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MAJOR ARTICLE

Diagnosis and Treatment of Vaginal Discharge Syndromes in Community Practice Settings

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(See the Editorial Commentary by Sobel on pages 1544–5.)

Background. Although vaginal symptoms are common, diagnosis of bacterial vaginosis (BV), vulvovaginal candidiasis (VVC), and *Trichomonas vaginalis* (TV) is not standardized. Diagnostic approaches and appropriateness of treatment were evaluated for women with symptoms of vaginitis who were seeking care at community practice sites.

Methods. Three hundred three symptomatic women, across 8 University of Pittsburgh Medical Center–affiliated clinics, were evaluated per standard office-based practice. Four of 5 vaginal swabs (1 cryopreserved) were collected for a US Food and Drug Administration–authorized nucleic acid amplification test (NAAT) for vaginitis/vaginosis diagnosis; Nugent scoring (BV); yeast culture (VVC); and a second NAAT (for TV). Two hundred ninety women had evaluable samples. Medical record extraction facilitated verification of treatments prescribed within 7 days of the index visit and return visit frequency within 90 days.

Results. Women had a mean age of 29.4 ± 6.5 years, 90% were not pregnant, 79% were of white race, and 38% reported vaginitis treatment within the past month. Point-of-care tests, including vaginal pH (15%), potassium hydroxide/whiff (21%), and wet mount microscopy (17%), were rarely performed. Of the 170 women having a laboratory-diagnosed cause of vaginitis, 81 (47%) received 1 or more inappropriate prescriptions. Of the 120 women without BV, TV, or VVC, 41 (34%) were prescribed antibiotics and/or antifungals. Among women without infectious vaginitis, return visits for vaginitis symptoms were more common among women treated empirically compared to those not receiving treatment (9/41 vs 5/79, $P = .02$).

Conclusions. Within a community practice setting, 42% of women having vaginitis symptoms received inappropriate treatment. Women without infections who received empiric treatment were more likely have recurrent visits within 90 days.

Clinical Trials Registration. NCT03151928.

Keywords. bacterial vaginosis; vulvovaginal candidiasis; *Trichomonas vaginalis*.

Bacterial vaginosis (BV), *Trichomonas vaginalis* (TV) infection, and vulvovaginal candidiasis (VVC) are common in women of reproductive age. The prevalence of BV and TV in the United States (US) is 29% and 3%, respectively, but can vary depending on the study population [1, 2]. Adverse sequelae associated with BV [3–5] and TV [6–9] include increased acquisition of sexually transmitted infections including human immunodeficiency virus, and pregnancy complications including preterm birth. While the prevalence of VVC cases is unknown, 20% of women are colonized by *Candida* species in the absence of signs and/or symptoms, and 70% are colonized over a year [10]. Approximately 75% of women will experience at least 1 episode of VVC infection requiring treatment during their lifetimes [11].

The Centers for Disease Control and Prevention (CDC) guidelines describe the point-of-care tests that can be performed as an adjunct to a clinical history and physical examination to support diagnosis of vaginal discharge syndromes (those not characterized by vulvodynia and noninfectious causes of vaginal symptoms) [12]. These tests include measurement of vaginal pH, "whiff" test (addition of potassium hydroxide [KOH] to vaginal fluid for assessment of amine odor), and microscopic examination of fresh samples of the discharge to identify presence of clue cells, motile trichomonads, and/or budding yeast/pseudohyphae. The sensitivity and specificity of microscopic detection of clue cells, yeast, and trichomonads by clinicians can vary considerably [13, 14]. Despite these limitations, the low cost and convenience of point-of-care testing have contributed to their continued use. In a variety of studies, laboratory testing (Nugent score, yeast culture, US Food and Drug Administration [FDA]–approved and independent molecular assays) performed better

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than clinician-diagnosed vaginitis [15–17]. CDC guidelines recommend use of alternative commercially available point-of-care tests or clinical laboratory testing in settings where pH paper, KOH, and wet prep evaluation by microscopy are not available [12].

The primary objective of this study was to assess how women with vaginal discharge syndromes were being evaluated in community practice settings and to assess the appropriateness of the treatments prescribed for BV, TV, and VVC. A second objective was to assess how often women returned for symptoms of vaginitis in the 90 days following treatment and to assess whether the provision of appropriate treatment was related to return office visits for vaginitis symptoms.

METHODS

Study Design

This was a multicenter, single-visit study comparing clinician diagnosis of vaginitis to CDC-recommended laboratory-based testing and an FDA-market authorized nucleic acid amplification assay. The primary objective of this study was to assess clinician diagnosis algorithms for women presenting with vaginitis and treatment(s) prescribed per standard of care within community practices. Additionally, participant outcomes following 90 days of the index visit were assessed to determine whether women returned with symptoms. The protocol was approved by the University of Pittsburgh Institutional Review Board.

Between July 2017 and March 2018, 303 women aged 18–45 years were enrolled at 8 community-based practice clinics affiliated with the University of Pittsburgh Medical Center (UPMC). Women with 1 or more of the following symptoms: abnormal vaginal discharge, vaginal odor, vulvar or vaginal itch, vulvar discomfort (burning pain; irritation) were invited to participate if they provided written informed consent for the collection of 5 additional vaginal swabs, provided demographic and symptom data, and agreed to the extraction of limited data through the electronic medical record. Of the 303 samples received, 290 (96%) were evaluable; 4 were excluded because they were not received by the laboratory within 7 days, 4 were not correctly placed in the transport tubes, and 5 were excluded because the molecular testing was unresolved for 1 or more targets.

Participants provided their age, race, reason for visit, recent antibiotic and antifungal use, past and current genital symptoms, and pregnancy status, which was collected on a paper data collection form by clinic staff. The clinician performing the examination provided information on the diagnostic tests performed, the results of their point-of-care tests (pH, amine odor test, or microscopy, if performed), the presumptive diagnosis, and treatment (if any) prescribed on the day of the visit. The results of reference laboratory testing were not provided to the clinicians or the study participants. Participants were counseled and treated according to the discretion of the clinician and current practices at each site.

Specimen Collection and Transport

The 5 vaginal swabs collected for research were as follows: BD MAX UVE Specimen Collection Kit (swab and buffer tube) (Becton, Dickinson and Company, Sparks, Maryland); BD BBL CultureSwab MaxV(+) Amies Medium Without Charcoal (Becton, DIckinson and Company); Xpert CT/NG Vaginal/Endocervical Specimen Collection Kit (swab and transport tube) (Cepheid, Sunnyvale, California); Puritan Sterile Polyester Tipped Applicator (Puritan Medical Products Company LLC, Guilford, Maine); and the PurFlock sterile flocked collection device (Puritan Medical Products). The order of the swab collection was randomized to prevent sampling bias. Sample processing for the nucleic acid amplification tests was performed per the package inserts, and all samples were processed with 8 days of collection. The vaginal swab for yeast culture was transferred into a BD BBL Culture-Swab MaxV(+) Amies Medium Without Charcoal. The Puritan Polyester Tipped Applicator was inserted vaginally, and fluid was rolled onto a glass slide for Gram stain evaluation using the Nugent criteria. The PurFlock collection device was collected and placed in a dry cryovial for future use. All swabs were stored at ambient temperature from collection through transport to the laboratory via the United States Postal Service. The mean transport time was 4 days (data not shown).

Laboratory Diagnosis of Vaginal Infections in Reference Laboratory

All samples were evaluated in a single Clinical Laboratory Improvement Amendments–certified laboratory by technologists masked to the clinical diagnosis. Technologists performing the BD MAX Vaginal Panel (MAX VP) were masked to and did not perform other laboratory-based testing (Gram stain evaluation, yeast culture identification, and TV testing). MAX VP is an automated assay that utilizes fluorogenic target-specific probes for the qualitative identification of BV-specific organisms (*Gardnerella vaginalis*, *Atopobium vaginae*, bacterial vaginosis–associated bacteria 2 [BVAB-2], and *Megasphaera*-1) and lactobacilli (*Lactobacillus* species [*L. crispatus* or *L. jensenii*]) and assigns a positive or negative result relative to the concentrations of organisms present. The definition of a laboratory-confirmed diagnosis of BV was Nugent score ≥ 7 [18] and a positive result for BV with the MAX VP. A laboratory-confirmed diagnosis of VVC was defined as a positive culture for yeast and a MAX VP test positive for *Candida* species group (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. dubliniensis*), *C. glabrata*, or *C. krusei*. Yeast culture used Sabouraud dextrose agar with chloramphenicol (Hardy Diagnostics, Santa Maria, California) and/or HardyCHROM Candida (Hardy Diagnostics), and yeast colonies were identified using the API ID 32 C Yeast Microbial Identification Kit (bioMérieux, Marcy-l'Etoile, France). A laboratory-confirmed diagnosis of TV was based on the detection of *T. vaginalis* by both the Xpert TV and the MAX VP.

Electronic Medical Record Extraction

The electronic medical records for all participants were accessed via an Honest Broker System, which collects and provides de-identified health information for research purposes when approved by the institutional review board and the UPMC Privacy Office. Health information obtained for this study included the antifungals and/or antibiotics prescribed to the women within 7 days of the index visit and any additional follow-up visits and treatments related to vaginitis based on review of the chart notes through 90 days after the index visit. Appropriateness of treatment was based on whether the treatment prescribed was an FDA-approved or CDC-recommended therapeutic agent for that condition [12].

Statistical Analyses

Statistical analyses were performed using SPSS statistical software version 26 (IBM Corp, Armonk, New York), and all statistical tests were evaluated at the 2-sided .05 significance level. Fisher exact test was used to evaluate differences in the frequency of diagnostic testing by type of provider and differences in return visits for vaginitis between women who did or did not receive appropriate treatment.

RESULTS

Study Population

For the 303 women presenting with symptoms of vaginitis who enrolled, the mean age was 29.4 ± 6.5 years; 79% of women were white, 18% were African American, and 3% were other or unreported race/ethnicity. Participants were predominately nonpregnant (n = 274 [90%]). At the time of presentation, abnormal vaginal discharge was reported by 206 (68%) women, vulvar/vaginal itching by 133 (44%) women, vaginal malodor by 138 (46%) women, and irritation or discomfort by 128 (42%) women. Many of the women (n = 194 [64%]) reported > 1 complaint consistent with vaginitis at presentation. One hundred fifteen of the 303 (38%) women reported treatment of vaginal symptoms in the prior 30 days, with 55 (18%) from the study population reporting use of antifungals and 42 (14%) women reporting the use of oral or vaginal metronidazole in the previous month.

Results of Laboratory-based Testing for Vaginitis

The results of the laboratory-based testing for the 290 evaluable samples is displayed in Table 1. Similar frequencies of BV were detected based on Nugent Gram stain score (n = 104 [36%]) vs MAX VP (n = 107 [37%]). Overall, there was 88% concordance between the 2 laboratory-based tests for a BV diagnosis; 88 (30%) women were positive for BV by both tests. Yeast cultures yielded more *Candida* species than the NAAT vaginitis panel, with 93 (32%) women having 1 of the *Candida* species group (*C. albicans*, *C. tropicalis*, *C. parapsilosis*, *C. dubliniensis*) by both culture and NAAT. *Candida glabrata* was detected by culture and MAX VP for 7 (2%) women, whereas *C. krusei* was not detected in any of the study participants. The level of agreement between culture and NAAT was 90% for the *Candida* species group and 98% for *C. glabrata*. *Trichomonas vaginalis* was detected by both NAAT tests in 19 (7%) women, with 100% concordance between the 2 test systems. Concordance/discordance between reference laboratory and MAX VP results for BV, VVC, and TV are shown in Supplementary Table 1.

Table 1. Prevalence Observed by Laboratory Diagnosis of Vaginal Infections in 290 Women Presenting With Symptoms

Infection	Reference Laboratory	MAX VP	Both
Bacterial vaginosis (n = 167)			
Nugent 7–10	104 (35.9)	107 (36.9)	88 (30.3)
Nugent 0–6			
Yeast			
Candida group[a]	112 (38.6)	92 (31.7)	90 (31.0)
Candida glabrata	12 (4.1)	7 (2.4)	7 (2.4)
Candida krusei	0 (0)	0 (0)	0 (0)
Trichomonas vaginalis	19 (6.6)	19 (6.6)	19 (6.6)

Data are presented as no. (%).

Abbreviations: MAX VP, BD MAX Vaginal Panel.

[a] *Candida albicans*, *C. tropicalis*, *C. dubliniensis*, and *C. parapsilosis*.

Performance of Point-of-Care Tests for Diagnosis of Vaginitis

Table 2 displays the use of point-of-care tests stratified by provider type (n = 281). Nine samples were excluded from this analysis because the provider information was not provided. Clinicians evaluated vaginal pH for 41 (15%) women, the KOH whiff test was performed for 59 (21%) women, and vaginal fluid was evaluated microscopically for clue cells, motile trichomonads, and yeast buds and pseudohyphae for 49 (17%) women (Table 2). Evaluation of discharge was the only point-of-care evaluation, which was performed for all women.

There were 27 clinicians providing data, with 99 visits conducted by physicians (35%) and 182 visits by advanced practice providers which included nurse midwives, physician assistants, and nurse practitioners (65%). As shown in Table 2, there were no differences in the frequency of tests performed comparing advanced practice providers vs physicians except for pH, which was collected more frequently by advanced practice providers. Ordering of laboratory-based testing was common, with 236 (84%) women having laboratory testing documented in the electronic medical record, the most common of which was a nonamplified DNA-based test panel. Advanced practice providers were more likely than physicians to order NAAT for *T. vaginalis* ($P = .003$).

Proportion of Women Prescribed Appropriate Treatments and Repeat Visits for Vaginitis in the Subsequent 90 Days

As shown in Table 3, 60 of 290 (21%) women had laboratory-confirmed BV alone, 74 (26%) had VVC alone, 7 (2%) women

Table 2. Point-of-Care Diagnostic Testing Performed and Laboratory Testing Ordered During the Study Visit

Test	No. of Visits With Advanced Practice Provider[a] (n = 182)	No. of Visits With Physician (n = 99)	*P* Value	No. of Visits Overall[b] (N = 281)
Assessment of pH	36 (19.8)	5 (5.1)	.001	41 (14.6)
Potassium hydroxide (whiff test)	41 (22.5)	18 (18.2)	.45	59 (21.0)
Microscopic evaluation[c]	31 (17.0)	18 (18.2)	.87	49 (17.4)
Visual inspection of discharge	182 (100)	99 (100)		281 (100)
Laboratory testing ordered	162 (89.0)	74 (74.7)	.003	236 (84.0)
Nonamplified vaginitis panel	135 (74.2)	70 (70.7)	.57	205 (73.0)
Non-FDA-cleared NAAT panel	3 (1.6)	1 (1.0)	> .99	4 (1.4)
FDA-cleared test for *Trichomonas*	21 (11.5)	2 (2.0)	.005	23 (8.2)

Data are presented as no. (%) unless otherwise indicated.

Abbreviations: FDA, US Food and Drug Administration; NAAT, nucleic acid amplification test.

[a]Advanced practice providers in this study included nurse practitioners, nurse midwives, and physician assistants.

[b]Provider information not available for 9 participants.

[c]Includes microscopic identification for 1 or more of clue cells, budding yeast and/or pseudohyphae, and trichomonas.

had TV alone, 29 (10%) had coinfections, and 120 (41%) had no vaginal infections detected. Based on the extracted prescription data from the electronic medical records for 60 women with BV alone, 42 (70%) received appropriate treatment, which included oral metronidazole (n = 30/42 [71%]) followed by vaginal metronidazole (n = 10/42 [24%]) or vaginal clindamycin (n = 2/42 [5%]). Because some clinicians treat women having BV empirically for VVC, use of concurrent antifungal with antibiotic therapy was considered appropriate for this analysis and occurred for 6 (10%) women with BV alone. As shown in Table 3, 18 of the 60 (30%) women with BV alone did not receive appropriate treatment; 16 (27%) were provided no prescriptions and 2 (3%) were provided antifungals alone. Return visits over the subsequent 90 days occurred for 21 (35%) women and did not differ by appropriateness of treatment.

Yeasts were detected in 93 (32%) women having symptoms of vaginitis. Of 74 women with VVC alone, 44 (59%) did not receive an appropriate treatment, with 26 (35%) receiving no

Table 3. Appropriateness of Treatment for 290 Women Having Vaginal Symptoms and Frequency of Repeat Visits Stratified by Diagnosis

Diagnosis	No. (%)	No Visits in Next 90 d	1 Visit in Next 90 d	2 Visits in Next 90 d	3 Visits in Next 90 d	*P* Value[a]
BV	60 (20.7)	39	16	4	1	.56
Appropriate treatment	42	26	13	2	1	
Inappropriate treatment	18	13	3	2	0	
Yeast vaginitis (VVC)	74 (25.5)	62	8	4	0	.34
Appropriate treatment	30	27	2	1	0	
Inappropriate treatment	44	35	6	3	0	
TV	7 (2.4)	3	1	2	1	> .99
Appropriate treatment	2	1	1	0	0	
Inappropriate treatment	5	2	0	2	1	
TV and BV	10 (3.4)	7	2	1	0	
Appropriate treatment	9	6	2	1	0	
Inappropriate treatment	1	1	0	0	0	
BV and VVC	17 (5.9)	13	4	0	0	> .99
Appropriate treatment	6	5	1	0	0	
Inappropriate treatment	11	8	3	0	0	
VVC and TV	1 (0.3)	1	0	0	0	
Appropriate treatment	0	0	0	0	0	
Inappropriate treatment	1	1	0	0	0	
BV, TV, and VVC	1 (0.3)	0	1	0	0	
Appropriate treatment	0	0	0	0	0	
Inappropriate treatment	1	0	1	0	0	
No infection	120 (41.4)	106	13	1	0	.02
No treatment	79	74	4	1	0	
Inappropriate treatment	41	32	9	0	0	

Abbreviations: BV, bacterial vaginosis; TV, *Trichomonas vaginalis*; VVC, vulvovaginal candidiasis.

[a]Fisher exact test to evaluate differences in return visits for vaginitis between women who did or did not receive appropriate treatment for that condition.

treatment, 9 (12%) being prescribed antibiotics for BV, and 9 (12%) being prescribed treatments for both BV and yeast. Of women having VVC alone, 12 (16%) presented with vaginitis symptoms in the subsequent 90 days (Table 3). Seventeen (6%) women had concurrent BV and yeast, and appropriate treatment was prescribed for only 6 (35%). Return visits for vaginitis symptoms occurred for 4 of 17 (23%) of women having BV and VVC.

Of the 19 (7%) women with TV, 12 (63%) had mixed vaginal infections. While 10 of the 11 (91%) women with concurrent TV and BV were prescribed oral metronidazole, only 2 of the 7 (29%) women having TV alone received oral metronidazole treatment. Seven (37%) women with TV (either alone or with coinfection) received no treatment. Of note, 8 (42%) women having TV returned for vaginitis symptoms over the next 90 days.

Of the 120 women having no diagnosed vaginal infection (BV, VVC, or TV), 41 (34%) received a prescription for antibiotics and/or antifungals; 6 (5%) received both antifungals and antibiotics, 8 (7%) received antifungals alone, and 27 (23%) received either oral or vaginal metronidazole for treatment of BV. Of the women who received prescription for treatment of infections when none were detected, 9 of 41 (22%) returned for repeat symptoms of vaginitis in the subsequent 90 days, compared to 5 of 79 (6%) women who were not prescribed a treatment ($P = .02$).

DISCUSSION

In this study of 290 women seeking healthcare for symptoms of vaginitis, more than half had a laboratory-diagnosed condition, with 30% of women having BV, 34% having VVC, and 7% having TV based on laboratory testing. This study documents how infrequently CDC-recommended point-of-care testing, such as assessment of vaginal pH, microscopic examination of vaginal fluid, or the whiff test, is performed when women present with vaginal symptoms in primary women's healthcare settings. Similarly, low rates of evaluation have been reported among women referred for management of recurrent vaginitis [19].

Nearly half of the 170 women having a laboratory-diagnosed cause of vaginitis received 1 or more prescriptions that were inappropriate, and one-third of the 120 women without any of the known infectious causes of vaginitis were prescribed treatment inappropriately. Overall, 4 of 10 women seeking healthcare for symptoms of vaginitis in this study were prescribed inappropriate treatments. Return visits for symptoms of vaginitis were common, occurring over the next 3 months in 20% of the women. The frequency of return visits ranged from 17% of women with VVC, 35% of women having BV, and 42% of women with TV. Surprisingly, follow-up visits for vaginal symptoms were also common for women having no laboratory-diagnosed vaginitis at the index visit, with 12% of women returning with symptoms of vaginitis. The women who were treated empirically for vaginitis were significantly more likely to return in the subsequent 3 months vs those who were not treated (22% vs 6%, $P = .02$). Empiric treatment of women having symptoms of vaginitis is common and is perceived to cause no harm. However, these data suggest that empiric treatment of women having symptoms, but no infectious cause of vaginitis, may result in more symptom-triggered visits and a greater burden both for women and health systems.

There was a high agreement in the present study between the reference laboratory and the FDA-cleared tests, which is consistent with previously published studies [16, 20, 21]. Culture for detection of *Candida* species and *C. glabrata* appeared to be more sensitive than the MAX VP. However, the samples for testing in the reference laboratory were mailed at ambient temperature and it is likely that *Candida* may have replicated in the Amies medium during transport [22], decreasing the apparent sensitivity of MAX VP. It is unlikely that this impacted the results of the current analysis since women were categorized as having yeast present only when both the culture and MAX VP were concordant.

There are several strengths to the current study. Studies evaluating the accuracy of vaginitis diagnosis have focused on review of medical records from women referred for recurrent vaginitis symptoms [19] or have focused on research sites where these tests are performed routinely [16], whereas the present study enrolled women at community practice sites employing both physicians and advanced care providers. A second strength of the study is the use of the medical record extraction, which provided prescription data and follow-up information on how many visits for symptoms of vaginitis occurred among women over the subsequent 3 months. There are significant limitations to the study, including the use of a limited numbers of sites within a single regional health system, lack of data for care outside the health system or treatments purchased over the counter, and the limited data collection from the women at the index visit. It is likely that some women received treatments based on symptom reporting by telephone or direct messaging, raising the possibility that the present study did not capture patients whose complaints were addressed without any clinical evaluation whatsoever. Published studies have documented the poor diagnostic accuracy of telephone triage [23].

The results of the present study suggest that the current approach to management of vaginal discharge provides suboptimal care. Significant time burdens placed on primary care providers and the time and effort necessary to perform inexpensive point-of-care tests are likely balanced against other competing priorities. Different models of care may be warranted for women having vaginal discharge syndromes. This requires a combination of sensitive and specific laboratory testing as well as careful patient evaluation and clinical acumen to accurately

diagnose women presenting with symptoms of vaginitis. One approach could be to ask women who contact a clinician's office with vaginal symptoms to provide self-collected vaginal swab samples, which have been proven to be equivalent to clinician-collected samples [21, 24], for testing. Prescriptions could be written to cover the specific pathogens identified and women having no infectious etiology identified could be counseled that no antifungal or antibiotic therapy is warranted. The excess healthcare costs associated with empiric treatment deserves further study.

Supplementary Data

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

Notes

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