“COMPARATIVE STUDY TO CHECK THE EFFICACY OF pH STRIP & pH GLOVES FOR DETECTION OF BACTERIAL VAGINOSIS IN A TERTIARY CARE HOSPITAL”

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ABSTRACT

Objectives: Comparative study to check the efficacy of pH Strip & pH Gloves for Detection of Bacterial Vaginosis in a Tertiary Care Hospital.

Methods: It was a duly approved, cross-sectional study in which 50 subjects were enrolled from Tertiary care hospital, New Delhi, India. Written informed consent was obtained from all women. Vaginal swabs were collected for vaginal pH measurement. Vaginal pH was evaluated immediately with the pH strips and vaginal pH glove simultaneously.

Results: The study was done to check the efficacy of pH strip & pH gloves in pregnant as well as non-pregnant women by regularly visiting the tertiary care hospital. Among 50 subjects 8(16%) were Pregnant and 42(84%) were Non-pregnant. The mean age of the patients included in the study was found to be 26±19.5 years. After a Gnm stain and microscopic examination of samples obtained from 50 women, those with intermediate flora and Candida infection were excluded and the final analysis was done on 40 samples. Among 40, 15 were diagnosed with BV and 25 had normal vaginal flora based on Nugents’ score.

Conclusions: Our findings show that vaginal pH determination is relatively sensitive, but less specific in detecting women with BV. Both pH glove and pH strip are equally suitable for screening women with BV on an outpatient basis. Further studies are required to explore the possibility of self-evaluation of vaginal pH with pH glove at community level.

Keywords: Bacterial Vaginosis, Cross-sectional study, pH Strip, pH Gloves, Nugents’ score.

INTRODUCTION

Vagina is a fibro muscular elastic tubular tract which is a sex organ and has two main functions: sexual intercourse and childbirth. In humans, this passage leads from the opening of the vulva to the uterus (womb), but the vaginal tract ends at the cervix. Unlike males, who have only one genital orifice, females have two, the urethra and the vagina. The vaginal opening is much larger than the urethral opening, and both openings are protected by the labia [1]. The vagina of a newborn is affected by the residual maternal estrogen still present. At birth, the vaginal mucosa is rich in glycogen and the vagina becomes colonized by lactic-acid producing bacteria, such as Lactobacillus spp., within the first day after birth [2]. These estrogen effects will slowly disappear by the fourth week after birth and the glycogen content will diminish. The vaginal pH becomes neutral or alkaline, likely due to the almost absence of lactic-acid producing microorganisms [3]. The healthy vagina of a woman of child-bearing age is acidic, with a pH normally ranging between 3.8 and 4.5 [4]. This is due to the degradation of glycogen to the lactic acid by enzymes secreted by the Döderlein’s bacillus. The acidity retards the growth of many strains of pathogenic microbes [5]. An increased pH to 4.5 or higher, can be caused by bacterial overgrowth, as occurs in bacterial vaginosis and trichomoniasis, or rupture of membranes in pregnancy [4].

The pH of the upper vagina is normally acidic (pH 3.8-4.5). Leakage of amniotic fluid (normal pH 7.0-7.5) raises the pH in vaginal fluid to>4.5. Similarly, bacterial overgrowth, as occurs in bacterial vaginosis and trichomoniasis, may increase vaginal pH to>4.5. Vaginal yeast infections do not change the pH of the vagina [6].

The pH paper is impregnated with the indicator dicy nitrazine (phenaphthazine). The color of the paper changes from bright yellow at pH 4.5 and lower to dark blue at pH 7.0 and higher. Changes in color shades occur with pH increments of 0.5 from pH 4.5 to 7.5. The pH of vaginal fluid is determined by comparing the color of pH paper that has come in contact with a fluid sample to a standard color chart provided with each roll of pH paper [7].

Bacterial Vaginosis (BV) is the most common vaginal infection among women in reproductive age. It is a condition of vaginal flora imbalance, in which the typically plentiful H2O2 producing lactobacilli are scarce and other bacteria such as Gardnerella vaginalis, Mycoplasma hominis, Ureaplasma urealyticum and anaerobes (e.g. Prevotella, Mobiluncus, Bacteroides) are overly abundant. [8, 9]. Bacterial vaginosis (BV) is a vaginal infection characterized by loss of the normal protective lactobacilli and overgrowth of diverse anaerobes [15]. This infection is one of the leading causes of vaginal discharge and is more prevalent in HIV-1-infected women compared to uninfected women.

Women with BV are at higher risk of infection with human papilloma virus (HPV), Herpes simplex virus type 2 (HSV-2), Trichomonas vaginalis, Neisseria gonorrhoeae and HIV [10, 11]. Given the high prevalence and gravity of associated morbidity, it is critical to diagnose and treat women, particularly pregnant women affected by BV appropriately. Conventional diagnostic methods for BV include the methods of Amsel criteria and Nugent. [12, 13]. An easy, rapid and inexpensive self-diagnostic test for BV may help to minimize the tendency to self-treat symptomatic BV blindly with antibiotics or treating inappropriately. Assessment of intra vaginal pH is a helpful, but frequently neglected procedure that can be used to evaluate vaginal health [14]. Bacterial vaginosis (BV) is highly prevalent among women in the reproductive age group.

Vaginal pH is a useful indicator for bacterial vaginosis. pH more than 4.5 of vaginal fluids is found to be indicative of bacterial vaginosis. In this regards pH determination if made a part of routine gynaecological examination can serve as a useful tool for preliminary diagnosis of bacterial vaginosis, moreover when the gloves, being used for routine examination are themselves pH sensitive and no additional procedures need to be carried out. Further these gloves can prove handy in self examination of vaginal pH and early detection of infections. The results of the study may be useful in developing a self diagnostic kit for bacterial vaginosis. Thus, pH determination during gynaecological examination which
has long been ignored can be made an integral part of routine gynecological examination with availability of such gloves.

MATERIALS AND METHODS

Study population

In this cross-sectional study 50 subjects were enrolled from Gynaecological outpatient Clinics of Tertiary care Hospital, New Delhi, India, between 8th December 2013 to 8th March 2014 these women visited the hospital for complaints such as white discharge, abdominal pain and back ache. Informed written consent was obtained from all women. The study protocol was approved by the Institutional Ethics Committee of Ram-Eesh Institute of Vocational and Technical Education, Greater Noida. Women with history of gynaecological cancer/who had bleeding during the examination/used antibiotics/vaginal medication during the previous three weeks or those who had sexual intercourse in the last two days were excluded from the study.

Sample collection

Vaginal swabs were collected for vaginal pH measurement, Gram stain, wet mount, and whiff test. Vaginal pH was evaluated immediately with the pH strips and vaginal pH glove simultaneously. Samples for Gram stain were collected and a smear was performed. Gram staining and Nugent scoring were done after transporting the smears to the laboratory with microscope facility (within 2 to 3 h of sample collection). The pH of secretions collected from the lateral vaginal wall was measured using a colour indicator ranging from 3.5-5.2. Secretions collected with other cotton tip applicator from the lateral wall were smeared on to a glass slide for Nugent Gram stain evaluation.

Quality control

Quality control assessment was done for gloves as well as pH paper

Statistical analysis

Descriptive statistics were calculated for all demographic and clinical variables. Patient characteristics were compared between women with and those without Bacterial Vaginosis by using the Student t test and Wilcoxon rank-sum test for continuous data and Chi-square test for non-parametric categorical data.

RESULTS

The study was done on to check the efficacy of pH strip & pH gloves in pregnant as well as non-pregnant women by regularly visiting the tertiary care hospital. Among 50 subject 8 (16%) were Pregnant and 42(84%) were Non-pregnant (table 1). The mean age of the patients included in the study was found to be 26±1.95 years. After a Gram stain and microscopic examination of samples obtained from 50 women, those with intermediate flora and Candida infection were excluded and the final analysis was done on 40 samples. Of the 40 women, 15 were diagnosed with BV and 25 had normal vaginal flora based on Nugents’ score. The mean age (in years) and body mass index (BMI in kg/m²) of the subjects were 26.1 and 22.2, respectively. A proportion of 33.3 per cent women were illiterate and 17.8 per cent had primary education. Illiterate women and women with only primary education had parity more than two compared to women with higher education (P<0.05). Majority (79.6%) of the women had adopted tubectomy as a sterilization method.

Vaginal discharge was the symptom in 84.8 per cent of the subjects with BV and 85.3 per cent with no BV. Cervical erosion incidence was similar in women with and without BV. However, women with cervical erosion had more frequent abnormal vaginal discharge or thin homogenous discharge on examination (P<0.0001) compared to women with healthy cervix. Similarly, laboratory diagnosed vaginal white blood cells by microscopy was more frequent (P<0.05) in women with cervical erosion compared to women with healthy cervix.

Overall, women had vaginal pH>4.5, when measured with pH strips and pH glove respectively. The mean vaginal pH in women with BV measured by pH strips and pH glove was 5 and 4.9, respectively, and the difference in vaginal pH between BV and normal women was significant (P<0.0001). Presence of clue cells and positive whiff test were significant (P<0.001) for BV. Women with vaginal WBC>5 had vaginal pH>4.5 (P=0.002). In the present study 3 (1.1%) women were infected with Trichomonas, but there was no significant difference between the groups.

Vaginal pH>4.5 detected by pH strips and pH glove had a sensitivity of 72 and 79 per cent, and a specificity of 60 and 53 per cent, respectively (table 2). Amsel’s criteria had 76.6 and 95 per cent sensitivity and specificity, respectively. Among the combination criteria, clue cells and glove pH>4.5 had highest sensitivity and specificity. pH test when combined with positive amine (whiff) test had 46 per cent and about 75 per cent sensitivity and specificity, respectively. Thin homogenous discharge had the lowest specificity (27%). The positive predictive values (PPV) of strip (pH>4.5) was 71 per cent (confidence interval: 0.63-0.78) and the negative predictive values (NPV) was 62 per cent (confidence interval: 0.52-0.71) when compared with Nugent score.

DISCUSSION

Vaginal pH of more than 4.5 was less than 80 per cent sensitive in diagnosing BV, that may be accurate only 60 per cent of the time. Inclusion of whiff test along with pH test further reduced the sensitivity, but improved specificity. The difference in mean pH measurement between the two methods (pH glove and pH strip) was not significant.

Reproductive tract infections continue to cause considerable morbidity among women. Our results confirmed the findings that women with bacterial vaginosis were more likely to have vaginal symptoms, specifically foul odour in comparison to healthy women. In resource-poor settings, the World Health Organization (WHO) syndromes management protocol for vaginal discharge is most commonly used to diagnose vaginal infections. It is based on clinical assessment with speculum examination only [16]. Though, this protocol is found to be effective in management of abnormal vaginal discharge [17], it is well known that cervical erosion can be associated with excessive non-purulent vaginal discharge due to the increased surface area of columnar epithelium containing mucus-secreting glands. The results of the present study confirmed that women with cervical erosion had vaginal discharge as the symptom in comparison to women with healthy cervix.

A previous study showed that the evaluation of pH plus amine (whiff) test was better than syndromes management protocols and easiest to implement in resource-poor settings [18]. Our results also confirm the same. In the present study 94.0 per cent women presented with abnormal vaginal discharge, but only 50.2 per cent of them were positive for BV. The sensitivity and specificity of Amsel criteria in our study were better than previous study [18, 19]. Our results demonstrated that clue cells were the most reliable single indicator for BV as reported previously [20]. However, identification of clue cells requires on-site microscopy facility, trained personnel and time.

Though the sensitivity of vaginal pH in detecting BV was considerably lesser, the specificity was much higher in the current study compared to an earlier study [21]. False elevations in pH can be encountered when semen and mucus were sampled, exclusion of women who had coitus in the previous two days might have contributed to improved specificity and an exclusion of women with Candida infection to improved negative predictive value in the present study. However, exclusion of women with intermediate flora, which is not practical, might have falsely contributed to better specificity. Contrary to our study, pH and whiff test together had a high sensitivity and specificity in previous study [21].

Whiff test seems less practical and requires a good sense of smell [22]. However, inclusion of whiff test along with pH test improves specificity. A study in a population with low prevalence of BV showed correlation of high vaginal pH with BV and suggested vaginal pH as a simple tool for the diagnosis of BV [23].

Self-sampling the vagina seems to be acceptable to women of multiple ethnic groups [24]. Self-sampling of vaginal pH seems suitable for implementation before using over the counter products for presumed vaginitis [24]. Moreover, a better informed self-
diagnosis would ultimately reduce delayed treatment and possible secondary complications. A major limitation of the study was exclusion of women with intermediate flora that might have contributed to better sensitivity and specificity of the pH test.  

CONCLUSION  

Our findings show that vaginal pH determination is relatively sensitive, but less specific in detecting women with BV. Inclusion of whiff test along with pH test may reduce the sensitivity, but improves specificity. Both pH glide and pH strip are equally suitable for screening women with BV on an outpatient basis. Further studies are required to explore the possibility of self-evaluation of vaginal pH with pH glide at community level. 

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Table 1: Distribution characteristics among study population

<table>
<thead>
<tr>
<th>Subjects</th>
<th>No of patients</th>
<th>% of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pregnant Women</td>
<td>08</td>
<td>16</td>
</tr>
<tr>
<td>Non-Pregnant Women</td>
<td>42</td>
<td>84</td>
</tr>
<tr>
<td>Total</td>
<td>50</td>
<td>100</td>
</tr>
</tbody>
</table>

Table 2: Sensitivity, specificity, and 95% confidence intervals of the clinical criteria for diagnosing bacterial Vaginosis

<table>
<thead>
<tr>
<th>Parameter to be assessed</th>
<th>Bacterial Vaginosis N=35</th>
<th>No Bacterial Vaginosis N=15</th>
<th>P value</th>
<th>Total N=50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Yr) (mean±SD)</td>
<td>26.1±4.8</td>
<td>27.8±5.2</td>
<td>0.386</td>
<td>27.0±4.0</td>
</tr>
<tr>
<td>BMI (Kg/m²)</td>
<td>22.5±5.1</td>
<td>22.0±5.0</td>
<td>0.996</td>
<td>22.2±5.1</td>
</tr>
<tr>
<td>Vaginal Discharge</td>
<td>15(43.5)</td>
<td>5(32.2)</td>
<td>0.035</td>
<td>20 (37.8)</td>
</tr>
<tr>
<td>pH G1oves (mean±SD)</td>
<td>4.9±0.35</td>
<td>4.6±0.35</td>
<td>0.001</td>
<td>43 (84.8)</td>
</tr>
<tr>
<td>pH Strip (mean±SD)</td>
<td>5.0±0.54</td>
<td>4.6±0.53</td>
<td>0.001</td>
<td>35 (58.9)</td>
</tr>
<tr>
<td>Clue cells present</td>
<td>33(95.5)</td>
<td>2(10.3)</td>
<td>0.001</td>
<td>19 (35.6)</td>
</tr>
<tr>
<td>Positive whiff test</td>
<td>16(46.1)</td>
<td>3(21.6)</td>
<td>0.001</td>
<td>26 (49.6)</td>
</tr>
<tr>
<td>Amsels Criteria</td>
<td>27(76.6)</td>
<td>2(13.8)</td>
<td>0.001</td>
<td>31 (58.1)</td>
</tr>
<tr>
<td>Trichomonas</td>
<td>2(1.3)</td>
<td>1(0.9)</td>
<td>0.735</td>
<td>3 (1.1)</td>
</tr>
<tr>
<td>Vaginal WBC&lt;5</td>
<td>7(20.8)</td>
<td>3(18.1)</td>
<td>0.584</td>
<td>19 (37.8)</td>
</tr>
<tr>
<td>pH Paper&gt;1.5</td>
<td>25(72.1)</td>
<td>6(39.7)</td>
<td>0.001</td>
<td>31 (58.1)</td>
</tr>
</tbody>
</table>

CONFLICT OF INTERESTS  

Declared None

REFERENCES  