Original Article

Clinical Profile and Diagnostic Evaluation of Bacterial Vaginosis: A Cross-Sectional Study

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ABSTRACT

Background: Bacterial vaginosis (BV) is a common cause of vaginal discharge among women of reproductive age and is associated with significant gynecological and obstetric complications. Accurate diagnosis using simple clinical methods is essential, particularly in resource-limited settings.
Objectives: To evaluate the clinical profile and diagnostic parameters of bacterial vaginosis using Amsel's criteria among women attending a gynecology outpatient department.
Materials and Methods: This hospital-based cross-sectional study was conducted among 120 women aged 15–45 years attending the gynecology outpatient department. Clinical features, including type of vaginal discharge and symptomatology, were recorded. Diagnostic evaluation included vaginal pH measurement, amine (whiff) test, and wet mount microscopy for clue cells. Bacterial vaginosis was diagnosed using Amsel's criteria. Data were analyzed using descriptive statistics.
Results: The prevalence of bacterial vaginosis was 9.2%. The most common clinical presentation was watery grey vaginal discharge. Elevated vaginal pH (>4.5) was observed in all BV cases. Clue cells showed a strong association with BV and were the most reliable diagnostic indicator. The amine test demonstrated high specificity, with all positive cases confirming the diagnosis. A considerable proportion of cases were asymptomatic.
Conclusion: Amsel's criteria provide a simple, reliable, and cost-effective method for diagnosing bacterial vaginosis in outpatient settings. Vaginal pH and clue cells are key diagnostic parameters. Routine screening is recommended for early detection, including in asymptomatic women.

Keywords: Bacterial vaginosis, clinical profile, Amsel's criteria, clue cells, vaginal pH, amine test.

INTRODUCTION

Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge among women of reproductive age and represents a significant clinical and public health concern worldwide. It is characterized by a disruption of the normal vaginal microbiota, with a reduction in hydrogen peroxide–producing lactobacilli and overgrowth of anaerobic organisms such as *Gardnerella vaginalis*, *Prevotella*, *Mobiluncus*, and *Mycoplasma hominis* (1).

The normal vaginal ecosystem is dominated by lactobacilli, which maintain an acidic pH and protect against pathogenic organisms. In BV, this protective mechanism is compromised, resulting in increased vaginal pH and production of volatile amines that contribute to the characteristic fishy odor and abnormal discharge (2).

Clinically, BV typically presents with thin, homogeneous, greyish-white vaginal discharge and malodor, especially after sexual intercourse or during menstruation. However, a distinctive feature of BV is that a large proportion of women—approximately 50–75%—remain asymptomatic, making diagnosis based solely on clinical symptoms unreliable (3). This asymptomatic nature contributes to underdiagnosis and increases the risk of untreated disease.

BV is associated with several important gynecological and obstetric complications. It has been linked to an increased risk of pelvic inflammatory disease, post-operative infections, and infertility. Furthermore, BV has been shown to increase susceptibility to sexually transmitted infections, including human immunodeficiency virus (HIV), herpes simplex virus, and *Chlamydia trachomatis* (4,5). In pregnancy, BV is associated with adverse outcomes such as preterm labor, premature rupture of membranes, and low birth weight (6).

Accurate diagnosis of BV is essential for timely management and prevention of complications. The diagnosis can be established using laboratory methods such as Gram staining with Nugent scoring, which is considered the gold standard. However, this method requires laboratory infrastructure, trained personnel, and is not always feasible in routine clinical practice, especially in resource-limited settings (7).

In contrast, Amsel's criteria provide a simple, rapid, and cost-effective clinical method for diagnosing BV. These criteria include the presence of homogeneous vaginal discharge, vaginal pH greater than 4.5, positive amine (whiff) test, and presence of clue cells on microscopic examination, with diagnosis established when at least three criteria are present (8). Several studies have demonstrated that Amsel's criteria have good sensitivity and specificity and are particularly useful in outpatient settings where advanced laboratory techniques are not available (9).

Among the diagnostic parameters, vaginal pH measurement is a simple bedside test with high sensitivity, while the presence of clue cells is considered the most reliable single indicator of BV. The amine test, although less sensitive, is highly specific and supports the diagnosis when positive (10).

In developing countries, including India, the diagnosis of BV often relies on clinical evaluation due to limited access to laboratory facilities. Despite its high prevalence and associated complications, BV remains under-recognized in routine clinical practice. There is a need to evaluate the effectiveness of simple diagnostic methods and understand the clinical profile of BV in outpatient settings.

Therefore, the present study was undertaken to assess the clinical profile and evaluate the diagnostic parameters of bacterial vaginosis using Amsel's criteria among women attending a gynecology outpatient department.

MATERIALS AND METHODS:
Study Design
This was a hospital-based descriptive cross-sectional study conducted to evaluate the clinical profile and diagnostic parameters of bacterial vaginosis among reproductive-aged women.

Study Setting
The study was carried out in the Department of Obstetrics and Gynaecology at a multispecialty hospital in Chennai, India. The hospital provides outpatient services to women from varied socio-economic backgrounds.

Study Duration
The study was conducted over a period of eight months, from September 2013 to April 2014.

Study Population
A total of 120 women aged 15–45 years attending the gynecology outpatient department (OPD) were included in the study. Both symptomatic and asymptomatic women were enrolled.

Sample Size
This was a time-bound study, and all eligible women presenting during the study period were included, yielding a total sample size of 120 participants.

Inclusion Criteria
- Women aged **15–45 years**
- Attending gynecology OPD
- Both symptomatic and asymptomatic individuals
- Willing to participate and provide informed consent

Exclusion Criteria
- Pregnant women

- Women with vaginal bleeding
- Women who had received antibiotics in the preceding two weeks
- Unmarried women

Ethical Considerations
Approval for the study was obtained from the institutional ethics committee. Written informed consent was taken from all participants.

Data Collection
Data were collected using a pretested structured proforma, which included:
- Socio-demographic details (age, education, religion)
- Clinical symptoms (vaginal discharge, odor, itching)
- Obstetric and gynecological history
- Sexual history and duration with partner
- Contraceptive practices

All interviews were conducted in Tamil or English, ensuring clarity and patient comfort.

Clinical Examination
Each participant underwent a detailed general and pelvic examination.
- A sterile speculum examination was performed without using antiseptic solutions
- The characteristics of vaginal discharge (color, consistency, odor) were noted
- The condition of vaginal walls and cervix was assessed

Sample Collection and Diagnostic Evaluation
Two high vaginal swabs were collected from the posterior fornix of the vagina under aseptic conditions:
1. Wet Mount Microscopy
- One swab was mixed with normal saline on a glass slide
- Covered with a coverslip and examined under light microscopy
- Evaluated for:
  - **Clue cells**
  - *Trichomonas vaginalis*
  - Fungal elements (candidiasis)
2. Amine (Whiff) Test
- The second swab was treated with 10% potassium hydroxide (KOH)
- A positive test was indicated by the presence of a fishy odor
3. Vaginal pH Measurement
- Vaginal pH was measured using pH indicator paper applied to vaginal secretions
- A pH value of >4.5 was considered abnormal

Diagnostic Criteria (Amsel's Criteria)
Bacterial vaginosis was diagnosed when at least three of the following four criteria were present:
1. Homogeneous, thin, greyish-white vaginal discharge
2. Vaginal pH > 4.5
3. Positive amine (whiff) test
4. Presence of clue cells on microscopy

Assessment of Clinical Profile
The clinical profile of BV was evaluated based on:
- Presence or absence of symptoms
- Type of vaginal discharge
- Associated findings on pelvic examination

Laboratory Analysis
All samples were analyzed in the microbiology laboratory of the hospital using standard procedures.

Statistical Analysis
Data were entered into Microsoft Excel and analyzed using SPSS version 14.
- Descriptive statistics (frequency and percentage) were calculated
- Results were presented using tables and charts
- Diagnostic parameters were interpreted based on their association with BV

RESULTS:

A total of 120 women aged 15–45 years attending the gynecology outpatient department were included in the study. Out of 120 participants, 11 women were diagnosed with bacterial vaginosis, yielding a prevalence of 9.2%.

The most common presenting complaint among participants was vaginal discharge. Among the types of discharge observed, watery grey discharge was the predominant type associated with bacterial vaginosis. (Table 1)

Table 1: Distribution of BV According to Type of Vaginal Discharge

Type of Discharge	Total (n)	BV Positive (n)	Percentage (%)
Watery grey	92	9	10%
Milky white	20	1	5%
Curdy	5	0	0%
Thick white	2	1	50%
Yellow	1	0	0%
Total	**120**	**11**	**9.2%**

BV was more commonly observed in symptomatic women compared to asymptomatic individuals; however, a notable proportion of asymptomatic cases was also identified. (Table 2)

Table 2: Association of BV with Symptoms

Symptoms	Total (n)	BV Positive (n)	Percentage (%)
Present	61	8	14%
Absent	59	3	6%
Total	**120**	**11**	**9.2%**

All patients diagnosed with BV had vaginal pH greater than 4.5, indicating a strong association between elevated vaginal pH and BV. (Table 3)

Table 3: Association of BV with Vaginal pH

Vaginal pH	Total (n)	BV Positive (n)	Percentage (%)
≤ 4.5	32	0	0%
> 4.5	88	11	13%
Total	**120**	**11**	**9.2%**

Clue cells were present in the majority of BV cases and showed a strong correlation with the diagnosis. (Table 4)

Table 4: Association of BV with Clue Cells

Clue Cells	Total (n)	BV Positive (n)	Percentage (%)
Present	9	9	100%
Absent	111	2	2%
Total	**120**	**11**	**9.2%**

The amine test showed high specificity, as all patients with a positive test were diagnosed with BV. (Table 5)

Table 5: Association of BV with Amine Test

Amine Test	Total (n)	BV Positive (n)	Percentage (%)
Positive	3	3	100%
Negative	117	8	7%
Total	**120**	**11**	**9.2%**

DISCUSSION:

The present study evaluated the clinical profile and diagnostic parameters of bacterial vaginosis (BV) among reproductive-aged women attending a gynecology outpatient department and found a prevalence of **9.2%**. This prevalence is comparable to several hospital-based studies but lower than community-based estimates, which have reported higher prevalence rates due to inclusion of high-risk populations and differences in diagnostic criteria (11,12).

The most common clinical presentation observed in this study was vaginal discharge, with watery grey discharge being the predominant type associated with BV. This finding is consistent with classical descriptions of BV in earlier studies, where thin, homogeneous discharge has been reported as the hallmark clinical feature (13). However, it is important to note that the clinical appearance of discharge alone is not sufficient for diagnosis due to overlap with other causes of vaginitis.

In the present study, BV was more frequently observed among symptomatic women (14%), yet a significant proportion of asymptomatic cases (6%) was also identified. This highlights the well-documented fact that a large proportion of BV cases remain asymptomatic, leading to underdiagnosis and delayed treatment (14). Previous studies have reported that up to 50–75% of women with BV may be asymptomatic, emphasizing the importance of routine screening in clinical practice (15).

One of the key findings of this study was the strong association between elevated vaginal pH (>4.5) and BV, with all BV-positive cases demonstrating increased pH. This observation is consistent with previous literature, which identifies vaginal pH as a simple, sensitive, and cost-effective screening tool for BV (16). The loss of lactobacilli and subsequent overgrowth of anaerobic organisms results in increased vaginal pH, which plays a central role in the pathogenesis of BV.

The presence of clue cells was found to be the most reliable diagnostic parameter in this study, with all patients exhibiting clue cells being diagnosed with BV. This finding is in agreement with earlier studies that consider clue cells as the single most specific indicator of BV (17). Clue cells represent vaginal epithelial cells coated with bacteria, reflecting the underlying microbial imbalance.

The amine (whiff) test demonstrated high specificity in this study, as all patients with a positive test were confirmed to have BV. Similar findings have been reported in previous studies, where the amine test, although less sensitive, is considered highly specific for BV when positive (18). The test detects volatile amines produced by anaerobic bacteria, which contribute to the characteristic fishy odor.

The findings of this study support the continued use of Amsel's criteria as a reliable and practical diagnostic tool in outpatient settings. Although Gram stain with Nugent scoring is considered the gold standard, it requires laboratory facilities and expertise, limiting its use in many clinical settings, particularly in developing countries (19). Amsel's criteria, being simple and cost-effective, provide an effective alternative for diagnosis in such settings.

Another important observation was that clinical symptoms alone were insufficient for accurate diagnosis, as a considerable number of asymptomatic cases were identified. This underscores the importance of combining clinical evaluation with simple diagnostic tests such as pH measurement, microscopy, and amine test for accurate diagnosis.

The present study has certain limitations. The sample size was relatively small, and the study was conducted in a single hospital setting, which may limit the generalizability of the findings. Additionally, advanced diagnostic methods such as Nugent scoring were not employed for confirmation.

CONCLUSION:
Bacterial vaginosis commonly presents with vaginal discharge but may also remain asymptomatic, emphasizing the need for careful clinical evaluation. In the present study, Amsel's criteria proved to be a simple, reliable, and cost-effective method for diagnosis in an outpatient setting. Among the diagnostic parameters, elevated vaginal pH and the presence of clue cells showed the strongest association with bacterial vaginosis, while the amine test demonstrated high specificity.

These findings highlight the importance of combining clinical assessment with basic diagnostic tests for accurate detection. Routine screening using simple bedside methods can facilitate early diagnosis and timely management, thereby reducing potential complications associated with bacterial vaginosis.

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