RESEARCH LETTER

Factors associated with vaginal detection of prostate-specific antigen among participants in a clinical trial in Malawi

Self-report of sexual behaviours in clinical studies is often subject to misreporting due to recall or social desirability bias or misinterpretation of the study questionnaires.[1] Use of biomarkers of semen exposure, such as the detection of prostate-specific antigen (PSA) in vaginal secretions, offers an additional means of assessing sexual behaviours and condom use that is not subject to reporting biases.[2] In a secondary analysis of a clinical trial of hormonal contraception in Malawi,[3] we examined associations of discordance between PSA detection and self-report of condomless sex over time with participant characteristics using log-binomial regression analyses with generalised estimating equations for repeated measures. All analyses were conducted using SAS V.9.3 (SAS Institute, Cary, North Carolina, USA). Testing for PSA was performed using the ABAcard p30 rapid immunochromatographic strip test (Abacus Diagnostics, West Hills, California, USA); samples containing ≥1.0 ng PSA/mL were considered positive for detection of semen, as previously described.[4] Discordance between PSA detection and self-report was defined as detection of PSA in the vaginal samples, with report of condom use at last sex or no sex since last study visit. Given the rapid clearance of PSA, negative results for PSA were not considered in the definition of discordance or concordance, regardless of whether condomless sex was self-reported or not.[4]

This analysis included 539 vaginal swabs from 97 women. Most women were HIV-positive (75.3%), married (70.1%); 40.2% had not completed primary education; their mean age was 32.5 years and median number of children was three. Fifty-four (55.7%) women reported unprotected sex at least once during the study. At least once during follow-up, 56.7% of women tested positive for PSA. PSA detection was significantly associated with younger age, HIV-negative status, and self-report of sex within 48 hours of a study visit (table 1). Of PSA-positive samples, 62.3% (66/106) were discordant with self-report. HIV-positive status (prevalence ratio (PR): 1.74, 95% CI: 1.19 to 2.54) and non-completion of primary school education (PR: 1.42, 95% CI: 1.12 to 1.78) were associated with such discordance (table 1).

Table 1 Factors associated with vaginal PSA detection and with discordance (between PSA test result and self-report of sexual activity), progestin study, Lilongwe, Malawi

	PSA detected		Discordance	
	Adjusted PR*	95% CI	Adjusted PR*	95% CI
Self-reported condomless last sex in last 48 hours	**2.46**	**1.7 to 3.57**	0.77	0.57 to 1.05
Last coitus within 48 hours	**4.45**†	**2.88 to 6.88**	0.55	0.14 to 2.10
HIV-positive (vs HIV-negative)	**0.59**	**0.09 to 0.38**	**1.74**	**1.19 to 2.54**
Younger age (per decrease 1 year)	**1.04**	**1.00 to 1.08**	‡	
Parity (per increase of 1)	0.87	0.75 to 1.01	0.98	0.91 to 1.07
Married (vs not married)	1.26	0.71 to 2.21	0.94	0.72 to 1.24
Did not complete primary school education (vs completed or more than primary)	0.93	0.57 to 1.49	**1.42**	**1.12 to 1.78**

Bold values are statiscally significant.
*All models adjusted for study arm and pre-randomisation vs post-randomisation visits.
†Additionally adjusted for age.
‡Non-estimable due to small sample size.
95% CI, 95% Confidence Interval; PR, prevalence ratio; PSA, prostate-specific antigen.

In our study, PSA detection was less prevalent among HIV-positive women than HIV-negative women. However, discordance between PSA test result and self-report of sexual activity was more prevalent among HIV-positive women and women who did not complete primary school education. We were unable to evaluate qualitative or individual reasons for such discordance. Misclassification of sexual exposure and misreported condom use can overestimate or underestimate associations of sexual behaviours with clinical outcomes, such as transmission of HIV, other STIs[5] or pregnancy. Incorporating objective biomarkers of sexual exposure in research studies may mitigate the biases of self-report.

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