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ASSOCIATION OF BACTERIAL VAGINOSIS WITH PRETERM LABOUR PAIN

Gynaecology

Dr. Sangeeta Tvinwal Resident, Department of Obstetrics & Gynaecology, R.N.T. Medical College, Udaipur

Dr. Sunita Maheshwari* Sr. Professor & Head, Department of Obstetrics & Gynaecology, R.N.T. Medical College, Udaipur *Corresponding Author

Dr. Pooja Meena Resident, Department of Obstetrics & Gynaecology, R.N.T. Medical College, Udaipur

ABSTRACT

INTRODUCTION: Preterm labour is defined by WHO as the onset of labour prior to the completion of 37 weeks of gestation, in a pregnancy beyond 20 weeks of gestations**.** Bacterial vaginosis has been associated with preterm labour, PROM and with postpartum maternal and neonatal infections. Bacterial vaginosis has been strongly associated with vaginal cuff infections following hysterectomy, PID, post abortal PID and caesarean endometritis.

AIM OF THE STUDY: To study the association of bacterial vaginosis with preterm labour, and to determine whether the presence of bacterial vaginosis is significantly associated with the maternal and neonatal outcome.

MATERIALS AND METHODS : Total 100 women fulfilling inclusion and exclusion criteria, 50 women with preterm abour as study group and 50 women with term labour as control group during 2018 to 2019. A complete history was taken with menstrual history and obstetrical history. Bacteriological study: pH test: Amine Test: Clue cells on wet mount, AMSEL'S Criteria: were conducted.

RESULTS: 18 cases had homogenous discharge characteristic of bacterial vaginosis. Bacterial vaginosis was found in 28% and 12% in preterm and term groups respectively ($p<0.05$). pH>4.5 has the highest sensitivity (100%) and least specificity. Whiff test was positive in 22 cases of which 19 cases were positive for bacterial vaginosis. Whiff test has a good sensitivity (95%) and a specificity (96.25%). Clue cell is the single most specific test but not a sensitive one specificity 98.75% sensitivity 75%. 100% cases who were positive for BV by Amsel's criteria. The sensitivity was 95%, specificity 100%, positive predictive value 100%, negative predictive 98.77%.

CONCLUSION : Significant association between bacterial vaginosis and preterm labour. Also significant association of various factors like low socio economic status, low maternal weight and history of previous preterm deliveries to the study group (pre term labour).

KEYWORDS

Amsel's criteria; Bacterial Vaginosis; Preterm Labour; Amine Test.

INTRODUCTION

Preterm labour is defined by WHO as the onset of labour prior to the completion of 37 weeks of gestation, in a pregnancy beyond 20 weeks of gestations (period of viability)**.**[1] The period of viability varies in different countries from 20 to 28 weeks depending on facilities available for newborn care and likelihood of survival. Preterm labour is considered to be established, if regular uterine contraction can be documented atleast four in 20 minutes or eight in 60 minutes with progressive change in cervical score in the form of effacement of 80% or more and cervical dilatation greater than 1cm.[2]

In INDIA, out of 27 million babies born every year (2010 data), 3.5 million babies born are preterm[3]. Preterm deliveries poses a problem because of the severe neonatal complications that often occur afterwards that includes death, respiratory distress syndrome, sepsis and necrotizing enterocolitis.

The etiology of preterm labor (PTL) is multifactorial with increasing evidence that infection is a possible cause in upto 40% of cases. Ascending infection have been identified as the most important preventable cause of preterm labour. Among ascending infection bacterial vaginosis is major cause of preterm labour[4].

Intrauterine infections are believed to trigger preterm labour by activation to innate immune system. In this hypothesis, microorganism elicit release of inflammatory cytokines such as interleukins and TNF -@, which in turn stimulate the production of prostaglandin and matrix degrading enzymes. Prostaglandin stimulate uterine contraction, whereas matrix degrading enzymes causes degradation of extracellular matrix in the fetal membrane. It is estimated that 25 to 40% of preterm birth result from intrauterine infection.[5]

Normal genital tract flora are dominated by Lactobacillus which produce lactic acid keeping the vaginal pH below 4.5, so discouraging the growth of other organisms. Concentration of Lactobacillus species increase 10 fold as pregnancy progresses. Increased levels of lactobacilli make the vaginal ecosystem inhibitory to the growth of many pathogens. In Bacterial vaginosis lactobacilli are altered resulting in 1000 fold increase in anaerobes mobiluncus species, Gardnerella and the genital mycoplasmas[5].

Bacterial vaginosis has been associated with preterm labour, PROM and with postpartum maternal and neonatal infections[5,6]. Bacterial vaginosis has been strongly associated with vaginal cuff infections following hysterectomy, PID, post abortal PID and caesarean endometritis.

Women with bacterial vaginosis and susceptible TNF-@ genotype had a ninefold increased incidence of preterm birth.[7] Using gram staining, relative concentration of bacterial vaginosis are determined and graded as the nugent score.

The diagnosis criteria commonly used for bacterial vaginosis is AMSEL'S criteria. It involve assessing four clinical parameters with existence of 3 or more parameters corresponding to a diagnosis of bacterial vaginosis.

Bacterial vaginosis can be cured by antibiotic, systemic and topical with spontaneous relapse occurring more among women treated with topical compared with systemic antibiotics.

Keeping in view the importance of bacterial vaginosis in predicting the outcome of pregnancy and its overall impact on maternal and child health and the need for its prompt and early diagnosis, this study is designed to look at the association of bacterial vaginosis with preterm labour pain.

AIM OF THE STUDY

- To study the association of bacterial vaginosis with preterm labour.
- To determine whether the presence of bacterial vaginosis is significantly associated with the maternal and neonatal outcome.

MATERIALS AND METHODS

Total 100 women fulfilling inclusion and exclusion criteria, 50 women with preterm labour as study group and 50 women with term labour as control group admitted in obstetrics ward at Pannadhay Zanana Hospital, Udaipur, Department of Obstetrics & Gynaecology of RNT

Medical College, Udaipur from 2018 to 2019.

Inclusion Criteria:
Preterm labour (Study Group) is defined as follows:
1. Gestational age <37 weeks.
2. Regular uterine contractions (four or more in 20 minutes or eight or more in 60 minutes), each lasting more than 40 seconds.
3. Cervical dilatation equal to or more than 1 cm but less than 4cm and effacement equal to or greater than 80%.
4. Intact fetal membranes.

Term labour (Control Group) is defined as follows
1. Gestational age >37 completed weeks.
2. Spontaneous in onset.
3. Regular uterine contraction (four or more in 20 minutes or eight or more in 60 minutes) each lasting for more than 40 seconds.
4. Cervical dilatation equal to or greater than 1 cm but less than 4cm.
5. Intact fetal membranes.

Exclusion Criteria:
1. GA <28 weeks, Cervical incompetence
2. Cases with Rh isoimmunization
3. Use of antibiotics in the preceding two weeks
4. Multiple gestations
5. Pregnancies complicated with medial disorders like hypertension, diabetes, chronic renal disorders, thyroid disorders, gastrointestinal disorders, severe cardiac disorders etc.
6. PROM, IUGR, IUD, Placenta previa / APH.
7. PIH, UTI

Clinical study: A complete history was taken with menstrual history and obstetrical history. The gestational age was confirmed from last menstrual period and was correlated with clinical examinations and ultrasonographic gestational age. In the case of previous history of preterm labour the ultimate fetal and maternal prognosis was carefully analysed. In the current pregnancy a detailed history of complication associated with pregnancy was taken. Abdominal, vaginal and speculum examination were done. Nature of discharge noted and vaginal swab was taken for bacteriologic study.

Bacteriological study: The specimen was collected by putting the patient in dorsal supine position. Under all aseptic conditions the posterior vaginal wall was retracted with sims speculum and vaginal swab was taken from posterior fornix by sterile cotton swab.

pH test : By using a piece of nitrazine paper, pH of the vaginal fluid can be obtained. Care was taken to avoid contact with cervical mucus, as the pH of cervical secretions is approximately-7.

Amine Test: A drop of 10% KOH was added to wet mount specimen and fishy odor was noted.

Clue cells on wet mount: Clue cells are found by mixing vaginal fluid with a drop of normal saline on a slide and examining this slide microscopically under high power magnification (x400). Specimens were considered adequate if at least 10 epithelial cells per high power field were seen. The presence of even as few as one clue cell per field in 20 field (x400) was considered positive. Clue cells were identified as vaginal epithelial cell with indistinct cell border obscured by the large number of attached organisms.

AMSEL'S Criteria: Amsel et al claimed that bacterial vaginosis was present if three of these four criteria was present.

1. Homogenous vaginal discharge
2. Vaginal pH > 4.5
3. Fishy odour on alkalinization of vaginal secretion.
4. Presence of clue cells

RESULTS

Table -1 : Age Distribution of Cases

Age groups (in years)	Pre term	Term
< 20	4	5
21 – 24	28	25
25 – 28	11	16
29 – 32	5	3
33 Yrs & above	2	1
Total	50	50
Range	**18 – 36 yrs**	**17 – 36 yrs**
Mean ± S.D.	**23.6 ± 3.8 yrs**	**23.8 ± 3.5 yrs**

The mean age in study group was 23.6 yrs + 3.8 yrs and in control group was 23.8yrs + 3.5 yrs. The age distribution of cases in the study and control group did not vary much which corresponds to that of Kavya et al[8] and Borah et al[9].

Table -2: Distribution of Bacterial Vaginosis Among the Subjects

Bacterial Vaginosis	(Study) Pre- Term	(Control) Term
Positive (n=20)	14	6
Negative (n=80)	36	44

According to Amsel's criteria bacterial vaginosis was positive in 28% of preterm and 12% of term cases, which is statistically significant. The presence of Bacterial vaginosis was significantly associated with preterm labour.

Table -3: Efficacy of various investigations / Homogenous Discharge

	Bacterial Vaginosis	
Present	**Positive (n=20)**	**Negative (n=80)**
Homogenous Discharge	16	2
PH > 4.5	20	14
Whiff Test	19	3
Clue cells	15	1
Amsel's criteria	19	0

18 cases (including term and preterm) had homogenous discharge characteristic of bacterial vaginosis. Of these, 16 had bacterial vaginosis according to Amsel's Criteria. The sensitivity was 80% specificity was 97.50% positive predictive value 88.89%, negative predictive value 95.12%.

In our study bacterial vaginosis was found in 28% and 12% in preterm and term groups respectively. The association of bacterial vaginosis and preterm labour was first studied by Eschenbach et al[10]. Their study showed bacterial vaginosis in 49% and 24% in preterm and term groups respectively. Nejad et al[11] in their study found bacterial vaginosis in 25% and 11% of preterm and term group respectively which was quite similar to our findings. Our study is showing significant association of bacterial vaginosis with preterm labour ($p<0.05$).

PH >4.5 found in 34 patients and diagnosed all of bacterial vaginosis positive cases with the false positivity rate of 0%, pH>4.5 has the highest sensitivity (100%) and least specificity However it is economical, extremely simple and a useful tool to rule out bacterial vaginosis.

Whiff test was positive in 22 cases of which 19 cases were positive for bacterial vaginosis. Whiff test has a good sensitivity (95%) and a specificity (96.25%). In the absence of microscope, Whiff test can be used as a specific and relatively sensitive method of detecting BV.

Detection of clue cell is the single most specific test but not a sensitive one specificity 98.75% sensitivity 75%. It has a high PPV (93.75%) and a NPV (94.05%). Similar findings were shows by Subha et al[12].

In the present study 100% cases who were positive for BV by Amsel's criteria had bacterial vaginosis. Amsel's criteria did not have any false positive cases. But this criteria failed to diagnose bacterial vaginosis in 1 case which was positive for bacterial vaginosis. The sensitivity was 95%, specificity 100%, positive predictive value 100%, negative predictive 98.77%.

Similar findings were noted in the study by Bansal R et al[13], prevalence of bacterial vaginosis by Amsel's criteria was 30.76%. Amsel's criteria had sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV) of 75%, 95%, 90%, 86%. These findings were consistent with other studies of Taj et al[56] (2012) and Moussavi et al[15] (2004). Among all Amsel criteria, PH>4.5 had highest sensitivity (97.50%), and lowest specificity (77.78%), which was similar to various other studies.[15-16] It can be explained by the fact that measurement of vaginal pH is easily affected by the presence of blood or semen or application of lubricant gel which can increase the vaginal pH. Cervical mucus itself has a pH of 6 which may interfere with vaginal pH. In previous studies, clue cells had high sensitivity and

specificity in contrast to present study.

Table -4: Efficacy of various test results

Tests	Sensitivity	Specificity	Accuracy	PPV	NPV
Nature of discharge	80%	97.50%	94%	88.89%	95.12%
pH > 4.5	100%	82.50%	86%	58.82%	100%
Whiff test	95%	96.25%	96%	86.36%	98.72%
Clue cells	75%	98.75%	94%	93.75%	94.05%
Amsel's criteria	95%	100%	99%	100%	98.77%

On analyzing various test results pH value >4.5 has highest sensitivity (sensitivity 100%). Whiff test, Amsel's criteria and clue cells have high specificity. Amsel's criteria - 100% specific. Clue cells - 99% specific. Whiff test - 96% specific. Whiff test & Amsel's criteria have good sensitivity and specificity.

In present study the specificity (98.75%) of clue cells was higher than its sensitivity (75%). Low sensitivity for identification of clue cells may depend upon the ability of the clinician to analyze wet mount microscopy these results are in agreement with other studies.[17] Whiff test was performed by smelling the odor, its results are subjective and depends on personal interpretation. In present study whiff test had best sensitivity (95%) and specificity (96.25%) which was similar to other studies[14].

Table -5: Distribution of bacterial vaginosis according to the birth weight of the baby

Birth weight (in Kg)	Bacterial Vaginosis	
	Positive (n=20)	Negative (n=80)
Range	1.25 – 3.5	1 – 3.8
Mean ±S.D	2.21±0.55	2.53±0.57

The mean birth weight of babies in the bacterial vaginosis. Positive group was 2.21 ± 0.55 Kg. where as in bacterial vaginosis. Negative group was 2.53± 0.57 Kg. The presence of bacterial vaginosis was significantly associated with low birth weight babies.

In our study, the mean birth weight of babies born to bacterial vaginosis positive mothers was 2.21 ± 0.55kg and in bacterial vaginosis negative group was 2.53± 0.53kg (p=0.0024). Hence BV is significantly associated with LBW babies. Whether it is the cause (or) association is not known. Similar findings were observed by Borah et al[9], Subha et al[12], Kavya et al[8].

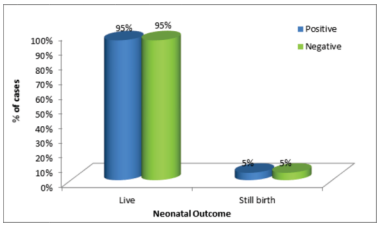
Table – 6: Impact of bacterial vaginosis on neonatal complications

Neonatal complications	Bacterial Vaginosis				X^2	P value
	Positive (n=20)		Negative (n=80)			
	No	%	No	%		
Present	5	25%	11	13.75%	1.50	0.22 (Not
Absent	15	75%	69	86.25%		significant)

From the table, the neonatal complications (including birth asphyxia, RDS, meconium aspiration syndrome, hyperbilirubinemia) were not increased in patients with bacterial vaginosis when compared with patients who did not have bacterial vaginosis.

There was only 1 still birth (5%) in bacterial vaginosis positive group and 4 (5%) in negative group. As there was equal stillbirth ratio, the difference was statistically not significant.

In our study, out of 20 patients who had bacterial vaginosis neonatal complications (birth asphyxia, RDS, meconium, aspiration syndrome, hyper bilirubinemia) were present in 5 cases (25%). In bacterial vaginosis negative group out of 80 patients, neonatal complications were present in 11 babies (13.75%). So the incidence of neonatal complications in bacterial vaginosis positive and negative group did not vary much (p - 0.53) in our study.



Impact of bacterial vaginosis on Neonatal outcome

In our study there was only 1 still birth (5%) in bacterial vaginosis positive group and 4 (5%) in negative group. As there was equal stillbirth ratio, the difference was statistically not significant. So the presence of bacterial vaginosis did not seem to influence the neonatal outcome.

Among maternal complications only the infectious morbidity (episiotomy wound infection, fever, foul smelling discharge) was analysed. One patient in study group and 1 patient in control group had atonic PPH and 1 patient in control group developed puerpural pyrexia. All these complications were excluded from analysis.

CONCLUSION

There was a significant association between bacterial vaginosis and preterm labour. There was also significant association of various factors like low socio economic status, low maternal weight and history of previous preterm deliveries to the study group (pre term labour). The neonatal and maternal outcome in the bacterial vaginosis positive and negative group did not differ much.

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