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Screening for *Trichomonas vaginalis* in a Large High-Risk Population: Prevalence Among Men and Women Determined by Nucleic Acid Amplification Testing

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Abstract: Men and women attending family planning and sexually transmitted disease clinics for sexually transmitted infection screening in 2012 to 2013 were tested for *Trichomonas vaginalis* (TV) using a sensitive nucleic acid amplification test. *T. vaginalis* prevalence in urogenital samples was 11.3% in 77,740 women and 6.1% in 12,604 men, and increased with age in both sexes.

Trichomoniasis, a common sexually transmitted disease (STD) affecting both men and women, is caused by urogenital tract infection with the protozoan *Trichomonas vaginalis* (TV). Untreated TV infections may increase the risk for acquisition of other sexually transmitted infections (STIs), including HIV,[1,2] and are associated with long-term sequelae, such as pelvic inflammatory disease, preterm births, and low-birth-weight infants.[3] Because TV infections are not required to be reported to the Centers for Disease Control and Prevention, estimating the prevalence of infection in a screening population is difficult.

Culture and wet mount microscopy methods for TV have long been the standard method for detection but suffer from relatively poor sensitivity.[4] A few previous studies have estimated the prevalence of TV infection in the United States using highly sensitive nucleic acid amplification tests (NAATs). Two analyses of the 2001–2004 National Health and Nutrition Examination Surveys (NHANES) data, which used polymerase chain reaction testing to detect TV in self-collected vaginal swabs from approximately 3650 to 3750 women aged 14 to 49 years, reported a TV prevalence of 3.1% to 3.2%.[1,2] The National Longitudinal Study of Adolescent Health, a prospective cohort study that used polymerase chain reaction testing to detect TV in approximately 12,500 young men and women sampled from April 2, 2001, to May 9, 2002, estimated the prevalence of TV at 2.8% in women and 1.7% in men.[3] Two recent studies using transcription-mediated amplification (TMA) NAAT to detect TV found a prevalence of 10% using in-home self-collected vaginal swabs from 1525 women older than 14 years,[4] and 8.7% prevalence in urogenital specimens from 7593 women (18–89 years old) undergoing *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing.[5]

Few studies have reported TV prevalence in large samples of men. Estimating the prevalence of TV in both men and women is important because most patients are asymptomatic and TV is easily transmitted. This study aimed at determining the prevalence of TV in men and women undergoing screening for STIs while attending family planning/STD clinics in Alabama.

Endocervical swab samples and male urine or urethral swab samples were collected from subjects attending family planning and STD clinics for routine STI screening and STD surveillance in 67 county health departments in Alabama. Collection of these specimens began in July 2012 for women and in November 2012 for men. Specimens were tested for TV by TMA NAAT using the Aptima *T. vaginalis* assay (Hologic, Inc) on the automated Panther instrumentation system. The Aptima *T. vaginalis* assay is Food and Drug Administration cleared for use with vaginal swab, endocervical swab, and liquid Papanicolaou specimens from asymptomatic and symptomatic women, but not urine specimens or male urethral specimens. Aptima *T. vaginalis* assay performance in urine and male urethral swab specimens has been described previously[6,7] and was validated for this use by the testing laboratory. Data collected from the beginning of the testing period in 2012 through March 2013 was used for analysis. Subject identification information was separated from test results before data analysis. Confidence intervals were calculated using the Wald test adjusted for continuity and variance. Significance of pairwise comparisons was performed using the *Z* test for 2 proportions with no correction for multiplicity.

The distributions of age, self-reported race status, and TV infection rate of female and male subjects are shown in Table 1. Of the 90,344 individuals screened, 77,740 (86%) were female and 12,604 (14%) were male. The overall prevalence of TV infection in the study sample was 10.6%. For all age groups, TV prevalence in female individuals was nearly twice the prevalence in male individuals (8807/77,740 [11.3%; 95% confidence interval, or CI, 11.1–11.6] vs 764/12,604 [6.1%; 95% CI, 5.7–6.5], $P < 0.001$), highest for African Americans (7927/54,390 [14.6%; 95% CI, 14.3–14.9]), and lower for multirace (52/920 [5.7%; 95% CI, 4.3–7.3], $P < 0.001$), white (1500/33,112 [4.5%; 95% CI, 4.3–4.8], $P < 0.001$), other race (3/72 [4.2%; 95% CI, 1.4–11.6], $P < 0.02$), American Indian (16/452 [3.5%; 95% CI, 2.2–5.7], $P < 0.001$), Pacific Islander/Hawaiian (7/245 [2.9%; 95% CI, 1.4–5.8], $P < 0.001$), and Asian (10/364 [2.7%; 95% CI, 1.5–5], $P < 0.001$) subjects when compared with African American race status.

In female individuals, TV prevalence gradually increased with age by 2% to 3% in each decade until age 40 years, after which infection prevalence plateaued at approximately 16%. In male individuals, TV prevalence also gradually increased with

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Source of Funding: None.

Conflicts of Interest: J.R.S. reports receiving research or consulting support from BD Diagnostics, Cepheid, Copan, and Hologic/Gen-Probe. D.G and C.H. are scientists employed by Hologic. For the remaining authors, none were declared.

Received for publication September 26, 2017, and accepted October 28, 2017.

DOI: 10.1097/OLQ.0000000000000757

TABLE 1. Prevalence of TV in 77,740 Women and 12,604 Men Determined Using NAAT, by Age Group, Race, and Sex

Category	No. With *T. vaginalis*/Total No. (% [95% CI])		
	Female	Male	Overall
Age, y			
<18	428/6785 (6.3 [5.8–6.9])	6/521 (1.2 [0.5–2.5])	434/7306 (5.9 [5.4–6.5])
18–19	773/9324 (8.3 [7.8–8.9])	40/1236 (3.2 [2.4–4.4])	813/10,560 (7.7 [7.2–8.2])
20–24	2634/25,821 (10.2 [9.8–10.6])	183/4048 ([4.5 [3.9–5.2])	2817/29,869 (9.4 [9.1–9.8])
25–29	1914/15,268 (12.5 [12–13.1])	144/2337 (6.2 [5.3–7.2])	2058/17,605 (11.7 [11.2–12.2])
30–34	1234/8829 (14 [13.3–14.7])	123/1424 (8.6 [7.3–10.2])	1357/10,253 (13.2 [12.6–13.9])
35–39	687/4807 (14.3 [13.3–15.3])	70/889 (7.9 [6.3–9.8])	757/5696 (13.3 [12.4–14.2])
40–44	477/2871 (16.6 [15.3–18])	36/571 (6.3 [4.6–8.6])	513/3442 (14.9 [13.8–16.1])
45–49	319/1907 (16.7 [15.1–18.5])	48/582 (8.3 [6.3–10.8])	367/2489 (14.7 [13.4–16.2])
≥50	338/2114 (16 [14.5–17.6])	114/989 (11.5 [9.7–13.7])	452/3103 (14.6 [13.4–15.9])
Missing	3/14 (21.4 [7.6–47.6])	0/7 (0 [0–35.4])	3/21 (14.3 [5–34.6])
Total	8807/77,740 (11.3 [11.1–11.6])	764/12,604 (6.1 [5.7–6.5])	9571/90,344 (10.6 [10.4–10.8])
Race			
American Indian	13/415 (3.1 [1.8–5.3])	3/37 (8.1 [2.8–21.3])	16/452 (3.5 [2.2–5.7])
Asian	10/332 (3.0 [16.4–54.5])	0/32 (0 [0–10.7])	10/364 (2.7 [1.5–5])
Black	7225/45,238 (16 [15.6–16.3])	702/9152 (7.7 [7.1–8.2])	7927/54,390 (14.6 [14.3–14.9])
Multirace	52/849 (6.1 [4.7–7.9])	0/71 (0 [0–5.1])	52/920 (5.7 [4.3–7.3])
Other	3/51 (5.9 [2–15.9])	0/21 (0 [0–15.5])	3/72 (4.2 [1.4–11.6])
Pacific Islander/Hawaiian	7/237 (2.9 [1.4–6])	0/8 (0 [0–32.4])	7/245 (2.9 [1.4–5.8])
White	1445/30,005 (4.8 [4.6–5.1])	55/3107 (1.8 [1.4–2.3])	1500/33,112 (4.5 [4.3–4.8])
Not stated	28/308 (9.1 [6.4–12.8])	2/106 (1.9 [0.5–6.6])	30/414 (7.2 [5.1–10.2])
Unknown	24/305 (7.9 [5.4–11.4])	2/70 (2.9 [0.8–9.8])	26/375 (6.9 [4.8–9.9])
Total	8807/77,740 (11.3 [11.1–11.6])	764/12,604 (6.1 [5.7–6.5])	9571/90,344 (10.6 [10.4–10.8])

age, starting at 2.6% for men younger than 20 years and increasing to 11.5% in men 50 years and older.

This is one of the first reports on a large-scale public health screening program for TV in both men and women using a highly sensitive NAAT. We found that TV prevalence overall was relatively high at 10.6% and was almost 2 times higher in younger female individuals than in younger male individuals. The highest prevalence was observed in African Americans. For both sexes, TV prevalence generally increased with age, but peaked at 40 to 49 years for women and at least 50 years for men. Results shown here for women are similar to that reported recently using the same TMA NAAT assay to test a population of women attending STD clinics for *C. trachomatis*/*N. gonorrhoeae* testing throughout the United States.[5] This increase in TV infection rates with increasing age in female individuals is also in agreement with the NHANES and other studies,[1–3,8,9] although the patient population described here differs by being geographically and demographically constrained compared with NHANES and other previous studies designed to survey cohorts representative of the US population. The present study demonstrates that TV prevalence in male individuals increased with age similarly to that observed in female individuals, but prevalence in younger male individuals was generally less than half that of female individuals of the same age group, whereas older women (40 years and older) and older men (50 years and older) had similarly high infections rates (16% for women, 11.5% for men). A similar increase in TV rates in men with increasing age was also previously reported in a population of men using self-collected samples in an Internet recruitment program.[10]

Historically, effective diagnosis of TV infection in men and women has been hampered by a lack of sensitive diagnostic methods for the organism. Clinics previously have relied on wet prep examination of vaginal fluid for TV diagnosis in female individuals, which is highly specific but only approximately 60% sensitive compared with NAATs.[4] Moreover, many clinics did not have access to microscopy. Diagnostic options for detecting TV in males were nearly nonexistent. The previous lack of appropriate screening tools for TV made public health control of this important infection untenable.

Our results suggest that both male and female individuals at high risk for STDs should also be screened for TV using NAAT, especially in individuals older than 40 years. Such a screening program could be implemented as an adjunctive method to current screening efforts for chlamydia and gonorrhea.

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