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# A Prospective Study of Proportion of Bacterial Vaginosis in Preterm and Term Labour Patients at Rajarajeswari Medical College and Hospital. , Bengaluru

Dr. Sai Prathyusha Ivvala., Dr. Pavana Ganga A., Dr. M.P.A Sai Lakshmi, Dr. Subhashini Revu.,

*M.S (OBG) Registrar , Rainbow hospital, Visakhapatnam.*
*M.S.,(OBG) ASSOCIATE PROFESSOR Department of obstetrics and Gynecology, Rajarajeswari Medical College and Hospital, Bengaluru.*
*, Professor and HOD, Department of OBG, Rajarajeswari Medical College & Hospital, Bengaluru - 560074.*
*M.D (OBG) ASSOCIATE PROFESSOR Department of obstetrics and Gynecology, Siddhartha Medical College, Vijayawada, Andhra Pradesh.*

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**ABSTRACT**

**BACKGROUND:**

Bacterial vaginosis is characterized by a diminished flora of lactobacilli, which increases the vaginal pH, and significantly increases colonization of anaerobic or facultative microorganisms. There is an increased risk of preterm labor in pregnant women with bacterial vaginosis. Routine screening and subsequent treatment for bacterial vaginosis can reduce neonatal morbidity and mortality. Hence, this study was designed to look at the correlation between bacterial vaginosis and preterm labour.

**AIM & OBJECTIVES**:

To study the proportion of bacterial vaginosis in preterm and term labor and its association as one of the causative factors of preterm labor

To determine the maternal and fetal complications associated with bacterial vaginosis.

**MATERIAL & METHODS:** An observational study involving 200 patients with preterm and term labour (100 in each group) was conducted at Rajarajeswari medical college and hospital, Bangalore. Bacterial vaginosis was determined to be present or absent on the basis of Nugent‘s criteria. Women with a Nugent‘s score of 7 or more on Gram's staining of the vaginal smear will be considered to have bacterial vaginosis. Maternal complications and perinatal outcome are assessed. Appropriate statistical methods were applied.

**RESULTS:** The proportion of patients who fulfilled Nugent‘s criteria are more in preterm labour group as compared to term labour group and the difference was significant statistically.

The significant findings in the study are as follows

The present study estimated the prevalence of Bacterial vaginosis among preterm labour group as 39% and among term labour as 4%. Hence, pregnant women with bacterial vaginosis were more prone for preterm labor and majority of pregnant women (72%) suffering with bacterial vaginosis belongs to lower socioeconomic status. Nugent‘s scoring stands better in comparison to other methods of diagnosis of bacterial vaginosis.

The preterm labour group had 38% primigravidas and 62% multigravidas while the term group had 46% primigravidas and 54% multigravidas.

The number of patients who had other genital tract infections was more in preterm labour group as compared to term group. (36% vs. 5%). Most commonly grown microorganism was Candida followed by Enterococcus and Group B Streptococcus.

Our study shows lower mean birth weight of babies born to bacterial vaginosis positive mothers compared to babies of bacterial vaginosis negative mothers. Incidence of neonatal complications in our study, were higher among infants born to preterm labour group than among term labour group (21% vs. 5%). The most commonly observed complication was neonatal sepsis followed by Respiratory distress syndrome.

In preterm group more number of patients who were bacterial vaginosis positive had postpartum complications compared to bacterial vaginosis negative (43.5% vs. 11.4%).The most common complication was puerperal pyrexia followed by atonic PPH.

**CONCLUSION:** Bacterial vaginosis plays a significant role in causation of preterm labour. Testing for bacterial vaginosis and prompt treatment may reduce the risk of preterm labour and reduce associated maternal and neonatal complications.

**Keywords**: Bacterial vaginosis; Preterm labour; Term labour

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## I. INTRODUCTION

The World Health Organization defines Preterm labor as the onset of labor prior to the completion of 37 weeks of gestation, in a pregnancy beyond 20 weeks of gestation[1.] . The rate of preterm birth ranges from 5% to 15%.[2-4] It is estimated that around 15 million infants are born preterm globally, mainly affecting low and middle income countries including India.[5] It is the leading cause of neonatal morbidity and mortality.[6] Preterm birth is related to severe perinatal complications such as Infant Respiratory Distress Syndrome (IRDS), sepsis, necrotizing enterocolitis, periventricular and intraventricular haemorrhage, periventricular leukomalacia, and cerebral palsy. Hence, prediction and prevention of preterm labor remains a major healthcare priority.

The etiological factors of preterm labor are complex and the pathophysiology that triggers preterm labor is still largely unknown. At least 50 - 70% of cases of preterm labor have no known risk factors.[3, 7]

Bacterial vaginosis (BV) is the most commonly reported microbiological entity among women of childbearing age. It is characterized by a shift in the vaginal flora from the dominant Lactobacillus to a polymicrobial flora[.8] It has been associated with a wide array of health issues, including preterm births, preterm premature rupture of membranes (PPROM), postpartum endometritis, pelvic inflammatory disease and increased susceptibility to HIV infection.[8, 9] A number of potential microbial pathogens, singly and in combinations, have been implicated in the disease process. The list of possible agents continues to expand and includes members of a number of genera like Gardnerella, Atopobium, prevotella, peptostreptococcus, Mobiluncus, Sneathia, Leptotrichia, Mycoplasma, and BV-associated bacterium 1 (BVAB1) to BVAB3. The testing for BV is of huge significance and its prompt treatment may reduce the risk of preterm labor. This will also go a long way in the prevention of neonatal complications due to prematurity.

In India, there have been only a handful of case control studies which have evaluated the association of bacterial vaginosis with preterm labor. However, they have limitations like retrospective design of the study, smaller sample sizes and use of Amsel‘s criteria which is not the gold standard for diagnosis of BV. The gold standard for diagnosis of BV is the Nugent criteria[.2, 10] Hence, this prospective study using Nugent‘s criteria was undertaken to evaluate the correlation between bacterial vaginosis and preterm labor in Rajarajeswari medical college and hospital, Bengaluru.

**Nugent’s criteria**[11]

Each bacterial morphotype was quantified under an oil immersion objective (1000x)

By using following scheme:

- 1+ : <1 per field
- 2+: 1 to 5 per field
- 3+: 6 to 30 per field
- 4+: > 30 per field

The large Gram positive rods were considered as lactobacillus morphotypes: the small Gram negative to Gram variable rods were considered as Gardenerella Vaginalis and bacteroides species morphotypes and curved Gram variable rods were considered as the Mobiluncus species morphotypes. The scoring was done as shown in the table

| Score | Lactobacillus morphotypes | Gardnerella and Bacteroides morphotypes | Curved gramvariable rods |
|---|---|---|---|
| 0 | 4+ | 0 | 0 |
| 1 | 3+ | 1+ | 1+ or 2+ |
| 2 | 2+ | 2+ | 3+ or 3+ |
| 3 | 1+ | 3+ | |
| 4 | 0 | 4+ | |

**Table 1: Nugent’s score**

For each smear whatever the organism and their numbers seen, scores were given. These scores were added up to yield a final score of 0 to 7 or more.

**Interpretations:**

- 0-3 : Normal
- 4-6 : Intermediate
- >/=7: Bacterial Vaginosis.

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## II. AIM & OBJECTIVES OF STUDY

1) To study the proportion of bacterial vaginosis (BV) in preterm and term labor, and to investigate its association as one of the causative factors of preterm labor.
2) To study Nugent score analysis as a predictor of bacterial vaginosis.
3) To determine the maternal and fetal complications associated with bacterial vaginosis.

## III. MATERIAL AND METHODS

**Source of data:**

Hundred pregnant women admitted to Rajarajeswari medical college for preterm labor (study group) who fulfilled the inclusion criteria were compared with equal number of women with term pregnancy in labor (control group) from November 2016 to May 2018 for a period of 18 months.

**Inclusion Criteria.**

**Preterm labor (Study group):**

1. Singleton pregnancy
2. Women with Gestational age less than 37 weeks with regular uterine contractions with or without cervical changes.
3. Intact fetal membranes.

**Term labor (Control Group):**

1. Singleton pregnancy.
2. Spontaneous in onset.
3. Regular uterine contractions with cervical dilatation.
4. Intact fetal membranes.

**Exclusion criteria:**

1. Multiple gestations.
2. Leaking per vaginum
3. Medical conditions like Pregnancy induced hypertension and gestational diabetes.
4. Placenta previa and abruption placenta.
5. Intrauterine fetal death.
6. Intrauterine growth restriction.
7. Rh isoimmunisation.
8. Antibiotic therapy in last one month.
9. Maternal medical disorders including Diabetes Mellitus, renal, cardiac and liver diseases.

**Method of data collection**: The study was approved by the Ethics Committee of Rajarajeswari Medical College, Bangalore. Informed consent was obtained from subjects who were enrolled in the study.

A case record form was used to record maternal age, obstetric history, past medical/surgical history, sexual history, socioeconomic status, history of drug and alcohol abuse, gestational age at admission, physical examination data, gestational age at delivery, the route of delivery, and the newborn birth weight and conditions.

The gestational age was calculated from the first day of the last menstrual period and earliest available ultrasound scan. If the estimated gestational age by menstrual and ultrasound estimation showed a difference of more than seven days, the ultrasound estimation was used.

Baseline parameters like pulse, blood pressure, temperature were recorded. Weight and height of the patient also were documented. Presence of pallor and pedal edema were evaluated. Cardiovascular and respiratory systems also were examined.

Abdominal examination was performed to study the height of uterus, presentation, position, lie of the fetus, liquor volume and fetal heart sound. These findings were recorded, along with number of uterine contractions, frequency of contractions and duration of each contraction.

Local examination It was done using a sterile vaginal speculum; vaginal swab was collected from upper one third of the vaginal wall. The vaginal swab was subjected to Gram staining and Nugent score for bacterial vaginosis was assigned. The pH of vaginal discharge was tested using litmus paper.

Per vaginum examination Length, dilatation of cervix and presence or absences of membranes were also noted.

**Investigations**

- Complete blood count
- Differential count
- Urine routine examination
- Ultrasound examination
- C-reactive protein (for preterm labor)
- Air dried smear of vaginal discharge for Gram‘s stain
- pH of vaginal discharge using litmus paper
- Saline wet mount of vaginal discharge for clue cell
- High vaginal swab for culture and sensitivity.

• **Primary outcome measures**: Diagnosis by Gram staining Predominance of large gram positive rods which were considered Lactobacillus morphotypes with or without smaller gram variable bacilli which were considered Gardnerella morphotypes constitutes normal vaginal fluid. A pattern of mixed vaginal flora which included Gardnerella morphotypes, gram negative rods, fusiform curved rods, gram positive cocci and absent or reduced number of Lactobacillus morphotypes was consistent with bacterial vaginosis.

Nugent‟s criteria[10] The laboratory diagnosis of bacterial vaginosis was done using Nugent‘s

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criteria which is considered as gold standard method.

The Gram stained smear was screened under oil immersion, the various morphotypes of Lactobacilli (Gram positive bacilli), Gardnerella/prevotella (short gram negative coccobacilli) and Mobiluncus (curved gram negative bacilli) were studied and approximate numbers were counted per oil immersion field and scoring was done. For each smear whatever the organism and their numbers seen, scores were given. These scores were added up to yield a final score of 0 to 7 or more.

**Interpretations**

0-3: Normal

- 4-6: Intermediate
- >/=7: Bacterial Vaginosis.

**Secondary outcome measures:**

1. Organisms grown on culture of high vaginal swab in both the groups.
2. CRP in both the groups.
3. Birth weight in both the groups.
4. Number of NICU admissions and neonatal complications in both the groups.
5. Post-partum complications in both the groups

**Definition of preterm labor and term labor**:

Preterm labor is defined by the World Health Organization as the onset of labor prior to the completion of 37 weeks of gestation, in a pregnancy beyond 20 weeks of gestation.

Premature labor is considered to be established if the following three criteria are present-

1. Regular contractions can be documented at least four in 20 minutes or eight in 60 minutes
2. Progressive change in the cervical score in the form of effacement of 80% or more
3. Cervical dilatation greater than 1cm.

Term labor is defined as the onset of regular uterine contractions accompanied by progressive dilatation and effacement of cervix and the descent of fetal presenting part at or after 37 completed weeks of gestation

**Statistical analysis**

SPSS version 22.0 (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.) was used to perform the statistical operations. Microsoft word and excel were used to prepare charts and tables. Categorical data has been represented as frequency and percentages.

Group (preterm and term), bacterial vaginosis (positive and negative) were considered as primary explanatory variable. Socio economic status, booked status, parity, gestational weeks, discharge, pH, clue cells, Nugent score, CRP, NICU admission, birth weight, mode of delivery, post-partum complications, high vaginal swab, previous history of STI‘s, APGAR score 1‘,APGAR score 5‘and neonatal complications were considered as other explanatory variables

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

The association between bacterial vaginosis and mode of delivery, post-partum complications, high vaginal swab, previous history of STI‘s, neonatal complications and vaginal discharge was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance.

**Normality test for quantitative variables**

A Shapiro- wilk‘s test ($p>0.05$) and a visual inspection of their histograms, normal Q-Q plots and box plots were also studied to assess the nature of distribution between bacterial vaginosis and parameters like maternal age, birth weight, gestational weeks, Nugent score, CRP, APGAR score at 1minute and APGAR score at 5 minutes.

The comparison between bacterial vaginosis and these parameters were assessed by comparing the median values. Mann Whitney U test was used to assess statistical significance. P value < 0.05 was considered statistically significant.

## IV. RESULTS

A total of 200 patients were included in the study.

| Parameter | Age (in years) Median (IQR | Mann Whitney U test (P value) |
|---|---|---|
| **Preterm labor BV positive** | 25 (23 to 27) | 0.039 |
| **Preterm labor BV negative** | 23 (21 to 26) | |
| **Term labor BV positive** | 24 (22 to 27) | 0.222 |
| **Term labor BV negative** | 23.50 (21 to 26) | |

**Table 2: Descriptive analysis of age (in years) in study population**

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Among the preterm, the mean age for BV positive group was 24.71 years, the minimum age was 18 years and maximum age was 38 years (95% CI 23.89to 25.53), and BV negative group the mean age was 23.87 years, minimum age was 19 years and maximum age was 35 years (95% CI 23.19to 24.55).The difference in the age between the bacterial vaginosis positive and negative groups was statistically significant (p value = 0.039). Among the term patients, the mean age for BV positive was 25.33 years, minimum age was 18 years and maximum age was 38 years (95% CI 24.14 to 26.52), and in BV negative group, the mean age was 24.01 years(95% CI 23.41 to 24.60). The difference in the age between the two groups was statistically not significant (p value = 0.222).

| Socio economic status | Preterm BV positive Frequency (%) | Preterm BV negative Frequency (%) | Term BV positive Frequency (%) | Term BV negative Frequency (%) |
|---|---|---|---|---|
| I | 0 (0%) | 5(8.1%) | 0 (0%) | 8(8.3%) |
| II | 0 (0%) | 7(11.4%) | 0 (0%) | 7(7.2%) |
| III | 1 (2.5%) | 10(16.3%) | 1(25%) | 15(15.6%) |
| IV | 9 (23.0%) | 15(24.5%) | 1(25%) | 18(18.7%) |
| V | 29 (74.3%) | 24(39.3%) | 2(50%) | 48(50%) |

**Table 3: Descriptive analysis of socio economic status in the study population**

Among the preterm patients, in BV positive group1 (2.5%) participant belongs to socio economic status class III, 9 (23.0%) participants were class IV, 29 (74.3%) participants were class V, and in BV negative group, 5 (8.1%) participants were class I, 7 (11.4%) participants were class II, 10 (16.3%) participants were socio economic status class III, s15 (24.5%) participants were class IV, 24(39.3%) participants were class V. Among term patients, in BV positive group 1 (25%) participant was class III, 1 (25%) participant was class IV. And in the BV negative group, 8 (8.3%) participants were socio economic status class I, 7 (7.2%) participants were class II, 15 (15.6%) participants were class III, 18(18.7%) participants were class IV, 48 (50%) participants were class V.

| Booked status | Preterm BV positive Frequency (%) | Preterm BV negative Frequency (%) | Term BV positive Frequency (% | Term BV negative Frequency (%) |
|---|---|---|---|---|
| Booked | 38(97.4%) | 59(96.7%) | 4 (100%) | 93 (96.8%) |
| Un booked | 1 (2.5%) | 2 (3.2%) | 0 (0%) | 3 (3.1%) |
| p-value | 0.68 | | 0.25 | |

**Table 4: Descriptive analysis of booked status in the study population**

Among the preterm group, in the patients with BV positive 38 (97.4%) participants were booked and 1 (2.5%) participant was unbooked. And in the patients with BV negative group 59 (96.7%) were booked and 2 (3.2%) were unbooked. Among the term group, in the BV positive 4 (100%) participants were booked. And in BV negative group 93 (96.8%) were booked, 3 (3.1%) participants were unbooked.The difference in proportion of booked status between bacterial vaginosis positive and negative groups in both preterm and term was statistically not significant.

| Parity | Preterm BV positive Frequency (%) | Preterm BV negative Frequency (%) | Term BV positive Frequency (% | Term BV negative Frequency (%) |
|---|---|---|---|---|
| Primi | 12 (30.7%) | 46 (40.9%) | 2(50%) | 43 (44.7%) |
| Multi | 27 (69.2%) | 36 (59.0% ) | 2(50%) | 53(55.2%) |
| p-value | 0.41 | | 0.76 | |

**Table 5: Descriptive analysis of parity in the study population**

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Among the preterm BV positive group,12(30.7%) participants were primigravidaand27 (69.2%) participants were multi parity, in the BV negative group 46 (40.9%) were primigravida and 36 (59.0%) were multiparous.Among the term BV positive group2 (50%) participants were primigravida and 2 (50%) participants were multiparous, and in BV negative group 43 (44%) were primigravida and 53 (55.2%) were multiparous. The difference in parity between bacterial vaginosis positive and negative groups was
statistically not significant

| Parameter | Gestational weeks Mean ± SD | Median | Min | Max | 95% C.I | |
|---|---|---|---|---|---|---|
| | | | | | Lower | Upper |
| Preterm BV positive | 35.12 ± 2.23 | 35.86 | 28.14 | 36.86 | 34.77 | 35.49 |
| Preterm BV negative | 34.43 ± 2.46 | 34.71 | 28.14 | 39.86 | 33.66 | 35.18 |
| Term BV positive | 38.57 ± 0.87 | 38.50 | 36.57 | 40 | 38.40 | 38.75 |
| Term BV negative | 37.52 ± 1.62 | 37.86 | 31.57 | 40 | 37.26 | 37.77 |

**Table 6: Descriptive analysis of Gestational weeks in fraction in study population**

Among the preterm BV positive group, the mean Gestation was 35.12 ± 2.23 in the study population. Range was between 28.14 weeks to 36.86 weeks (95% CI 34.77to 35.49) and in bacterial vaginosis negative group, the mean Gestation was 34.43 ± 2.46 in the study population. Range between was 28.14 weeks to 39.86 weeks (95% CI 33.66 to 35.18). Among the term BV positive group mean Gestation was 38.57 ± 0.87in the study population. Range was between 36.57weeks to 40 weeks (95% CI 38.40to 38.75) and in the bacterial vaginosis negative group, the mean Gestation was 37.52 ± 1.62 in the study Population. Range between was 31.57 weeks to 40 weeks (95% CI 37.26 to 37.77).The difference in the gestational weeks in fraction between the bacterial vaginosis positive and negative groups was statistically significant (p value <0.001).

| Discharge | Preterm labor Frequency (%) | Term labor Frequency (%) |
|---|---|---|
| Greenish Frothy | 4 (4%) | 0 (0%) |
| Greyish Frothy | 12 (12%) | 0 (0%) |
| Greyish white | 22 (22%) | 4 (4%) |
| White Curdy | 24 (24%) | 8 (8%) |
| White Mucoid | 19 (19%) | 37 (37%) |
| No discharge | 19(19% ) | 51 (51%) |

**Table 7: Descriptive analysis of discharge in preterm and term labor groups**

Among the preterm group, 4 (4%) participants had greenish frothy discharge, 12 (12%) participants had greyish frothy discharge, 22 (22%) participants had greyish white discharge, 24 (24%) participants had white curdy discharge, 19 (19%) participants had white mucoiddischargeand19(19%) participants had no discharge. Among the term group, 4 (4%) participants had greyish white discharge, 8 (8%) participants had white curdy discharge, 37 (37%)

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participants had white mucoid discharge and 51(51%) participants had no discharge.

| PH | Preterm BV positive Frequency (%) | Preterm BV negative Frequency (%) | Term BV positive Frequency (% | Term BV negative Frequency (%) |
|---|---|---|---|---|
| Acidic | 1 (2.5%) | 46 (75.4%) | 0(0%) | 78 (81.2%) |
| Basic | 38 (97.4%) | 15 (24.5%) | 4 (100%) | 18 (18.7%) |
| p-value | **<0.001** | | | **0.001** |

**Table 8: Descriptive analysis of pH in the study population**

Among the preterm BV positive group, 1 (2.5%) participant had acidic pH and 38 (97.4%) participants had basic pH. And in BV negative group 46 (75.4%) had acidic pH, 15(24.5%) had basic pH. Among the term BV positive group, all 4 participants had basic pH, BV negative group 78 (81.2%) had acidic pH and18 (18.7%) participants had basic pH. The difference in the pH between the bacterial vaginosis positive and negative groups was statistically significant (p value <0.001).

| Clue cells | Preterm labor Frequency (%) | Term labor Frequency (%) |
|---|---|---|
| Present | 6 (6%) | 0 (0%) |
| Absent | 94 (94%) | 100 (100%) |

**Table 9: Descriptive analysis of clue cells in preterm and term labor groups**

Among the preterm group, 6 (6%) participants had presence of clue cells and 94 (94%) participants had no clue cells. Among the term group, for all 100 (100%) participants had no clue cells.

| Parameter | Nugent score Mean ± SD | Median | Min | Max | 95% C.I | |
|---|---|---|---|---|---|---|
| | | | | | Lower | Upper |
| Preterm | 4.11 ± 2.45 | 3 | 1 | 9 | 3.62 | 4.60 |
| Term | 2.26 ± 1.24 | 2 | 1 | 9 | 2.01 | 2.51 |
| BV positive | 7 ± 1.5 | 7 | 6 | 9 | 6 | 9 |
| BV negative | 2 ± 1.0 | 2 | 1 | 3 | 1 | 3 |

**Table 10: Descriptive analysis of Nugent score in study population**

Among the preterm group, the mean Nugent score was 4.11 ± 2.45 in the study population. Range between was 1 to 9 (95% CI 3.62to 4.60). Among the term group mean Nugent score was 2.26 ± 1.24in the study population. Range between was 1 to 9 (95% CI 2.01to 2.51).The difference in the Nugent score between bacterial vaginosis positive and negative groups was statistically significant (p value <0.001).

| Bacterial vaginosis | Preterm labor Frequency (%) | Term labor Frequency (%) |
|---|---|---|
| **Positive** | 39 (39%) | 4 (4%) |
| **Negative** | 61 (61%) | 96 (96%) |

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**Table 11: Descriptive analysis of bacterial vaginosis in the study population**

Among the preterm group, 39 (39%) participants were BV positive and 61 (61%) participants were BV negative. Among the term group, 4 (4%) participants were BV positive and 96 (96%) participants were BV negative. The difference in proportion of preterm and term labor between bacterial vaginosis positive and negative groups was statistically significant (P value <0.001).

| Parameter | CRP Mean ± SD | Median | Min | Max | 95% C.I | |
|---|---|---|---|---|---|---|
| | | | | | Lower | Upper |
| Preterm | 1.76 ±1.01 | 1.50 | 0.4 | 4 | 1.56 | 1.96 |
| Term | 1.13 ± 0.54 | 1 | 0.4 | 2.5 | 1.02 | 1.24 |
| BV positive | 2.64 ± 0.83 | 2.80 | 0.9 | 4 | 2.39 | 2.90 |
| BV negative | 1.12 ± 0.52 | 1 | 0.4 | 2.6 | 1.03 | 1.20 |

**Table 12: Descriptive analysis of CRP in study population**

Among the preterm group, the mean C-reactive protein was 1.76 ±1.01 in the study

Population, minimum level was 0.4 mg/dl and maximum level was 4mg/dl (95% CI 1.56 to 1.96). Among the term group mean C reactive protein was 1.13 ± 0.54 in the study population, minimum level was 0.4 mg/dl and maximum level was 2.5mg/dl (95% CI 1.02 to 1.24). Among the bacterial vaginosis positive group, the mean C reactive protein was 2.64 ± 0.83 mg/dl in the study population, minimum level was 0.9 mg/d land maximum level was 4mg/dl (95% CI 2.39 to 2.90). Among the bacterial vaginosis negative group, the mean C reactive protein was 1.12 ± 0.52 mg/dl in the study population, minimum level was 0.4 mg/dl and maximum level was 2.6mg/dl (95% CI 1.03 to 1.20). The difference in the CRP between bacterial vaginosis positive and negative groups was statistically significant (p value <0.001).

| NICU admission | Preterm BV positive Frequency (%) | Preterm BV negative Frequency (%) | Term BV positive Frequency (% | Term BV negative Frequency (%) |
|---|---|---|---|---|
| Yes | 15 (38.4%) | 6 (9.8%) | 1 (25%) | 4 (4.1%) |
| No | 24 (61.5%) | 95 (90.1%) | 3 (75%) | 92 (95.8%) |
| p-value | **0.001** | | 0.48 | |

**Table 13: Descriptive analysis of NICU admission in the study population**

Among the preterm BV positive group, 15 (38.4%) babies had NICU admission, BV negative group 6 (9.8%) had NICU admissions. Among the term BV positive group, 1 (25%) baby had NICU admission and in BV negative group 92 (95.8%) had NICU admissions. The difference in proportion of NICU admission among preterm patients between bacterial vaginosis positive and negative groups was statistically significant (P value = 0.001).

| Parameter | Birth weight Mean ± SD | Median | Min | Max | 95% C.I | |
|---|---|---|---|---|---|---|
| | | | | | Lower | Upper |

| | | | | | | |
|---|---|---|---|---|---|---|
| Preterm | 2.28 ± 0.51 | 2.30 | 0.70 | 3.25 | 2.18 | 2.38 |
| Term | 2.83 ± 0.39 | 2.80 | 1.80 | 3.90 | 2.75 | 2.91 |
| BV positive | 2.08 ± 0.55 | 2.10 | 0.70 | 3 | 1.92 | 2.25 |
| BV negative | 2.68 ±0.45 | 2.70 | 1.20 | 3.90 | 2.61 | 2.75 |

**Table 14: Descriptive analysis of Birth weight in study population**

Among the preterm group, the mean birth weight was 2.28 ± 0.51 in the study population. Range between was 0.70kg to 3.25kg (95% CI 2.18 to 2.38). Among the term group mean birth weight was 2.83 ± 0.39 in the study population. Range between was 1.80kg to 3.90kg (95% CI 2.75 to 2.91). Among the bacterial vaginosis positive group, the mean birth weight was 2.08 ± 0.55 in the study population. Range between was 0.70kg to 3kg (95% CI 1.92 to 2.25). Among the bacterial vaginosis negative group, the mean birth weight was 2.68 ± 0.45 in the study population. Range between was 1.20 kg to 3.90kg (95% CI 2.61 to 2.75). The difference in the birth weight between bacterial vaginosis positive and negative groups was statistically significant (p value <0.001).

| **Mode of delivery** | **Preterm labor Frequency (%)** | **Term labor Frequency (%)** | **Bacterial vaginosis positive Frequency (%)** | **Bacterial vaginosis negative Frequency (%)** |
|---|---|---|---|---|
| LSCS | 39 (39%) | 29 (29%) | 17 (39.5 %) | 51 (32.5 %) |
| PTVD | 59 (59%) | 1(1%) | 24 (55.8 %) | 36 (22.9 %) |
| VBAC | 1(1%) | 0 (0%) | 1 (2.3 %) | 0 (0 %) |
| FTND | 1(1%) | 67 (67%) | 1 (2.3 %) | 67 (42.7 %) |
| Instrumental | 0 (0%) | 3 (3%) | 0 (0 %) | 3 (1.9 %) |

**Table 15: Descriptive analysis of mode of delivery in the study population**

Among the preterm group, 39 (39%) participants had LSCS, 59 (59%) participants had PTVD, 1 (1%) participant had VBAC and 1 (1%) participant had FTND. Among the term group, 29 (29%) participants had LSCS, 1 (1%) participants had PTVD, 67 (67%) participants had FTND and 3 (3%) participant had instrumental delivery.

| **Post-partum complications** | **Preterm BV positive Frequency (%)** | **Preterm BV negative Frequency (%)** | **Term BV positive Frequency (%** | **Term BV negative Frequency (%)** |
|---|---|---|---|---|
| Fever | 17 (43.5%) | 3 (4.9%) | 0 (0%) | 14 (14.5%) |
| Atonic PPH | 0 (0%) | 4 (6.5%) | 0 (0%) | 3 (3.1%) |
| Nil | 23 (58.9%) | 54 (88.5%) | 0 (0%) | 79 (82.2%) |
| P value | **<0.001** | | NA | |

**Table 16: Descriptive analysis of post-partum complications in the study population**

Among the preterm BV positive group, 17 (43.5%) participants had fever and in BV negative group 3 (4.9%) participants had fever, 4 (6.5%) had atonic PPH. Among the term BV positive there were no maternal complications and in BV negative group 14 (14.5%) had fever and 3 (3.1%) had atonic PPH. The difference in postpartum complications among bacterial vaginosis positive and bacterial vaginosis negative groups in preterm patients was statistically significant (p value =<0.001).

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| High vaginal swab | Preterm labor Frequency (%) | Term labor Frequency (%) | Bacterial vaginosis positive Frequency (%) | Bacterial vaginosis negative Frequency (%) |
|---|---|---|---|---|
| Normal | 64 (64%) | 95 (95%) | 23 (53.5%) | 136 (86.6%) |
| Candida | 16 (16%) | 5 (5%) | 0 (0%) | 21 (13.4%) |
| Enterococcus | 16 (16%) | 0 (0%) | 16 (37.2%) | 0 (0%) |
| Group B Streptococcus | 4 (4%) | 0 (0%) | 4 (9.3%) | 0 (0%) |

**Table 17: Descriptive analysis of high vaginal swab in the study population**

Among the preterm group, 64 (64%) participants had Normal, 4 (4%) participants had Candida, 16 (16%) participants had enterococcus and 4 (4%) participants had group B streptococcus. Among the term group, 95 (95%) participants had Normal and 5 (5%) participants had Candida.

| Previous history of STI"s | Preterm BV Positive Frequency (%) | preterm labor Frequency (%) | Bacterial vaginosis positive Frequency (%) | Bacterial vaginosis negative Frequency (%) |
|---|---|---|---|---|
| Yes | 4(4%) | 4(4%) | 0 (0%) | 8 (5.1%) |
| No | 96 (96%) | 96 (96%) | 43 (100%) | 149 (94.9%) |

**Table 18: Descriptive analysis of previous history of STI"s in the study population**

Among the preterm group, 4(4%) participants had previous history of STI's. Among the term group, 95 (95%) participants had previous history of STI's. Among the bacterial vaginosis negative group, 8 (5.1%) participants had previous history of STI's.

| Parameter | APGAR1 minutes Mean ± SD | Median | Min | Max | 95% C.I | |
|---|---|---|---|---|---|---|
| | | | | | Lower | Upper |
| Preterm | 7.37 ± 1.07 | 8 | 3 | 8 | 7.15 | 7.58 |
| Term | 7.81 ± 0.59 | 8 | 5 | 9 | 7.69 | 7.92 |
| BV positive | 7.07 ± 1.43 | 8 | 3 | 8 | 6.62 | 7.51 |
| BV negative | 7.73 ±0.61 | 8 | 5 | 9 | 7.63 | 7.82 |

**Table 19: Descriptive analysis of APGAR at 1minute in study population**

Among the preterm group, the mean APGAR 1 minute was 7.37 ± 1.07 in the study population. Range between was 3 to 8 (95% CI 7.15to 7.58). Among the term group, the mean APGAR 1 minute was 7.81 ± 0.59 in the study population. Range between was 5 to 9 (95% CI 7.69to 7.92). Among the bacterial vaginosis positive group, the mean APGAR 1 minute was 7.07 ± 1.43 in the study population. Range between was 3 to 8 (95% CI 6.62 to 7.51). Among the bacterial vaginosis negative group, the mean APGAR 1 minute was 7.73 ± 0.61 in the study population. Range between was 5 to 9 (95% CI 7.63 to 7.82). The difference in the APGAR 1minute between bacterial vaginosis positive and negative groups was statistically significant (p value = 0.002).

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| Parameter | APGAR 5 minutes Mean ± SD | Median | Min | Max | 95% C.I | |
|---|---|---|---|---|---|---|
| | | | | | Lower | Upper |
| Preterm | 8.49 ± 0.88 | 9 | 4 | 9 | 8.32 | 8.66 |
| Term | 8.39 ± 0.29 | 9 | 8 | 10 | 8.87 | 8.99 |
| BV positive | 8.30 ± 1.16 | 9 | 4 | 9 | 7.94 | 8.66 |
| BV negative | 8.82 ±0.43 | 9 | 7 | 10 | 8.75 | 8.89 |

**Table 20: Descriptive analysis of APGAR at 5minutes in study population**

Among the preterm group, the mean APGAR 5 minutes was 8.49 ± 0.88 in the study population. Range between was 4 to 9 (95% CI 8.32to 8.66). Among the term group, the mean APGAR 5 minutes was 8.39 ± 0.29 in the study population. Range between was 8 to 10 (95% CI 8.87to 8.99). Among the bacterial vaginosis positive group, the mean APGAR 5 minutes was 8.30 ± 1.16 in the study population. Range between was 4 to 9 (95% CI 7.94 to 8.66). Among the bacterial vaginosis negative group, the mean APGAR 5 minutes was 8.82 ± 0.43 in the study population. Range between was 7 to 10 (95% CI 8.75 to 8.89). The difference in the APGAR 5minutes between bacterial vaginosis positive and negative groups was statistically significant (p value 0.001).

| Neonatal complications | Preterm BV positive Frequency (%) | Preterm BV negative Frequency (%) | Term BV positive Frequency (% | Term BV negative Frequency (%) |
|---|---|---|---|---|
| RDS | 1(2.5%) | 0 (0%) | 1 (25%) | 2 (2%) |
| Sepsis | 8 (20.5%) | 2 (3.2%) | 0 (0%) | 2 (2%) |
| Nil | 30 (76.9%) | 59(96.7%) | 3 (75%) | 92 (95.8%) |
| P value | **<0.001** | | 0.03 | |

**Table 21: Descriptive analysis of neonatal complications in the study population**

Among the preterm BV positive group, 1(2.5%) participant had RDS, 8 (20.5%) participants had sepsis, and in BV negative group 2 (3.2%) participants had sepsis.

Among the term BV positive group, 1 (25%) participant had RDS and in BV negative group 2 (2%) participants had sepsis and 2 (2%) participants had RDS. The difference in proportion of neonatal complications between bacterial vaginosis positive and negative groups was statistically significant (P value <0.001).

| Clue cells | Bacterial vaginosis Positive | Bacterial vaginosis Negative |
|---|---|---|
| **Present** | 6 (14%) | 0 (0%) |
| **Absent** | 37 (86%) | 157 (100%) |

**Table 22: Association of bacterial vaginosis with clue cells**

Among the bacterial vaginosis positive group, 6 (14%) participants had clue cells and 37 (86%) participants did not have clue cells.

## V. DISCUSSION

Bacterial vaginosis is the most common lower genital tract disorder among women of reproductive age and is extremely prevalent among low-income, urban pregnant women and is frequently chronic. Bacterial vaginosis is often asymptomatic. This is not due to classical infection

caused by a single pathogen, but is rather a complex alteration of the vaginal ecosystem, where the physiologic lactobacilli- dominant flora is replaced by an overgrowth of mixed flora, with a high concentration of anaerobic bacteria, normally present in the vagina in substantially fewer numbers.

In our study, we observed that there was statistically significant difference in terms of the maternal age between the preterm group who have bacterial vaginosis (24.71 ± 4.15 years) and Bacterial negative group (23.87 ± 3.44). The similar finding was also noted in the studies by Chaterjee P et al (25.6 years in the bacterial vaginosis positive group and 23.3 years in the bacterial vaginosis group) and Chawanpaiboon S et al (26.7 years in preterm group and 26.6 years in the term group).[3, 12]

In our study, the mean gestational age in the preterm group was 35.12 weeks and the mean gestational age in the term group was 38.57 weeks. Chaterjee P et al observed that the mean gestational age in preterm group was 33.5 weeks and the mean gestational age in term group was 39.0 weeks.[3]Chawanpaiboon S et al observed that the mean gestational age in preterm group was 33.6 weeks and the mean gestational age in term group was 38.6 weeks.[12]

In our study, there were 38% primigravidas and 62% multigravidas in the preterm group and 46% primigravidas and 54% multigravidas in the term group. Chawanpaiboon S et al observed that there were 60% primigravidas and 40% mutligravida in preterm group while the term group had 51.8% primigravidas and 48.2% multigravida.[12] In the study by Chaterjee P et al; both the preterm and term groups had equal number of primigravidas and multigravidas.[3]

In the present study, majority of pregnant women (72%) suffering with bacterial vaginosis belong to lower socioeconomic status. Few studies have reported association of bacterial vaginosis with low socioeconomic status and lack of proper vaginal hygiene practices eg: using clothes during menstruation etc.[13]

In our study, preterm labour is more frequent in low socioeconomic group, which was similar to the observations reported by Whitehead NS et al.[14] In our study, the preterm labour group had significantly more number (81%) of patients with different grades of discharge as compared to term group(49%), which coincides with the findings of Karan et al who reported 72% of cases in preterm and 50% in term group.[15] Nous et al reported40% of cases in preterm and 28% in term group.[16] Study done by Paulo. CG et al have proved that lower genital tract infections are very common among apparently healthy looking pregnant women with an overall prevalence of 40- 54%.[17]

In our study, about 53% of Preterm cases, and 22% of term cases had basic vaginal pH. The findings were similar to those of Priyanka Chatterjee et al where Preterm group had more number of patients with basic vaginal pH as compared to term group (44% vs.14%).[3]

Clue cells in our study, are not detectable in term labour group, where as in preterm group, only 6% cases had clue cells. Absence of clue cells can be explained by the possibility of them having chronic infection in which clue cells were absent due to local immune response to IgA antibodies. According to Easmon et al. it is not always necessary to see clue cells to make a diagnosis of BV and it is not included in the scoring system by Nugent which is more systematic and has a specificity of 95%.Findings in the study of Paulo. CG et al have proved that lower genital tract infections are very common among apparently healthy looking pregnant women with an overall prevalence of 40-54%.[17]

The prevalence of BV during pregnancy has been reported as 20-30% in various studies. The present study estimated the prevalence of BV among preterm labour group as 39% and among term labour as 4% which coincides with the findings of Svareet al.[18] Findings in the study of Hiller and co-workers and Subtil et al demonstrated the increased association of preterm delivery with bacterial vaginosis which is also demonstrated in the present study.[19, 20]

The mean C - reactive protein value recorded in preterm labour was 1.76 and in term labour group it was 1.13. similar observations were reported by Priyanka Chatterjee1 et al where CRP in preterm labour group was 1.287 and in term labour group it was 0.748.3 In the study done by Halder A et.al out of 250 patients, 78 (31.2%) were CRP positive and 172 (68.8%) were CRP negative.[21]

Incidence of neonatal complications in our study, were higher among infants born to preterm labour group and those with bacterial vaginosis positive (23%) than among group bacterial vaginosis negative group (3.2%). Findings of Hay AE et al confirms with our findings but some studies have reported other factors in association with bacterial vaginosis as a cause of increases neonatal complications.[22]

In the present study, preterm babies had lower birth weight (2.28kg), than term babies (2.83kg) for obvious reasons. Babies born to mothers with bacterial vaginosis positive weighed

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2.08kg on an average, where as those babies born to bacterial vaginosis negative mothers had an average weight of 2.68kg .Study done by Hillier et al also showed the relation of bacterial vaginosis with a significantly reduced mean birth weight. Study by Svare et al also showed lower mean birth weight in bacterial vaginosis.[19]

The number of patients who had other genital tract infections was more in preterm labour group as compared to term group. 64 % of preterm labour cases are normal compared to 95% of term labour case. 16% of preterm cases had Candida infection, where as only 5% of term cases had Candida infection. 16% of preterm cases had Enterococcus infection and 4% of preterm patients were positive for Group B Streptococci. Similar findings were observed by kiran etal.[15] This finding is contrary to findings of Benchetrit et al who reported the prevalence of GBS as 26% among pregnant women in his study.[23] In the study done by Priyanka Chatterjee et al, the number of patients who had other genital tract infections were more in PTL group as compared to term group (22% vs. 6%). The commonest infections found were Enterococcus (12%) followed by Candida (8%) and Group B Streptococcus (2%) in PTL group and Candida (7%), Enterococcus (6%) and Group B Streptococcus (1%) in term labour group.3 Simoes et al. studied Candida albicans and found a prevalence of 19.3% for vaginal candidiasis in normal pregnant women in the third trimester.[24]

In the present study, Candida albicans was identified in 16% of Preterm labour group and 5% of term labour group. In the previous studies it has been shown that this association was influenced by increased levels of circulating oestrogens and deposition of glycogen and other substrates in the vagina during pregnancy. Microbes that inhabit the vagina play an important role in the spread of illnesses and the maintenance of a healthy genital tract.

In a study done by Priyanka Chatterjee et al, they have observed that 12% of preterm labour cases had previous history of sexually transmitted infections as compared to 2% in term labour group.[3] In our study in both term and preterm groups 4% of cases had previous history of sexually transmitted diseases. No one with Bacterial vaginosis positive reports had previous history of STDs, where as 5% of patients with negative bacterial vaginosis reports had previous history of STDs. In a study done by Deepa Masand et al, 16% of preterm labour group had previous history of sexually transmitted infections as compared to 4% in term labour group.[24]

In our study, in preterm labour having bacterial vaginosis group, 1% of neonates had respiratory distress and 9% had sepsis, as compared to 3% neonates born to term mothers had respiratory distress and 2% had sepsis.4% of neonates born to bacterial vaginosis positive mothers had respiratory distress and 16% had sepsis, when compared to 1% of neonates born to bacterial vaginosis negative mothers had respiratory distress and 2.5% had sepsis.

In a study done by Priyanka Chatterjee et al, in preterm labour group 20% of neonates born to BV positive mothers had congenital pneumonia, as compared to 11.4% of neonates born to BV negative mothers who had respiratory distress.[3] In term labour group none of the neonates of BV positive mothers had neonatal complications, while 4.1% of neonates of BV negative mothers had respiratory distress, whereas none of the neonates of BV positive mothers had neonatal complications. The difference in the observations can be explained by the probable chances of other factors giving rise to such a complication in the term group such as birth asphyxia.

We found that the proportion of genital tract colonization with BV was higher among women with Preterm labour compared with women who had term labour. The clinical implications of our study findings would be that bacterial vaginosis infection could contribute significantly to the occurrence of preterm labour

| No | Size of study population | Size of study population | % of BV in preterm group | % of BV in term group |
|---|---|---|---|---|
| 1 | Present study | 200 | 39 | 4 |
| 2 | Chatterjee P | 100 | 30 | 4 |
| 3 | Eschenbach | 150 | 49 | 24 |
| 4 | Nejad V M | 160 | 25 | 11.3 |
| 5 | Renu Jain | 150 | 38 | 16 |

Table 23: Comparison of the present study with similar studies

The strengths of our study include the method employed in diagnosing BV. The use of Nugent scoring system to diagnose bacterial vaginosis in this study allows for the correct

identification of bacterial morphotypes in abnormal vaginal flora. Compared to other diagnostic scoring systems for bacterial vaginosis, Nugent scoring system has greater reproducibility and sensitivity, and it is the gold standard diagnostic scoring system for bacterial vaginosis.

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