Understanding the Importance of Accurately Diagnosing Vaginal Infections

Vaginal discharge syndromes (VDS)—encompassing bacterial vaginosis (BV), *Trichomonas vaginalis* infection (TV), and vulvovaginal candidiasis (VVC)—are among the most common reasons why women in the United States seek medical care. These infections are typically characterized by discharge, itching, or odor and are associated with several adverse reproductive health sequelae (e.g., increased susceptibility to other sexually transmitted infections, including HIV).[1,2] Women with BV or TV are also more likely to contract pelvic inflammatory disease (PID), which can result in tubal infertility.[3] In addition, both BV and TV have been linked to higher rates of preterm birth.[4] 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 for over a year.[5] Although VDS is a common complaint by women, diagnosis and the suitability of treatment for VDS in community practices remain inadequate.[2]

The Centers for Disease Control (CDC) guidelines rely heavily on the provision of point-of-care (POC) tests for diagnosing VDS. However, as convenient as POC testing is for VDS, it requires several time-consuming steps performed in the clinician's office, all of which may not be possible in every office. POC tests for TV miss half of all infections,[6] and while excellent nucleic acid amplification tests (NAATs) are available, they are not incorporated into the TV diagnostic algorithm as frequently as observed for *Chlamydia trachomatis* or *Neisseria gonorrhoeae*.[7-9] Diagnosis of BV entails combination of a vaginal pH ≥4.7, appearance of clue cells on the saline wet mount, and a positive whiff test. This series of tests can detect >80% of suspected BV infections, but overall is much less accurate when women have mixed vaginal infections. Although two sensitive and specific NAATs have been approved by the US Food and Drug Administration (FDA) for BV, neither is POC.[10] Finally, VVC is also difficult to diagnose using a potassium hydroxide wet mount as it is relatively insensitive, and many symptomatic women with infections likely caused by *Candida albicans* will not have yeast buds or pseudohyphae visually present on the microscopic slide. Thus, many women with vaginal infections remain undiagnosed.[10] Unfortunately, the low cost and convenience of POC testing for VDS have contributed to their continued use in the community practice setting.

Evaluation and Treatment of VDS in the Community Practice Setting

To assess methods of evaluating women with VDS in community practice settings—and the appropriateness of treatments prescribed—Hillier and colleagues[2] undertook a multicenter, single-visit study to compare clinicians' diagnostic approaches to vaginal discharge syndromes to both the CDC-recommended laboratory-based testing as well as FDA-approved NAATs. Those data follow.

Methodology

An evaluation of 303 symptomatic women was conducted according to the standard of each office-based practice. Women with 1 or more of the following symptoms were invited to participate: 1) abnormal vaginal discharge; 2) vaginal odor; 3) vulvar or vaginal itch; and/or 4) vulvar discomfort (burning pain, irritation). Participants were subsequently counseled and treated according to the discretion of the attending clinician and current practices at each site. Participant outcomes within the following 90 days of the index visit were also assessed to determine the rate at which women returned with new or continuing vaginitis symptoms.

Study Population Demographics

The mean age for women enrolled in the study was 29.4 ± 6.5 years; 79% of women were white, 18% were African American, and 3% were other or unreported race/ethnicity. At initial presentation, abnormal vaginal discharge was reported by 206 (68%), vulvar/vaginal itching by 133 (44%), vaginal malodor by 138 (46%), and irritation or discomfort by 128 (42%) women.

Performance of POC Tests for Vaginitis

Table 1 breaks out the utilization of POC tests segmented by provider type (n = 281). Twenty-seven clinicians provided data, totaling 99 visits (35%) conducted by physicians and 182 visits (65%) conducted by advanced practice providers (nurse midwives, physician assistants, nurse practitioners). POC tests performed were consistent between provider groups with the exception of the vaginal pH test. Vaginal discharge was the only POC evaluation performed for all women.

Table 1. Point-of-Care Diagnostic Testing Performed and Laboratory Testing Ordered During 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 presented as number (%).

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 clue cells, budding yeast and/or pseudohyphae, and trichomonas.

Appropriateness of Treatments Prescribed and Repeat Visits

Of 60 women with BV alone, 42 (70%) received appropriate treatment (e.g., oral or vaginal metronidazole, vaginal clindamycin); 16 (27%) received no prescriptions; and 2 (3%) received antifungals. Twenty-one women (35%) had return visits within 90 days from the index visit independent of the appropriateness of treatment.

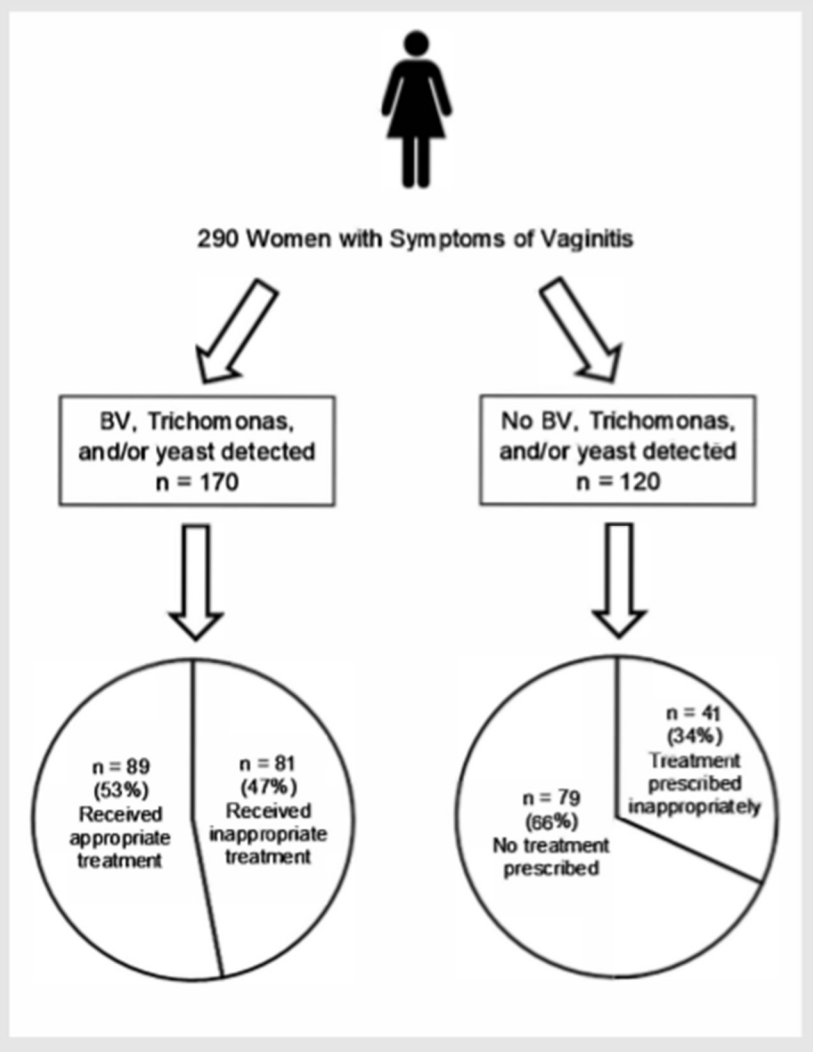
Of 74 women with VVC alone, 44 (59%) did not receive an appropriate treatment; 26 (35%) received no treatment; 9 women (12%) were prescribed antibiotics for BV; and 9 (12%) were prescribed treatments

for both BV and yeast infection. Among women with a VVC infection, 12 (16%) returned with symptoms of vaginitis within the subsequent 90 days. Of the 19 women with TV, 7 (37%) who had either a single infection or co-infection received no treatment. Eight women (42%) with TV returned with vaginitis symptoms within the subsequent 90 days.

Of the 120 women having no diagnosed infection, 41 (34%) received a prescription for antibiotics and/or antifungals. Of the women who received a prescription for treatment of an infection when none existed, 9 of 41 (22%) returned with symptoms of vaginitis in the subsequent 90 days, compared with 5 of 79 women (6%) who were not prescribed a treatment ($P = 0.02$).

Study Conclusions

The study by Hillier and colleagues[2] documents how infrequently CDC-recommended POC testing is performed when women present with symptoms of vaginitis in a primary care women's community practice setting. As depicted in Figure 1, of 170 women with symptoms of vaginitis, 53% received one or more inappropriate prescriptions as did 34% of women without any known infectious cause of vaginitis. Overall, about 40% of women with symptoms of a vaginal discharge syndrome received inappropriate therapy. Moreover, 1 in 5 women had return visits for symptoms of vaginitis within 90 days of the index visit.



Another interesting finding was that empiric treatment of symptoms associated with vaginitis is not harmless as is commonly believed. The data suggest that empiric treatment of symptomatic women having no infectious cause of vaginitis may lead to an increase in symptom-triggered visits resulting in a greater healthcare burden for the woman and increased costs to healthcare systems.[2,11]

These findings from Hillier and colleagues[2] also clearly demonstrate that the current approach to managing VDS is suboptimal and ineffective. New models of identifying and treating VDS are needed, with more attention paid to replacing the current POC testing with more sensitive NAATs. A practical step toward improving the outcomes of VDS management is for women who suspect an infection to contact a clinician's office and provide a self-collected vaginal swab for NAAT. Appropriate prescriptions could be written, or in absence of infection, women could be counseled that no therapy is warranted. These steps could help expedite VDS diagnosis while reducing widespread and inappropriate prescribing.

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