

Full Length Research Paper

Comparison of OSOM BV Blue test with conventional methods for diagnosis of bacterial vaginosis

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Bacterial vaginosis is the commonest cause of vaginal discharge in sexually active females. It is often associated with adverse pregnancy outcomes and increased susceptibility to other sexually transmitted diseases. In the present study, we evaluated efficacy of OSOM BV Blue test and compared it with conventional methods like Gram staining and Amsel's criteria for diagnosing bacterial vaginosis. A total of 635 females attending gynaecology OPD and antenatal clinic with complaints of vaginal discharge were included in the study along with 50 healthy females as controls. Two vaginal swabs were collected aseptically from each patient. One swab was used for Gram staining and the other for OSOM BV Blue test. Amine test and vaginal pH test as defined in Amsel's criteria were also performed. Bacterial vaginosis was detected in 60.8% of patients. OSOM BV Blue test detected maximum number of cases with sensitivity and specificity of 95.3 and 92.1%, respectively. Thus, it can be used as a point-of-care test useful in making rapid and accurate diagnosis of bacterial vaginosis in setups lacking microscopic facilities or technical expertise.

Key words: OSOM BV Blue test, Gram staining, Amsel's criteria, bacterial vaginosis.

INTRODUCTION

Vaginal discharge is one of the most common gynaecological symptoms affecting women of reproductive age group and Bacterial Vaginosis (BV) is the most common cause of abnormal vaginal discharge in sexually active females throughout the world (Schwebke, 2000, 2009; Kalra et al., 2007; Allsworth and Peipert, 2007). It is characterized by an increased vaginal pH (pH>4.5) and the replacement of vaginal lactobacilli with anaerobes such

as *Gardnerella vaginalis* (Gardner and Duker, 1955), *Morbilluncus* spp. (Spiegel et al., 1983), *Prevotella* spp. (Fredricks et al., 2005), *Mycoplasma hominis* (Hillier et al., 1995) and the recently identified metronidazole resistant *Atopobium vaginae* (Verstraelen et al., 2004), resulting in reduced levels of hydrogen peroxide and organic acids usually present in the vagina (Hainer and Gibson, 2011). Abnormal vaginal discharge may be the only symptom

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of BV, although, many affected women are asymptomatic (Klebanoff et al., 2004). BV affects millions of women annually (Wang, 2000) and is strongly associated with several adverse health outcomes, including preterm labor and delivery (Gravett et al., 1986; McGregor et al., 1994, 1995; Hillier et al., 1995; Howe et al., 1999), pelvic inflammatory disease (Eschenbach et al., 1988; Spiegel, 1991; Sweet, 1995), postpartum and postabortal endometritis (Haggerty et al., 2004). Also, there is an increased risk of acquiring infection due to Herpes simplex virus 2 (HSV 2), *Trichomonas vaginalis*, *Neisseria gonorrhoeae* and human immunodeficiency virus (HIV) in females suffering from bacterial vaginosis than in women with normal vaginal flora (Bhalla et al., 2007).

Diagnosis of BV should be rapid, reliable and safe. This is especially vital in pregnant women where intervention may be necessary for the well-being of both the mother and the foetus (Africa, 2013). The laboratory methods for the diagnosis of BV include direct Gram stain of vaginal secretions, culture for *G. vaginalis* and other organisms associated with BV, biochemical tests for metabolic by products of vaginal bacteria (gas liquid chromatography) and Proline amino peptidase tests, etc (Mathew et al., 2001). There is no basis for routine culture for diagnosing bacterial vaginosis as *Gardnerella* is found in 5 to 60% of healthy women and positive culture for *Gardnerella* has positive predictive value less than 50% (Majeroni, 1998). Culture is also time consuming, expensive and misleading as it can lead to considerable over or under treatment. Conventional methods like Gram staining based on Nugent's scoring and Amsel's criteria have been routinely used in the diagnosis of bacterial vaginosis (Amsel et al., 1983; Nugent et al., 1991). Newer diagnostic techniques based on molecular fingerprinting methods like PCR-denaturing gradient gel electrophoresis (PCR-DGGE) have been recently introduced, which detect bacterial diversity in vaginal microflora in patients suffering from BV (Vitali et al., 2007; Ling et al., 2010). But its high cost and limited availability is the main drawback for its use in routine diagnosis. Also, these diagnostic tests require laboratory facilities along with trained and expert personnel, which is sometimes difficult especially in remote and peripheral areas. Thus, clinicians largely depend on syndromic management of such patients which may cause therapeutic failure, ultimately leading to poor patient compliance and problem of drug resistance (Tann et al., 2006).

Elevated level of enzyme sialidase in vaginal fluid has earlier been detected in patients suffering from bacterial vaginosis (von et al., 1984; Wiggins et al., 2000; Smayevsky et al., 2001). OSOM BV Blue test is a new point-of-care rapid chromogenic test based on the principle of detection of elevated sialidase activity in vaginal fluid produced by pathogens such as *G. vaginalis*, *Bacteroides* spp., *Prevotella* spp. and *Mobiluncus* spp. Hence, the present study was done to determine the efficacy of OSOM BV Blue test in diagnosing bacterial

vaginosis, and to compare it with other routinely used conventional methods like Gram staining and Amsel's criteria.

MATERIALS AND METHODS

The study group comprised of 635 patients in the reproductive age group (15 to 45 years) who came to gynaecology OPD and antenatal clinic of Jawaharlal Nehru Medical College and Hospital, Aligarh Muslim University, Aligarh, India, with complaints of foul smelling vaginal discharge, pruritis, dysuria and pain in lower abdomen. In addition, 50 healthy age-matched females attending gynaecology OPD for intrauterine device (IUD) insertion and who were otherwise healthy in all respect were taken as controls. After detailed history and physical examination, two vaginal swabs were taken from each patient. First swab was used to prepare smear for Gram staining, which was performed to look for clue cells, large gram positive rods (lactobacilli), small gram negative or gram-variable rods, curved gram-variable rods and Nugent's scoring was done accordingly (Nugent et al., 1991). In addition, Amsel's criteria was also determined on the basis of 3 out of 4 findings: presence of vaginal discharge, vaginal pH > 4.5, positive Amine test and presence of clue cells (Amsel et al., 1983). Vaginal pH was tested by dipping pH strip in vaginal discharge with the help of sterile forceps. Change in colour was noted. A pH of more than 4.5 was taken as positive for bacterial vaginosis. Amine (Whiff) test was performed by adding 10% KOH on discharge collected on posterior blade of speculum. A fishy odour indicated a positive test for bacterial vaginosis. Second swab was used to perform OSOM BV Blue test (Genzyme Diagnostics, UK) according to manufacturer's instruction. Before running the test, the kit was brought to room temperature. The vaginal swab was put into the BV test vessel and gently swirled to mix properly. Then, the vessel was allowed to stand for 10 min at room temperature followed by addition of 1 drop of developer solution. The test vessel was then gently swirled to mix.

The results were read immediately. Appearance of blue/green colour in the BV test vessel or on the head of the swab indicated positive result, and a yellow colour indicated negative result.

RESULTS

Out of 635 patients included in our study, bacterial vaginosis was detected in 386 (60.8%) patients by different diagnostic tests. Gram staining detected bacterial vaginosis with Nugent's score of > 7 in 54.0% patients (Table 1). Clue cells were seen in 100% of patients suffering from bacterial vaginosis (Figure 1). Amsel's criteria detected infection in 40.5% patients. Positive OSOM BV Blue test as shown by appearance of blue/green colour in the test vessel (Figure 2) was seen in 55.1% patients. Thus, we detected maximum number of cases of bacterial vaginosis by OSOM BV Blue test, followed by Gram staining and Amsel's criteria (Figure 3). A correlation was done between different diagnostic tests performed and it was found that among the 386 positive cases of bacterial vaginosis, 237 (61.4%) patients were detected by all the three tests (Gram staining, OSOM BV Blue test and Amsel's criteria), whereas, 249 out of 635 patients were negative for bacterial vaginosis by these tests (Figure 4). No infection was detected in control group by any of these

Table 1. Distribution of patients with vaginal discharge having bacterial vaginosis as diagnosed by Gram staining based on Nugent's score.

Vaginal morphotypes based on Nugent's score			Total number of patients
Bacterial vaginosis	Intermediate	Normal	
Score	Score	Score	
7-10	4-6	0-3	635
343 (54.0)	215 (33.9)	77 (12.1)	

* Figure within parentheses indicates percentage.

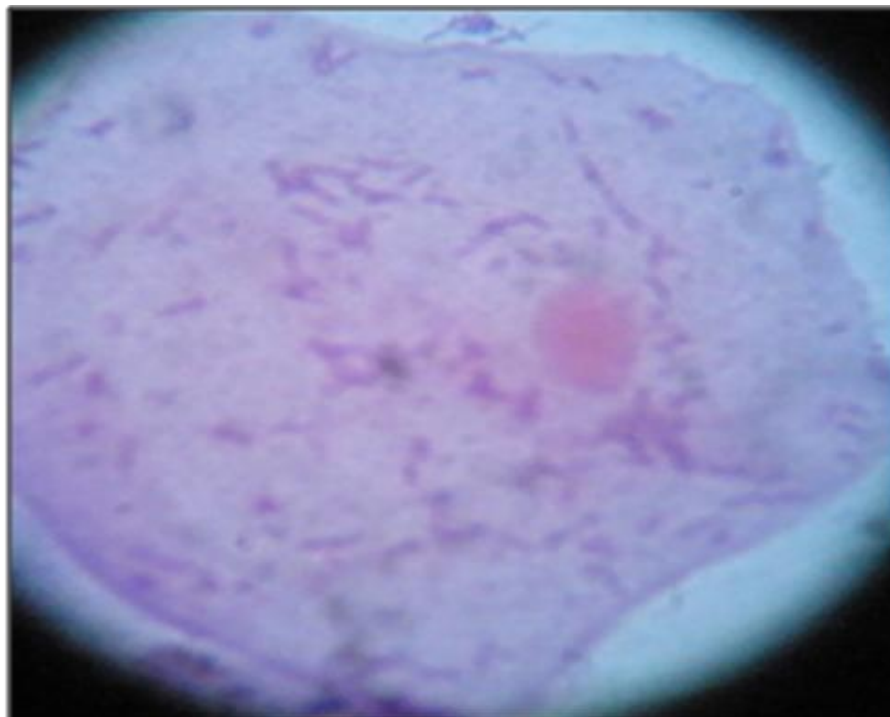


Figure 1. Clue cell as seen on Gram staining. Clue cells are shed-off vaginal epithelial cells with many bacteria adherent to its surface.

methods. Comparison of different methods used for diagnosing bacterial vaginosis was done with Gram staining taken as gold standard and sensitivity and specificity of the tests were calculated (Table 2).

DISCUSSION

In our study, Gram staining detected bacterial vaginosis (Nugent's score > 7) in 54.0% of patients, while a shift from normal flora (score 4 to 6) was observed in 33.9% cases. In a study done by Sewankambo et al. (1997), bacterial vaginosis was reported in 50.8% and intermediate flora in 31.7% women. An intermediate score (4 to 6) may be found in women who were either recovering from bacterial vaginosis or may develop it subsequently. Clue cells were demonstrated in all the cases of bacterial

vaginosis with sensitivity and specificity of 100%. A similar study done by Agarwal et al. (2005) also showed sensitivity and specificity of clue cells to be 100%. Amsel's criteria detected bacterial vaginosis in 40.5% of patients with a sensitivity and specificity of 69.0 and 93.1%, respectively which is comparable to the study done by Dadhwal et al. (2010) who showed the sensitivity and specificity of Amsel's criteria as 51.2 and 98%, respectively.

In our study, OSOM BV Blue test performed well and detected maximum cases (55.1%) of bacterial vaginosis. Its performance was better in comparison to Gram staining (Nugent's scoring) and Amsel's criteria with a high sensitivity and specificity of 95.3 and 92.1%, respectively. This is similar to the study done by Myziuk et al. (2003) who demonstrated the sensitivity and specificity of OSOM BV blue test as 91.7 and 97.8%, respectively.

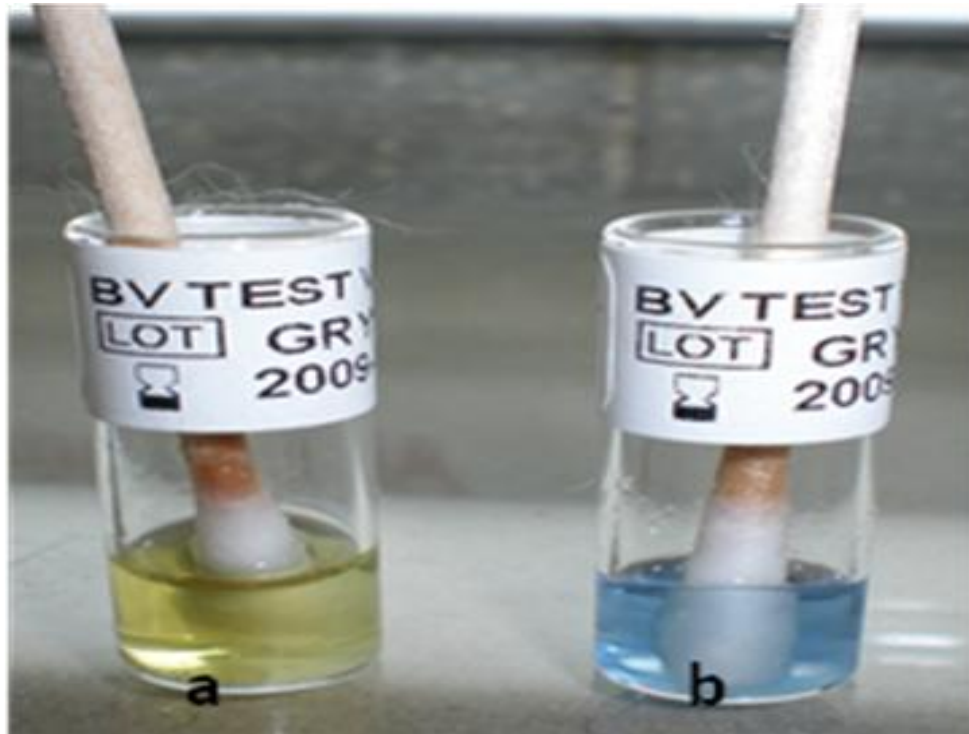


Figure 2. Result of OSOM BV Blue test. a) Negative result; b) positive result.

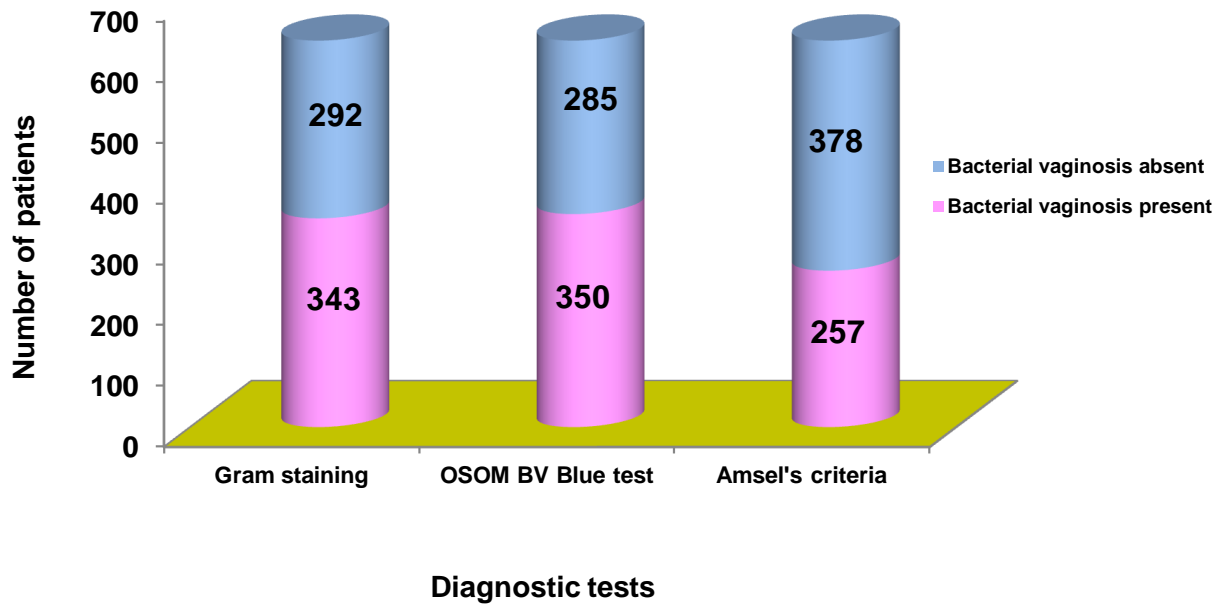


Figure 3. Bacterial vaginosis detected by different diagnostic tests.

Conclusion

Bacterial vaginosis is the most common cause of vaginal discharge in females of reproductive age group. As non-treatment of this condition may give rise to several gynae-

cological and obstetric complications, prompt diagnosis and treatment should be considered. Although, Gram staining has been used traditionally in the diagnosis of bacterial vaginosis, but it requires microscopic facility and technical expertise. Amine test and vaginal pH test used

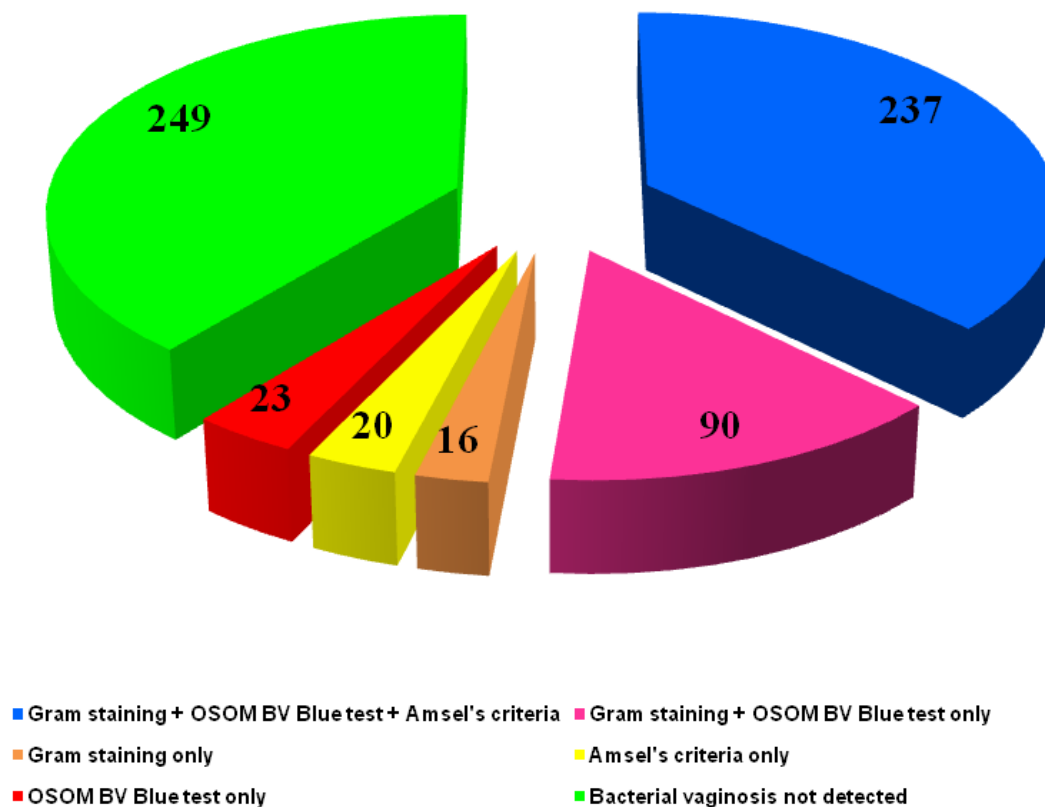


Figure 4. Correlation of different tests performed in diagnosing bacterial vaginosis.

Table 2. Comparison of different methods with Gram staining for diagnosis of bacterial vaginosis.

Diagnostic test	Sensitivity (%)	Specificity (%)	Positive predictive value (%)	Negative predictive value (%)
OSOM BV Blue test	95.3	92.1	93.4	94.4
Amsel's criteria	69.0	93.1	92.2	72.0

in Amsel's criteria are rapid and easy methods, but accurate identification of clue cells is not easy and requires experience. Also, they have low sensitivity which can lead to under diagnosis of patients suffering from bacterial vaginosis. OSOM BV Blue test is a rapid diagnostic test which can be performed at the clinic avoiding the time delay of sending a sample to the laboratory and the results are available in 10 min. As OSOM BV Blue test performed well in comparison to routinely used conventional methods like Gram staining and Amsel's criteria, it should be used for quick diagnosis and prompt treatment of patients that will help prevent women from developing adverse sequelae that can arise from a delayed or missed diagnosis.

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