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# Effectiveness Of Supplementary Probiotics In Initial Cure Rate And Prevention Of Recurrence Of Bacterial Vaginosis After Vaginal Clindamycin Therapy.

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***Abstract:***
***Objectives: To investigate the effectiveness of supplementary probiotics in initial cure rate of Bacterial Vaginosis (BV) after vaginal clindamycin therapy and their role in delaying recurrence of BV.***

***Materials & Methods: This comparative study, conducted between July 2011 to June 2012 among the married, non-pregnant patients of child bearing age from middle class society with bacterial vaginosis diagnosed by Amsel criteria. Fifty patients each in study and control group were included. Oral probiotics (containing $10^9$Lactobacillus rhamnosus GR-1, $10^9$Lactobacillus reuteri RC-14) twice daily for one month to the study and placebo to the control groups were given after vaginal clindamycin therapy. Patients were followed up at one, three and six months by Nugent scoring.***

***Results: After 1 month, 88% in study group and 86% patients in control group had normal flora (p 0.965). After 3 months 94% and 46% patients in the study and control groups respectively had normal vaginal flora (p 0.001). At six months 98% patients in the study group still had BV free vaginal flora in compare to 22% of control group (p 0.0003).***

***Conclusion: Supplementary probiotics does not improve the efficacy of BV therapy initially but they definitely help to prolong relapse of bacterial vaginosis. .***

***Key words: Bacterial vaginosis, Nugent score, supplementary probiotics***

**Introduction**: Bacterial vaginosis is a complex vaginal infection and the most prevalent cause of vaginal discharge or malodor[1], occurring in up to 40-50 % of women of childbearing age[2-4]. The

underlying cause is not fully understood. Even when asymptomatic, it is associated with a high incidence of endometritis and pelvic inflammatory disease, late miscarriages, premature rupture of membranes and preterm labor[5]. There are various drugs available for treatment of BV. Metronidazole was the mainstay of treatment but because of several unpleasant complications few other drugs like clindamycin, tinidazole have also been tried. These are equally effective. Though initial cure rate is high with metronidazole and other drugs but recurrence of bacterial vaginosis is quite high. Therefore there are constant search for remedy to prevent relapse. Probiotics are such promising agents. The aim of our study was assess the effectiveness of supplementary probiotics in initial cure rate and prevention of recurrence of bacterial vaginosis after vaginal clindamycin therapy.

**Materials and Methods** : This study was a comparative study, conducted between July 2011 to June 2012 among the married and non-pregnant patients (15-45 years) from middle class society with bacterial vaginosis diagnosed by Amsel criteria attending Gynaecology OPD, Department of Gynecology and Obstetrics, BURDWAN MEDICAL COLLEGE AND HOSPITAL, BURDWAN, West Bengal. Fifty patients in the study group and Fifty patients in the placebo group were selected. Ethical permission was taken (After detailed and careful scrutinization, discussion and assessment of your subject matter, members of the Ethical Committee arrived at a conclusion that the plan of your research project entitled **"Effectiveness= of supplementary probiotics in initial cure rate and prevention of recurrence of bacterial vaginosis after vaginal clindamycin therapy"** is approved and you are at liberty to carry on with your said research work. A periodical review will made by I.E.C. till completion of your thesis work. CHAIRMAN, ETHICAL COMMITTEE BURDWAN MEDICAL COLLEGE, BURDWAN ) and informed consent oral probiotics (containing $10^9$Lactobacillus rhamnosus GR-1, $10^9$Lactobacillus reuteri RC-14 - Ecoflora) capsules twice daily for one month to

the study and vitamin B complex to the placebo groups were given after initial three consecutive nights vaginal clindamycin (softule) therapy. The patients were followed up at 1, 3, and 6 month using Nugent score.

**Results**: After 1 month following initial cure rate of 90% ( cure of symptoms ) with three night vaginal clindamycin therapy 88% (44 of 50)in the study group and 86% (43 of 50) patients in control group had normal flora which is not statistically significant(p 0.965, t 0.046, df 98). After 3 month follow up 94 %( 47 of 50) and 46% (23 of 50) patients in the study and control groups respectively had normal vaginal flora. The difference was statistically significant (t -6.812, df 98, p 0.001). At the end of the follow up 98% (49 of 50 ) patients in the study group still had BV free vaginal flora in compare to 22% (11 of 50 women) of control group. So, on long run adjuvant probiotic therapy had not only improved the cure rate but also significantly lowered the risk of recurrence of bacterial vaginosis ( p 0.0003, t -12.502, df 98).

**Discussion**: Larsson PG, Stray-Pedersen B, Ryttig KR, Larsen S[6] had similar result. At the end of follow up for 6 menstrual cycles more patients (24/37, 64.9%) had BV free vaginal ecoflora in compared to placebo treated group where 46.2 %(18/39) patients had normal vaginal flora. Time from cure to relapse was statistically significant (p=0.027) in favour of lactobacilli treatment.

Ya W, Reifer C and Miller LE[7] in their study had found that probiotic prophylaxis resulted in lower recurrence rates for BV 15.8% as compared to placebo group which had 45% recurrence (p<0.001) after 2 month follow up.

**Conclusion**: In the light of our observation supplementary probiotics do not improve the efficacy of BV therapy initially but they definitely help to prolong relapse of bacterial vaginosis.

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Table 1: Laboratory examination of vaginal smears and the determination of Nugent scoring.

| N = Sum of scores for each bacterial mophotype listed below ( note the number of organism seen / 100X objective) | | | | | |
|---|---|---|---|---|---|
| Lactobacilli | Score | Gardenerella bacteroids | Score | Curve gram negative bacilli | Score |
| >30 | 0 | 0 | 0 | 0 | 0 |
| 5-30 | 1 | <1 | 1 | <1 | 1 |
| 1- 4 | 2 | 1- 4 | 2 | 1- 4 | 1 |
| <1 | 3 | 5- 30 | 3 | 5- 30 | 2 |
| 0 | 4 | >30 | 4 | >30 | 2 |

Table 2: Interpretation of nugent score

| If nugent score | And | Then report |
|---|---|---|
| 0-3 | | Smear not consistent with bacterial vaginosis |
| 4-6 | Clue cells are not present | |
| 4-6 | Clue cells are present | Smear consistent with bacterial vaginosis |
| ≥7 | | |

Table 3: Demographic profile of patients of both groups

| Sl No. | Demographic profile | | Study Group N (%) | Control Group N (%) | p value |
|---|---|---|---|---|---|
| 1 | Age ( Mean ± SD) | | 28.28 (±5.849) | 27.52 (± 5.737) | 0.513 |
| 2 | Contraceptive user | Contraceptive used | 24 (48%) | 20 (40%) | 0.42 |
| | | Contraceptive not used | 26 (52%) | 30 (60%) | |
| 3 | Background | Rural | 36 (72%) | 39(78%) | 0.488 |
| | | Urban | 14 (28%) | 11 (22%) | |
| 4 | Parity | Primiparous | 32 (64%) | 29 (58%) | 0.539 |
| | | Multiparous | 18 (36%) | 21 ( 42%) | |
| 5 | Body-Mass Index ( Mean ± SD) | | 24.579 (± 2.049) | 22.989 (± 2.752) | 0.145 |

Table 4: Abnormal bacterial flora in follow up of patients of both groups

| Follow up | Abnormal bacterial flora in vagina | | p value |
|---|---|---|---|
| | Study group<br>N (%) | Control group<br>N (%) | |
| 1st month | 44 (88%) | 43 (86%) | 0.766 |
| 3rd month | 47 (94%) | 23 (46%) | < 0.001 |
| 6th month | 49 (98%) | 11 (22%) | < 0.001 |