

# Prevalence of Bacterial Vaginosis and Its Outcome in Women Attending Antenatal Care in Dhiraj Hospital, Waghodia, India

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**Abstract:** Bacterial vaginosis (BV) is a complex clinical syndrome characterized by imbalance in the vaginal microflora and a malodorous discharge when symptomatic. In pregnancy, BV has been associated with adverse outcomes such as miscarriage, premature rupture of membranes, preterm birth, and low birth weight. This study was conducted to determine the prevalence and associations of BV and pregnancy outcomes among pregnant women in Dhiraj Hospital, Vadodara. **Methods-** We conducted a prospective observational study with high vaginal swabs obtained from consecutive newly registered antenatal women between 14 and 36 weeks gestation. The women were monitored until delivery, and their pregnancy outcome and demographic data were obtained using an interviewer-administered questionnaire. **Results-** Bacterial vaginosis was diagnosed by Nugent score in 58 of 156 women, giving a prevalence rate of 37%. Bacterial vaginosis was significantly associated with preterm delivery (risk ratio [RR], 2.68; 95% confidence interval [CI], 1.44–4.98), low birth weight (RR, 3.10; 95% CI, 1.29–7.94), and premature rupture of membranes (RR, 5.9; 95% CI, 3.11–14.67). The association between BV and miscarriage (<20 weeks gestation) and neonatal admission for various morbidities was not statistically significant. **Conclusions-** The prevalence rate of BV among pregnant women in Dhiraj Hospital is high and is significantly associated with adverse pregnancy outcome. Routine screening and treatment of women preconceptually may enable interventions to prevent these adverse outcomes.

**Keywords:** Vaginitis, Bacterial vaginosis, Clinical diagnosis, Pregnancy

## 1. Introduction

Bacterial vaginosis (BV) is a common, complex clinical syndrome characterized by imbalance in the vaginal microflora. They may be symptomless but when symptomatic, it is associated with a malodorous vaginal discharge and, on occasion, vaginal itching or burning sensation<sup>[1]</sup>. Under normal conditions, lactobacilli constitute 95% of the bacteria in the vagina and produce several antimicrobial compounds, including lactic acid and hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>), thereby acidify the vaginal pH to less than 4.5<sup>[2]</sup>. Bacterial vaginosis is associated with severe reduction or absence of the normal H<sub>2</sub>O<sub>2</sub>-producing lactobacilli and overgrowth of anaerobic bacteria, including *Gardnerella vaginalis*, *Ureaplasma urealyticum*, *Mycoplasma hominis*, *Mobiluncus* species, *Prevotella* species, and other anaerobes<sup>[3]</sup>. The risk factors vary like cigarette smoking, intrauterine device, early age of sexual intercourse, new or multiple sexual partners and vaginal douching were reported<sup>[4]</sup>. Bacterial vaginosis was found to more than double the risk of preterm delivery in both asymptomatic patients and those with preterm labour symptoms in a meta-analysis<sup>[5]</sup>. The adverse perinatal outcome following preterm delivery is huge, accounting for up to 70% of perinatal mortality worldwide. Bacterial vaginosis has also been associated with low birth weight (LBW), premature rupture of membranes (PROM), miscarriage, and chorioamnionitis<sup>[6]</sup>. There are several studies reporting on BV in India in both pregnant and nonpregnant women, with prevalence rates ranging between 17.3% and 64.3%<sup>[7-9]</sup>. For pregnant women, the one study noted to report on pregnancy outcome did not find any

significant adverse effect of BV on pregnancy despite a relatively high prevalence<sup>[10]</sup>. Therefore, this study aims to estimate the current prevalence of BV in our pregnant women and to examine for any associated adverse pregnancy outcome.

## 2. Materials and Methods

The study was conducted on 180 pregnant women in the Department of Obstetrics and Gynaecology in Dhiraj Hospital, Vadodara between November 2018 to June 2019. It was a prospective observational study carried out among healthy pregnant women registering at the antenatal clinic for the first time, ie, booking, between 14 and 36 weeks gestational age with or without symptoms of vaginal discharge. Women with medical conditions including human immunodeficiency virus (HIV) or women with known obstetrics complications which can be a factor for preterm labour such as severe anaemia, pregnancy induced hypertension, antepartum haemorrhage etc were excluded from the study. Bacterial vaginosis was diagnosed in these women by Nugent score, and they were monitored during and after delivery for pregnancy outcomes. Informed written consent of each participant was obtained. Ethical approval from institution was also obtained.

### Specimen Collection

Specimens were collected using sterile cotton swabs by swabbing the lateral and posterior fornices of the vagina and is incorporated with a transport medium (Amies medium) within a sterile container. The swabs were transported within

45 minutes of collection to the Department of Microbiology for processing.

### Nugent Score

Smears were made from the swab specimens on clean grease-free slides and Gram stained using crystal violet as the primary stain, lugol's iodine as the mordant, acetone as the decolorizer, and safranin as counterstain. Evaluation of the specimen was done using the method by Nugent et al [24]. This scoring system counts the individual morphotype frequency of lactobacilli and other organisms and summed to give one final score ranging from 0 to 10. A Gram stain score of 7 to 10 was considered positive for BV, a score of 0 to 3 was considered "normal", and a score of 4 to 6 was considered "intermediate". Patients with an intermediate score were also categorized as normal for the analysis.

### Follow up

Women diagnosed with BV, whether symptomatic or not, were treated with oral clindamycin 300 mg twice daily for 7 days as soon as their results were obtained. All of the women were monitored until delivery. Follow up was also enhanced by taking the phone numbers of all the women for ease of communication. All neonates in this study were observed for at least 1 week after delivery, especially those admitted into the neonatal intensive care unit.

### Data Collection and Analysis

Data were collected using interviewer-administered questionnaires. The questionnaires included questions on demographic characteristics and adverse pregnancy outcomes studied. Premature rupture of membranes was diagnosed as rupture of membranes occurring at least 1 hour before the onset of labour pains. Miscarriage was diagnosed as spontaneous pregnancy loss occurring before 20 completed weeks of gestation in the current pregnancy, 20 weeks being the age of viability in India. Preterm delivery was diagnosed as delivery occurring before 37 completed weeks of gestation. Low birth weight was diagnosed as birth weight <2.5 kg at delivery. Data analysis was done with Epi-info 7, 2012. Fisher's exact and  $\chi^2$  tests were used for comparison of proportions. Risk ratios were calculated to determine the causal association of BV with pregnancy outcomes including preterm delivery, spontaneous abortions, PROM, LBW, and neonatal unit admissions. The level of significance was set at 0.05.

## 3. Results

180 pregnant women were recruited for the study, but 156 women were eventually studied because 24 were lost to follow up. The age range of the study participants was 20 to 44 years (mean age, 30.9  $\pm$  4.5 years), and they were all Indian women. The majority of the women were from lower social economic class.

**Table 1: Sociodemographic Characteristics of Participants**

Age (years)	No of cases	Percentage (%)
20-24	18	11.5
25-29	63	40.3
30-34	46	29.4
35-39	24	15.3
40-44	5	3.2

Socio-economic status		
Higher	16	10.2
Upper middle	31	19.8
Lower middle	45	28.8
Lower	64	41.0
Gravida		
Primigravida	65	41.6
Multigravida	91	58.4

Fifty-eight of the women studied had BV, giving an overall prevalence of 37%. The remaining 98 women were analyzed as normal. Thirty-seven (23.7%) of them had intermediate scores, and 61 (39.1%) had negative scores. The women were enrolled between 14 and 36 weeks gestation. Eighty-eight (56.4%) of them were recruited before 28 weeks, and the remaining 68 (43.5%) women were recruited between 29 and 36 weeks. The median gestational age at recruitment was 29 weeks, and the median gestational age at delivery was 38 weeks.

**Table 2: Bacterial Vaginosis status and Pregnancy Outcome**

Pregnancy Outcome	BV Positive (N = 58)	BV Negative (N=98)	RR (95% CI)	P Value
Preterm delivery N (%)	14 (24.1)	20 (20.4)	2.70(1.44–4.98)	.003
LBW	11(18.9)	7 (7.1)	3.1 (1.29–7.94)	.007
PROM	15 (25.8)	6 (6.1)	5.9 (3.11–14.67)	<.001
Miscarriage	3 (5.1)	6 (6.1)	1.38 (0.37–5.52)	.209
Neonatal Unit Admission	12 (20.6)	15 (15.3)	1.45 (0.75–2.67)	.146

Of the 58 women who were positive for BV, 24.1% had preterm delivery, 18.9% had LBW, and 25.8% had PROM. They had 2.7 times the risk of preterm delivery (95% confidence interval [CI], 1.44–4.98), 3.1 times the risk of LBW (95% CI, 1.29–7.9), and 5.9 times the risk of PROM (95% CI, 3.1–14.7) compared with those who were negative. However, only 5.7% of these positive women had miscarriage, and 20.6% of the newborns were admitted in the neonatal intensive care units: BV was not significantly associated with miscarriage or neonatal unit admission (Table 2).

Abbreviations: BV, bacterial vaginosis; CI, confidence interval; LBW, low birth weight; PROM, premature rupture of membranes; RR, risk ratio.

## 4. Discussion

The prevalence rate of BV of 37% among pregnant women in this study is within the range of other recent studies, i.e. from 17.3% to 64.3% [7-9]. The Nugent criteria used in this study have been shown to have a higher sensitivity and specificity compared with the Amselcriteria<sup>[11]</sup>. Three of these studies also used the same Nugent criteria used in our study, and their BV prevalence ranged from 38% to 64.3%. One of them found to have prevalence of 64.3%, which is much higher than ours.<sup>[12]</sup> These differences could be due to the type of population studied. The fetus is protected from microorganism infection by the cervix, which controls and limits microbial infection by production of immune cytokines, and antimicrobial molecules. If this barrier is affected, bacteria may enter the uterine cavity, leading to

adverse perinatal outcome. Therefore, improving women's living ways and knowledge regarding reproductive health issues will help decrease the incidences of vaginitis and reduce adverse pregnancy outcomes. In this study, 58 patients with BV showed a significantly higher risk of preterm birth, which correlates with other studies in the literature.<sup>[13-14]</sup> Study done by Adesiji et al<sup>[10]</sup> did not find any such association with adverse pregnancy outcome, including preterm birth. The main differences between their study and ours are their use of Amsel criteria for the diagnosis of BV and the fact that they studied women in their 1<sup>st</sup> and 2<sup>nd</sup> trimesters whereas we studied in 2<sup>nd</sup> and 3<sup>rd</sup> trimester. There are several reports linked with BV with LBW, PROM, neonatal morbidity, and spontaneous miscarriage.<sup>[5,6,15,16]</sup> Our study also showed a statistically significant association of BV with LBW and PROM but not with miscarriage or neonatal admissions into the neonatal intensive care unit. Other studies found BV to be associated with spontaneous second trimester miscarriage, but they studied the women in their first trimesters and had larger sample sizes.<sup>[17]</sup> It is important to note that strict exclusion criteria of women with obstetric complications or medical conditions that could influence pregnancy outcome were adhered to in this study. Therefore, we believe our findings to be accurate, because most of the confounding variables have been considered from the outset of the study.

## 5. Conclusions

The prevalence rate of BV among pregnant women in Dhiraj Hospital is high and is significantly associated with preterm delivery, LBW and PROM. Awareness of the condition and treatment before pregnancy may help reduce the adverse outcome associated with it.

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