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Research Article

Evaluation of various tests of amsels criteria for diagnosis of bacterial vaginosis in patients of preterm labor

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Abstract: Bacterial vaginosis is the most common vaginal infection in women of reproductive age.. We undertook this study to evaluate various tests of amsels criteria for diagnosis of bacterial vaginosis in preterm patients considering amsels clinical criteria as gold standard. Case-control study, the materials and method is in this prospective study included 200 antenatal preterm women .Pregnant women of gestational age between 28-37 weeks with preterm labor were taken as study group and pregnant women of same gestational age without any signs and symptoms of preterm labor were taken as control group. Data obtained were statistically analysed by chi-square test and student t-test, significance was expressed in terms of "p" value. All women were subjected to clinical examination and various tests of amsels criteria. . Amsel's criteria were taken for interpretation of results. Statistical analysis was done by calculating proportions, percentage, sensitivity and specificity and predictive values. The results in our study group 33% women were having bacterial vaginosis compared to 17% in control group on the basis of amsels criteria. The sensitivity of pH, homogenous discharge, and whiff test were 100% but the specificity was 47.7%, 51.4%, 86% respectively. The clue cells had lowest sensitivity (80%) but highest specificity (92%). In our study conclusion was bacterial vaginosis was found to be an important risk factor for preterm delivery. The whiff test is the best clinical criteria of Amsel's criterion in the diagnosis of BV due to its high sensitivity and specitivity. Clue cell test has the highest specificity among all tests.
Keywords: Bacterial vaginosis, Preterm labor, Amsel's criteria.

INTRODUCTION:

Preterm labor is defined as the presence of uterine contractions of sufficient frequency and intensity to effect progressive effacement and dilation of the cervix prior to term gestation. The rate of preterm birth ranges from 5% to 10% [1]. It is estimated that 25-40 % of preterm birth result from intrauterine infections [2]. Among all of intrauterine infections, bacterial vaginosis has a major role in preterm labor.

Bacterial vaginosis is characterized by a change from the normal lactobacillus dominated flora with a pH below 4.5 to a mixed anaerobic flora with a pH above 4.5. Symptoms include malodorous (fishy) increased vaginal discharge. Complications of bacterial vaginosis in pregnancy include preterm labor, PROM (premature rupture of membrane), amniotic fluid infection, chorio-amniotic infection and histologic chorio-amnionitis. Bacterial vaginosis can be diagnosed by clinical criteria or by lab testing. The Gram stain method (Nugent scoring) is considered to be gold standard, but in urgent situations where an immediate result is needed, clinical methodology is useful. The most widely accepted clinical criteria is Amsel's criteria as it is simple, less time consuming and results are comparable to gram stain technique [3]. .Shahzadi N. in 2002 found Amsel's criteria are a sensitive method for diagnosis of bacterial vaginosis when compared with gram staining [4].

MATERIAL AND METHOD:

Material:

This study was conducted in department of obstetrics & gynaecology, Kamla Raja Hospital, Gwalior (M.P.) during year 2010-11 after obtaining approval from Hospital Ethics committee. Written informed consent was taken by the patients after explaining the procedure which was included in the study.

Inclusion criteria:

1. Singleton pregnancy

2. Gestational age between 28-37 weeks
3. Intact membranes
4. Painful uterine contractions >2 in 10 minutes, each lasting >45 seconds
5. Cervical dilatation between 1 to 4 cm.
6. Cervical effacement >25%.

Exclusion criteria:

1. Gestational age <28 weeks and >37 weeks
2. History of antepartum haemorrhage
3. Urinary tract infection, respiratory tract infection, diarrhoea or any other obvious cause for Preterm labor.
4. Medical complication of pregnancy such as moderate to severe anaemia, pregnancy induced Hypertension and diabetes mellitus.
5. History of leaking per vaginum or absent membranes.
6. Intrauterine growth restriction.
7. Intrauterine fetal death
8. Antibiotic therapy in the last 30 days
9. Coitus during last 24 hr.

METHOD:

Per speculum examination of the study and control group was done at their outpatient department visit. A non-lubricated speculum was passed into the vagina and the condition of the vaginal wall, nature of the discharge (amount, colour, consistency) and the condition of the cervix was noted. First sample was taken with the help of sterile cotton tipped swab, from the posterior vaginal fornix. This was first tested for pH with the help of pH indicator strip (3.5 to 6) and the vaginal discharge collected on the speculum was tested for 'Fishy odour' on addition of two drops of 10% potassium hydroxide solution. Then sample rolled onto a glass slide and wet mount with normal saline, covered with cover slip and examined under microscope. Patients of study group were admitted for further management and patient of control group was advised for follow up after 1 week. Patients of study and control group were grouped as positive and negative for bacterial vaginosis as per Amsel's clinical criteria.

At least three of the following clinical criteria must be fulfilled to establish the diagnosis of bacterial vaginosis [5].

The criteria's are:

1. Thin homogenous vaginal discharge
2. Vaginal pH >4.5
3. Release of a fishy odor from the vaginal discharge on alkalinizaton with 10% potassium hydroxide solution (Amine Odor test).
4. Vaginal epithelial cells heavily coated with bacilli (>20%Clue cells).

Patients who fulfilled three of the four clinical criteria were labeled as bacterial vaginosis positive and those who not fulfilled at least three clinical criteria were labeled as bacterial vaginosis negative. Sensitivity, specificity, positive and negative predictive value of all individual criteria was calculated. All patients testing positive for BV were treated with oral metronidazole 500mg twice daily for 5 days and followed to know any further complications.Data obtained at the end of the study was noted and statistically analyzed by chi-square test and student t-test, significance was expressed in terms of "p" value.

RESULTS:

A total of 200 preterm patients were examined. Incidence of bacterial vaginosis in preterm patients with labor was 33% by Amsel's criteria and the same in preterm patients without labor was 17%. The result was statistically significant (p=0.0143), R.R=1.48(C.I=1.43-1.93). The sensitivity of pH, homogenous discharge, and whiff test were 100% but the specificity was 47.7%, 51.4%, 86% respectively. The clue cells had lowest sensitivity (80%) but highest specificity (92%).

Table-1: Results of various tests of Amsel's criteria

Clinical Criteria	Total no of patients with bacterial vaginosis positive by Amsel's criteria (n=50)	Total no of preterm patients (n = 200)
pH test positive	50	126
Whiff test positive	50	123
Homogenous milky discharge positive	50	71
Clue cells positive	40	52

Table-2: Value of various tests

Individual criteria	Sensitivity	Specificity	Positive predictive value	Negative predictive value
pH Test	100	47.7	39.4	100
Homogenous milky discharge	100	51.4	40.6	100
Whiff test	100	86	70.4	100
Clue cells	80	92	100	93.3

DISCUSSION:

The preterm labor and its associated complications to the mother are a challenge to the obstetrics. The accurate identification of a patient at risk of preterm labour and its prevention is of immense importance. In our study group 33% women were having bacterial vaginosis compared to 17% controls. The result was highly significant statistically to prove bacterial vaginosis as a cause of preterm labour (p value 0.0143 and RR 1.48). In our study clue cells criteria was most specific (92%) followed by whiff test (86%) among other criteria. Sensitivity of pH test, homogenous white discharge, and whiff test was equal i.e. (100%) while that of clue cells was less i.e. (80%).

Thulkar *et al.;* also reported that vaginal pH is the most sensitive criteria in diagnosis of bacterial vaginosis [6]. In previous studies, clue cells had higher sensitivity and specificity among all four Amsel criteria in contrast to our study [7] Shahzadi N *et al.;* conducted a study and conclude whiff test had the highest sensitivity (87%) and specificity (96%) among all other criteria, this result also correlates with our study result[4].

CONCLUSION:

The incidence of bacterial vaginosis in patients with preterm labor was more as compared to patients without preterm labor (33 % vs 17 %). Among the various tests of Amsels criteria whiff test was the most sensitive and highly specific criteria and clue cells was most specific individual criteria.

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