Rapid Antigen Testing for Trichomoniasis in an Emergency Department

Nikki R. Postenrieder, BS, Jennifer L. Reed, MD, Elizabeth Hesse, BS, Jessica A. Kahn, MD, Lili Ding, PhD, Charlotte A. Gaydos, MS, MPH, DrPH, Anne Rompalo, MD, ScM, Lea E. Widdice, MD

BACKGROUND AND OBJECTIVES: Trichomoniasis is a prevalent cause of vaginitis among adolescents that increases the risk of acquiring other sexually transmitted diseases and of negative pregnancy outcomes. Treatment of trichomoniasis is therefore essential for improving sexual and reproductive health outcomes. A timely, sensitive diagnostic test for *T vaginalis* may increase the accuracy of clinician’s treatment decisions, resulting in more infected women receiving treatment and fewer uninfected women receiving treatment.

METHODS: This study was a retrospective observational assessment of electronic medical records before and after point-of-care (POC) implementation of the rapid antigen test. Records were collected from women aged 14 to 20 years who received a *T vaginalis* test in the emergency department during either study period. The main outcome measures were rates of accurate treatment, inaccurate treatment, and missed treatment of trichomoniasis in each study period.

RESULTS: Overall rates of accurate treatment increased from 78.7% pre-POC to 87.7% post-POC (*P* = .02). Specifically, rates of not treating uninfected women increased from 61.4% pre-POC to 70.4% post-POC (*P* = .06), and rates of treating infected women were the same pre-POC (17.3%) and post-POC (17.3%; *P* = .99). Rates of inaccurate treatment decreased from 23.1% pre-POC to 13.1% post-POC (*P* = .02). Changes in missed treatment rates (14.0% pre-POC; 8.8% post-POC; *P* = .73) were not statistically significant.

CONCLUSIONS: POC testing can improve clinical care by decreasing the use of antibiotics in uninfected women. The results of this study support the use of a *T vaginalis* rapid antigen POC test for adolescents presenting to the emergency department.

WHAT'S KNOWN ON THIS SUBJECT: *Trichomonas vaginalis* is a common cause of vaginitis among adolescents associated with several negative health outcomes. Studies have shown that *T vaginalis* rapid antigen testing outperforms *T vaginalis* culture and wet preparation of a vaginal swab as a diagnostic tool.

WHAT THIS STUDY ADDS: The impact of the *T vaginalis* rapid antigen test on clinical care has not been determined. This study showed that after implementation of rapid testing, improvement in clinical care occurred through a decrease in antibiotic treatment of uninfected women.
Vaginal trichomoniasis is a sexually transmitted disease (STD) caused by the protozoan *Trichomonas vaginalis*. Treating women with antibiotics is important to cure infection, reduce risks associated with infection, and lessen the possibility of developing antibiotic-resistant *T vaginalis*.1–8 Treating women for trichomoniasis when they are not infected (inaccurate treatment) exposes them to potential side effects of medication and the emotional distress associated with an STD diagnosis while also generating unnecessary costs.5,6 Failure to treat women for trichomoniasis when they are infected (missed treatment) places them at higher risk for asymptomatic trichomoniasis, pregnancy complications, and acquisition of HIV.1,2,7 Inaccurate treatment and missed treatment of STDs are especially concerning in a population in whom follow-up for treatment is difficult, such as in adolescent patients presenting to an emergency department (ED).

Studies have demonstrated that *T vaginalis* rapid antigen testing outperforms *T vaginalis* culture and wet preparation of a vaginal swab (ie, wet mount) as a diagnostic tool.10–13 However, little is known about the impact of *T vaginalis* rapid antigen testing on clinical care, specifically in the ED setting. To determine the effects of *T vaginalis* rapid antigen testing on clinical care, we examined treatment outcomes both before and after implementation of the *T vaginalis* rapid antigen test in our institution’s ED. Comparisons before and after point-of-care (POC) implementation were possible because the institution’s clinical laboratory replaced the use of *T vaginalis* culture in clinical care with *T vaginalis* rapid antigen testing in February 2010. The primary aim of this study was to examine treatment outcomes, including accurate treatment, inaccurate treatment, and missed treatment, among all women tested for *T vaginalis* in the ED before and after implementation of the *T vaginalis* rapid antigen test. We hypothesized that the rate of accurate treatment would be higher and rates of inaccurate treatment and missed treatment would be lower after implementation of *T vaginalis* rapid antigen testing.

**METHODS**

The study design was a retrospective observational review of electronic medical records (EMRs) approved by the hospital’s institutional review board.

**Study Setting**

The study was conducted in the ED of an urban pediatric academic center managing ~90,000 visits per year. Testing for STDs is the standard of care for any woman presenting with lower abdominal pain or genital complaints who is sexually active. Testing was ordered in the ED by using an order set within the EMR that included a wet mount with either *T vaginalis* culture (pre-POC) or *T vaginalis* rapid antigen testing (post-POC). In our institution, 3 diagnostic tests for *T vaginalis* have been used in the clinical laboratory: the wet mount, the Inpouch TV Culture System (BioMed Diagnostics, Inc, San Diego, CA), and a *T vaginalis* rapid antigen test (OSOM Trichomonas Rapid Test; Sekisui Diagnostics, LLC, Lexington, MA). Wet mount was used during both time periods because it also served as a diagnostic test for other causes of vaginitis and vaginosis. Specificity of *T vaginalis* cultures approaches 100%, and sensitivity ranges between 75% and 95%.10,14 However, culture results are not available for 1 to 5 days. Wet mount is a POC test, with sensitivity ranging from 51% to 65% and specificity up to 100%.11,12,14 The *T vaginalis* rapid antigen POC test also tests vaginal swabs and has the highest sensitivity (82%–95%) of the 3 diagnostic tests as well as high specificity (97% to 100%).13,14 Samples for testing were collected in the ED, and all samples were delivered to the hospital’s central laboratory for processing and results.

**Participants**

Patient records were eligible for review if the ED encounter occurred between November 11, 2009, and February 3, 2010 (pre-POC) or between November 11, 2012, and February 3, 2013 (post-POC). Records from each time period were reviewed if the patient was female, aged 14 to 20 years, and had ≥1 order placed for either *T vaginalis* culture and/or wet mount (pre-POC) or *T vaginalis* rapid antigen test and/or wet mount (post-POC). Records from encounters that included a diagnosis of sexual abuse or suspected sexual abuse were excluded from analyses.

**Data Collection**

The start date of the pre-POC time period was chosen to coincide with the introduction of an EMR system and order set for STD testing, which occurred in November 2009; the end date coincides with the discontinuation of culture testing and the introduction of *T vaginalis* rapid antigen testing. The post-POC time period began after quality improvement research related to implementation of POC testing concluded. The months of the post-POC time period are the same as the pre-POC time period.

Data extracted from the EMRs included age, date of visit, length of ED stay, self-reported race, insurance status, *T vaginalis* tests ordered and date of testing, *T vaginalis* test results and date of results, orders for and documentation of dispensing metronidazole and/or tinidazole, and prescriptions for metronidazole and/or tinidazole.
Main Outcome Measures and Predictor Variables

The primary outcome measures were the rate of accurate, inaccurate, and missed treatment of *T. vaginalis* among women in each study period within 30 days of testing. Women were considered to have received accurate treatment in 2 situations: (1) treatment given for a positive *T. vaginalis* test result or (2) no treatment given for a negative *T. vaginalis* test result. Women were considered to have received inaccurate treatment when treatment was given for negative *T. vaginalis* test results. Women were considered to have missed treatment when no treatment was given for a positive *T. vaginalis* test result. A woman was considered positive for *T. vaginalis* if results of ≥1 of the ordered tests were positive, and she was considered negative for *T. vaginalis* if all of the ordered test results were negative. Treatment was considered to have occurred if metronidazole or tinidazole was either given to the patient in the ED or prescribed within 30 days of the *T. vaginalis* test result. Predictor variables included age, date of visit, length of ED stay, self-reported race, and insurance status.

Analysis

Data were analyzed by using SAS version 9.3 (SAS Institute, Inc, Cary, NC). Descriptive statistics generated frequencies and percentages for categorical variables as well as means and SDs for continuous variables. Differences between predictor variables in the pre-POC and post-POC time periods were determined by using χ² tests for categorical variables and Wilcoxon rank-sum tests for continuous variables. The χ² tests and 2-sided Fisher’s exact tests were used to test for significant differences in accuracy of treatment between the pre-POC and post-POC time periods. Unadjusted logistic regression model analyses were used to evaluate the associations of the predictors of age, race, and insurance status with accuracy of treatment in the pre-POC and post-POC time periods. A post hoc analysis was conducted to further describe the number of infected women who were treated during the ED encounter. Differences in the proportions of infected women treated during their ED encounter in the pre-POC and post-POC periods were tested for significance by using a 2-sided Fisher’s exact test.

RESULTS

Records from 249 encounters in the pre-POC time period and 179 encounters in the post-POC time period were used in the analyses. Characteristics of the women and description of the clinical encounter in each time period are shown in Table 1; there were no statistically significant differences in age, race, insurance status, or length of ED visit. Prevalence of *T. vaginalis* was 20.1% (*n* = 50) in the pre-POC time period and 19.0% (*n* = 34) in the post-POC time period (*P* = .78). Of the 249 encounters in the pre-POC time period, 95.2% (*n* = 237) had results from both *T. vaginalis* culture and wet mount, 2.4% (*n* = 6) from *T. vaginalis* culture alone, and 2.4% (*n* = 6) from wet mount alone. Of the 179 encounters in the post-POC time period, 86.0% (*n* = 154) had results from both the *T. vaginalis* rapid antigen test and wet mount, 14.0% (*n* = 25) from the *T. vaginalis* rapid antigen test alone, and none from the wet mount alone.

Table 2 shows the rates of accurate, inaccurate, and missed treatment in the pre-POC and post-POC time periods. Rates of accurate treatment were higher post-POC (87.7%) compared with pre-POC (78.7%; *P* = .02). Among those who received accurate treatment, rates of not treating uninfected women were higher post-POC (70.4%) compared with pre-POC (61.4%; *P* = 0.06), and rates of treating infected women were the same post-POC (17.3%) and pre-POC (17.3%; *P* = 0.99). Rates of inaccurate treatment were lower post-POC (13.1%) compared with pre-POC (23.1%, *P* = .02). Rates of missed treatment were not significantly different between pre-POC (14.0%) and post-POC (8.8%; *P* = .73). In unadjusted logistic regression model analyses, the variables of age, race, and insurance status were not significantly associated with accurate treatment in the pre-POC or post-POC time period.

During the pre-POC period, 30 of the 43 infected women who received treatment (69.8%) were treated during the ED encounter, and the remaining 13 infected women were treated after they had left the ED. During the post-POC period, 30 of the 31 infected women who received treatment (96.8%) were treated...
Data are presented as n (%) unless otherwise indicated.

<table>
<thead>
<tr>
<th>Treatment Group</th>
<th>Pre-POC</th>
<th>Post-POC</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total no. of women tested</td>
<td>249</td>
<td>179</td>
<td></td>
</tr>
<tr>
<td>Accurate treatment: infected and treated or uninfected and not treated</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Total                    | 196     | 157      | 0.02
| Uninfected and not treated | 153     | 126      | 0.06
| Infected and treated     | 43      | 31       | 0.99
| Inaccurate treatment: uninfected and treated |         |          |     |
| Total uninfected, n      | 199     | 145      |     |
| Total uninfected and treated | 46      | 19       | 0.02
| Missed treatment: infected and not treated |         |          |     |
| Total infected, n        | 50      | 34       |     |
| Total infected and not treated | 7      | 3        | 0.73

a Evaluated by using $\chi^2$ tests.

b Evaluated by using Fisher’s exact tests.

To understand whether patients with inaccurate treatment may have received treatment of a diagnosis other than trichomoniasis, we first evaluated records of patients with inaccurate treatment to determine whether metronidazole or tinidazole may have been used to treat other infections. Because it was not possible to ascertain the clinical reasoning for metronidazole in each case, we conducted a second analysis in which patients with inaccurate treatment who received a treatment other than 2 g of metronidazole were considered not treated because a single 2-g dose is the standard trichomoniasis treatment in the ED. None of the encounters documented tinidazole as treatment. After removing these patients from the inaccurate treatment group, the results were similar: rates of accurate treatment were higher post-POC (94.4%) compared with pre-POC (83.1%; $P < .001$), and rates of inaccurate treatment were lower post-POC (4.83%) compared with pre-POC (17.6%; $P < .001$).

Because no single test or criterion standard was used during testing, and sensitivity of the wet mount, $T$ vaginalis culture, and $T$ vaginalis rapid antigen tests are known to differ, we performed a post hoc analysis to determine the impact of using multiple tests with differing sensitivities in the study population. The post hoc sensitivity of the $T$ vaginalis culture and $T$ vaginalis rapid antigen test were calculated to be 100%. Wet mount sensitivity was calculated to be 64.1% (95% confidence interval, 53.5–74.8). All women were diagnosed by using a wet mount as well as either $T$ vaginalis culture or $T$ vaginalis rapid antigen test except for 6 women who were tested with only the wet mount approach. Using the calculated test sensitivities from this population to determine the number of projected false-negative test results among women tested only with a wet mount, we projected that 2.2 (95% confidence interval, 1.5–2.8) of these 6 tests would produce false-negative results. To determine the impact of 2 false-negative test results on accurate, inaccurate, and missed treatment, 2 scenarios were considered: If 2 patients in the accurate treatment group had false-negative results, they would be assigned to the missed treatment group in the first scenario. If 2 patients in the inaccurate treatment group had false-negative results, these patients would be assigned to the accurate treatment group in the second scenario. When these 2 scenarios were considered, the direction of comparisons of the treatment rates did not change.

**DISCUSSION**

This study evaluated the outcome rates of women tested for $T$ vaginalis both before and after a reliable, valid POC test, the $T$ vaginalis rapid antigen test, replaced $T$ vaginalis culture in a pediatric ED. Use of a reliable, valid POC test improved treatment outcomes. Rates of accurate treatment (ie, no treatment given to women with a negative $T$ vaginalis test result) were higher and rates of inaccurate treatment (ie, treatment given to women with a negative $T$ vaginalis test result) were lower after $T$ vaginalis rapid antigen testing was implemented. This outcome notably resulted in a decrease in the overuse of antibiotics. To our knowledge, this report is the first to examine the clinical impact of POC $T$ vaginalis testing on trichomoniasis treatment outcomes.

Our findings of improved treatment outcomes associated with POC testing for $T$ vaginalis are supported by studies of testing and treatment of other STDs. When test results for gonorrhea and Chlamydia are not available at the time of the visit, high rates of inaccurate treatment have been reported in an ED setting. After the implementation of $T$ vaginalis rapid antigen testing, we observed a decrease in the treatment of uninfected women. This outcome is consistent with previous findings demonstrating that empirical treatment of $T$ vaginalis and other STDs can result in significant rates of inaccurate treatment, especially in asymptomatic women, because clinicians must rely on their clinical suspicion as to whether to empirically treat the patient. We believe that the decrease in the treatment of uninfected women was largely due to clinicians having
access to a POC test with higher sensitivity and specificity than wet mount. Although culture testing has a high sensitivity, the delayed turnaround time of the culture test results precludes the culture result informing the treatment decision made by clinicians when the patient is being evaluated in the ED.

Avoiding the use of antibiotics in women without infection promotes the individual and public health benefits of antibiotic stewardship. Increasing appropriate use of antibiotics shields patients from exposure to possible side effects of antibiotics and lowers medical costs. It can also help prevent \textit{T. vaginalis} antibiotic resistance. \cite{5, 6} Low-level in vitro \textit{T. vaginalis} metronidazole resistance has already been reported in several sites around the country, and clinical treatment failure has been demonstrated in \textit{T. vaginalis} strains with even lower in vitro minimum lethal concentrations. \cite{17, 18}

The Centers for Disease Control and Prevention has estimated that 4\% of \textit{T. vaginalis} cases have some level of metronidazole resistance. \cite{17} Because the nitroimidazoles are the only approved treatment of \textit{T. vaginalis}, clinical resistance to metronidazole presents formidable challenges for clinicians and patients. The \textit{T. vaginalis} rapid antigen test improves accurate treatment rates, and implementation of this test therefore has the potential to increase antibiotic stewardship. Our study showed that after the implementation of the \textit{T. vaginalis} rapid antigen test, a higher proportion of infected women received treatment during their ED visit. This finding suggests that using a reliable, valid POC test for \textit{T. vaginalis} can affect clinical care in numerous ways. POC testing allows women to receive treatment more quickly and efficiently, and it provides medical staff and patients the opportunity for timely education and counseling regarding results. We have shown previously that women with positive STD results from a POC test accurately recalled their positive test result, and this knowledge was associated with abstinence, partner discussion, and partner treatment. \cite{19} In addition, the use of the POC test eliminates the need for laboratory resources to train personnel to prepare, incubate, and interpret \textit{T. vaginalis} cultures and lowers the need for staffing resources to contact women to notify them of positive results, provide education, and arrange for treatment.

The patient population served by the study pediatric ED is predominantly African American. \textit{T. vaginalis} rates are known to be higher in this population, which may limit generalizability. \cite{20} Individual provider practices may also affect results. However, there can be multiple trainees and handoffs for 1 patient, making assessment by provider impractical in this retrospective observational review. In addition, the introduction of EMR may have effects on the pre-POC results that cannot be measured. Future studies should consider conducting a cost analysis of the \textit{T. vaginalis} rapid antigen test to evaluate its cost-effectiveness in other clinical settings.

CONCLUSIONS

This study revealed significant improvement in decreasing the use of antibiotics in uninfected adolescent female subjects in an ED setting after implementation of \textit{T. vaginalis} rapid antigen testing. Because ED populations have historically low follow-up rates and carry high STD risk, methods to improve the accuracy of treatment, such as POC testing, are essential. In addition, decreasing the rate of inaccurate treatment leads to better antibiotic stewardship. Consequently, the success of \textit{T. vaginalis} rapid antigen testing supports its use in the ED setting for adolescent patients along with the further development of POC tests for treatment of other STDs.

ABBREVIATIONS

ED: emergency department
EMR: electronic medical record
POC: point-of-care
STD: sexually transmitted disease

REFERENCES


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