

Full Length Research Paper

OSOM BV blue test: A new point-of-care test for diagnosing bacterial vaginosis and its comparison with Gram staining

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Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge in females of reproductive age group which predisposes them to other sexually transmitted diseases including human immunodeficiency virus (HIV) and various obstetric complications. In the present study, efficacy of OSOM BV Blue test was evaluated for diagnosing bacterial vaginosis in comparison with Gram staining. The study included 635 females with complaints of foul smelling vaginal discharge along with 50 healthy age-matched females as controls. Two vaginal swabs were collected aseptically from each patient. One swab was used for OSOM BV blue test and the other for Gram staining. OSOM BV blue test detected bacterial vaginosis in 350 (55.1%) patients, whereas, Gram staining based on Nugent's score (7 to 10) detected BV in 343 (54.0%) patients. The sensitivity and specificity of OSOM BV blue test in comparison with Gram staining was 95.3 and 92.1% respectively. To conclude, OSOM BV blue test is a new point-of-care test useful in making prompt diagnosis and early treatment of bacterial vaginosis in the absence of microscopic facility. This test is yet to be used in India for routine diagnosis of bacterial vaginosis.

Key words: OSOM BV Blue test, bacterial vaginosis, Gram staining.

INTRODUCTION

Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge in sexually active females (Kalra et al., 2007; Schwebke, 2009), which is characterized by an increased vaginal pH (pH>4.5) and replacement of vaginal lactobacilli with *Gardnerella vaginalis* and other anaerobic rods like *Prevotella* spp. and *Mobiluncus* spp. (Gardner and Dukes, 1955; Spiegel, 1991; Fredricks et al., 2005).

Various studies have found its association with several obstetric complications like preterm delivery (McGregor et al., 1994,1995; Hillier et al., 1995; Howe et al., 1999),

chorioamnionitis (Gibbs, 1993), postpartum and postabortal endometritis (Haggerty et al., 2004). It has also been found to be associated with pelvic inflammatory diseases (Eschenbach et al., 1988) and increased risk of acquiring infection due to Herpes simplex virus 2 (HSV 2), *Trichomonas vaginalis*, *Neisseria gonorrhoeae* and human immunodeficiency virus (Bhalla et al., 2007). Hence, prompt diagnosis and early treatment of BV is required to prevent such hazardous complications (Africa, 2013).

Laboratory methods commonly employed for diagnosis

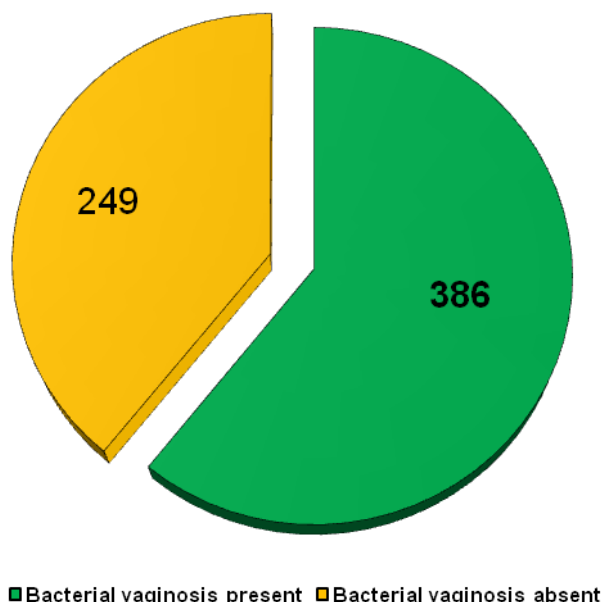


Figure 1. Distribution of patients suffering from bacterial vaginosis.

of bacterial vaginosis include Gram staining, culture, gas liquid chromatography, proline amino peptidase tests, etc (Mathew et al., 2001).

Routine culture is usually not recommended because of its low positive predictive value. Also, it is time consuming, expensive and misleading to over or underdiagnosis (Majeroni, 1998).

Gram staining based on Nugent's scoring (7 to 10) have been used routinely for diagnosing bacterial vaginosis (Nugent et al., 1991) but it requires laboratory facility and expert personnel, which is sometimes difficult especially in remote and peripheral areas. Thus, clinicians largely depend on empirical treatment of patients which may cause therapeutic failure and drug resistance, leading to poor patient compliance (Tann et al., 2006).

Vaginal pathogens like *G. vaginalis*, *Bacteroides* spp., *Prevotella* spp. and *Mobiluncus* spp. cause elevated level of enzyme sialidase in vaginal secretion, which has been used to detect bacterial vaginosis (von et al., 1984; Wiggins et al., 2000; Smayevsky et al., 2001; Anukam and Bassey, 2005). OSOM BV Blue test is a new point-of-care rapid chromogenic test based on the detection of elevated sialidase activity in vaginal fluid of patients suffering from bacterial vaginosis (Kampan et al., 2011).

The present study was done to evaluate the efficacy of OSOM BV Blue test in comparison with Gram staining for diagnosing bacterial vaginosis.

MATERIALS AND METHODS

A total of 635 patients in the reproductive age group (15 to 45 years) who came to Jawaharlal Nehru Medical College and Hospital,

Aligarh Muslim University, Aligarh, India, with complaints of foul smelling vaginal discharge and pruritus vulvae, were included in the study. In addition, 50 healthy age-matched females who were healthy in all respect were taken as controls.

Two vaginal swabs were taken from each patient. The first swab was used for Gram staining and Nugent's scoring was done on the basis of relative proportions of large gram positive rods (lactobacilli), small gram negative or Gram-variable rods and curved gram-variable rods (Nugent et al., 1991).

The second swab was used to perform OSOM BV Blue test (Genzyme Diagnostics, UK) according to the manufacturer's instruction. 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 AND DISCUSSION

A total of 635 patients were included in our study with mean age of 30.56 ± 0.34 years. Bacterial vaginosis was detected in 60.8% patients (Figure 1). 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, whereas, Gram staining detected bacterial vaginosis (Nugent's score 7 to 10) in 54.0% patients (Figure 3).

An intermediate score (4 to 6) was found in 33.9% patients and 12.1% patients had normal score (0 to 3). OSOM BV Blue test showed excellent performance and had 84.7% agreement with Gram staining. Taking Gram staining as gold standard, sensitivity, specificity, positive and negative predictive values of OSOM BV Blue test was estimated. OSOM BV blue test showed high sensitivity and specificity of 95.3 and 92.1%, respectively. Its positive and negative predictive values were 93.4 and 94.4% respectively. No infection was detected in the control group by any of these methods.

In our study, Gram staining detected bacterial vaginosis (Nugent's score 7 to 10) in 54.0% patients, while a shift from normal flora (score 4 to 6) was observed in 33.9% cases. An intermediate score (4 to 6) may be found in females who were either recovering from bacterial vaginosis or may develop it subsequently.

In a study done by Anukam and Bassey (2005), bacterial vaginosis was reported in 64.2% patients based on Nugent's scoring, whereas, Bhalla et al. (2007) reported bacterial vaginosis in 32.8% and intermediate flora in 16.9% women.

In the present study, OSOM BV blue test detected bacterial vaginosis in 55.1% patients. The performance of OSOM BV blue test was found to be better in comparison with Gram staining, 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, whereas, in a study done by Kampan et al. (2011), BV Blue test showed a sensitivity of 100.0% and specificity of 98.3% compared



Figure 2. Blue colour indicative of positive OSOM BV blue test.

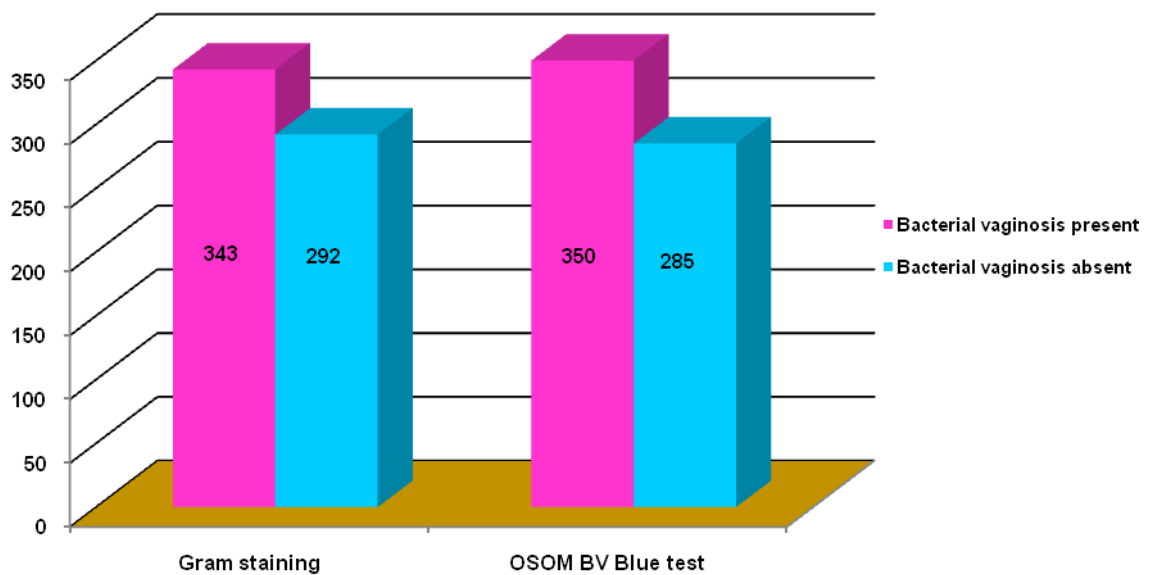


Figure 3. Distribution of bacterial vaginosis cases as detected by gram staining and OSOM BV blue test.

to Gram stain (Nugent's method).

Conclusion

OSOM BV Blue is a simple and rapid point-of-care diagnostic test based on the detection of sialidase activity of bacteria implicated in the causation of bacterial vaginosis. The clinician can perform the test at the clinic avoiding the time delay of sending a sample to the laboratory. The results are available in 10 min. This is quite beneficial in the clinical settings where microscopic facilities are not available. Its use should be encouraged for routine diagnosis and prompt management of patients suffering from bacterial vaginosis, thus, preventing development of adverse sequelae.

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