

Detecting *Trichomonas vaginalis* in High-Risk Women: A Tricky Situation

Mariea Snell, DNP, FNP-C, Mary Lee Barron, PhD, FAANP, and Cathy Koetting, DNP, NP-C

ABSTRACT

Trichomonas vaginalis (TV) is an easily treated but difficult-to-diagnose infection with the standard wet prep (WP) method. A point-of-care (POC) test has been developed with a sensitivity of 85%–90% and specificity of 100%. This new test is more costly than the traditional WP. Incorporating this POC test with the WP using a step approach may increase detection of TV while minimizing cost. In this pilot study of 50 subjects, 12 (24%) tested positive for TV. With the WP method, 7 (14%) tested positive. Of the 43 negative patients, an additional 5 (11.6%) tested positive using the POC test, indicating a significant result.

Keywords: STI testing, *Trichomonas vaginalis*, vaginitis

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INTRODUCTION

Trichomonas vaginalis (TV) has long been seen as an easily treated infection, yet it is deceptively difficult to diagnose. This infection affects approximately 7.4 million people in the United States and 276.4 million people worldwide each year.^{1,2} For many years, TV was considered a harmless parasitic infection, presumably due to the fact that most patients presented asymptotically or with mild symptoms. In recent years, research has linked this infection with higher rates of HIV-1 acquisition and transmission, preterm births, cervical cancer, pelvic inflammatory disease, and infertility.^{3–5} Risk factors for TV include poverty, lower educational level, concurrent chlamydia infection, African American ethnicity, multiple sex partners, and increased age.⁵

Currently, the method used most often for diagnosis is a wet prep (WP) test.² This method of testing allows for in-office detection, which improves treatment rates. However, there are limitations to the effectiveness of this testing method. Research has shown this approach to have a sensitivity of 38%–66% and specificity of 100%.^{6–8} The observers' experience, time from collection to assessment, and the adequacy of the specimen account for much of the variability in sensitivity.⁹

A newer point-of-care (POC) test has become available exclusively from OSOM, and can be performed in the office. The test has a sensitivity of 85%–90% and specificity of 100%, and can be read in 10 minutes.^{6,8} Although this form of testing is more costly (approximately \$11 per test) than the traditional WP, providing immediate results and therefore improved patient outcomes may make this worth the added expense.⁷ Pattullo et al.⁸ studied 345 low-risk women with and without clinical symptoms of vaginal infection and argued for a step approach to TV testing. By adding a POC TV test to 307 of the 345 women (participants who had negative WP testing), an additional 27 cases were identified, giving an overall prevalence of 18.8%.⁸ The investigators reported that a WP test followed by POC testing was the most sensitive approach. This suggests that this same step approach to testing in a high-risk population could yield an even higher rate of detection. The aim of this study was to evaluate this step approach and test its efficacy in women who are at high risk for TV infection.

LITERATURE REVIEW

A strong argument exists for improvement in detection of TV infections. Evidence for this comes from earlier public health studies of female sex

workers who acquired HIV-1 and had a history of previous TV infection.^{4,5} Other researchers examining the use of polymerase chain reaction analysis for detecting TV in a general population also noted a correlation of HIV-1 acquisition with a prior history of TV infection.¹⁰ Noting the strong correlation of TV infection with subsequent HIV-1 infection in parts of the world where both infections are common, the increased ability to diagnose TV could also help reduce the spread of HIV-1. The United States Centers for Disease Control and Prevention (CDC) recommends testing all women with vaginal discharge for TV, yet there are no national guidelines for screening asymptomatic women.¹¹ Thus, it is unknown how many asymptomatic women are not being treated for TV as a result of a lack of guidelines. Meites et al.¹⁰ studied the prevalence of TV in symptomatic and asymptomatic women in 15 sexually transmitted disease (STD) clinics in the US. “Symptomatic” was operationally defined as complaint of any relative subjective symptom and/or objective sign, and “asymptomatic” if no relevant sign or symptom was reported. Although the clinics varied in their rates of screening asymptomatic women (1.6%–15%), 3,909 of the total 19,197 asymptomatic women were screened and 254 (6.5%) were found to be infected (2013). The rates of detecting infection were highly dependent on the screening practices of a particular clinic. Overall, the clinics showed a lack of consistent practice. However, the researchers did find that those clinics that performed more screening tests detected a higher rate of TV.¹⁰

Meites et al.¹⁰ also found the highest prevalence of TV-infected women among those who self-defined racially as black non-Hispanic and in the 50⁺-year age range. Notably, in all races in the study (black non-Hispanic, white non-Hispanic, and Hispanic), the prevalence of TV infection increased with age. Among black non-Hispanic women in New York City who use drugs, researchers found that 38% screened positive for TV infection.¹² Of those who initially screened as negative, 31% subsequently became infected, as detected in repeated screening. Due to the possibility that TV infection has become pervasive in the black non-Hispanic population, the researchers advocate for a control strategy to combat the disease prevalence.¹ This strategy includes

screening in nonclinical settings and rapid POC testing to more effectively treat an easily curable infection.^{13,14}

Nathan et al.⁷ provided support for the use of a rapid detection POC test: the OSOM *Trichomonas* Rapid Test (Sekisui Diagnostics, Lexington, MA). The study consisted of 246 sexually active women, age ≥ 18 years, who presented with symptoms of vaginitis. Subjects were screened for TV using 5 methods: the WP; the POC test; culture; in-house real-time polymerase chain reaction; and the Aptima test. The prevalence of TV was 9.75% (24 of 246 women). Only 7 women were positive by all 5 methods. Another 11 women were negative by WP but positive by the other 4 methods. The WP method yielded 9 (3.66%) cases. When 1 of the other 4 methods was added to the WP, a further 14 cases were identified. Compared with a testing regime consisting of WP and culture, the OSOM test had a sensitivity of 83.3% and a specificity of 98.8%, as compared with 71.4% and 100% for WP. Culture results took 48–72 hours to detect TV. The OSOM test provided results in 10 minutes. Most importantly, the rapid test detected an additional 27% (8 of 30) of TV infections that were WP negative but culture positive. Similar to previous studies, the researchers also found that prevalence of TV did not decrease with age as with other sexually transmitted infections (STIs) such as *Chlamydia trachomatis* and *Neisseria gonorrhoea*.⁷ Researchers concluded that the OSOM test is projected to cost significantly less than culture and nucleic acid amplification methods and the same as WP when looking at costs based on a clinician’s time. Most importantly, use of a rapid POC test such as the OSOM could increase detection in a difficult-to-reach population, have a significant impact on a clinician’s time, and impact the consequences of this STD.⁷

Huppert et al.¹⁵ tested the sensitivity and specificity of 4 types of tests for TV: WP; culture; rapid antigen testing (using OSOM TV); and transcription-mediated amplification (TMA) testing using Gen-Probe. They found that both TMA and rapid antigen testing were highly sensitive and specific; both were superior in identifying TV compared with WP in 330 adolescent women (14–21 years of age) who presented to a teen health center or emergency room over a 2-year period. Of those

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