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Correlates of Incident *Trichomonas vaginalis* Infections Among African American Female Adolescents

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Abstract

Background—*Trichomonas vaginalis* is the most common curable sexually transmitted infection (STI), associated with adverse reproductive health and pregnancy outcomes and may amplify HIV transmission. The objective was to identify correlates of incident *Trichomonas vaginalis* infections among African American adolescent females.

Methods—Data were collected via audio computer-assisted self-interviews at baseline and every 6 months for 18 months from 701 African American females (14–20 years) in an HIV prevention trial. At each assessment, self-collected vaginal swabs were assayed for *T. vaginalis*, *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. Generalized estimating equations assessed associations between incident *T. vaginalis* infection and sociodemographic characteristics, substance use, partner-level factors, sexual risk behaviors, douching and other STIs.

Results—Of 605 (86.3%) participants who completed 1 follow-up assessment, an incident *T. vaginalis* infection was detected among 20.0% (n=121). Factors associated with incident infection in adjusted analysis included: cigarette smoking (AOR: 1.66, 95% CI: 1.04, 2.64), using alcohol on an increasing number of days in the past 3 months (AOR: 1.02, 95% CI: 1.00, 1.04), acquisition of *C. trachomatis* (AOR: 2.27, 95% CI: 1.40, 3.69) or *N. gonorrhoeae* (AOR: 5.71, 95% CI: 2.97, 11.02) and *T. vaginalis* infection at the previous assessment (AOR: 3.16, 95% CI: 1.96, 5.07).

Conclusions—Incident *T. vaginalis* infections were common. Strategies to reduce infection rates among this population may include improving partner notification and treatment services. The benefits of re-screening, screening adolescents screened for or infected with *C. trachomatis* or *N. gonorrhoeae* and associations between substance use and *T. vaginalis* acquisition warrant further investigation.

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Keywords

Adolescents; African American; Risk Factors; *Trichomonas vaginalis*

Introduction

Trichomonas vaginalis, the most common curable sexually transmitted infection (STI), is associated with adverse reproductive health and pregnancy outcomes and may amplify transmission of viral STIs, such as HIV.^{1,2} *T. vaginalis* may be associated with a 2–3-fold increased risk of acquiring HIV.^{1,2} African American women have disproportionate risk for both HIV and *T. vaginalis* infection.^{3–7} HIV is a leading cause of death among women of color in the USA, with African American women accounting for two-thirds of new HIV infections among women.⁶ In the 2001–2004 National Health and Examination Survey (NHANES), a nationally-representative survey of reproductive-age women in the USA, *T. vaginalis* prevalence was 13.3% among African Americans as compared to 1.3% among Whites.⁴ Other factors associated with prevalent infection among women in the NHANES study included: birth in the USA, a greater number of lifetime sex partners, increasing age, lower educational attainment, poverty and douching in the past 6 months.⁴ Approximately 85% of infected women reported no symptoms.⁴

Although *T. vaginalis* prevalence appears to increase with age,^{3,4,7} high estimates of infection have been reported among adolescents.^{7–9} In the National Longitudinal Study of Adolescent Health (AddHealth), overall *T. vaginalis* prevalence was 2.8% but 10.5% among young African American women.⁷ A study among predominantly African American females 13–19 years attending an adolescent health clinic in the Southeast, where *T. vaginalis* prevalence is highest among adolescents,⁷ reported *T. vaginalis* prevalence was 14.4%;⁹ factors associated with prevalent infection included having a sex partner 5 years older and gonorrhea infection.⁹

Few studies have investigated *T. vaginalis* incidence.^{3,10,11} Factors associated with incident infection among women have included older age, Black race, Chlamydia infection, multiple sexual partners, new sexual partners, previous *T. vaginalis* infection, smoking and alcohol use.^{3,12–15} Among adolescent females, one study reported an incident rate of 22.1 per 100 person-years.⁹ Other studies reported the proportion of adolescent females experiencing an incident infection as 23.3% over 27 months¹⁶ and 8.9% and 10.2% over 6 month follow-up periods.⁸ Baseline predictors of *T. vaginalis* acquisition over time among young African American women have included a history of delinquency, low perceived parental monitoring, biologically-confirmed marijuana use, heavy alcohol use, recent use of both alcohol and marijuana, sex partners who were generally 5 years older, sex with non-steady partners, and having an STI.^{8,17–19}

Despite high estimates of infection among African American women and adverse outcomes, including HIV, few studies have investigated factors related to incident *T. vaginalis* infections among this population.¹⁰ In particular, there is a dearth of information about risk factors for *T. vaginalis* among female adolescents.^{9,16} Thus, the objective of this study was to identify correlates of incident *T. vaginalis* infections among African American adolescent

females participating in an HIV/STI prevention trial. Given limited diagnostic technology, a lack of screening guidelines, high proportions of asymptomatic infections and concerns regarding treatment failures, identifying factors associated with incident infection may be important for preventing *T. vaginalis* and other STIs.

Methods

Study sample and intervention procedures

This study was a secondary analysis of data collected to test the efficacy of a behavioral HIV/STI prevention intervention. The study methods have been previously described.^{20,21} Briefly, from June, 2005, to June, 2007, African American adolescent females aged 14–20 years were recruited from reproductive health clinics in Atlanta, GA, to participate in an HIV/STI prevention trial. The study was a two-arm randomized controlled supplemental treatment trial.²⁰ All participants received the same primary treatment,²² a single, group-delivered HIV risk reduction intervention with demonstrated efficacy and one of two supplemental treatments. Both supplemental treatments were a series of phone calls conducted every 8 weeks for 18 months (9 total calls). The Emory University Institutional Review Board approved all study protocols.

Data collection

Data collection occurred at baseline and every 6 months following the primary treatment through 18-months of follow-up. At each assessment visit, participants provided a self-collected vaginal swab specimen and completed an audio computer-assisted self-interview (ACASI). The vaginal swab specimen was assayed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* using the BDProbeTec ET *Chlamydia trachomatis* and *Neisseria gonorrhoeae* Amplified DNA Assays (Becton Dickinson and Company, Sparks, MD)²³ and *T. vaginalis* using a noncommercial real-time polymerase chain reaction assay with high sensitivity and specificity.²⁴ Participants with a positive STI test result received directly-observed single-dose treatment and risk-reduction counseling per Centers for Disease Control and Prevention recommendations and were encouraged to refer their sex partners for treatment.

Summary of trial findings

There were no differences between conditions on sociodemographic characteristics, STI prevalence or sexual behaviors at randomization, and retention between conditions was similar.²⁰ Through 18 months, generalized estimating equations (GEE) showed participants in the intervention condition had fewer incident chlamydial infections and a greater number of condom-protected sex acts.²⁰ However, there was no intervention effect on *T. vaginalis* infection over 18 months ($p=0.218$).

Measures

Outcome—*Incident T. vaginalis infection* was defined as a positive test result during follow-up subsequent to a negative result or documented treatment at the previous visit.

Baseline characteristics and potential correlates—The following factors were assessed at baseline and each follow-up assessment.

Sociodemographic factors included age (years), having a paid job (yes/no) and family aid index. Family aid was assessed with a 4-item index. Participants reported whether anyone in their household received the following services during the past year: a) welfare, b) food stamps, c) Women, Infants and Children (WIC) and d) Section 8 housing subsidies (yes/no). The number of “yes” responses was summed to create a total score.

Cigarette smoking and substance use: Cigarette smoking was assessed with “Do you smoke cigarettes?” (yes/no). Frequency of recent alcohol and marijuana use was assessed with “In the past 90 days, how many days have you used [alcohol/marijuana]?” Heavy alcohol use was assessed with “How many alcoholic drinks do you usually have at one time?” Participants who endorsed consuming ≥ 3 drinks during a single drinking occasion were categorized as heavy users.

Partner-level factors included: a) currently having a boyfriend (yes/no); b) currently having a casual partner (yes/no); c) general age of partners (≥ 4 years older vs. < 4 years older, the same age or younger); d) sex in the past 6 months with a male partner recently released from jail, prison or detention (yes/no) and e) sex with a partner who was high or drunk during sex in the past 90 days (yes/no).

Sexual risk behaviors in the 90 days prior to assessment included number of vaginal sex partners, having unprotected vaginal sex and being high or drunk during sex. Condom use and use of hormonal contraceptives at last sex were also assessed as potential risk factors. Number of partners was assessed with “In the past 90 days, how many guys have you had vaginal sex with?” Participants’ responses were categorized as 0–1, 2–3 and ≥ 4. Unprotected sex was based on the questions “In the past 90 days, how many times have you had vaginal sex?” and “How many of the xx times you’ve had vaginal sex in the past 90 days did you use a condom?” The number of times condoms were used was subtracted from the total number of vaginal sex acts. Participants reporting ≥ 1 episode of vaginal sex without a condom were categorized as having unprotected sex. Being drunk or high during sex was assessed with “In the past 90 days, how many times did you have sex while high on alcohol or drugs?”; reports of ≥ 1 time(s) were categorized as engaging in the behavior. We also explored whether condom use and hormonal contraceptive use (“pills/patch/depo”) at last sex (yes/no) were associated with *T. vaginalis* acquisition.

Douching: Recent douching was assessed with “In the past 90 days, how many times did you douche?” Reports of ≥ 1 time(s) were categorized as engaging in the behavior.

STIs: *C. trachomatis* and *N. gonorrhoeae* prevalence were measured at baseline. Acquisition of *C. trachomatis* or *N. gonorrhoeae* at the current assessment was assessed during follow-up. We also assessed *T. vaginalis* infection at the previous assessment as a predictor of infection.

Data analysis

T-tests and chi-square statistics were used to compare baseline characteristics among participants who did and did not complete at least one post-intervention assessment. Descriptive statistics were used to summarize retention and frequency of incident infections during the 18-month follow-up period. Unadjusted GEE models assessed associations between potential correlates, measured during follow-up, and incident *T. vaginalis* infection. Factors significant at $p < 0.1$ were considered for the final multivariable model, which controlled for age and trial condition. Variance inflation factors (VIFs) of the fully adjusted model were examined to detect multicollinearity between independent variables. To identify the most parsimonious multivariable model, we used backwards selection procedures and examined the quasi-likelihood information criterion (QIC) for each stepwise model; the model with the lowest QIC was selected as the final model.²⁵

Results

Sample characteristics

Of 701 participants who completed the baseline assessment, 605 (86.3%) completed 1 follow-up assessment. Most, 63.8% ($n = 386$), completed all three follow-up assessments; only 15.4% ($n = 93$) completed one. Table 1 compares baseline characteristics among participants according to completion of 1 follow-up assessment. Individuals who did not complete 1 follow-up assessment were significantly less likely to report a paid job (27.1% vs. 37.9%) and more likely to report a history of sexual abuse (32.3% vs. 19.6%), cigarette smoking (25.0% vs. 15.5%), heavy alcohol use (25.6% vs. 14.5%), recently being high or drunk during sex (38.5% vs. 26.5%) and to be infected with *T. vaginalis* (17.7% vs. 10.7%).

Frequency of incident *T. vaginalis* infections

A total of 121 participants (intervention condition $n = 55$; control condition $n = 66$, $p = 0.350$) (20.0%) experienced an incident infection. The majority, 86.0% ($n = 104$) experienced only 1 incident infection; 12.4% ($n = 15$) experienced 2 and 1.7% ($n = 2$) experienced 3 incident infections. At the 6-month assessment, 9.3% (51/546) of tests were categorized as incident infections. At the 12-month assessment, 10.2% (51/502) and at the 18-month assessment 8.4% (38/451) of tests were considered incident infections. Of the 140 incident *T. vaginalis* infections, 38 (27.1%) were among individuals treated for *T. vaginalis* at the previous assessment.

Correlates of incident *T. vaginalis* infections

Table 2 presents unadjusted associations between potential correlates and incident *T. vaginalis* infection. Having a paid job (OR: 0.61, 95% CI: 0.42, 0.88) and using hormonal contraceptives at last sex (OR: 0.60, 95% CI: 0.41, 0.93) were associated with a reduced likelihood of *T. vaginalis* acquisition. Factors significantly associated with an increased likelihood of incident infection included family aid index (OR: 1.31, 95% CI: 1.12, 1.54), using alcohol (OR: 1.02, 95% CI: 1.01, 1.04) or marijuana (OR: 1.01, 95% CI: 1.00, 1.02) on an increasing number of days, *C. trachomatis* acquisition (OR: 3.13, 95% CI: 2.01, 4.87), *N. gonorrhoeae* acquisition (OR: 7.56, 95% CI: 4.29, 13.30) and *T. vaginalis* infection at the

previous assessment (OR: 4.14, 95% CI: 2.66, 6.45). Douching (OR: 1.52, 95% CI: 0.99, 2.33) was marginally associated with an increased likelihood of incident infection ($p=0.053$).

All VIFs of the fully adjusted model were <4 ; therefore, no factors were excluded due to multicollinearity. Table 3 presents the final adjusted model. In adjusted analyses, cigarette smoking (AOR: 1.66, 95% CI: 1.04, 2.64), using alcohol on an increasing number of days (1.02, 95% CI: 1.00, 1.04), *C. trachomatis* acquisition (AOR: 2.27, 95% CI: 1.40, 3.69), *N. gonorrhoeae* acquisition (AOR: 5.71, 95% CI: 2.97, 11.02) and *T. vaginalis* infection at the previous assessment (AOR: 3.16, 95% CI: 1.96, 5.07) were associated with incident infection.

Discussion

This study identified correlates of incident *T. vaginalis* infections detected over an 18-month follow-up period among African American female adolescents participating in an HIV/STI prevention trial. We are unaware of other studies which have longitudinally identified correlates of incident *T. vaginalis* infection exclusively among African American female adolescents. Overall prevalence was high; 11.7% of participants tested positive for *T. vaginalis* at baseline assessment. This estimate is nearly twice as high as the overall prevalence of gonorrhea (6.3%) in this sample and over two-thirds the Chlamydia prevalence (17.1%). Incident infections were common; 20% of the analytic sample experienced an incident infection.

Similar to studies of *T. vaginalis* incidence among adult women,¹² both cigarette smoking and alcohol use were associated with *T. vaginalis* acquisition. A prospective study in China reported dose-response relationships between number of cigarettes smoked per day and years of cigarette smoking and *T. vaginalis* incidence.¹² Cigarette smoking has been shown to be associated with *T. vaginalis* prevalence among both adult and adolescent samples of women.^{9,26} Several pathways to account for the association between cigarette smoking and *T. vaginalis* acquisition have been proposed. According to problem behavior theory, the relationship may be due to their co-occurrence.²⁷ Researchers have also suggested that cigarette smoking may influence the vaginal environment making individuals more susceptible to infection.²⁶ Whereas alcohol consumption and heavy alcohol use have been previously reported to be associated with *T. vaginalis* acquisition,^{12,17} we are unaware of other studies identifying frequency of alcohol use to be associated with incident infection. This finding is consistent, however, with research supporting an overall association between more frequent alcohol use and STIs.²⁸

None of the sexual risk behaviors assessed were associated with incident *T. vaginalis* infection. In contrast to studies among adult women and not limited to adolescent samples,^{3,13–15} having multiple sex partners was not associated with incident infection. The median number of vaginal sex partners was one at all assessments, which may account for the lack of observed associations in this study. Measures of condom use were also unrelated. Although condoms protect against *T. vaginalis*, we were unable to assess condom use errors. Additionally, the lack of association may be attributable to the fact that all participants

received an efficacious sexual risk reduction intervention. This may also account for the lack of significant intervention effect on *T. vaginalis* acquisition. Lack of power may account for the non-statistically significant reduction in incident *T. vaginalis* infections among participants assigned to the intervention. However, lack of association between condom use, the key sexual risk behavior targeted by the intervention, and *T. vaginalis* acquisition may also account for the lack of intervention effect on *T. vaginalis* acquisition.

Consistent with other studies,^{3,15} *C. trachomatis* and *N. gonorrhoeae* infections were associated with *T. vaginalis* acquisition. Although in practice, adolescent females are usually concurrently screened for *C. trachomatis* and *N. gonorrhoeae*, high-risk adolescents are often not screened for *T. vaginalis*. Given relatively high estimates of *T. vaginalis* prevalence and acquisition in this study and strong associations with Chlamydial and gonorrhea infections, routine *T. vaginalis* screening along with *C. trachomatis* and *N. gonorrhoeae* screening or among adolescent females infected with these STIs may be warranted among this population. In addition, testing positive for *T. vaginalis* at the previous assessment was associated with an increased likelihood of infection. Treatment failures may have occurred, participants may have acquired a new infection or lack of partner treatment may have resulted in re-infection. However, none of the partner-level factors assessed in this study were associated with *T. vaginalis* acquisition. Although other studies have observed older partner age to be associated with *T. vaginalis* prevalence and to predict *T. vaginalis* acquisition,^{8,9} older partner age was unrelated to *T. vaginalis* acquisition in this study. However, this finding is consistent with a recent systematic review which concluded that older partner age was associated with prevalent infection but largely unrelated to incident STIs among adolescents.²⁹

Strengths and Limitations

The findings should be interpreted in light of the study's limitations. Participants were enrolled in an HIV/STI prevention trial; the degree to which these findings may be generalized to other young African American women is unknown. Nevertheless, participants in this sample represent an important high-risk population. Although no differences in incident *T. vaginalis* infections were observed between trial conditions, given that all participants received an effective sexual risk reduction intervention, incident infections may be underestimated. Although the study achieved high retention, the analysis excluded individuals who did not complete a follow-up assessment. Adolescents excluded from analysis were more likely to smoke cigarettes, be heavy alcohol users and be infected with *T. vaginalis*; therefore, our estimates may further underestimate true associations between these factors and *T. vaginalis* acquisition. In addition, substance use and sexual risk behaviors were self-reported. Despite use of ACASI, which has been shown to increase reporting of sensitive behaviors,³⁰ misclassification of self-reported behavior may have occurred due to socially desirable responding; thus, our findings may underestimate true associations between these measures and *T. vaginalis* acquisition. Further, this study was unable to distinguish between new infections, re-infections and treatment failures. Therefore, our findings may overestimate the number of incident infections and reported associations may be under- or over-estimated, depending on true associations between type of infection and the correlates identified. However, clinicians and service providers are also

not likely to be able distinguish between new infections, re-infections and treatment failures; therefore, our methods and findings are consistent with an overall public health approach. Particular strengths of this study include use of PCR testing, duration of follow-up and examination of a diverse set of risk factors.

Implications

The identification of factors associated with *T. vaginalis* acquisition may be important for developing strategies to prevent *T. vaginalis* infection and HIV among young African American women. Exploring the mechanisms by which cigarette smoking and more frequent alcohol use are related to *T. vaginalis* acquisition may aid the development of prevention interventions. High levels of infection and strong associations between *C. trachomatis* and *N. gonorrhoeae* acquisition and *T. vaginalis* acquisition suggest that routine *T. vaginalis* screening for this population combined with *C. trachomatis* and *N. gonorrhoeae* screening or among adolescents infected with these STIs warrants further evaluation. Given that *T. vaginalis* infection at the previous assessment predicted infection at the next assessment and infections are often asymptomatic, the benefits of re-screening should be further investigated. Strategies to reduce infection rates among this population may include improving partner notification and treatment services; however, challenges exist. *T. vaginalis* is not subject to mandatory reporting, most health departments have limited existing capacity to conduct partner notification and treatment and evidence regarding the efficacy of expedited partner therapy for *T. vaginalis* is limited, particularly among adolescents. Additional research is needed to identify effective strategies for treating male partners.

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Table 1

Selected baseline characteristics among African American adolescent females participating in an HIV/STI prevention trial according to completion of at least one follow-up assessment during 18 months of follow-up

Variable	1 follow-up assessment (n=605)	Baseline assessment only (n=96)	p-value
	% (n)		
Sociodemographic characteristics			
Age (years)			0.137
14–15	11.9 (72)	7.3 (7)	
16–17	34.9 (211)	29.2 (28)	
>18	53.2 (322)	63.5 (61)	
Paid job	37.9 (229)	27.1 (26)	0.042
Family aid index, mean (SD)	0.8 (1.0)	0.8 (1.0)	0.484
Current cigarette smoking and substance use, past 90 days			
Cigarette smoking	15.0 (91)	25.0 (24)	0.014
Number of days used alcohol, median (range)	1 (0–70)	1 (0–60)	--
Heavy alcohol use	10.1 (61)	18.8 (18)	0.013
Number of days used marijuana, median (range)	0 (0–90)	0 (0–90)	--
Partner-level factors			
Current boyfriend	78.8 (477)	83.3 (80)	0.312
Current casual partner	34.9 (211)	32.3 (31)	0.621
Partners generally at least 4 years older	17.2 (104)	15.6 (15)	0.704
Partner recently released from incarceration	15.2 (92)	16.7 (16)	0.713
Partner drunk or high during sex, past 90 days	44.5 (269)	47.9 (46)	0.527
Sexual behavior, past 90 days			
Number of vaginal sex partners			0.705
0–1	63.6 (385)	59.4 (57)	
2–3	30.3 (183)	34.4 (33)	
4	6.1 (37)	6.3 (6)	
Unprotected vaginal sex	78.5 (475)	79.2 (76)	0.885
Condom use at last sex	43.3 (262)	41.7 (40)	0.763
Drunk or high during sex	26.5 (160)	38.5 (37)	0.014

Variable	1 follow-up assessment (n=605)	Baseline assessment only (n=96)	p-value
	% (n)		
Hormonal contraceptive use during last sex	35.9 (217)	26.0 (25)	0.060
Douching, past 90 days			
Douched	28.3 (171)	31.3 (30)	0.548
STIs			
C. trachomatis infection	16.4 (99)	21.9 (21)	0.183
N. gonorrhoeae infection	6.5 (39)	5.2 (5)	0.642
T. vaginalis infection	10.7 (65)	17.7 (17)	0.049

Table 2

Unadjusted associations between potential correlates and incident *Trichomonas vaginalis* infections over 18 months of follow-up among 605 African American adolescent females participating in an HIV/STI prevention trial

Variable	OR	CI	p-value
Sociodemographic characteristics			
Age (years)			
14–15	1	--	--
16–17	1.50	0.60, 3.73	0.385
>18	1.09	0.46, 2.59	0.845
Paid job	0.61	0.42, 0.88	0.008
Family aid index	1.31	1.12, 1.54	0.001
Current cigarette smoking and substance use, past 90 days			
Cigarette smoking	2.79	1.83, 4.26	<0.001
Number of days used alcohol	1.02	1.01, 1.04	0.005
Heavy alcohol use	0.87	0.50, 1.49	0.608
Number of days used marijuana	1.01	1.00, 1.02	0.005
Partner-level factors			
Current boyfriend	1.11	0.74, 1.66	0.617
Current casual partner	1.32	0.89, 1.95	0.172
Partners generally at least 4 years older	0.87	0.53, 1.42	0.577
Partner recently released from incarceration	1.04	0.55, 1.96	0.909
Partner drunk or high during sex, past 90 days	1.08	0.74, 1.56	0.700
Sexual behavior, past 90 days			
Number of vaginal sex partners			
0–1	1	--	--
2–3	1.29	0.87, 1.90	0.198
4	1.73	0.78, 3.87	0.179
Unprotected vaginal sex	1.07	0.73, 1.58	0.726
Condom use at last sex	1.04	0.73, 1.58	0.828
Drunk or high during sex	0.87	0.57, 1.34	0.534
Hormonal contraceptive use during last sex	0.60	0.41, 0.93	0.022

Variable	OR	CI	p-value
Douching, past 90 days			
Douched	1.52	0.99, 2.33	0.053
STIs			
<i>C. trachomatis</i> infection	3.13	2.01, 4.87	<0.001
<i>N. gonorrhoeae</i> infection	7.56	4.29, 13.30	<0.001
<i>T. vaginalis</i> infection at last assessment	4.15	2.67, 6.45	<0.001

OR: odds ratio; CI: 95% confidence interval; STI: Sexually transmitted infection

Table 3

Final adjusted associations between potential correlates and incident *Trichomonas vaginalis* infections over 18 months of follow-up among 605 African American adolescent females participating in an HIV prevention trial

Characteristic	AOR	CI	p-value
Paid job	0.75	0.50, 1.10	0.144
Family aid index	1.16	0.98, 1.38	0.084
Cigarette smoking	1.66	1.04, 2.64	0.032
Number of days used alcohol, past 90 days	1.02	1.00, 1.04	0.029
Hormonal contraceptive use during last sex	1.73	0.47, 1.14	0.145
<i>C. trachomatis</i> infection	2.27	1.40, 3.69	0.001
<i>N. gonorrhoeae</i> infection	5.71	2.97, 11.02	<0.001
<i>T. vaginalis</i> infection at last assessment	3.16	1.96, 5.07	<0.001

AOR: adjusted odds ratio, adjusted for age, trial condition and other covariates in the model; CI: 95% confidence interval