Factors Associated with the Prevalence and Incidence of *Trichomonas vaginalis* Infection among African American Women in New York City Who Use Drugs

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(See the article by Van Der Pol et al., on pages 548–54, and the editorial commentary by McClelland, on pages 487–9.)

**Background.** Trichomoniasis vaginalis, the most prevalent nonviral sexually transmitted infection, is associated with negative reproductive outcomes and increased HIV transmission and may be overrepresented among African Americans.

**Methods.** A total of 135 African American women who used drugs were screened for *Trichomonas vaginalis* on ≥2 occasions between March 2003 and August 2005. Women were administered a structured questionnaire in a community-based research center, underwent serological testing for human immunodeficiency virus and herpes simplex virus type 2, and were screened for *Neisseria gonorrhoeae* and *Chlamydia trachomatis*.

**Results.** Fifty-one women (38%) screened positive for *T. vaginalis* at baseline. Twenty-nine (31%) of 95 women with negative results of baseline tests became infected, for an incidence of 35.1 cases per 100 person-years at risk (95% confidence interval [CI], 23.5–49.0). Prevalent infection was associated with drug use in the past 30 days, and incident infection was associated with sexual behavior in the past 30 days, namely having 1 male sex partner. Women who reported having 1 partner were 4 times as likely as women with fewer partners to acquire *T. vaginalis* (hazard ratio, 4.3; 95% CI, 2.0–9.4).

**Conclusion.** *T. vaginalis* may be endemic in this community of African American women. A control strategy that includes *T. vaginalis* screening in nonclinical settings and rapid point-of-care testing could contribute to the disruption of transmission of this pathogen.

Trichomoniasis vaginalis is one of the most common sexually transmitted infections (STIs) in the United States [1–5], and effective treatment is inexpensively available [6, 7]. Incidence estimates for the United States suggest that up to 7.4 million cases occur annually [1, 8]. Many cases remain undiagnosed because *T. vaginalis* is not a reportable disease, is not currently a target of STI control, and is asymptomatic in half of infected women [9]. *T. vaginalis* has been associated with several negative reproductive outcomes [10, 11]. More recently, it has been associated with a 2–3-fold increase in the risk of acquiring HIV infection [12–14] and has been estimated to have facilitated 6%–30% of all new HIV infections among US women [15, 16].

Despite the fact that *T. vaginalis* is so common, prevalence estimates vary tremendously, because all data come from observational studies and because diverse diagnostic methods are used. One review of the literature suggested that 3%–48% of sexually active young women were infected [10]. A more recent summary reported a similar prevalence range of 6% to 54% among women of reproductive age [3]. However, prevalence estimates still vary widely, even when reviewing data that use similar diagnostic methods,
since the observed populations are not representative of the general population.

More than 80% of US women who currently have HIV/AIDS are African American or Latina [17]. Although no national data exist, African American women may also have the highest burden of *T. vaginalis* infection. In a recent review of studies that assessed *T. vaginalis* infection among urban women by race or in predominantly African American populations, the prevalence was 23%–51% and was 1.5–4 times higher among African American women than among women of other racial/ethnic groups [16]. These data suggest that designating *T. vaginalis* control a public health priority has the potential to seriously address existing health disparities while also having a significant impact on health care costs [15].

To develop effective, multifaceted *T. vaginalis* control strategies, it will be essential to understand the correlates and predictors of infection in both clinical and nonclinical populations. Much of the previous research has been conducted in clinical settings and has focused on prevalence [16], although more recent studies have examined the incidence of this common and curable STI [7, 18]. The current study examines the prevalence, incidence, correlates, and predictors of *T. vaginalis* infection in a nonclinical population of African American female drug users in an urban community with a high prevalence of HIV infection.

**SUBJECTS, MATERIALS, AND METHODS**

**Study population.** Participants were African American women recruited in central Brooklyn, where active markets for illicit drugs have existed for many years. Recruitment methods included street outreach and chain-referral methods that have been successfully used to recruit “hidden” populations since the 1980s. Eligible women met the following criteria: self-identified as “black” or “African American”; aged ≥18 years or aged 16 or 17 years and living as an emancipated minor; used heroin, crack, or noncrack cocaine in the past 30 days or used marijuana daily; and had no plans to change residence in the year following enrollment. Broad criteria regarding drug use were instituted to capture a range of women, as well as to limit incentives to lie about drug use. Therefore, women who had used drugs were eligible for inclusion, regardless of the mode of drug use.

**Study design and procedures.** Data were collected as part of a larger social network cohort study initiated in 2002. Additional funds were secured to screen for treatable STIs, and data collection for this component of the study began in March 2003. Data were obtained from 139 eligible African American women who were interviewed at a minimum of 2 visits and a maximum of five visits between March 2003 and August 2005; follow-up interviews were scheduled to occur every 6 months. Of these women, 135 (97%) were screened for *T. vaginalis* at least twice. The interview during which the first *T. vaginalis* specimen was collected was considered to be the baseline interview; the “prevalence” analysis database consisted of data obtained during this interview. Data for the “incidence” analysis database were obtained during interviews of all women who screened negative at baseline and of women who had positive results of a screen at baseline and negative results of a subsequent screen and who participated in follow-up interviews after the negative result.

Women were confidentially administered a computerized questionnaire at a community-based research site. Sociodemographic information, medical histories, and drug use practices and sexual behaviors during the past 30 days were assessed. With the exception of the number of male sex partners, variables were dichotomized to facilitate comparisons of the presence or absence of a risk factor with *T. vaginalis* infection status. In addition to reporting the number and aggregate characteristics of 30-day sex partners (e.g., 3 African American partners and 1 Latino partner), women were asked to nominate specific men with whom they had had sex in the past 30 days. Nominees in social network research are individuals with whom respondents typically interact; therefore, nominated sex partners represented men with whom the women regularly had sex. For each nominated male sex partner, women were asked about the duration of the relationship, the partner’s age, his race/ethnicity, and his involvement in concurrent sexual partnerships (i.e., whether he had sex partners in addition to her).

After completion of the interview, women received pretest counseling and screening for a panel of STIs, including HIV, herpes simplex virus type 2 (HSV-2), *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, and *T. vaginalis*. Blood specimens for HIV and HSV-2 serotyping were collected using venipuncture. To collect specimens for *N. gonorrhoeae*, *C. trachomatis*, and *T. vaginalis*, women were given 2 polyester fiber swabs ~20 cm in length for self-sampling. Women were instructed to cleanse the vaginal area, squat, gently insert 1 swab at a time high into the vagina, and rotate the swab in the vaginal vault for 15–30 s [5]. Women who were menstruating agreed to either provide a urine sample or to return when they were no longer menstruating; all but 4 respondents complied. All urine samples were processed and frozen within 30 min of collection [19]; <5% of samples were urine. At the completion of screening, women were scheduled to return for their results. Respondents who screened positive were referred to local health care professionals. Women were compensated a nominal amount for study participation. All respondents provided informed consent and the study protocol was approved by the institutional review board of Columbia University (New York, NY).

**Microbiologic evaluation.** A repeated enzyme immunoassay (Vironostika) with Western blot confirmation (Bio-Rad) was administered to detect HIV antibodies. The HSV-2 type-specific IgG antibody test (HerpeSelect HSV-2 enzyme-linked immunosorbent assay [Focus Technologies]) was used for HSV-2 screening; specimens with an index ratio of >1.1 were designated to be HSV-2 seropositive.
Specimens collected via self-swabbing of the vaginal vault underwent real-time polymerase chain reaction (PCR) (BDProbe-Tec ET CT/NG amplified DNA assay [BD]) for N. gonorrhoeae and C. trachomatis. Results were available to staff within 72 h. T. vaginalis specimens (in swabs or pelleted urine) were stored at 4°C until weekly shipment to the test site at the International Sexually Transmitted Diseases Laboratory at Johns Hopkins University (Baltimore, MD). Samples were resuspended in 200 μL of Tris-EDTA buffer and extracted via the Roche Magna Pure LC robot with a positive processing control and a negative processing control. Extracted specimens and controls were subsequently analyzed on the Roche Lightcycler for detection of T. vaginalis by FRET-based real-time PCR, using a set of primers targeting a conserved region of the β-tubulin genes of T. vaginalis (btub1, btub2, and btub3) [20, 21].

Statistical analysis. Univariate relationships used χ² tests for comparisons between categorical variables, and the Student t test was used to examine differences between means of continuous dependent variables. The Wilcoxon 2-sample test was used to compare the median values of nonnormally distributed variables (e.g., the number of sex partners). Incidence rates were calculated using person-years of follow-up from baseline to the midpoint between the last visit with a negative result and the first visit with a positive result or, for women who remained T. vaginalis negative, the final interview date. The incidences of T. vaginalis infection are reported per 100 person-years at risk. Risk factor data for incident infection were derived from the first visit with a positive test result or the last noninfection visit [22]. Cox proportional hazards ratios (HRs) and 95% confidence intervals (CIs) summarize the relationship between incidence rates by statistically significant predictors. To assess the potential risk associated with relationship characteristics of nominated male sex partners in the prevalence and the incidence analyses, logistic regression was used to assess the association between each risk characteristic (e.g., duration of relationship) and women’s T. vaginalis infection status, controlling for the number of nominated sex partners, since some women nominated more partners than others. Odds ratios (ORs) are reported. Two-tailed P values are significant at an α of <.05; P values calculated by the Fisher exact test are reported when cells have expected counts of <5. SAS, version 9.1.3 (SAS Institute), was used for all statistical analysis.

RESULTS

Prevalence and incidence of T. vaginalis infection. Fifty-one (38%) of 135 African American women screened positive for T. vaginalis at their baseline interview, but only 1 was aware of her infection before testing. A total of 22 women (16%) who had a positive screen result at the first interview continued to have positive results at subsequent interviews, 18 (13%) subsequently screened negative at 1 interview but had no additional follow-up screen performed, 6 (4%) subsequently had negative screen results and continued to have negative results at all additional follow-up interviews, and 5 (4%) became reinfected during the follow-up period. Therefore, the final sample for the incidence analysis included 84 women who had negative results of an initial screen, 5 who became reinfected, and 6 who had positive results of an initial screen but had negative results of a subsequent screen and at least 2 additional follow-up screens. Women included in the incidence analysis were followed for a mean duration (±SD) of 11.4 ± 5.9 months after their first negative T. vaginalis screen.

Twenty-nine (31%) of 95 women with negative results of the initial screen became infected during the course of the study; the incidence rate of T. vaginalis infection was 35.1 cases per 100 person-years at risk (95% CI, 23.5–49.0). Again, only 1 woman was aware of her infection before screening positive at the interview visit.

Overall, 19 women (14%) at baseline and 17 women (18%) at follow-up reported having ever received a diagnosis of T. vaginalis infection; there was no association between currently screening T. vaginalis positive and a history of diagnosis for either group. The prevalence at each of 4 subsequent interviews for women who initially screened negative for T. vaginalis ranged 11% to 22%.

Sociodemographic characteristics and 30-day drug use and sexual practices. Women in the study had a mean age (±SD) of 33.9 ± 9.9 years (range, 17–57 years). Potential risk factors for prevalent T. vaginalis infection at study entry and for incident infection over the course of the study are summarized in table 1. At the baseline interview, women reported having had a mean (±SD) of 1 ± 1.3 male sex partner in the past 30 days (median, 1 partner [range, 0–13 partners]). Data from the follow-up interview were similar: women reported a mean (±SD) of 1 ± 1.1 partner (median, 1 partner [range, 0–7 partners]). Neither the mean nor median numbers of 30-day male sex partners were associated with prevalent infection (P = .36 and P = .82, respectively). However, both the mean and the median numbers of male sex partners were associated with incident T. vaginalis infection (P = .02 and P = .01, respectively). In general, prevalent infection was associated with 30-day drug use practices, and incident infection was associated with 30-day sexual practices, namely having >1 male sex partner. The incidence rates of T. vaginalis acquisition were 98.7 cases per 100 person-years at risk (95% CI, 49.0–165.7) for women with ≥2 male sex partners in the past 30 days and 25.1 cases per 100 person-years at risk (95% CI, 14.9–38.1) for women with <2 male sex partners in the past 30 days. Women who reported having >1 male sex partner in the past 30 days were 4 times as likely as women with fewer male sex partners to acquire T. vaginalis (HR, 4.3; 95% CI, 2.0–9.4).

Sex partner–specific risk. At the baseline interview, 94 women nominated 140 men with whom they had sex in the
past 30 days (mean number of partners [±SD], 1.5 ± 1.4 [range, 1–13 partners]) and, at follow-up, 63 women nominated 94 male sex partners (mean number of partners [±SD], 1.5 ± 1.0 [range, 1–7 partners]). Most men were African American, and relationships had a mean duration (±SD) of 6.4 ± 7.5 years at baseline and 5.3 ± 6.2 years at follow-up. Table 2 describes the characteristics of the relationships with nominated male sex partners and their association with T. vaginalis infection status. Only the number of nominated male sex partners was associated with incident (OR, 2.92; 95% CI, 1.26–6.75) but...
most none of these women were aware of their infection status before undergoing screening, and few reported having symptoms. Different sets of risk factors were associated with prevalent and incident \textit{T. vaginalis} infection. Prevalent infection was associated with crack use and was not associated with sexual practices. Incident infection was associated exclusively with sexual practices, a finding confirmed in sex partner–specific analyses. Neither prevalent nor incident \textit{T. vaginalis} infection was associated with HIV serostatus.

The natural history of \textit{T. vaginalis} infection remains unclear, although 1 study suggests that the majority of infections may be asymptomatic and long in duration \cite{7}. Therefore, the correlates of prevalence may represent both the correlates of infection, as well as the correlates of a lack of screening or care for \textit{T. vaginalis}. A significant minority (16\%) of women from the baseline sample continued to screen \textit{T. vaginalis} positive at subsequent interviews. These women were aware of their infection status because they returned for continued study participation, but they did not report receiving treatment. \textit{T. vaginalis} infection remained unresolved in these women. Moreover, most (>.85\%) of the women who acquired \textit{T. vaginalis} did not report having symptoms, a factor that might have prompted women to seek medical attention. This figure is much higher than the average of 50\% that has been reported in previous research \cite{9} and has serious implications for increased morbidity, given the range of negative reproductive health sequelae and the increased risk of HIV infection associated with \textit{T. vaginalis} infection. Finally, the significant association between crack use and infection, which has been previously reported \cite{23–26}, supports the notion of protracted colonization, particularly in light of the lack of association between infection and sexual practices among those who were infected at baseline.

The association between sexual practices, namely multiple male sex partners, and incident \textit{T. vaginalis} infection was expected. Given the likely high prevalence and incidence of \textit{T. vaginalis} infection in this community, there is an increased probability of encountering an infectious individual, particularly under circumstances where neither partner is aware of their infection. 

\begin{table}[h]
\centering
\begin{tabular}{|l|c|c|c|c|c|}
\hline
\textbf{Infecting pathogen(s)} & \textbf{Prevalence analysis by screen result, no. (\%)} & \textbf{Incidence analysis by screen result, no. (\%)} & \\
& \textbf{of women} & & \\
& \textbf{Positive} & \textbf{Negative} & \textbf{Positive} & \textbf{Negative} & \textbf{P} & \textbf{P} \\
& \textbf{(n = 51)} & \textbf{(n = 84)} & & \textbf{(n = 29)} & \textbf{(n = 66)} & \\
\hline
Human immunodeficiency virus & 12 (23.5) & 13 (15.5) & .24 & 6 (20.7) & 11 (17.5) & .49 \\
Herpes simplex virus type 2 & 47 (92.2) & 59 (70.2) & .003 & 23 (79.3) & 48 (72.7) & .50 \\
\textit{Neisseria gonorrhoeae} & 1 (2.0) & 4 (4.8) & .65 & 3 (10.3) & 0 (0.0) & .03 \\
\textit{Chlamydia trachomatis} & 2 (3.9) & 11 (13.1) & .13 & 4 (13.8) & 4 (6.1) & .24 \\
\textit{N. gonorrhoeae or C. trachomatis} & 3 (5.9) & 15 (17.9) & .05 & 7 (24.1) & 4 (6.1) & .03 \\
\hline
\end{tabular}
\caption{Concurrent sexually transmitted infections among inner-city African American women who use drugs.}
\end{table}
fection status. In this study, that risk was 4 times as great for women having >1 male sex partner in the past 30 days. Women with incident *T. vaginalis* infection were also significantly more likely than other women to concurrently screen positive for *N. gonorrhoeae* or *C. trachomatis*, although the incidence of these infections was much lower than that of *T. vaginalis* infection, as has been found in other studies [23, 27]. Of interest, the association with incident *T. vaginalis* infection was not linked to new sex partners, as is often the case with *N. gonorrhoeae* or *C. trachomatis* infection [23, 28]. Many of the sex partnerships described by the women were of long duration. However, one-third of women with incident *T. vaginalis* infection reported current participation in sex work, which likely consists of a mix of “old regulars” and new paying partners [29]. The number of regular and new sex work partners was not assessed, and women would be unlikely to label new paying partners as new sex partners. Therefore, new sex partners could have played a role in the high transmission rates observed in this study. However, it is more likely that the high background prevalence; low levels of awareness, testing, and treatment; and protracted colonization play a larger role in *T. vaginalis* transmission dynamics than do new sex partnerships.

The lack of association between HIV infection and either prevalent or incident *T. vaginalis* infection is surprising. HIV infection has been associated with an alteration of the natural history of various STIs, in that it has been found to extend the duration of infection and increase the infectiousness [30, 31]. Theoretically, HIV infection should also have been associated with a risk of acquiring *T. vaginalis*, because of increased biological vulnerability [31]. Previous research suggests that the incidence rate of *T. vaginalis* infection among HIV-infected women is high [26, 32]. The current research finds the incidence comparable to previous estimates among both HIV-infected and HIV-uninfected women. However, HIV infection is highly prevalent in this community [33], and almost one-fifth of the study population was already HIV infected. It is possible that the high baseline prevalence of both HIV and *T. vaginalis* infection reduced the power to observe this relationship. Alternatively, the presence of concurrent viral and bacterial STIs could also influence natural history and infection rates, which may play a role in increased vulnerability.

Calls for the public health establishment to prioritize *T. vaginalis* control have been increasing [4, 16, 34]. *T. vaginalis* is the most prevalent, curable STI in the United States [1]. Furthermore, there is an effective, single-dose treatment with currently negligible treatment resistance [6]. In addition, there is mounting evidence to suggest that African Americans bear the brunt of *T. vaginalis* infection and associated reproductive morbidities, as well as an increased risk of acquiring HIV infection [15]. Therefore, *T. vaginalis* control strategies have the potential to effectively address multiple negative health outcomes that are disparately experienced by African Americans. Control strategies targeting *T. vaginalis* could increase health care opportunities for those at risk though screening in novel settings that involves simple specimen collection methods and rapid point-of-care testing [35, 36]. Screening women by means of self-swabbing of the vaginal vault (which woman performed correctly and willingly, as evidenced by the high prevalence and incidence documented here and elsewhere [24, 37, 38]) should provide better management of *T. vaginalis* infection, particularly in high-risk populations. In this study, STI treatment increased 6-fold over time among African American women who used drugs and who were screened for STIs at a community-based research center, even in the absence of on-site STI treatment availability.

Much of the data used in this study are based on self-report; therefore, the associations should be interpreted with caution. Self-reported data may underreport individual or network practices. The 30-day risk assessment period provides a snapshot of risk and may be a conservative estimate of sexual partnerships. The small sample size limited the power to detect possible associations between the risk factors measured and both the prevalence and incidence of *T. vaginalis* infection, as well as the ability to conduct more complex analyses. Although a variety of strategies were used to access women, future research efforts should consider other methods, such as respondent-driven sampling [39, 40] and conducting multisite studies to increase sample size and diversity.

*T. vaginalis* may be endemic in this community of African American women who use drugs and among their sex partners. Elevating *T. vaginalis* control to a public health priority has the potential to directly and effectively address multiple health disparities observed in minority communities in the United States. A range of control strategies that include *T. vaginalis* screening in nonclinical settings and the use of rapid point-of-care tests could contribute significantly to the disruption of transmission by the provision of immediate treatment, since high-risk populations may represent a reservoir of infection in the community.

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**References**


