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# A Prospective Observational Study to Evaluate Association of Bacterial Vaginosis with Preterm Labour and Threatened Preterm Labour in a Tertiary Care Set Up of South Gujarat

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**ABSTRACT**

This study investigates the relationship between bacterial vaginosis (BV) and preterm labor, conducted as a prospective observational study at a tertiary care center in South Gujarat. Preterm birth, defined as delivery before 37 weeks of gestation, is a leading cause of neonatal morbidity and mortality worldwide. BV, a common vaginal infection caused by an imbalance of vaginal flora, has been strongly associated with increased risk of preterm labor, premature rupture of membranes (PROM) and other adverse pregnancy outcomes. The study enrolled 100 pregnant women under 37 weeks of gestation who presented with spontaneous preterm labor, threatened preterm labor, or medical conditions like PROM, with data collected over a 12-month period. Diagnostic criteria for BV included Amsel's criteria, such as vaginal discharge, elevated vaginal pH and presence of clue cells. The results indicated that 18% of the participants tested positive for BV, with a statistically significant correlation between elevated vaginal pH and the presence of grey-white discharge. The study found that BV-positive women had higher rates of preterm labor, PROM and neonatal complications, including low birth weight and NICU admissions. The findings underscore the importance of early BV screening and management during pregnancy to reduce the risk of preterm births and improve maternal and neonatal outcomes. Despite the complexity of preterm birth etiology, BV emerges as a significant and modifiable risk factor. Routine BV screening in prenatal care could significantly reduce preterm labor rates, especially in high-risk populations. The study concludes that timely diagnosis and treatment of BV may help mitigate adverse pregnancy outcomes and contribute to reducing neonatal morbidity and mortality in regions with high preterm birth rates.

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**Key Words**

Bacterial vaginosis, preterm labor, neonatal morbidity, prenatal care, vaginal microbiome, preterm birth

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## INTRODUCTION

Preterm birth, defined as delivery before 37 weeks of gestation, remains a critical contributor to neonatal morbidity and mortality. Globally, it is the leading cause of perinatal complications, with approximately 11% of all babies born prematurely each year. This translates to nearly 15 million infants born before full term. Given the rising proportion of neonatal deaths as a key factor in overall childhood mortality, efforts to reduce preterm births are essential for improving child survival rates. One significant factor linked to preterm labor and birth is bacterial vaginosis (BV), a common lower genital tract infection among women of reproductive age, both pregnant and non-pregnant. BV is the leading cause of vaginal discharge and malodor, and during pregnancy, it poses a serious risk of adverse outcomes, including preterm labor, premature rupture of membranes (PROM) and low birth weight in neonates[1,2]. Research has highlighted the role of microbial infections, particularly those involving the amniotic cavity, in preterm births. The ascending route of infection, in which bacteria travel from the vagina to the uterus, is the most common pathway leading to intrauterine infections. These infections may be present early in pregnancy or even before conception, often remaining asymptomatic for months. However, they can eventually manifest as preterm labor or PROM. It is estimated that intrauterine infections contribute to approximately 25% of all preterm births, with higher frequencies observed as gestational age decreases. Among these infections, bacterial vaginosis has been shown to significantly increase the likelihood of preterm birth, underscoring the need for early detection and management of this condition[3-5]. This study aims to determine the prevalence of bacterial vaginosis in women presenting with preterm labor or threatened preterm labor and to assess its impact on both maternal and neonatal outcomes. By understanding the relationship between BV and preterm birth, healthcare providers can better target interventions to reduce the risk of adverse outcomes in vulnerable populations[6]. Bacterial vaginosis is a condition characterized by an imbalance in the vaginal flora, where the normally dominant Lactobacillus species are replaced by a mixture of organisms, including Gardnerella vaginalis and various anaerobes. This shift in microbial composition leads to an increase in vaginal pH, resulting in symptoms such as vaginal discharge and malodor. Although BV is not a reportable disease, its prevalence is estimated to range from 10% to 41% among pregnant women, with rates varying across different populations. The condition has been associated with a host of pregnancy-related complications, including spontaneous abortion, preterm labor, PROM, amniotic fluid infection, postpartum endometritis and post-cesarean wound infections[7-9]. Historically, the understanding of BV has evolved over the past century. In the late 19th century, Lactobacillus was identified as the primary bacterium in healthy vaginal flora. By the mid-20th century, researchers began to recognize the role of mixed bacterial flora in the development of non-specific vaginitis, now known as bacterial vaginosis. Gardner and Dukes, in 1955, described the clinical features of BV and identified Hemophilus vaginalis (later renamed Gardnerella vaginalis) as the organism responsible for the condition[10,11]. The diagnosis of bacterial vaginosis is typically based on Amsel's criteria, which include the presence of a homogeneous vaginal discharge, a vaginal pH greater than 4.5, a positive whiff test (the release of a fishy odor upon the addition of potassium hydroxide to vaginal secretions) and the identification of clue cells on microscopic examination. These composite clinical criteria are widely used in both research and clinical practice to diagnose BV. Clue cells, which are vaginal epithelial cells coated with bacteria, are considered the most specific and sensitive indicator of BV. Other diagnostic methods, such as Gram staining, can also be used to confirm the diagnosis by evaluating the relative abundance of Gardnerella and other bacterial morphotypes compared to Lactobacillus[12-14]. The consequences of bacterial vaginosis during pregnancy are significant. In addition to the increased risk of preterm birth, BV has been linked to low birth weight, postpartum infections and complications in the neonate. The condition is also associated with an increased susceptibility to other sexually transmitted infections, including HIV, making it a critical public health concern[15]. Given the high prevalence of bacterial vaginosis and its association with preterm birth, there is an urgent need for improved screening and management strategies. Early diagnosis and treatment of BV in pregnant women can help mitigate the risk of preterm labor and other complications, ultimately contributing to better maternal and neonatal outcomes. Through continued research and public health efforts, addressing bacterial vaginosis can play a key role in reducing the global burden of preterm births and improving the health of both mothers and their babies[16]. The study aims to assess the association between bacterial vaginosis and preterm or threatened preterm labor, determine the frequency of bacterial vaginosis in preterm births and evaluate the outcomes after treatment for threatened preterm labor and preterm labor in women diagnosed with bacterial vaginosis.

## MATERIALS AND METHODS

This prospective observational study was conducted at the Department of Obstetrics and Gynecology, a tertiary care center of New Civil hospital in Surat, South Gujarat for12 months. Ethical approval has been obtained from the Ethical Approval Committee of New Civil Hospital, Surat a tertiary care center, South Gujarat.

**Study Population:** The study population included pregnant women under 37 weeks of gestation

presenting with spontaneous preterm labor, threatened preterm labor, or conditions such as PROM, vaginal discharge, prior preterm labor, cervical incompetence, or medical complications like infections and hypertension. Women with gestational age above 37 weeks, induced labor, or who did not consent were excluded.

**Data Analysis:** Data was coded and recorded in MS Excel and analyzed using SPSS v25. Descriptive statistics included means, medians, standard deviations and frequencies. Graphs such as histograms, bar charts and pie charts were used for visualization. Group comparisons were made using independent t-tests, ANOVA and Chi-squared tests. A p-value of less than 0.05 was considered statistically significant.

## RESULTS AND DISCUSSIONS

This prospective observational study, conducted at a tertiary care hospital in South Gujarat, aimed to assess the association of bacterial vaginosis (BV) with preterm and threatened preterm labor. Approved by the Human Research Ethics Committee, it enrolled 100 subjects over 12 months. Most participants (85%) were aged 21-29, with a mean age of 24.9 years and a standard deviation of 3.79.

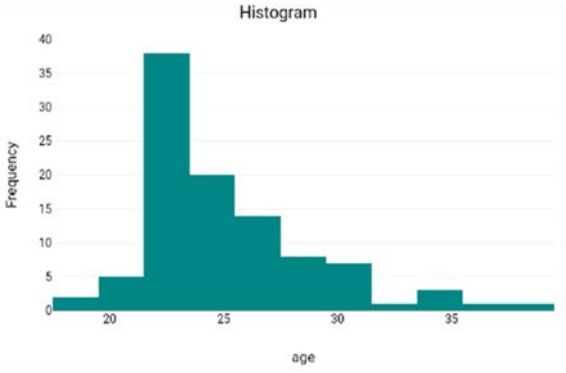


Fig 1: Age Distribution Histogram

The study provides detailed demographic and health-related data on 100 pregnant women regarding their residence, socioeconomic status, registration status, antenatal care (ANC) visits, parity and history of previous preterm births or abortions. A significant majority (75%) of participants were from urban areas and most (79%) belonged to the middle class. Regarding registration status, 67% were registered patients. The mean number of ANC visits was 4.43, with notable variability and the parity distribution revealed 46% nulliparous women. Additionally, 25% of participants had a history of previous preterm birth or abortion, indicating diverse reproductive histories that could influence study outcomes related to maternal and child health. The findings align with existing literature, highlighting consistency in demographics and healthcare access. The study provides a comprehensive overview of the health characteristics of 100 pregnant women, detailing comorbidities, gestational age, provisional diagnosis, fetal presentation and number of fetuses. While 49% of participants reported no comorbidities, moderate anemia (13%), pregnancy-induced hypertension (11%) and gestational diabetes (9%) were notable conditions that may affect pregnancy outcomes. Most participants were at 32-35 weeks of gestation (61%), with 60% diagnosed with established preterm labor. A majority (88%) of fetuses were in a cephalic position and 97% of the pregnancies were singleton. These findings align with existing literature, highlighting trends in maternal health and fetal outcomes and ensuring data reliability due to the absence of invalid entries. The study evaluated the parameters of Amsel's criteria among 100 participants to assess the prevalence of bacterial vaginosis (BV). A grey-white homogeneous discharge was present in 30% of participants, with a significant chi-square statistic of 16.0 (P=0.00006), indicating its relevance in diagnosis. Vaginal pH levels revealed that 74% had pH levels below 4.5, suggesting a healthy vaginal environment, while the Whiff test and Clue Cell Wet Mount test indicated that 30% and 14% of participants tested positive for BV, respectively, both showing strong statistical significance. The findings underscore the utility of these diagnostic tests in clinical settings for managing vaginal infections, with consistent patterns aligning with existing literature. The analysis of the correlation between vaginal pH levels and the presence of grey-white homogeneous discharge among 100 participants revealed that 15 out of 26 women with a pH greater than 4.5 had the discharge, compared to only 15 out of 74 women with a pH below 4.5. The chi-square test indicated a statistically significant association (chi-square=12.83, $p<0.001$), suggesting that a higher vaginal pH is strongly correlated with this type of discharge, which may indicate bacterial vaginosis (BV) or other infections. These findings are consistent with previous studies, such as those by Patil (2020) and Chawanpaiboon et al. (2010), which identified elevated pH levels as significant indicators of BV. Additionally, a separate examination of the Whiff test results showed that all 14 positive cases also contained clue cells, while the remaining 86 negative cases did not. The chi-square value of 37.98 ($p<0.001$) indicated a highly significant association between a positive Whiff test and the presence of clue cells, reinforcing the likelihood of detecting BV when the Whiff test is positive. These results align with findings by Prajarto *et al*. (2020), highlighting the importance of these diagnostic markers in identifying vaginal infections. Among the 100 study subjects, the prevalence of bacterial vaginosis (BV) was found to be 18%, indicating that 18 participants tested positive for the condition. This data highlights the occurrence of BV

Table 1: Diagnosis of BV According to Amsel's Criteria

| | Criteria for BV | |
|---|---|---|
| Types of Discharge | No of study subjects (n=100) | Percentage |
| Grey white homogenous | 30 | 30% |
| Curdy white | 10 | 10% |
| White mucoid | 22 | 22% |
| No discharge | 38 | 38% |
| **Ph** | | |
| <4.5 | 74% | 74% |
| >4.5 | 26 | 26% |
| **Whiff test** | | |
| Positive | 30 | 30% |
| Negative | 70 | 70% |
| Clue cells | | |
| Present | 14 | 14% |
| Absent | 86 | 86% |
| **Amsel's (>/=3) BV Positive** | | |
| Present | 18 | 18% |
| Absent | 82 | 82% |

Table 2: Performance of Various Individual Criteria as Compared to Whole Amsel's Criteria

| Positive Test | BV Positive | BV Negative | Sensitivity | Specificity | PPV | NPV |
|---|---|---|---|---|---|---|
| Grey white Homogenous discharge (n=30) | 16 | 14 | 80% | 80% | 53% | 94% |
| Whiff test (n=30) | 18 | 12 | 90% | 85% | 60% | 97% |
| pH >4.5 (n=26) | 12 | 14 | 63% | 83% | 46% | 91% |
| Clue cells present (n=14) | 14 | 0 | 78% | 100% | 100% | 95% |

Table 3: History of Previous Preterm Birth/Abortion Among the BV Positive Study Participants

| History of Previous Preterm Birth/Abortion | (N=18) | Percentage |
|---|---|---|
| No | 13 | 72% |
| Yes | 5 | 28% |

Table 4: After Treatment Outcomes in Study Population with Bacterial Vaginosis

| No of study subjects | | Antibiotic Treatment given Percentage of after Oral metronidazole | treatment outcome | |
|---|---|---|---|---|
| Threatened preterm labour | BV Positive (n=7) | | Delivered Preterm (n=5) 71% | Delivered Full-term (n=2) 29% |

Chi-square value=1.29., P value=0.26

Table 5: Final Maternal and Neonatal Outcome in BV Positive Study Population

| | No of study subjects (n=18) | Maternal outcome (n=18) | Neonatal outcome(n=18) | Percentage |
|---|---|---|---|---|
| Preterm Birth | 16 | Discharged | Alive | 100%Full term Birth |
| | 2 | Discharged | 100% | 100% |

within the study population, represented visually in Chart 12, which shows the frequency of BV positivity.

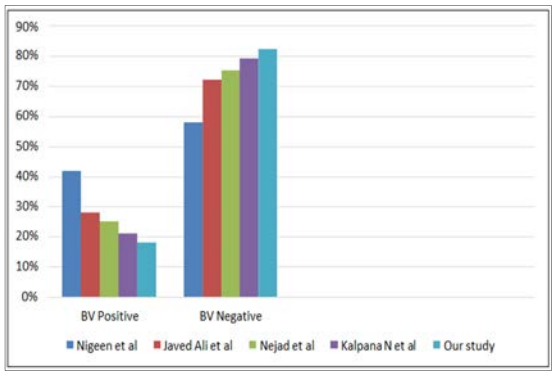


Fig 2: Frequency of BV in Different Studies

The age distribution of bacterial vaginosis (BV) positive study subjects revealed a mean age of 24.9 years (SD 3.79), with ages ranging from 18 to 38. This finding aligns with previous research, including a study by Kalpana N *et al.* (2024), which reported similar age patterns. Most studies indicate that the majority of women experiencing preterm labor with BV are typically between 21 and 29 years of age. Furthermore, regarding registration status, 67% of the BV positive subjects in our study were registered patients, while 22% were emergency cases and 11% were referrals, mirroring trends found in Ali J *et al.* (2015). This consistency suggests that our cohort's age and registration distribution reflect broader patterns seen in similar studies. Lastly, when examining gestational age, our data showed that 7 out of 18 BV positive cases were below 34 weeks, compared to 11 above 34 weeks. This distribution is comparable to findings from Avula Shashikala *et al.*, reinforcing the consistency of our results across different studies. The analysis of threatened preterm labor (TPL) among study subjects revealed that 30% (n=7) of those experiencing TPL were bacterial vaginosis (BV) positive, while 70% (n=16) were BV negative, with a chi-square value of 3.52 and a P-value of 0.06, indicating a borderline significant association between BV and TPL. Among the 23 subjects with TPL, 11 progressed to preterm birth, suggesting effective management or a low-risk

population for preterm labor. In the examination of PrePROM, 18% (n=3) of BV positive subjects had a history of premature rupture of membranes, though further research is needed for conclusive results. Additionally, among BV positive subjects, 14% (n=8) had established preterm births. The distribution of delivery methods showed that among 100 patients, BV status did not significantly influence delivery outcomes., only 13% of preterm vaginal deliveries (PTVD) were BV positive and 3% of preterm cesarean sections (PTLSCS) were BV positive, with a chi-square value of 0.18 and P-value of 0.67. These results suggest that BV may not significantly affect the mode of delivery, aligning with findings from previous studies by Chawanpaiboon S *et al.* (2010) and Yadav N *et al.* (2023), which indicated a minimal role of BV in influencing delivery methods despite its association with preterm labor. The analysis of maternal outcomes among the study subjects revealed a mean duration of labor of 10.05 hours, with considerable variability (ranging from 1-20 hours) and an average hospital stay of 4.98 days, indicating moderate variation in recovery time. The majority (95%) of patients who underwent vaginal delivery were discharged within 10 days, while a small percentage (5%) stayed longer. In terms of post-delivery morbidity, 78% of participants reported no complications, although 8% experienced puerperal pyrexia and 5% required blood transfusions. Among the 18 BV-positive subjects, 17% experienced postpartum complications, suggesting a potential trend toward an association between BV and complications, with a p-value of 0.0584, although this did not reach statistical significance. Overall, these findings indicate positive maternal health outcomes, but the potential link between BV and postpartum morbidity warrants further investigation with larger samples.

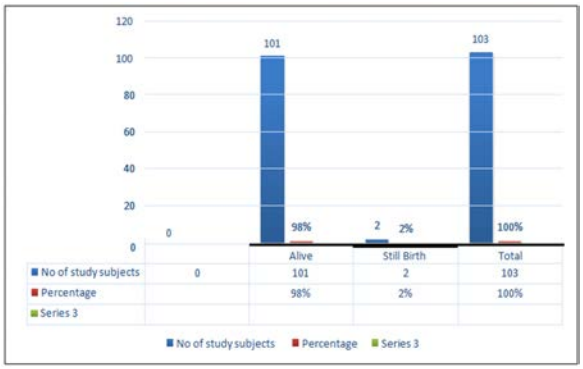


Fig 3: Condition at Birth Among the Study Participants

The neonatal parameters from the study indicated that out of 103 participants, 98% resulted in live births, reflecting a high survival rate, while 2% were stillbirths. Among the newborns, 71% did not require NICU admission, suggesting stable health conditions, but 29% were admitted due to complications, highlighting the need for careful neonatal monitoring. The primary reasons for NICU admissions included respiratory distress (37%) and neonatal jaundice (33%), with low-birth-weight accounting for 27% of cases. Among BV-positive newborns, 22% had low birth weight and 28% experienced neonatal complications, with a significant association noted between BV and adverse outcomes, particularly in birth weight and neonatal complications, though NICU admissions showed a trend towards significance but did not meet the conventional threshold. These findings underscore the importance of continuous monitoring and intervention in newborn care, particularly for those born to mothers with bacterial vaginosis. This study evaluates the association between bacterial vaginosis (BV) and preterm labor, including threatened preterm labor, within a tertiary care setting in South Gujarat. Preterm birth, defined as delivery occurring before 37 weeks of gestation, is a significant contributor to neonatal morbidity and mortality. Understanding the various factors that lead to preterm birth is essential for improving maternal and neonatal health outcomes. This research specifically focuses on the role of vaginal infections, particularly BV, in contributing to these adverse outcomes[17]. Bacterial vaginosis is characterized by a shift in the vaginal flora, wherein normal lactobacilli are replaced by a predominance of anaerobic bacteria. This change not only increases the risk of infections but also contributes to various complications during pregnancy. The prevalence of BV among pregnant women has been linked to several adverse pregnancy outcomes, including preterm labor, premature rupture of membranes and low birth weight. Thus, understanding how BV contributes to preterm birth is critical and this study examines women presenting with either preterm labor or threatened preterm labor[18]. The diagnosis of BV was made using clinical criteria, primarily Amsel's criteria, which include the presence of characteristic vaginal discharge, a vaginal pH greater than 4.5 and a positive whiff test, among other indicators. Preterm labor is one of the leading causes of neonatal morbidity and it is often triggered by ascending infections originating from the lower genital tract. Research indicates that intrauterine infections are present in approximately 25% of preterm births, with BV playing a crucial role in heightening the susceptibility of pregnant women to these infections[19]. The pathogenesis of BV in relation to preterm labor involves the production of inflammatory cytokines, which can lead to uterine contractions and cervical ripening, precipitating the onset of labor. This inflammatory response is exacerbated in the presence of BV., the resulting imbalance in the vaginal microbiome increases the presence of harmful bacteria, further contributing to the risk of preterm birth. The findings from this study suggest that BV is more prevalent among women who experience preterm labor, indicating that treating BV

could potentially mitigate the risk of preterm birth[20]. However, the study acknowledges the multifaceted nature of preterm labor's etiology, which encompasses various risk factors, including previous preterm births, uterine overdistension and psychological stress. Despite these complexities, BV stands out as a modifiable risk factor. If diagnosed and treated early, there is a possibility of improving pregnancy outcomes for women at risk of preterm labor[21]. The research underscores the importance of early screening for BV among pregnant women, especially those who present with symptoms indicative of preterm labor. The established association between BV and adverse neonatal outcomes, such as low birth weight and the need for neonatal intensive care admissions, reinforces the necessity for targeted interventions. Women diagnosed with BV are more likely to give birth to neonates who face complications like respiratory distress syndrome and sepsis, highlighting the broader public health implications of BV during pregnancy[22]. Management strategies for preterm labor typically involve the administration of tocolytic drugs and corticosteroids aimed at delaying delivery and enhancing neonatal outcomes. However, the presence of BV complicates this management. The underlying infection can lead to premature rupture of membranes or other complications, making it challenging to prolong the pregnancy effectively. This study emphasizes the necessity of incorporating BV screening into routine prenatal care, particularly for women who are at high risk of preterm labor[23]. Moreover, the research provides an in-depth examination of the microbial changes associated with BV and their subsequent impact on pregnancy outcomes. It underscores the role of BV in increasing the risk of preterm birth through mechanisms that involve inflammatory responses and disruption of the vaginal microbiome. The findings suggest that interventions aimed at restoring the vaginal microbiome-such as the use of probiotics or targeted antibiotic treatments-could potentially decrease the incidence of preterm labor linked to BV. This study adds to the growing body of evidence supporting the association between BV and preterm labor. It highlights the critical need for early detection and treatment of BV to enhance maternal and neonatal outcomes. The research advocates for routine BV screening among pregnant women, particularly within high-risk populations, as a strategy to reduce preterm births and their associated complications. These findings are especially relevant within the context of public health initiatives aimed at decreasing neonatal morbidity and mortality rates, particularly in regions where preterm birth rates are notably high. By addressing BV through proactive screening and management, healthcare providers can significantly contribute to improving the health and well-being of both mothers and their newborns[24,25].

## CONCLUSION

Preterm birth significantly contributes to neonatal morbidity and mortality, leading to complications like respiratory distress and long-term impairments. This study highlights a strong association between bacterial vaginosis (BV) and preterm labor, emphasizing the need for early diagnosis and treatment. Routine screening for BV in prenatal care can improve maternal and neonatal outcomes, reducing the risk of preterm labor and complications.

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