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Original article

Accuracy and Trust of Self-Testing for Bacterial Vaginosis

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A B S T R A C T

Purpose: Two point-of-care tests are available to detect bacterial vaginosis (BV), a common vaginal condition. This study aimed to (1) compare the accuracy of two self-performed BV tests with clinician-performed BV tests and with clinical diagnosis of BV; and (2) compare trust of results for self-performed BV testing with clinician-performed BV testing.
Methods: Participants (14–22 years old) in a study assessing self-testing for *Trichomonas vaginalis* were also asked to perform a self-test for BV (using a pH or sialidase test). Results were compared with clinician-performed tests and with clinical diagnosis of BV (defined by modified Amsel criteria). A two-item subscale from a larger acceptability scale was used to assess trust at baseline, after testing, and after discussion of results.
Results: All 131 women performed self-BV testing correctly. Agreement between self- and clinician-performed tests was good (κ: .5–.7) Compared with clinical diagnosis of BV, self-pH was 73% sensitive and 67% specific, and self-sialidase was 40% sensitive and 90% specific. Trust in self-performed BV testing was lower than trust in clinician-performed BV testing at baseline, but increased after testing and discussion of results.
Conclusions: Young women can perform self-tests for BV with reasonable accuracy, which could increase testing when pelvic examinations are not feasible. Trust in self-testing increased after experience and after discussion of test results. Although the pH test is available over the counter, young women may continue to rely on clinicians for testing.

IMPLICATIONS AND CONTRIBUTION

We evaluated the accuracy and trust of self-testing for BV, a common condition that is distressing to many women. Our findings show that BV self-testing is feasible and acceptable to young women, as trust increased after experience and discussion with a clinician. This "skills-based" approach may enhance use of POC tests.

Bacterial vaginosis (BV) is the most common lower genital tract condition among women. Data from the 2001–2004 National Health and Nutrition Examination Survey prevalence survey determined that BV affects nearly one-third of American women aged 14–49 years [1]. BV was reported in approximately 23% of women aged 14–19 years, and was found in 10%–18% of women who reported never having vaginal sex [1–4]. BV is caused by disruptions of the normal flora in the vagina and has been associated with several other conditions, such as pelvic inflammatory disease, preterm labor, and postsurgical infections [5–9]. Most concerning is a link between the presence of BV and acquisition of HIV [10,11]. Because BV is both common and often linked to poor reproductive health outcomes, improved detection of BV may be warranted.

Diagnosis of BV can be difficult. The research gold standard to diagnose BV is to use a Nugent score of ≥7 on a Gram stain of a vaginal sample [12]. However, Gram stain is rarely available or used in clinical settings and is reported to be about 85% sensitive and 85% specific compared with the Amsel clinical criteria

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Table 1
Comparison of diagnostic methods for BV

BV test	Sensitivity vs. Nugent	Specificity vs. Nugent	References
Amsel (any 3 of 4)	69–78	58–94	[13,16,17]
Modified Amsel: pH >4.5 + >20% clue + positive whiff	55	98	[13]
pH >4.5	77–89	70–74	[1,13,17]
>20% clue	60–74	86–94	[13,17]
Positive whiff	67	93	[17]
pH + amine	64	95	[17]
Sialidase (BVBlue)	88–92	95–98	[18,19]
pH or amines (FemExam[a])	89	61	[17]

When Nugent is compared with Amsel as the gold standard, Nugent is 80%–89% sensitive and 83%–91% specific [13,14].
BV = bacterial vaginosis.
[a] The FemExam card returned a positive result if either elevated pH or amines were detected, but is no longer commercially available.

[13,14]. The most common method used to diagnose BV is the Amsel criteria, in which three of the following four findings are present: (a) homogeneous white discharge, (b) >20% clue cells on wet mount, (c) positive "whiff" (i.e., the presence of an amine odor after application of potassium hydroxide to the vaginal sample), and (d) vaginal pH >4.5 [15]. However, a significant amount of clinical experience and microscopy skill is required to identify these fairly subjective criteria. Therefore, in many settings, clinicians use modifications or components of the Amsel criteria to ascertain BV [16]. We present the relative sensitivities and specificities of various BV diagnostic tools in Table 1.

In addition to limited test modalities, another barrier to BV diagnosis is that both the Gram stain and Amsel criteria require samples obtained during a pelvic examination. For adolescent women, a pelvic examination is a barrier to care [20]. However, vaginal samples can be collected by the clinician or the patient, which would remove the need for a speculum examination [21,22]. A final barrier to BV diagnosis and treatment is that women with BV may erroneously diagnose themselves with another condition, such as a yeast infection, if they do not seek care from a clinician [23]. Self-treatment for a yeast infection may delay appropriate diagnosis and treatment. Therefore, if a BV self-testing option were available, it may increase the proportion of women who are accurately diagnosed and treated for BV.

Two simple point-of-care (POC) tests are now available to improve the detection of BV. An over-the-counter vaginal pH test has been available since 2001. With this test, women who detect an abnormal pH (>4.5) are directed to seek medical care for further diagnosis [24]. Some authors have shown that the pH test will increase appropriate diagnosis and treatment [25]. Abnormal pH alone is reported to have 77%–90% sensitivity and approximately 70% specificity for BV [1,13,17]. Another POC test for BV detects sialidase, an enzyme produced by BV-associated bacteria. This test is Clinical Laboratory Improvement Amendments (CLIA) waived and has been marketed for use by health professionals since 2004. The sialidase test has a reported 90% sensitivity and 95% specificity for BV [18,19]. Both these tests are somewhat subjective in that they require the tester to recognize a color change, from yellow to green for pH and from yellow to blue for sialidase. Neither of these tests has been evaluated for use in adolescent women, and the sialidase test has not been evaluated as either a self-collected sample or as a self-performed test.

In our previous work, we showed that young women could accurately use a POC product developed for use by health professionals to self-test for *Trichomonas vaginalis* (TV), and that acceptability for self-testing improved after experience with self-testing [26,27]. However, it is unknown whether young women can accurately perform self-tests for BV and whether BV self-testing would be acceptable to them.

The goal of this study was to evaluate strategies to improve the diagnosis of BV in adolescent women. The specific aims were: (1) to compare the accuracy of self-performed pH and sialidase tests with the corresponding clinician-performed test and with the clinical diagnosis of BV (using modified Amsel criteria; and (2) to compare trust in the results of self-performed BV testing with clinician-performed BV testing.

Methods

Participants and study flow

Sexually active women aged 14–22 years were recruited from an urban children's hospital for a larger study assessing the accuracy and acceptability of self-testing for TV [26,27]. The methods and results of the larger study have been described, and the study was approved by the local institutional review board with a waiver for the requirement of parental permission for those women aged <18 years. In addition to self-testing for TV, each woman in the parent TV study was offered the option of self-testing for BV (using either the pH or sialidase test) on a self-obtained vaginal swab. Participation was voluntary, as the investigators and institutional review board considered the addition of the second self-test to be an additional burden that could have dissuaded subjects from participating in the parent TV study.

The study flow was as follows: At baseline, after obtaining informed consent, we collected information on demographic characteristics, sexual history, and behavior, as well as conducted a brief (pretesting) acceptability survey. BV testing was then performed; the clinician collected swabs during a pelvic examination, and the participant self-collected swabs and performed the BV test. During the pelvic examination, the clinician collected additional endocervical swabs for chlamydia and gonorrhea nucleic acid amplification tests, and a vaginal swab for trichomoniasis testing. The order of testing (clinician-collected first vs. self-collected first) depended on clinic flow. After the testing, the participant completed the second (post-testing) acceptability survey. Then, the study team reviewed the results of the self- and clinician-performed tests with the participant. After this discussion, the participant completed a third (postdiscussion) acceptability survey.

Laboratory testing

Clinician-collected vaginal swabs were tested for BV (wet mount, pH, amines, and sialidase) and for TV (using a POC rapid antigen test). Endocervical swabs were tested for chlamydia and gonorrhea by nucleic acid amplification tests (Aptima Combo2, Gen-Probe, Inc., San Diego, CA). After written and verbal instructions, each participant tested her vaginal swab with one BV test, either pH (pHem-alert, Gynex Corporation, Redmond, WA) or sialidase (OSOM BVBlue, Sekisui Diagnostics, LLC, Framingham, MA). After the participant reported her result, the research assistant observed the device, confirmed that the participant's read-