Effect of Bacterial Vaginosis in the Second Trimester of Pregnancy on the Outcome of Pregnancy

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Publication Date: 2025/02/27

Abstract:

> Objective:

To study the prevalence of bacterial vaginosis in second trimester pregnancy and its effect on pregnancy outcome

> Methods:

A study was conducted over a period of 2 years from October, 2018 to October, 2020 wherein 240 patients in their second trimester cases were examined. In addition, data of deliveries collected during the past few years has been compared vis-a-vis 240 cases and analyzed.

> Results:

The prevalence of bacterial vaginosis was 36% in our study. There was no significant association of demographic factors like literacy, age and parity. Anemia was assessed as a high risk factor for bacterial vaginosis, but no significant association could be derived. The number of patients presenting with symptomatic bacterial vaginosis was more than the asymptomatic positive patients. The most common presenting complaint was of vaginal discharge and on examination, homogenous mucoid discharge was found in majority of the patients. Presence of homogenous mucoid discharge, alkaline pH and presence of clue cells was the most common diagnostic triad fulfilled by patients with bacterial vaginosis. Recurrence was seen in 2 patients inspite of completing the entire course of treatment. PROM and preterm vaginal delivery were the common complications noted. Bacterial vaginosis did not have a significant effect on the neonatal outcome.

> Conclusion:

Bacterial vaginosis, the polymicrobial inflammation of the vagina, has a high prevalence rate of upto 36%. All pregnant women in their second trimester coming for antenatal checkup should undergo per speculum examination and the three most common parameters of the Amsel's criteria, that is, homogenous mucoid discharge, raised vaginal pH and presence of clue cells in vaginal smear can be used to diagnose bacterial vaginosis. Pregnant women in their second trimester presenting without any symptoms should also undergo per speculum examination for the diagnosis of asymptomatic bacterial vaginosis and its treatment. The presence of bacterial vaginosis in the second trimester of pregnancy does not affect the maternal and neonatal outcome significantly because after its diagnosis and treatment, the recurrence rate was very low but detection of bacterial vaginosis before the onset of labour for its effect on maternal and neonatal outcome needs further research. Anemia is not a risk factor for bacterial vaginosis, but further studies are required for identification of other potential high risk factors.

Keywords: Bacterial vaginosis, Anemia, Amsel Criteria, Nugent Criteria, Mucoid, pH, Clue Cells, PROM, PPROM, Preterm Vaginal Delivery.

How to Cite: Dr. Harshini Thirumaran; Dr. Gauri Bapat; Dr. Swati Shiradkar (2025) Effect of Bacterial Vaginosis in the Second Trimester of Pregnancy on the Outcome of Pregnancy. *International Journal of Innovative Science and Research Technology*, 10(2), 740-746. https://doi.org/10.5281/zenodo.14930546

Volume 10, Issue 2, February – 2025

https://doi.org/10.5281/zenodo.14930546

I. INTRODUCTION

Bacterial vaginosis is the most common vaginal infection in women in the age group of 15-40 years and has a prevalence rate of 10 -30% among pregnant women ^[1, 2]. It is caused by the disruption of the natural vaginal flora which consists of *Lactobacillus* and extensive proliferation of other pathogenic anaerobic species like *Gardernella vaginalis*, *Mobiluncus* species, *Prevotella* species, *Mycoplasma* species and *Bacteroides* species.

Bacterial vaginosis is typically a mild infection. The lactobacilli act on the glycogen deposited on the mature vaginal epithelium under the effect of estrogen, maintaining an acidic pH, making sure that hydrogen peroxide is present in the genital environment, thereby preventing other infections. Any disturbance in this well-established vaginal ecosystem predisposes it to proliferation of other atypical bacterial species. When left untreated, the infection can increase the risk of complications during pregnancy. It has been associated with a significant number of obstetric complications such as ^[4, 5, 6, 7]:

- Spontaneous abortion
- Pretermbirth
- Preterm premature rupture of membranes
- Chorioamnionitis
- Postpartum endometritis
- Post-caesarean delivery wound infections
- Subclinical pelvic inflammatorydisease

The organisms characteristic of bacterial vaginosis ascend from the lower genital tract and through the cervix cause deciduitis, chorioamionitis, amniotic fluid and fetal infections. They cause an increase in the endotoxin and protease levels, stimulate pro-inflammatory cytokine production and decrease leucocyte levels. The release of sialidases and mucinase promotes placental inflammation and weakening of chorioamniotic membrane leading to preterm labour^[8]. These entities are known to have a significant influence on the maternal and neonatal morbidity and mortality.

Organisms causing bacterial vaginosis do not follow the Koch's postulates, and hence, the pathogenesis, diagnosis and the management of bacterial vaginosis has been considered challenging. The diagnosis of bacterial vaginosis is based on real-time clinical/microbiological tests. There are two main categories of diagnostic tests for bacterial vaginosis: clinical criteria (Amsel's Criteria) and laboratory-based testing (Nugent Criteria). The current gold standard is the standardized evaluation of bacterial morphology on Gram stain analysis, that is, the Nugent criteria. Because of the simplicity, specificity and cost effectiveness, most clinicians apply the Amsel's criteria for the diagnosis of bacterial vaginosis^[10]. The Amsel's Criteria consists of:

- Homogenous vaginal discharge
- pH test >4.5
- Whiff's test: a few drops of 10 %KOH is added to the vaginal swab sample and a fishy odour indicates a positive test.
- Presence of 'Clue cells' on wet mount preparation of the vaginal swab. Clue cells are vaginal epithelial cells which are laden with the pathogenic anaerobic bacteria.

Bacterial vaginosis can be prevalent anytime during the course of pregnancy. In accordance with the Centers for Disease Control and Prevention protocol, screening of pregnant women is necessary for early detection of bacterial vaginosis, treatment and prevention of the adverse outcomes.

Antibiotics are the mainstay of therapy for bacterial vaginosis. Medications include:

- Metronidazole
- Clindamycin

Both of these drugs are available as oral tablets and vaginal pessaries. The treatment regimens include administration of the above-mentioned antibiotics with an additional supplementation with oral probiotics^[11].

II. MATERIALS AND METHOD

An observational & prospective longitudinal cohort study was conducted at MGM Medical College and Hospital, Aurangabad, on the prevalence of bacterial vaginosis in second trimester pregnancy and its effect on pregnancy outcome. All pregnant women in their second trimester coming to the Obstetrics and Gynecology OPD and planning to deliver in MGM Medical College and Hospital, Aurangabad have been examined from October, 2018 to October, 2020. The inclusion and exclusion criteria are as follows:

➢ Inclusion Criteria

Women in their second trimester of pregnancy with a singleton pregnancy coming to outpatient department for antenatal registration

- Exclusion Criteria
- Pregnant women with high risk factors for preterm labour like cervical incompetence, history of previous preterm deliveries, twin/multiple gestation, pre-eclampsia, anomalous fetus, uterine malformations
- Pregnant women with immune-compromised status, for example, presence of diabetes, HIV positive women

III. METHODOLOGY

Informed consent was taken after explaining the procedure and the importance of the test in detail to the patient in their own language. After informed consent was obtained, detailed history was taken and the information required was noted in the case proforma, clinical Volume 10, Issue 2, February – 2025

ISSN No:-2456-2165

examination was done followed by per speculum examination before the patient passes urine. High vaginal swab from posterior fornix was taken and a wet mount preparation was made using glass slide, cover slip and few drops of normal saline. Examination of the vaginal swab was done using the pH indicator strips and Whiff test was performed by adding a few drops of 10% Potassium hydroxide. The slide prepared was examined for the presence of 'clue cells'. The positive cases were treated with suppository containing a combination of vaginal clindamycin, clotrimazole and tinidazole (Clingen Forte) to be kept per vaginum in the night before sleeping for 7 days, along with a capsule probiotic containing Lactobacilli (Rinilab), once a day dose for 15 days. At 36 weeks of gestational age or earlier (if significant complaints), the patient was re-examined for bacterial vaginosis. In cases of recurrence, patient was given the necessary treatment. Follow up was maintained till the patient delivered and details regarding the mode of delivery, baby status (if any

complications / NICU admission) were noted down.

IV. OBSERVATIONS AND RESULTS

https://doi.org/10.5281/zenodo.14930546

Analysis of the data collected after examination of the 240 patients enrolled in the study was done and appropriate test of significance has been applied to find relations between the factor under study and bacterial vaginosis. The P-value indicated in the tables below is the probability value calculated from Z score (Two proportions significance test statistic) using Z-Table. The Z score is worked out using specific formulas for pooled proportion and standard error.

Out of the 240 patients examined, 86 pregnant women tested positive for bacterial vaginosis. The prevalence of bacterial vaginosis was 36% in our study population. Most women enrolled in the study were in their peak reproductive age group of 20 - 30 years of age (82%) and 13% of women were < 20 years of age and 5% of women were > 30 years of age. No significant association could be established between bacterial vaginosis and age of pregnant patients. More than half the patients enrolled in the study were multigravida and made up almost 62% of the population with bacterial vaginosis. The demographic variables of age and parity status of the patient did not hold a statistical significance in the prevalence of bacterial vaginosis.

Table 1 : Presenting symptoms in patients			
Symptom	Patients without bacterial vaginosis (n = 154)	Patients with bacterial vaginosis (n = 86)	P value
Urinary complaint	10 (6.5%)	14 (16%)	0.0078 (Significant)
Itching	10 (6.5%)	12 (14%)	0.0274 (Significant)
Vaginal discharge	57 (37%)	58 (68%)	0.0002 (Significant)

Significant relation between the above mentioned symptoms with bacterial vaginosis was established. Vaginal discharge was the most common symptom that patients with bacterial vaginosis presented with. The next common symptom was urinary complaints.

The Per Speculum Examination Conducted on all 240 Patients Enrolled in the Study Gave an Insight on the Types of Vaginal Discharge Encountered in Pregnancy.

The most common type of discharge was mucoid in nature, seen in 88% of patients without bacterial vaginosis and 97% of the patients with bacterial vaginosis. Watery consistency of the discharge was noticed in 14% of the patients without bacterial vaginosis. Curdy white discharge was found in 5% and 2% of the patients without and with bacterial vaginosis, respectively.

Table 2 : Mucoid discharge in patients			
	Patients without bacterial vaginosis (n=154)	Patients with bacterial vaginosis (n=86)	P value = 0.008 Highly
Present	134(88%)	83(96.5%)	significant
Absent	20(12%)	3(3.5%)	~

On applying the test of significance for proportion using Z-table, p value of 0.008 was strongly suggestive of association between the presence of mucoid discharge and bacterial vaginosis. As homogenous mucoid discharge is one of the Amsel's criteria, further visual quantification of the amount of discharge in patients with bacterial vaginosis was done. Most patients of bacterial vaginosis presented with moderate amount of discharge.

Moderate amount of mucoid discharge was seen in 43% of affected patients. 36% patients had minimal amount of discharge and 10.5% of the patients had profuse mucoid discharge. Out of the 86 patients with bacterial vaginosis, 25 patients with minimal amount of mucoid discharge did not report the symptoms. These patients fall under the category of aymptomatic bacterial vaginosis and form a significant part of the study.

> Application of the Amsel's Criteria on the Data Collected Yielded the Following Results:

Table 3 : Patients as per Amsel's individual criteria (n = 86)				
Amsel's Criteria	Mucoid		Clue Cells	Whiff Test
		Alkaline pH		
Number of patients	83/86	86/86	86/86	25/86

The most common criteria fulfilled were clue cells and alkaline pH.

Table 4 : Patients as per Amsel's Criteria		
Amsel's Criteria	Number (n=86)	
Mucoid, Alkaline pH & Clue Cells	81	
Mucoid, Alkaline pH & Whiff Test	21	
Mucoid, Whiff Test & Clue Cells	24	
Alkaline pH, Whiff Test & Clue Cells	21	

Clue cells and an alkaline pH > 4.5 were consistently seen in all the patients with bacterial vaginosis. The following 3 criteria - mucoid discharge, alkaline pH and presence of clue cells, were most commonly encountered and lead to the diagnosis of bacterial vaginosis.

Out of 86 bacterial vaginosis patients, 84 (98%) had no recurrence and only 2 (2%) bacterial vaginosis patients had recurrence. They were treated with a second course of the same vaginal suppositories and oral probiotics

Almost 74% of the patients with bacterial vaginosis delivered at our institute. 86% of the patients with bacterial vaginosis underwent delivery in the institute and 14% of these patients delivered at an outside hospital. This 14% of the study group includes 12 patients with bacterial vaginosis who did not follow up for delivery.

<u>Note:</u> Fifty two patients preferred to deliver at a maternity centre close to their place of residence in view of the COVID-19 pandemic which occurred during the course of the study period of the dissertation. This necessitated a change in the methodology wherein follow up was kept via telephonic conversation with the patient and delivering doctor. Out of 52 patients who delivered at an outside institute, 12 patients had bacterial vaginosis. All patients who delivered at outside hospitals were contacted telephonically, information obtained, but due to the possibility of inaccuracy of the data obtained, they were excluded from the analysis.

Table 5 : Maternal Outcome			
Complications	Patients without bacterial vaginosis (n=114)	Patients with bacterial vaginosis (n=74)	
PROM	3(2%)	7(8%)	
Preterm Vaginal Delivery	2(1.3%)	2(2.3%)	

The most common complications seen were premature rupture of membranes (PROM) and preterm vaginal delivery.

Table 6 : Presence/Absence of Complications			
	Patients without	Patients with bacterial	
	bacterial vaginosis	vaginosis	
	(n = 114)	(n =74)	P value = 0.01
Absent	109(96%)	65(88%)	Highly significant
Present	5(4%)	9(12%)	

The data presents strong evidence that bacterial vaginosis patients are more likely to have complications than non-bacterial vaginosis patients.

> Neonatal Outcome

Out of the 114 patients without bacterial vaginosis, 89% of the babies delivered did not suffer any complications and were shifted to be with the mother in the postnatal period. Only 12 babies (11%) required NICU admission for further care and management. 85% of the babies born to mothers with bacterial vaginosis were shifted to be with the mother in the postnatal period, whereas 11 babies required NICU admission.

The observations made on the numerical data shows a significant association between babies born to mothers with bacterial vaginosis suffering complications like PROM and preterm vaginal delivery and requirement of NICU admission in view of neonatal sepsis. The other common cause of the babies being shifted to NICU was birth asphyxia.

V. DISCUSSION

The present study was conducted to study the effects of bacterial vaginosis, detected in the second trimester, on the maternal and neonatal outcome. Woodrow et al ^[85], in their study claim a prevalence rate of around 10-30% amongst pregnant women which is consistent with this study.

A cross-sectional study conducted by Meng Li et al ^[88], concluded that the parity of the patient did not influence the occurrence of bacterial vaginosis. Similarly, though the number of multigravida women was higher than the number of primigravida in our study, there was no significant association between parity and prevalence of bacterial vaginosis. On further evaluation, we found that vaginal discharge was the most common presenting symptom amongst the pregnant women although it can be attributed to the normal vaginal discharge which occurs due to the increased blood supply to the genital tract in pregnancy. This makes it mandatory for a pregnant women coming with this complaint to undergo a per speculum examination for detection of bacterial vaginosis for early detection and treatment. Elgantri et al ^[93] had similar findings in their study, where there was an association between the presence of symptoms and bacterial vaginosis, with vaginal discharge being the commonest symptoms which was noticed in 60.9% of the patients enrolled in their study. Mullick et al ^[94] in their survey of infections during pregnancy also had similar observations where vaginal discharge was the most common presenting complaint.

Vaginal discharge is a blanket term which includes the normal pregnancy variant of watery kind, the thick curdy white discharge associated with Candidiasis, the greenish discharge of Trichomonial infection and the homogenous mucoid discharge typical to bacterial vaginosis. This necessitates a per speculum examination to ascertain the type of discharge. Amongst the women with bacterial vaginosis in our study, mucoid discharge was the commonest type. Ranjit et al ^[95] in their cross-sectional study noted that 39.8% women homogenous mucoid discharge. Ambike et al ^[96], in their study conducted at a tertiary care hospital, indicate at a significant association between the presence mucoid discharge and testing positive for bacterial vaginosis.

Amsel's criteria includes 4 clinical parameters. If 3 out of 4 parameters are fulfilled, the patient is said to have bacterial vaginosis. The following representation provides an insight on the most common parameters encountered in the diagnosis of bacterial vaginosis:

Table 7 : Inference of Similar Studies on Bacterial Vaginosis		
<u>Study (year)</u>	Place of Study	Inference
Gjerdingen et al(2000) ^[98]	Minnesota, USA	Mucoid vaginal discharge and raised vaginal pH
Krauss-Silva et al (2008) ^[99]	Rio de Janeiro	Raised vaginal pH was the commonest criteria fulfilled
Modak et al (2011) [100]	Kolkatta	Homogenous discharge and raised pH of vaginal secretions
Our Study	Aurangabad	Clue cells and raised vaginal pH were the commonest finding.

The maternal outcome of the 188 pregnant women studied revealed premature rupture of membranes and preterm vaginal delivery as the most common complications. Diejomaoh et al ^[106], in their longitudinal study conducted at a maternity hospital in Kuwait had similar findings where they noted that 21% of pregnant women with bacterial vaginosis had premature rupture of membranes and a significantly higher percentage, 27% of the pregnant women with bacterial vaginosis underwent preterm vaginal delivery.

The neonatal outcomes of the 188 delivered patients suggested that babies born to 15% of the pregnant women with bacterial vaginosis required NICU admission for

further evaluation as they showed signs of neonatal sepsis whereas only 11% of babies born to pregnant women without bacterial vaginosis required NICU care for management of birth asphyxia but a majority of the babies were shifted to be with the mother in the postnatal period. Similarly, in a study conducted by Laxmi et al ^[113], 14% of the babies born to mothers with bacterial vaginosis required further management in NICU. Dingens et al ^[114], in his study noted similar findings where 60% babies born to term pregnant women with bacterial vaginosis needed NICU support for further evaluation of neonatal sepsis. Chaim et al ^[115], in their study also found a significant association between babies born to women with bacterial vaginosis being predisposed to NICU care in view of signs of sepsis.

https://doi.org/10.5281/zenodo.14930546

ISSN No:-2456-2165

VI. CONCLUSION

Bacterial vaginosis, the polymicrobial inflammation of the vagina, has a high prevalence rate of upto 36%. All pregnant women in their second trimester coming for should undergo per antenatal checkup speculum examination and the three most common parameters of the Amsel's criteria, that is, homogenous mucoid discharge, raised vaginal pH and presence of clue cells in vaginal smear can be used to diagnose bacterial vaginosis. Pregnant women in their second trimester presenting without any symptoms should also undergo per speculum examination for the diagnosis of asymptomatic bacterial vaginosis and its treatment. The presence of bacterial vaginosis in the second trimester of pregnancy does not affect the maternal and neonatal outcome significantly because after its diagnosis and treatment, the recurrence rate was very low but detection of bacterial vaginosis before the onset of labour for its effect on maternal and neonatal outcome needs further research. Anemia is not a risk factor for bacterial vaginosis, but further studies are required for identification of other potential high riskfactors.

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