

The OSOM® Trichomonas Test is unable to accurately diagnose *Trichomonas vaginalis* from urine in men



Trichomonas vaginalis is the most common non-viral sexually transmitted infection (STI) in the world, but there is extremely limited data on the epidemiology and diagnosis of *T. vaginalis* in men in the emergency department (ED) [1,2]. The OSOM® Trichomonas Test (Sekisui Diagnostics, Framingham, MA) is a U.S. Food and Drug Administration (FDA)-approved rapid diagnostic test for *T. vaginalis* [3]. The assay uses an endovaginal swab and an immunochromatographic capillary flow dipstick test with primary anti-*Trichomonas* antibodies [3]. The OSOM® Trichomonas Test is CLIA-waived, the results are available in about 10 min, and it has a sensitivity of 83% and specificity of 99% [3]. The OSOM® Trichomonas Test has not been evaluated using urine.

The APTIMA *T. vaginalis* assay (Hologic Gen-Probe, San Diego, CA) is FDA-approved to diagnose *T. vaginalis* by transcription-mediated amplification [3]. The APTIMA *T. vaginalis* assay has a sensitivity of 93.7% (84.8–97.5%) and a specificity of 99.1% (98.0–99.6%) from the urine of women [4]. The analyte-specific reagents of the APTIMA *T. vaginalis* assay can be used on male urine as the sale, distribution, and use of analyte-specific reagents are covered under the Code of Federal Regulations, Title 21, Part 809.30, pertaining to human use of *in vitro* diagnostic products [4]. The sensitivity and specificity of the APTIMA *T. vaginalis* assay in male urine is undefined and poorly studied, but it is the diagnostic test used in our hospital for diagnosing *T. vaginalis* in men. The objective of our study was to compare the sensitivity of the OSOM® Trichomonas Test against with the APTIMA *T. vaginalis* assay from the urine of men.

This study was approved by University Hospitals institutional review board (IRB) (#03-16-25). We enrolled a convenience sample of 158 men between the ages of 18–40 years from October 2016–October 2017 at an urban academic emergency department in downtown Cleveland, OH. All subjects reported having at least one penile-vaginal act of sexual intercourse in the last month without using a condom and had a home address and a working phone number. We excluded subjects who were allergic to metronidazole (Flagyl) or tinidazole (Tindamax), had taken metronidazole or tinidazole in the last six months, drank more than two alcoholic drinks per day on average, were prisoners, had altered mentation, were being evaluated for a sexual assault, were currently known or suspected to be intoxicated, had acute mental health disease being treated in the emergency department, or were critically ill.

Study subjects provided a urine sample from which the OSOM® Trichomonas Test was performed according to manufacturer's instructions except that the sterile rayon swab for obtaining a vaginal swab was instead placed into the urine sample for several minutes. The urine swab was then placed into the plastic test tube provided with the OSOM® Trichomonas Test kit along with the sample buffer. The swab was mixed in the buffer 10 times and the excess fluid removed. An OSOM® Trichomonas Test stick was placed into the tube, and the test was read at 10 min. The urine sample was then sent to the institution's clinical laboratory where the urine was evaluated using

the APTIMA *T. vaginalis* assay. The results of the APTIMA *T. vaginalis* assay were available the day after the subject was enrolled. Subjects that received a positive APTIMA *T. vaginalis* assay were contacted by phone or certified letter for a prescription of metronidazole, sexually transmitted disease education, and a referral for sexual partner testing. Chi-square test for 2 × 2 table analysis was used to determine the sensitivity and specificity of the OSOM® Trichomonas Test compared to our gold-standard APTIMA *T. vaginalis* assay.

We enrolled a total of 158 subjects with six subjects unable to provide a urine sample after informed consent, one subject did not have their OSOM® Trichomonas Test result recorded, one subject had an indeterminate APTIMA *T. vaginalis* assay results, two subjects inadvertently did not have their APTIMA *T. vaginalis* assay performed in the clinical laboratory.

We found 8/151 (5.3%) subjects tested positive for *T. vaginalis* by the APTIMA *T. vaginalis* assay (3 were indeterminate/not performed), and 27/151 (17.9%) subjects tested positive by the OSOM® Trichomonas Test (of which 3 were also positive by the APTIMA *T. vaginalis* assay). There were 124 subjects that tested negative by the OSOM® Trichomonas Test of which 5 were positive by the APTIMA *T. vaginalis* assay. Table 1 shows the sensitivity of the OSOM® Trichomonas Test which was 37.5% (95% CI 8.5–75.5%); specificity 82.9% (95% CI 75.6–88.7%); positive predictive value 11.1% (4.5–24.7%); and negative predictive value 95.9% (93.1–97.6%) when compared to the APTIMA *T. vaginalis* assay. Using a 2 × 2 contingency table and Fisher's exact test, the difference between the two *T. vaginalis* tests was significant ($p = 0.001$). Our data suggest that the OSOM® Trichomonas Test lacks adequate sensitivity for diagnosing *T. vaginalis* from male urine.

Funding declaration

The research was funded by Sekisui Diagnostics, Lexington, MA, with an investigator-initiated research award.

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Table 1

Performance of the OSOM® Trichomonas Test when compared to the APTIMA Trichomonas *vaginalis* test for diagnosing *T. vaginalis* from the urine in men.

	Value	95% confidence interval
Sensitivity	37.5%	8.5–75.5%
Specificity	82.9%	75.6–88.7%
Positive likelihood ratio	2.2	0.8–5.8
Negative likelihood ratio	0.8	0.4–1.3
Disease prevalence	5.4%	2.4–10.4%
Positive predictive value	11.1%	4.5–24.7%
Negative predictive value	95.9%	93.1–97.6%

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Clinical teaching in a busy emergency department: Interruptions during case presentations



The oral case presentation (OCP) plays an essential role in the care of emergency department (ED) patients. Medical students and house officers communicate important information about their patients through the OCP whereby a patient's story is filtered, organized and presented in a concise manner to generate a diagnostic impression and appropriate plan. In a clinical teaching setting, the OCP delivered by learners serves to support patient care and plays an essential role in medical education [1]. However, in a busy ED, faculty are challenged to instruct learners while simultaneously caring for multiple patients, including the critically ill. Attending physicians must balance the need to quickly devise patient assessments and plans with teaching responsibilities [2]. This workload is often uncontrolled and punctuated by frequent interruptions and competing demands. Time-motion studies have demonstrated that emergency physicians frequently multitask and are interrupted an average of 10 times per hour, significantly more often than other ambulatory care specialists [3,4]. The objectives of this study were to determine the incidence and type of interruptions that occur during case presentations in the ED.

This was a 5-month prospective observational study undertaken at a single university-affiliated teaching hospital with an emergency medicine residency training program and an annual ED census of 95,000 patients. A convenience sample of house officers and fourth-year medical students were observed during the initial OCPs of new patients presented to attending EM clinicians. None of these physicians or students were aware of the purpose of the study. They were informed only that a second-year medical student was observing case presentations as part of their elective. As many different attending physicians as possible were sampled while maintaining equal hours of observation for each daily shift. Each shift was observed five times for a total of 200 h of observation. The student completed a simple data sheet after each case presentation and recorded OCP duration, interruption frequencies, and interruption types. An "interruption" was defined as any event that diverted the physician's attention from the task at hand [3]. To minimize the Hawthorne effect, the observer completed the data sheet after each case presentation. Descriptive statistics (frequency tables, confidence intervals) were used to summarize the data. Chi-square and ANOVA tests were used to compare demographic differences. Effects of learner level or time of day on frequency of interruption were evaluated using analysis of variance.

A total of 860 new patient presentations were observed during the study period. The study involved 53 EM faculty members, 77 resident physicians and 24 medical students. The mean duration of presentation was 3.1 ± 2.5 min (range 0.5 to 15 min). There were a total of 2838 interruptions during case presentations; mean $3.3 (\pm 2.8)$ interruptions per presentation or $0.94 (\pm 0.71)$ interruptions per minute. At least one interruption occurred in 94% of OCPs, with a maximum of 32. The interruptions were categorized as follows: interruptions by faculty members who were being presented to (85%), questions by nursing

and/or medical staff (8%), phone calls (5%), ECG interpretation (1%), and orders on other patients (1%). Faculty interruptions were categorized into four types: 1) probing for further data, 2) teaching points, 3) instructions for managing the case, and 4) prompting for expected sequence.

In 39% of OCPs, attending physicians interrupted to give an assessment and/or a plan before the learner had done so. The number of interruptions (per OCP) and duration of OCPs varied by learner level of training ($p < 0.001$), with less experienced learners giving longer, less structured presentations and being interrupted more often. For example, faculty interruptions occurred in 12% of third-year resident OCPs compared to 66% of fourth-year medical student OCPs. Neither frequency nor number (per OCP) of interruptions was statistically different by time of day.

One simple explanation for the number of interruptions during OCPs is that more people work together and interact in EDs, increasing the chance that interruptions could occur [3]. However, we found that the greatest number of interruptions came from the attending physicians. Reasons for faculty physician interruptions include the duration of the OCP, quality and organization of the presentation, patient complexity, and varying faculty expectations of learners [2]. The primary focus of our study was on quantifying and characterizing such interruptions; we did not determine the detrimental effect, if any, of interruptions on the learner's education. There are situations in the ED during which such interruptions provide the attending physician an excellent opportunity to teach, gather more information on the patient, and guide treatment. However, these same interruptions may cause the learner to lose focus and omit relevant details [4,5]. Faculty should be cognizant of how frequently they interrupt and use strategies such as prompting and summarizing to reorient the learner after an interruption.

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<https://doi.org/10.1016/j.ajem.2018.10.023>

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