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A STUDY OF THE INCIDENCE OF BACTERIAL VAGINOSIS IN PRETERM AND TERM LABOUR AND ITS EFFECTS ON MATERNAL AND FETAL OUTCOMES

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Abstract:
Background: Bacterial vaginosis (BV) is a common genital tract disorder during pregnancy, often asymptomatic but associated with adverse outcomes such as preterm labour. This study aimed to determine the incidence of BV among women in preterm and term labour and analyze maternal and neonatal outcomes.
Materials and Methods: A prospective observational study was conducted on 120 pregnant women (60 preterm, 60 term labour) at Government General Hospital, Eluru (2024–2025). BV was diagnosed using Amsel's criteria. Data were collected on vaginal pH, discharge, clue cells, whiff test, and high vaginal swab cultures. Maternal and neonatal outcomes were analyzed using SPSS v17.0.
Results: The incidence of BV was 30% in preterm labour cases and 6% in term labour cases ($p=0.002$). Basic vaginal pH, positive whiff test, and clue cells were significantly more frequent in the preterm group ($p<0.05$). Pathogenic organisms were isolated more often in preterm patients. Neonatal complications and postpartum outcomes showed no significant differences between BV-positive and BV-negative groups.
Conclusion: The incidence of BV is significantly higher among women in preterm labour. Routine antenatal screening and timely treatment may help reduce preterm births and associated complications.

Keywords: Bacterial vaginosis, Amsel's criteria, Preterm labour, Term labour, Vaginal microflora, Incidence

INTRODUCTION

Preterm labour (PTL), defined as the onset of regular uterine contractions leading to cervical changes before 37 completed weeks of gestation, remains a major challenge in obstetric care worldwide. It complicates approximately 5–10% of all pregnancies globally and is responsible for 70–80% of neonatal morbidity and mortality [1,2]. Preterm birth is now the leading cause of death among children

under five years of age, contributing to approximately 1 million deaths annually [3]. The complications of prematurity extend beyond neonatal mortality and include long-term morbidities such as neurodevelopmental impairment, cerebral palsy, respiratory distress syndrome, retinopathy of prematurity, and hearing loss [4].

The etiology of PTL is multifactorial, involving genetic predisposition, environmental factors, maternal stress, uterine overdistension, and infections [5]. Among these, intrauterine and lower genital tract infections are increasingly recognized as key contributors to spontaneous preterm labour and delivery [6]. It is estimated that subclinical infections account for up to 40% of preterm births [7].

Bacterial Vaginosis: A Common but Underestimated Infection

Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge among women of reproductive age. It represents a shift in the vaginal microflora from a healthy Lactobacillus-dominated environment to one dominated by anaerobic bacteria such as Gardnerella vaginalis, Mobiluncus species, Mycoplasma hominis, and Prevotella species [8,9]. This dysbiosis leads to a reduction in lactic acid production, resulting in an elevated vaginal pH (>4.5) and increased production of volatile amines, often causing a characteristic fishy odor and homogeneous grayish-white discharge [10]. However, more than 50% of BV cases during pregnancy are asymptomatic, leading to underdiagnosis and undertreatment [11].

Globally, studies have reported variable rates of BV during pregnancy, reflecting differences in populations, diagnostic methods, and healthcare practices [12]. In India, the incidence of BV in pregnant women remains underexplored, with limited data on new cases developing during gestation [13,14]. This highlights the need for region-specific research to assess the occurrence of BV and its clinical implications, especially in populations at high risk for preterm birth.

BV and Adverse Pregnancy Outcomes

The association between BV and adverse pregnancy outcomes has been documented in multiple studies. Women who develop BV during pregnancy are at increased risk for preterm premature rupture of membranes (PPROM), chorioamnionitis, postpartum endometritis, and low birth weight infants [15,16]. The proposed mechanism involves ascending infection from the vagina to the amniotic cavity, triggering an inflammatory response characterized by elevated levels of proinflammatory cytokines (IL-1β, TNF-α) and prostaglandins, which stimulate uterine contractions and cervical ripening [17,18].

Eschenbach et al. were among the first to demonstrate a significant association between incident BV cases and preterm delivery [19]. Subsequent studies, including the Prematurity Prediction Study in the United States, have consistently supported this link [20]. A meta-analysis by Leitich et al. concluded that BV is associated with a twofold increase in the risk of spontaneous preterm birth [21].

Diagnosis and Management of Incident BV in Pregnancy

While Gram stain-based Nugent scoring is considered the gold standard for diagnosing BV, it requires laboratory facilities and trained personnel. In contrast, Amsel's clinical criteria, which rely on identifying at least three of four findings (elevated pH, homogeneous discharge, positive whiff test, and clue cells on microscopy), remain widely used in clinical practice due to their simplicity and cost-effectiveness [22]. The role of treating newly diagnosed BV during pregnancy to prevent adverse outcomes remains debated. Some studies suggest that treatment with oral metronidazole or clindamycin may reduce the risk of preterm birth in women with incident BV, particularly in high-risk populations [23,24].

The Indian Context and Rationale for This Study

India accounts for nearly 3.5 million preterm births annually, representing one of the highest burdens worldwide [26]. Despite this, routine screening for BV during antenatal care is uncommon, and data

on the incidence of BV in pregnant women are scarce. The present study was undertaken to address this gap by evaluating the incidence of BV among women presenting with preterm and term labour at a tertiary care center in Andhra Pradesh. It also aimed to assess maternal and neonatal outcomes in women with incident BV, providing insights into the potential benefits of early detection and treatment in this population.

AIMS AND OBJECTIVES OF THE STUDY

1. To study the incidence of bacterial vaginosis in women presenting with preterm labour and term labour.
2. To analyze maternal and fetal complications associated with bacterial vaginosis.

MATERIALS AND METHODS

Study Design and Setting

This prospective observational study was conducted in the Department of Obstetrics and Gynaecology, Government General Hospital, Eluru, a tertiary care center serving urban and rural populations.

Study Period

The study was conducted over 12 months, from February 2024 to January 2025.

Study Population

A total of 120 pregnant women admitted for delivery were enrolled and categorized into two groups:

- Preterm labour group (n=60): Gestational age <37 weeks.
- Term labour group (n=60): Gestational age ≥37 weeks.

Inclusion Criteria

- Singleton pregnancy.
- Regular uterine contractions (≥4 in 20 minutes or ≥8 in 60 minutes).
- Cervical dilatation ≥1 cm but <4 cm.
- Intact membranes.

Exclusion Criteria

- Multiple gestations.
- Antibiotic use within the preceding two weeks.
- Structural uterine anomalies or known fetal anomalies.
- Complicating medical disorders (hypertension, diabetes, renal disease).
- Women unwilling to provide informed consent.

Data Collection and Diagnostic Procedure

A detailed history was obtained, including maternal age, parity, socioeconomic status, and gestational age confirmed by ultrasound. Speculum examination was performed under aseptic conditions to collect vaginal swabs from the posterior fornix for the following investigations:

1. **pH testing:** Using litmus paper (pH >4.5 considered abnormal).
2. **Whiff test:** Addition of 10% potassium hydroxide to vaginal fluid to detect a fishy odor.
3. **Microscopy:** Saline wet mount for detection of clue cells.
4. **Culture and sensitivity:** High vaginal swab for aerobic and anaerobic organisms.

The incidence of BV was determined based on the number of newly diagnosed cases during the study period, using Amsel's criteria (at least three of four criteria positive).

Outcomes

Primary Outcome: Incidence of BV in preterm and term labour groups.

Secondary Outcomes: Maternal and neonatal complications, including low birth weight, neonatal sepsis, respiratory distress syndrome (RDS), NICU admissions, and postpartum infections.

Ethical Considerations

The study was approved by the Institutional Ethics Committee of Siddhartha medical College, Vijayawada (Mentor college). Written informed consent was obtained from all participants.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using SPSS v17.0. Categorical variables were presented as frequencies and percentages, and continuous variables as means ± standard deviations. Chi-square test and Fisher's exact test were used for categorical comparisons, and independent t-tests for continuous variables. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 120 pregnant women were enrolled in the study, divided into two groups: preterm labour (n=60) and term labour (n=60). The demographic and clinical characteristics, diagnostic findings, and outcomes are presented below.

Table 1: Demographic and Obstetric Characteristics

Parameter	Preterm Labour (n=60)	Term Labour (n=60)	p-value
Mean maternal age (years)	22.98 ± 4.39	22.78 ± 4.01	0.795
Primigravida, n (%)	23 (38.3%)	24 (40.0%)	0.84
Multigravida, n (%)	37 (61.7%)	36 (60.0%)	
Mean gestational age (weeks)	35.17 ± 2.56	39.16 ± 1.09	<0.001*

KeyFindings:

The mean maternal age and parity distribution were comparable between groups. However, the mean gestational age at admission was significantly lower in the preterm labour group (p<0.001).

Table 2: Vaginal Discharge and Diagnostic Parameters

Diagnostic Parameter	Preterm Labour (n=60)	Term Labour (n=60)	p-value
Discharge suggestive of BV, n (%)	18 (30%)	4 (6%)	<0.001*
Basic vaginal pH (>4.5), n (%)	26 (44%)	8 (14%)	<0.001*
Positive whiff test, n (%)	24 (44%)	8 (18%)	<0.001*
Presence of clue cells, n (%)	12 (20%)	4 (6%)	0.05*
BV diagnosis by Amsel's criteria, n (%)	18 (30%)	4 (6%)	0.002*

Key Findings:

All diagnostic parameters for BV were significantly more frequent in the preterm labour group, confirming a strong association between BV and preterm labour.

Table 3: Vaginal Swab Culture Results

Organism Identified	Preterm Labour (n=60)	Term Labour (n=60)	p-value
Normal flora	42 (70%)	54 (90%)	-
Candida species	12 (20%)	6 (10%)	0.12
Enterococcus species	6 (10%)	0 (0%)	0.009*

Key Findings:
Candida and Enterococcus species were isolated more often in preterm labour patients. Enterococcus growth was statistically significant (p=0.009).

Table 4: Neonatal Outcomes

Parameter	BV Positive (n=22)	BV Negative (n=98)	p-value
Low birth weight (<2.5 kg), n (%)	Preterm: 8 (44%) Term: 2 (50%)	Preterm: 32 (76%) Term: 11 (20%)	Preterm: 0.02* Term: 0.2
Neonatal complications, n (%)	Preterm: 3 (30%) Term: 0 (0%)	Preterm: 4 (10%) Term: 2 (3.5%)	Preterm: 0.42 Term: 1
Mean birth weight (kg)	Preterm: 2.44 ± 0.56 Term: 2.77 ± 0.50	Preterm: 2.14 ± 0.58 Term: 2.95 ± 0.43	Preterm: 0.07 Term: 0.43
Mean APGAR (1 min)	Preterm: 6.78 ± 1.0 Term: 7.25 ± 0.96	Preterm: 6.62 ± 1.10 Term: 7.38 ± 0.78	Preterm: 0.6 Term: 0.76
Mean APGAR (5 min)	Preterm: 8.39 ± 0.98 Term: 8.75 ± 0.50	Preterm: 8.17 ± 0.76 Term: 8.66 ± 0.69	Preterm: 0.35 Term: 0.8

Key Findings:
No significant association was observed between BV status and neonatal complications or birth weight in both groups.

Table 5: Maternal Postpartum Complications

Parameter	BV Positive (n=22)	BV Negative (n=98)	p-value
Postpartum complications, n (%)	Preterm: 3 (16%) Term: 0 (0%)	Preterm: 6 (14%) Term: 6 (11%)	Preterm: 1 Term: 1

Key Findings:
There was no statistically significant difference in postpartum complications between BV-positive and BV-negative groups.

Summary of Statistical Findings

- BV was significantly associated with preterm labour (p=0.002).
- Diagnostic parameters (pH, whiff test, clue cells) were all significantly more frequent in preterm group (p<0.05).
- Pathogenic organisms were more common in preterm labour patients (p=0.009 for Enterococcus).
- No significant differences were found in neonatal or maternal postpartum outcomes between BV-positive and BV-negative groups.

DISCUSSION

This prospective observational study highlights a significant association between bacterial vaginosis (BV) and preterm labour (PTL) in pregnant women from the West Godavari district of Andhra Pradesh, India. The prevalence of BV was markedly higher in women with preterm labour (30%) compared to those in term labour (6%), a statistically significant difference (p=0.002). This finding aligns with global literature, including studies by Nezar et al. and Kiran CK et al., reinforcing the notion that BV is a modifiable risk factor for preterm birth [14,24].

Association Between BV and Preterm Labour

Multiple studies have consistently reported a strong link between BV and spontaneous preterm delivery. For instance, Eschenbach et al. observed a BV prevalence of 49% among preterm cases, while Leitich et al.'s meta-analysis found a 2.19-fold increased risk of PTL in women with BV [19,21]. Indian studies by Priyanka Chatterjee et al. and Kiran CK et al. report similar trends, confirming the relevance of BV as a contributing factor to PTL in diverse populations [24,26].

Pathophysiological Insights

The biological mechanisms underlying this association are complex and involve the disruption of normal vaginal flora. BV is characterized by a decline in protective hydrogen peroxide–producing lactobacilli and an overgrowth of anaerobic bacteria such as *Gardnerella vaginalis*, *Prevotella* spp., and *Mobiluncus* spp. [8,9]. These pathogens produce enzymes like mucinases and sialidases that degrade cervical mucus, facilitating ascending infection [17]. This, in turn, induces the release of inflammatory cytokines (IL-1β, IL-6, TNF-α) and prostaglandins, which may prematurely trigger uterine contractions, membrane rupture, and cervical ripening [10,11,18].

Elevated levels of these inflammatory mediators in amniotic fluid and vaginal secretions have been reported in BV-positive women who later deliver preterm, further supporting the causative role of BV in PTL [27].

Diagnostic Parameters

Our findings show that clinical indicators of BV—such as elevated vaginal pH (>4.5), positive whiff test, and presence of clue cells—were significantly more frequent in the preterm group. For example, 44% of preterm patients had elevated pH compared to 14% of term patients ($p<0.001$), while clue cells were detected in 20% vs. 6% respectively ($p=0.05$). These results are consistent with those of Priyanka et al. and highlight the utility of Amsel's criteria in resource-constrained settings [26].

While Nugent scoring remains the gold standard for BV diagnosis due to its higher specificity, Amsel's criteria offer practical advantages in clinical settings. Previous studies have demonstrated its sensitivity (>90%) and acceptable specificity (77%) compared to Nugent scoring [12,22,23].

Microbiological Findings

The presence of other genital pathogens, particularly *Enterococcus*, was significantly higher in the preterm group ($p=0.009$), suggesting potential co-infections. Although *Candida* and other organisms were also more frequent among preterm cases, their association did not reach statistical significance. These findings suggest that polymicrobial interactions may amplify the risk of PTL in BV-positive women.

Maternal and Neonatal Outcomes

Contrary to several previous reports, our study did not observe a statistically significant association between BV and adverse neonatal outcomes such as low birth weight, respiratory distress syndrome (RDS), or neonatal sepsis. Interestingly, low birth weight was more common among BV-negative preterm cases (76%) compared to BV-positive cases (44%) ($p=0.02$), a paradox that may reflect confounding factors such as maternal nutrition or socioeconomic conditions.

Other studies, such as those by Bijetha et al. and Renu Jain et al., reported stronger associations between BV and poor neonatal or postpartum outcomes, including puerperal sepsis and PROM [16,30]. The discrepancy may stem from differences in study design, population characteristics, and the early use of intrapartum antibiotics in our setting, which may have mitigated adverse outcomes.

Comparison with Guidelines and Literature

The debate over routine screening for BV in pregnancy continues. The Society of Obstetricians and Gynaecologists of Canada (SOGC) recommends targeted screening in high-risk women, a stance

echoed by a Cochrane review showing a modest reduction in PTL with screening and treatment programs [13,31]. Our findings support these recommendations and advocate for integrating BV screening into antenatal care, particularly in women with a history of PTL or other risk factors.

Strengths and Limitations

The prospective nature of our study, the use of standardized clinical criteria, and the focus on a population with limited existing data are notable strengths. However, limitations include the small sample size, single-center setting, and lack of Nugent scoring or molecular diagnostics. Additionally, potential confounders such as nutritional status, sexual behavior, and socioeconomic background were not fully addressed.

Clinical and Research Implications

Routine BV screening during antenatal care could serve as a cost-effective strategy to reduce preterm birth rates in high-risk populations. Treatment with antibiotics such as metronidazole or clindamycin has been shown to reduce the risk of PTL in BV-positive women [31]. Future multicentric studies with larger cohorts and incorporation of molecular techniques (e.g., PCR, microbiome profiling) are warranted to better understand the microbial dynamics and host interactions driving this association.

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