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A Cross Sectional Study on Prevalence of Bacterial Vaginosis in Preterm and Term Labor

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Abstract

Background: The aim is to examine bacterial vaginosis (BV) in women with preterm and term labor, explore the link between bacterial vaginosis and preterm labor (PTL), and analyze complications for both mother and baby related to bacterial vaginosis.

Design: Hospital based cross sectional study.

Materials and Method: We had conducted an observational study at Basaveshwara Medical College and Hospital, involving 100 pregnant patients with preterm and term labor (50 patients in each group). Eligible patients attending the Obstetrics and Gynecology Outpatient Department (OBG OPD) and inpatient department will be included. Bacterial vaginosis will be determined using Amsel's criteria, which include evaluating discharge characteristics, vaginal pH, amine odor with KOH test, and presence of clue cells under microscopic examination. Additionally, vaginal swabs will undergo Gram staining.

Results: The percentage of patients meeting Amsel's criteria for diagnosing bacterial vaginosis was significantly higher in the preterm labor group compared to the term labor group, with a statistically significant difference. According to Amsel's criteria, the prevalence of bacterial vaginosis was 30% in the preterm labor group and 2% in the term labor group.

Conclusion: Bacterial vaginosis is a significant risk factor for preterm labor. Hence, conducting tests for bacterial vaginosis and promptly treating it can help reduce the risk of preterm labor.

Keywords: Preterm labour; Term labour; Bacterial vaginosis; Amsels criteria.

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INTRODUCTION

Bacterial Vaginosis (BV) is defined by a shift in the natural vaginal flora, with lower levels of the normally prevalent Lactobacilli and an increase in anaerobic bacteria. Detecting women with subclinical infection at an early stage is a critical area of study for preventing premature birth. However, the infectious markers now in use are not especially useful for this purpose. Because it is linked to preterm delivery, premature rupture of membranes (PROM), and chorioamnionitis, existing research suggests that BV might serve as an early infection sign (Goffinet *et al.*, 2003).[1] PTL resulting in the birth of a premature baby continues

to be a significant cause of perinatal health problems and deaths in India. The exact cause of PTL remains unclear in a significant number of cases, leading to a higher occurrence of unexplained PTL. However, recent evidence suggests that lower genital tract infections, particularly BV, may play a significant role in previously unexplained cases of PTL.

In developed countries, preterm labor is the leading cause of perinatal mortality and morbidity. The complications resulting from preterm birth contribute to around 70% of neonatal deaths and half of all neurological health issues [Mc Cormick *et al*, 1985].[2] One of the major risk factors for preterm labour is the presence of intrauterine infections. The majority of investigations on the identification of causes of preterm delivery and labour focused on microbial infections of the amniotic cavity and discovered that the most prevalent route of infection is ascending [Romero *et al.*,1988].[3] Bacterial vaginosis is one of the most prevalent vaginal diseases during pregnancy, with frequency ranging from 4 to 64% depending on race and geography [Guaschino *et al.*, 2008].[4] Bacterial vaginosis during pregnancy is linked to a number of problems, including chorioamnionitis, premature delivery, and low birth weight in neonates [Donders *et al.*, 2000].[5] The highest risk of preterm birth is associated with the presence of bacterial vaginosis before 16 weeks of gestation. BV is a common cause of vaginal discharge during the reproductive age. The development of bacterial vaginosis is attributed to the displacement of normal vaginal flora by anaerobic bacteria such as Gardenella, Peptostreptococcus, and Bacteroides. These bacteria produce substances that stimulate the decidua and can lead to preterm labor [Lamont *et al.*, 1990].[6] The majority of instances of bacterial vaginosis during pregnancy are asymptomatic and go unnoticed. According to several research, therapy for bacterial vaginosis is not connected with a reduction in preterm birth rates among moms who have no history of preterm delivery.

Screening and treating asymptomatic pregnant women, particularly those with a history of prior preterm delivery, might help to reduce preterm birth [Brocklehurst *et al.*, 2013].[7] There may be advantages to screening and treating pregnant women, but there is inadequate evidence to support it as a normal practice [Okun *et al.*, 2005, US Preventive Services Task Force *et al.*, 2008].[8-9] To ease uncomfortable symptoms, all pregnant women with symptomatic BV should be treated with metronidazole or clindamycin [Brocklehurst *et al.*, 2013].[7] However, there was no evidence to compare bacterial vaginosis detected in threatened preterm, preterm, and term pregnancy. The prevalence of bacterial vaginosis in pregnancy and its association with preterm labour varies among populations [Goffinet *et al.*, 2003] and is affected by clinical situation, socio-demographic characteristics, diagnostic criteria, gestational age, and other factors [Trabert *et al.*, 2007].[10] In India, approximately 10-12% of pregnancies are affected by PTL, but there is a lack of Indian studies investigating the correlation between BV and PTL, as well as preterm delivery [Dhawane *et al.*, 2002].[11] As a result, the current study was designed to investigate the relationship between BV and Idiopathic PTL and premature labour.

MATERIALS AND METHODS

A total of 100 pregnant women receiving care at Basaveshwara Medical College and Hospital in Chitradurga, in both the Obstetrics and Gynecology Outpatient Department (OPD) and the inpatient setting, were included in this cross sectional study. Prior approval from the Institutional Ethical Committee (IEC) was obtained. And it was conducted from 1st March 2021 to 31st May 2022, covering a period of 14 months. The participants undergo a through examination, which involves collecting detailed history, noting gestational age at admission, and conducting physical and systemic examinations. To assess the condition of the vaginal wall, cervix, and discharge, a clean, unlubricated speculum is gently inserted into the vagina. A vaginal swab is then collected from the lower one-third of the vaginal wall. The swab is subjected to Gram staining and scored using Nugent's scoring system. Vaginal discharge is also examined using wet mount to detect clue cells and the KOH test (Whiff test).

Inclusion Criteria:

The study enrolled participants in the preterm labor group (Group 1), characterized by gestational age below 37 weeks, regular uterine contractions lasting more than 30 seconds, cervical dilatation ranging from 1 cm to less than 4 cm, and effacement equal to or less than 80%. In the term labor group (Group 2), participants had a gestational age of more than 37 completed weeks, experienced spontaneous onset of labor pains, had regular uterine contractions lasting more than 30 seconds, and cervical dilatation ranging from 1 cm to less than 4 cm.

Exclusion Criteria:

The study excluded participants with multiple gestation, cervical cerclage, structural uterine abnormalities, established fetal anomalies, and pregnancies complicated by medical disorders such as hypertension, diabetes, chronic renal disorders, thyroid disorders, gastrointestinal disorders, and severe cardiac disorders.

Statistical Analysis:

Statistical analysis of the data was performed using SPSS 22.0 and R environment ver. 3.2.2. Microsoft Word and Excel were utilized to create charts and tables. Categorical data will be presented as frequencies and percentages.

RESULTS

As detailed in table 1, the average age of the participants was 25.29±4.47. Among the study subjects, 48% (n=24) were in the age group of <25 years, 46% (n=23) were in the age group of 25-35 years, 3% (n=3) were in the age group of above 35 years in Group-1. Similarly among the study subjects in Group-2, 48% (n=24) were below the age of 25, 52% (n=26) were between the ages of 25-35, and 0% (n=0) were above the age of 35, there was no significant difference between agegroup. The number of primigravidas and multigravidas in both groups was comparable in group-1, wherein 38 (76%) of the individuals were multigravida and 12 (24%) were Primigravida. The distribution of primigravidas and multigravidas in Group 2, was found to be 27 participants (54%) were multigravidas, while 23 participants (46%) were primigravidas.

Table 1: Shows the characteristics of pregnant women based on their bacterial vaginosis (B.V) status.

Parameter	Group-1 (N=50)	Group-2 (N=50)
Age Group	–	–
<25	24 (48%)	24 (48%)
25-35	23 (46%)	26 (52%)
>35	3 (6%)	0 (0%)
Mean±SD	25.28±5.05	25.30±3.86
Total	**50 (100%)**	**50 (100%)**
Total Mean±SD	25.29±4.47	
p-value	0.982	
Parity		
Multigravida	38 (76%)	27 (54%)
Primigravida	12 (24%)	23 (46%)
Total	**50**	**50**
p-value	P=0.035*	

P=0.035 is significant*

Table 2 Displays the gestational age in weeks was assessed for all the study participants. In group-1, 10 (20.0%) of study subjects wherein in the gestational week of 30-32, followed by 40 (80.0%) were found between 33-36 weeks. Similarly in Group 2, 50 (100%) of research individuals were identified in the gestational week of 37-40, there was significant difference found between age group.

Table 2: Showing distribution of gestational age in weeks

POG (Weeks)	Group 1	Group 2	Total	p-value
30-32	10 (20.0%)	0 (0%)	7 (7%)	P≤0.001**
33-36	40 (80.0%)	0 (0%)	31 (31%)	
37-40	0	50 (100%)	62 (62%)	
Total	50 (100.0%)	50 (100%)	100 (100%)	

*P≤0.001** is significant*

Table 3 shows that out of 50 cases in each group 1 & 2, 40 participants had vaginal discharge in group-1 and only 26 cases in group 2. The nature of the discharge was also noted and characterized as showed in (Table 3) and p-value was found to be statistically significant.

Table 3: Attributes of vaginal discharge.

Discharge Details	Group 1 (n=50)	Group 2 (n=50)	Total (n=100)	P value
No Discharge	10 (20%)	24 (48%)	34 (34%)	0.006**
White Mucoid	14 (28%)	19 (38%)	33 (33%)	0.396
Curdy white Discharge	10 (20%)	6 (12%)	16 (16%)	0.413
Greenish Frothy	8 (16%)	1 (2%)	9 (9%)	0.030*
Greyishmucoid	8 (16%)	0 (0%)	8 (8%)	0.005**

***,* indicates significant*

Table 4 indicate that the incidence of bacterial vaginosis on the study participants 33 (66%) of them were negative and 17 (34%) were positive. And similarly 49 (98%) of them were negative and 1 (2%) were positive. Preterm labour patients had a considerably higher proportion of patients with discharge indicative of bacterial vaginosis than term labour patients which indicates significant.

Table 4: Incidence of Bacterial Vaginosis

Bacterial Vaginosis	Group 1 (n=50)	Group 2 (n=50)	Total (n=100)	P value
Negative	33 (66%)	49 (98%)	82 (82%)	
Positive	17 (34%)	1 (2%)	18 (18%)	P≤0.001**
Total	50 (100%)	50 (100%)	100 (100%)	

***, indicates significant*

Below table 5 shows that the percentage of patients with a positive whiff test was considerably higher in the preterm group compared to the term group, with a statistical significance. In clue cells test the distribution of participants in preterm and term group was found absent indicating no statistical significant. According to Amsel's criteria, the proportion of patients diagnosed with bacterial vaginosis in the preterm labour group was substantially higher than in the term labour group.

Table 5: Distribution of subjects according to WHIFF Test, Clue cells, Amsel's Criteria

WHIFF Test	Group 1 (n=50)	Group 2 (n=50)	Total (n=100)	P value
Negative	18 (36%)	39 (78%)	57 (57%)	
Positive	32 (64%)	11 (22%)	43 (43%)	P≤0.001**
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**	
Clue cells				
Absent	50 (100%)	50 (100%)	100 (100%)	
Present	0 (0%)	0 (0%)	0 (0%)	P=1.000
Total	**50 (100%)**	**50 (100%)**	**100 (100%)**	
Amsel's Criteria				
>3Criteria	15 (30%)	35 (70%)	50 (100%)	
>Criteria	1 (2%)	49 (98%)	50 (100%)	P≤0.001**
Total	**16 (100%)**	**84 (100%)**	**100 (100%)**	

***, indicates significant*

DISCUSSION

The significance of the connection between vaginal microflora and spontaneous preterm birth has become increasingly important, yet the exact mechanisms involved remain unclear. Priestly *et al.*, 1997[12] showed the impact of particular vaginal microorganisms as a risk factor for spontaneous preterm birth differs based on various factors such as the conducted study, geographical location, and ethnic race of the participants. Bacterial vaginosis is a prevalent reproductive tract infection linked to vaginal discharge, with a prevalence rate of 10-15%. It is detected in approximately 20% of pregnant women. Hillier *et al.*, 1993[13] in their study stated that the majority of these cases during pregnancy do not exhibit symptoms and may go unnoticed unless screened. Newton *et al.*, 1997[14] in their studies have indicated a connection between bacterial vaginosis and low socio-economic status, as well as inadequate vaginal hygiene practices such as using cloth during menstruation. The primary objective of this study was to examine the occurrence of bacterial vaginosis in patients admitted to Basaveshwara Hospital with preterm and term labor. A total of fifty patients were assessed in each group, and the obtained results were analyzed statistically.

The average maternal age in both the preterm labor group and term labor group was similar, with values of 25.28 years and 25.30 years, respectively. This is consistent with a similar study conducted by Chawanpaiboon *et al.*,2010[15] where the mean maternal age was 26.7 years and 26.6 years in the respective groups.

In our study the term group had 23% primigravidas and 27% multigravidas, whereas the preterm group had 12% primigravidas and 38% multigravidas. Chawanpaiboon *et al.*, 2010[15] conducted a study in which the preterm group consisted of 60% primigravidas and 40% multigravidas, whereas the term group had 51.8% primigravidas and 48.2% multigravidas.

In our present study group-1, 10 (20.0%) of research individuals were detected in the gestational week of 30-32, followed by 40 (80.0%) in the gestational week of 33-36. Similarly, in Group 2, 50 (100%) of research participants were identified in the gestational week 37-40, with a significant difference between age groups found.

Another study done by Desai Veena *et al.*, 2009[16] in their study group-1, 5 (35.7%) followed by 20 (2.8%) of research individuals in group-1&2 were detected in the gestational week of 29-31. Similarly 6 (42.9%) followed by 25 (40.9%) of research individuals in group-1&2 were detected in the gestational week of 32-34 and finally 3 (21.4%) followed by 16 (26.3%) of research individuals in group-1&2 were detected in the gestational week of 35-37.

The findings reveal that in our present study among the 50 cases in each group (Group 1 and Group 2), 40 participants in Group 1 had vaginal discharge, while only 26 cases in Group 2 exhibited the same symptom. The calculated p-value indicated a statistically significant difference between the two groups. In our current study among the study participants, 33 individuals (66%) tested negative for bacterial vaginosis, while 17 individuals (34%) tested positive. Similarly, in another group, 49 individuals (98%) tested negative, while 1 individual (2%) tested positive. The proportion of patients with discharge indicating bacterial vaginosis was significantly higher in the preterm labor group compared to the term labor group, highlighting a notable difference.

According to the study done by Kiran *et al.*, 2017[17], 36 patients (72%) had vaginal discharge in the preterm group and 25 cases (50%) in the term group, which is consistent with the findings of Nwosu *et al.*, 2007[18] who reported 40% of cases in the preterm group and 28% in the term group. Similarly Chawanpaiboon *et al.*, 2010[15] discharge indicative of bacterial vaginosis was identified in 24% and 25% of patients with preterm labour and term labour, respectively.

In our present study, there were a significantly higher percentage of patients in the preterm group who tested positive in the whiff test compared to the term group. However, when it came to the clue cells test, there was no statistical significance observed in the distribution of participants between the preterm and term groups, indicating its absence. According to Amsel's criteria, the proportion of patients diagnosed with bacterial vaginosis in the preterm labor group was notably higher compared to the term labor group.

Similarly in the study, done by Kiran *et al.*, 2017[17] the prevalence of bacterial vaginosis (BV) was determined using positive Amsel's criteria. The study found a BV prevalence of 30% among the preterm labor group and 4% among the term labor group. These results align with the findings of previous studies conducted by [Sangita *et al.*, 1999[19] and Svare *et al.*, 2006[20]. Similarly, the studies conducted by Hiller *et al.*, 1995[21] and as well as Subtil *et al.*, 2002[22] also demonstrated an increased association between preterm delivery and bacterial vaginosis, which is consistent with the findings of the present study.

LIMITATIONS

This study had several limitations that should be considered. Firstly, it was carried out in a single center, limiting the generalizability of the findings to all patients with bacterial vaginosis. Secondly, as a cross-sectional study, it provides less robust evidence compared to other study designs such as randomized controlled trials, cohort studies, or case control studies. Thirdly, the study did not include a comparison group of individuals without bacterial vaginosis, which could have provided valuable insights. Fourthly, the recruitment of patients from hospitals might introduce some bias. Lastly, the sample size was small, warranting further investigation to assess the impact of bacterial vaginosis on both preterm and term labor.

CONCLUSION

In conclusion, the findings of the current study provide evidence of a significant association between preterm labor and bacterial vaginosis. Therefore, it is recommended to include routine screening for bacterial vaginosis during pregnancy and ensure its prompt treatment. Implementing these measures may effectively reduce the risk of preterm labor and, consequently, contribute to the prevention of neonatal complications associated with prematurity.

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