum in married patients.

Vaginal smears were subjected to sniff test, whiff test, gram stain and vaginal pH examination using litmus paper. Gram stain of the vaginal smear were scored by Nugent's scoring criteria for BV. Microscopic examination of the vaginal discharge under wet mount using normal saline and 10% potassium hydroxide was done for Trichomonas vaginalis and candida species respectively. Gram stain of the endocervical swab was examined for gram negative intracellular diplococci and pus cells. Culture for gonococci using modified Thayer

Martin medium, for trichomonas with modified Diamond medium, for candida using Sabouraud's dextrose agar was done. All the patients were subjected to blood VDRL, TPHA and HIV testing after pretest counseling.

Patients diagnosed as bacterial vaginosis were given probiotics [Ecoflora capsules – contains lactobacillus rhamnosus and lactobacillus reuteri] orally twice daily for one month followed by once daily for next one month. They were followed up at one week, one month, two months and three months after initiating the treatment. At each visit sniff test, whiff test, vaginal pH, gram stain of the vaginal discharge were repeated. Response were analyzed using the Amsel's and Nugent's criteria.

Observation:

Among 100 patients, mean age was 34.6 years, highest being 50 years while the lowest being 20 years [Figure.1] Mean duration of the complaints was around one month. 96 were married and 4 were unmarried. Among the married, 53 individuals were married before the age of 20 years; 26 individuals between 21 to 25 years of age and 17 after the age of 25 years. Analysis of sexual history showed that 34 had single partner, 12 had multiple partners while 4 were unmarried and denied any sexual contact.

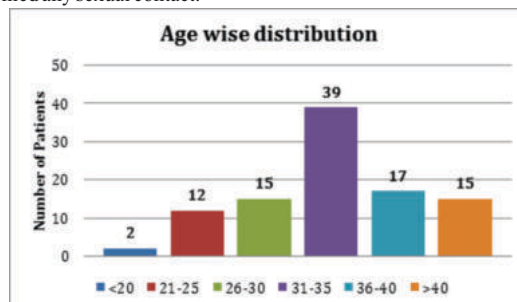


Figure.1

Menstrual period were regular in 85 patients and 2 had attained menopause. Obstetric history revealed nearly 21 patients had history of one abortion while 3 had primary infertility. Puerperal sterilization was done in 78 patients.

Among 86 symptomatic patients, genital discharge was in 72 patients followed by genital itching in 39 patients, malodorous discharge in 22 patients and lower abdominal pain in 9 patients. 14 patients were completely asymptomatic.

Speculum examination revealed profuse vaginal discharge in 26, moderate discharge in 52 and mild discharge in 10 patients. Cervical erosions were noted in 18 patients. Gram stained preparation of the vaginal smears demonstrated clue cells in all the 100 patients while only 92% of wet mount in normal saline had clue cells. Whiff test was positive in 86% of smears producing rotten fish odour on addition of 10% potassium hydroxide solution. Regarding vaginal pH, 75 had pH between 5 to 5.5, 12 had above 5.5 and 13 patients below 5.0. Associated co morbidities were diabetes in 22 patients, vulvovaginal candidiasis in 13 patients, trichomoniasis, genital wart and herpes each in 1 patient and HIV infection in 4 patients. 1 patient had reactive VDRL test for syphilis. Partner screening was done which had revealed balanitis among 6 partners, genital wart in 1, HIV infection in 4 and reactive VDRL in 6 partners.

Patients were assessed on the basis of improvement in Amsel's criteria and Nugent scoring system during their follow up. In Amsel's criteria, 1 and 2 were considered as good response to treatment while 3 & 4 as no response to treatment. With respect to the Amsel's criteria, at the end of the first week 42 patients had good response to treatment while 58 had no response at all. At the end of one month, 72 patients showed good response while no response was seen in 22 patients. 6 patients never turned up for follow up. At the end of two months, 88 patients had good response while 6 patients never responded. [Figure.2]

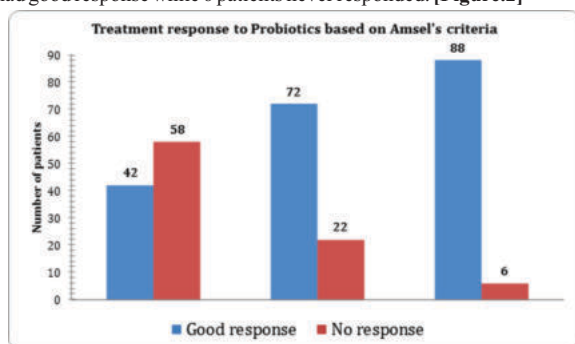


Figure.2

Response in the patients during follow up was graded based on Nugent's scoring as follows,
Grade 1: good response – 0 to 3
Grade 2: moderate response – 4 to 6
Grade 3: poor response – 7 to 10

With respect to the above scoring system, at the end of first week, 38 patients had good response, 42 had no response while 20 patients showed intermediate response. At the end of the first month, 70 patients showed good response, 8 patients showed intermediate response and 16 patients showed poor response. 86 patients showed good response, 2 had poor response and 6 had intermediate response at the end of the second month [Figure.3]

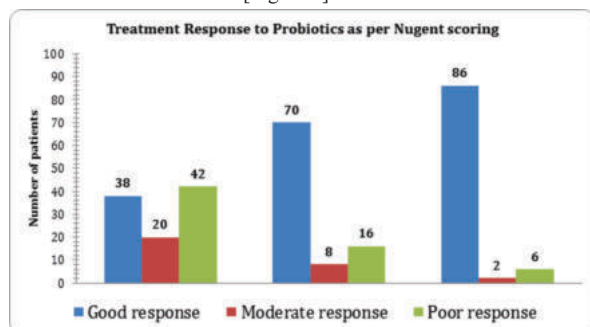


Figure.3

DISCUSSION:

Bacterial vaginosis is one of the most common causes of vaginal discharge among the women of reproductive age group.^[8] The effect of antibiotic therapy for urinary tract infection [UTI] on the urogenital flora had been well documented and it has been concluded that the probiotics protect the urogenital tract against infections^[9,10,11]. This study supports the efficacy of probiotics in treatment of bacterial vaginosis. Only 94 patients completed the study and 6 were lost for

follow up. The mean age of patients in our study was 33.7 years which correlated with Morris study^[12], in which BV was found to be more common among the sexually active women. Our study showed a high incidence of BV among the married sexually active women, 53% of them married before the age of 20 years. This associates younger age at the time of marriage and hence the first sexual exposure with the BV which is in accordance to the Australian study by Larsson et al^[13]. Our study coincides with the study conducted by Rao et al^[14] which concluded high incidence of BV among married, sexually active individuals. About 30 patients in our study had more than 2 children which demonstrate the correlation between the number of pregnancies and the incidence of BV. This is similar to the study conducted by Bradshaw et al.^[15]

In our study patients had associated STIs like trichomoniasis, herpes genitalis and genital wart each in 1 patient, syphilis in 6 patients and HIV infection in 4 patients, which portrays the increased risk for STIs in presence of BV^[15,16]. Vulvovaginal candidiasis was observed in 13 patients in our study which is in contrast to study conducted by Rodrigues AG et al^[17]. This is similar to the observation made by Larsson PG and Klein RS et al in their study. Vaginal pH was found to be alkaline ranging from 5.0 to 5.5 in 75 patients and more than 5.5 in 12 patients. None of the patients in our study had signs or symptoms of the UTI which is in contrast to several references relating increased incidence of urethritis, cystitis among the patients with BV^[11]. In our study 21 patients gave history of abortion and 3 were infertile which links the ascending genital tract infections due to BV associated organisms and altered uterine milieu to bad obstetric history, as seen in Critchlow et al study^[18].

On subsequent follow up patients were monitored for cure or improvement, which is defined based on resolution of 2 or more features in Amsel's criteria and reduction in the Nugent's scoring system to 0 – 3. Upon treatment with probiotics significant improvement has been seen with gram stain being negative for clue cells in 72 patients at the end of 1 month and in 88 patients at the end of 2 months. This is in concurrence with study concluded by R.C.R Martinez et al^[19].

Based on Amsel's criteria at 1 week, 1 month and 2 months, probiotics demonstrated comparable therapeutic benefits in 72% at 1 month and in 88% at the end of 2 months. This is in correlation with the study conducted by Reid et al^[20], who had shown that there was significant increase in vaginal lactobacilli following the oral administration of probiotics in association with notable decrease in Amsel's criteria. On comparing the efficacy based on Nugent's scoring system, at the end of the study 86% showed good response, 2% had moderate response and 6% who had no improvement were treated with metronidazole. This correlates with the study conducted by Reid G, Burton, Beuerman D^[21,22] who showed significant restoration to normal Nugent score in women receiving Lactobacilli.

CONCLUSION:

Most recent clinical trials have suggested that oral administration of probiotics increase the number of vaginal lactobacillus and hence restore the vaginal flora. Administration of probiotics aid in the recovery from infection, restore and maintain a healthy vaginal ecosystem, thus improving the female reproductive and sexual health.

REFERENCES:

- R. E. M. Mascarenhas, M. S. C. Machado, B. F. B. E. Costa Silva et al., "Prevalence and Risk Factors for Bacterial Vaginosis and Other Vulvovaginitis in a population of Sexually Active Adolescents from Salvador," in Infectious Disease of Obstetrics Gynecology, p. 6, Brazil, Bahia, 2012.
- Hellberg, D, Nilsson, S, and Mardh, P— A. The diagnosis of bacterial vaginosis and vaginal flora changes. Arch Gynecol Obstet. 2001; 265: 11–15
- Ness, RB, Kip, KE, Hillier, SL et al. A cluster analysis of bacterial vaginosis— associated microflora and pelvic inflammatory disease. Am J Epidemiol. 2005; 162: 585–590
- Larsson, PG, Bergstrom, M, Forsum, U, Jacobsson, B, Strand, A, and Wolner— Hanssen, P. Bacterial vaginosis. Transmission, role in genital tract infection and pregnancy outcome: an enigma. APMIS. 2005; 113: 233–245
- Jameson, DJ, Duerr, A, Klein, RS et al. Longitudinal analysis of bacterial vaginosis: findings from the HIV epidemiology research study. Obstet Gynecol. 2001; 98: 656–663
- Klebanoff, SJ, Hillier, SL, Eschenbach, DA, and Waltersdorff, AM. Control of the microbial flora of the vagina by H2O2— generating lactobacilli. J Infect Dis. 1991; 164: 94–100
- Aroucheva, A, Gariti, D, Simon, M et al. Defense factors of vaginal lactobacilli. Am J Obstet Gynecol. 2001; 185: 375–379
- Allsworth JE, Peipert JF. Prevalence of bacterial vaginosis: 2001–2004 National Health and Nutrition Examination Survey data. Obstet Gynecol. 2007; 109: 114–20.
- G Reid, A, W Bruce, R, L Cook, M Llano. —Effect on the urogenital flora of antibiotic therapy for urinary tract infection. Scandinavian Journal of Infectious Diseases, 1990; 22: 43–47.
- G Reid, A, W Bruce, N Fraser, C Heinmann, J, Owen, B Henning. —Oral probiotics can resolve urogenital infections. FEMS Immunology & Medical Microbiology, 2001; 30: 49–52.

11. Reid G. Probiotic lactobacilli for urogenital health in women. *J Dis Gastroenterol* 2008;42(Suppl 3 PT2):S234-236.
12. Morris MC, Rogers PA, Kinghorn GR. Is bacterial vaginosis a sexually transmitted infection? *Sex Transm Infect* 2001;77(1):63-68.
13. Larrson P, Platz-Christensen J, Sundstorm E. Is bacterial vaginosis a sexually transmitted disease? *Int J STDs, AIDS* 1991;2:362-364.
14. Rao PS, Devi S, Shriyan A, et al. Diagnosis of bacterial vaginosis in a rural set up: comparison of clinical algorithm, smear scoring and culture (smauc) by semi quantitative technique. *Indian J Med Microbiology* 2004;22(1):47-50.
15. Bradshaw CS, Morton AN, Garland SM, et al. Higher-risk behavioral practices associated with bacterial vaginosis compared with vaginal candidiasis. *Obstet Gynaecol* 2005;106(1):105-114.
16. Hilliers S. Bacterial vaginosis. In: Holmes KK, Mardh PA, Sparling PF, eds. *et al. Sexually transmitted diseases*. 3rd edn. New York: McGraw-Hill 1999:563-586.
17. Rodrigues AG, Mardh PA, Pina-Vaz C, et al. Is the lack of concurrence of bacterial vaginosis and vaginal candidosis explained by the presence of bacterial amines? *Am J Obstet Gynaecol* 1999;181(2):367-370.
18. Eschenbach DA, Hillier S, Critchlow C, et al. Diagnosis and clinical manifestation of bacterial vaginosis. *Am J Obstet Gynaecol* 1988;158(4):819-824.
19. R. C. R. Martinez, S. A Franchesini, M. C Patta, S. M. Quintana, B. C. Gomes, , E. C. P De Martinis, G Reid. □ Improved cure of bacterial vaginosis with single dose of tinidazole(2g), Lactobacillus rhamnosus GR-1, and Lactobacillus reuteri RC-14: a randomized, double blind, placebo-controlled trial □. *Can. J. Microbiol.*, 2009;55:133-8.
20. Reid G, Charbonneau D, Erb J, et al. Oral use of lactobacillus rhamnosus GR-1 and L.fermentum RC-14 significantly alters vaginal flora: randomized, placebo-controlled trial in 64 healthy women. *FEMS Immunol Med Microbiol* 2003;35(2):131-134.
21. Reid, G, Burton, J, Hammond, JA, and Bruce, AW. Nucleic acid— based diagnosis of bacterial vaginosis and improved management using probiotic lactobacilli. *J Med Food*. 2004; 7: 223–228
22. Reid, G, Beuerman, D, Heinemann, C, and Bruce, A. Probiotic Lactobacillus dose required to restore and maintain a normal vaginal flora. *FEMS Immun Med Microbiol*. 2001; 32: 37–41