Unprotected sex in an STD clinic population: Agreement between self-reported condom use and PCR detection of y-chromosome in vaginal fluid

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Consistent and correct use of male latex condoms reduces transmission of HIV and other sexually transmitted diseases, including mucosal and ulcerative diseases.(1-3) In research settings, measurement of consistent and correct condom use is not directly observable thus requiring quantification by self-report. Measurement of these sensitive behaviors can be susceptible to nontrivial levels of reporting bias, in addition to participation bias.(4, 5) Biological markers have been proposed as alternative, and perhaps more accurate, measures of condom use.(6-8)

We measured the level of agreement between self-reported condom use within the past two weeks and results of a polymerase chain reaction (PCR) assay developed to detect Y-chromosome (Yc) fragments in vaginal fluid to assess the performance of each method in the measurement of unprotected vaginal intercourse. Our study population comprised patients attending an urban STD clinic. STD clinic patients may have a tendency to under-report certain risk taking behaviors and over-report socially desirable behaviors such as condom use.(9, 10) Given this self-presentation bias, our working hypothesis was that the two measurements would not be in complete agreement.

Main Study Design

This study was conducted within the context of a larger cross-sectional study of men and women presenting at an urban STD clinic in Baltimore, MD between July 2000 and May 2002.

Patients were eligible to participate if they were between 15 and 39 years of age, English-speaking, mentally competent to consent to participation, and did not have a known HIV diagnosis. Study participants completed a detailed behavioral audio computer-assisted self-interview (ACASI) questionnaire on sexual behaviors, prior STD history and symptoms, partner characteristics, condom use, and individual demographic characteristics. Participants and interviewers were matched by gender. Interviews were conducted in a private exam room prior to the patient being seen by the clinician. During the clinical exam, participating patients were asked to provide up to 20 ml of urine for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by ligase chain reaction (LCR). For this sub-study, female participants were asked to provide a self-collected vaginal swab for detection of male DNA in vaginal fluid. All patients were provided a $30 food coupon for their participation.

Study Population

Of 1,079 female patients approached to participate in the study, 195 refused to participate, 188 patients did not show up for their scheduled interview, and 80 were found to be ineligible after initial screening. Of the 616 participants who completed the behavioral ACASI questionnaire, 607 participants provided a urine specimen for gonococcal and chlamydial infection testing. Furthermore, 511 female participants who completed the main study also provided a vaginal swab for Yc fragment testing, of which 478 produced a valid test result. The population of interest for this analysis comprises the 478 participants who completed the ACASI questionnaire and provided a self-collected vaginal swab which produced a valid result.

Percent agreement and the kappa statistic were used to quantify the level of agreement between self-reported condom use and PCR detection of Yc fragment. Prevalence odds ratios and 95 percent confidence intervals were estimated from generalized linear models using Stata v8.0.(11) Bivariable and multivariable binomial regression models were fit to examine factors associated with the prediction of discordance between the two measures. Multinomial regression models were also fit to examine factors associated with the prediction of general

agreement between the two measures. Agreement or non-agreement of the measures are compared to participants who self-reported no condom use longer than 2 weeks and tested negative for Yc fragment in vaginal fluid. Participant's age, martial status, douching activity, number of concurrent partners, frequency of vaginal sex, digital penetration activity, sex under the influence of alcohol, and the rate of broken or leaky condoms during vaginal intercourse were included in the models.

Population Characteristics

The study population (N= 478) comprised 94.8% African American and 5.2% non-African American women. The mean age was 24.5 years (SD=6.5). Approximately two-thirds of the study population had never been married and two-fifths had less than a high school education. Roughly 60% reported no concurrent partnerships. Two-fifths of participants reported engaging in sexual activity 3 to 9 times during the past 2 weeks. Nearly 28% reported an experience with a broken or leaky condom during the past 30 days.

Agreement Between Self-reported Condom Use and Y-chromosome Detection

Agreement beyond that expected by chance alone between the two measurements of unprotected vaginal intercourse, self-reported condom use and PCR assay, was "fair" (kappa = 0.29, 95% CI, 0.20 - 0.38). Self-reported condom use and PCR assay result were concordant in 66% of participants. Of the 34% with discordant results, 15.7% had a positive PCR result but did not report engaging in sexual intercourse without a condom during the past 2 weeks while 18.4% of those who reported engaging in sexual intercourse without a condom in the past 2 weeks had a negative PCR result.

In our research, the measurement tools we select should depend on the nature of what we are attempting to measure. Defining the construct of unprotected sexual intercourse is less clear than might be expected. The distinction between endeavoring to measure the rate of actual exposure to specific sexually transmitted pathogens and the subsequent risk of disease development and measurement of the *risk* of exposure to these pathogens should be made

clear at the outset of study. Behavioral indices such as condom use, number of sexual partners, and frequency of sex, as well as objective biological markers, such as prostate specific antigen in vaginal fluid, amplification of y-chromosome DNA, and results from nucleic acid amplification tests for bacterial STDs such as gonorrhea and chalmydial infection, have all been employed in attempts to measure unprotected sexual intercourse as a proxy measurement of the risk of exposure to infectious pathogens.(12-16)

Maybe the search for one perfect measure of unprotected sex or, more precisely, the risk of exposure to sexually transmitted pathogens is not the end point towards which we should be striving. Given the complex nature of the constructs we are attempting to measure, perhaps multi-faceted measurements are the more appropriate paradigm.

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