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Rapid and point-of-care tests for the diagnosis of *Trichomonas vaginalis* in women and men

Charlotte A Gaydos,[1] Jeffrey D Klausner,[2] Nitika Pant Pai,[3] Helen Kelly,[4] Cordelia Coltart,[4] Rosanna W Peeling[4]

[1]Division of Infectious Diseases, Medicine Baltimore, Johns Hopkins University, Baltimore, Maryland, USA
[2]Division of Infectious Diseases, Department of Medicine, University of California Los Angeles, Los Angeles, California, USA
[3]Department of Epidemiology, McGill University, Montreal, Canada
[4]London School of Hygiene & Tropical Medicine, London, UK

Correspondence to
Dr Charlotte A Gaydos, Division of Infectious Diseases Johns Hopkins University 855 North Wolfe St., 530 Rangos Building Baltimore, MD 21205, USA; cgaydos@jhmi.edu

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ABSTRACT

Background *Trichomonasvaginalis* (TV) is a highly prevalent parasitic infection worldwide. It is associated with many adverse reproductive health outcomes. Many infections are asymptomatic and syndromic management leads to underdetection of TV. Traditional methods of TV detection such as wet preparation are insensitive. New rapid, point-of-care (POC) tests can enhance the diagnosis of trichomoniasis.

Methods The authors reviewed the literature and discuss older POC tests for TV detection, as well as the OSOM lateral flow test, the AmpliVue test, the Solana test and the GeneXpert test as well as the limitations of wet preparation and culture for detection of TV.

Results The OSOM test is easy to perform, compared with other POC tests, and is Clinical Laboratory Improvement Amendments (CLIA)-waived, equipment-free, has sensitivities of 83%–86% compared with nucleic acid amplification tests (NAATs) and can be performed in 15 min. The AmpliVue and the Solana tests are not CLIA waived and require small pieces of equipment. They are molecular amplified assays and can be completed in <1 hour. AmpliVue demonstrated a sensitivity for vaginal swabs of 100% compared with wet preparation/culture and 90.7% compared with NAATs. Solana demonstrated a sensitivity of 98.6%–100% for vaginal swabs and 92.9%–98% for female urines, compared with wet preparation/culture. Compared with other NAATs, the sensitivity for Solana was 89.7% for swabs and 100% for urine. The GeneXpert TV test for women and men is a moderately complex test, requires a small platform and can be performed in <1 hour. The sensitivity compared with wet preparation/culture for self-collected vaginal swabs was 96.4%, 98.9% for endocervical specimens and 98.4% for female urine. For men, sensitivity for urines was excellent (97.2%). The specificity for all assays was excellent.

Conclusions Several rapid POC tests have the potential to rapidly diagnose trichomoniasis in women and one is available for detection of TV in men.

INTRODUCTION

Trichomonas vaginalis (TV) is a common motile protozoan parasite, which is the most prevalent non-viral sexually transmitted infection (STI) in the world and was estimated by the WHO to cause 276.4 million new infections per year in persons between the ages of 15 and 49 years in 2008.[1] It infects approximately 3.7 million people in the USA.[2] These infections represent the most common curable STI in young, sexually active men and women.[1]

In women, trichomoniasis has been associated with poor reproductive health outcomes such as low birth weight (LBW) and premature birth.[3–5] In a cohort of over 13 000 women, there was an attributable risk of trichomonas associated with LBW in blacks of 11% versus 1.6% in Hispanics and 1.5% in Whites.[3] Data from the National Health and Nutrition Examination Survey (NHANES) 2001–2004 estimated that 3.1% of women in the USA are infected with TV[6] and of importance over 80% of cases were asymptomatic.[7] Data from the NHANES also demonstrated that TV was highly associated with coinfections with other STIs.[7] TV infection is also associated with twofold to threefold increased risk of HIV acquisition and pelvic inflammatory disease (PID) among HIV-infected women.[8–11] Older age is also linked to the epidemiology of trichomonas, and TV may affect over 11% of women age ≥40 years and 13% of black women in the USA.[12 13] Cases of TV are not reportable to the Centrrs for Disease Control and Prevention in the USA, so exact surveillance prevalence data are lacking in the USA and worldwide data are probably underestimated.

Because infection with TV is so common and can be associated with such serious adverse events, diagnostic testing for detection of TV and treatment of trichomonal infections are recommended for symptomatic women and men. For asymptomatic individuals, screening is only recommended for HIV-positive women and is only encouraged for persons in such locations as sexually transmitted disease clinics and correctional facilities.[14]

The conventional methods to detect TV in vaginal swabs are wet mount microscopy and culture techniques. Wet mount microscopy is the most common method for detection of TV, and although this technique is rapid and inexpensive, it is only about 36%–75% sensitive compared with culture even in the hands of trained microscopists.[15] This sensitivity of culture method is less in studies than what can be achieved by nucleic acid amplification tests (NAATs).[16] Thus, the use of more highly sensitive molecular tests is recommended for detection of TV in women and men,since they have higher sensitivity than culture. Among women, NAATs may detect a prevalence of threefold to fivefold higher than wet preparation microscopy.[4] Presently, there are two large robotic FDA-cleared NAAT platforms, which are not point-of-care (POC) tests, for the detection of trichomonas in women. They include the Aptima TV assay (Hologic Gen-Probe, San Diego, California, USA),[12] the BD ProbeTec Q^{x} Assay on the

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BD Viper System (Becton Dickinson, Sparks, Maryland, USA).[17] A third NAAT is the POC assay, GeneXpert Assay[18] (Cepheid, Sunnyvale, California, USA), which is also FDA cleared for detection of trichomonas in men. The authors of this review will discuss the literature for older and recent, rapid and POC tests for detection of trichomonas.

METHODS

A PubMed (US National Library of Medicine and the National Institutes of Health) search was conducted for literature published between 2000 and 2016 using the search terms TV and diagnosis, trichomonas and POC tests and trichomonas rapid diagnosis.

Another excellent independent search in PubMed, MEDLINE, Embase, Global Health, BIOSIS and Web of Science has been conducted previously for literature published in January 2004–December 2013.[19]

Descriptive analyses were performed using STATA V.12. For each study, we calculated sensitivity and specificity along with 95% CIs, compared with the reference standard. A third PubMed search and review was conducted by de Cortina *et al* for literature published between January 2010 and August 2015.[20]

The manufacturers of the newer TV diagnostic rapid tests discussed include: the OSOM lateral flow test (Bedford, Massachusetts, USA), the AmpliVue test, the Isothermal Helicase-Dependent AmpliVue Assay (Quidel, San Diego, California, USA), the Solana TV-Assay (Quidel) and the GeneXpert TV test (Cepheid). Culture was performed in studies by InPouch TV (BioMed Diagnostics, White City, Oregon, USA).

POC laboratory diagnostic tests for detection of TV

In addition to the wet saline preparation for microscopy for motile trichomonads, there are older tests that have been evaluated.[21] These are the Affirm VPIII Microbial Identification Test (Becton Dickinson) and the Kalon TV latex test (Kalon Biological, Surrey, UK). The Kalon test uses latex beads coated with antibodies specific to TV proteins but is not FDA cleared or CE (Conformité Européenne) marked in Europe.[22] The Xenostrip-Tv (Xenotope Diagnostics, San Antonio, Texas, USA) was a rapid immunochromagraphic antigen detection test. It detected heat-stable trichomonas alpha-actinin protein in vaginal swabs. The patent, filed by University of Texas in 2006, included a saliva-based assay that was never commercialised. The vaginal swab studies had reported sensitivities of 78.5% and 90% in two published studies, but it is no longer available.[23] The Xenostrip-tv product was later acquired by Genzyme, a Sanofi company based in Cambridge, Massachusetts, USA, and sold under the brand name, OSOM. In 2011, Genzyme sold its diagnostic products business to Sekisui Chemical, UK, which continues to sell the test as the OSOM Trichomonas rapid test.

Affirm VPIII

The first molecular assay to offer detection of trichomonas was the Affirm VPIII test (Becton Dickinson), which is a nucleic acid hybridisations test that also detects *Gardnerella vaginalis* and *Candida albicans*.[24] It uses synthetic nucleic acid capture probes and colour development detection probes complementary to unique genetic sequences of the target organisms. This assay is considered a moderately complex test with at least 10 steps and requires 45 min to achieve results. However, when this assay was compared with a NAAT assay for the detection of trichomonas, the sensitivity was only 46%.[25]

OSOM Trichomonas test

This trichomonas rapid antigen test is an immunochromatographic capillary-flow enzyme immunoassay based on trichomonas membrane proteins, which can detect trichomonas in 10 min.

Compared with wet preparation and culture, OSOM Trichomonas test has a much improved sensitivity, excellent specificity and compares favourability to NAAT assays with reported sensitivities of 83%–90%.[15 16 26] This assay is Clinical Laboratory Improvement Amendments (CLIA) waived and requires five steps to complete. An early study compared the sensitivity and specificity of the OSOM test, wet mount and culture performed on vaginal swabs from 449 sexually active women.[26] The overall prevalence of TV was 23.4% by the reference standards of either wet mount or culture test being positive. For the vaginal swabs, the OSOM test displayed 83.3% and 98.8% sensitivity and specificity, respectively, and it performed better than wet preparation. In another comparison with wet preparation, culture and a NAAT assay, the OSOM assay performed very well with a sensitivity and specificity of 90% and 100%, respectively, in 330 sexually active females aged 14–21 years.[16] The prevalence of trichomoniasis in this population was 18.5%; the sensitivity of wet preparation ranged from 50% to 54% and for culture was 75%. In symptomatic women, the sensitivity of the OSOM test was 92.5% and for the NAAT, 97.5%. Similar low sensitivities for culture and wet preparation methods have been reported in other publications.[15 27] Huppert *et al* has reported high acceptability and accurate results when allowing adolescents to perform their own OSOM assay.[28 29]

Additionally, women have been enrolled in a research study to perform the OSOM assay themselves at home after ordering a home TV test kit via the internet; they obtained accurate results compared with a mailed-in NAAT assay and found the home test to be highly acceptable.[30] Use of this assay as a standard of care POC test for the detection of trichomoniasis in an emergency department was also shown to prevent overtreatment of vaginal infections compared with historical controls before the introduction of the POC test, resulting in good antibiotic stewardship.[31]

AmpliVue assay

This new technology utilises isothermal helicase-dependent amplification (HDA) and has a turnaround time of approximately 45 min.[32] The test targets a conserved repeat DNA sequence of TV. The assay employs a helicase to separate DNA before amplification. It consists of three steps: (1) sample lysis preparation with dilution/heating in a heat block for 10 min at 95°C; (2) isothermal DNA amplification of TV DNA for 25 min at 64°C by HDA in a heat block; and (3) lateral-flow strip-based colorimetric detection in a disposable device.

The AmpliVue Trichomonas assay was recently FDA cleared as a moderately complex test for vaginal swabs from symptomatic and asymptomatic women, and its potential to be CLIA waived may increase its usefulness as a POC test that could be used for the rapid diagnosis and immediate treatment of trichomoniasis while patients are still in the clinic.

The results from 992 women were compared with the results from wet preparation microscopy and/or culture, which comprised a composite positive comparator standard and demonstrated high sensitivity of 100% and specificity of 97.9%–98.3% (table 1). The prevalence of TV by symptom status was asymptomatic: 9.4%, symptomatic: 17.3% and for all women: 12.1%. The AmpliVue Trichomonas was also compared with the Aptima TV NAAT assay as a reference standard. Sensitivity for AmpliVue compared with Aptima was 90.7% overall

Table 1 Comparison of AmpliVue results in symptomatic and asymptomatic women to composite reference method of wet preparation and culture

Symptom status	N	Prevalence%	Sensitivity % (95% CI)	Specificity % (95% CI)	PPV (95% CI)	NPV % (95% CI)
Asymptomatic women	648	9.4	100 (94.1 to 100)	98.3 (96.9 to 99.1)	85.9 (76.0 to 92.2)	100 (99.3 to 100)
Symptomatic women	342	17.3	100 (93.9 to 100)	97.9 (95.5 to 99.0)	90.8 (81.3 to 95.7)	100 (98.6 to 100)
All women	990	12.1	100 (96.9 to 100)	98.2 (97.0 to 98.9)	88.2 (81.7 to 92.6)	100 (99.6 to 100)

NPV, negative predictive value; PPV, positive predictive value

(90.1% for symptomatic and 87.2% for asymptomatic women). The overall per cent agreement versus Aptima TV was 97.8% (Cohen's kappa=90.7), 97.1% for symptomatic women and 97.7% for asymptomatic women.[32]

Solana Trichomonas assay

The Solana Trichomonas assay is an in vitro qualitative NAAT for the detection of TV for the diagnosis of trichomoniasis using the HDA technology and the Solana instrument.[33] In order to detect TV directly from vaginal swab specimens, the assay targets a conserved repeat DNA sequence of the trichomonas genome. The assay consists of two steps: (1) specimen preparation and (2) amplification and detection of target sequence specific to the trichomonas genome by HDA in the presence of a target-specific fluorescence probe. The assay is intended for use in clinical laboratories but has the potential to be useful in a doctor's office or clinic that has a laboratory. It was recently FDA cleared as a moderately complex POC assay for the diagnosis of trichomoniasis.

Results from the FDA clinical trial are summarised.[33] Vaginal swabs and urines were obtained by clinicians from 1044 women of whom 501 were asymptomatic and 543 were symptomatic. The prevalence of TV by swabs and/or urines was 11.5%. For these clinician-collected swabs, the Solana Trichomonas assay showed high sensitivity and specificity for swabs from both asymptomatic (100%/98.7%) and symptomatic (98.6%/98.5%) women compared with a FDA-composite reference standard of wet preparation and/or culture for detection of TV. Urines were similarly sensitive and specific from asymptomatic (98.0%/98.4%) and symptomatic (92.9%/97.9%) women when compared with the FDA-composite reference methods (table 2).[33] Compared with a NAAT assay (Aptima-TV), the sensitivity/specificity performance was 89.7%/99.0% for swabs and 100%/98.9% for urines.

GeneXpert TV assay (Cepheid)

A multicentre study of this 'near-patient' assay prospectively collected urine, endocervical swabs and patient-collected vaginal swabs from female subjects presenting with symptoms associated with TV infection and subjects who were asymptomatic.[18] Urine, endocervical swabs and patient-collected vaginal swabs were tested with the GeneXpert TV assay, the Gen-Probe APTIMA TV assay and cultured with InPouch (BioMed). The performance was determined relative to a patient-infected status (PIS) algorithm, based on results from the reference standard comparator tests of either culture and/or the NAAT assay being positive. Sequencing was performed on specimens with discordant results, as allowed by the FDA.

From 1867 eligible study participants, 714 were symptomatic and 1153 were asymptomatic. The GeneXpert TV assay demonstrated a sensitivity and specificity for TV on patient-collected vaginal swabs (n=1791) of 96.4% and 99.6%, respectively (table 3). Prevalence was 10.8%. For endocervical swabs, the GeneXpert TV assay revealed a sensitivity and specificity for TV (n=1799) of 98.9% and 98.9%, respectively; prevalence was 9.8%. The GeneXpert TV assay showed a sensitivity and specificity for TV on female urine specimens (n=1793) of 98.4% and 99.7%, respectively; prevalence was 10.2%. There were no statistically significant differences in performance with respect to symptomatic status.[18] This assay was recently FDA cleared for use with male urine.

DISCUSSION

These POC and near-patient studies discussed herein provide evidence of new diagnostic options for detection of trichomoniasis in symptomatic and asymptomatic women, with one also being FDA cleared for detection of TV in urine from men. They indicate that the performance of new amplified testing methods is highly accurate and able to provide rapid turnaround times.

The OSOM assay is the only POC assay that is CLIA waived, meaning it does not need to be performed in a laboratory, and is the only one that does not require special instrumentation. Its high sensitivity (83%–90%) and excellent specificity make it an ideal assay for resource limited settings.[27] The OSOM test has

Table 2 Sensitivity and specificity of the Solana assay for *Trichomonas vaginalis* compared with the composite reference methods of saline wet mount and culture

Vaginal swabs	N	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	
Asymptomatic women	501	100 92.7% to 100%	98.7 97.1% to 99.4%	
Symptomatic women	543	98.6 92.3% to 99.7%	98.5 97.6% to 99.2%	97.0% to 99.3%
Total	1044	99.2 95.4% to 99.9%	98.6 97.6% to 99.2%	
Urine				
Asymptomatic women	501	98.0 89.5% to 99.6%	98.4 96.8% to 99.2%	
Symptomatic women	543	92.9 84.3% to 96.9%	97.9 96.2% to 98.8%	
Total	1044	95.0 89.5% to 97.7%	98.2 97.1% to 98.8%	

Table 3 Comparison of GeneXpert TV assay results in symptomatic and asymptomatic women compared with a patient-infected status of culture and/or a NAAT assay

Sample type	Status	Total (n)	Sens	Spec	Prev (%)	PPV (%)	NPV (%)
ES	Symp	685	100% (71/71)	98.5% (605/614)	10.4	88.8	100
	Asymp	1114	98.1% (104/106)	99.1% (999/1008)	9.5	92.0	99.8
	Overall	1799	98.9% (175/177)*	98.9% (1604/1622)†	9.8	90.7	99.9
	Difference	p Value	p=0.517	p=0.331			
PC-VS	Symp	682	98.6% (73/74)	99.5% (605/608)	10.9	96.1	99.8
	Asymp	1109	95.0% (113/119)	99.6% (986/990)	10.7	96.6	99.4
	Overall	1791	96.4% (186/193)‡	99.6% (1591/1598)§	10.8	96.4	99.6
	Difference	p Value	p=0.254	p=1.000			
UR	Symp	688	98.6% (71/72)	99.8% (615/616)	10.5	98.6	99.8
	Asymp	1105	98.2% (109/111)	99.6% (990/994)	10.0	96.5	99.8
	Overall	1793	98.4% (180/183)¶	99.7% (1605/1610)**	10.2	97.3	99.8
	Difference	p Value	p=1.000	p=0.655			

*Testing results by sequencing: 1 of 2 FN was TV positive; 1 of 2 was TV negative.
†Testing results by sequencing: 8 of 18 FP were TV positive; 10 of 18 were TV negative.
‡Testing results by sequencing: 3 of 7 FN were TV positive; 4 of 7 were TV negative.
§Testing results by sequencing: 5 of 7 FP were TV positive; 2 of 7 were TV negative.
¶Testing results by sequencing: 3 of 3 FN were TV negative.
**Testing results by sequencing: 5 of 5 FP were TV negative.
ES, endocervical swab; NAAT, nucleic acid amplification test; PC-VS, patient-collected vaginal swab; UR, urine.

been successfully used in adolescent clinics, emergency departments and self-testing programmes.[28–31]

The AmpliVue rapid assay demonstrated that an amplified molecular NAAT assay can perform as well as saline microscopy/culture and provided comparable results with another FDA cleared NAAT assay while yielding results in real time of 45 min.[32] The AmpliVue Trichomonas assay is FDA cleared as moderately complex; it identified all of the culture and saline microscopy positive cases of trichomonas infections and substantially more than culture or saline microscopy, as shown by detecting additional confirmed positives and the strong agreement with Aptima TV NAAT assay.

The Solana TV assay provided evidence that this NAAT molecular assay can perform as well as saline microscopy/culture and provided comparable results as another FDA-cleared NAAT assay for detection of trichomoniasis in symptomatic and asymptomatic women while providing results in approximately 45 min.[33] This assay has the potential to be CLIA waived in the future, which may increase its usefulness as a POC test that can be used for immediate treatment of infected patients.

The GeneXpert TV assay demonstrated a very high sensitivity and specificity compared with a PIS of culture and/or NAAT assay. The sample preparation, amplification and real-time detection are all fully-automated and completely integrated in the test cartridge. The assay offers a rapid result in less than 40 min at the time the test turns positive but requires 60 min if the test result is negative. These results can be potentially used to treat infected patients in a clinic or emergency department.[18] Because the assay is fully automated, it has the potential to achieve CLIA waiver in the future providing highly sensitive and specific results in women.[33] It is the only rapid assay for detection of TV approved for use in men.

Because of the association of trichomonas infections with many adverse health events, especially adverse birth outcomes and perinatal morbidity,[3 34] as well as its strong association with HIV transmission,[35 36] it may be time to advocate for more testing and treatment of persons with trichomoniasis.[37] Since we now have more highly accurate new POC testing methods available, it seems reasonable to promote more public health national and international recognition for trichomonas infections and support more testing. Redesign of clinic flow for patients that can take advantage of self-collected vaginal swabs may be able to take advantage of the newer POC assays to facilitate treatment, so patients do not have to have return appointments to receive test results.[37] Additionally, since most trichomonas infections in men and women are asymptomatic, syndromic management programmes for symptomatic patients will not be able to detect and treat those asymptomatic-infected patients who do not have symptoms to qualify them for syndromic management. Furthermore, modelling and review studies of the potential of treatment for trichomonas to impact and to improve health outcomes, especially for HIV, are powerfully intriguing.[11 38 39] In summary, the newer POC tests for the detection of TV in clinical samples appear to far outperform the sensitivity of wet preparation and culture assays and can be recommended for the detection of TV in clinical settings.

Key messages

- *Trichomonas vaginalis* infection is the most prevalent curable sexually transmitted infection but diagnostic methods are suboptimal.
- We know that an antigen detection rapid test and a few molecular assays are available, but there has not been a systematic review of their performance and operating characteristics.
- This review demonstrates that the OSOM antigen detection test has reasonable sensitivity and high specificity compared with a variety of reference tests, including wet mount, culture and PCR.
- Molecular assays like AmpliVue, Solana and the GeneXpert show excellent performance against laboratory-based PCR assays but are more expensive than antigen detection rapid tests.

LICENCE

Contributors CAG wrote the review, and all authors contributed. CAG, HK and CC did the search and data extraction; NPP, CAG and RWP did the data analysis; RWP and JDK designed the systematic reviews.

Competing interests None declared.

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