ORIGINAL RESEARCH

A study on clinical profile of pregnant women with preterm delivery

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ABSTRACT
Bacterial vaginosis is characterized by high concentrations of *Gardnerella vaginalis* and a set of potentially pathogenic bacterial vaginosis associated microorganisms. *Lactobacillussp.* which are normally present in high number [10 -10^6 CFU\gm fluid] are decreased in number or absent in bacterial vaginosis. Under aseptic precautions, an unlubricated sterile Sim's speculum will be inserted into the vagina and the type of discharge noted. If any vaginal discharge is present, its colour, amount and odour is noted. Vaginal pH will be evaluated using conventional pH strips. The change in colour is compared to the colour indicator ranging from 3.5-5.2. Next a high vaginal swab (HVS) will be taken from posterior vaginal fornix and sent to microbiology for Gram staining. Amine test also known as whiff test will be done by noting the fishy odor on addition of 10% KOH to the discharge on the blade of the speculum. Diagnosis of bacterial vaginosis will be done by Amsels composite criteria. There was a significant association of BV with Preterm (p value=), Early preterm (p value=),Premature Rupture of membranes (p value=) and low birth weight (p value=). There was no relation of Parity and Socioeconomic status with Bacterial Vaginosis.There was an increased rate of normal vaginal delivery in association with bacterial vaginosis.
Key words: Clinical profile, pregnant women, preterm delivery

INTRODUCTION
Bacterial vaginosis is a polymicrobial condition in which there is a synergistic overgrowth of certain organisms and cause local genital symptoms.
In the healthy vagina the predominant microorganisms detected are acidophilic facultative lacto bacilli. Hydrogen peroxide producing *Lactobacillus crispatus, L. Jensenii, L fermentum and L Gasseri* represent the predominant species. Other bacteria account for approximately 10 percent of the bacteria recovered from the healthy vagina [1].
Bacterial vaginosis is characterized by high concentrations of *Gardnerella vaginalis* and a set of potentially pathogenic bacterial vaginosis associated microorganisms. *Lactobacillus* sp. which are normally present in high number [10-10^6 CFU\gm fluid] are decreased in number or absent in bacterial vaginosis [2].

The total bacterial count in the normal vaginal ecosystem is 10^5 to 10^6/ml (<10^6 per ml) secretions, but in bacterial vaginosis the concentrations increase greatly often to 10^9 to 10^{11}/ml of secretions [3].
Lactobacilli likely contribute to the acidic environment characteristic of the healthy vagina through metabolism of glucose produced by vaginal epithelial cells form glycogen to lactic acid. H$_2$O$_2$ producing lactobacillus species are predominant in the vaginal fluid of healthy women.
Amines, primarily trimethylamine, putrescence and cadaverine are produced during amino acid metabolism by bacterial vaginosis-associated anaerobic bacteria; these volatile amines are released as pH increases and are responsible for the characteristically "sharp" or "fishy" odour noticed in the presence of bacterial vaginosis [4].

METHODOLOGY
SAMPLE SIZE
The sample size is 214 pregnant women.

INCLUSION CRITERIA
- Singleton pregnancy.
- At 1st visit, and 2nd and 3rd trimesters.

EXCLUSION CRITERIA
- Women with risk for preterm delivery in previous and present pregnancy-multiple pregnancy, cervical insufficiency, fetal malformations, polyhydramnios, ruptured membranes, cervical surgery.
- Women with medical disorders and hypertensive disorders in pregnancy
- Labor induction before 34 weeks for obstetric and medical conditions.

The study was done in the department of OBG.

Written consent in patients own language will be taken. All antenatal women will be assessed at the first visit and followed up in the subsequent trimesters. First, detailed history followed by general and obstetric exmination is done. All these women will be subjected to routine antenatal investigations.

SAMPLE COLLECTION
Under aseptic precautions, an unlubricated sterile Sim's speculum will be inserted into the vagina and the type of discharge noted. If any vaginal discharge is present, its colour, amount and odour is noted. Vaginal pH will be evaluated using conventional pH strips. The change in colour is compared to the colour indicator ranging from 3.5-5.2. Next a high vaginal swab (HVS) will be taken from posterior vaginal fornix and sent to microbiology for Gram staining. Amine test also known as whiff test will be done by noting the fishy odor on addition of 10% KOH to the discharge on the blade of the speculum. Diagnosis of bacterial vaginosis will be done by Amsels composite criteria.

Amsels criteria depend on the presence of three of the following four signs:
1. Presence of clue cells.
2. Homogenous white, non-inflammatory discharge that adheres to the vaginal walls.
3. pH of vaginal fluid >4.5.
4. Fishy odor from vaginal discharge before or after addition of 10% potassium hydroxide.

RESULTS
The prevalence of Bacterial vaginosis was found to be 18.69%. Among 214 antenatal women, 40 pregnant women were found to have bacterial vaginosis.

Table 1:Age Distribution of Study Group

Age Group	Number of Pregnant Women	Percentage
18-20	18	8.4
21-23	46	21.49
24-26	66	30.84
27-29	44	20.56
30-32	23	10.74
32-34	13	6.07
>35	4	1.86
Total	214	100

Mean age is 25.76± 3.88 years.
Majority of pregnant women are between 24-26 years of age.

Table 2: Number of Preterm Births in Various Age Groups

Age Group (Years)	Preterm Births	Term Births
18-20	4	18
21-23	10	36
24-26	19	46
27-29	6	36
30-32	6	24
32-34	2	4
>35	1	2
Total	48	166

In our study, majority of preterm births occurred among women of 24-26 years of age.

Table 3: Parity Distribution of Study population

Parity	Frequency (N)	Percentage
Primi	123	57.47
G2	74	34.57

G3	15	7
>G4	2	0.93
Total	**214**	**100**

Most of the pregnant women in the study population are primigravida with 57.47%.

Table 4: Number of Preterm Births in Relation to Parity

Parity	Preterm Births	Term Births
PRIMI	28	95
G2	19	55
G3	6	9
>G4	1	1
Total	54	160

Most of the preterm births occurred in primigravida compared to multigravida.

Table 5: Association of Low and High Socioeconomic Class with Bacterial Vaginosis

Socioeconomic Class	Bacterial vaginosis Positive	Bacterial vaginosis Negative	Total
Lower (Class 3 And 4)	26	113	139
High (Class 1 And 2)	14	61	75
Total	40	174	214

Chi-square with Yates correction.

Ch-squared equal 0.000 with 1 degrees of freedom. The one tailed P value equals 0.4973. Hence, there is no association between lower socioeconomic class and bacterial vaginosis.

Table 6: Number of Preterm Births in Low and High Socioeconomic Class

Socio Economic Class	Preterm Births	Term Births	Total
Low (class 3 and 4)	35	104	139
High (class 1 and 2)	19	56	75
Total	54	160	214

Chi-square with Yates correction.

Ch-squared equal 0.000 with 1 degrees of freedom. The one tailed P value equals 0.4902. Hence, there is no association between lower socioeconomic class and preterm births.

Table 7: Number of Amsel's Positive Cases in Each Trimester

Gestational Age of Diagnosis	Amsels Positive	Amsels Negative	Percentage
Till 12 weeks	0	214	0%
12-28 weeks	5	209	12.5%
>28 weeks	35	179	**87.5%**

In first trimester, none of the pregnant women in our study population developed bacterial vaginosis. Between 12-28 weeks, 12.5% of pregnant women developed bacterial vaginosis. 87.5% of pregnant women developed bacterial vaginosis.

Table 8: Mode of Delivery in of Bacterial Vaginosis (BV) cases diagnosed by Amsel's Criteria

Mode	BV+	Percentage	BV-	Percentage
Full term normal vaginal delivery	2	2.63	74	97.36
Preterm normal vaginal delivery	25	92.59	2	7.40
Emergency Caesarean	13	14.44	77	85.55
Elective Caesarean	2	12.5	14	87.5
Outlet Forceps	1	33.33	2	66.66

Majority of pregnant women with bacterial vaginosis (92.59%) diagnosed by Amsel's criteria delivered by normal vaginal delivery.

DISCUSSION
Diagnosis of bacterial vaginosis is complicated by the poly microbial nature of the condition. Culture for single microorganisms such as *G vaginalis* does not provide an accurate diagnosis for the clinical condition bacterial vaginosis [5].

In 1983, Amsel developed a set of composite clinical criteria which are still widely used both in clinical practice and in research. The diagnosis is made by finding three of the following four signs:

1359

A homogenous vaginal discharge.

An elevated vaginal pH> 4.5:

A positive whiff test on addition of a solution of 10% potassium hydroxide (KOH) to a sample of vaginal secretions.

The presence of clue cells on microscopic examination of a wet preparation of vaginal secretions.

The presence of at least three out of four of these criteria is regarded as diagnostic of bacterial vaginosis.

Patients with bacterial vaginosis have a thin, copious, malodorous watery vaginal discharge that does not form clumps, is often present at the introitus and sticks to the anterior and lateral vaginal walls. This discharge can be distinguished from the normal vaginal discharge, which has a thick, milky, clumpy, appearance [6].

Vaginal pH is measured using narrow-range pH paper and assessing the colour change produced by a sample of vaginal secretion taken from the posterior fornix. A low pH virtually excludes bacterial vaginosis an elevated pH is the most sensitive, but least specific of the criteria used for the diagnosis of bacterial vaginosis, as an increase can also be associated with menstruation, recent sexual intercourse or infection with *T. vaginalis*.

Vaginal fluid pH determination is simple to perform and it is economical and has a high negative predictive value.

The whiff test involves the addition of a drop of 10% KOH to a sample of vaginal secretions which produces a characteristic fishy odour in the presence of bacterial vaginosis.

Subjective complaints of vaginal odor can be associated significantly with bacterial vaginosis. Pheifer *et al.*, were the first to report the presence of such a characteristic odor. The odor may be recognized on speculum examination, but the intensity will increase with the addition of potassium hydroxide.

As a single entity, the whiff test has a positive predictive value of 90% and a specificity of 70% [7].

'Clue cells' are desquamated vaginal epithelial cells that are densely coated with adherent bacteria such that their borders are indistinct.

The detection of clue cells on direct microscopy is the single most sensitive and specific criterion for bacterial vaginosis but it is operator-dependent. Clue cells can be identified on a Gram stain or a wet preparation (small sample of vaginal secretions to which drop of saline has been added) and are regarded as pathognomonic of bacterial vaginosis [8].

Atleast there should be 20% of epithelial cells having the appearance or clue cells in a wet mount of vaginal fluid (Escherbach *et al.*, 1998) to diagnose bacterial vaginosis.

Recognition of clue cells which is an excellent predictor of bacterial vaginosis is subject to variability. Because of these drawbacks a simple,

inexpensive method for diagnosis of Bacterial vaginosis was assessed. Gram stain of the vaginal fluid has been used for confirmation of bacterial vaginosis since 1965.

It has been demonstrated that Gram stain diagnosis alone corresponds well to the use of composite criteria and to the presence of the associated bacteria. It is a more objective method of diagnosis.

The OSOM BV Blue assay (Genzyme Diagnostics, Cambridge, MA) is a chromogenic point-of-care test (POCT) that measures sialidase levels in vaginal fluid. Sialidases, formerly known as neuraminidases, are produced by bacteria such as *Gardnerella* and *Bacteroides* species. The test is a dipstick and the results are available within 10 min; hence, it is a very useful bedside tool, especially in clinics without microscopy. The sensitivity and specificity for the OSOM BV Blue assay range from 88% to 94% and 91% to 98%, respectively, compared to Nugent and Amsel's criteria [9].

The FemExam (Cooper Surgical, Shelton, CT) POCT detects metabolic products of *G. vaginalis*, which include amines and the activity of proline aminopeptidase, and measures vaginal pH. It consists of two plastic cards; one card is for pH measurement and the presence of trimethylamine, and the second card is for proline aminopeptidase measurement. The combined sensitivity of cards 1 and 2 is 91% and the specificity is 61% compared with the Nugent score. It is very fast (2 min), objective, and easily performed.

Given the limitations of microscopy and other POCTs for Bacterial vaginosis diagnosis, new technologies using molecular markers of Bacterial vaginosis have been developed. Molecular technologies are advantageous over POCTs and microscopy-based tests because they are objective, are able to detect fastidious bacteria, enable quantitation, and are ideal for self-collected vaginal swabs. These technologies offer higher performance and are based on the detection of specific bacterial nucleic acids. The primary types of commercial molecular assays available in the United States for BV diagnostics are direct DNA probe and nucleic acid amplification assays [10].

CONCLUSION

- There was a significant association of BV with Preterm (p value< 0.5), Early preterm (p value<0.5), Premature Rupture of membranes (p value<0.5) and low birth weight (p value<0.5).
- There was no relation of Parity and Socioeconomic status with Bacterial Vaginosis.
- There was an increased rate of normal vaginal delivery in association with bacterial vaginosis.

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