PREVALENCE OF BACTERIAL VAGINOSIS IN CASES OF PRETERM LABOUR AND ITS EFFECTS ON OBSTETRIC OUTCOME

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ABSTRACT

BACKGROUND

Abnormal vaginal flora is an important cause of preterm labour with subsequent delivery of a preterm newborn, which is associated with significant morbidity and mortality. Bacterial vaginosis is a condition where there is a decrease in concentration of Lactobacillus and an increase in pathogenic bacteria.

The aim of the study is to study the-

1. Prevalence of bacterial vaginosis in preterm labour in comparison with term pregnant women in labour.
2. Adverse obstetric outcome associated with bacterial vaginosis.

MATERIALS AND METHODS

Study was carried out in the Department of Obstetrics and Gynaecology and Microbiology, Government Medical College, Kozhikode. It is a prospective, cross-sectional descriptive study from August 2012 to January 2013. Subjects included 100 women in spontaneous preterm labour. 100 term women in labour were the controls. All patients had vaginal discharge collected from the posterior vaginal fornix with cotton swabs. Clinical composite criteria by Amsel's and Nugent's scoring was used to diagnose bacterial vaginosis. The saline wet mount of the discharge was examined microscopically for 'clue' cells, 10% KOH added to get an amine odour. Vaginal smear was Gram stained and evaluated by Nugent's criteria. Obstetric outcome noted in both groups.

RESULTS

Prevalence was more (38%) in the preterm group. Bacterial vaginosis detected by Amsel's criteria was 30% in preterm and 7% in term group. Sensitivity of Amsel's criteria was 48.7%, specificity was 88.8% with a positive predictive value of 51.4% and negative predictive value of 87.7%. With Nugent's criteria, number of patients with score >7 was significantly higher (19%) in preterm than term (4%) patients.

CONCLUSION

Prevalence of bacterial vaginosis was higher in the preterm group. Clinical method using Amsel's criteria together with Gram stain is a simple, inexpensive, easily reproducible method for diagnosis. Bacterial vaginosis in pregnancy has a significant risk of preterm labour and associated neonatal morbidity.

KEYWORDS

Bacterial Vaginosis, Preterm Labour, Obstetric Outcome.

HOW TO CITE THIS ARTICLE: Chenicheri M, Chandramathy K, Govi R, et al. Prevalence of bacterial vaginosis in cases of preterm labour and its effects on obstetric outcome. J. Evid. Based Med. Healthc. 2017; 4(28), 1669-1673. DOI: 10.18410/jebmh/2017/326

BACKGROUND

Abnormal vaginal bacterial flora is an important cause of obstetric and gynaecological adverse sequelae. Bacterial vaginosis is a condition in which the normal, Lactobacillus-predominant vaginal flora is replaced with anaerobic bacteria, Gardnerella vaginalis and Mycoplasma hominis. In obstetrics, it has been implicated in miscarriage, preterm pre-labour rupture of membranes, spontaneous preterm labour, chorioamnionitis, low birth weight, postpartum endometritis and post caesarean delivery wound infections. Abnormal vaginal flora may predispose women to ascending colonisation of genital tract, infiltration of the foetal membranes, microbial invasion of the amniotic cavity and foetal damage.[1-4]

Preterm labour is onset of labour before 37 completed weeks of gestation. Preterm labour with subsequent delivery of a premature newborn is associated with significant morbidity and mortality. Preterm births occur in about 6-10% of all deliveries. 70-80% of perinatal deaths occur in preterm infants. The causes of preterm labour vary, but infection is highly suspected. Up to 80% of early premature

Financial or Other, Competing Interest: None.
Submission 27-03-2017, Peer Review 29-03-2017,
Acceptance 01-04-2017, Published 06-04-2017.
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DOI: 10.18410/jebmh/2017/326

births is associated with an intrauterine infection prior to rupture of membranes. In a meta-analysis by Flynn et al,[5] there was 60 times increase in the risk of preterm delivery in the presence of bacterial vaginosis. Although, bacterial vaginosis is present in almost 20% of pregnant women, most cases remain asymptomatic and not all women will deliver prematurely. However, the exact condition under which bacterial vaginosis correlates with preterm labour is not known. Bacterial vaginosis is a polymicrobial syndrome resulting in a decreased concentration of Lactobacilli and an increase in pathogenic bacteria. Thus, the diagnosis of bacterial vaginosis does not depend upon the recovery or identification of any single microorganism from the vagina, but rather requires the recognition of an altered vaginal microbial milieu.

To achieve a real reduction in the preterm delivery rates due to bacterial vaginosis, there needs to be a better understanding of the background and diagnosis of bacterial vaginosis, mechanism of preterm labour in bacterial vaginosis, prevention of its occurrence and early detection and treatment of BV.

In India, not many studies are done to estimate the association of bacterial vaginosis with peripartum and perinatal complications. Hence, this study is being taken up to know the prevalence of bacterial vaginosis in term and preterm patients.

Aims of the Study

1. To study the prevalence of bacterial vaginosis in preterm labour in comparison with term pregnant women.
2. To study the adverse obstetric outcome associated with bacterial vaginosis.

MATERIALS AND METHODS

Study Design- Prospective, cross-sectional descriptive study conducted in Department of Obstetrics and Gynaecology and Department of Microbiology, Government Medical College, Kozhikode, for a period of 1 year from August 2012 to January 2013 after getting clearance from Institutional Research and Ethics Committee.

Study Subjects- Included 100 women in spontaneous preterm labour and 100 women with term pregnancy in labour were taken as controls.

Sample size was calculated using the formula-

$$n = \frac{4pq}{d^2}$$

Where 'p' is the prevalence of bacterial vaginosis in preterm labour (prevalence obtained from the pilot study was 50%) and q=100-p=50. 'd' is allowable error, here taken as 20% of prevalence (p).

Inclusion Criteria

Patients with spontaneous onset of labour between 28-36 weeks 6 days were included as study subjects. Women with term gestation beyond 37 weeks with spontaneous onset of labour were included in the control group.

Exclusion Criteria

Patients with preterm labour induced for medical or obstetric indications, history of cervical incompetence and cervical surgery, history of antepartum haemorrhage, polyhydramnios, urinary tract infection, diarrhoea or any other obvious cause of preterm labour, multiple pregnancies, intrauterine growth restriction, intrauterine death, history of leaking per vaginum or absent membranes, medical complication of pregnancy such as moderate or severe anaemia, diabetes mellitus or any other maternal diseases.

Method of Study

After admission to the labour room, demographic profile of all patients were noted. Patient's symptoms and any history suggestive of infections, trauma or coitus, which may have precipitated preterm labour were enquired.

A detailed history of current pregnancy including bleeding per vaginum, gestational hypertension or GDM was taken. Obstetric examination was then carried out and the height of the uterus, whether contractions present or not and foetal heart sounds were made out and a diagnosis of preterm labour was established clinically. Investigations like complete haemogram, urine for microscopy and sensitivity and ultrasonogram were done.

An unlubricated vaginal speculum was inserted and appearance of discharge noted. The vaginal pH was determined by using a pH paper. Specimens were collected from the posterior vaginal fornix with sterile cotton tipped swabs for wet mount and Gram staining. The saline wet mount was examined microscopically for clue cells and 10% KOH was added to get an amine order. In the laboratory, vaginal smear was Gram stained and evaluated for bacterial vaginosis by Nugent's criteria. Medications given to the study group including corticosteroids, antibiotics and tocolytics were recorded. Details of labour and condition of baby noted.

Analysis

Statistical analysis was done using SPSS version 16.0 for Windows. Data was expressed as frequencies and percentages. Analysis of the data was done using Pearson's Chi-square test and Fisher's exact test. A 'p' value of less than 0.05 was considered to indicate statistical significance.

RESULTS

One hundred patients with spontaneous onset of labour pain between 28 and 36 weeks 6 days gestation were recruited in the study group. The control group contained 100 patients past 37 weeks of gestation with spontaneous onset of labour.

	Bacterial Vaginosis		**Total**
	Positive	**Negative**	
Term	13 (13%)	87 (87%)	100 (100%)
Preterm	38 (38%)	62 (62%)	100 (100%)
Total	**51 (25.5%)**	**149 (74.5%)**	**100 (100%)**

Table 1. Prevalence of Bacterial Vaginosis

Prevalence of bacterial vaginosis in preterm patients is 38% and term patients is 13%.

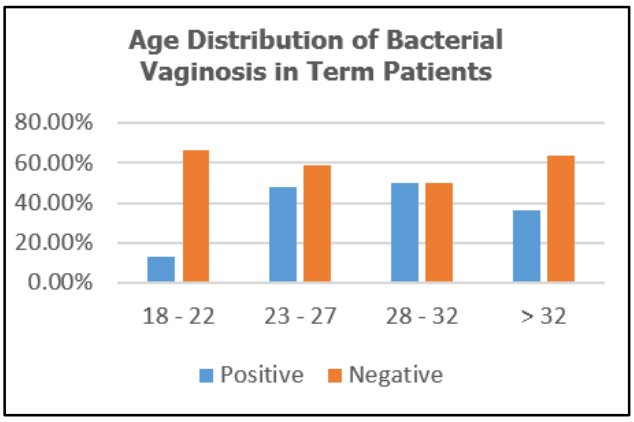

Chart 1

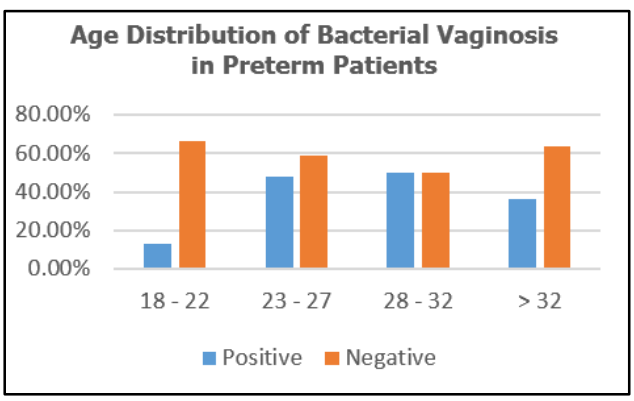

Chart 2

No difference was noted in different age groups.

Parity and Bacterial Vaginosis- Bacterial vaginosis was seen in 13% of term patients. The incidence in primigravida was 12.8% and in multigravida was 61.5%. Bacterial vaginosis was seen in 38% of preterm patients. Incidence in primigravida was 55.3% and in multigravida 44.7%. This was not statistically significant.

Socioeconomic class and bacterial vaginosis- no association was seen.

Diagnosis

Diagnosis is done by two criteria.

1. Amsel's clinical composite criteria.
2. Nugent's Criteria.

	Discharge PV		Total
	Non-Homogenous	White Homogenous	
Term	79 (79%)	21 (21%)	100 (100%)
Preterm	52 (52%)	48 (48%)	100 (100%)
Total	**131 (65.6%)**	**69 (43.55%)**	**200 (100%)**

Table 2. White Homogenous Discharge p/v

Discharge pv was significantly higher among preterm patients; Chi-square value = 16.554, p <0.00001.

	pH		Total
	<4.5	>4.5	
Term	89 (89%)	11 (11%)	100 (100%)
Preterm	67 (67%)	33 (33%)	100 (100%)
Total	**156 (78%)**	**44 (22%)**	**200 (100%)**

Table 3. pH of Vaginal Fluid

A significant number of preterm patients had pH >4.5; Chi-square value = 14.103, p <0.00001.

	Clue Cells		Total
	Negative	Positive	
Term	90 (90%)	10 (10%)	100 (100%)
Preterm	84 (84%)	16 (16%)	100 (100%)
Total	**174 (87%)**	**26 (13%)**	**200 (100%)**

Table 4. Presence of Clue Cells

	Whiff Test		Total
	Negative	Positive	
Term	95 (95%)	5 (5%)	100 (100%)
Preterm	85 (85%)	15 (15%)	100 (100%)
Total	**180 (90%)**	**20 (10%)**	**200 (100%)**

Table 5. Whiff Test and Bacterial Vaginosis

	Amsel's Criteria		Total
	Negative	Positive	
Term	93 (93%)	7 (7%)	100 (100%)
Preterm	70 (70%)	30 (30%)	100 (100%)
Total	**163 (81.5%)**	**37 (18.5%)**	**200 (100%)**

Table 6. Amsel's Criteria

Diagnosis by Nugent's scoring is done by Gram staining of vaginal smear.

	Gram Stain			Total
	>7	4-7	<4	
Term	4 (4%)	8 (8%)	88 (88%)	100 (100%)
Preterm	19 (19%)	8 (8%)	73 (73%)	100 (100%)
Total	**23 (11.5%)**	**16 (8%)**	**161 (80.5%)**	**200 (100%)**

Table 7. Nugent's Criteria

Nugent's score >7 was considered positive. It was significantly higher among preterm; Chi-square value = 11.192, p = 0.011. The sensitivity was 48.7% and specificity 88.8%; and positive and negative predictive value were 51.7% and 87.7%, respectively.

Relationship of Gestational Age at Birth and Bacterial Vaginosis- Early preterm deliveries, <34 weeks was 25 (65.75%) and late preterm births 34-37 weeks was 12 (31.6%) in bacterial vaginosis positive patients. This showed an increase in early preterm deliveries in bacterial vaginosis patients, p = 0.013.

Bacterial Vaginosis and Neonatal Outcome- Incidence of respiratory distress, sepsis and jaundice were studied. Among term patients, there was no significant difference in neonatal outcome between bacterial vaginosis, positives or negatives; all p >0.05. Among preterm patients, sepsis and jaundice were slightly higher in bacterial vaginosis positives, but not statistically significant; p = 0.057, while there was no difference in respiratory distress in two groups; Chi-square test = 2.2, p = 0.138.

Bacterial Vaginosis and Maternal Outcome- Puerperal sepsis was studied. There was no association in both term and preterm group; p = 0.756 and p = 0.382.

DISCUSSION

Our study included 100 preterm women in spontaneous labour and 100 term women in labour. The overall prevalence of bacterial vaginosis was 25.5%. Prevalence of bacterial vaginosis in the preterm group was 38%.

Jacobsson et al in their cohort study of 924 patients in a Swedish population using 'clue' cells in Pap smear as diagnostic criteria for bacterial vaginosis reported a prevalence of 15.6%.[6] Another study conducted under National AIDS Control Organisation (NACO) reported a prevalence of 32.8% bacterial vaginosis by Gram staining method, which is similar to the present study.[7]

In the study by Mathew et al of 200 antenatal women (150 symptomatic and 50 asymptomatic), they reported a prevalence of 38% using Nugent criteria[8] with a higher incidence of preterm labour in bacterial vaginosis patients.

Purwar et al in a cohort study of 1006 asymptomatic pregnant women between 16 to 28 weeks of gestation using Nugent's criteria reported a prevalence of 11.3%.[9] Sewankambo et al reported bacterial vaginosis in 50.8% and intermediate flora in 31.7% of women.[10]

Prevalence of bacterial vaginosis in pregnancy in various studies varies. (Gravett et al[11] - 19%, Jacobsson et al - 15.6%, Purwar - 11.53%, Mathew et al - 38.5%, our study - 38.5%). The method used for diagnosis of bacterial vaginosis is not uniform in all studies. However, more studies have reported a high degree of correlation between clinical criteria and laboratory methods.

In this study, when parity and bacterial vaginosis was compared, no association was found. Among term patients, more cases (6) belonged to 18-22 years followed by 23-27 years age group. In preterm patients, there was no association.

In preterm group, bacterial vaginosis was diagnosed in 30 (30%) cases by Amsel's clinical composite criteria.

1. Thin homogenous white discharge was present in 48%.
2. pH was >4.5 in 33 (33%).
3. Amine test (Whiff test) was positive in 15 (15%).
4. Clue cells were present in 16 (16%).

In a study by Gutman,[12] homogenous discharge was not independently related to bacterial vaginosis. A pH of >7, amine odour and clue cells provided unique information that independently contributed to the diagnosis. According to Larsson, the most sensitive individual criterion was vaginal pH, but with lowest specificity. The highest specificity was for clue cells. The combination of these two criteria had best positive and negative predictive values of 60.5 and 97.8%, respectively.[13]

The other method for the diagnosis of bacterial vaginosis was Nugent's method of scoring and grading of Gram stained vaginal smears. In a study by Gibbs, bacterial vaginosis was found in 32.8% of women, while a score of 4 to 6 was found in 16.9%.[14] Sewankambo et al reported bacterial vaginosis in 50.8% and intermediate flora in 31.7% of women.[10] Intermediate grade maybe found in women who are either recovering from or who may develop bacterial vaginosis subsequently.[15] Compared to Nugent's method, the Positive Predictive Value (PPV) and the Negative Predictive Value (NPV) of Amsel's criteria was 51.4% and 87.7%, respectively.

Study (Ref)	Sensitivity (%)	Specificity (%)
Dadhwal V et al[16]	51.2	98
Gutman RE et al[12]	69	93
Schwebke J R et al[17]	70	94
Goyal R et al[18]	60.7	97.8
Present study	48.7	87.7

Table 8. Comparison of Sensitivity and Specificity of Amsel's Criteria When Compared to Nugent's Method in Various Studies

The studies mentioned above show different sensitivities and specificities for Amsel's criteria. The sensitivity of Amsel's criteria in the present study is in accordance with a study by Dadhwal et al. The frequency of bacterial vaginosis was 8.6% by Nugent's method. For Amsel's criteria, sensitivity and specificity was 51.2 and 98% with 71% PPV and 95.5% NPV.

The inverse relation between the presence and concentration of Gardnerella and Lactobacillus morphotypes in the Gram stained smears observed in the present study is in agreement with other studies.[19]

Gram staining of vaginal smears are least expensive, easy to transport and requires less time to perform compared to Amsel's criteria. This method is unaffected by physiological conditions and can be preserved for future reference.

Eschenbach et al[19] compared the diagnosis of bacterial vaginosis on the basis of Amsel's criteria or presence of clue cells alone with Gram stain criteria and isolation of G. vaginalis on culture. They reported that Gram stain criteria correlated better than results of cultures for G. vaginalis with presence or absence of clue cells and with composite clinical criteria. The independent diagnosis of bacterial vaginosis by Gram stain alone had a sensitivity of 97% and specificity of 79% and PPV of 69%.

A study by Jacobsson et al observed no statistical significance for spontaneous preterm birth among women with bacterial vaginosis, although the risk of preterm birth was doubled. Our study showed a higher incidence of low birth weight babies and low Apgar in bacterial vaginosis positive patients. The neonatal sepsis was not found

significantly high. This may be explained by the hospital policy of prophylactic antibiotics.

In a study by Hillier et al, bacterial vaginosis was detected in 24.34% of women with preterm labour. There was a significant increase in the incidence of respiratory distress (14% versus 6%), requirement of intermittent positive pressure ventilation (14% versus 5%), admission to Neonatal Intensive Care Unit (NICU) (15% versus 6%) and duration of NICU stay >2 days (15% vs. 6%) in babies of patients with bacterial vaginosis. No difference was found in the mean birth weight, Apgar, incidence of neonatal sepsis, perinatal mortality and postpartum fever.

CONCLUSION

The prevalence of bacterial vaginosis in threatened preterm and preterm labour group was observed to be more than term labour group. Clinical method using Amsel's criteria in combination with Gram stain is a simple inexpensive, easily reproducible method for diagnosis and can be used on a mass scale. Bacterial vaginosis in pregnancy is associated with significant risk of preterm labour and preterm birth. Foetal morbidity in terms of low birth weight, low Apgar and neonatal jaundice is significantly higher among bacterial vaginosis, positive pregnant women and this maybe because of lower gestational age at birth.

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