Suboptimal *Trichomonas vaginalis* Antigen Test Performance in a Low-prevalence Sexually-transmitted Infection Community

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Trichomonas vaginalis is the most common non-viral etiology of sexually transmitted infection (STI) worldwide [1]. The OSOM Trichomonas Rapid Test (OSOM; Sekisui Diagnostics, San Diego, CA) is a rapid surrogate to microscopic analysis in symptomatic patients [2], but its performance in low-prevalence STI populations has been assessed on a limited basis in the literature [3]. OSOM has widespread usage, as College of American Pathologists accreditation data report that over 300 participant laboratories utilize this assay on an annual basis [4]. We sought to characterize analytical and clinical performance of OSOM in a low-prevalence STI population on the basis of a commercial transcription-mediated amplification (TMA) reference.

Results from 1421 consecutive performances of OSOM using vaginal saline suspensions were audited from a four-month interval in a low-prevalence southeast Wisconsin STI population [5]. The concomitant APTIMA specimen transport tube from the healthcare encounter (98.7% endocervical, 1.3% vaginal), previously subjected to Chlamydia trachomatis and Neisseria gonorrhoeae TMA (APTIMA Combo 2 Assay; Hologic, San Diego, CA), was forwarded for retrospective T. vaginalis TMA (APTIMA Trichomonas vaginalis Assay; Hologic) performance on TIGRIS DTS per manufacturer specifications [6]. A previous assessment of T. vaginalis TMA reported 100% molecular concordance between data from vaginal saline suspension aliquots and endocervical specimens maintained in APTIMA specimen transport tubes [7]. In addition, Napierala et al. [8] have shown equivalent T. vaginalis TMA detection from endocervical swabs and vaginal swabs in our population. This study was governed by the Wheaton Franciscan Healthcare Institutional Review Board.
The low-prevalence STI population exhibited TMA detection rates of 6.4% and 0.6% for *C. trachomatis* and *N. gonorrhoeae*, respectively, while the *T. vaginalis* TMA detection rate was 4.0%. On the basis of a *T. vaginalis* TMA reference standard, sensitivity and specificity of OSOM were 35.1% and 99.9%, respectively (Table 1). The kappa value for this dataset was 0.502 (95% confidence interval, 0.346-0.658) and agreement was 0.973 (95% confidence interval, 0.963-0.981).

In analogous fashion, 98 consecutive tandem vaginal saline specimens and endocervical swabs from an increased-prevalence STI setting (*C. trachomatis* TMA detection rate 11.2%, *N. gonorrhoeae* TMA detection rate 6.1%; setting also characterized in [7,9]) were retrospectively analyzed via OSOM and *T. vaginalis* TMA, respectively, per manufacturer guidelines [2,6]. Improved concordance between OSOM and *T. vaginalis* TMA was observed within this study set, with a 21.4% *T. vaginalis* TMA detection rate (Table 2). An increased kappa value of 0.904 (95% confidence interval, 0.797-1.000) was calculated, with agreement of 0.969 (95% confidence interval, 0.907-0.992).

Campbell *et al.* [3] reported 94.7% sensitivity of OSOM compared to microscopy in a population with a 1.9% *T. vaginalis* detection rate. Molecular diagnostics did not factor into determination of the overall *T. vaginalis* incidence. From a high-prevalence population, Huppert and colleagues [10,11] reported 83-90% sensitivity of OSOM. One can hypothesize that the significant *T. vaginalis* TMA/*T. vaginalis* antigen discordant frequency in our low-prevalence population is related to organism burden [12] or to *T. vaginalis* TMA detection in asymptomatic patients. However, 56.8% of OSOM-negative/*T. vaginalis* TMA-positive data in the low-
prevalence population were derived from symptomatic patients (determined by chart review to have pelvic pain, abdominal pain, vaginal discharge, irritation, or itching). This symptomatic rate did not vary from that in patients yielding positive OSOM and *T. vaginalis* TMA results (*P* = 0.17; Table 3). Moreover, symptomatic status did not impact concordant and discordant OSOM/*T. vaginalis* TMA frequencies in the increased-prevalence population (*P* = 0.54).

It has been documented that up to 70% of infections with *T. vaginalis* are asymptomatic [13]. Detection of subclinical trichomoniasis is important, as studies have demonstrated persistent indolent infection via laboratory detection of the agent following previously-negative results in the face of sexual abstinence [14,15]. In further support of this paradigm, 27% of the 37 patients with OSOM-negative/retrospective *T. vaginalis* TMA-positive results in our low-prevalence population returned for clinical evaluation of an STI (data not illustrated). In conclusion, poor reliability of OSOM in a low-prevalence population combined with inability to detect the organism in a significant proportion of symptomatic patients may warrant consideration of *T. vaginalis* TMA for accurate laboratory diagnosis of this protozoan.
REFERENCES


TABLE 1: Performance of OSOM Trichomonas Rapid Test and APTIMA Trichomonas vaginalis Assay in a low-prevalence STI community.

<table>
<thead>
<tr>
<th></th>
<th>APTIMA Trichomonas vaginalis Assay</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>20</td>
<td>1(^a)</td>
<td>21</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>37</td>
<td>1363</td>
<td>1400</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>57</td>
<td>1364</td>
<td>1421</td>
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</table>

\(^a\) Repeat APTIMA Trichomonas vaginalis Assay testing yielded a negative result.
TABLE 2: Performance of OSOM Trichomonas Rapid Test and APTIMA Trichomonas vaginalis Assay in an increased-prevalence STI community.

<table>
<thead>
<tr>
<th>OSOM Trichomonas Rapid Test</th>
<th>APTIMA Trichomonas vaginalis Assay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
</tr>
<tr>
<td>Positive</td>
<td>18</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>21</td>
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</table>
TABLE 3: Symptomatic status of APTIMA Trichomonas vaginalis Assay-positive patients from low- and increased-prevalence STI communities, respectively, stratified by OSOM result.

<table>
<thead>
<tr>
<th>OSOM Trichomonas Rapid Test</th>
<th>Low-prevalence community</th>
<th>Increased-prevalence community</th>
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<tr>
<td>Positive</td>
<td>15 (75.0)</td>
<td>16 (88.9)</td>
</tr>
<tr>
<td>Negative</td>
<td>21 (56.8)&lt;sup&gt;a&lt;/sup&gt;</td>
<td>3 (100.0)&lt;sup&gt;b&lt;/sup&gt;</td>
</tr>
</tbody>
</table>

<sup>a</sup> $P = 0.17$ versus positive OSOM result; significance test of proportions

<sup>b</sup> $P = 0.54$ versus positive OSOM result; significance test of proportions