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A Comparison between Self and Clinician-collected Vaginal Swabs for Detection of Bacterial Vaginosis among Women in Kisumu, Kenya

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Abstract

Two tests are available for diagnosis of bacterial Vaginosis (BV), Amsel and Nugent. The latter is considered more sensitive. Laboratory diagnosis for BV requires a vaginal swab specimen. In developing countries, vaginal swabs are only collected by trained health clinicians and use of speculum, examination couch and expensive equipment like autoclave is necessary. In contrast, women in developed countries have a choice of either collecting self swab or allowing a trained health clinician to collect the vaginal swab. This study sought to evaluate the validity and reliability of self collected vaginal swabs for diagnosis of BV by comparing with clinician collected ones. Ten beaches were identified based on convenience along Lake Victoria in Kisumu County from which 105 women volunteers were enrolled. Three vaginal swabs were collected from each woman. The first two swabs were self collected while the third one was collected by a qualified clinician. Smears were prepared, read and interpreted by Nugent method while demographic and clinical data were obtained by use of structured questionnaires and pelvic examination forms respectively. There was high agreement (validity) between the clinician collected and the first self collected swab, Kappa score of K=0.952 (p<0.001). The reliability of the clinician and the second self collected swab had a Kappa score of K=0.905 (p<0.001). The self collected vaginal swabs (SCVS) were found to be valid and reliable for use in diagnosis of bacterial vaginosis.

Keywords: Clinician collected vaginal swabs, self collected vaginal swab, reliability, validity, bacterial vaginosis.

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Introduction

Bacterial Vaginosis (BV) is the most common vaginal condition among reproductive age women and is associated with a change in vaginal ecology, resulting in overgrowth of certain bacteria such as *Gardnerella vaginalis*, and other anaerobes which replace the hydrogen peroxide producing *Lactobacillus species* that dominates in normal vagina (Spiegel et al., 1980). The prevalence of BV is high, between 20 and 48% in populations in sub Saharan Africa (Bukusi et al., 2006; Demba et al., 2005). However, BV is normally asymptomatic in more than 50% of these women (Koumans et al., 2007). BV is associated with increased risk of STI acquisition including HIV (Cohen et al., 1995). The diagnosis of BV in low resource settings remains a challenge. The Spiegel (Spiegel et al., 1983; Amsel et al., 1983), Nugent (Nugent et
al., 1991) and Hay-Ison criteria (Hay & Ison, 2002) require trained technicians and may involve clinician collected samples. The Nugent criterion is currently employed as gold standard (Nugent et al., 1991). More so, BV management cannot be left to syndromic management alone as it is not effective (Vishwanat et al., 2000). Unwillingness to undergo pelvic examination, specimen collection procedures and early STI diagnosis remain a major barrier to healthcare among women (Kissinget et al., 2005). This unwillingness has been associated with fear of discomfort during examination, distrust of healthcare providers, perceived lack of privacy, perceived lack of vulnerability among women and denial of being at risk (Wiesendfeld et al., 2001). Following standardizing and validating the microscopic image area used for scoring bacterial morphotypes (Larsson et al., 2004), there is a dire need for effective and simplified method of collecting vaginal swabs for BV diagnosis in developing countries. The use of self-collected vaginal swabs (SCVS) for BV diagnosis has worked in other countries (Tankale et al., 2003). The objectives of this study were to determine the validity of SCVS, reliability of SCVS in diagnosis of BV, preference of women on vaginal swab collection method and to assess women’s awareness and perceptions on abnormal vaginal discharge.

**Methods**

This was an experimental study. The study took place at ten fishing beaches along Lake Victoria within Kisumu County, Kenya among women working in the fishing camps, who were considered to be at high risk for Sexually Transmitted Infections/Human Immunodeficiency Virus (STI/HIV). These women visit the fishing beaches to buy fish which they later retail in urban and residential areas. Approval for this study was given by Kenya Medical Research Institute Scientific Steering Committee, Maseno University and ethical clearance by the National Ethical Review Committee (NERC). The sample size that had adequate power (90%) to detect a high rate of agreement (Kappa = 0.90) for a two-sided, alpha = 0.05 test was determined using the following formula which calculates comparative samples:

\[
 n = \frac{D(k + \sqrt{2p(1-p)}) + Z_0 p(1-p) + p_1(1-p_1))}{\sigma^2}
\]

(See Appendix)

One hundred and five women participants aged 18–49 years, involved in the fishing industry that is, selling, buying or processing fish on the beaches located on the Kenyan shores of Lake Victoria and were able and willing to give informed consent, were recruited and enrolled in the study. Those on menses were requested to return after one week while those who cook for fishermen but do not trade in fish were not eligible. The first structured questionnaire was administered to the volunteers to collect information on participant’s demographic and hygiene behaviour. After completion of the first structured questionnaire volunteers were sent to a clinic room where they were requested to self-collect the first and second Self Collected Vaginal Swabs (SCVS), for BV diagnosis. Subsequently, the Clinician Collected Vaginal Swabs (CCVS) was collected. The clinician filled-in the history and clinical form for the participants. Following this, the second questionnaire, which collected information on both SCVS and CCVS methods, was administered to the volunteers by trained community health workers. Bacterial Vaginosis (BV) vaginal smears were made from the three swabs collected, stained and read using Nugent criteria. This test was performed as described by Nugent (Nugent et al., 1991). The laboratory technologists were blinded from clinical criteria to prevent observer bias. The three sets of smears from each participant were read independently. Any difference in reading the Gram stained smears between the two medical laboratory technologists was noted.
and discussed by the first and second medical laboratory technologist. A final diagnosis was reached by consensus after observing the slides in question together.

The study questionnaire had been formatted into TeleForm version 8.1.0 (Cardiff™, Vista, California) for the collection of all quantitative survey data. TeleForm Data Collection Instruments (TDCIs) were filled at Nyalenda Health Centre during the volunteers' visits. TDCIs were scanned in computer. These data were exported to SPSS 12.0 (SPSS Inc, Chicago, IL) programme. BV results were entered into worksheet in Micro-Soft (MS) Excel software before being exported to Statistical Package for Social Scientists (SPSS) programme and MS Excel 2003 for analysis. These data were quality controlled and checked for validity through data cleaning and coding. Data were analyzed using MS Excel 2003 by simple descriptive statistics for demographic variables, while the Kappa score was used as a measure of correlation of diagnosis of BV. The scores of the first SCVS and the CCVS gram smears were compared to give the validity of the first SCVS. A comparison of scores of the first SCVS and the scores of the second SCVS gave the reliability of the vaginal swabs by participants. Scores of the CCVS and the second SCVS yielded validity of second SCVS. The proportion of participants with positive and negative preferences to SCVS was also assessed.

Results

One hundred and five women volunteered to participate in this study. CCVS was used as standard method of collecting vaginal specimen for BV diagnosis. The validity of first SCVS in diagnosis of BV was 0.952 (p-value < 0.001). The validity of second SCVS was 0.905 (p-value < 0.001). The comparisons of first and second SCVS gave the reliability of the clients in collecting self specimens. The Kappa score for the reliability was k=0.857 (p value=0.001) which is highly significant and therefore highly reliable. The BV prevalence among these women was 50.48% by CCVS, 49.53% by first SCVS and 51.43% by second SCVS (Table 1a, b, c & d).

Table 1a: Comparison of first self collected vaginal swabs (SCVS) with clinician collected vaginal swab (SCVS) for diagnosis of Bacterial Vaginosis

<table>
<thead>
<tr>
<th>BV Status by First SCVS</th>
<th>Normal</th>
<th>Intermediate</th>
<th>BV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>Frequency</td>
<td>%</td>
<td>37</td>
<td>0</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Frequency</td>
<td>%</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>Bacterial Vaginosis</td>
<td>Frequency</td>
<td>%</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>Frequency</td>
<td>%</td>
<td>39</td>
<td>14</td>
</tr>
</tbody>
</table>

P-value: 0.001
Kappa Score: 0.952
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## Table 1b: Comparison of second self collected vaginal swabs (SCVS) with clinician collected vaginal swab (CCVS) for diagnosis of Bacterial Vaginosis

<table>
<thead>
<tr>
<th>BV Status by Second SCVS</th>
<th>Normal</th>
<th>Inter</th>
<th>BV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>36</td>
<td>1</td>
<td>0</td>
<td>37</td>
</tr>
<tr>
<td>%</td>
<td>100.0</td>
<td>6.7</td>
<td>0.0</td>
<td>35.2</td>
</tr>
<tr>
<td>Intermediate</td>
<td>0</td>
<td>12</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>%</td>
<td>0.0</td>
<td>80.0</td>
<td>5.6</td>
<td>14.3</td>
</tr>
<tr>
<td>Bacterial Vaginosis</td>
<td>0</td>
<td>2</td>
<td>51</td>
<td>53</td>
</tr>
<tr>
<td>%</td>
<td>0.0</td>
<td>13.3</td>
<td>94.4</td>
<td>50.5</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>15</td>
<td>54</td>
<td>105</td>
</tr>
<tr>
<td>%</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

P-value: 0.001  
Kappa Score: 0.905

## Table 1c: Comparison of first self collected vaginal swabs (SCVS) with second self collected vaginal swab (SCVS) for diagnosis of Bacterial Vaginosis

<table>
<thead>
<tr>
<th>BV Status by First SCVS</th>
<th>Normal</th>
<th>Inter</th>
<th>BV</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>36</td>
<td>3</td>
<td>0</td>
<td>39</td>
</tr>
<tr>
<td>%</td>
<td>1.0</td>
<td>0.2</td>
<td>0.0</td>
<td>3.1</td>
</tr>
<tr>
<td>Intermediate</td>
<td>0</td>
<td>10</td>
<td>4</td>
<td>14</td>
</tr>
<tr>
<td>%</td>
<td>0.0</td>
<td>0.7</td>
<td>7.4</td>
<td>13.3</td>
</tr>
<tr>
<td>Bacterial Vaginosis</td>
<td>0</td>
<td>2</td>
<td>50</td>
<td>52</td>
</tr>
<tr>
<td>%</td>
<td>0.0</td>
<td>0.1</td>
<td>92.6</td>
<td>49.5</td>
</tr>
<tr>
<td>Total</td>
<td>36</td>
<td>15</td>
<td>54</td>
<td>105</td>
</tr>
<tr>
<td>%</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

P-value: 0.001  
Kappa Score: 0.857

## Table 1d: Summary of diagnosis by Nugent criteria obtained from the three vaginal swabs/smears namely CCVS, first SCVS and second SCVS

<table>
<thead>
<tr>
<th></th>
<th>CCVS</th>
<th>First SCVS</th>
<th>Second SCVS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Frequency</td>
<td>%</td>
<td>Frequency</td>
</tr>
<tr>
<td>Normal</td>
<td>37</td>
<td>35.2381</td>
<td>39</td>
</tr>
<tr>
<td>Inter</td>
<td>15</td>
<td>14.2857</td>
<td>14</td>
</tr>
<tr>
<td>BV</td>
<td>53</td>
<td>50.4762</td>
<td>52</td>
</tr>
<tr>
<td>Total</td>
<td>105</td>
<td>100</td>
<td>105</td>
</tr>
</tbody>
</table>
About 15% (15/105) of the participants said they preferred SCVS while 61.9% (65/105) said they preferred the CCVS method. About 23.81% (25/105) had no preference on method of swab collection (Figure 1). More than 93.3% (n=15) of those who preferred SCVS did so because it was easy, they could do it; it was a less painful procedure and more private. More than 90% of (n=65) who preferred CCVS liked it because it was easy, safer, less painful procedure, done by clinician, and one need not to know how to do it (Table 2). Twenty two percent (23/105) women participants said they did not know what abnormal vaginal discharge was. Most of the women (92.38) said that they had not experienced abnormal vaginal discharge. All of them said they would seek treatment if they had abnormality of vaginal discharge. Whereas 98% would do it in a health institution, only 2% would seek help from herbal or witch doctor. Sixty eight percent (71/105) thought their friends would suspect that they were HIV positive if they sought treatment on vaginal related health services. Only 12% (13/105) of their friends thought it was a good idea. These friends further associated abnormal vaginal discharge with infection while 35% (37) said they did not know it (See Table 3).

Figure 1: Preferences on method of vaginal collection for BV diagnosis

Table 2: Reasons for the choice of method of collecting a vaginal swab

<table>
<thead>
<tr>
<th>Why they preferred CCVS n=65</th>
<th></th>
<th>Why they preferred SCVS n=15</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Easy to perform</td>
<td>59 (90.77%)</td>
<td>Easy to perform</td>
<td>14 (93.33%)</td>
</tr>
<tr>
<td>A less painful procedure</td>
<td>59 (90.77%)</td>
<td>A less painful procedure</td>
<td>14 (93.33%)</td>
</tr>
<tr>
<td>Procedure done by a clinician</td>
<td>64 (98.46%)</td>
<td>It's more private</td>
<td>14 (93.33%)</td>
</tr>
<tr>
<td>They do not need to know how to do it</td>
<td>65 (100%)</td>
<td>They can do it themselves</td>
<td>15 (100%)</td>
</tr>
</tbody>
</table>
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### Table 3: Understanding of women participants on aspects of BV

<table>
<thead>
<tr>
<th>Understanding of abdominal vaginal discharge</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dirt</td>
<td>10</td>
<td>9.52</td>
</tr>
<tr>
<td>Ovulation</td>
<td>7</td>
<td>6.67</td>
</tr>
<tr>
<td>Seminal fluid</td>
<td>12</td>
<td>11.43</td>
</tr>
<tr>
<td>An infection</td>
<td>8</td>
<td>7.62</td>
</tr>
<tr>
<td>Flow from uterus</td>
<td>34</td>
<td>32.38</td>
</tr>
<tr>
<td>Lubricant</td>
<td>3</td>
<td>2.86</td>
</tr>
<tr>
<td>I do not know</td>
<td>23</td>
<td>21.9</td>
</tr>
<tr>
<td>Unpleasant discharge</td>
<td>6</td>
<td>5.71</td>
</tr>
<tr>
<td>menses</td>
<td>2</td>
<td>1.9</td>
</tr>
</tbody>
</table>

Would seek cure

- Yes                                         | 105 | 100  |

Where would you seek cure?

- Health facility                             | 103  | 98.1 |
- Herbalist / witch doctor                    | 2    | 1.9  |

What friend say about those seeking treatment for vaginal discharge

- Suspect them of having STI, HIV/AIDS         | 71   | 67.62|
- A very good idea                            | 13   | 12.38|
- I do not know                               | 5    | 4.76 |
- Do not say anything                         | 7    | 6.67 |
- Decline to answer                           | 7    | 6.67 |
- It is not ok                                | 2    | 1.9  |

What friends say on vaginal discharge

- Associated with infection                   | 23   | 21.9 |
- Associated with dirt                        | 3    | 2.86 |
- Associated with fertility                   | 6    | 5.71 |
- Associated with fertility                   | 2    | 1.9  |
- Decline to answer                           | 13   | 12.38|
- They say nothing                            | 3    | 2.86 |
- I do not know                               | 37   | 35.24|
- Pre-menstrual sign                          | 1    | 0.95 |
- It is normal                                | 2    | 1.9  |
- It shows maturity                           | 2    | 1.9  |
- Unpleasant discharge                        | 6    | 5.71 |
- Post coital discharge                       | 7    | 6.67 |

If you had a bad smell, what would you think it is?

- Do not know well                            | 8    | 7.62 |
- An infection                                | 65   | 61.9 |
- Could be blood                              | 1    | 0.95 |
- Dirt                                       | 30   | 28.57|
- It is a discharge                           | 1    | 0.95 |

What would you do to clear the smell?

- Seek hospital treatment                     | 55  | 52.38|
- Take a bath                                 | 47  | 44.76|
- Take herbal medicine                        | 2   | 1.9  |
- Do not know what to do                      | 1   | 0.95 |
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Discussion

This study sought to determine the validity and reliability of SCVS. Similar studies in developed countries have shown strong validity and reliability (Tanksale et al., 2003 and Nelson et al., 2003) that are comparable to the results of this study. Women in Africa can equally collect valid and reliable vaginal specimens as it was revealed in this study. SCVS was found to have a high degree of accuracy in diagnosis of BV and women performed it themselves well. These data demonstrate that with specific instructions, SCVS can perfectly approximate BV status in women. This method therefore can be used in place of clinician obtained swabs in determining BV prevalence among women.

As in a previous studies (Wiesenberg et al., 2001) women said that collecting SCVS is easy and comfortable. Even though most women in this study had done well on SCVS, majority preferred a CCVS. This was in contrast to other similar studies in Rakai, Uganda (Gray et al., 1998) and other places (Chernsky et al., 2005 and Holland-Hall et al., 2002) where majority preferred SCVS. The method of choice used can be decided on depending on the availability of a clinician. Both methods were readily available and this could have influenced these women to prefer CCVS over the SCVS due to perceived high quality results from CCVS. Women who participated in this study were from homogeneous background. Similar studies can be performed on women of diverse background and regions as opposed to the study at hand which dealt with women trading in fish. Randomization can also be done when enrolling volunteers as opposed to this study where only those who ‘wanted’ to participate were enrolled (‘first come first served basis’). The results on preference may not therefore be generalizable to all women in Kenya.

Need to disseminate information on BV

The overall BV prevalence among three sets of vaginal specimens for BV diagnosis compared relatively well with a 50.5%, 49.5% and 51.4% in Clinician, first self and second self collected vaginal swab respectively. This is yet another confirmation that SCVS is as good as CCVS.

Women with BV may have an abnormal vaginal discharge with an unpleasant odour. Some women report a strong fish-like odour, especially after intercourse (Soper et al., 1999). Discharge, if present, is usually white or grey and it can be thin (homogeneous). Women with BV may also have burning sensation during urination or itching around the outside of the vagina, or both. Some women with BV report no signs or symptoms at all (Klebanoff et al., 2004). Most women reported washing inside of the vagina or douching. This study did not enquire why they were doing it, but previous studies show that they do it to ensure they are clean (Hassan et al., 2007). Fishy odour is a symptom of BV. Women in this study said they would bathe if they had fishy odour. These women perceived that a bad smell was a sign of dirt, and therefore bathing alone could clear it. These perceptions are more likely to cause women to practice douching. Others bathe and use drying or astringent agents to make the vagina dry for dry sex claiming their sex partners prefer it to normal (lubricated) sex (Runganga et al., 1992). However, douching is known to increase chance of one developing BV due to clearing/killing Lactobacillus species which are responsible for a healthy vagina (Hassan et al., 2007). Increasing frequency of vaginal washing is associated with a higher likelihood of BV (Hassan et al., 2007). Women should not practice douching because of fishy smell, but rather seek health services. There is need to disseminate information on BV to women.
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The study further sought to determine the reaction of women if they discovered they had fishy vaginal odour. Sixty two percent (65/105) said they would suspect infection while twenty eight percent (30/105) would think they were unclean (dirty). Women in the fishing industry in Kisumu do not fully understand what fishy smell in vagina is all about. A good number said they would seek hospital treatment in case of fishy smell but it is unfortunate that sixty eight percent (71/105) of their friends would suspect that they are HIV positive, an indication that HIV stigma is still high among women who trade in fish in Kisumu District. Inaccurate perceptions on BV cause an unfounded fear (stigma) and therefore high prevalence of STI as many women do not seek health services.

Conclusions

The SCVS for diagnosis of BV was found to be both significantly valid and reliable. Women preferred CCVS over SCVS for diagnosis of BV. However, participants were willing to obtain their own vaginal swab specimens for BV diagnosis. No participant declined to obtain one or reported difficulty in obtaining SCVS. Women's awareness and perceptions of vaginal discharge and STI/HIV/AIDS was found to be inaccurate and misleading.

Acknowledgement

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Appendix

Sample size determination

The sample size that had adequate power (90%) to detect a high rate of agreement (Kappa = 0.90) for a two-sided, alpha = 0.05 test was determined by:

$$n = \frac{D(z_{\alpha} + z_{\alpha/2} + z_{\alpha/2} + z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Where:

- \(p = p_1 + p_2\) is mean proportion of success
- \(n\) is sample size
- \(P\) represents swabs taken from volunteers
- \(P_1\) is the proportion of good clinician collected swabs (specimen) from women
- \(P_2\) is the proportion of good self collected swabs (specimen) from women
- \((P_1 - P_2)^2\) is the difference to be detected
- \(D\) is the design effect. The design effect = 2 because we used clusters (beaches) while sampling.
- \(Z_{\alpha}\) is the critical value for a type 1 error. This is the value of the standard normal distribution corresponding to the significance level of alpha.
- \(Z_{\beta}\) is the critical for a (1-beta) power. This is the value of the standard normal distribution corresponding to the desired level of power.

For the study at hand estimates of \(P_1 = 99\%\); \(P_2 = 80\%\) and 90% power (1.28) and 5% type 1 error (1.96) were used. This was because the study was interested in the convectional alpha of 0.05 and beta level of 0.1, representing a power of 90% to detect the effect of the magnitude if it really existed. The sample size for this study was calculated as follows,

$$n = \frac{2(1.96\sqrt{2*0.895(1-0.895)} + 1.28\sqrt{0.99(1-0.99) + 0.8(1-0.8)})^2}{(0.99 - 0.80)^2}$$

$$n = \frac{2(1.434 + 1.28*0.412)^2}{(0.19)^2}$$

$$n = \frac{2(0.8497 + 0.5274)^2}{(0.19)^2}$$

$$n = \frac{2(1.3771)^2}{(0.19)^2} = 105.06$$

The final size was \(n=105.06\). The study therefore used **105 women volunteers**.