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Biomarker evaluation of self-reported condom use among women in HIV-discordant couples

F Mose, BSc^{*,}, LP Newman, MHS^{†,**}, R Njunguna, BSc^{*}, H Tamoooh, MB, ChB[‡], G John-Stewart, MD, PhD[§], C Farquhar, MD, MPH[§], and J Kiarie, MB, ChB, MPH[‡]**

^{*}Institute of Tropical and Infectious Diseases, University of Nairobi, Nairobi, Kenya

[†]Department of Epidemiology, University of Washington, Seattle, WA, USA

[‡]Department of Obstetrics and Gynaecology, University of Nairobi, Nairobi, Kenya

[§]Department of Epidemiology, Department of Medicine, and Department of Global Health, University of Washington, Seattle, WA, USA

Summary

Self-reported condom use is a commonly collected statistic, yet its use in research studies may be inaccurate. We evaluated this statistic among women in HIV-discordant couples enrolled in a clinical trial in Nairobi, Kenya. Vaginal swabs were acquired from 125 women and tested for prostate-specific antigen (PSA), a biomarker for semen exposure, using an enzyme-linked immunosorbent assay. Ten (10%) of 98 women who reported 100% use of condoms in the previous month tested PSA positive. In a bivariate logistic regression analysis, among women who reported 100% condom use in the previous month, those with ≥ 8 years of school had significantly higher odds of testing PSA-positive (odds ratio [OR] = 8.39, 95% confidence interval [CI] 1.02–69.13) than women with more schooling. Our estimate may be conservative, as the ability to detect PSA may be limited to 24–48 hours after exposure. Less educated women may be a target group for counselling regarding reporting sexual behaviour in clinical trials.

Keywords

HIV; AIDS; transmission; prevention; condom use; self-reported; semen exposure; biomarker; prostate-specific antigen; PSA; women; discordant couples; sexual behaviour

INTRODUCTION

Self-reported condom use is a commonly collected statistic in research studies. It is especially pertinent in analyses of behaviour and sexually transmitted infections. However, self-reported sexual behaviour validity is often questioned due to the influence of social desirability.^{1–4} This is especially a concern in research studies that include intensive behavioural risk reduction counselling.

Correspondence to: LP Newman, MHS, Department of Epidemiology, University of Washington, Box 357236, Seattle, WA 98195, USA, lpnewman@u.washington.edu.

^{*,**}These authors contributed equally to this work.

Prostate-specific antigen (PSA) is the most commonly used biological marker for semen exposure,⁵ and has been tested in vaginal samples with enzyme immunoassays for forensic medicine and to determine condom efficacy.⁶ The PSA immunoassay has high specificity, ranging from 91% to 99%; its sensitivity wanes rapidly due to clearance after exposure.⁷

The majority of new HIV infections in Sub-Saharan Africa occur among stable HIV-discordant heterosexual couples, in which one partner is HIV-positive and the other is HIV-negative.^{8–10} For this reason, HIV-discordant couples have recently been a focus of HIV prevention efforts. Previous studies in HIV-discordant couple and female sex worker cohorts have shown that self-reported condom use is over-reported.^{11–16} However, no studies have looked at covariates associated with reporting consistent condom use yet testing positive for semen biomarkers in an HIV-discordant couple cohort. This research aimed to evaluate the collected statistic of self-reported condom use among women in heterosexual HIV-discordant couples in Nairobi, Kenya. We compared socio-demographic, behavioural and clinical factors among women reporting 100% condom use with positive PSA to those with negative PSA results.

METHODS

Study design

This study recruited and consented women between January and December 2010 at the enrolment visit of the Partners Pre-Exposure Prophylaxis (PrEP) Study at Kenyatta National Hospital in Nairobi, Kenya. The Partners PrEP Study is a phase III, multisite, randomized, double-blind, placebo-controlled trial of the parallel comparison of daily oral tenofovir disoproxil fumarate or emtricitabine/tenofovir disoproxil fumarate PrEP for prevention of HIV acquisition within HIV-discordant couples, whose recruitment has been described elsewhere.¹⁷

Data collection

At the enrolment PrEP visit, trained clinicians and nurse counsellors administered questionnaires to separate members of the discordant couple. The questionnaire included information about sociodemographic factors and sexual behaviour, along with questions about condom use. Vaginal swabs were acquired from women during their enrolment PrEP visit for study assays including PSA testing. A trained clinician or nurse counsellor inserted a cotton swab 2 cm into the participant's vagina and rolled it along the vaginal circumference for at least 15 seconds, removed it, and inserted into a conical tube containing 3 mL phosphate-buffered saline (PBS). We eluted vaginal material from swabs by vortexing the tube and pressing the swab against the tube. The tube was then centrifuged at 1200 rpm for 10 minutes at 4°C. The supernatant was aliquoted into a 2 mL cryovial and store at –20°C until testing for PSA. Vaginal swab elutant supernatants were tested for PSA using an enzyme-linked immunosorbent assay (ELISA) assay (Pishtaz Teb Diagnostics, Tehran, Iran) according to manufacturer's instructions. PSA concentrations above 1 ng/mL were considered positive.^{6,7}

Sociodemographic, clinical and behavioural data were extracted from a database of information gathered from structured questionnaires administered at PrEP enrolment.¹⁷ This was done by linking data to each participant using a unique identifying study number. The behavioural data section collected information on the number of times participants had sexual intercourse in the previous one month, and how many times they used a condom.

Data analysis

We calculated the proportion of women who tested positive for PSA despite reporting 100% condom use in the last one month. A chi-squared test for significance was used to compare PSA results in women who reported 100% condom use and women who did not. Among women who reported 100% condom use, bivariate logistic regression was used to compare characteristics between women with a positive PSA and those with a negative PSA. Factors that were evaluated as potential correlates of a positive PSA included: HIV status, recent vaginal washing, age, completed years of school, income and number of children in the household. Stata version 11.1 was used for all analyses (StatCorp, College Station, TX, USA).

Ethics statement

Ethical approval was obtained from the Kenyatta National Hospital/University of Nairobi Ethics Review Committee and the University of Washington Human Subjects Division. Written informed consent was obtained from study participants before enrolment.

RESULTS

A total of 125 women were recruited and enrolled from the PrEP HIV-discordant couple cohort, and 91 (77%) of these women were HIV-positive. The median age was 29 years (inter-quartile range [IQR] 24–34), and median number of school years completed was 8 (IQR 8–12). Marriage to study partner was reported by 119 (98.3%) women and participants had a median of one child (IQR 0–2) with their current partner. At least one sex act was reported in the last one month by 118 (94.4%) participants and there was a median of four sex acts reported in the last one month (Table 1).

Of the 125 women enrolled, 124 were tested for PSA. One test sample was not completed due to collection of insufficient sample volume. Ninety-eight (83.7%) of those 124 women reported using condoms for every sex act in the last one month, and these women were included in the logistic regression analysis (Figure 1).

Overall, 13 (10.5%) out of 124 women tested positive for PSA. Ten (10.1%) of the 98 women who reported 100% condom use tested positive for PSA and three (15.8%) of the 19 women who reported less than 100% condom use tested positive for PSA. A χ^2 test for independence showed no significant association between reporting 100% condom use and a positive PSA test ($P = 0.48$). Zero of the seven women who reported no sexual activity in the last one month tested positive for PSA (Table 2).

We focused the covariate analyses on the group of women who reported 100% condom use in the previous one month to determine if there were any differences between women who

tested positive for PSA and those who tested negative for PSA. Women who completed eight or fewer years of school were 8.36 times more likely to have a positive PSA test (odds ratio [OR] = 8.36; 95% confidence interval [CI], 1.02–69.13; $P = 0.048$) compared with women who completed more than eight years of school, among those who reported 100% condom use in the previous one month. Women who tested PSA positive did not statistically differ in HIV status, age, number of children, income or vaginal washing compared with those who tested PSA-negative (Table 3).

DISCUSSION

We found that 10% of the women in this HIV-discordant couples study who reported condom use during every sexual act in the previous one month had exposure to semen. Previous studies have shown 12.9–39% of women had biological measurements that suggested exposure to semen despite their reporting of consistent condom use, though the population, HIV status and collected behaviour times vary.^{11–16} Our estimates are lower than in other groups that are at high risk for HIV, such as female sex workers in Guinea (35.7%),¹¹ Madagascar (39%)¹³ and Kenya (12.9%).¹⁴ They are also lower than estimates from a study that enrolled women in HIV-discordant couples who attended a voluntary HIV counselling and treatment clinic in Zambia (15.1%)¹² and reported consistent condom use in the last three months.

In comparison to other cohorts, our estimate of exposure to semen despite reporting condom use during every sex act may be lower for a number of reasons. Our study looked at HIV-discordant couples who were involved in intensive couples counselling, which may have resulted in a lower reporting bias than in female sex worker or other treatment clinic couple cohorts. Alternatively, couples who are highly motivated to comply with condom use may have less exposure to semen in comparison with female sex workers who do not have as much choice in condom use. Finally, the number of sex acts may be lower in couples compared with sex workers, thus lowering the potential for exposure to semen.

To our knowledge, this was the first study to look at correlates of association between the presence of PSA and reporting consistent condom use in women in HIV-discordant couples. Having fewer than eight years of schooling, equivalent to primary school education, was a risk factor for PSA presence. It has been established that social desirability may bias reporting of behaviour,^{1–4} however it is still unclear how to reduce this bias. Development of counselling specific to women with less education may be an approach to reduce the bias regarding the reporting of sexual behaviour in clinical trials, especially if these women are more susceptible to it. Use of PSA testing could be utilized to evaluate validity of self-reported condom use in studies assessing education-specific counselling.

While this study benefited from being nested within a much larger study that provided a high level of quality assurance, it does have limitations. It is likely that our estimate of over-reported condom use is a conservative one. We collected data on sexual behaviour from the month prior to enrolment. Depending on the exposure level, ability to detect PSA may be limited 24–48 hours after exposure, as PSA is rapidly cleared from the vagina. This phenomenon is not unique to PSA, and is comparable to other biomarkers.⁵ However, use of

PSA has many advantages. Levels of PSA are very low in vaginal secretions, typically below 0.1 ng/mL⁶. The cut-off point of 1 ng/mL used in our analysis is above this typical level, and is lower than other cut-off values which limit sensitivity to detect PSA.^{6,7} The PSA immunoassay has high specificity up to 48 hours after exposure, ranging from 97% to 99%,⁷ so detection of PSA in vaginal secretion yields few false-positives. It is also widely used, extensively characterized and is commercially available. Though PSA is not normally found in high concentration in vaginal secretions,^{5–7} presence of PSA could also be due to condom breakage, slippage or other types of failure. Finally, we were limited in our analysis due to the small number of women who tested PSA-positive. Given that only 10 women tested PSA-positive, we had relatively limited power to detect associations. Furthermore, bivariate logistic regression was the most appropriate test for this small sample size, as there were not enough pairwise comparisons to merit multivariate logistic regression. Thus, we were unable to control for potential confounding factors.

In summary, we found an over-reporting of condom use behaviour from women in HIV-discordant couples who were intensely counselled on HIV prevention behaviour, and identified low education as an important predictor of PSA presence. The accuracy of studies in high-risk cohorts is dependent on self-reported data, which are often biased. Targeted efforts to increase validity of self-report for women with low education, and integrated biological specimen testing for semen are encouraged for future studies within HIV-discordant couples when accurate reporting of condom use is desirable.

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References

1. Catania JA, Gibson DR, Chitwood DD, Coates TJ. Methodological problems in AIDS behavioral research: influences on measurement error and participation bias in studies of sexual behavior. *Psychol Bull.* 1990; 108:339–62. [PubMed: 2270232]
2. Fenton KA, Johnson AM, McManus S, Erens B. Measuring sexual behaviour: methodological challenges in survey research. *Sex Transm Infect.* 2001; 77:84–92. [PubMed: 11287683]
3. Langhaug LF, Sherr L, Cowan FM. How to improve the validity of sexual behaviour reporting: systematic review of questionnaire delivery modes in developing countries. *Trop Med Int Health.* 2010; 15:362–81. [PubMed: 20409291]
4. Morisky DE, Ang A, Sneed CD. Validating the effects of social desirability on self-reported condom use behavior among commercial sex workers. *AIDS Educ Prev.* 2002; 14:351–60. [PubMed: 12413181]
5. Mauck CK, Doncel GF. Biomarkers of semen in the vagina: applications in clinical trials of contraception and prevention of sexually transmitted pathogens including HIV. *Contraception.* 2007; 75:407–19. [PubMed: 17519146]
6. Lawson ML, Maculuso M, Bloom A, Hortin G, Hammond KR, Blackwell R. Objective markers of condom failure. *Sex Transm Dis.* 1998; 25:427–32. [PubMed: 9773437]
7. Macaluso M, Lawson L, Akers R, et al. Prostate-specific antigen in vaginal fluid as a biologic marker of condom failure. *Contraception.* 1999; 59:195–201. [PubMed: 10382083]

8. Dunkle KL, Stephenson R, Karita E, et al. New heterosexually transmitted HIV infections in married or cohabiting couples in urban Zambia and Rwanda: an analysis of survey and clinical data. *Lancet*. 2008; 371:2183–91. [PubMed: 18586173]
9. Eyawo O, de Walque D, Ford N, Gakii G, Lester RT, Mills EJ. HIV status in discordant couples in sub-Saharan Africa: a systematic review and meta-analysis. *Lancet Infect Dis*. 2010; 10:770–7. [PubMed: 20926347]
10. Mermin J, Musinguzi J, Opio A, et al. Risk factors for recent HIV infection in Uganda. *JAMA*. 2008; 300:540–9. [PubMed: 18677026]
11. Aho J, Koushik A, Diakite SL, Loua KM, Nguyen VK, Rashed S. Biological validation of self-reported condom use among sex workers in Guinea. *AIDS Behav*. 2010; 14:1287–93. [PubMed: 19680799]
12. Allen S, Meinzen-Derr J, Kautzman M, et al. Sexual behavior of HIV discordant couples after HIV counseling and testing. *AIDS*. 2003; 17:733–40. [PubMed: 12646797]
13. Gallo MF, Behets FM, Steiner MJ, et al. Prostate-specific antigen to ascertain reliability of self-reported coital exposure to semen. *Sex Transm Dis*. 2006; 33:476–9. [PubMed: 16865047]
14. Gallo MF, Behets FM, Steiner MJ, et al. Validity of self-reported 'safe sex' among female sex workers in Mombasa, Kenya – PSA analysis. *Int J STD AIDS*. 2007; 18:33–8. [PubMed: 17326860]
15. Gallo MF, Sobel JD, Rompalo AM, Cu-Uvin S, Schoenbaum E, Jamieson DJ. Discordance between spermatozoa detection and self-reported semen exposure. *Sex Transm Dis*. 2011; 38:909–12. [PubMed: 21934562]
16. Minnis AM, Steiner MJ, Gallo MF, et al. Biomarker validation of reports of recent sexual activity: results of a randomized controlled study in Zimbabwe. *Am J Epidemiol*. 2009; 170:918–24. [PubMed: 19741042]
17. Mujugira A, Baeten JM, Donnell D, et al. Characteristics of HIV-1 serodiscordant couples enrolled in a clinical trial of antiretroviral pre-exposure prophylaxis for HIV-1 prevention. *PLoS One*. 2011; 6:e25828. [PubMed: 21998703]

Figure 1.
Flow chart of women enrolled into PSA study. PSA, prostate-specific antigen

Table 1

Characteristics of women in HIV-discordant couples enrolled in the cross-sectional PSA study

Biological markers	Women (<i>n</i> = 125)	
	<i>n</i>	%
HIV infected	91	72.8
Behaviour characteristics		
Vaginal washing (any)	65	52.3
Married to study partner	119	98.3
Had sex in last one month (any)	118	94.4
Self-reported 100% condom use	99	83.9
	Median	IQR
Sex acts in the last month	4	3–5
Demographic characteristics		
	Median	IQR
Age (years)	29	24–34
Children with partner	1	0–2
Years of school	8	8–12
Personal income (USD/Month)	0	0–47

PSA, prostate-specific antigen

Table 2

PSA test results of 124 women enrolled in PSA study cohort

PSA test	Self-reported condom use in one month prior to test (<i>n</i> = 117)				No reported sex acts in one month prior to test (<i>n</i> = 7)	
	100% Use		<100% Use		<i>n</i>	%
Positive	10	10.1	3	15.8	0	0
Negative	88	89.8	16	84.2	7	100
Total	98	79.0	19	14.5	7	5.6

PSA, prostate-specific antigen

Table 3

Correlates of association for testing PSA-positive among women who self-reported 100% condom use

Characteristic	OR	95% CI	P value
HIV (positive)	2.07	0.41–10.36	0.376
Vaginal washing (any)	0.67	0.18–2.53	0.551
<30 years of age	0.67	0.18–2.54	0.552
8 Years of school	8.39*	1.02–69.13*	0.048*
Any income	0.61	0.16–2.31	0.465
1 or fewer children in household	0.66	0.16–2.74	0.570

OR = odds ratio; CI = confidence interval; PSA, prostate-specific antigen

* Statistically significant result