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Degrees of disclosure: A study of women's covert use of the diaphragm in an HIV prevention trial in sub-Saharan Africa☆

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ABSTRACT

In sub-Saharan Africa more women are infected with HIV/AIDS than men and new prevention methods are urgently needed. One major attribute of female-initiated HIV prevention methods is that they can be used covertly, without a male partner's knowledge. Using mixed methods, we explored the predictors and dimensions of covert use of the diaphragm in a randomized controlled trial that tested its effectiveness for HIV prevention. The Methods for Improving Reproductive Health in Africa (MIRA) trial was conducted in Zimbabwe and South Africa, and data collection took place between September 2003 and January 2007. This study is a secondary analysis of quantitative and qualitative data from participants randomized to the intervention group, and their male partners. It includes survey data from 2316 women (mean age = 28.3), 14 focus group discussions (FGD) conducted with 104 women, and 7 FGD and 10 in-depth interviews with 37 male partners. The median follow-up for trial participation was 21 months (range: 12–24). At their final visit, approximately 9% of women had never disclosed to their primary partners that they were using the diaphragm (covert use). In multivariate analysis, predictors of covert use included being older, not co-habiting with the partner, having a partner who did not use condoms, and being from South Africa. Qualitative analysis revealed that covert use was not dichotomous, but ranged along a continuum, which we categorized into five levels (i.e. full disclosure; mostly open use; occasional covert use; mostly covert use; and completely covert use). We discuss the critical role of the option of covert use for many women in the context of an HIV prevention trial, as well as gender power dynamics which may influence women's decisions about disclosure.

Introduction

Globally, 67% of the world's 33 million people living with HIV/AIDS are in sub-Saharan Africa and women are disproportionately affected in comparison with men (UNAIDS, 2008). In Zimbabwe, among those aged 15–49, 21% of females are estimated to be HIV positive compared to 15% of males (Central Statistical Office and Macro International Inc., 2007). In South Africa, young women are almost three times as likely to be infected with HIV when compared with young men in the 15–24 age group (15.5% versus 4.8%) (Pettifor, et al., 2005).

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Providing women with an HIV prevention method that they can initiate and which does not require the participation of male partners is a major need, especially under circumstances where women find it difficult to negotiate condom use with their partners (Mantell, Stein, & Susser, 2008). The Methods for Improving Reproductive Health in Africa (MIRA) was a randomized controlled trial to test the effectiveness of the female diaphragm and lubricant gel for HIV prevention among southern African women (Padian, et al., 2007). The diaphragm is one of the oldest contraceptives; it is safe, durable, and reusable. The trial was based on the premise that a simple low-cost prevention method that women can initiate and control, such as the female diaphragm, could have an important effect on slowing the HIV epidemic, if found effective. In addition, there is substantial biological plausibility that covering the female cervix with a diaphragm could decrease the risk of HIV and cervical sexually transmitted infections (STIs) (Ellertson & Burns, 2003; Harvey, Bird & Branch, 2003; Minnis & Padian, 2005; Moench, Chipato & Padian, 2001). However, the MIRA trial was unable to demonstrate any added protective benefit against HIV infection from provision of the diaphragm and lubricant gel (Padian, et al., 2007), when intervention group was given diaphragm, gel and condoms and the control group had only condoms.

One advantage of the diaphragm is that it can be used covertly, and does not necessitate cooperation or knowledge of the male partner (Kang, et al., 2007; van der Straten, et al., 2005). Very few studies have directly focused on covert use of the diaphragm for HIV prevention. Disclosure of diaphragm use (or not) seemed to influence consistent use of the method in a 6-month acceptability study from Zimbabwe (van der Straten, et al., 2005). In another analysis of the same sample, women found it more important to be able to use the diaphragm discreetly if: their partners had other partners; drank alcohol; believed to prefer condoms to diaphragms; or if they had experienced negative consequences (such as refusal, verbal or physical violence) when asking their partners to use condoms (Kang, et al., 2007). The same study population perceived diaphragms as the barrier method "most under women's control" compared with female and male condoms, because they could use it without male partners noticing (Buck, 2005). Similarly in South Africa, women were more interested in using the diaphragm and microbicides rather than female condoms because of its potential to be used covertly (Terris-Prestholt, Kumaramayake, MacPhail, Rees & Watts, 2006). In another study from Mombasa, Kenya, which assessed diaphragm continuation rates over 6 months among sex workers and reproductive health clinic clients, approximately half of the participants used the device covertly and found the disclosure process to their partner highly problematic (Okal, et al., 2008).

This study used a mixed methods approach to examine covert use of the diaphragm among women who have used the product (with a lubricant gel) in the MIRA trial. Understanding the practice of covert use, its dimensions and predictors, along with conditions shaping women's decisions about disclosure are very important in informing future research on female-initiated HIV prevention methods that could potentially be used covertly, such as microbicides and other barrier methods.

Methodology

Study setting

The MIRA trial was conducted in five clinics at three sites in two countries: Two clinics near the Durban site, South Africa (Medical Research Council, Kwazulu-Natal); one clinic in Soweto at the Johannesburg site, South Africa (Perinatal HIV Research Unit, University of Witwatersrand Johannesburg); and two clinics around the Harare site, Zimbabwe (University of Zimbabwe and University of California San Francisco-Research Collaborative Programme in Women's Health). MIRA was a community-based randomized controlled trial, and included a total of 5039 eligible women randomly assigned to the intervention (diaphragm, lubricant gel and condom) and control (condom only) groups. For the main trial, study accrual began in September 2003, and all participants were followed up quarterly for 12–24 months for the primary outcome of incident HIV infection. The details of the trial methodology and procedures have been previously reported (Padian, et al., 2007).

Study design: mixed methods

We conducted secondary analysis of quantitative and qualitative data from the MIRA trial by using complementary mixed methods approach (Greene, Caracelli, & Graham, 1989). Quantitative analyses were used to identify the extent of covert use of the diaphragm among female trial participants at their last follow-up visit, as well as its predictors. MIRA qualitative data, collected after the main trial exit (August 2006–January 2007) were analyzed to understand the parameters defining covert use as well as its dimensions both from the perspectives of female participants and their male partners. The insights gained from the qualitative analyses were integrated as hypotheses to be further tested quantitatively (depending on the availability of relevant data) and were used to finalize the quantitative analytical framework. While quantitative analyses helped to quantify different measures of participant behaviors and attitudes as they relate to covert use of the diaphragm, qualitative analyses provided a more comprehensive and nuanced understanding of covert use as a phenomenon. We also took an approach where some of the significant findings of the quantitative analysis (e.g. site differences) were further explored by qualitative data to understand the underlying reasons. We present first the quantitative analyses followed by qualitative analyses, which happened concurrently in real time and informed each other.

Quantitative data and analyses

Eligible for this quantitative analysis were 2316 women participants in the MIRA intervention group who were 49 years old or younger, who had completed a diaphragm acceptability survey at their last follow-up visit and responded to the covert use question (see Fig. 1 for a description of the study sample). Women who responded "No" to the question for their primary partners: "Did you ever tell your partner that you were using the diaphragm and gel" were classified as "completely covert users" and used as the dichotomous outcome variable. Because women were enrolled in the study for varying amounts of time, we controlled for the time spent in the study in all quantitative analysis. We tested the association between five different domains of baseline predictor variables with the outcome variable. The domains were: 1) sociodemographic indicators (e.g. age, education, employment status, study site); 2) STI/HIV risk factors and condom use (e.g. baseline STI diagnosis, frequency of sexual intercourse, STI symptoms, number of sexual partners); 3) partner related indicators (e.g. partner's employment status, and partner's other sexual partners); 4) experience of domestic violence; and 5) fertility and contraception (i.e. number of live births and contraceptive use). Data analyses for descriptive statistics, bivariate associations and multivariate models were performed with SAS® software version 9.1 (SAS Institute Inc., 2002–2003).

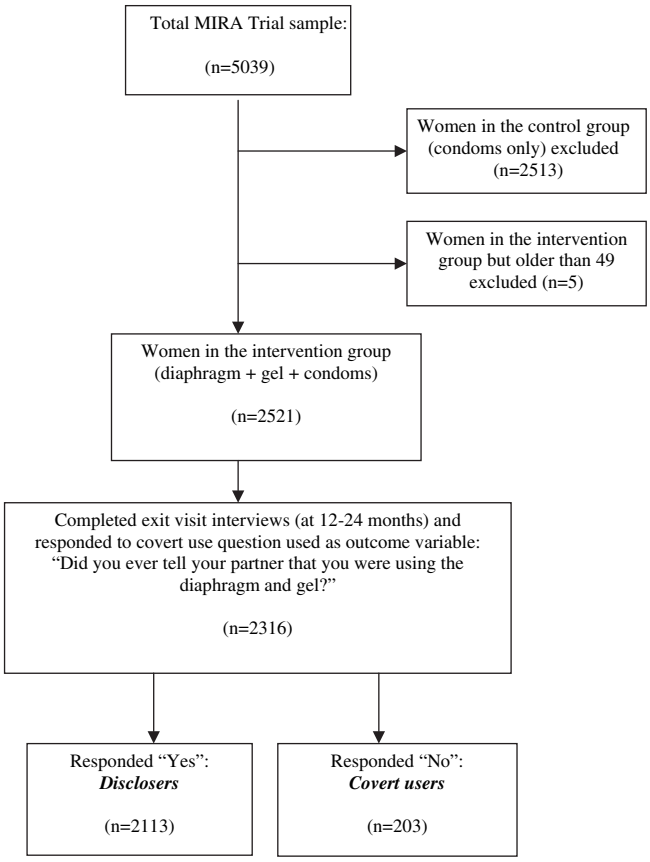

Fig. 1. Description of the final eligible sample used for the quantitative analysis of covert use of the diaphragm in the Methods for Improving Reproductive Health in Africa (MIRA) Trial.

Qualitative data and analyses

In addition to the main MIRA trial to test the diaphragm, we conducted a qualitative study (i.e. MIRA Social Science Study) with participants who had exited the trial (between August 2006 and January 2007), using qualitative research methods to investigate female participants' and their male partners' experiences with the trial (i.e. "trial experience"), and perceptions and experiences with the use of the diaphragm, gel, and condoms (i.e. "acceptability and feasibility"). The complete Social Science Study dataset included 20 focus group discussions (FGD) (with a total of 151 participants) to explore trial experience of participants and 33 FGD and 10 in-depth interviews (IDI) (with a total of 252 participants) to inquire about acceptability and feasibility of the trial products. Of the 33 acceptability and feasibility FGD, 12 were conducted with the female participants in the control (condom only) group, 14 were conducted with female participants in the intervention (diaphragm + gel + condom) group, and 7 were conducted with the male partners of women in the intervention group. Originally, only FGD were planned, but IDI were later conducted after modifying the study protocol for South Africa to address challenges in recruiting male partners into FGD.

This analysis focused on covert use of the diaphragm, and therefore used data only from the intervention group acceptability and feasibility FGD and IDI. The final qualitative dataset for this analysis consisted of a total of 14 FGD conducted with 105 women in the intervention group who had exited the trial. Of the 14 FGD, 3 were conducted in Johannesburg, 5 in Harare, and 6 in Durban (with 16, 39 and 50 participants respectively). In addition, data from male partners of women in the intervention group (7 FGD; 6 from Harare and 1 from Durban; with 27 and 4 participants respectively), also to include 10 IDI with men from South African sites (3 from Durban and 7 from Johannesburg) were included in this analysis. Female trial participants were eligible to participate in the qualitative FGD from the time of their final trial visit (up to nine months after their exit visit), and if they were not HIV positive. A list of eligible participants was assembled at each site, and a systematically selected sample of eligible women from the list was invited to participate in the FGD. Overall, participation rate was approximately 60% for female participants. Male partners were only approached if women previously gave permission and participation rate in FGD in this group remained low (14%).

Interviews were conducted in local languages, digitally recorded, transcribed then translated into English. The structured interview guides included questions about reasons for joining and staying in the trial; acceptability and feasibility of diaphragm, gel and condom use; factors influencing adherence to product use; and partner dynamics surrounding the use of study products, such as decision making for product use; and covert use of the diaphragm and gel.

Data were analyzed using a modified grounded theory approach, to identify the categories, themes and patterns emerging from the data (Strauss & Corbin, 1998). A codebook development team, which included staff from each site developed, tested, and refined a codebook on themes of acceptability and feasibility of diaphragm and gel use. Coders from the sites were in most cases facilitators of the FGD and interviewers. Each group member applied the initial set of thematic codes to a common transcript, based initially on the research questions captured in the interview guides, and discussed their coding experiences over email and regular conference calls, and refined the codebook in an iterative process with such changes as modifying code names, categories and definitions when necessary. Once the group agreed on a common set of codes, some staff coded by hand, and others coded their transcripts directly in Atlas.ti software (Muhr, 2004). To establish coding consistency at the beginning of the coding process, eight percent of the transcripts were double coded. Two different coders each coded the same transcript, and exchanged their coded transcript. A third person identified the discrepant portions, and convened conference calls for the coders to discuss the discrepancies. After discrepancies were resolved through consensus, final codes were entered into Atlas.ti master file kept by the social science coordinator in Ibis Reproductive Health.

The study received ethical review and approval by the University of California at San Francisco (UCSF) Institutional Review Board Committee on Human Research, the Biomedical Research Ethics Committee of the University of KwaZulu-Natal, the Human Research Ethics Committee of the University of the Witswatersrand, the Medical Research Council of Zimbabwe, the Medicines Control Authority of Zimbabwe, and the Western Institutional Review Board.

Results

Quantitative analyses results

The mean age of the participants was 28.3 (SD = 7.8), and median time women participated in the trial was 21 months (range: 12–24). At the end of their study participation, overall, 8.8% of women never told their regular partners that they had used the diaphragm and gel (Fig. 1). In a previous analysis, we found that most women disclosed diaphragm use to their partners early in the trial, and after 3 months of trial participation, covert use rate was approximately 12% (data not shown). More than half of women

Table 1
Frequency and reasons for covert use of the diaphragm in the MIRA Trial and perspectives on using the diaphragm covertly.

Responses to survey questions about covert use	*n*	%
Did you ever tell your partner that you were using the diaphragm and gel? ($n = 2316$)		
No	203	8.8
Yes	2113	91.2
What was the main reason why you did not tell your regular partner? (Asked only to covert users, $n = 202$[a])		
You thought he would disapprove or be upset	121	59.9
He would insist on not using the diaphragm and gel	36	17.8
It is none of his business	31	15.3
He wouldn't have sex with you	4	2.0
You didn't think he would care whether or not you were using the diaphragm and gel	2	1.0
Don't know	2	1.0
Other[b]	6	3.0
Women like diaphragm because they can use it without partner knowing ($n = 2305$)		
Agree or strongly agree	2022	87.7
Disagree or strongly disagree	283	12.3
How important to use diaphragm and gel without your partner knowing? ($n = 2316$)		
Not at all important	1135	49.0
Somewhat important	235	10.2
Very important	1100	40.9

[a] One person did not respond to this question.
[b] Other reasons: He uses the condom anyway; He will refuse to use a condom if he knows I am wearing a diaphragm; I wanted to know if he can feel it inside of me; I want to keep diaphragm use as my secret; no particular reason.

reporting covert use reported that the main reason for not disclosing diaphragm use to their partners was that they thought he would disapprove or would be upset (Table 1). Almost 40% of study participants considered it very important that the diaphragm and gel could be used without partner's knowledge, and a great majority (87.7%) agreed that this was one favorable feature.

Of the total 203 women who had used the diaphragm covertly all through the trial, great majority (92.6%) were from South Africa. To be able to explain site differences, further site-stratified analyses were conducted for all descriptive, bivariate and multivariate statistics. However, individual site analyses did not yield any significant differences, and therefore only results of the combined analyses are presented here.

In bivariate analyses (Table 2), covert use of the diaphragm was most strongly associated with study site (OR = 13.05, 95% CI = 7.47–22.78) for Durban; and (OR = 18.37, 95% CI = 10.35–32.62) for Johannesburg both as compared to Harare; not living with one's primary partner (OR = 2.43, 95% CI = 1.80–3.30); and having 2 or more sexual partners in the past 3 months (OR = 2.83, 95% CI = 1.90–4.21). Suspecting or knowing that the male partner had other partners (OR = 2.34, 95% CI = 1.57–3.49) and having a partner who did not use condoms during the trial (OR = 2.04, 95% CI = 1.37–3.03) were among the other predictors which significantly increased the likelihood of covert use.

Other predictors which were hypothesized to possibly influence a woman's decision to disclose her use of the diaphragm and gel, such as having an HIV positive partner or experience of any emotional, physical or sexual violence by their primary partner were not found to be associated with covert use (Table 2).

In the multivariate logistic regression analysis (Table 3), study site was most strongly associated with covert use [adjusted odds ratio (AOR) = 8.78, 95% CI = 4.61–16.74 for Durban; AOR = 12.40, 95% CI = 6.27–24.52 for Johannesburg]. Partner not using male condoms since the start of study (OR = 4.14, 95% CI = 1.88–9.14); age older than 35 (AOR = 1.67, 95% CI = 1.01–2.62); not living with primary partner (AOR = 1.61, 95% CI = 1.08–2.41); and knowing or suspecting he had other partners in the last 3 months (AOR = 1.71, 95% CI = 1.10–2.65) were also significantly associated with covert use. The direction for the frequency of sexual intercourse was changed in the multivariate analysis, and women who had sexual intercourse three times or less were less likely to use diaphragm covertly (AOR = 0.61, 95% CI = 0.42–0.87).

Qualitative analyses results

Perceptions on covert use and experiences of disclosure

Qualitative findings supported the results of the quantitative analysis in that, most women and their partners valued transparent communication and believed that participating in the MIRA trial and using the products should be a joint decision. Female participants also indicated that it would be very hard to follow the trial procedures and use the products consistently if the male partners were not informed about their use. Women also emphasized that it would be risky and could create problems with partners if they tried to use the products without telling them, especially if the partner discovered. On the other hand, telling partners about participating in the MIRA trial and that it entailed diaphragm use were not easy for several women. Many women agreed that one would have to wait for the perfect moment to tell the partner, maybe even after a demonstration that he would not feel it:

> I used [the diaphragm] secretly at first as I hid it from my husband. He did not even know that I had done that. One day when we were all very happy, I removed it when he was present. "What is that?"[he asked], and I told him saying, "How come you did not feel that I had something inside me? So it's the same". He showed interest in it, even today he likes it. (Harare, Female FGD)

While some male partners indicated that it would be "impossible" for their partners to use the diaphragm and gel without them noticing, others reported being unaware of the device until their partners showed them:

> She is not supposed to insert the diaphragm without my knowledge, but in other instances I found that I could not feel it. Maybe she used it without my knowledge. (Durban, Male IDI)

Indeed, one male partner found out only during a FGD that his partner had used the diaphragm and gel during the trial. This male partner reported never seeing or feeling the diaphragm. He knew about his partner's participation in the MIRA trial, but apparently did not know that it involved diaphragm use. Similarly, most women believed that it would be very hard for their partners to accidentally discover covert use of the diaphragm and gel. This belief was verified with the finding that only a few men discovered covert use (either through feeling the device; catching their partners when she was inserting or removing the device; or learning from others that she was participating in the MIRA trial). Even though male partners had mixed opinions about whether the use of gel could create any difference in men's ability to detect product use, overall, gel did not seem to influence women's ability to use the diaphragm covertly. Several women enjoyed extra lubrication provided by the gel, and it was pointed out in different male interviews that it would be hard for a man using condoms to feel a difference.

Consequences of discovery by the partner

Many men indicated that if they found out that their partners had been using the products covertly, that would mean a lack of trust between them, and that several men would interpret it as

Table 2
Distribution of women who have used the diaphragm covertly and the unadjusted odd ratios based on socio-demographic characteristics and other predictors analyzed in this study ($n = 2316$).

Domain and Predictor	*n*	%	% Used covertly	OR[a] (95% CI)
Socio-demographic indicators				
Age group				
18–24	918	39.7	9.0	1.00
25–34	894	38.6	6.8	0.76 (0.53–1.07)
35–49	503	21.7	11.7	1.30 (0.91–1.85)
Education				
High school or more	1033	44.6	7.7	1.00
Less than high school	1282	55.4	9.7	1.26 (0.94–1.70)
Employed in the past year				
Yes	1323	57.3	5.4	1.00
No	988	42.8	13.1	2.43 (1.80–3.30)
Living with the primary partner				
Yes	1587	68.5	4.7	1.00
No	729	31.5	17.7	4.10 (3.02–5.56)
Number of people per room in residence				
≥3 people per room	977	42.2	5.9	1.00
≤2 people per room	1339	57.8	10.8	1.83 (1.33–2.52)
Study site				
Harare, Zimbabwe	1174	50.7	1.3	1.00
Durban, South Africa	688	29.7	14.5	13.05 (7.47–22.78)
Johannesburg, South Africa	454	19.6	19.4	18.37 (10.35–32.62)
STI/HIV risk factors				
STI diagnosis at screening or enrollment[b]				
No	1965	84.8	7.8	1.00
Yes	351	15.2	14.0	1.85 (1.31–2.62)
Frequency of sexual intercourse				
>3 per week	829	35.8	7.0	1.00
≤3 per week	1487	64.2	9.8	1.39 (1.01–1.91)
STI symptoms in the past 3 months[c]				
No symptoms	1818	78.5	8.5	1.00
At least one symptom	497	21.5	9.9	1.25 (0.89–1.76)
Frequency of sex in exchange for money, food, drugs or shelter in the last 3 months				
Ever (at least once or more)	185	8.0	6.5	1.00
Never	2126	92.0	8.9	1.42 (0.77–2.60)
Number of male sexual partners in the last 3 months				
0–1	2129	92.1	7.7	1.00
≥2	182	7.9	20.9	2.83 (1.90–4.21)
Used male condoms since the start of study				
Yes	2266	98.0	8.5	1.00
No	47	2.0	23.4	3.67 (1.82–7.39)
Partner related indicators				
Regular partner's employment status				
Employed	1775	77.5	7.7	1.00
Unemployed	449	19.6	10.7	1.39 (0.98–1.97)
Student/other	66	2.9	16.7	2.41 (1.23–4.74)
Regular partner had other partners in the last 3 months				
No	686	29.7	5.5	1.00
Don't know	929	40.2	8.2	1.54 (1.03–2.30)
Yes (she knows or suspects)	696	30.1	12.5	2.34 (1.57–3.49)
Ever had a sexual partner who tested HIV positive				
No	1657	71.7	7.5	1.00
Don't know	587	25.4	11.6	1.61 (1.18–2.21)
Yes	67	2.9	11.9	1.69 (0.79–3.64)
Domestic partner violence[d]				
Experience of any emotional, physical or sexual violence				
No	659	52.3	9.9	1.00
Yes	602	47.7	12.8	1.34 (0.95–1.91)
Fertility and contraception				
Number of live births				
≥1	2113	91.2	7.7	1.00
0	203	8.8	19.7	2.68 (1.83–3.95)
Contraceptive use at enrollment				
Not using any effective contraceptive	152	6.7	9.9	1.00
Using a contraceptive[e]	2164	93.4	8.7	0.89 (0.51–1.56)

[a] Adjusted for time spent in the trial (from enrollment until exit interview; range 12–24 months).
[b] Participants were tested for *Chlamydia trachomatis*, *Neisseria gonorrhoea*, *Trichomonas vaginalis* and syphilis at screening and enrollment.
[c] Abnormal vaginal discharge, abnormal vaginal odor, genital irritation, painful urination, frequent urination, genital sores or ulcers, genital warts, pain during sex, lower abdominal pain unrelated to menstruation, other symptoms.
[d] Domestic partner violence questions were asked of a subset of participants. Emotional, physical, and sexual violence measures had non-significant associations with discreet use when analyzed separately (not shown in table).
[e] Pills, injections, implants, male or female sterilization, IUD, male or female condoms, other barrier methods.

a "definite" indication of her "having outside sex". One male participant reported:

> Yes, she can wear [the diaphragm] without you knowing but when you get to know, you get troubled and question why she did not tell the truth. It means we do not trust each other when one uses without the knowledge of the other partner. (Harare, Male FGD)

Women, especially from Zimbabwe, strongly agreed that there would be "fires" (i.e. serious fights) between the couples if the husband found out. Both men and women reported that other possible consequences of being caught varied from being divorced to being beaten.

Table 3
Predictors of covert use of the diaphragm and gel among MIRA trial participants: multivariate logistic regression analysis.

Domain and predictor	Adjusted odds ratio[a] (95% CI)
Age group	
18–24	1.00
25–34	1.20 (0.79–1.80)
35–49	1.67 (1.01–2.62)
Living with the primary partner	
Yes	1.00
No	1.61 (1.08–2.41)
Site	
Harare, Zimbabwe	1.00
Durban, South Africa	8.78 (4.61–16.74)
Johannesburg, South Africa	12.40 (6.27–24.52)
Frequency of sexual intercourse	
>3 times per week	1.00
≤3 per week or less	0.61 (0.42–0.87)
Used male condoms since the start of study	
Yes	1.00
No	4.14 (1.88–9.14)
Regular partner had other partners in the last 3 months	
No	1.00
Don't know	1.76 (1.14–2.73)
Yes (she knows or suspects)	1.71 (1.10–2.65)

[a] When controlled for age, education, employment in the past year, number of people living in a room, number of sexual partners, partner's employment status, having an HIV positive sexual partner, number of live births, and time in the study.

One can actually be sent back to their home [getting divorced]… We think that maybe…my woman…there is something that she is doing or she is being unfaithful…or she has suspicions on me… So it's a bit difficult. (Harare, Male FGD)

- [You] may fight or shout at each other, or be sent to your home for that…

- [He will tell you] "Let us go to where you took them". Then you [will see us] coming… I will be having swollen cheeks… [from being beaten] (Harare, Female FGD)

Degrees of disclosure

In the quantitative analysis, covert use was defined strictly for situations where women never told their partners that they were using the diaphragm. However, qualitative analysis revealed that covert use was not an all or nothing phenomenon, but it was rather a continuum of disclosure, and that for most women, it was important to be able to exercise some degree of covertness. Table 4 summarizes the continuum of covert use, and defines five levels of covertness, from full disclosure to completely covert use, with exemplary quotes. On one end of the spectrum were women who readily and consistently told their partners about their use, either because it was easy for them to disclose to some supportive partners; or because they were too afraid of the consequences of their partner finding out later (Level 1, Table 4). At the other end of the spectrum were women who never told their partners that they were using the diaphragm and gel (and some have used it covertly for up to 24 months); either because they believed that it should be their personal decision, especially with casual partners; or because they were too afraid that if they disclosed, they would be banned from using the methods and/or would face violence for suggesting using them (Level 5, Table 4). Another reason for not disclosing was women's unwillingness to deal with their partners' reactions since they expected men to complain about the diaphragm no matter what. One participant recalled how her husband complained about the intra-uterine device (IUD) after she told him about it, so she decided to keep quiet with the diaphragm:

"It is just because of the issue of the loop [IUD]; that I told him and he complained afterwards. So I just decided not to tell him [about the diaphragm] because he will make up other stories. It's not that I am not free. I don't want to hear him saying, "Hey this diaphragm is closing somewhere" or "I don't feel okay". (Johannesburg, Female FGD)

In between (Levels 2–4 in Table 4) were women with different needs and circumstances for hiding or disclosing their use of the products. Some women had initially informed their partners of the diaphragm and gel, showed them the devices, and the brochures from the MIRA trial on their first day back from the trial clinic. Then, some continued to inform their partners regularly that they were using the products, yet, for others, the partner did not see the diaphragm and gel again, and most of the time did not have an idea if she was still using them. This "don't ask don't tell" strategy worked especially for some men who reported being turned off sexually if they saw their female partners inserting the diaphragm and felt uncomfortable during intercourse if they knew that the device was inserted.

Several other women talked about experiences when they used the diaphragm covertly for the first few times, to find out for themselves if the male partner could feel it during sex. Women agreed that if male partners knew about the device in the beginning, they would be more likely to claim that they were feeling the device. Therefore the covert use strategy in this case was to test if male partners could really feel the device or a difference in sex with the diaphragm and the gel, which – based on women's accounts – they did not.

In the middle of the continuum, defined as Level 3 in Table 4, women occasionally resorted to covert use when their partners did not want to use condoms. Indeed, one of the major themes from the qualitative analysis was that, both men and women found that male partner's refusal to use condoms would be a rightful justification for women to use the diaphragm covertly. This finding also supports the quantitative finding that women whose partners did not use condoms since the start of the study were more likely to have used the products covertly. An important insight from qualitative analysis is that some men, especially husbands who refused to use condoms, also did not want their wives to use anything else for disease prevention. Therefore, husbands' not wanting to use condoms did not always mean that they would not use them because condoms distracted from sex or decreased their sexual pleasure, but because they did not want to be positioned as a man who cannot be trusted, or who could possibly infect his wife. Within this context, a man's refusal to use condoms made it harder for women to suggest diaphragm use openly, and in those cases it was better to use it covertly:

The other one [male partner] simply does not like one to protect oneself. Then one sees that it is better to use it privately. (Johannesburg, Female FGD)

Site differences for covert use

Qualitative data were further analyzed to understand the unanticipated site differences, with significantly higher levels of reported covert use in South Africa. Women in South Africa seemed to emphasize individual rights and personal agency to justify covert use as compared to women from Zimbabwe, who made a stronger case about negative consequences if caught. Compared to men from Harare, who are quoted above and in Table 4 for possibly beating or divorcing their partners if they found out about covert use, men from South Africa seemed to have higher tolerance for their partner's covert use:

I won't feel bad [if he discovers that his wife had been using the products without telling him], because everybody has the right of doing what she likes. (Johannesburg, Male IDI)

Discussion

The quantitative analysis, using a dichotomous definition of covert use, identified that approximately 9% of women had used the diaphragm "completely covertly" throughout their trial participation. Yet, an examination of the qualitative data revealed that occasional and circumstantial covert use was important for many women; that at different times and for different reasons they had resorted to covert use; and that covert use was a continuum. To our knowledge, this is the first study which attempts to define and categorize the continuum of covert use of a female-initiated method, the diaphragm, in the context of an HIV prevention trial.

Our findings highlight that the boundaries for the degrees of covert use were fluid, and that a woman could possibly report different degrees of disclosure based on the situation. This broader understanding sheds light on what had previously been described as a "discrepancy between theory and practice" in the context of covert use of vaginal methods, where women have highly valued the secrecy and control they could potentially get through covert use in their discourse, but did not seem to be exercising this control to its full potential when the measure of covert use was dichotomous (Green, et al., 2001). Within the context of microbicide use, it has been previously implied that covert or discreet use categories are not strictly binary, and that some strategies would be more covert than others (MacPhail, et al., 2006; Woodsong, 2004). Thus,

Table 4
Continuum of disclosure of diaphragm use from full disclosure to completely covert use, reasons cited by participants and exemplary quotes.

Degrees of disclosure	Description and reasons	Exemplary quotes
Level 1: Full disclosure	Told her partner on the first day, showed the device and how to insert it; informed partner about diaphragm always/most of the time that she was using it. Reasons: ◆ Free sharing of information with the partner ◆ Too afraid to be caught later	■ In my case, he knew that I joined the MIRA study and he used to encourage me and ask if I have it on or not and we both decided that we are also going to use the condoms. We both know that we are supposed to use the products. (Johannesburg, Female FGD) ■ He will beat you if he does not know [and finds out] [He will say]: "You were doing it behind my back. There is another man that you using them with." So I told him, so that I would not have problems. (Harare, Female FGD)
Level 2: Mostly open use	Did not tell the partner initially to "test" him, or told partner only in the beginning and did not discuss about products again. Reasons: ◆ Test the partner if he can feel the device ◆ No further communication with the partner (don't ask, don't tell). ◆ Partner turned off if he saw or knew that she was using the device	■ I did not tell him about diaphragm for the first time, because I wanted to see if he will feel it. I agree with you, you can hide it and no one will ask you something about that, but if he felt it, that [would have been] a problem. (Durban, Female FGD) ■ I feel comfortable (with the diaphragm), but now the problem is I don't know whether she has inserted it or not…She does not tell me. (Durban, Male in-depth interview) ■ It injects [irritates] me when I see it being inserted but if it is inserted [without me seeing] I don't feel it. But if I know that it is inserted, I usually have that thing. (Durban, Male FGD)
Level 3: Occasional covert use	Occasionally uses the diaphragm covertly when her partner does not want to use condoms. Reasons: ◆ Wants to protect herself from diseases ◆ Afraid to confront the partner about condom use	■ You are supposed to take care of yourself and have your own protection. If he doesn't like a condom, what more with the diaphragm, so I think you can just keep the diaphragm to yourself and know that you are protected. (Johannesburg, Female FGD) ■ The diaphragm is good for us women especially some of us who do not have the power to tell our husbands to use a condom. So, if only it succeeds in preventing from the [HIV] virus it's good because you use it discreetly. (Harare, Female FGD)
Level 4: Mostly covert use	Did not tell the partner for a long time that she was using the device; and in some cases lied to her partner to give the impression that she was not using the device. Reason: ◆ To make the partner use condoms for disease prevention and/or contraception	■ It is better maybe not to tell him that you've inserted the diaphragm, so that he'll always put on a condom when you have sex, unless they say that the diaphragm is approved. (Durban, Female FGD) ■ I also have a problem these days; he also refuses to use the condom because of the diaphragm. So that's why I don't tell him and [even] if he asks, I just say I don't have it on, it's your chance to put on your condom. (Johannesburg, Female FGD) ■ Yes [she used the diaphragm covertly]. She thought I was going to sleep with her without condoms. She was afraid since our child is still too young. (Harare, Male FGD)
Level 5: Completely covert use	Never disclosed that she was using the device. Reasons: ◆ It's her decision ◆ Does not want to deal with partner's issues with the products ◆ Casual partner ◆ Too afraid to disclose, afraid he might refuse if she asked ◆ Partner does not want her to use contraception	■ I still stick to the point that why should I ask him about how I should protect my private part? It's for myself. (Johannesburg, Female FGD) ■ I keep mine in the toilet because he doesn't know about it and I don't want him to complain about it irritating him. Or he will say he feels it, so I thought it was better for him not to know. When the time comes, I just go to the toilet and put on my thing. If it happens that I don't use it, it's just because of my laziness. (Johannesburg, Female FGD) ■ I go with it to Durban [city]. I take it because it might happen that I meet my sexual partner there in Durban North, and he would say "Let's make love". I won't utter a word. I'll just say [to myself] "It's okay my love. There is my thing and it's silent in there." (Durban, Female FGD) ■ Yes, he is right… She will be protecting herself [with the diaphragm, without telling her husband] because she knows the ways of her husband. So she will be afraid that, 'If I tell my husband, I have shot the lion's leg. Let me keep quiet.' (Harare, Male FGD) ■ One simply becomes scared that maybe he will not agree. He will say "You will not insert it here, this thing you are carrying" (Durban, Female FGD) ■ I had never told him at all because he did want me to use contraceptives. (Durban, Female FGD)

the seemingly discrepant attitudes and practice of covert use is resolved when disclosure is defined as a continuum, even if a smaller proportion of women end up using the devices consistently covertly for extended periods of time; women value covert use as most of them occasionally may feel the need to do so.

Similar to previous reports, many women preferred to inform their partners about the products that they were using (Buck, et al., 2005; Kang, et al., 2007; van der Straten, et al., 2005), and partnerships that are more stable, meaningful, trusting and communicative may be more conductive to open use of any method (Mantell, et al., 2008). One contrary finding was from Kenya, where most women supported the idea of using the diaphragm secretively (Okal, et al., 2008). However, more than half of the participants in the latter study were sex workers, and their preference for not disclosing is possibly related to the commercial nature of their partnerships.

In our study, accidental discovery by men, especially through feeling the diaphragm during intercourse seemed to be a relatively rare event, and it enhances the notion of the feasibility of covert use of the diaphragm and gel. The fact that the diaphragm was used

with a lubricant gel in this study and that the gel did not make a big difference in the discussions of covert use also makes the results of this study comparable and informing for future microbicide trials, where currently most of the products studied are in a gel form. It should be noted that men in this study were expected to be using condoms with diaphragm and gel, and reportedly did so approximately half of the time (Padian, 2007), which could have affected their ability to feel the diaphragm and gel, and accidental discovery could be higher in other contexts, when the diaphragm and/or gel are used without the male condom (Okal, et al., 2008).

In terms of implications for future microbicide studies, extra lubrication provided by gel was welcomed by almost all women and most men in this study (unpublished paper). Despite the earlier reports of the preference of dry sex in the region, and the widespread vaginal practices by women, more recent studies point out that even though excess lubrication may still be seen as messy and problematic the "right amount of lubrication", especially that which relieved the pain of intercourse for women is seen as an advantage (Braunstein & Van De Wijgert, 2005; Veldhuijzen, et al., 2006; Woodsong & Alleman, 2008).

While in the condom negotiation framework, empowerment and condom use have typically been described as having a positive correlation (i.e. more empowered women are more likely to negotiate condom use) (Blanc, 2001), findings from this study suggest that the association between women's level of empowerment and covert use of the diaphragm and gel is complex, and could correlate either positively or negatively with each other. For instance, women who appear disempowered in their relationships may not be using the diaphragm and gel covertly, fearing that discovery could lead to being beaten or divorced. At the same time, some disempowered women may fear partners' refusal and choose not to disclose if they believe that their partner is not likely to find out. In contrast, women who appear empowered may also be using the products covertly, mainly because it is seen as a personal decision that does not involve male partners. This latter group of women is also more likely to believe that they would not face negative consequences if their partners discovered diaphragm use. Women's perception of their own risk of transmitting HIV further complicates the decision-making process (Woodsong, 2004). For less empowered women particularly, the decision about whether it is worth to use the diaphragm covertly (and thus risking the consequences of being discovered) has to be weighted against the perceived risk of getting infected with HIV.

Another related and more practical concern – and one of the major attributes and promises of female-initiated methods – is how much the possibility of covert use increases women's control over method use, regardless of their empowerment level. In this study, some women perceived to be able to protect themselves from diseases or pregnancy when their partners refused to use condoms. Furthermore, covert use of diaphragm and gel was a strategy they used to ensure their partners used condoms, since some men did not want to use multiple methods simultaneously (Kang, et al., 2007). It has been indicated that providing female-initiated methods – either for HIV prevention or contraception – will give increased control to women and increase their sexual and reproductive health choices, and that this effect would be accentuated with methods that could be used covertly, but that there are challenges and limitations to how this potential control can be exercised by women (Green, et al., 2001; Mantell, et al., 2006; Mantell, et al., 2008). Challenges such as not being able to get permission from husbands to use the methods, the fear of discovery, stigma associated with using female-initiated methods and men's ambivalence towards these methods should be addressed appropriately, with the recognition that female-initiated methods for HIV/STI prevention will have to be used in the same gendered "landscape" that necessitated their need in the first place (Mantell, et al., 2006).

An important limitation of this study of covert use is that it was conducted in the context of the MIRA trial, and women's and their partner's experiences could be different outside of a trial setting. While trial participation may have facilitated disclosure to partners about the products and their use, it is also likely that frequent clinic visits for the trial follow-up have made it more difficult for women to use the diaphragm and gel covertly. Therefore it is possible that covert use rates might be higher under non-study conditions. Data in this study come from male partners who were informed by their partners about diaphragm use (except for one who found out about his partner's use of the diaphragm during a FGD), and therefore reflect the views of only this group, as opposed to men who were not informed. Additionally, due to relatively low levels of recruitment into FGD, the results may not be reflective of all trial participants, particularly for male partners. Another caveat is the secondary data analysis nature of this study, which limited our inquiry of covert use with the data available, and therefore it was not possible to address some important issues such as direct experiences/discourses of women who have used the diaphragm covertly; more details on how disclosure occurred; and experiences and reactions of male partners to disclosure or accidental discovery.

Women participants from Zimbabwe and South Africa had significantly different levels of covert use, and the difference remained after controlling for other significant predictors in the multivariate model. Even after further analyses of qualitative data to specifically explore site differences, conclusive results cannot be drawn due to lack of specific data. One suggestive finding was that relationship dynamics (e.g. level of male control over women's body; the gendered norms and expectations around female subordination to men; the ways in which sexual power dynamics were reflected in HIV prevention behavior, etc.) and women's perceptions of autonomy about product use appeared to differ at the Harare and South African sites, and these could play at least a partial role in explaining the site differences in covert use. A greater proportion of women in Harare were living with their primary partners (as compared to Durban and Johannesburg), indicating more stable relationships, and thus it is possible that the women were operating from different gender role expectations and relationship dynamics in the two countries. Further inquiry would be necessary to understand the reasons causing the observed country differences.

Conclusions

The use of a mixed method design has been instrumental in drawing a more complete and nuanced picture of covert use of the diaphragm and gel in the context of the MIRA trial, highlighting that disclosure and covert use existed along a continuum, rather than as a strict dichotomy. While only about 9% of women used the diaphragm and gel completely covertly in our study, occasional and circumstantial covert use was strategically important for many women, and gender power dynamics and women's behavior (i.e. covert use) can be related in complex ways. More empirical research on the connection between gender dynamics and disclosing the use of female-initiated methods is required to understand the need and preference for covert use across different populations.

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