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The Impact of Information about the Female Condom on Female Condom Use Among Males and Females from a US Urban Community

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Abstract

This study investigates the impact of exposure to information about a relatively new prevention method, the female condom (FC), on actual FC use in a community of adults at risk of HIV/STI. A community-wide survey from a mid-size US city is used to estimate unbiased effects of information about the FC on FC use among sexually active men and women. To control for potential confounders we use propensity score matching which matches the group exposed to FC information to participants who were not exposed, achieving a statistical quasi-randomization in terms of ten measured confounders. Comparisons of exposed to unexposed participants matched on their propensity scores conclude that information about the FC increases initiation of FC use, such that eleven percent more of the men and women who receive FC information reported ever using the FC. We demonstrate the use of propensity score matching and illustrate some of its strengths and limitations.

Keywords

HIV prevention; female condom; propensity score matching; observational design

Introduction

The female condom (FC) is a highly effective alternative to the male condom (MC) for the prevention of HIV and sexually transmitted infections (STI) [1–2]. It was invented in 1984 by Lasse Hessels [3] and is now widely available in a number of forms [4], most common in

the U.S. being the FC1, made of polyurethane, and FC2, of synthetic nitrile rubber latex, both produced by the Female Health Company. The FC has the advantage that women can initiate its use with their partners, including steady, casual and paying partners, and can negotiate FC use when a partner refuses the MC, or encourage protected sex with either option [5–7]. A recent review of numerous FC acceptability studies indicated that the FC can become acceptable to women and men in a wide variety of ethnic populations, age groups, and risk groups across the U.S. and worldwide [8]. Most reported user concerns about the FC diminish with practice, and in some studies, some women and men have reported liking it better than MC [9]. Hence, the FC contributes to increased protection from HIV and STIs, in addition to women's sense of empowerment [10, 31].

Despite its advantages, the FC has not achieved the widespread acceptance and use of the MC. Awareness of FC in particular still lags behind that of MC, despite efforts to promote it [11]. Further, several studies have demonstrated that women show tremendous initial interest in the FC, but that this interest is not always sustained [10, 12–14]. A number of barriers have been cited in the research literature to explain the slow adoption of the FC as a protective method on par with the MC, among them affordability, price per unit being many times higher than MC [3], low availability due to skepticism among health care providers themselves [15–17], as well as some reluctance related to perceived initial inconveniences [11].

Accurate information about the FC, coupled with supplying free FCs, training and practice for women and couples, have been shown to help with its acceptability and adoption as an alternative STI/HIV protective method [1, 18]. Health campaign efforts to increase FC acceptability, promotion and adoption at the community, population or national level are increasingly recognized as necessary [19–21]. Evaluation of the impact of such campaigns that target entire populations are difficult, because exposure is not achieved through randomization, but participants self-select themselves in the 'treated' (or exposed) group [22].

We investigate the potential impact of information about the FC on actual FC use by men and women from an observational community-based study of FC awareness and use [11, 14] using Propensity Score Matching (PSM). The study was conducted in Hartford, Connecticut, among adults at elevated risk of STI/HIV infection, i.e., sexually active men and women over 16 years of age living in a city with high prevalence of these diseases. The multi-year project, called Enhancing HIV Prevention through a Multi-level Community Intervention to Promote Woman-Initiated Prevention Options, was designed to increase the community availability, accessibility, and support for use of the FC. In this paper, we are interested in the potential effect of receiving information about the FC on the use and adoption of FC by *both* men and women, before the actual intervention was implemented.

Methods

Study sample

As part of the evaluation design of the multilevel community intervention to promote the FC, the project conducted annual cross-sectional risk, attitude, and behavioral surveys with a community sample of Hartford residents. The data for this paper comes from the third annual cycle of the community wide cross-sectional surveys collected in 2011–2012. The sample analyzed here includes residents who are at least 16 years of age, and currently sexually active (in the last 30 days) heterosexual males and females. The recruitment was done using Respondent Driven Sampling (RDS) [23], which begins with 'seeds' with desired characteristics, in our case diversity in terms of ethnicity, gender, age, and region of residence in the target neighborhoods of the city. After completing the survey, these 'seeds'

were asked to give out three coupons to people in their networks, who, if eligible and completed a survey, were also offered three coupons to pass on. This procedure was continued until the desired sample size of approximately 400 was achieved. RDS promises to produce estimates that are asymptotically unbiased [24].

The original study was designed to assess over time the impact of multilevel interventions created and implemented by a community coalition to increase FC promotion and use at the individual, health/service organization, and overall community levels. The actual intervention was still in planning stages at the time of the survey reported here. Furthermore, multilevel community change processes are slow [25–26], and require significant time and sustained effort in order to achieve a measurable impact. Therefore, we focus here on the influence of FC information (primarily positive) from any source on FC use using a proxy variable that represents exposure in the natural (community) environment, and that was demonstrated to predict FC use practices [11, 14].

Measures

The FC exposure variable, which is the proxy used for the ‘treatment’, was based on survey questions about how many people had spoken positively to the participant about the FC and how many had spoken negatively about it. Participants who reported being spoken to positively by their peers were considered ‘exposed’ (regardless of also receiving negative information), while those who received no FC information were considered ‘not exposed’; five participants who received only negative information were excluded, because it is unclear whether this could encourage the use of this novel device. This yielded 229 unexposed and 164 exposed cases. We decided to measure exposure with reception of positive (with or without negative) information, primarily because the FC is known for a number of inconveniences [11] that cannot simply be overlooked. Moreover, more men and women who received both positive and negative information use the FC than those who received only positive information.

In our cross-sectional community survey, FC attitudes were measured with the average of 23 items about responses to perceived FC characteristics [27] (range 1–4, higher score is more positive attitudes; Cronbach’s alpha .79). Six items were used to assess the FC-related knowledge index; sample item: ‘Female condoms can be inserted up to 8 hours before having sex’ (yes = correct). Those choosing the right answer were scored 1 on each item, while wrong answers and ‘*don’t know*’s were scored 0; the proportion correct index ranges from 0 to 1 ($M = 0.69$, $SD = 0.19$). We use unit weight total scores for all multi-item measures, which are reliable replacements for true scores [28]. FC use was measured with a question about ever having used the FC (no/yes). We also included as confounders ever having seen the FC (no/yes), self-assessed likelihood to get HIV (one question with a 5-point responses from very unlikely to very likely), and ever having seen/heard of FC anywhere (yes/no composite) built from a list of venues and media.

Analytical procedures

When health interventions are conducted in community-based settings, randomized control trials (RCT) designs are not feasible, e.g., when researchers or health care providers cannot refuse offering HIV/STI protective measures to at-risk participants, or when intervention recipients are likely to interact with those not directly exposed to formal interventions, thereby contaminating the exposure groupings [29–30]. Furthermore, community-based health communication campaigns aimed at preventing diseases like HIV/AIDS and STIs often contain components offered to entire communities, making randomization to treated vs. control conditions impossible. These observational designs, however, have the advantage

of being more generalizable, better resembling real-world settings than RCT designs [22, 32].

Even when assignment to conditions is not achieved with randomization, researchers can obtain unbiased effects of exposure to health information. When no good matching comparison group can be obtained to achieve a quasi-experimental or experimental design, researchers can rely on analytical methods for observational data that estimate the unbiased effects of health interventions by accounting for confounders and self-selection effects. The major threat to evaluating true intervention exposure effects in observational designs is the potential impact of omitted confounders on the exposure – outcome relationship [33]. Such potential confounders for evaluating community level FC interventions are suggested by prior research on FC use and adoption. Some variables that have been shown to impact women's FC use, for example, are: having multiple sex partners [11], MC use [9], having heard of the FC [34], substance use [35], marital status, ethnicity, and previously having had a STI [36]. One well-known option for estimating health intervention effects while accounting for such potential confounders is Propensity Score Matching (PSM) [37–38]. PSM estimates unbiased effects of exposure to interventions from observational designs by properly accounting for confounding effects.

Our analyses follow the Rosenbaum and Rubin's PSM method [38]. To summarize the approach, PSM is based on estimating the likelihood (propensity) of being exposed to an intervention [39] by examining a number of potentially confounding variables that may jointly affect self-assignment (or self-selection) into the exposure or treatment group, as well as the outcome of interest (like protected sex). These scores are then used to stratify participants into subgroups or blocks of unexposed ('control') and exposed ('treated') cases, such that matched blocks become similar on the confounding variables (as they would, had random assignment been used). This is followed by the estimation of several treatment effects by comparing the matched blocks on the outcome of interest, and then averaging the effects across all pairs of blocks. In point of fact, PSM 're-randomizes statistically' participants from non-RCT research designs into pairs of RCT-like blocks, based on propensity scores emerged from a logistic model that predicts the self-selection (or exposure) process. Alternatively, participants can be matched individually or in small clusters [40].

The first step in PSM estimation is to identify the likely common causes of both self-selection into the exposed group and of the outcome of interest, which need to be included in the confounder pool. This ensures that the effect of exposure on outcome will be not be affected by the bias due to self-selection [33]. Choosing what variables are expected to act as confounders, rather than as covariates or mediators, is a difficult theoretical rather than a statistical decision that will affect the results of the analyses [39]. The task is even harder in our case, because little is known about male use of FC, its predictors, and potential confounders for male self-selection into health interventions and men's FC use.

Good candidates for such potential confounders are background variables that precede temporally and causally both self-selection and FC use, like gender, education, income, having sought out HIV/STI preventive services, or having had STIs in the past. Also, attitudinal measures related to sexual behavior, like attitudes and knowledge about MC or FC, or behavioral measures like the proportion of unprotected sex or MC use are good candidates. Variables that function as potential mediators, i.e., are influenced by the exposure (to information or health messages), and in turn impact the FC use outcome, like the sense of self-efficacy to use FC, should not be included in the confounder pool [29]. Clear outcomes of the exposure variable should also not be considered among confounders, e.g., the women's sense of empowerment [10].

Accordingly, the potential confounders we selected to estimate the propensity scores were: 1) gender; 2) age; 3) having seen a FC before; 4) ever having had an STI; 5) having sought HIV services ('In the last 6 months, did you seek HIV prevention or contraception services?'); 6) FC attitudes scale (range 1–4); 7) FC knowledge; 8) use of MC in the past 30 days (yes/no); 9) having seen/heard of FC in any media or from local venues; and 10) self-perceived likelihood to get HIV. The estimation of propensity scores and effects was performed in Stata 12 [41] and data management and basic analyses were done in SPSS 16 [42]. The propensity scores were obtained by regressing the exposure variable on the ten confounders using logistic regression, and then saving the probability of belonging to the exposed group for each case in the data. Thus the propensity scores are simply the model estimated probabilities of belonging to the exposed group, or the conditional probability of exposure given the measured covariates [43]. We assessed the sensitivity of our estimation method by testing whether important confounders have been missed, and using three alternative estimation procedures available in *Stata*.

Results

The sample analyzed here consisted of 200 women and 193 men, of average ages $M = 42.09$ ($SD = 10.95$) and $M = 43.11$ ($SD = 10.83$), respectively. Forty-two percent of the sample was exposed to positive or to positive and negative messages about the FC. Among those exposed were more women and younger participants, and more who had a past STI, sought HIV services, had ever seen the FC before, reported seeing/hearing about FC in media, more who had used MC, and had more positive FC attitudes, but they reported similar FC knowledge. More of the participants exposed to FC information (primarily positive) reported ever using the FC, and they used it more times than the unexposed. We present in Table 1 the main descriptive variables by condition and gender. Few differences were found by gender within each condition, though more women than men reported a past STI in the exposed group, and women in the unexposed group had more positive FC attitudes than men.

A first look at the difference in ever using the FC between conditions indicates that there are significantly more FC users in the exposed group, but the observational nature of the data casts doubt on such statistical tests, because potential causes of both exposure and FC use may be biasing it. One alternative approach can estimate the confounder adjusted exposure effects in pairs of blocks that are extracted from the sample, which are balanced on all the confounders, and then average the effects across all pairs of blocks [39], which resembles a mini-meta-analysis [40]. Other approaches can match individuals in pairs or small clusters [39, 40, 44–46], yet each method matches different total cases overall.

The ten confounders were collectively good predictors of the exposure variable; the probability of at least one predictor being significant was $p < .001$, likelihood ratio chi-square of 89.75 ($df=10$), pseudo (for logistic regression) $R^2 = .19$. Moreover we tested the sensitivity of the model with Stata's *linktest* [54], was not significant ($p = .854$), indicating that most predictors were included in the model.

We extracted four pairs of blocks that ensured that the means of the confounders were not different between exposed and unexposed in each block, using the *pscore* Stata command. The region of common support for the four pairs of blocks, i.e., the range of propensity scores that span over both the exposed and unexposed groups, was [.11, .93]. Seventy-seven participants were not successfully matched, so 168 unexposed participants were ultimately matched against 148 exposed ones. The four pairs of matched blocks achieved balance on all confounders, i.e., no differences were seen on these confounders between exposed and unexposed conditions within each pair of blocks.

If we express the impact of exposure on FC use as percentage differences between FC users in each exposed block and those in the paired unexposed block, we find the effect significant in all four blocks, i.e., the 95% confidence interval for the percentage difference does not include zero (see Figure 1). The average treatment effect was computed using the formulas for estimated overall exposure effect and for the estimated standard error of the exposure effect in Yanovitzky et al. [39]. The difference was found to be 11.0% in ever-used FC between men and women who were exposed to information about the FC (primarily positive) and those unexposed, 95% CI [2.7, 19.3]. To further test the sensitivity of the method, we re-estimated the effect by excluding the strongest two then three predictors in the model. Moreover, we used Stata's *psmatch2*, which matched 133 exposed to 168 unexposed cases using the nearest neighbor method [47–48], and found a difference in FC use between the exposed and unexposed matched participants of 17.3%, SE = 7.4, $t = 2.33$, $p = .020$. Yet an additional test (*attnd*) matched only 69 exposed to 148 unexposed cases and showed an average effect on the treated of 20.9%, bootstrap SE = 8.2, $t = 2.54$, $p = .011$. We report the most conservative estimate, the significant 11% difference.

Discussion and Limitations

This study evaluated the impact of exposure to FC information on FC use by women, as well as directly by men, rather than indirectly from female partner accounts [49]. We found a statistically significant effect of being exposed to information about the FC (primarily positive, accompanied or not by negative information) on whether males and females ever used the FC in a community sample of adults at risk of HIV/STI. Eleven percent more adults who are sexually active and exposed to HIV/STI risk are using the FC when someone has ever spoken to them about the FC. These findings seem to corroborate a diffusion of innovation type of effect [50, 53], whereby men and women engage in new preventive behaviors and use new devices when exposed to information about them; alternatively, peers may act to emphasize existing knowledge and attitudes about the FC which encourages FC use. Initial FC use, however, does not guarantee sustained use [14], and especially for the FC, repeated trials and troubleshooting seem necessary for adoption of FC as a regular HIV/STI preventive alternative.

We are not aware of other major interventions aimed at high risk women that had been ongoing in Hartford, CT, during the time of this study [11]. While the manufacturing company itself (Female Health Company) has launched marketing campaigns in several large cities in the U.S., our study location was not one of the main targeted sites [51–52]. Further, the survey did not include detailed measures of exposure to specific interventions or messages. Therefore, we cannot directly link the measure of exposure we selected to specific past or current interventions or health campaigns.

The distinction drawn here between 'exposed to information about FC' vs. 'not exposed to information' is, of course, only a proxy for a true exposure to messages propagated from health interventions. It has the advantage, however, that it does not need to assume that the cognitive and emotional processes involved in deciding whether to use the FC are based solely on the valence of information, which would be a simplified view. FC are known for a number of perceived disadvantages, like unappealing appearance and difficulty in initial use [9], which are captured in the FC attitudes scale in this study. These disadvantages cannot just be overlooked or hidden from potential users, but require trial and troubleshooting for the product to become part of routine HIV/STI protective practices [14]. Health interventions promoting FC use have consistently addressed initial perceived shortcomings of the FC, compared to the existing MC.

The primary benefit of the Propensity Score Matching (PSM) approach illustrated here is to provide a method to assess unbiased effects of real exposure to community interventions on HIV/STI protective behaviors in the absence of a pre-defined non-intervention control group. When estimating the effects of exposure to preventive health information messages or campaigns using PSM, the choice of potential confounders is tantamount for the estimation of the effects. Some decision criteria to ensure researchers select the best candidates for estimation of propensity/likelihood of exposure are provided in the results section, like a high probability that at least one of the predictors of exposure is significant, or the fit of the propensity score model.

Thus, the nuances of specific health intervention components (mechanisms) and content (positive, neutral, or negative information or behavioral skills building) suggest identification of appropriate confounders in the development of the best propensity score matching models. In our case, we were interested in the long-term impact of past information about the FC on whether men and women currently use the FC. Because the FC use measure likely captures sustained use rather than recent initiation, some variables were deemed better candidates than others for confounding the exposure-FC use relationship. FC attitudes and knowledge particularly were considered as better predictors of FC use (and exposure) than FC self-efficacy. This is because FC self-efficacy depends on repeated trials of the product rather than predicting FC initiation [14], and as such is likely to be a mediator of the exposure – long-term FC use relation: FC users with high scores of self-efficacy have likely overcome initial barriers and have used FC several times already.

Researchers can alternatively test directly competing models separately for propensity score (selection models) and for the outcome (outcome models), or better yet, in a simultaneous model [32]. Some authors suggest using as many potential confounders as possible [38], so we repeated our analyses using all the variables listed in Table 1 as potential confounders, and the reported effects are virtually unchanged. The PSM method rests on the assumption that all potential confounders have been measured, which is rarely true. Also, matching cannot correct for misspecification of causal models at work [43].

Notwithstanding these limitations, this study is among the first to have tested the impact of exposure to information in a community-based setting on both male and female use of the FC, and demonstrated the utility and relative ease of accounting for potential confounders when evaluating the effects of exposure to health preventive messages in non-RCT designs. It also demonstrated the effect of exposure to information about the FC, which is naturally disseminated in community context, on actual FC use. Our analyses provide support for the benefit of health interventions and campaigns aimed at increasing awareness of and knowledge about alternative prevention methods like the FC among sexually active adults who are at risk of contracting HIV/STIs. The project also suggests that providers of HIV/STI and medical services in the communities should include among their services information and training on the FC and its use.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Fig. 1. Percentage Differences in FC Use between Exposed and Unexposed Participants from Matched Blocks
 No CI contains zero (all estimates are significantly > 0); mean propensity scores in each pair of blocks are shown below each block, as well as the numbers of cases in each unexposed (U) and exposed (E) block; weighted average effect shown last by filled circle.

Table 1

Descriptive Characteristics of the Female Condom Cross-sectional Survey Sample by Exposure to Information about the FC^a (N = 393)

	Unexposed		Exposed			
	All (n=229)	Males ^b (n=128)	Females ^b (n=101)	All (n=164)	Males ^b (n=65)	Females ^b (n=99)
Percentage	58.3% ^d	55.9% ^c	44.1% ^c	41.7% ^d	39.6%	60.4% ^{7c}
HS Education	46.6%	51.6%	40.6%	53.4%	52.3%	42.4%
Hispanic	54.1%	52.3%	56.4%	51.8%	40.0%	51.5%
African American	32.8%	32.0%	33.7%	34.8%	33.8%	35.4%
Married/living together	73.4%	75.0%	71.3%	70.1%	73.8%	67.7%
Separated/widowed	12.7%	14.8%	9.9%	11.6%	13.8%	10.1%
Past STI	39.7%	36.7%	43.6%	56.7% [*]	44.6%	64.6% [†]
Sought HIV services	30.6%	29.7%	31.7%	53.7% [*]	49.2%	56.6%
Have ever seen FC	62.0%	60.2%	64.4%	90.9% [*]	89.2%	91.9%
Seen/heard of FC in any media	5.7%	4.7%	6.9%	29.9% [*]	29.2%	30.3%
MC use (past 30 days)	51.4%	52.0%	50.5%	62.5% [*]	69.2%	57.9%
Ever used FC	17.5%	15.6%	19.8%	39.6% ^{*,c}	38.5%	40.4%
Age	43.71 [*] (10.84)	43.68 (10.30)	43.75 (11.53)	41.0 (10.81)	42.00 (11.81)	43.9 (10.11)
Proportion unprotected sex	.20 (.25)	.19 (.24)	.21 (.25)	.27 [*] (.30)	.26 (.30)	.27 (.29)
Likely to get HIV	1.44 (0.77)	1.44 (0.72)	1.44 (0.83)	1.61 (0.89)	1.69 (0.90)	1.55 (0.88)
Times used FC	0.59 (1.64)	0.52 (1.56)	.68 (1.74)	1.71 [*] (2.88)	1.82 (3.11)	1.64 (2.73)
FC attitudes	2.76 (0.29)	2.70 (0.26)	2.83 [†] (0.32)	2.82 [*] (0.31)	2.77 (0.31)	2.85 (0.31)
FC knowledge	0.70 (.18)	0.70 (.18)	0.71 (.18)	0.68 (.20)	0.64 (.21)	0.70 (.19)
Propensity score	.31 (0.20)	.27 (0.17) (0.21)	.38 [†] (0.23)	.56 [*] (0.23)	.48 (0.21)	.62 [†]

^a Percentages are shown for variables above the middle line, and means (standard deviations) below.^b Percentages are shown for participants in each category (e.g. Hispanic) of all males (or females).^c Percentages are of all exposed, respectively unexposed, participants.^d Percentages are of entire sample.^e p < .001

* $p < .05$ for differences between all exposed and unexposed participants, next to higher mean or percentage.

† $p < .05$ for differences between males and females, within each exposed and unexposed group, next to higher mean or percentage.