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Anal Use of the Female Condom: Does Uncertainty Justify Provider Inaction?

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Abstract

Despite limited safety data and the absence of efficacy data, several studies have reported that the female condom is being used for anal sex by men who have sex with men. We describe providers' awareness of female condom use during anal sex among their clients and their experiences in counseling clients. We conducted semi-structured interviews with 78 health care providers recruited from various health care delivery systems in New York City: a family planning agency, a sexually transmitted disease agency, a hospital-based obstetrics and gynecology clinic, and two community-based AIDS service organizations. While two-thirds of providers reported that they were uncertain as to whether the female condom could or should be used for anal intercourse, nearly one-third believed that anything is better than nothing to prevent HIV/STIs during anal sex. Few providers had actually talked with clients about anal use of the female condom, and clients themselves had seldom mentioned nor asked for information about such use. Our findings highlight providers' uncertainty about anal use of the female condom. Lacking guidelines regarding the safety and efficacy of female condom use during anal sex, health care providers are left to make their own well-intentioned recommendations (or not) to potential users. The dearth of information on female condom use during anal sex could encourage individuals to use the female condom for anal sex, which may increase HIV transmission risk or represent a missed opportunity for protecting non-condom users. There is a need for a series of safety, acceptability, and efficacy studies and, in the interim, for the development of a carefully qualified harm-reduction set of guidelines regarding anal use of the female condom for health care providers.

Keywords

anal intercourse; female condom; health care providers; HIV/STI prevention

Contributors

J. E. Mantell, T. M. Exner, and S. Hoffman designed the study. J. E. Mantell, S. Hoffman, E. Kelvin, and S. Needham analyzed the data and wrote the article. Z.A. Stein contributed to the writing of the article.

Introduction

Two physical barriers — the male and female condom — are currently available for preventing unintended pregnancy and HIV/STIs, both of which have been tested in the laboratory against the passage of bacterial and viral infections and sperm (Drew, Blair, Miner, & Conant, 1990; Voeller, Coulter, & Mayhan, 1991). The male condom has been "grandfathered in as "safe" and efficacious for vaginal sex (de Vincenzi, 1994), and presumably for anal sex, and the female condom received FDA approval for vaginal use as a contraceptive in 1993 (Food and Drug Administration). The female condom also has a high likelihood of efficacy for protection against sexually transmitted infections (STIs) (French et al., 2003; Soper et al., 1993).

Unprotected anal intercourse is a well-established risk factor for HIV and other STIs among MSM (Caceres, Marin, Hudes, Reingold, & Rosasco, 1997; Koblin et al., 2003; Valleroy et al., 2000), and possibly among heterosexual women as well (Halperin, 1999; Satterwhite et al., 2007; Schwandt, Morris, Ferguson, Ngugi, & Moses, 2006). Although the FDA has neither evaluated nor approved the female condom for anal use, several studies document female condom use for anal intercourse among men who have sex with men (MSM) (Gibson, McFarland, Wohlfeiler, Scheer, & Katz, 1999; Gross et al., 1999; Renzi et al., 2003; Wolitski, Halkitis, Parsons, & Gomez, 2001). Moreover, Population Services International has promoted the female condom to MSM in Myanmar (AIDSMark, 2007) and Thailand (Population Services international (PSI), 2007).

However, questions regarding safety and efficacy of the female condom for anal intercourse remain, creating an information vacuum for health care providers. What should be providers' stance when they know that clients use the female condom during anal sex? Studies have reported that providers' acceptance and endorsement of contraceptive methods are central to their clients' initial uptake and continued use (Mantell, Hoffman, Exner, Stein, & Atkins, 2003; Simmons et al., 1997). Providers are also a conduit for information about sexual risk-reduction, and they need to be prepared to answer questions about anal use of the female condom.

To date, there is no information about how health care providers view the use of the female condom for anal sex and what messages they are giving their clients. This paper aims to fill that gap by exploring health care providers' understanding of anal use of the female condom and their experiences in counseling clients on this topic.

Materials and Methods

Participants and procedures

The data for this paper come from a qualitative study of health care providers' opinions about and experiences with a range of proven and unproven methods for HIV/STI and pregnancy prevention (Hoffman, Cooper, Ramjee, Higgins, & Mantell, 2008). Participants were recruited from among health care providers working at one of five different health care settings in New York City in 2001: a network of family planning clinics, a network of sexually transmitted diseases clinics, an obstetrics and gynecology unit of a large hospital, and two community-based AIDS service organizations. To be eligible for study participation, providers had to be conducting sexual risk-reduction counseling with agency clientele or be managers of a sexual risk-reduction counseling program. In order to recruit providers for this study, we informed the staff at the participating organizations about the study through presentations and the distribution of recruitment materials. Interested providers were invited to contact the study staff to confirm eligibility and, if eligible, arrange for an interview. All those eligible and interested in participating in the study were interviewed. The recruitment goal was to enroll

three managers and 15 health care providers at each site (total sample size goal of 90), and we successfully recruited and interviewed 78 providers and managers.

Semi-structured interviews of approximately 90-minute duration were conducted by study staff who were trained in the interview format. Interviews were audio-taped and transcribed verbatim. Participants at agencies that allowed distribution of a financial incentive received $45 for completing the interview. The study was approved by the Institutional Review Board (IRB) of the New York State Psychiatric Institute and Columbia University Department of Psychiatry and the IRBs of the participating agencies.

Measures

As part of the female condom section of the interview, we included one question specifically about female condom use for anal sex, “Even though the female condom was designed for vaginal use, some people are using it for anal intercourse. What do you think about use of the female condom for anal intercourse?” Interviewers were trained to probe based on the participants’ responses to this question to elicit more details about the providers’ opinions and experiences.

Data analysis

Six study staff independently generated broad thematic codes based on a subset of transcripts. We first examined the “a priori themes”, which were based on our interview guide, and then used grounded-theory to explore new concepts emanating from the qualitative interviews. Three research team members coded the data for this analysis; coding discrepancies were resolved through discussion until consensus was achieved. The coded data were organized using a qualitative data computer program (NVIVO 1.2 and 2, QSR International, Doncaster, Victoria, Australia). Unless otherwise noted, verbatim comments by participants reflect typical statements.

Results

Sample characteristics

The 78 health care providers participating in this study included 19 medical personnel (physicians, nurses, nurse practitioners, and physician assistants); 12 psychologists or social workers; 38 counselors or health educators; and nine managers. Two-thirds of these providers were women and they were diverse in terms of race and ethnicity (41% Black, 25% White, 4% Asian, 17% Hispanic, 11% other or mixed race, and 1% unknown), and highest educational attainment (4% had completed high school, 22% had some college or technical school training, 26% had completed a Bachelor's degree, and 49% had at least some graduate school). Across all sites, the participating providers described their clientele as being generally young, low-income, largely Black and Hispanic women and men at high risk for HIV and other STIs.

Since we found no discernable patterns in providers’ knowledge, attitudes, and practices on this topic by agency type for this analysis, we report aggregate findings on themes that emerged across 76 of the 78 participants who were asked the question about anal use of the female condom (in two cases, the interviewer neglected to ask this question).

Knowledge and concerns about anal use of the female condom

Fifty-two (68%) providers indicated that they were uncertain as to whether the female condom could or should be used for anal intercourse. In fact, our question about anal use of the female condom triggered questions from providers, such as “but is it effective?” or “What do they do? They put it on the penis and insert it that way? Or is there an applicator?” These concerns were

reflected in statements such as “I don't know if it is intended to be used that way.” “...it probably would not work as effective because the anal tract is a different tract to the vaginal tract”

Any barrier is better than no barrier

Despite concerns about the effectiveness of using a method in a manner other than that for which it was designed, nearly one-third of the providers believed that anything is better than nothing when it comes to HIV/STI protection during anal sex. Anal use of the female condom was seen as an option for couples who were unwilling to use the male condom, reflected in statements such as: “to be honest with you, if they're using something, it's better than using nothing....”

More general support for anal use of the female condom

A number of providers (n =18) endorsed the idea of using the female condom for anal sex reflected in such comments as

> “...on a scale of one to ten, a plus. Anything that you keep asking me as far as a condom and their use, I got to promote.... Of course, I think it's great, sure. Why not? Sure. You're protecting yourself. Smart person there.”

> “I think every way they can be used...even rectally, they should be used.”

However, in some cases (n = 13), providers’ support of anal use of the female condom was conditional upon its HIV/STI prevention efficacy, for example, “Well, if it helps to prevent HIV, then that's good.”

Uncertainty about clients’ anal use of the female condom

Only six providers reported having talked with their clients about using the female condom for anal sex. Most indicated that their clients had never mentioned that they used the method in this way, nor had they asked for information about it. One provider felt that discussing female condom use for anal sex was taboo: “I never recommend it and I don't believe that it was an option for us to venture into that department, anal sex with the female condoms.” However, those who reported discussing this with their clients felt ill prepared and uninformed about the specifics regarding this use.

> “There have been clients for whom I have brought that up as an option. Honestly, I don't know how easily the insertion goes.”

> “I've spoken to some people that called when I was on the hotline and they were males and they were asking about using the female condom in their anus and...I asked one of my co-workers about that and they said it wasn't a sure thing as far as preventing [STIs].”

One provider described his reservations about the method because it was unproven.

> “My sense has been....that the female condom has been tested a lot for vaginal use, but hasn't been tested a lot for anal use ...as far as efficacy. And that concerned me...because we [provider and client] talked about it a lot, that many gay men were using the female condom for anal sex, but I couldn't reliably say it had been tested or FDA-approved ...for that use.”

Another provider noted having researched how to use the female condom for anal sex and presenting those findings to the hotline volunteers who counsel clients.

> “Contrary to what I hear on the street, so to speak, they recommend leaving the inner ring in, whereas some have been saying that ‘no,’ they were taking it out for anal intercourse. So I have conveyed that information to volunteers.”

Unmet needs of providers and their clients

One sentiment expressed repeatedly by providers was the desire to have more information about whether and how the female condom should be used for anal sex and how well this method protects against STIs. This was reflected both in providers' questions about the method to the interviewers and their comments regarding the hope that more information will be forthcoming.

> "I would like to have more information about the anal use for the female condom ... for vaginal use, I know they have diagrams and ways of showing visually how to insert and use and things like that. But similar materials for anal use, and it wouldn't have to be particularly for men, but for women who use it anally."

> "Hopefully the FDA will find out some information regards to it [sic] and maybe it would be on the market."

In addition, a number of providers described a general unmet need for products that would protect against HIV/STI transmission during anal intercourse. As one provider said: "I would think that the manufacturers would be able to come up with one for the anal tract, since it is known ...that it is another way intercourse takes place."

Because of this unmet need, several providers described a long history in the MSM community of adapting products developed for other purposes to suit their specific needs.

> "I think men who have sex with men or gay or bisexual men...are and have been very creative about finding ways to...have sex that is pleasurable to them and finding ways of taking things that maybe weren't designed for them and making them theirs in some way."

Finally, the need for anal products and to brand and market them appropriately for anal intercourse was expressed.

> "Maybe it needs to get renamed and repackaged so that it's not called a female condom if it's going to be used in the gay male community."

Discussion

Although not FDA-approved for anal use, several studies conducted before our study found that the female condom was being used for anal intercourse among MSM. One study conducted between 1996-1997 in multiple U.S. cities found that 48% of 2,277 MSM participants had heard about using the female condom for anal sex, among whom 13% reported having used it themselves in this way (Gross et al., 1999). While a study in 1997 in New York City and San Francisco found that 35% of 240 MSM participants had heard of anal use of the female condom, among whom 16% had used the female condom for anal sex themselves (Wolitski et al., 2001). In addition, a study of MSM conducted in 2001 in Seattle reported that 21% of 76 study participants had used the female condom for anal intercourse (Renzi et al., 2003). (Table 1) Thus, it is likely that at least some of the clients of the providers we interviewed had heard about anal use of the female condom, or perhaps even used the product in this manner themselves. Therefore, it is surprising that only six providers reported having talked to their clients about using the female condom for anal sex. Perhaps providers consciously avoid the topic as they feel that they are unable to promote or discourage this use without more information. This idea was brought up by one provider who said that she thought this topic was officially off limits in her agency. It is also possible that the small number of providers who report talking to their clients about this topic may reflect a majority heterosexual clientele. No studies have looked at whether heterosexual couples use the female condom for anal sex.

The providers in our study also suggested that there is a general unmet need for new products that provide HIV/STI protection during anal intercourse. Such products are needed not just for the MSM and transgender communities, but for heterosexual couples as well, among whom anal sex is commonly practiced (Mosher, Chandra, & Jones, 2005).

Our study had a number of limitations. First, it was conducted in only five agencies in one city (New York). Therefore, our findings may not be generalizable to other groups of providers. In addition, our study was conducted in 2001 and therefore may not accurately represent the views of health care providers on this topic today. However, since our study was conducted, there have been no new studies regarding the prevalence of anal use of the female condom or on the safety and efficacy of anal use of the female condom. Thus, there is no new information that might influence provider opinions, and thus we might expect many of the doubts and questions providers had in 2001 to remain. Finally, we asked only one question about anal use of the female condom, after which additional information came from follow-up questions and probing, which relies on the training and abilities of the interviewer, and may therefore lead to bias in the responses.

Given the lack of recent research on this topic, we feel that our study has identified some key issues that providers in New York and elsewhere will likely confront in counseling potential female condom users even today. Our findings highlight the uncertainty about anal use of the female condom among providers in this study and mirror the contradictory messages found on a number of health department websites in the US and Canada. For example, the New York State Department of Health's website is the only one that asserts that female condoms should not be used for anal sex (New York State Department of Health, 2007), while those websites that are supportive of female condom use for anal sex provide contradictory instructions about inner ring use – removal (Hawaii State Department of Health, 2007; Massachusetts Department of Public Health, 2007), leave the ring in or take it out, depending upon preference (District of Columbia Department of Health, 2007; Public Health Seattle and King County, 2007), and no instructions regarding ring use (Texas Department of State Health Services, 2007).[1]

The uncertainty expressed by the providers and the conflicting messages on websites are not surprising, given that the efficacy of the female condom for use during anal intercourse has never been tested. Because there is not a unified message regarding female condom use for anal sex or on the best way to use the female condom during anal sex, both providers and clients are left in a quandary. If the female condom does not adequately protect against HIV/STIs when used for anal sex, or if the level of protection differs by whether the inner ring is removed or left in, then the contradictory messages regarding female condom use for anal sex could encourage individuals to experiment with off-label use of the device that may increase the risk of disease transmission. On the other hand, the lack of information on the female condom during anal sex may represent a missed opportunity for couples who are not using the male condom, but would use the female condom if its HIV/STI efficacy for anal sex were demonstrated. Either way, the public health community is failing to address the needs of a substantial segment of the population, and health care providers are put in the awkward situation of having to either avoid discussing use of the female condom for anal sex completely or address the topic with clients who bring it up, and who may already be using the method, without having the information they need to provide these clients with definitive answers.

To enable providers to counsel clients accurately about anal use of the female condom, the next steps should be the development of interim guidelines around anal use of the female

[1]We do not know if this information about anal use of the female condom was available on these websites at the time of our study, nor if the providers interviewed took the initiative to access any information regarding anal use of the female condom from these health department websites or any other sources.

condom, followed by a series of safety, acceptability, and efficacy studies. The three interim safety studies conducted to date have had serious methodological limitations, including inconsistent instructions, small sample size, high rates of loss to follow-up, and poor adherence to protocol, making their results inconclusive (see Table 1). In addition, we need to document the extent to which the female condom is being used for anal sex by both MSM and heterosexual populations and understand condom preferences and choices for anal intercourse.

The determination of some couples to find new forms of protection for anal sex speaks to the urgent need for alternatives to the male condom. Female condoms could provide an additional option for protection during anal intercourse for both men who have sex with men and heterosexuals. With no immediate prospect of either a vaccine or an efficacious anal microbicide and lack of evidence regarding the efficacy of male circumcision in reducing rectal HIV transmission, the safety and efficacy of the female condom for anal sex should be tested now, and providers should be given guidelines in the interim.

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Table 1

Summary of Studies on Anal Use of the Female Condom

Author & Year	Eligibility Criteria & Sample Characteristics	Study Focus	Study Design	Measures	Selected Findings
Jobst & Johns 1991	MSM Chicago, IL, 14 sexually active, 16-50 (X=32 yrs) monogamous HIV- gay couples, practiced anal sex, with no penile/anal abrasion, STIs, latex or polyurethane allergies, IV drug use, passed general physical exam, recruited from Howard Brown Memorial Clinic and enrolled 11 couples completed study; 3 lost to follow-up	Acceptability of FC (“Aegis” barrier pouch) as alternative to MC for anal sex and compare acceptability by HIV serostatus, relationship status, and partner serostatus. Protective capability Comfort and compatibility Asked to use FC and MC during anal sex, and instructed to push the female condom's inner ring past the sphincter muscle.	Acceptability and side effects Clinical trial 3-week follow-up	Functionality of FC via ASTM water-leak test to measure failure rate of used FCs HIV test at end of study	Average of 15 anal sex acts per couple during study period All FCs returned were found to have no leaks or tears; the one used MC had no leaks or tears All participants found concept of protection for anal sex partner acceptable All responding participants reported design and usage difficulties with FC (feeling seam or inner ring during intercourse)
Gibson, McFarland, Wohlfeiler, Scheer, & Katz (1999)	Convenience sample of 100 MSM in San Francisco recruited via venues frequented by MSM (neighborhood bars, free clinic project office) Low (14%) response rate	Opinions about experience using FC for anal sex	Acceptability and side effects Cross-sectional Anonymous	Frequency of FC use, experiences with insertion and use, likes and dislikes, overall approval rating	86% said they would use FC again 54% said they preferred FC to MC Acceptability was higher among HIV+MSM, in non-monogamous, in or HIV-discordant monogamous partnerships 33% reported difficulty with insertion, 17% irritation, 12% bunching up, 10% unpleasant texture, 9% noise Breakage reported in 3/334 episodes of use Only 16% removed inner ring and 29% used oil-based lubricant
Gross, Buchbinder, Holte, Celum, Koblin, & Douglas for the HIVNET Vaccine Preparedness	2,227 HIV-MSM enrolled in HIV Network for Prevention Trials Vaccine Preparedness Study; Recruited from 6 US cities; predominantly White and well educated 18 years, HIV- and older, reported anal sex with	Assess the frequency of use of the female condom for and sex among MSM, and describe the problems encountered	Acceptability Observational Self-administered	Frequency of insertive and receptive FC use in prior 6 months, problems encountered, likelihood they would use FC in future	48% of 2,277 had heard about using FC for anal sex 13% of 1084 who had heard of FC for anal sex reported use in prior 6 months Men with HIV+ partners were 2x more likely to have used FC than men with partners who were HIV- or of unknown status Among 95 receptive users, 47 (49%) reported problems such as pain, discomfort, lack of

Author & Year	Eligibility Criteria & Sample Characteristics	Study Focus	Study Design	Measures	Selected Findings
Study Protocol Team (1999)	another man in past 12 months	and the likelihood that they would use the female condom for anal sex in the future.			pleasure, insertion difficulties; difficulty keeping FC in place if inner ring removed Among 94 insertive users, 37% reported problems, e.g., lack of pleasure, difficulty keeping FC in place or inserting it. 2 receptive and 2 insertive users reported rectal bleeding
Wolitski et al. 2001	240 HIV+ MSM (69.2% of color) in NYC and San Francisco: mean age of 37.3 years Targeted sampling of MSM from AIDS service organizations, gay community venues (gay bars, gay pride events, bathhouses, sex clubs), cruising areas Self-identification as HIV +, had sex with man in prior year, age 18 years or older, race/ethnicity recruitment venue quotas fell within set for each venue by the study protocol.	Survey of untested barrier methods for anal sex (FC, N-9, simultaneous use of 2 MCs, i.e., “double bagging”)	Self-administered survey and qualitative interview	Sexual practices, substance use, access to health care, adherence to treatment, mental health, awareness and use of N-9, FC, “double bagging”	35.4% had heard of FC use for anal sex; such awareness was higher in San Francisco than in NY 5.4% of overall sample had used FC during anal sex, of whom 53.8% rated FC more pleasurable than MC 32.9% perceived FC to be as effective as MC, 4.7% to be less effective, and 17.6% as more effective, 44.7% were unsure
Renzi, Tabet, Stucky, Eaton, Coletti, Surawicz, et al. (2003)	56 monogamous HIV-seroconcordant MSM couples who were inconsistent condom users in past 3 months recruited from HIV clinics, advertisements and outreach in Seattle At least 18 yrs, relationship of 3 months or more, willingness to use MC and FC for anal sex between 3-10 times , and no inflammatory bowel disease, rectal bleeding or rectal surgery among receptive partners	Compare approval ratings and reports of interim safety outcomes of both male and female condom use during anal sex	Cross-over trial with randomization to latex MC and FC use with anal sex, with 3- month follow-up assessing safety and acceptability	Safety: self-reported condom breakage, condom slippage, semen spillage, rectal bleeding, & pain or / discomfort during condom use; anal pap smears and rectal biopsies at baseline and end of each condom phase from receptive partners Acceptability: willingness to use FC or MC for anal sex in future partnerships of varying degrees of HIV risk 5-point Likert scale from strongly prefer FC to strongly prefer MC for anal sex with new partner of unknown HIV status. Strong or somewhat preferences of FC or MC for anal sex with	21% of 76 study participants had used FC for anal sex Safety Significantly more incidents of condom slippage, pain, discomfort, and rectal bleeding with FC than MC among receptive partners More episodes of rectal bleeding with FC, but this difference was not statistically significant. No difference in condom breakage rate and prevalence of inflammation on anal pap smears or epithelial disruption by type of condom among receptive partners Acceptability 21% of receptive and 26% of insertive partners reported they would be willing to use FC compared to MC with a partner of unknown HIV status (61% of both receptive and insertive partners). Willingness was associated with comfort, ease of use, perceptions of FC being stronger and safer than MC. Among receptive partners, willingness was associated with past problems with MC and no problems with FC during study, whereas among insertive partners, willingness was associated with past use of FC and being HIV +

Author & Year	Eligibility Criteria & Sample Characteristics	Study Focus	Study Design	Measures	Selected Findings
				new partner of unknown HIV status	
Female Health Company, Hindustan Latex Ltd, National AIDS Control Program (2006)	372 female sex workers, 144 MSM out of 170 contacted, and 201 couples in India (Andhra Pradesh, Kerala, & Maharashtra) Among MSM, 58.3% were between 21-25 years and 68.1% had completed middle school	Acceptability	3 months	Structured interviews and Focus groups Perceived efficacy, reliability, ease of use, enabling factors affecting initiation and negotiation effects on partner communication	Among MSM only Almost half knew of FC 94% used FC consistently over 3- month period MC use decreased from 94 % to 84% during study period Main reasons for FC use was non- reliability of MC condoms (35%) and desire for more lubrication (37%) 81% liked the lubrication, 79% reliability during sex, 42% felt FCs gave better protection due to larger size of device, 40% felt that they could use FC with partners/clients who refused MC use, about 1/3 thought sex was more pleasurable 57% reported difficulties with insertion, but this was reduced with practice 80% intend to use FC in future, with 57% wanting to use it in all sexual encounters MSMs wanted appropriate and relevant educational materials re: anal use

FC = Female condom; MC = Male condom