Original Research Article

Comparison of Amsel's criteria and Nugent's criteria for diagnosis of bacterial vaginosis in tertiary care centre

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ABSTRACT

Background: Bacterial vaginosis is an imbalance in the ecology of the normal vaginal flora which is characterized by depletion of lactobacilli, and proliferation of anaerobic bacteria. It most often manifests clinically as a vaginal pH of > 4.5, presence of thin whitish homogenous vaginal discharge, detection of "clue" cells and presence of an amine odour after the addition of 10 percent potassium hydroxide. These anaerobic bacteria through specific products stimulate the decidual tissue causing an increase of cytokine level, release of phospholipase A2 and prostaglandins leading to preterm labor, premature rupture of membranes, chorioamnionitis and development of PID following abortion. To compare Amsel Criteria and Nugent Criteria for diagnosis of bacterial vaginosis.
Methods: A cross sectional study involving 260 patients with preterm and term labour was conducted at a tertiary care hospital in North India. BV was determined to be present or absent on the basis of Amsel's criteria and Nugent's criteria. Pearson's chi-square test was used to demonstrate the difference between both groups with respect to various categorical data.
Results: Amsel's criteria and Nugent's criteria were reliable diagnostic methods. As compared to Nugent scoring system, Amsel's criteria had sensitivity of 75%, specificity of 95%, positive predictive value of 90% and negative predictive value of 86%.
Conclusions: Although the Amsel's criteria is a convenient and inexpensive method of diagnosing bacterial vaginosis, it is not always reliable. Nugent's criteria is considered as a gold standard for the diagnosis of bacterial vaginosis but it requires an experienced slide reader and considerable time and skill. If lab equipment is not available as in many developing countries, the diagnosis of BV can be simplified by using a combination of any two Amsel's criteria like vaginal pH and whiff test which had highest sensitivity and specificity (90.19% and 97.78%) respectively as seen in present study.

Keywords: Amsel's criteria, Bacterial vaginosis (BV), Nugent's criteria, Sensitivity, Specificity, Prevalence

INTRODUCTION

Bacterial vaginosis is the most common infection among the women of reproductive age group. It is a pathological condition characterized by alteration of vaginal flora in which normal flora (lactobacilli) is replaced by a mixed bacterial flora which includes Gardnerella vaginalis, Mobiluncus species, Mycoplasma hominis, Bacteroides species and other anaerobes.[1] It is more prevalent in developing countries than developed countries.[2] Timely diagnosis and treatment of bacterial vaginosis is important as it has been implicated as an important causative factor for many obstetrical complications namely spontaneous abortion, preterm labour and delivery, Preterm rupture of membranes (PROM), chorioamnionitis, postpartum endometritis and post caesarean wound infection.[3] The most common diagnostic method for Bacterial Vaginosis is the clinical

criterion described by Amsel's et al and microscopic criteria proposed by Nugent et al.[4,5]

Nugent scoring system is a gold standard due to its reproducibility and high sensitivity, but it is time consuming, costly, needs laboratory equipment and specialist, which would place a great strain in a developing country with limited resources such as India.

On the other hand, Amsel's criteria is rapid, inexpensive and simple, thus one should know the sensitivity and specificity of Amsel's criteria in relation to Nugent scoring system. Hence, aim of this study was to compare diagnostic ability of Amsel's criteria with Nugent scoring.

METHODS

It was a cross-sectional study of 260 pregnant women attending Department of Obstetrics and Gynecology, in collaboration with Microbiology department, AIMSR Bathinda over a period of July 2016-July 2017 after getting permission from institutional ethical committee. Patients were selected after applying Inclusion and Exclusion criteria.

Inclusion criteria

- Singleton pregnancy
- Gestational age 28 weeks till Term
- Intact membranes or PROM <4 hours
- Uterine contractions- 2 contractions/45 seconds/10 minutes
- Cervical dilatation >1 cm
- Cervical effacement >80%.

Exclusion criteria

- Ruptured membranes>4 hours
- Use of antibiotics in the preceding two weeks
- Multiple gestation
- Structural uterine anomalies
- Established fetal anomalies
- Pregnancies complicated with medical disorders
- Patients who are not willing to give consent.

Criteria for diagnosis: The following diagnostic criteria were used in the study; under all aseptic precautions vaginal discharge was taken from posterior vaginal fornix for PH, wet mount, KOH (Amine test) and Gram stain. Bacterial vaginosis was diagnosed based on the standard Amsel's Criteria (wet mount test) and Nugents gram stain.

Amsel's criteria

The diagnosis of bacterial vaginosis was defined as presence of at least 3 of the following criteria:

- Homogenous vaginal discharge.
- Vaginal PH>4.5.
- Presence of clue cells (mature vaginal squamous epithelial cells coated with bacteria) on wet mount.
- Fishy odour after addition of KOH (whiff test).

Nugent's criteria

This diagnosis involves gram stain of vaginal discharge and use Nugent's criteria (scoring system).

Statistical analysis

Collected data was analyzed by frequencies, percentages and by chi square test. Diagnostic efficacy of Amstel's criteria was determined by calculating sensitivity (true positive), specificity (true negative), positive predictive value, and negative predictive value. A chi square test was applied for statistical analysis using SPSS software.

RESULTS

Based on Amsel's criteria, 80 cases were labeled to have BV. Among 260 women, prevalence of bacterial vaginosis by Amsel's Criteria was 30.76%. While examining the sensitivity and specificity of individual components of Amsel's criteria we found that PH>4.5 had highest sensitivity (97.50%) followed by whiff test (92.50%) then vaginal discharge (76.25%) and clue cells (72.50%) while clue cells had highest specificity (96.67%), followed by whiff test (90.00%), vaginal discharge (81.11%), and PH>4.5 (77.78%) (Table 1).

Table 1: Amsel's criteria.

Variable	Present	Absent	SN	SP	PPV	NPV
Vaginal discharge	95 (36.5%)	165 (63.5%)	76.25	81.11	64.21	88.48
Clue cells	64 (24.6%)	196 (75.4%)	72.50	96.67	90.62	88.78
Whiff test	92 (35.4%)	168 (64.6%)	92.50	90.00	80.43	96.43
Ph>4.5	118 (45.4%)	142 (54.6%)	97.50	77.78	66.10	98.59
> 3 Amsel criteria	80 (30.8%)	180 (69.2%)				

Table 2: Nugent's scoring.

Score	Number of cases
0-3	75 (28.8%)
4-6	89 (34.3%)
7-10	96 (36.9%)
Total	260 (100%)

Based on nugent's criteria, 96 cases were labeled to have bacterial vaginosis. Among 260 women, prevalence of bacterial vaginosis by Nugent's Criteria was 36.92% (Table 2). As compared to Nugent scoring system, Amsel's criteria had sensitivity of 75%, specificity of 95%, positive predictive value of 90%, and negative predictive value of 86% as shown in table 3.

Table 3: Comparison of bacterial vaginosis by Amsel's criteria with Nugent's score as a gold standard.

Method of diagnosis		Nugent's criteria			SN	SP	PPV	NPV
		Positive	Negative	Total				
Amsel's criteria	Positive	72 (75%)	8 (4.9%)	80	0.75	0.95	0.90	0.86
	Negative	24 (25%)	156 (95.1%)	180				
	Total	96	164	260				

The combination of pH and whiff test had high sensitivity of 92.50% and specificity of 90.00% as shown in table 4.

Table 4: Diagnostic accuracy of combination of two Amsel's criteria.

Amsel's criteria	SN (%)	SP (%)
Vaginal PH+ whiff test	92.50	90.00
Vaginal PH +clue cells	72.50	66.67
whiff test + clue cells	72.50	81.11
Discharge + whiff test	70.53	98.11
Discharge + vaginal PH	74.34	95.80

DISCUSSION

Most women present with increased vaginal discharge to gynecological opd and prenatal clinics. Proper diagnosis of bacterial vaginosis is challenging. Polymerase Chain Reaction (PCR), hybridization techniques, and tests based on extra cellular protein elaboration such as proline amino peptidase activity are recently developed diagnostic methods. More recently, up-to-date techniques have been introduced based on RNA and sensor arrays, but these are very expensive, and their sensitivities and specificities do not offer more advantage over traditional method. Therefore, Amsel's and Nugent criteria remain the most economical and practical option for diagnosing bacterial vaginosis in developing countries.

In present study, prevalence of bacterial vaginosis by Amsel's criteria and Nugent Criteria were 30.76% and 36.92% respectively. Amsel's criteria had sensitivity, specificity, negative predictive value (NPV), positive predictive value (PPV) of 75%, 95%, 90%, 86% as compared to Nugent scoring system. These findings were consistent with other studies (Table 5).[6,7] Among all Amsel criteria, PH>4.5 had highest sensitivity (97.50%), and lowest specificity (77.78%), which was similar to various other studies.[8-11] It can be explained by the fact that measurement of vaginal pH is easily affected by the presence of blood or semen or application of lubricant gel which can increase the vaginal ph. Cervical mucus itself has a ph of 6 which may interfere with vaginal ph. In previous studies, clue cells had high sensitivity and specificity in contrast to present study.[12]

Table 5: Comparison of prevalence of bacterial vaginosis with other studies.

	Prevelance by Amsel	Prevelance by Nugent	SN	SP	PPV	NPV
Present study	30.76%	36.92%	75%	95%	90%	86%
Taj et al[6]	62%	78%	77	91	97	53
Moussavi et al[7]	-	-	78	88	95	58

In present study the specificity (96.67%) of clue cells was higher than its sensitivity (72.50%). Low sensitivity for identification of clue cells may depend upon the ability of the clinician to analyze wet mount microscopy these results are in agreement with other studies.[6] Whiff test was performed by smelling the odor, its results are subjective and depends on personal interpretation. In present study whiff test had best sensitivity (92.50%) and specificity (90.00%) which was similar to other studies.[7] The combination of PH and whiff test had high

sensitivity (90.19%) and specificity (97.78%) so recommended for evaluation of vaginosis similar to previous studies.[13-14]

CONCLUSION

Amsel's criteria had moderate sensitivity (75%) as compared to Nugents criteria (95%) but high specificity (95%) because it makes use of clinical signs which cannot be standardized or quantified. Its components are subjective and dependent upon the acuity of the physician.

Although Amsel's method is convenient and inexpensive but detection of clue cells requires microscope and trained labour as in Nugents method which may not always be available especially in rural areas. Thus, the diagnosis can be simplified by using combination of 2 criteria i.e. PH and whiff test, with high sensitivity (90.19%) and high specificity (97.78%) (as seen in present study) particularly in rural areas where microscopic facilities are not available.

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