Section: Obstetrics & Gynaecology

Research

ASSOCIATION BETWEEN BACTERIAL VAGINOSIS WITH PRETERM LABOUR IN PREGNANT WOMEN: A PROSPECTIVE STUDY IN A TERTIARY MEDICAL COLLEGE IN NORTHEAST INDIA

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Abstract

Background: To estimate proportion of pregnant women having Bacterial Vaginosis (BV) and secondly determination of the association between it and preterm labour. **Materials and Methods:** A prospective study was carried out in the Department of Obstetrics and Gynaecology, Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur from November 2020 to October 2022. Pregnant women attending the OPD or admitted in the Ward of the Department of Obstetrics & Gynaecology, JNIMS and whose period of Gestation were preterm and have symptoms of bacteruria and bacterial vaginosis and who were willing to undergo required investigations and participate were included. They were selected by consecutive sampling till the sample was reached. Chi-square test was used for test of significance and p-value of less than 0.05 was taken as significant. Approval was taken from the institutional ethics committee and informed consent was taken from all the participants. **Result:** Out of 270 participants, bacterial vaginosis was present in 158 which accounts for 58.5%. Of the 158 cases of bacterial vaginosis, 54.4% (n = 86) were found to be associated with preterm labour, which is found to be statistically significant (p-value = 0.002), and among the same cases of bacterial vaginosis, 35.4% (n = 56) were found to be associated with preterm birth as pregnancy outcome, which is also statistically significant (p-value = 0.001). **Conclusion:** Bacterial vaginosis prevalence was high in the study and this study found a positive association of bacterial vaginosis with preterm labour and preterm birth. This needs to be confirmed by further studies with better study design and sample size.

INTRODUCTION

Bacterial vaginosis (BV) is an alteration of normal vaginal bacterial flora i.e., a shift from normal abundance of Lactobacillus spp. to the overgrowth of various gram negative and/or anaerobic bacteria.[1] Anaerobic bacteria can be found in less than 1% of the flora of normal women. In women with BV, however, the concentration of anaerobes, and G. vaginalis and Mycoplasma hominis, is 100 to 1,000 times higher than in normal women.[2] It is associated with significant adverse sequelae. Pregnant women with BV are at risk for premature rupture of the membranes, preterm labour and delivery, chorioamnionitis, and post-caesarean endometritis.[3]

Preterm labour is defined as the onset of labour before 37 completed weeks of gestation after the period of viability. Preterm labour is a leading cause of neonatal morbidity and mortality worldwide. Approximately 1 million children die each year due to complications of preterm birth.[4] Its etiology is multifactorial. Several studies in developed countries have reported an association between bacterial vaginosis in pregnancy and preterm labour. Women with bacterial vaginosis have been documented to have strong risk factor of preterm birth, but the relative risk can be substantially higher

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when bacterial vaginosis is diagnosed earlier in pregnancy.[5] This study was conducted in an attempt to establish an association between the presence of bacterial vaginosis in pregnant women and the development of preterm labour in a Tertiary Medical college in North East India. The main objective of the study was to estimate proportion of pregnant women having Bacterial Vaginosis (BV) and secondly determination of the association between it and preterm labour.

MATERIALS AND METHODS

This prospective study was carried out in the Department of Obstetrics and Gynaecology, Jawaharlal Nehru Institute of Medical Sciences, Imphal, Manipur from November 2020 to October 2022. Pregnant women attending the OPD or admitted in the Ward of the Department of Obstetrics & Gynaecology, JNIMS and whose period of Gestation were preterm and who were willing to undergo required investigations and participate were included. Singleton pregnancy of any gravida or parity were included. Pregnant women who are found to have bacteriuria, both asymptomatic as well as symptomatic cases, which is defined as urine culture positive cases i.e., colony count of >1,00,000 colony forming units (CFU)/mL, with or without symptoms were included. Pregnant women who report vaginal discharge at any time during pregnancy, and which fulfil Amsel's criteria[6] for bacterial vaginosis, which includes –

- A fishy vaginal odour which is particularly noticeable following coitus, and vaginal discharge are present.
- Vaginal secretions are grey and thinly coat the vaginal wall.
- The pH of these secretions is higher than 4.5.
- Addition of KOH to the vaginal secretions releases a fishy, amine-like odour (the whiff test)
- Microscopy of the vaginal secretions reveals an increased number of clue cells, and leukocytes are conspicuously absent (based on Nugent's scoring).

Preterm labour was defined as onset of labour before 37 completed weeks of pregnancy but after period of viability, with regular uterine contractions occurring once in every 5-8 minutes or less accompanied by one or more of the following:

- Progressive changes in cervix.
- Cervical dilatation of more than or equal to 1cm.
- Cervical effacement of more than or equal to 80%.

Patients with other known risk factors of preterm labour such multiple gestation, abruptions, smokers, Pre-eclampsia, PPROM, Cervical incompetence, Domestic violence, Retained IUDs, Poly/Oligohydramnios, Maternal age below 16yrs or over 40yrs, Congenital abnormalities of uterus, or IUGR/IUD were excluded. Patients whose culture and sensitivity screening results show other infections like fungal/candida infections, viral infections, Gonorrhoea, Syphilis were also excluded. Sample size of 270 was calculated by considering the probability of event in unexposed group as 0.33 and probability of event in experimental group as 0.4 with a power of 80% at 95% confidence level and also consideration a 15% loss to follow-up. All eligible cases were enrolled by consecutuve sampling until the sample size was achieved. A pre-tested semi-structured proforma was used for data collection. The study was undertaken after obtaining proper clearance from the ethics committee of JNIMS. Written informed consent was taken from all the study participants. After taking detailed history, general and systemic physical examination including obstetrical examination was done for all participants. Gestational age was estimated by last menstrual period and was confirmed by first trimester scan. Routine investigations were sent either at JNIMS or any accredited laboratories. For screening of bacteriuria, patients were instructed to collect mid-stream urine samples which were then sent for cytology and culture-sensitivity at accredited laboratories at the point of induction into the study and at routine follow ups to detect infection at any point. Those participants who tested positive for Bacteriuria, were treated with appropriate antimicrobial therapy according to culture-sensitivity report – usually Nitrofurantoin or Fosfomycin or both. Such participants were followed up till the termination of their pregnancy and the pregnancy outcomes were noted. Statistical analysis was performed using IBM SPSS version 21. Differences in categorical variables were tested using a Chi-square test. A p-value < 0.05 was considered statistically significant in all statistical tests. For sampling of patients with discharge per vaginum to test for Bacterial Vaginosis, patients were placed in lithotomy position and two High Vaginal Swab samples were taken from the posterior fornixes by sterile swabs via per speculum examination under proper sterile technique. One of the collected samples were examined for colour and consistency of the discharge, vaginal pH tested using Litmus paper and Amine's test (using 10% KOH solution) was done to see the fulfilment of Amsel's criteria. The other sample was used to make stain on a clean glass slide and then sent for Gram's staining at the Department of Microbiology, JNIMS to look for clue cells or to calculate Nugent's score. Reports of the sent samples were collected and recorded. Those participants who tested positive either for Bacteriuria or Bacterial Vaginosis (BV) or both, were treated with appropriate antimicrobial therapy according to Culture-Sensitivity report – usually Nitrofurantoin or Fosfomycin or both for Bacteriuria cases, and Fenticonazole 600mg for BV cases, or a combination of the therapy in cases of concomitant infection. Such participants were followed up till the

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termination of their pregnancy and the pregnancy outcomes were noted, whether it was Term or Preterm Birth, irrespective of the method of termination.

RESULTS

More than half of the participants were from the age group 21-30 years, 62.2% of them were from urban areas and more than one-third of them were multipara and from low SES [Table 1]. Bacterial vaginosis was present in 58.5% (n = 158), out of 270 participants in this study, bacteriuria in 70.4% (n = 190 cases) and concomitant infection with both these conditions in 28.9% (n = 78) cases [Table 2].

Of the 158 cases of bacterial vaginosis, 54.4% (n = 86) were found to be associated with preterm labour, which is found to be statistically significant (p-value = 0.002), and among the same cases of bacterial vaginosis, 35.4% (n = 56) were found to be associated with preterm birth as pregnancy outcome, which is also statistically significant (p-value = 0.001). This is illustrated in [Table 4].

Table 1: Distribution of most common socio-demographic variables among study participants

Socio-demographic	Frequency	Percentage
Age in years (21-30)	153	56.7
Urban	168	62.2
Low SES	188	69.6
Multipara	180	66.7

Table 2: Distribution of bacterial vaginosis, bacteriuria and concomitant infection among the total participants

Bacterial vaginosis ❖ Present ❖ Absent	**Frequency (%)** ❖ 158 (58.5) ❖ 112 (41.5)
Bacteriuria ❖ Present ❖ Absent	Frequency (n) ❖ 190 (70.4) ❖ 80 (29.6)
Concomitant infection ❖ Present ❖ Absent	Frequency (n) ❖ 78 (28.9) ❖ 192 (71.1)

Table 3: Pregnancy outcome of study participants

Outcome indicator	Frequency (%)
Preterm Labor Present Absent	 126 (46.7) 144 (53.3)
Preterm Delivery Present Absent	 70 (25.9) 200 (74.1)

Table 4: Association between bacterial vaginosis and pregnancy outcome.

Bacterial vaginosis	Preterm labour		P- value	Bacterial vaginosis	Pregnancy outcome		P- value
	No N (%)	Yes N (%)			Preterm N (%)	Term N (%)	
Negative	72 (64.3)	40 (35.7)	0.002	Negative	14 (12.5)	98 (87.5)	0.001
Positive	72 (45.6)	86 (54.4)		Positive	56 (35.4)	102 (64.6)	

DISCUSSION

The prevalence of bacteriuria and bacterial vaginosis in this study was 70% and 58.5% respectively. Several previous studies have shown a prevalence of bacteriuria in pregnancy between 20-35% of cases,[7] and that of bacterial vaginosis was found to range between 16 – 32 % cases,[8] which is lower than our current prevalence rate of 70.4% and 58.5% respectively. This may be because of the fact that our participants were enrolled from a high-risk hospital-based population group, and also due to the selection process in the present study where participants were enrolled based on the presence of either bacteriuria or bacterial vaginosis or both to fulfil selection criteria, which ultimately increases the number participants having the two conditions in the study.

In this study, out of the total bacterial vaginosis women, 54.4% were significantly associated with preterm labour and 35.4% were significantly associated with preterm birth. This finding was in concordance with the finding by Donders et al,[9] where bacterial vaginosis was associated with increased risks of preterm birth and miscarriage. In the study by Leitich H et al,[10] also, bacterial vaginosis present in early pregnancy was a strong risk factor for preterm delivery and spontaneous abortion. Moreover, Bánhidy F et al,[11] found that preterm birth was significantly higher in cases with VV-BV not receiving antimicrobial therapy. Oakeshott P et al,[12] also found that there was decreased incidence of preterm birth and second

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trimester miscarriage when bacterial vaginosis was treated at an early stage of pregnancy. Hence, this study finding is consistent with the findings of other previous studies that there is a positive association between bacterial vaginosis and preterm labour and preterm birth.

Concomitant infection was significantly associated with preterm labour and preterm birth in this study. In a previous study by Verma Indu et al,[13] urogenital infection was found in 36.54% cases of preterm labour, which is close to the finding in this study.

Of the total 270 participants, there were 46.7% (n = 126) cases of preterm labour, out of which 55.6% (n = 70) progressed to preterm birth, which is statistically significant (p-value = 0.001). This is lower than the global rate of about 75% of spontaneous onset preterm labour which progress to preterm birth as found in a study conducted by Vogel JP et al,[14] This may be due to small sample size of the study, and the more or less identifiable causes of preterm labour for the participants of our study, i.e. bacteriuria and bacterial vaginosis, which are mostly manageable with appropriate treatments and counselling, although other factors which could contribute to preterm labour cannot be definitely ruled out.

CONCLUSION

Prevalence of bacterial vaginosis is high in the study and this study found a positive association of bacterial vaginosis with preterm labour and preterm birth. But some potential confounding factors like mistaken LMP, history of previous preterm birth, personal and perineal hygiene, nature of daily activity or work during pregnancy, maternal gestational weight gain, anaemia, prediabetes or gestational diabetes, pregnancy-induced hypertension, diet structure, sexual activity and sexual partner(s), psychological state such as anxiety and stress, which might have direct or indirect impact on onset of preterm labour and preterm birth, were missing in this study due to high percentage of missing information. Spontaneous onset preterm labour is also a major contributor in the global incidence of preterm labour and preterm birth in general, whose contribution in the overall prevalence cannot be definitely ruled out. These may affect the development of preterm labour or birth in the patients. Therefore, further studies with better study design and with larger population base are needed to confirm the findings of the current study.

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