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An evaluation of OSOM BV blue test in the diagnosis of bacterial vaginosis

Fatima Shujatullah[1*] Haris M Khan[1], Razia Khatoon[1], Tamkin Rabbani[2], Abida Malik[1]

[1] *Department of Microbiology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, India*
[2] *Department of Obstetrics and Gynecology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, India*

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ABSTRACT

Objective: To determine the prevalence of bacterial vaginosis (BV) in patients with vaginal discharge and evaluate the efficacy of OSOM BV blue test in diagnosis. **Methods:** OSOM BV blue test, a rapid diagnostic test based on the principle of detection of bacterial sialidase activity in vaginal fluid specimens was conducted. A total of 405 patients in the reproductive age group (15–45 years) having vaginal discharge were included in the study along with 10 healthy age–matched controls. Two high vaginal swabs were collected aseptically from each patient. One swab was used to make smear for gram staining, and the other was for OSOM BV blue test. Amine test and vaginal pH test were taken as well. **Results:** The prevalence of bacterial vaginosis was 60.7%. OSOM BV blue test showed good efficacy, as compared with gram staining in diagnosing BV. The sensitivity and specificity of OSOM BV blue test were 97.6% and 97.5% respectively. Amsel's criteria diagnosed 180 (44.4%) cases of BV and had sensitivity and specificity of 67.1% and 90.6% respectively. Thus the performance of OSOM BV blue was better than the methods based on Amsel's criteria. **Conclusions:** OSOM BV blue test is an efficacious bed side test, helpful in rapidly making an accurate diagnosis of BV in setups lacking laboratory facilities or expert microbiologists.

1. Introduction

Bacterial vaginosis is the foremost cause of abnormal vaginal discharge in women of reproductive age. It is associated with adverse pregnancy outcome[1-5], pelvic inflammatory disease[5,6], chorioamnionitis[2,5,7], endometritis[8] and increased susceptibility to Human Immunodeficiency Virus[9]. Routine diagnostic procedures require laboratory expertise. As the prevalence is high [10], patients usually do not have access to hospitals with microscopic facilities for correct diagnosis. Thus, the general approach of clinicians in management of patients with abnormal vaginal discharge is largely empirical and syndromic based upon naked eye examination of discharge which is less accurate. The failure of empirical therapy does not only cause financial and social impact but also lead to poor patient compliance as well as drug resistance.

Conventional diagnostic methods such as gram staining based on Nugent scoring system[11] are popular. However, recently, OSOM BV blue test with almost equally efficacious, less time consuming and minimal technical expertise requiring is emerged for rapid diagnosis of bacterial vaginosis. OSOM BV blue test is based on the principal of detection of bacterial sialidase activity (an enzyme produced by bacterial pathogens such as Gardnerella vaginalis, *Bacteroides spp.*, *Prevotella spp.*, and *Mobiluncus spp.*) in vaginal discharge. A prospective study was performed to determine the efficacy of OSOM BV blue test as a diagnostic tool for the diagnosis of bacterial vaginosis and compare it with the conventional methods, Amsel's criteria and gram staining.

2. Materials and methods

A hospital based study was conducted on 405 patients attending gynaecology and antenatal clinics with complaints of foul smelling vaginal discharge, pruritis, dysuria, and pain in lower abdomen etc. at J. N. Medical College Hospital, A.M.U, Aligarh, U.P., India. The study

*Corresponding author: Fatima Shujatullah, Department of Microbiology, Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh (U.P.) 202002, India.
Tel: 091-98-3756-8948
Fax: 091-571-272-0382
E-mail: sfatima777@gmail.com

was performed from October 2008 to September 2009. Detailed history and physical examinations of the patient were recorded and two vaginal swabs were taken from the posterior fornix by using sterile cotton swabs. Vaginal pH was tested by dipping pH strip in the vaginal discharge and the discharge collected on the posterior blade of speculum was used to perform whiff (Amine) test. Gram staining was done on the smear prepared from the first swab and the second swab was for OSOM BV blue test. 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 minutes at room temperature. After that one drop of developer solution was added to the test vessel and gently swirled to mix. The results were read immediately. A positive result was indicated by the appearance of blue or green colour in the BV test vessel or on the head of the swab, and a negative result was indicated by yellow colour.

3. Results

A total of 405 patients (114 pregnant and 291 non-pregnant) were included in the study. The mean age of the patients was (30.56 ± 0.34) years. By gram staining, the most widely used method, 246 (60.7%) patients were diagnosed as bacterial vaginosis with Nugent's score 7-10. The infectious reports by Amsel's criteria and OSOM BV blue test were 180 (44.4%) and 244 (60.2%) respectively (Table 1).

OSOM BV blue test displayed high sensitivity and specificity compared with gram staining. The sensitivity, specificity, positive and negative predictive value of OSOM BV blue test were 97.6%, 97.5%, 98.4% and 96.3% respectively, while those of Amsel's criteria were 67.1%, 90.6%, 91.7% and 64.0% accordingly. Clue cells were present in all patients of bacterial vaginosis, with sensitivity and specificity of 100% each, whereas, Amine test and vaginal pH test had sensitivity of 62.2% and 63.4% respectively (Table 2).

Table 1
Distribution of patients having bacterial vaginosis as diagnosed by different methods and their correlation with results on gram staining(*n*,%).

Diagnostic test used	Gram staining indicative of bacterial vaginosis		
	Present 246	Absent 159	Total number of patients 405
OSOM BV blue test	240 (97.6)	4 (2.5)	244 (60.2)
Vaginal pH > 4.5	156 (63.4)	19 (11.9)	175 (43.2)
Vaginal fluid amines	153 (62.2)	11 (6.9)	164 (40.5)
Clue cells	246 (100.0)	0 (0.0)	246 (60.7)
Amsel's criteria	165 (67.1)	15 (9.4)	180 (44.4)

* Figure within parentheses indicates percentage.

Table 2
Comparison of various rapid diagnostic tests with gram staining for diagnosis of bacterial vaginosis (%).

Diagnostic tests performed	Sensitivity	Specificity	Positive predictive value	Negative predictive value
OSOM BV blue test	97.6	97.5	98.4	96.3
Amsel's criteria	67.1	90.6	91.7	64.0
pH test	63.4	88.1	89.1	60.9
Amine test	62.2	93.1	93.3	61.4
Clue cells	100.0	100.0	100.0	100.0

4. Discussion

The OSOM BV blue test is reliable compared with routine diagnostic procedures such as gram staining, vaginal pH determination and Amine test in patients with clinical symptoms of bacterial vaginosis. Amine test and vaginal pH test, though being good predictors, have low sensitivities (62.2% and 63.4% respectively), which tend to misdiagnosis. Clue cells are observed in all the patients suffering from bacterial vaginosis. Diagnosis with clue cells is perfect, but recognizing the cells in wet mount or gram staining requires expertise and microscopy. The OSOM BV blue test is an excellent procedure for rapid diagnosis compared with conventional diagnostic methods[12]. This test can be performed easily in peripheral hospitals where the expert microbiologist is not available. Detection of elevated sialidase activity has previously been reported to be both sensitive and specific for diagnosis of bacterial vaginosis compared with gram staining (sensitivity and specificity, 96% and 96% respectively) and Amsel's method (sensitivity and specificity, 81% and 94% respectively)[13,14] . The BV blue test has been evaluated by different workers[15]. They also reported high sensitivity and specificity of BV blue test with Nugent's scoring method[16] although their sample sizes were smaller than that of our study[17] . In our study the performance of BV blue test is almost similar to that

of Nugent's method and better than Amsel's method for diagnosis of bacterial vaginosis which is also consistent with other studies[17].

OSOM BV blue test is a rapid method, which is accurate, simple, stable and do not require high levels of training for interpretation of results, and can be used as a diagnostic measure for improving the syndromic management of patients with vaginal discharge. It can help to effectivly diagnose and thus, prevent various sequelaes associated with bacterial vaginosis such as preterm labour, premature rupture of membrane, fetal prematurity, and pelvic inflammatory disease etc. Even in settings which conventional diagnostic methods are available, it still benefits as OPD or bedside procedure by its rapidity.

Conflict of interest statement

We declare that we have no conflict of interest.

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