Published in final edited form as:

Int J STD AIDS. 2020 February ; 31(2): 127–135. doi:10.1177/0956462419886228.

Sexually transmitted infections and sexual behaviors of men who have sex with men in an American Deep South PrEP clinic

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Abstract

HIV pre-exposure prophylaxis (PrEP) effectively prevents HIV acquisition among men who have sex with men (MSM), but PrEP uptake has been associated with sexually transmitted infections (STIs). The effect of PrEP on STIs in MSM in the Deep South of the United States is unknown. We performed a retrospective analysis of adult MSM at an American Deep South PrEP clinic to calculate the prevalence and incidence rate of bacterial STIs (chlamydia, gonorrhea, and syphilis) and identify associated risk factors by linking incident STI to patient-reported outcomes; 139 MSM accessed the clinic between 2014 and 2018 with baseline bacterial STI prevalence of 11%. Twenty-six of 81 eligible MSM on PrEP had incident STIs with an incidence rate of 33.1 cases per 100 person-years. Significantly higher proportions of high PrEP adherence, multiple sexual partners, and inconsistent condom use were seen in those with incident STI, and we identified MSM with both high PrEP adherence and multiple sexual partners as being at especially high risk for bacterial STIs (hazard ratio: 7.57, 95% confidence interval: 1.75–32.74). Bacterial STIs are common after initiating PrEP in this clinic, and MSM reporting high PrEP adherence and multiple sexual partners have a significant risk for incident STI. Highrisk sexual behaviors persisted after starting PrEP, highlighting the importance of ongoing, intensive sexual health screening and interventions.

Short Summary

HIV and bacterial sexually transmitted infections (STIs) disproportionately affect men who have sex with men (MSM) in the American Deep South. We found a high incidence among MSM after starting PrEP and identified MSM with high PrEP adherence and multiple sexual partners as

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RMG, CAM, and EFE designed the study. AOW assisted with data analysis and interpretation. KK and ETO assisted with data collection and oversight. RMG, CAM, and EFE wrote and revised the manuscript. All authors reviewed the manuscript and approved prior to submission.

Declaration of conflicting interests

The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: CAM is a consultant for Lupin Pharmaceuticals and BioFire Diagnostics and has received honoraria from Roche Diagnostics. RMG, AOW, and KK have no conflicts of interest to report.

highest risk for STI. Our findings signal a need for intensive, targeted sexual health counseling and intervention to curb the rise in STIs.

Keywords

Pre-exposure prophylaxis; sexually transmitted infections; HIV prevention; health risk behaviors; medication adherence; condoms

Introduction

Sexually transmitted infection (STI) incidence has been increasing in recent years, most notably among men who have sex with men (MSM). In the Deep South of the United States (a sub-region of the Centers for Disease Control and Prevention [CDC]-defined South region), both HIV and STI rates are higher than in other regions, and the South has the highest rates of Chlamydia and gonorrhea.^{1,2} These data are alarming given that STIs, particularly rectal gonorrhea and Chlamydia and syphilis, have been independently associated with incident HIV infection in MSM.^{3,4} Fortunately, pre-exposure prophylaxis (PrEP) effectively prevents HIV if taken consistently (i.e. greater than four doses weekly).⁵ For this reason, PrEP is recommended by the CDC for MSM at risk for HIV and other susceptible groups.⁶ There is a concern, however, that PrEP use will lead to changes in sexual behaviors (i.e. such as increased condomless anal sex and/or number of sexual partners) and increased STI acquisition when HIV acquisition risk is perceived to be low.⁷ Although post hoc analysis of early PrEP clinical trials failed to identify evidence of risk compensation, there are concerns about increasing sexual risk behavior in real-world, clinical settings based on increasing rates of STIs among MSM in regions with high PrEP uptake.^{8,9} Additionally, STI diagnoses have been associated with changes in sexual behaviors, such as decreases in condom use.^{9–11} Traeger et al. reported a high incidence rate and significant increase in STIs, particularly rectal STIs, after PrEP initiation among a large cohort of MSM.^{12,13} STIs among MSM on PrEP increased in more recent studies, which suggests that, as PrEP use becomes more mainstream, STIs among PrEP users will increase with declining concern for HIV acquisition.¹² Because PrEP uptake has not been as robust in the Deep South as in other parts of the United States, there are limited data examining the relationship of PrEP uptake, sexual risk behaviors, adherence, and STIs among MSM in the South.¹⁴

In this study, we aimed to determine the prevalence and incidence of bacterial STIs (Chlamydia, gonorrhea, and syphilis) among a cohort of MSM at university-based PrEP clinic in Birmingham, AL, USA, as well as the risk factors associated with STIs to determine if sexual behaviors contributed to incident STI. We hypothesized that bacterial STIs would be common among this at-risk group of men at baseline and that the incidence rate of bacterial STIs would be high after starting PrEP.

Methods

This retrospective analysis included only adult MSM aged 17 to 67 years receiving care at a university-affiliated PrEP clinic in Birmingham, AL, between 2014 and 2018. PrEP clinic

clients attended quarterly visits with HIV screening at each visit (initial screen: Architect HIV-1/2 Ag/Ab Assay, Abbott, Chicago, IL; follow-up: Determine HIV-1/2 Ag/Ab Assay, Abbott, Chicago, IL) and bacterial STI screening at initial visit and every six months subsequently by nucleic acid amplification testing of urine, rectum, and oropharynx for Chlamydia and gonorrhea (BD Viper Qx Assay, Becton Dickinson, Sparks, MD) plus syphilis by the traditional screening algorithm.¹⁵ Additionally, at the initial and follow-up visits, each clinic attendee completed patient-reported outcome (PRO) questionnaires related to sexual behaviors such as frequency of condom use with anal sex ('all of the time', 'most of the time', 'some of the time', or 'never') and sexual partner number within the last three months. PrEP adherence was queried at follow-up visits. We assessed adherence by asking when the client last missed a dose of PrEP ('Not taking currently', 'within the last week', 'one week ago', 'two weeks ago', 'more than two weeks', or 'never skip medications'); there currently is not a single best validated measure for self-reported PrEP adherence, but self-report has been validated when compared to dried blood spots.^{16–18} Using STI screening at the initial visit, we calculated the bacterial STI prevalence at first PrEP clinic visit. MSM diagnosed with an STI at PrEP clinic entry were excluded from the primary incident STI analysis but later included in a sensitivity analysis. Demographic and socioeconomic factors were collected for all PrEP clinic attendees.

For individuals diagnosed with an incident bacterial STI after starting PrEP, PROs at the time of the first positive STI result (within 120days) were linked to the incident STI diagnosis. For individuals with no STI diagnosis, the PRO closest to the most recent negative STI result (within 120days) was used. The significant majority of clients had an STI result and PRO on the same day. Clients were also assessed for symptoms of acute HIV infection, counseled on safe sex practices, and offered condoms at each visit. For this analysis, we categorized behavior variables as follows: sexual partner number as zero or one partner versus multiple partners in the last threemonths; condom use with anal sex as consistent, inconsistent, or NA (no anal sex); and higher adherence or lower adherence to PrEP. The term 'consistent condom use' meant anal sex with condom use 'all of the time' within the prior three months; 'inconsistent condom use' meant any anal sex with condom use described as 'never, some of the time, or most of the time' within the prior three months. The three levels of condom use allow for more detailed examination of incident STIs that occur outside the context of anal sex, e.g. a urethral or oropharyngeal STI. Higher adherence meant last missed PrEP dose was two or more weeks ago, and lower adherence meant last missed PrEP dose within the last two weeks. Effective HIV prevention depends on adequate PrEP adherence; among MSM at risk of HIV acquisition by sexual exposure, at least four doses of PrEP per week is adequate.^{19,20} This cutoff for categorizing adherence was used to go beyond adequately protective dosing and to also include individuals who self-reported as recently very adherent; this was compared to other individuals that may have lower adherence (including individuals with missed doses that could put them at risk for HIV acquisition, i.e. less than four doses per week).

Incident bacterial STI was the outcome of interest. We calculated the bacterial STI incident rate per 100 person-years with exact Poisson 95% confidence intervals (CIs). The follow-up period was defined as time from the initial PrEP clinic visit to either incident STI or time from the initial PrEP clinic visit to most recent negative STI result. To test differences

between MSM with incident STI and those without incident STI, a Chi square test was used for categorical variables and the Wilcoxon rank-sum test was used for non-parametric continuous values such as age. Cumulative incidence plots for time to incident STI were produced. Cox proportional hazard regression models were fit to identify demographics, sexual risk behaviors, and PrEP adherence factors associated with time to incident bacterial STI. The predictors included in this model were chosen *a priori* based on literature review and clinician researcher experience. Additionally, PRO variables were also treated as time-varying covariates. Because of the particular interest in the relationship between PrEP adherence and sexual risk behaviors with incident bacterial STIs, a model including an interaction term between PrEP adherence (higher vs. lower) and number of sexual partners (0/1 vs. multiple) was fit. Hazard ratios (HRs) and corresponding 95% CIs are reported. A sensitivity analysis was performed including individuals excluded from the primary incidence analysis because of baseline STI diagnosis. Those individuals were excluded from the primary analysis because they did not have negative STI results to enter the survival analysis. Although transgender individuals were not excluded from our study, there were no transgender individuals receiving care in our clinic over the study period. All analyses were completed using SAS v9.4. The University of Alabama at Birmingham (UAB) Institutional Review Board approved this study (protocol #: IRB-300001538).

Results

One hundred thirty-nine MSM attended the PrEP clinic from 2014 and 2018. Fifteen of the 139 MSM who attended an initial visit at the clinic had a bacterial STI diagnosed on initial screen (i.e. prevalent at baseline) and were removed from the incident bacterial STI analysis. The baseline bacterial STI prevalence was 11%. Table 1 shows demographic and sexual behavior data at baseline for all MSM who had at least an initial visit at the PrEP clinic. The median age of MSM at their initial visit to the clinic was 32years (17–68 years); 27% were black, and 92% were insured. At initial visit, 73% reported multiple partners in the prior threemonths, and 66% reported inconsistent condom use with anal sex in the prior threemonths.

After exclusion of baseline STIs and examination of MSM with follow-up data (at least one follow-up visit with an STI result and PRO data), 81 eligible MSM were identified (Figure 1); of these, 26 clients had an incident bacterial STI diagnosis after starting PrEP. The bacterial STI incidence rate among PrEP users was 33.1 per 100 person-years through 78.5years of follow-up. The 26 clients with incident STIs included 15 cases of gonorrhea, 13 cases of Chlamydia, and 4 cases of syphilis. The median age among those with incident STI was 32 (range: 18–60) and those without incident STI was 32 (range: 20–65).

Of total MSM on PrEP (n=81), 67% had multiple sex partners, 65% reported inconsistent condom use, and 71% reported not missing a PrEP dose in the last two weeks or longer. Table 2 compares the demographics, insurance status, sexual behaviors, and PrEP adherence between MSM who had an incident bacterial STI and MSM who did not. Of those who had an incident STI, 88% of the MSM reported not missing a dose of PrEP within the last two weeks or longer; comparatively, only 63% of those MSM without an STI reported not missing a dose within the last two weeks or longer (p=0.03). Additionally, in the incident

STI group, 85% had multiple sex partners and 83% used condoms inconsistently compared to 58% and 56%, respectively, in the STI-negative group ($p=0.02$ and $p=0.04$).

Among those 26 MSM with incident STI, the median time to incident bacterial STI diagnosis was 218 days. Figure 2 shows cumulative incidence plots for the overall population as well as for PrEP adherence, multiple sexual partners, and condom use with anal sex. Time to incident STI for multiple sexual partners reached statistical significance, and inconsistent condom use and higher adherence showed marginally significant different times to incident STI.

In the univariate Cox proportional hazard model (Table 3), having multiple sex partners was significantly associated with incident STI (HR: 4.82, 95% CI: 1.65–14.10). Additionally, adherence measured as not missing a dose of PrEP in the last two weeks or longer had a large effect with HR 3.05 (95% CI: 0.91–10.22), although this did not reach statistical significance. Age, race, and insurance status did not meet statistical significance. In the time-varying proportional hazard model, adherence, sexual partner number, and inconsistent use all had a large effect size, but these variables did not meet statistical significance. All variables included in the models met the proportional hazard assumption.

The interaction model (Table 4) comparing adherence (higher adherence or lower adherence) and sexual partner number (0–1 partner vs. multiple partners) showed significantly increased risk for incident STI among MSM who were more adherent to PrEP (last missed dose >2 weeks ago) with multiple partners. Condomless anal sex was not significantly associated with STI in the univariate analysis, so it was not included in the interaction model. MSM with higher adherence had a higher hazard of incident STI (HR: 7.50, 95% CI: 1.00–56.09) with multiple partners than compared to those more adherent MSM with only zero or one partner (HR: 0.47, 95% CI: 0.07–3.36). Similarly, MSM with multiple partners who had higher adherence had higher hazard of incident STI (HR: 7.57, 95% CI: 1.75–32.74) when compared to less adherent MSM with multiple partners (HR: 0.48, 95% CI: 0.04–5.25).

Of the 15 excluded initially, 7 of these individuals were included in the sensitivity analysis, which increased the number included in the incidence analysis to 88. For these seven individuals, the time of their first negative STI result was used as time zero for the HR calculation. Two of the additional seven had incident STI diagnoses, which increased the number of individuals with incident STI diagnoses to 28. The remaining 8 of the 15 were not included in the sensitivity analysis due to insufficient follow-up data (i.e. no follow-up clinic visit, PRO data, or STI result). Multivariable results were similar to the primary analysis and are included in Tables 3 and 4. There were no HIV seroconversions during the study period.

Discussion

In a university-affiliated PrEP clinic in the Deep South of the United States, we found a high number of bacterial STIs (Chlamydia, gonorrhea, and syphilis) at baseline among MSM accessing the clinic. After excluding baseline infections, we found a high bacterial STI incidence rate among MSM on PrEP. The high incidence rate demonstrates that bacterial STIs are very common after starting PrEP, which raises concern that PrEP use may

contribute to STI acquisition in a real-world clinic setting. Gonorrhea and Chlamydia both had higher prevalence and incidence rates when compared to syphilis in our clinic, which reflects national and regional trends.^{1,21} High bacterial STI incidence rates are common among MSM on PrEP and particularly in regions of high uptake.^{11,22} The limited data on STIs in Southern US PrEP clients shows similar rates of incident bacterial STIs.^{21,23} These data show that bacterial STIs are also a significant problem among MSM on PrEP in the Deep South.

Although new HIV and STI diagnoses disproportionately affect younger MSM of color,^{1,24} there was no difference in age, race, or insurance status among those with and without incident STI in this study. However, these at-risk, young MSM of color were a minority in this study population, reflecting the disparities seen in PrEP uptake in the Deep South.¹⁴ More significantly, the comparison between those with and without incident STI demonstrated behavioral differences: clients with incident STI after starting PrEP were more adherent to PrEP, were more likely to have multiple partners, and used condoms inconsistently. In the regression model, multiple partners showed significant association with incident STI. Although adherence and inconsistent condom use did not reach statistical significance, a high effect size was seen. Intuitively, higher sexual partner number and inconsistent condom use may predispose to more STIs, but better adherence usually suggests better outcomes, e.g. persons living with HIV and antiretroviral adherence. Thus, in this clinical setting, a higher proportion of MSM with more adherence to PrEP seen in the incident STI group may be at higher risk for STI acquisition.

As higher PrEP adherence among MSM with multiple partners was associated with nearly eight-fold increased risk for incident STI in the interaction model, this demonstrates that PrEP clients who are more adherent to PrEP are still at risk of STI acquisition. Although the CIs in the interaction model were wide, adherence and multiple partners interacted and were associated with incident STI. Despite the counseling and support provided as part of routine PrEP care, adherent PrEP clients are still participating in high-risk sexual activity and experiencing adverse sexual health outcomes.⁶ One explanation for our findings is that clients are aware of their HIV risk and as such are more likely to take PrEP consistently to reduce HIV acquisition, but they may not be aware of or even minimize their risk of other STIs. Alternatively, PrEP adherence may enable participants to participate in sexual behaviors under the assumption that they are protected from infection, or perhaps they are aware that their behaviors may lead to infection and are more adherent to PrEP for HIV risk reduction. Fortunately, there were no HIV seroconversions in this study, a surrogate indicator for adequate adherence to PrEP. Because higher adherence and multiple partners may interact to increase incident STI risk more so, we must identify persons with these reported behaviors and equip them with comprehensive sexual health education as we would similarly do for less adherent and/or less engaged clients. For example, perhaps we should spend more time counseling adherent clients on the broad implications of STIs: reproductive health outcomes, morbidity, and mortality as well as economic costs and public health burden.¹

Whether diagnosed with incident STI or not, the majority of MSM on PrEP reported multiple sexual partners or inconsistent condom use both at baseline, initial visit, and after

starting PrEP. Additionally, having multiple sex partners was significantly associated with incident bacterial STI. At baseline, this cohort has a high risk for HIV acquisition, and by engaging with the PrEP clinic, they have taken steps to mitigate this risk. However, behaviors that place these MSM at risk for both HIV and STI acquisition persist after starting PrEP, and, even though HIV risk may be reduced, risk for STI acquisition persists.

Inherent to analyses of PRO data is the selection bias of clients who attend their clinic visits, excluding more vulnerable populations who may represent a hidden epidemic of STIs among MSM not engaged in care. Similarly, a majority of the clients in this analysis were insured, which limits the generalizability of results to populations with restricted access to care who likely have disparate sexual health outcomes and risk behaviors. Additionally, PROs have been associated with overreporting of PrEP adherence in young MSM and underreporting of sexual behaviors,^{25–27} which may be the reason for positive HR seen in zero reported partners in the multivariable model. Although this study had relatively small sample size and was from a single university center, which may not reflect community-based practices, the sexual health outcomes of this real-world PrEP cohort may inform PrEP care and sexual health of MSM in the Deep South. There was a significant loss to follow-up and non-persistence after the initial clinic visit such that 43 individuals were not included in the incidence analysis. There were no transgender persons receiving PrEP care during the study period, which limits the generalizability of this study to the transgender population. The CIs in the interaction model are wide and may limit their interpretation, but the statistically significant positive results indicate that multiple partners and higher adherence as risk factors may interact to be associated with incident STI. Because we used categorical variables for condom usage ('inconsistent' vs. 'consistent'), there are some changes within the inconsistent usage group that may have been inadequately quantified. This might underestimate the actual risk behavior changes after starting PrEP. The sensitivity analysis included individuals excluded from the primary analysis, and the results demonstrated the robustness of the initial analysis.

In summary, MSM in a real-world American Deep South PrEP cohort had high incident rates for bacterial STI after starting PrEP. We identified MSM who report higher adherence and high partner number as a phenotype whose behaviors may be at higher risk for acquiring STIs. Our results suggest a need for more frequent STI screening for MSM on PrEP. Following our analysis, we increased our clinic protocol from STI screening every six months, which is currently recommended by CDC, to every three months in order to more rapidly identify those with incident STI.⁶ This practice is supported by recently updated guidelines from the International Antiviral Society-USA (IAS-USA) group which supports STI screening in MSM on PrEP every three months.²⁸ Furthermore, at-risk groups of MSM reporting higher PrEP adherence, multiple sexual partners, and inconsistent condom use following PrEP initiation should be closely monitored and managed with frequent STI testing and intensive sexual health counseling, such as dedicated, condom-affirming counseling in order to prevent widening sexual health disparities among MSM in the Southern US.^{29,30} This study highlights the need for ongoing STI screening and prevention models to reduce the economic and public health burden of STIs among MSM on PrEP in the Deep South.

Acknowledgements

The authors would like to thank the laboratory of Barbara Van der Pol, PhD, MPH, for performing the STI testing for the UAB PrEP clinic. The authors also wish to acknowledge Jeanne Marrazzo, MD, MPH, and Michael Mugavero, MD, MHS, for their guidance and mentorship throughout this study.

Funding

The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the University of Alabama Birmingham Walter B. Frommeyer Jr. Fellowship in Investigative Medicine Award and by the University of Alabama at Birmingham Center for AIDS Research [CFAR P30 AI0277067]. RMG is supported by Agency for Healthcare Research and Quality training grant to the University of Alabama at Birmingham (2T32HS013852-16). ETO receives research funding through his institution from Gilead. EFE has received research support from the Agency for Health Research and Quality (AHRQ K12HS023009), the Bristol Myers Squibb Virology Fellowship, the Gilead HIV Research Scholarship, and Viiv.

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Figure 1.
Flow diagram showing subject selection for primary analysis.

Figure 2.

Cumulative incidence plots for time to incident STI: top left: overall, top right: adherence (light shade line: >2 weeks from last missed dose, dark shade line: 0–2 weeks from last missed dose), bottom left: multiple sex partners (light shade line: >1 partner, dark shade line: 0–1 partner), bottom right: condom use with anal sex (light shade: inconsistent, dashed: no anal sex, dark shade line: consistent).

Table 1.

Initial visit characteristics of all MSM accessing PrEP clinic.

	Overall n (%) n = 139
Age, median in years (range)	32 (17–68)
Age category, years	
18–24	34 (24%)
25–34	85 (37%)
35 +	139 (39%)
Race	
Black	39 (27%)
White	91 (65%)
Other	11 (8%)
Insurance	
Yes	126 (92%)
No	11 (8%)
Sexual partner number	
0–1 partners	35 (27%)
>1	96 (73%)
Condom use with anal sex	
Consistent	25 (20%)
Inconsistent	85 (66%)
N/A	18 (14%)

Note: Missing value counts: insurance 2, sexual partner number 8, and condom use 11. N/A: no anal sex.

Table 2.

Comparison of MSM with incident STI to those with no STI.

	No STI (n = 55) N (%)	Incident STI (n = 26) N (%)	Chi square p value
Age, median in years (range)	32 (18–60)	32 (20–65)	
Age category, years			
18–24	11 (20)	8 (31)	p = 0.49
25–34	21 (38)	10 (38)	
35+	23 (42)	8 (31)	
Race			
Black	17 (31)	5 (19)	p = 0.50
White	33 (60)	19 (73)	
Other	5 (9)	2 (8)	
Insurance			
Yes	52 (95)	24 (92)	p = 0.70
No	3 (5)	2 (8)	
Adherence			
Less adherent	18 (37)	3 (12)	p = 0.02
More adherent	30 (63)	22 (88)	
Sexual partner number			
0–1 partners	22 (42)	4 (15)	p = 0.02
>1	30 (58)	22 (85)	
Condom use with anal sex			
Consistent	13 (25)	1 (4)	p = 0.04
Inconsistent	29 (56)	20 (83)	
N/A	10 (19)	3 (13)	

Note: missing value counts: adherence 8, sexual partner number 3, and condom use 5. N/A: no anal sex; STI: sexually transmitted infection.

Table 3.

Univariate cox proportional hazard analysis.

	Primary analysis		Sensitivity analysis	
	HR (95% CI)	p value	HR (95% CI)	p value
Age, years				
18–24	1.95 (0.73–5.23)	0.18	1.80 (0.69–4.69)	0.23
25–34	1.56 (0.61–4.0)	0.35	1.30 (0.53–3.16)	0.56
35+	Referent			
Race				
Black	0.52 (0.19–1.39)	0.19	0.46 (0.17–1.22)	0.12
White	Referent			
Other	0.82 (0.19–3.5)	0.79	0.73 (0.17–3.14)	0.68
Insurance				
Yes	Referent			
No	1.28 (0.30–5.47)	0.74	1.62 (0.49–5.39)	0.43
Adherence				
Less adherent	Referent			
More adherent	3.05 (0.91–10.22)	0.07	3.51 (1.06–11.67)	0.04
Sexual partner number				
0–1	Referent			
>1	4.82 (1.65–14.10)	0.004	4.73 (1.63–13.72)	0.004
Condom use with anal sex				
Consistent	Referent			
Inconsistent	5.28 (0.71–39.58)	0.11	5.15 (0.69–38.40)	0.11
N/A	2.11 (0.22–29.39)	0.52	1.96 (0.20–18.95)	0.56

CI: confidence interval; HR: hazard ratio; N/A: no anal sex.

Table 4.

Interaction model comparing adherence and multiple sexual partners.

	Primary analysis		Sensitivity analysis	
	HR (95% CI)	p value	HR (95% CI)	p value
More adherent vs. less adherent (among patients with 0–1 partners)	0.47 (0.07–3.36)	0.45	0.51 (0.07–3.62)	0.50
More adherent vs. less adherent (among patients with multiple partners)	7.50 (1.00–56.09)	0.05	8.72 (1.17–64.94)	0.03
Multiple partners vs. 0–1 partners (among less adherent patients)	0.47 (0.04–5.25)	0.54	0.44 (0.04–4.81)	0.50
Multiple partners vs. 0–1 partners (among more adherent patients)	7.57 (1.75–32.74)	0.01	7.47 (1.74–32.17)	0.01

CI: confidence interval; HR: hazard ratio.