Assessment of Changes in Condom Use Among Female Sex Workers in a Prospective Cohort Study Introducing Diaphragm Use for Disease Prevention

Maria F. Gallo*, Lee Warner, April J. Bell, Jeffrey Wiener, David A. Eschenbach, Elizabeth A. Bukusi, Anjali Sharma, Betty Njoroge, Elizabeth Ngugi, and Denise J. Jamieson

* Correspondence to Dr. Maria F. Gallo, Division of Reproductive Health, 4770 Buford Highway, Mail Stop K-34, Atlanta, GA 30341-3724 (e-mail: mgallo@cdc.gov).

Initially submitted February 18, 2010; accepted for publication May 4, 2010.

Changes in the rates of condom use and number of sexual partners were evaluated among 140 female sex workers in Kibera, Kenya, participating in a 6-month study of diaphragm safety and acceptability for prevention of sexually transmitted infections conducted in 2004–2005. Analyses were stratified by partner type. Multivariable Tobit regression modeling was used to assess the association between study visit and proportion of acts protected. Participants completed 140 baseline visits and 390 bimonthly follow-up visits. The mean percentage of coital acts reported as protected by a condom increased from 56% at baseline to 68% at the 6-month visit ($P < 0.01$). Similar increases were observed for condom use by all partner types. Additionally, the mean number of sexual partners decreased over the study. Furthermore, consistent (i.e., 100%) diaphragm use during follow-up was associated with a higher proportion of coital acts protected by a condom in analyses adjusted for study visit and coital frequency. These findings suggest that, despite concerns that introduction of the diaphragm would result in more risky sexual behaviors, reported condom use increased and number of partners decreased.

Africa; condoms; contraceptive devices, female; prostitution; women

Abbreviations: HIV, human immunodeficiency virus; STI, sexually transmitted infection.
MATERIALS AND METHODS

Study procedures

We conducted a 6-month prospective cohort study from 2004 to 2005 to assess the safety and acceptability of the diaphragm used to prevent infection among female sex workers (21). Women were recruited from an established cohort of female sex workers in the Kibera settlement of Nairobi, Kenya. Eligible women were 18–57 years of age and had traded sex for money or gifts in the previous 2 weeks. Exclusion criteria included pregnancy or plans for pregnancy in the next 6 months, latex allergy, history of toxic shock syndrome, gynecologic abnormalities precluding use of the diaphragm, and reporting condom use for every coital act in the previous 2 months. Only women who gave written, informed consent were eligible for participation. The institutional review boards at the University of Nairobi, the University of Washington, and the Centers for Disease Control and Prevention provided ethical review and approved the study.

Upon enrollment, participants received a pelvic examination and fitting for the silicone Milex Wide Seal diaphragm (Milex, Inc., Chicago, Illinois). After a demonstration on a pelvic model, participants practiced insertion and removal of the diaphragm at the clinic. Using KY Jelly (Johnson & Johnson, New Brunswick, New Jersey) to ease insertion, participants were to insert the diaphragm up to 6 hours before coitus and to leave it in place for 6–24 hours after coitus. Because the diaphragm was not to be used with a spermicide, participants were counseled on the unknown efficacy of the diaphragm against HIV/STIs and pregnancy and were advised to use male condoms for each coital act. Women currently using another contraceptive method were encouraged to continue its use. They received counseling on safer sex practices, including condom use, at every study visit. Participants were treated following national guidelines for the syndromic management of STIs and supplied with male condoms at baseline and at visits scheduled at 1 week and 2, 4, and 6 months postenrollment.

Data collection

At baseline and at each follow-up visit, participants used stickers to complete a pictorial self-administered questionnaire detailing their overall frequency of coitus, number of sexual partners, and use of diaphragms, KY Jelly, and condoms in the previous 2-week period. Drawing on prior formative research conducted among the target population, we repeated the questions for 3 types of sexual partners: helping (i.e., partner to whom the woman could go to for help or support if needed); regular (i.e., partner with whom she has coitus on a regular basis); and casual (i.e., all other partners). At baseline and at the bimonthly follow-up visits, trained female staff interviewed participants on demographic characteristics, gynecologic symptoms, sexual behaviors, and related knowledge, attitudes, and practices. All questionnaires were translated and back-translated into Kiswahili to ensure accuracy.

Statistical analysis

To assess changes in sexual risk behaviors after the introduction of the diaphragm to the study population, we evaluated 4 behavioral measures for the 2-week period preceding the interview as measured with self-administered questionnaire data at the baseline and each of the 3 bimonthly follow-up visits: 1) proportion of coital acts protected by a condom; 2) continuous (100%) condom use versus inconsistent or no condom use; 3) proportion of coital acts protected by a condom and/or diaphragm; and 4) number of sexual partners. Each measure was calculated cumulatively across all partners and separately for each of the 3 types of partners. We constructed 16 separate models to assess whether the 4 outcome measures changed over time during the study visits for each of the 4 partner types (i.e., overall, helping, regular, and casual). Analyses were restricted to visits in which participants reported ≥1 coital act with the relevant partner type.

We used Tobit regression for modeling both the proportion of coital acts protected by a condom and the proportion of coital acts protected by either a condom and/or diaphragm (22, 23). These variables had a bimodal distribution with peaks at 0% and 100%. Several factors (e.g., recall bias, self-presentation bias, and recall periods too short to be representative) can contribute to excessive reporting of always using condoms or never using condoms (23). On the basis of the assumptions that the responses were censored in the middle and that the underlying distribution was normal, we used the SAS, version 9.1, procedure PROC LIFEREG (SAS Institute, Inc., Cary, North Carolina) with a censored interval of 0–1 to transform the observed scores for the outcome measure into latent scores, which subsequently were used for the multivariable modeling. One limitation of this approach is that this SAS procedure does not include options to account for clustering. Although measuring condom use as the proportion of acts protected has the benefit of being more easily understood, the absolute number of unprotected acts is a better measure of an individual’s risk of infection (24–27). To address this, we adjusted for coital frequency (with the relevant type of partner) in all analyses. For modeling consistent (100%) condom use, we used logistic regression with generalized estimating equations, specifying the exchangeable working correlation matrix, to account for multiple visits from individual women. For modeling the number of sexual partners, we used Poisson regression with generalized estimating equations to adjust for correlated measures. Because we used 3 different types of regression (i.e., Tobit, logistic, and Poisson), we report the β coefficients from the models for consistency, so that each analysis shows a 1-unit increase in the outcome of interest.

Finally, we used Tobit regression to assess the relationship between consistent diaphragm use and the proportion of coital acts protected by condoms at the bimonthly study visits by type of partner. The following variables were evaluated as potential confounders for this relation: age (18–29 years vs. ≥30 years); marital status (single and not cohabiting vs. cohabiting, divorced, or widowed); parity (0–1 vs. ≥2 children); educational level completed (<8 vs. 9–12 years); and weekly income (≤9 vs. >9 US dollars).
To assess potential confounders, we fit a full model with all the variables above and then used manual, backward elimination to reduce those that did not change the crude effect estimate for consistent diaphragm use by more than 10%. Because of a priori beliefs and to be consistent with the other analyses, we retained the variables for study visit and coital frequency in the final model.

RESULTS

Study population

Of 180 women screened for enrollment, 140 (78%) were eligible, agreed to enroll, and completed the baseline visit. The 2-, 4-, and 6-month visits were completed by 134, 130, and 126 women, respectively, yielding a total of 390 follow-up visits. The median age of participants was 31 years. Most women (69%) were divorced, separated, or widowed and had a low level of education (median, 7 years). Half of the participants had engaged in sex work for 6 years or more. Most women (85%) reported the use of contraception at baseline; the primary method most commonly reported was male condoms (36%), followed by injectable contraception (21%), the rhythm method (10%), oral contraceptives (9%), implants (4%), tubal ligation (4%), and intrauterine devices (2%). Although 19% of women had heard of the diaphragm at baseline, none had ever used the diaphragm before enrollment into the study. Most women at baseline reported having had coitus with a helping partner (75%), regular partner (75%), and a casual partner (67%) in the prior 2 weeks.

Changes in condom and diaphragm use

At baseline, a mean 56% of overall coital acts (regardless of partner type) in the prior 2 weeks were protected by condoms (Figure 1). The percentage of mean acts protected by condoms steadily increased during follow-up to peak at 68% at the final, 6-month visit. When coital acts were disaggregated by type of partner, an increase in the mean percentage of protected acts over study visits was found for each type of partner. The increase in the mean percentage of acts in which a condom was used during coitus was statistically significant overall ($\beta = 0.062; P < 0.01$), as well as with helping partners ($\beta = 0.319; P = 0.02$) and with regular partners ($\beta = 0.107; P < 0.03$) (Table 1). The frequency of condoms used with casual partners did not significantly increase. We found similar patterns for increases in consistent (100%) condom use (Figure 2; Table 1).

The mean percentage of coital acts protected by $\geq 1$ barrier method (condoms and/or diaphragm) in the prior 2 weeks increased from 56% of overall coital acts at baseline (when only condoms were available) to 93% at the 6-month visit (when both condoms and diaphragms were available).

Table 1. Association Between Study Visit and Sexual Behaviorsa by Type of Partners, Nairobi, Kenya, 2004–2005

<table>
<thead>
<tr>
<th>Overall</th>
<th>Helping Partner</th>
<th>Regular Partner</th>
<th>Casual Partner</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\beta$</td>
<td>$P$ Valueb</td>
<td>$\beta$</td>
<td>$P$ Valueb</td>
</tr>
<tr>
<td>% of coital acts protected by a condomc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study visitd</td>
<td>0.062</td>
<td>&lt;0.01</td>
<td>0.319</td>
</tr>
<tr>
<td>Consistent (100%) condom usec</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study visitd</td>
<td>0.288</td>
<td>&lt;0.01</td>
<td>0.285</td>
</tr>
<tr>
<td>% of coital acts protected by a condom and/or diaphragmc</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study visitd</td>
<td>0.289</td>
<td>&lt;0.01</td>
<td>1.436</td>
</tr>
<tr>
<td>No. of sexual partnersd</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study visitd</td>
<td>−0.046</td>
<td>0.03</td>
<td>−0.019</td>
</tr>
</tbody>
</table>

a Self-reported sexual behaviors (coitus, condom use, diaphragm use, and sexual partners) in prior 2 weeks measured at baseline and 2-, 4-, and 6-month follow-up visits.

b Two-sided $P$ value.

c From Tobit regression models with interval censoring; analyses restricted to visits with $>1$ coital act with the relevant partner type and adjusted for coital frequency with the relevant partner type.

d Continuous variable for study visit (baseline, 2-month, 4-month, and 6-month visits).

e From logistic regression models using generalized estimating equations.

f From Poisson regression models using generalized estimating equations.

Am J Epidemiol 2010;172:606–612
The mean increases in the percentage of acts protected by either barrier method were statistically significant for overall coital acts and for acts with each of the 3 types of partners (Table 1).

**Number of sexual partners**

The mean number of total sexual partners reported for the prior 2 weeks decreased from 5.0 at baseline to 4.3 men at the 6-month visit (Figure 4). Separate calculations for each of the 3 types of partners show similar small decreases in the mean number of sexual partners reported. These decreases were significant for the overall number of partners ($\beta = -0.046; P = 0.03$) and for casual partners ($\beta = -0.082; P = 0.01$); however, the decrease was not statistically significant for helping or regular partners (Table 1).

**Association with consistent use of the diaphragm**

At the final 6-month visit, most women used both diaphragms and condoms (Figure 5). Overall, women reporting consistent (100%) diaphragm use in the prior 2 weeks reported a higher proportion of acts with condom use compared with women who reported inconsistent or no diaphragm use ($\beta = 0.146; P < 0.01$) (Table 2). Although not statistically significant, the relation between consistent use of the diaphragm and a higher percentage of acts protected by a condom remained for each of the 3 types of partners.

**Sensitivity analyses**

To assess the effect of study attrition or incomplete visit attendance, we reran all models after restricting the data set to include only the 121 participants who completed the baseline as well as each of the 3 bimonthly follow-up visits. Because these analyses yielded results similar to those of the full data set and did not alter study conclusions, we do not provide the data here.

**DISCUSSION**

We found no evidence that introduction of diaphragm use resulted in lower levels of condom use among this selected cohort of female sex workers in Kenya participating in a prospective trial of diaphragm acceptability. In contrast, the mean percentage of coital acts reported as protected by condoms in the prior 2 weeks increased significantly between baseline and the final, 6-month visit. In addition, the mean number of sexual partners in the prior 2 weeks decreased over the course of the study, further suggesting that women were not adopting other risky behaviors as...
a result of a perceived decrease in risk that they might have associated with diaphragm use. These results are consistent with those of 2 prior studies, which also demonstrated increases in the overall proportion of coital acts protected by either the diaphragm or condoms following the introduction of the diaphragm (19, 20). However, in the first trial, the rate of male condom use remained unchanged (19) and, in the second, diaphragm use appeared to serve as a substitute for some condom use (20).

Despite these promising results, the present study cannot definitively rule out the possibility of risk compensation from introducing the diaphragm. First, as with past studies on this topic (19, 20), our evaluation relied on self-reported sexual behavior. Women might intentionally (or unintentionally) misreport these behaviors for many reasons (28, 29); for example, studies using biologic markers of semen exposure have found evidence of overreporting of condom use (30, 31). Although we found a positive association between consistent use of the diaphragm and the percentage of acts protected by a condom, women who overreport use of the diaphragm also might be more likely to overreport use of condoms, which could result in a spurious association. In addition, the validity of self-reported data could have changed over the course of the study. For example, the cumulative effect of safer sex counseling messages received by the participants at each visit might have led to more overreporting of condom use as the study progressed. On the other hand, the short, 2-week timeframe used to assess behaviors might have minimized the potential for recall bias (32). Future studies would be strengthened by the use of objective biologic markers of exposure instead of self-reported data or, at least, by corroboration of participant reports of sensitive behaviors.

Several observational studies suggest a protective effect of the diaphragm against risk for STIs other than HIV (33–35). However, the only randomized controlled trial did not demonstrate protection of the diaphragm against HIV/STIs in the intent-to-treat analyses (36). Still, methodological issues (e.g., low adherence to diaphragm use or differential condom use between the intervention and control arms) could have hindered the trial’s ability to detect a protective effect (20, 37). Thus, the protective effect of the diaphragm used alone to prevent HIV/STIs remains unknown. Given its uncertain degree of protection and because the diaphragm was used without spermicide, participants in the present study were counseled at every visit on the unknown efficacy of the diaphragm against pregnancy and infection. Risk compensation might be more likely to occur if the method had known efficacy.

Findings from this study of female sex workers in Kenya might not be generalizable to other populations. The study population likely was well aware of HIV mortality among coworkers. Also, they were highly educated on HIV/STI prevention as a result of their past participation in a study of the effect of STI treatment on HIV acquisition. Their high motivation at study entry was demonstrated by their continued participation in studies on HIV/STIs. Furthermore, involvement in the present study occurred before any prospects of benefitting from widespread HIV treatment could have influenced their decision on study participation.

Mathematical modeling suggests that increased HIV risk from condom substitution is more of an issue among women with higher rates of initial condom use than among those with lower initial use (12). In this study, participants could have been highly motivated to report using both the diaphragm and male condom either as a result of self-selection into the study or as a result of the frequent counseling at each study visit on the importance of using both the condom and diaphragm for all coitus. Thus, the rates of condom use reported in the study might not be generalizable to nonstudy settings, able to be maintained without frequent counseling, representative of behavior longer than 6 months, or applicable to less motivated populations.

The present study had several strengths. We assessed risk compensation with 4 different outcomes, each of which yielded similar conclusions. These findings reinforce the conclusion that risky behaviors did not increase following the introduction of the diaphragm. A second study strength was our ability to disaggregate behaviors by partner type. Acceptability and adherence to barrier methods (e.g., condoms, diaphragm, and candidate microbicides) can differ by type of partner (17, 21, 38, 39); for example, we found an increase in condom use with helping and regular partners but not with casual partners. Condom use with casual partners was relatively high at baseline, and women might have already been using condoms to the degree to which they could negotiate use with this partner type. In contrast, condom use was lower with the other partner types at baseline, and women might have increased use with these partners as a result of the repeated counseling received during the study on the importance of using condoms with all partner types. Future research on risk compensation related to these methods must evaluate behaviors separately by partner type to ensure that changes in risk patterns are not overlooked.
Finally, the study had high (90%) follow-up rates at the final, 6-month visits. This, together with our sensitivity analyses on the effects of study attrition, suggests that the potential for bias from loss to follow-up was low.

In conclusion, we found no evidence of risk compensation in terms of reduced condom use from an intervention promoting the diaphragm to this population. That study participants received routine counseling on the importance of the use of male condoms for protection from HIV/STIs and were supplied with adequate levels of male condoms might have helped to ensure that diaphragm use did not replace male condom use. Future trials should evaluate the diaphragm for effectiveness against acquisition of HIV/STI. If the diaphragm is shown to be protective, prevention efforts targeting populations in which male condom use is suboptimal might need to promote both the diaphragm and male condom together to succeed in decreasing HIV/STI risk.

ACKNOWLEDGMENTS

Author affiliations: Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia (Maria F. Gallo, Lee Warner, April J. Bell, Jeffrey Wiener, Denise J. Jamieson); Department of Obstetrics and Gynecology, University of Washington, Seattle, Washington (Elizabeth A. Bukusi, Anjali Sharma, David A. Eschenbach); Center for Microbiology Research, Kenya Medical Research Institute, Nairobi, Kenya (Anjali Sharma, Betty Njoroge, Elizabeth A. Bukusi); Department of Obstetrics and Gynecology, University of Nairobi, Nairobi, Kenya (Betty Njoroge, Elizabeth A. Bukusi); Department of Global Health, University of Washington, Seattle, Washington (Elizabeth A. Bukusi); International Training and Education Center on HIV (I-TECH), University of Washington, Seattle, Washington (Anjali Sharma); and Department of Community Health and Centre for HIV Prevention and Research, University of Nairobi, Nairobi, Kenya (Elizabeth Ngugi).

This study was funded by the US Centers for Disease Control and Prevention through an interagency agreement with the US Agency for International Development and CONRAD.

The authors thank Dr. Scott Hershberger of California State University for his statistical assistance.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

Conflict of interest: none declared.

REFERENCES


