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Male partner circumcision associated with lower *Trichomonas vaginalis* incidence among pregnant and postpartum Kenyan women: a prospective cohort study

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Abstract

Objective—*Trichomonas vaginalis* (TV) is the world's most common curable sexually transmitted infection (STI) and has implications for reproductive health in women. We determined incidence and correlates of TV in an HIV-uninfected peripartum cohort.

Methods—Women participating in a prospective study of peripartum HIV acquisition in Western Kenya were enrolled during pregnancy and followed until 9 months postpartum. TV was assessed every 1–3 months using wet mount microscopy. Correlates of incident TV were determined using Cox proportional hazards models.

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COMPETING INTERESTS

The authors declare that no competing interests exist.

AUTHORS' CONTRIBUTIONS

J.P., A.L.D., J.K., J.A.U., D.M., R.S.M., and G.J-S. conceived the question and designed the study. G.J-S. obtained funding for the study. A.L.D., J.K., J.A.U., D.M., R.S.M., and G.J-S. participated in data collection. J.P, A.L.D., and G.J-S. conducted the data analyses. All authors participated in preparation of the manuscript and approved the final draft for submission.

DATA SHARING

Detailed information on study data is available from the last author (Grace John-Stewart) upon request at gjohn@uw.edi

Results—Among 1271 women enrolled, median age was 22 years (interquartile range [IQR] 19–27) and gestational age was 22 weeks (IQR 18–26); most (78%) were married and had uncircumcised male partners (69%). Prevalent TV was detected in 81 women (6%) at enrolment. Among women without TV at enrolment, 112 had TV detected during 1079 person-years of follow-up (10.4 per 100 person-years). After adjustment for socio-economic factors, male partner circumcision status, pregnancy status and other STIs, TV incidence was higher during pregnancy than postpartum (22.3 vs 7.7 per 100 person-years, adjusted hazard ratio [aHR] 3.68, 95% CI 1.90–7.15, p<0.001). Women with circumcised male partners had a 58% lower risk of incident TV compared to women with uncircumcised partners (aHR 0.42, 95% CI 0.23–0.76, p=0.004). Employed women had lower risk of incident TV than unemployed women (aHR 0.49, 95% CI 0.31–0.79, p=0.003); recent STI was associated with increased TV risk (aHR 2.97, 95% CI 1.49–5.94, p=0.002).

Conclusion—TV was relatively common in this peripartum cohort. Male circumcision may confer benefits in preventing TV.

Keywords

Trichomonas vaginalis; incidence; reproductive health; female; male circumcision; peripartum period

INTRODUCTION

Trichomonas vaginalis is the most common curable sexually transmitted infection (STI) worldwide, with regional prevalence rates in women ranging from 5% in the Western Pacific to 18% in Africa.[1–5] Each year, 25 million *T. vaginalis* infections occur during pregnancy, with women in sub-Saharan Africa disproportionately affected compared to other regions.[6,7] *T. vaginalis* is associated with pelvic inflammatory disease and risk of HIV acquisition in women.[8–12] Several individual studies[13–19] and two meta-analyses[20,21] implicate *T. vaginalis* infection in poor infant outcomes including preterm birth, small-for-gestational-age, premature rupture of membranes and low birth weight.

Hormonal changes during pregnancy and postpartum may alter susceptibility to *T. vaginalis* infection or persistence of infections.[2,22] Changes in sexual behaviour may also influence *T. vaginalis* exposure during and after pregnancy. Cross-sectional studies have estimated *T. vaginalis* prevalence between 15–32% in peripartum African cohorts, and older age, younger age at sexual debut, higher education, being married and comorbid STIs have been all been associated with prevalent *T. vaginalis* infection.[23–26] In non-pregnant African women, male partner circumcision status has been associated with lower *T.* vaginalis incidence; however, this relationship has not been evaluated in pregnant and postpartum populations.[23,27] In addition, there are limited data on *T. vaginalis* incidence and cofactors among pregnant and postpartum African women.[28,29] We evaluated incidence and correlates of *T. vaginalis* among pregnant and postpartum women in Western Kenya.

METHODS

Design & participants

We used data from a longitudinal study investigating rates and cofactors of acute HIV infection among HIV-uninfected women at two rural antenatal care (ANC) clinics in Western Kenya (the Mama Salama Study) conducted between May 2011 and July 2014. Recruitment, eligibility criteria, and follow-up procedures for the parent study have been previously described.[30] Briefly, pregnant women were eligible if they were ≥14 weeks gestation, were ≥14 years old, had negative rapid HIV test at enrolment or within the 3 months prior, planned to remain in the study area for the duration of pregnancy through 9 months postpartum, were willing to have a home visit, and were not enrolled in another research study.

Ethics approval

All study procedures were approved by the Kenyatta National Hospital/University of Nairobi Ethical Research Committee (#P11/4/2010) and the University of Washington Institutional Review Board (#38472A) prior to study initiation.

Study procedures

Women attended follow-up visits during pregnancy (20, 24, 32, 36 weeks gestation) and postpartum (2, 6, 10, 14 weeks; 6 and 9 months). At each study visit, standardized questionnaires were administered by study nurses on sociodemographic factors, reproductive history, sexual behaviour, hormonal contraception and condom use, medical history and genital symptoms. Male partner characteristics were reported by participating women. Women self-collected vaginal swabs, had physical exams at each study visit and had pelvic exams at enrolment, 28 weeks gestation, 6 weeks postpartum, and 6 months postpartum. Swabs were not collected during menstruation. All women with *T. vaginalis* infection were treated with metronidazole (one dose of 2 grams) per the World Health Organization and Kenya Ministry of Health's national treatment guidelines for laboratory-confirmed genital infections in pregnancy.[w1 w2] Antimicrobials were administered at no cost as part of the study. Women were counselled to have their partner come to the study clinic for complete STI testing and treatment.[w3]

Laboratory procedures

C. trachomatis and N. gonorrhoeae were assessed at enrolment using endocervical samples for nucleic acid amplification tests (NAAT) with the APTIMA Combo 2 Assay (HOLOGIC/GEN-PROBE, Inc, San Diego, CA). Syphilis serology was based on rapid plasma reagin (RPR) tests conducted at enrolment as part of routine ANC and abstracted from maternal child health booklets, or conducted by study staff if the test was not performed. Candidiasis and bacterial vaginosis (BV) were assessed at every study visit. Candidiasis was detected by direct microscopy after addition of 10% KOH. Vaginal Gram stained slides were evaluated using Nugent's criteria, with BV defined as a score of 7–10. *T. vaginalis* was assessed at every study visit and infection was determined by detection of motile trichomonads using wet mount microscopy. All laboratory procedures were performed by study laboratory

technicians, who had received standardized training on microscopy. Quality assurance was performed monthly by comparing results in a subset of samples with an external lab. Genital symptoms for *T. vaginalis* were defined as abnormal discharge, foul odour, vaginal itching, or vaginal burning.

Statistical analysis

HIV-uninfected women with baseline *T. vaginalis* assessment and at least one reassessment of *T. vaginalis* at study follow-up were included in the analyses. Women who acquired HIV infection during the study were excluded to control for potential underlying differences in that group. Incident *T. vaginalis* was defined as a new infection detected among women who did not have prevalent *T. vaginalis* at enrolment. Timing of incident *T. vaginalis* was estimated to be at the midpoint between the pre-infection visit and the visit at which the infection was detected.

Cox proportional hazards models were used to determine correlates of time-to-first incident *T. vaginalis* infection. All models used robust standard errors. Variables associated with *T. vaginalis* (alpha = 0.10) in the univariate analyses were included in the multivariate models and were tested for collinearity. Potential correlates included sociodemographic and sexual partnership characteristics, hormonal contraception and condom use, other curable STIs (*C. trachomatis*, *N. gonorrhoeae* and syphilis), sexual behaviours, and vaginal washing or drying practices. Unprotected sex, number of sexual partners, BV, candidiasis, vaginal washing and drying, and postpartum hormonal contraception use were included as time-varying. Women were classified as hormonal contraception nonusers if no hormonal contraception was ever used, including women that did not use another form of contraception.

We conducted sensitivity analyses to reduce potential misclassification of undetected prevalent infections as incident infections due to low sensitivity of wet mount microscopy.[w4-w6] We repeated all analyses excluding women with *T. vaginalis* detected at enrolment and/or at first post-enrolment visit to evaluate whether *T. vaginalis* incidence and correlates would remain similar to our primary analyses. Data were analysed using Stata 13.1/MP for Windows (Stata Corporation, College Station, TX).

RESULTS

Overall, 1271 women (97% of women in the parent study) met criteria for inclusion for this analysis; women were excluded due to HIV infection (n=25) and lack of *T. vaginalis* results (n=8). Most women were married (78%), median age was 22 years (interquartile range [IQR] 19–27), median gestational age at enrolment was 22 weeks (IQR 16–26) and median level of highest education completed was 8 years (IQR 7–10) (Table 1). Among women with male partners, median partnership duration was 4 years (IQR 1–7) and one-third (31%) reported their male partner was circumcised. No male partners were reported to have been circumcised during follow-up. At enrolment, about half (55%) of women reported condomless sexual intercourse in the last 30 days. Bacterial vaginosis (23%) and candidiasis (25%) were the most common genital infections detected at enrolment. Other curable STIs were detected in 109 (9%) women (*C. trachomatis* 5%, *N. gonorrhoeae* 3% and syphilis 1%).

T. vaginalis prevalence and incidence

At enrolment, 81 (6%) of women had prevalent *T. vaginalis;* 16 (20%) of whom were co-infected with another curable STI. During 1079 total person-years of follow-up (median 0.9 years, IQR 0.8–1.1), 112 incident infections of *T. vaginalis* were detected (44 in pregnancy and 68 postpartum), resulting in an overall incidence of 10.4 per 100 person-years (Figure 1). Women with either prevalent or incident *T. vaginalis* infection were 3 times as likely to report genital symptoms at any time during follow up compared to women that never had *T. vaginalis* (Odds Ratio [OR] 3.08, 95% CI 1.92–4.94, p<0.001). However, symptoms were only reported by 41 (51%) women with prevalent and 9 (8%) women with incident *T. vaginalis* infections at the time of detection.

Correlates of *T. vaginalis* incidence

Incidence of *T. vaginalis* was higher in pregnancy versus postpartum (22.3 vs 7.7 per 100 person-years, respectively, p<0.001, Table 2). In unadjusted models, male circumcision (hazard ratio [HR] 0.48, 95% CI 0.29–0.81), pregnancy (HR 3.08, 95% CI 1.93–4.91), and detection of other curable STIs (HR 2.03, 95% CI 1.14–3.65) were associated with incident *T. vaginalis*. Among postpartum women, we did not detect an association between those using implant, injectable, or oral, hormonal contraception and incident *T. vaginalis* infection compared to non-users (HR 0.86, 95% CI 0.27–2.72, p=0.795; HR 0.84, 95% CI 0.34–2.09, p=0.713; HR 0.92, 95% CI 0.28–2.97, p=0.886, respectively).

In the multivariate model, risk of incident *T. vaginalis* was 3-fold higher during pregnancy compared to postpartum (adjusted hazard ratio [aHR]=3.68, 95% CI 1.90–7.15, p=<0.001) after adjusting for employment, male partner circumcision, and infection with other STIs during pregnancy. Women with circumcised male partners had a 58% lower risk of incident *T. vaginalis* compared to women with uncircumcised partners (aHR=0.42, 95% CI 0.23–0.76, p=0.004). Risk of incident *T. vaginalis* was also lower among women who were employed versus unemployed (aHR=0.49, 95% CI 0.31–0.79, p=0.003), and higher among women with other curable STIs (aHR=2.10, 95% CI 1.16–3.79, p=0.014). When non-TV STIs were individually assessed, only *N. gonorrhoeae* was significantly associated with incident *T. vaginalis* infection (aHR=2.97, 95% CI 1.49–5.94, p=0.002), though infection with *C. trachomatis* trended towards an association (aHR=1.82, 95% CI 0.90–3.69, p=0.097); syphilis was not associated with incident *T. vaginalis* (aHR=2.56, 95% CI 0.62–10.46, p=0.192).

Sensitivity analyses

In sensitivity analyses, we excluded women with *T. vaginalis* detected at enrolment and/or at first post-enrolment visit. Overall *T. vaginalis* incidence was comparable to the primary results (6.8 per 100 person-years), though incidence during pregnancy was lower (9.5 per 100 person-years) than in the primary analysis. Pregnancy and STIs remained associated with increased risk of incident *T. vaginalis* (aHR=4.97, 95% CI 2.41–10.24, p≤0.001 and aHR=2.09, 95% CI 1.04–4.22, p=0.040, respectively). Male circumcision also remained associated with reduced risk (aHR=0.42, 95% CI 0.21–0.87, p=0.019). Other cofactors were not significantly associated with incident *T. vaginalis* (data not shown).

DISCUSSION

In this prospective study of HIV-uninfected pregnant and postpartum Kenyan women, *T. vaginalis* infection was relatively common. Incidence of *T. vaginalis* during follow-up was high, with increased *T. vaginalis* incidence during pregnancy compared to the postpartum period. Infection with other STIs at enrolment was associated with increased risk of incident *T. vaginalis*. In multivariate analyses, employment and male partner circumcision were associated with a lower risk of incident *T. vaginalis*. These data suggest that there is persistent risk of *T. vaginalis* during pregnancy and postpartum, and that male circumcision is a potential modifiable factor that may decrease risk of *T. vaginalis* in this period.

Male circumcision has been associated with decreased risk of human papillomavirus, genital ulcers, herpes simplex virus 2, BV, syphilis and *T. vaginalis* in women in randomized clinical trials (RCT).[27 w7-w13] One RCT from Uganda reported a 48% reduction of *T. vaginalis* associated with male partner circumcision, similar to our findings.[27] In contrast, an observational study of HIV-uninfected women from Zimbabwe, Uganda and Thailand reported no association between male partner circumcision and incident *T. vaginalis*.[w11] Male circumcision may decrease men's risk of *T. vaginalis* infection, and, in turn, reduce the probability that female partners are exposed to *T. vaginalis.* Additionally, the moist subpreputial space in uncircumcised men may enhance survival of trichomonads; thus, foreskin removal may reduce male-to-female transmissions of *T. vaginalis*.[27 w11 w14] We are not aware of other studies examining STI acquisition and male circumcision specifically during or after pregnancy, a critical period of potential vulnerability with implications for pregnancy outcomes. Male circumcision promotion may confer benefits in preventing *T. vaginalis*. Thus, additional benefits of expanding male circumcision as a strategy to prevent HIV acquisition may include prevention of transmission of other STIs, such as *T. vaginalis*.

Our finding that other curable STIs increased risk of acquiring *T. vaginalis* infection is consistent with other studies in non-pregnant women that have found recent infection with STIs increases risk of acquiring other STIs.[w15 w16] Exposure to sexual networks where multiple STIs are prevalent could explain this relationship. Alternatively, there could be biological factors that concurrently increase susceptibility to multiple STIs. Similar to other studies, we found sociodemographic and relationship characteristics, including partner characteristics, were associated with *T. vaginalis*.[2425 w17] Women with lower socioeconomic status may have less access to STI preventative information and care or may have less power in relationships to negotiate safer sexual practices due to economic dependence on male partners.[w18] Maximal cure rates in infected women are achieved with concurrent treatment of their sexual partners.[w19] Treatment of male partners is critical to preventing reinfection with *T. vaginalis*, especially during pregnancy when prevention has immediate benefits for mothers and infants. We have previously reported results from a pilot study of patient-delivered partner treatment (PDPT) for management of *T. vaginalis*, which demonstrated acceptability and feasibility among pregnant and postpartum Kenyan women.[w3]. Further evaluation of this model will be useful in settings with high *T. vaginalis* prevalence.

Prevalence of *T. vaginalis* infection at enrolment was lower in our HIV-uninfected cohort than some previous studies in African pregnant and postpartum women (prevalence 15–

32%)[2 4 25 28 w20]. Previous studies did not exclude HIV-infected women and used a variety of *T. vaginalis* diagnostics, including more sensitive assays which may account for differences with our results. However, a recent study of HIV-uninfected, non-pregnant women from Malawi, South Africa, Uganda, and Zimbabwe reported a *T. vaginalis* prevalence of 7%, similar to our findings.[w21] Our estimate of incidence of *T. vaginalis* infection during pregnancy of 22.8 per 100 person-years was similar to another study of HIV-uninfected women in South Africa, which reported an incidence of 17.6 per 100 person-years.[28] We found increased incidence of *T. vaginalis* in pregnancy compared to postpartum. Hormonal alterations unique to pregnancy may alter susceptibility to *T. vaginalis*, similar to other infectious diseases.[2 22 w22] Among pregnant and postpartum women in other studies, 72–88% of *T. vaginalis* infections were asymptomatic, similar to our cohort in which over half of prevalent infections were asymptomatic.[2 4 28] We also found that incident infections were less frequently symptomatic which could be due to early detection as symptoms can arise up to 28 days after initial infection in women. Thus, many early *T. vaginalis* infections may go undetected and untreated in settings with exclusively syndromic management.

Our findings raise important questions about the diagnosis and management of *T. vaginalis* infection in pregnant and postpartum women in high prevalence settings particularly in areas of high HIV risk. Meta-analyses have found associations of *T. vaginalis* infection in pregnancy with premature birth, SGA, and premature rupture of membranes.[20] However, it has not been clear that treatment of *T. vaginalis* will decrease this risk. One systematic review suggested that treatment of *T. vaginalis* during pregnancy may increase incidence of preterm birth[21]; perhaps due to use of higher dosages of metronidazole than typically recommended in included studies or coinfection with other STIs.[20 25] More recent studies, including a RCT, noted no association of *T. vaginalis* infection or treatment in pregnancy with preterm birth.[25 w23 w24] In our study, women were regularly screened *for T. vaginalis* and women with confirmed *T. vaginalis* were treated with metronidazole according to national guidelines. The benefit and cost-effectiveness of routine screening for *T. vaginalis* in asymptomatic pregnant women has not been established. However, prenatal *T. vaginalis* screening and prompt treatment are recommended for HIV-infected pregnant women because *T. vaginalis* infection is a risk factor for vertical transmission of HIV. Our results suggest that *T. vaginalis* incidence is high during pregnancy and often asymptomatic, and will thus requires alternative approaches to syndromic management for adequate detection and treatment.

Our study has some limitations. We used microscopy for *T. vaginalis* detection, which is less sensitive for *T. vaginalis* detection than polymerase chain reaction (PCR) or other types of NAAT.[2 4 25 w17 w4-w6] However, this approach is similar to other studies in Africa, and is easy to contextualize given the same approach.[2 4 25 w17] While some studies from Africa have demonstrated comparable specificity of wet mount to PCR and other diagnostic methods for *T. vaginalis*,[w25] lower sensitivity would result in underestimates of prevalence and incidence in our cohort. We did conduct exploratory analyses to estimate the potential impact of misclassifying undetected prevalent infections, and results were similar in both analyses. We relied on women's report of male partner circumcision status, which may have introduced exposure misclassification based on the accuracy of women's report. While studies from Zambia and Swaziland suggest that women overestimate male partner circumcision,[w26]

recent data from Uganda, a setting with male circumcision sensitization programs more similar to Western Kenya, suggest <10% of women misreport male partner circumcision status.[w27] Therefore, misreporting likely did not substantially influence our results. Finally, other curable STIs were only assessed at baseline and we were unable to evaluate the relationship of incident STIs on *T. vaginalis.*

In summary, our results suggest that pregnant and postpartum women frequently acquire *T. vaginalis* and most infections are asymptomatic, supporting scale-up of improved diagnostic techniques for *T. vaginalis* infections in this group.[28] We found male circumcision was associated with reduced *T. vaginalis* incidence, adding to the body of evidence that male circumcision prevents STIs in female partners. Our results suggest that male circumcision could reduce *T. vaginalis* incidence and related sequelae among pregnant and postpartum female partners. Improved *T. vaginalis* control through detection of asymptomatic infections and reduced male-to-female transmissions could have important implications, particularly in settings of high STI morbidity and where poor birth outcomes persist as a public health problem.

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KEY MESSAGES

- Pregnant and postpartum women frequently acquire *T. vaginalis* and most infections are asymptomatic
- Male circumcision could reduce *T. vaginalis* incidence among pregnant and postpartum female partners.

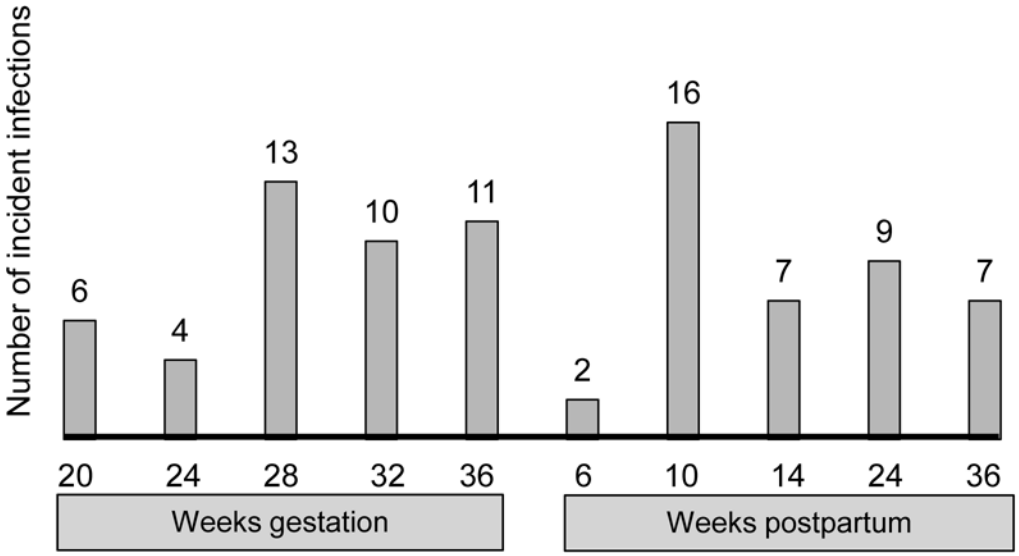

Figure 1.
Timing of detection of incident TV infection during pregnancy and postpartum

Table 1

Characteristics of study population[1]

	N (Percentage) or Median (Interquartile range)	
Characteristic	**All women n=1271**	
Demographic		
Age (years)	22	(19–27)
Highest level of education (years)	8	(7–10)
≤8 years of completed education	813	(64%)
Currently married	997	(78%)
Duration of partnership (years)[2]	4	(1–7)
Partner ≥10 years older[2]	181	(18%)
Employed	557	(44%)
Crowding (≥3 people/room)	414	(33%)
Sexual behaviour and partner characteristics		
Number of sexual acts (last 30 days)	1	(0–4)
Any reported condomless sex (last 30 days)	690	(55%)
Number of sexual partners (last 30 days)	1	(1–1)
Circumcised male partner[2,3]	353	(31%)
HIV-infected partner[2,3]	17	(2%)
Gynaecological history		
Number of children	2	(1–3)
<2 years since last birth[4]	164	(19%)
Any reported vaginal washing (last week)	762	(60%)
Any reported vaginal drying (last week)	224	(18%)
Self-reported history of STIs	81	(6%)
Postpartum hormonal contraceptive use[5]		
Implant	114	(9%)
Injectable	181	(15%)
Oral	49	(4%)
None	901	(72%)
STI diagnosis		
Trichomonas vaginalis	81	(6%)
Non-TV curable STIs[6]	85	(9%)
Chlamydia trachomatis	70	(6%)
Neisseria gonorrhoeae	31	(2%)
Syphilis	10	(1%)
Bacterial vaginosis	288	(23%)
Candidiasis	312	(25%)

[1] Missing data not shown all characteristics assessed at baseline unless indicated

[2] Among women reporting current relationship

[3] Male circumcision and HIV status of male partners reported by female partner

[4] Among women with ≥1 children

[5] Among postpartum women only; current use at 9 months postpartum

[6] Includes *Chlamydia trachomatis, Neisseria gonorrhoeae* and syphilis

Table 2

Correlates of time-to-first incident *Trichomonas vaginalis*[1]

Characteristic	*T. vaginalis* infections/Person-years	Incidence (per 100 person-years)	Univariate Analysis		Multivariate Analysis	
			HR (95% CI)	p-value	Adj HR (95% CI)	p-value[2]
Overall	112/1078.9	10.4 (8.6–12.5)				
Demographic						
Age (years)						
≤21	58/497.7	11.7 (9.0–15.1)	1.28 (0.89–1.86)	0.189		
>21	54/581.2	9.3 (7.1–12.1)	ref			
Level of education (years)						
≤8	77/666.0	11.6 (9.2–14.5)	1.36 (0.91–2.01)	0.133		
>8	35/412.9	8.5 (6.1–11.8)	ref			
Current marital status						
Married	87/857.5	10.1 (8.2–12.5)	0.88 (0.56–1.38)	0.577		
Unmarried	25/221.3	11.3 (7.6–16.7)	ref			
Duration of partnership (years)[3]						
≤1	30/270.1	11.1 (7.7–15.9)	1.14 (0.74–1.75)	0.544		
>1	67/686.2	9.8 (7.7–12.4)	ref			
Partner age[3] (years older)						
≥10	16/149.0	10.7 (6.6–17.5)	1.02 (0.59–1.75)	0.954		
<10	76/732.7	10.4 (8.3–13.0)	ref			
Employment status						
Employed	40/483.2	8.3 (6.1–11.3)	0.69 (0.47–1.02)	0.060	**0.49 (0.31–0.79)**	**0.003**
Unemployed	72/595.7	12.1 (9.6–15.2)	ref			
Crowding living conditions (people/room)						
≥3	41/335.7	12.2 (9.0–16.6)	1.26 (0.86–1.824)	0.243		
<3	71/742.0	9.6 (7.6–12.1)	ref			
Sexual behavior						
Reported condomless sex (last month)						

Characteristic	*T. vaginalis* infections/Person-years	Incidence (per 100 person-years)	Univariate Analysis		Multivariate Analysis	
			HR (95% CI)	p-value	Adj HR (95% CI)	p-value[2]
Any	52/507.8	10.2 (7.8–13.4)	1.14 (0.77–1.68)	0.517		
None	60/565.4	10.6 (8.2–13.7)	ref			
Number of sexual partners (last month)						
>1	1/3.2	31.2 (4.4–221.4)	1.29 (0.52–22.98)	0.196		
≤1	111/1075.3	10.3 (8.6–12.4)	ref			
Male partner circumcision status[4]						
Circumcised	18/316.4	5.7 (3.6–9.0)	0.48 (0.29–0.81)	0.006	**0.42 (0.23–0.76)**	**0.004***
Uncircumcised	80/657.6	12.2 (9.8–15.1)	ref			
Male partner HIV status[4]						
HIV-infected	1/13.7	7.3 (1.0–51.9)	0.82 (0.12–5.61)	0.840		
HIV-uninfected	65/718.6	9.0 (7.1–11.5)	ref			
Gynaecological history						
Pregnancy status						
Pregnant	44/197.5	22.3 (16.6–29.9)	3.08 (1.93–4.91)	<0.001	**3.68 (1.90–7.15)**	**<0.001***
Postpartum	68/881.3	7.7 (6.1–9.8)	ref			
Number of living children						
≥3	24/243.8	9.8 (6.6–14.7)	1.04 (0.64–1.70)	0.873		
<3	47/504.5	9.3 (7.0–12.4)	ref			
Time since previous birth (years)[5]						
<2	13/137.2	9.5 (5.5–16.3)	1.10 (0.60–2.03)	0.749		
≥2	56/583.9	9.6 (7.4–12.4)	ref			
Reported vaginal washing (last week)						
Any	65/641.9	10.1 (7.9–12.9)	0.90 (0.62–1.31)	0.595		
None	47/435.3	10.8 (8.1–14.4)	ref			
Reported vaginal drying (last week)						
Any	15/106.5	14.0 (8.5–23.4)	1.22 (0.70–2.12)	0.482		
None	97/972.1	100 (8.2–12.2)	ref			
Self-reported history of STIs						
Any	9/68.7	13.1 (6.8–25.2)	1.30 (0.66–2.59)	0.448		

Characteristic	*T. vaginalis* infections/Person-years	Incidence (per 100 person-years)	Univariate Analysis		Multivariate Analysis	
			HR (95% CI)	p-value	Adj HR (95% CI)	p-value[2]
None	103/1010.2	10.2 (8.4–12.4)	ref			
Hormonal contraceptive use[6]						
Implant	3/50.8	5.9 (1.9–18.3)	0.86 (0.27–2.72)	0.795		
Injectable	5/74.9	6.7 (2.8–16.0)	0.84 (0.34–2.09)	0.713		
Oral	3/38.2	7.9 (2.5–24.4)	0.92 (0.28–2.97)	0.886		
None	57/717.4	7.9 (6.1–10.3)	ref			
STI diagnoses[7]						
Non-TV curable STI [8]						
Yes	13/63.3	20.5 (11.9–35.3)	2.03 (1.14–3.65)	0.017	**2.10 (1.16–3.79)**	**0.014***
No	78/778.0	10.0 (8.0–12.5)	ref			
Chlamydia trachomatis						
Yes	9/54.4	16.5 (8.6–31.8)	1.70 (0.87–3.30)	0.119		
No	103/1022.9	10.1 (8.3–12.2)	ref			
Neisseria gonorrhoeae						
Yes	7/23.0	30.4 (14.5–63.8)	2.90 (1.38–6.09)	0.005		
No	105/1054.3	9.96 (8.2–12.1)	ref			
Syphilis						
Yes	2/6.6	30.3 (7.6–121.0)	2.68 (0.64–11.3)	0.179		
No	89/834.8	10.6 (8.7–13.1)	ref			
Current bacterial vaginosis						
Yes	36/235.7	15.3 (11.0–21.2)	1.21 (0.82–1.79)	0.339		
No	75/572.0	13.1 (10.5–16.4)	ref			
Current candidiasis						
Yes	15/101.5	14.8 (8.9–24.5)	0.95 (0.55–1.64)	0.864		
No	97/711.3	13.6 (11.2–16.6)	ref			

HR = hazards ratio; Adj HR = adjusted hazards ratio; 95% CI = 95% confidence interval

[1]Missing data not shown, all correlates assessed at enrolment unless indicated

[2]Cox proportional hazards p-value adjusted for employment, male partner circumcision status, pregnancy status and other non-TV curable STIs detected at enrolment

[3] Among women reporting current relationship

[4] Male circumcision and HIV status of male partners reported by female partner

[5] Among women with ≥1 children

[6] Among postpartum women only

[7] *Chlamydia trachomatis, Neisseria gonorrhoeae* and syphilis were assessed enrolment only. Bacterial vaginosis and candidiasis were assessed at enrolment and at follow up visits during pregnancy

[8] Includes *Chlamydia trachomatis, Neisseria gonorrhoeae* and syphilis