Rapid Clinical Diagnostic Tests for Bacterial Vaginosis and its Predictive Value

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Objective: To determine the sensitivity and specificity of Amsel’s criteria for diagnosis of bacterial vaginosis.

Study Setting: This study was carried out at the Outdoor Department of Obstetrics & Gynaecology Fauji Foundation Hospital Rawalpindi from 20th Feb to 20th August 2008. A total of 556 pregnant patients were seen among which 208 patients had complaints of vaginal discharge. These patients were then scrutinized for the diagnosis of bacterial vaginosis by employing rapid clinical tests i.e. Amsel criteria, which was further confirmed by gram staining in laboratory.

Results: Among 208 symptomatic women bacterial vaginosis was diagnosed in 38.55% (n=80). These women had 3 out of 4 Amsel's criteria fulfilled i.e. presence of milky white vaginal discharge, clue cells, whiff test or alkaline pH. The specificity of each criterion was calculated which came out to be 96% while for the Amsel's criteria it was 96.8%. The sensitivity was 84% of milky white discharge, 87% of Whiff test, 82% of clue cells and 86% of pH while the overall sensitivity of Amsel criteria was 92%.

Conclusion: Amsel’s criteria are a sensitive method for the diagnosis of bacterial vaginosis when compared with gram staining. It provides us with a rapid clinical results with sensitivity of Whiff test being 87%.

Key Words: Bacterial vaginosis, rapid diagnostic tests, Amsel’s criteria, gram staining.

Introduction

Vulvovaginal symptoms are extremely common accounting for over 10 million clinic visits per year in USA. This has lead to frequently self diagnosis & therapy. A survey when conducted on telephone in USA in 1995 found that 8% of Caucasian, 18% of African women had reported one episode of vaginal symptoms in the said year. In this survey a healthcare professional was consulted in 55 & 83% of cases respectively.

Bacterial vaginosis is the most common vaginal infection in women of childbearing age. In the United States 16% of pregnant women have Bacterial Vaginosis. Many studies carried out in Pakistan have reported a frequency of Bacterial vaginosis ranging from 1 to 68% in pregnant females. The most common causes of vaginitis in symptomatic women include bacterial vaginosis (20-50%), vulvovaginal candidiasis (17-39%), and Trichomoniasis (4-35%), yet 7-72% of women with vaginitis may remain undiagnosed. Since the symptoms of vaginitis are nonspecific neither self diagnosis nor diagnosis by a physician is reliable without laboratory or histological confirmation of a specific disorder. Empirical therapy in the management of vaginitis is usually employed although this practice should be discouraged, as it leads to misdiagnosis and wrong treatment. Approximately 50 to 75% of women with bacterial vaginosis are asymptomatic. The symptoms include an off white, thin discharge which has got an unpleasant smell. Dysuria and dysparunia are rare while pruritis, erythema and inflammation are typically absent.

The simplest criteria is that of Amsel which have been established for the diagnosis of bacterial vaginosis clinically. On the other hand gram staining is the technique used in the laboratory for the confirmation of clinical findings and this has also been regarded as the gold standard. Gram staining however is not frequently employed in clinical practice because it is cumbersome to use therefore its use is mostly restricted to research studies. Taking gram stain as the gold standard, the the sensitivity and specificity of Amsel’s criteria was calculated.
Materials and Methods
The study was conducted over a period of six months i.e. from 20th Feb to 20th August 2008. During this time we had 208 symptomatic women who were pregnant and complainant of vaginal discharge. All of these patients irrespective of their parity & gestation were tested for bacterial vaginosis. The women with ruptured membranes, per vaginal bleeding and coitus during last 24 hours were excluded from our study, as this could affect the pH. The patients were selected through non probability consecutive sampling from the outpatient department of Obs/Gynae Fauji Foundation Hospital Rawalpindi.

At the start the study protocol was approved from the hospital ethics review committee, later on consent was taken from all the patients prior to examination then they were asked to lie in lithotomy position for sterile speculum examination in which no lubricant was used as it could elevate the pH. Pooling of secretion, colour and consistency of the discharge was noted. A high vaginal swab stick was used to make two slides of the secretion. To one slide few drops of normal saline were added to study the presence of clue cells. Clue cells were identified as desquamated vaginal epithelial cells which were densely coated by adherent bacteria such that their borders were indistinct. The clue cells can be identified on a wet mount preparation i.e. small sample of vaginal secretion mixed with drops of saline and also on gram staining. The other slide was air dried and was sent to pathologist for gram staining. Whiff test was done by placing few drops of 10% potassium hydroxide on the secretions and fishy odour was noted in the positive cases. Vaginal pH was tested by dipping the pH paper into the secretion and the change in the colour was noted. For the laboratory confirmation, bacterial vaginosis was diagnosed on gram staining when the stain showed mixed flora consisting predominantly curved gram negative or gram variable or gram variable rods and / or gardennella and bacteroides morphocytes, while lactobacilli were either typically absent or very few in number.

Bacterial vaginosis was diagnosed when three out of following four criteria were fulfilled:

- Homogenous thin milk like vaginal discharge
- Positive whiff test
- Presence of clue cells under microscope
- pH > 4.5 (Normal vaginal pH 3.8 -4.2)

Data Analysis: The data was analysed by using SPSS version 10. Mean ± standard deviation was calculated for numerical data like age & parity. Frequency % was calculated for bacterial vaginosis and parameters of Amsel's criteria.

Results
A total of 208 pregnant women with symptomatic vaginal discharge were examined for the diagnosis of bacterial vaginosis. Age range of the patients was between 18-40yrs with mean 32.32±5.3 yrs. Gravidity was from 1-11 with mean of 4.8 ±2.04 while parity was 0-8 with a mean of 3.11±1.6.

Bacterial vaginosis on the basis of 3 out of 4 Amsel criteria was present in 80 (38.5%) patients. Out of these 80 patients 73(91.25%) had homogenous milk like discharge, 76 (95%) had a positive whiff test, 72 (90%) had clue cells and 75 (93.75%) had a pH > 4.5 (table I).

When the laboratory testing was undertaken as being the gold standard, 82 (39.2%) patients were diagnosed having bacterial vaginosis with gram staining. In our study the sensitivity and specificity of Amsel criteria came out as 92% and 96% respectively.

When the predictive value of individual criterion of Amsel was calculated, whiff test had the highest sensitivity of 87% and specificity of 96% (table II). While all the other parameters had less sensitivity, the specificity was same as that of all other criterion i.e. 96%.

The positive predictive value was calculated as the person is test positive, the number of times that she is actually diseased10 and for Amsel criteria it came out to be 95%. Similarly negative predictive value was calculated as the person being healthy if she tests negative10 and for Amsel criteria it was 95.3%.

Table I: Number of Patients with bacterial vaginosis diagnosed On Amsel’s Criteria (n = 80)

<table>
<thead>
<tr>
<th>Amsel’s Criteria</th>
<th>No. of patients</th>
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<tbody>
<tr>
<td>Homogenous milk like vaginal discharge</td>
<td>73 (91.2%)</td>
</tr>
<tr>
<td>Whiff test</td>
<td>76 (95%)</td>
</tr>
<tr>
<td>Clue cells</td>
<td>72 (90%)</td>
</tr>
<tr>
<td>pH &gt; 4.5</td>
<td>75 (93.7%)</td>
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</tbody>
</table>

Table II: Sensitivity & Specificity of Amsel’s Individual Criterion

<table>
<thead>
<tr>
<th>Individual criterion</th>
<th>Sensitivity %</th>
<th>Specificity %</th>
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<tbody>
<tr>
<td>Homogenous milk like vaginal discharge</td>
<td></td>
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<tr>
<td>Whiff test</td>
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<tr>
<td>pH &gt; 4.5</td>
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</table>
Homogenous milk like discharge 84% 96%
Whiff test 87% 96%
P H > 4.5 86% 96%
Clue cells 82% 96%

Discussion

Vaginitis is a common medical problem in women that can be associated with significant morbidity and complications. Bacterial vaginosis being one of the important causes of vaginal discharge during pregnancy merits early and accurate diagnosis as it can lead to serious complications like premature rupture of membranes, chorioamnionitis, preterm delivery postpartum and endometritis. The diagnosis of bacterial vaginosis is based on clinical findings and laboratory testing. Clinically Amsel criteria are the most widely accepted for the diagnosis of bacterial vaginosis. Alternatively bacterial vaginosis (BV) can be diagnosed by gram stain which is probably the most reliable method to differentiate BV from other vaginal infections. The same authors (Nugent et al) also developed a grading system for gram stain of vaginal discharge based on presence or absence of certain bacterial morphocytes (and their relative numbers), which gives more objective assessment of BV. Vaginal culture has got no role in the diagnosis of bacterial vaginosis therefore it is advised that Amsel's criteria may be used for he diagnosis. In this study we had diagnosed bacterial vaginosis on the basis of Amsel’s criteria as 38.5% among 208 women. The sensitivity of Amsel's criteria came out to be 92% and specificity was 96% in contrast to our results it was 70% and 94% respectively in an international study done in USA. These results were 51.2 % specificity and 98% sensitivity in the study done by Grataco et al.

In our study we had 82 patients diagnosed as bacterial vaginosis when gram staining was employed. Landers and colleagues used gram staining and found the sensitivity of Amsel’s criteria was over 90%. The specificity was 77%. In the diagnosis of bacterial vaginosis the patients predictive value came out to be 95% while the negative predictive value was 95.3% this was found to be high in comparison to gram staining which was 83% and 85% respectively. Gram staining although a reliable diagnostic method but is mostly performed in research studies because it is more cumbersome to use it in clinical practice than Amsel’s criteria. Therefore whenever clinical criteria is used the sensitivity reported from gram staining has ranged from 62-100%. However a definitive advantage of gram staining is that it is more objective as slide can be stored for future reference. The main difficulty for clinician is the lack of access to direct microscopy. A pH paper is also cheap and normal vaginal pH virtually exclude BV. The whiff test is also easy to do with high specificity and sensitivity. Therefore the diagnosis of bacterial vaginosis according to Amsel’s criteria may be simplified in settings where gram staining is not available.

Conclusion

Amsel’s criteria when used as a set of composite clinical criteria in which all the four clinical signs are seen has got a good reliability and can be replaced in busy clinical practice when gram staining is difficult to perform.

References

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