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ACCEPTABILITY OF A SELF-SAMPLING TECHNIQUE TO COLLECT VAGINAL SMEARS FOR GRAM STAIN DIAGNOSIS OF BACTERIAL VAGINOSIS

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Abstract

To diagnose asymptomatic bacterial vaginosis (BV), self-sampled vaginal smears were collected during a study of risk factors for preterm birth in African American women. More than 90% of those women who were willing to participate in the interview portion of the study were also willing to provide a self-sampled vaginal smear. The smears are an acceptable and efficient way of detecting BV in an urban minority population.

Introduction

Bacterial vaginosis (BV) is a significant public health problem. Depending on the population, it has been found to have a prevalence of between 15% and 30% in nonpregnant women in the United States, with African American women being particularly at risk (Goldenberg et al., 1996; Holzman, Leventhal, Qiu, Jones, & Wang, 2001). During an episode of BV, the typically dominant vaginal bacteria, lactobacilli, decrease markedly in number and a polymicrobial mix of other organisms, including *Gardnerella vaginalis*, mycoplasma, and various anaerobes, dramatically increase in concentration with a concomitant increase vaginal pH. Typical symptoms include an abnormal vaginal discharge or a fishy odor after sex (owing to the volatilization of the bacterial amines in the presence of the high-pH semen); however, many cases of bacterial vaginosis are asymptomatic. BV is associated with an increased risk for many serious upper genital tract problems, including pelvic inflammatory disease and cervical intraepithelial neoplasia (McNicol, Paraskevas, & Guijon, 1994; Paavonen et al., 1987). Pregnant women with BV are at increased risk for preterm birth, amniotic fluid infection, and endometritis (Hillier et al., 1988; Gravett, Hummel, Eschenbach, & Holmes, 1986; Holst, Goffeng, & Andersch, 1994). Furthermore, recent domestic and international studies have shown that BV is a significant risk factor for acquisition of HIV (Cohen et al., 1995; Hillier, 1998; Martin et al., 1999; Sewankambo et al., 1997; Taha et al., 1999).

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One of the difficulties with research involving BV is the frequency of recurrence even after successful treatment. Full resolution, or partial resolution, may be difficult to assess when a patient is seen in an office visit only once every 3 months if her flora are changing on a monthly, or even weekly, basis. Furthermore, these recurrent episodes, even when asymptomatic, may contribute to future health problems (Hay, 2000). Unfortunately, owing to difficulty in obtaining repeated samples, only a few studies have been able to effectively assess changes in women's vaginal flora over time (Hay, Ugwumadu, & Chowns, 1997).

As part of an ongoing prospective cohort study of preterm birth in African American women in Baltimore City, self-sampled vaginal smear specimens are collected in the prenatal clinic. The self-samples are collected privately by the patients following verbal and written instructions from our interviewers. This protocol could be easily adapted to a home setting for daily, weekly, or monthly monitoring of women's vaginal flora. The purpose of this substudy was to determine whether vaginal self-sampling techniques can be a useful adjunct to both basic and clinical research—for example, when clinician compliance to research protocols is low or when women are reluctant to receive an internal examination. The analysis presented here assesses whether the self-smear protocol for BV was acceptable to this relatively high-risk population by assessing willingness to provide smears. Because one of the concerns of the study investigators was that comfort with one's own body could vary by age, willingness was analyzed by age. Smear quality was also qualitatively assessed to determine whether these samples were an acceptable substitute to physician-provided samples, which were difficult to obtain in the overarching study.

Methods

Women were recruited into the overarching study during a prenatal care visit between week 22 and week 28 of gestation. All eligible women—pregnant, African American, Baltimore City residents—receiving care at one of the study clinics were invited to enroll. The women in this substudy were those enrolled from November 2001 (the start of the self-sampling protocol) through the end of June 2003.

After women consented to provide a self-sampled smear, they were given two sterile-wrapped Dacron (or cotton) swabs, a slide, a plastic slide case, and the instruction sheet (Figure 1). The interviewer then reviewed the instruction sheet with the woman before sending her to a private bathroom in the clinic where she took her sample. The woman would then return the slide, in its case, to the interviewer. The provided slide cases had small plastic insets to prevent the slide from touching the top or bottom of the case, which allowed the participants to immediately close the slide into the case without waiting for it to air dry. Samples were stored, in the slide cases, at room temperature until processing. This protocol is an adaptation of one previously used in Rakai District, Uganda (Wawer et al., 1998). Willingness to provide a smear was assessed quantitatively as the number of women who both consented and provided a self-smear. Willingness was also assessed subjectively through discussions with one study interviewer about her experience using the self-swab protocol.

Approximately every 2–3 months for the first year and then intermittently thereafter, samples were heat fixed, gram stained, and scored according to the Nugent criteria (Schwebke, Hillier, Sobel, McGregor, & Sweet, 1996). Self-obtained samples were treated identically to smears done by clinicians and were read by the same member of the research staff. Slide quality was assessed subjectively by the staff member reading the slides. Slides were considered poor quality if smears were placed on the wrong side of the slide, smears were too thick on the slide for the sample to be read (probably just dabbed onto the slide rather than rolled out as specified in the protocol), there was no sample on the slide, or the slide could not be read for a different reason.

Results

The study population consists of the first 306 women enrolled in an ongoing prospective cohort study after the self-sampling protocol was initiated. Participants were all pregnant, African American, Baltimore City residents receiving care at one of three outpatient clinics associated with Johns Hopkins Hospital, and were between the ages of 13 and 40 with approximately one quarter of the women under the age of 20.

The self-sampling procedure was highly acceptable to women. Willingness to provide a self-smear increased, over time, from 62% in the initial phase of the study to >95% after 6 months (when there was a staff change)—by the end of the analysis period, 92% of the patients had provided a self-smear (Table 1). Willingness did not vary by age after controlling for the staff member change.

Of the 24 women who did not provide self smears, 8 refused, 1 was lost to follow-up (some women were recruited into the study sample before the interview/smear window), and the reason was not documented for the remaining 15 (Table 1). One reason for not participating may have been limited time to collect the specimen. Study subjects who were interviewed prior to specimen collection may not have been willing to stay the additional time required to collect the specimen. Overall, slide quality of the self-smears was comparable to that of physician-obtained smears, although concurrent samples were rarely available.

Discussion

Women are very interested in self-sampling techniques for the diagnosis of vaginal infections (Mercer, Taylor, Fricke, Baselski, & Sibai, 1995; Serlin et al., 2002). Diagnosis based on self-obtained vaginal samples has previously been reported for bacterial vaginosis, *Chlamydia*, group B *Streptococcus* infection, and human papillomavirus (Coutlee, Hankins, & Lapointe, 1997; Domeika & Drulyte, 2000; Domeika et al., 1999; Mercer et al., 1995; Sturm, Moodley, Nzimande, Balkistan, Connolly, & Sturm 2002; Wiesenfeld, Heine, Rideout, Macio, DiBiasi, & Sweet, 1996). However, these sampling procedures have not necessarily been practical for repeated samples by the patient, which could be stored and turned in at a later date or for mailed in specimens.

We have reported here on a protocol where women collect their own vaginal secretions and prepare slides suitable for a Gram stain diagnosis of BV. A previous report of self-collected samples for diagnosis of BV used vaginal tampons and diagnosed the disease using the Amsel (clinical) criteria (Sturm et al., 2002). Gram stain scoring is an acceptable way of diagnosing BV with similar sensitivity and specificity to the Amsel criteria. In one study comparing the two methods, the Gram stain had a sensitivity and specificity of 89% and 83%, respectively, when the clinical criteria were considered the gold standard (Schwebke et al., 1996). Gram stains have also been found to detect a higher percentage of women with asymptomatic BV (Schmidt & Hansen, 2000).

Despite anecdotal suggestions that women in this population might be uncomfortable touching their genitals, greater than 90% of the women enrolled in this study were willing to provide a vaginal smear. Discussions with one of the study interviewers suggested that patients in this study were highly receptive to the fact that they did not have to undress and submit to a physician examination to provide a smear. The interviewer also suggested that the ability for a woman to “do it herself” without the embarrassment or inconvenience of an internal examination was one reason for the high level of acceptability, particularly when the patient was in the clinic for a visit that would not normally require such an examination. Although acceptability of the procedure might have been expected to vary by age, we did not find that in this population.

What variation we did find in acceptability was related to a change in our project staff. Approximately 6 months into the study, we replaced our initial interviewers and saw a dramatic increase in willingness to provide a self-smear. The staff change probably affected patient compliance for several reasons. First, the protocol changed midstream for the original interviewers—they had been working for several months before the self-smear protocol was implemented and it was not as integral a part of their training as it was for later interviewers. Second, the original project interviewers had been focused throughout the early part of the study on obtaining provider smears (part of the study protocol), and when those were present they were less likely to attempt to get a self-smear. Finally, the early interviewers were spending a lot of time attempting to get providers to take smears, which may have affected how and if they approached patients. All of these factors could have affected whether or not patients provided smears, through both the mechanism of patient willingness and whether or not they were actually properly approached.

In conclusion, we have found that self-sampled vaginal smears are an acceptable way to diagnose bacterial vaginosis in a high-risk population. Furthermore, this protocol would be straightforward to implement for repeated sampling in a home-based setting; samples can be stored at room temperature for an extended period of time and could be brought in at the next scheduled clinic visit or returned to an investigator or clinician by mail.

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Figure 1.

Instruction Sheet for the collection of self-obtained vaginal smears

1. Lay the slide flat on the sink, top side up. Try to only hold it by the frosted end. The rough side is the top.
2. Pick up the wrapped swab. Feel for the soft end of the swab, and then open the package at the other end. To open the package, tear off the end of the wrapper and then pull the paper down until the end of the stick (not the soft swab) is exposed. You have been given an extra swab in case you open the wrong end, but you only need to use one.
3. Take the swab stick out of the wrapper and put the soft tip into your vagina so that about one inch is inside. Turn the swab around several times inside the vagina so that it touches all walls.
4. Try squatting or put one foot on the toilet seat, as if you were putting in a tampon. Remove the swab from your vagina and roll it across the clear portion of the slide like you were rolling out a paint roller (see diagram below)
5. Throw away the swab and wrapper.
6. Holding the slide by the frosted end, place it in the slide case, close it, and return it to the interviewer.

Table 1

Willingness to provide a self-smear by age

Age	Smear Taken (N = 282)		No Smear Taken (N = 24)	
	# (%)	Refusal	Lost to Follow-up	Unknown
≤15	6 (86)	1 (14)	0 (0)	0 (0)
16–20	85 (94)	2 (2)	0 (0)	3 (3)
21–25	118 (94)	1 (1)	1 (1)	6 (5)
26–30	35 (82)	3 (7)	0 (0)	5 (12)
31–35	27 (96)	0 (0)	0 (0)	1 (4)
>35	9 (90)	1 (10)	0 (0)	0 (0)
Unknown	2 (100)	0 (0)	0 (0)	0 (0)
Staff change				
Before	16 (62)	1 (4)	0 (0)	9 (35)
After	266 (95)	7 (2)	1 (<1)	6 (2)