

Does a Choice of Condoms Impact Sexually Transmitted Infection Incidence? A Randomized, Controlled Trial

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Objective: The objective of this study was to assess whether providing a choice of condoms would increase condom acceptability, increase self-reported use, and decrease incident sexually transmitted infection.

Study: We randomized 414 men presenting with urethral discharge in Jamaica to receive either the “standard” clinic condom or a choice of 4 different types of condoms. Men were treated presumptively at enrollment and followed up at 1, 2, 4, and 6 months.

Results: Participants in the choice group had a strong preference ($P < 0.01$) for the most popular condom available in Jamaica. This preference did not translate into higher condom use ($P = 0.16$). The 6-month cumulative probability of first incidence of gonorrhea, chlamydia, or trichomoniasis was slightly higher in the choice group (21%; 95% confidence interval [CI], 15–28%) versus the control group (17%; 95% CI, 11–23%); the difference in the survival curves was not significant ($P = 0.35$).

Conclusion: A choice of condoms may increase perceived acceptability but not lead to increased condom use and subsequently lower sexually transmitted infection rates.

WE ARE ENTERING THE THIRD decade of the HIV pandemic, and access to condoms is still dismal in many parts of the world where they are needed most.^{1,2} Although access to condoms is a necessary first step, even in situations in which they are readily available, condoms are often not used. Reasons for condom nonuse are well documented and include reduced spontaneity and sexual sensation, introduction of distrust into relationships, cost, and basic lack of confidence that the method works.^{3,4} Many interventions have been designed to increase condom use but surprisingly few have been evaluated rigorously⁵ in randomized, controlled trials (RCTs) using biologic outcomes.⁶ A recent group-randomized trial

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evaluating a 1-day cognitive behavioral intervention demonstrates the importance of using objective biologic outcomes in addition to relying on self-reported behaviors.⁷ In that trial, men assigned to the intervention group reported slightly fewer acts of unprotected anal intercourse but experienced significantly more incident cases of sexually transmitted infections (STIs) compared with the control group. Unfortunately, interventions that have been shown effective in rigorous trials often involve labor-intensive counseling^{8–10} and may be difficult to scale up in developing countries where both resources and qualified staff are limited.¹¹

We sought to design an intervention that, if shown to be effective, could readily be scaled up in resource-poor settings. Studies have documented preferences for different condom attributes,¹² and some argue that providing a choice of condoms will increase use.¹³ The choice of condoms in the private sector is vast with over 100 different brands available in the United States alone.³ Whether this choice of condoms in the private sector translates into increased condom use overall or if consumers simply substitute condoms of lower perceived acceptability with condoms of higher perceived acceptability is not known. A San Francisco observational study in which women were offered a choice of different barrier methods found no link among: 1) hypothetical acceptability, 2) product choice, or 3) satisfaction while using the product with subsequent use. The authors urged a reframing of how product acceptability is measured in prevention research.¹⁵ A more recent observational analysis of couples randomized to one of 5 spermicidal agents found a similar lack of association between acceptability measures collected during the study and subsequent clinically relevant outcomes (time to pregnancy, duration of use, and consistency of use).¹⁶ The authors argue because their analysis was observational, they “may not have been able to adjust for all of the relevant confounders of any possible association between acceptability and pregnancy.” Only in an RCT can we be assured that associations, or lack thereof, are not influenced by unmeasured confounders.

In the public sector, providing a choice of condoms requires spending additional resources (Eli Carter, Director, Product Quality and Compliance, Family Health International, personal communication, May 24, 2005). In the absence of good evidence that

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choice translates into clinically relevant outcomes, we cannot justify this investment, especially with basic access to condoms lacking in many settings. Our objective for this RCT was to determine if providing men attending an STI clinic with a choice of male condoms would increase acceptability and self-reported use and, most importantly, decrease incident STI.

Methods

We conducted our trial at Jamaica's largest STI clinic in Kingston. Our intervention consisted of making available 3 different latex condoms in addition to the current public sector Unidus condom widely available in Jamaica. The Unidus condom is straight-walled, 52-mm layflat width, reservoir-tipped, lubricated with silicone and cornstarch, and packaged in a square silver foil pouch. The first intervention condom was the Rough Rider, which is the most popular private sector condom in Jamaica.^{17,18} It is straight-walled, 52-mm layflat width, reservoir-tipped, studded and ribbed, lubricated with silicone and cornstarch, and packaged in a rectangular blue plastic pouch. The second intervention condom was the Inspiral, which has been described by the popular press as "America's #1 rated condom" as a result of the unique loose-fitting shape designed to enhance sexual pleasure.¹⁹ It is screw-shaped, 54-mm layflat width (70 mm at the bulbous end), lubricated with cornstarch, and packaged in a purple, yellow, and black square foil pouch. The final intervention condom was a public sector condom distributed worldwide by USAID. This condom is contour-shaped, 52-mm layflat width, reservoir-tipped, lubricated with cornstarch, and packaged in a square white foil pouch.

To be eligible for inclusion in this study, the male participant had to be: 1) seeking treatment for urethral discharge, 2) willing and able to give written informed consent, 3) at least 16 years old (legal age of consent in Jamaica), 4) currently sexually active, 5) willing to use condoms, 6) willing to adhere to the follow-up schedule and all study procedures, 7) willing to refrain from self-medication with antibiotics during study participation, and 8) willing to ingest single-dose treatment for gonorrhea, trichomoniasis, or chlamydia infection observed by study staff. Exclusion criteria were a history of adverse reactions to the study drugs or products containing latex or previous enrollment in the study.

During the screening visit, eligible participants provided written informed consent, answered an interviewer-administered questionnaire, and provided a urine specimen for STI screening (gonorrhea, trichomoniasis, and chlamydia). They were examined and diagnosed (using a syndromic approach) and then were observed taking treatment for gonorrhea and chlamydia infection (500 mg ciprofloxacin and 1 g azithromycin, respectively) with food and drink. Study staff demonstrated proper condom use to participants, provided them with Unidus condoms free of charge, and asked them to use condoms with every act of intercourse until the enrollment visit scheduled 1 week later. The enrollment visit was scheduled 1 week later to allow us to enroll participants who had a proven ability to return for a follow-up visit and to allow participants to take the presumptive treatment on 2 days and thus reduce side effects.

During the enrollment visit, all participants were observed taking single-dose treatment for trichomoniasis (2 g metronidazole) with food and drink and then randomized to either the choice or control group using sequentially numbered, sealed, opaque envelopes containing the group assignment. Family Health International (FHI) prepared the randomization envelopes using a random permuted block scheme, randomly selecting block size among 3 different sizes. Study staff then administered a questionnaire, counseled participants about condom use and STI prevention, and

provided condoms (minimum of 20) to each participant at no charge. An upper limit was determined by the participant's self-reported coital frequency. The choice participants were provided an equal number of each of the 4 condom types. Follow-up visits were scheduled at 1, 2, 4, and 6 months when participants were administered a questionnaire, received STI risk reduction counseling, were treated syndromically for STIs, and provided a urine specimen for gonorrhea, chlamydia, and trichomoniasis screening. At these follow-up visits, participants could purchase condoms at the standard clinic cost of JM \$20 for 4 condoms (US \$0.33). The choice group was free to choose the quantity and type of condom. Participants received JM \$100 for travel reimbursement and either JM \$100 or \$200 (depending on type of visit) that could be used to purchase condoms. Finally, study staff encouraged participants to return to the study site between the scheduled visits to undergo STI screening if they thought they may be infected or to purchase additional condoms. Participants did not receive compensation for these interim visits.

The primary study outcome was time to first reinfection (gonorrhea, trichomoniasis, or chlamydia infection) in the choice group compared with time to first reinfection in the control group. For trichomoniasis detection, we used a previously validated in-house polymerase chain reaction (PCR) assay²⁰ coupled with the Roche PCR DIG ELISA (Roche Diagnostic System) throughout the study. For gonorrhea/chlamydia detection, we initially used the Abbott LCx Probe System (Abbott Park, IL) until this product was discontinued, and we switched to the Roche Amplicor CT/NG PCR assay in June 2003 (32% specimen tested with ligase chain reaction; 68% with PCR). We determined cumulative infection probabilities using the Kaplan-Meier method and Greenwood's formula for standard errors.

Given our planned study size of 1000 participants, we would have approximately 80% power to reject the one-sided null hypothesis that the STI rate ratio is greater than or equal to one, assuming that the true 6-month reinfection probability is 20% in the control group, the true rate ratio between groups is 0.67, a 20% loss to follow-up rate, and a 0.05 one-sided type I error rate. As a result of slow recruitment and financial constraints, we stopped screening after 19 months with 414 enrolled participants.

Secondary outcomes included acceptability measures and self-reported condom use. To determine if an overall preference for certain condom types was evident, an analysis was performed for the men in the choice group based on responses to repeated questions at each follow-up visit regarding their ratings of each condom type (5-point scale: 1 = liked it very much, 2 = liked it, 3 = neither liked nor disliked it, 4 = disliked it, 5 = disliked it very much) of 7 acceptability parameters (feel during intercourse, ease of putting on, lubrication, length, width, smell, strength). A 2-sided, 0.05-level Mantel-Haenszel mean score test, stratified by participant, was used to determine if a significant overall difference emerged in scores across condom types. If the overall test was found to be significant, then all pairwise comparisons between the individual condom types were performed at the 2-sided 0.05 significance level (i.e., using the least significant difference method of multiple comparisons). Self-reported condom use was assessed for each coital act during the 7-day interval before a participant visit as well as comparing condom use on a 5-point scale (never, less than half the time, half the time, more than half the time, always) in the 6 months before the study with condom use reported during the 6-month study. A Wilcoxon rank sum test on the difference scores (i.e., condom use during the entire study minus condom use during 6 months before the study) was used to determine if there was a significant overall difference in condom use across treatment groups. We planned these analyses before completion of data collection. As a result of the study design, neither participants nor

site staff could be masked to group assignment. However, we masked all FHI staff involved in the analysis and interpretation of the data.

The ethical review boards at FHI, the University of North Carolina, and the local Ministry of Health approved the protocol. All participants provided written informed consent. We adhered to the CONSORT guidelines in our reporting of results.²¹

Results

We randomized 414 participants between July 2002 and January 2004 and completed follow up in September 2004. Of these 414 participants, 37 (9%) were lost to follow up and 128 (31%) discontinued early (Fig. 1) with no difference in continuation between the 2 groups ($P = 0.6$). Baseline characteristics were similar for the participants in the choice and control groups (Table 1). Both groups had a median age of 26 and most had used condoms in the past (choice = 95% and control = 98%), although few reported using condoms always in the past 6 months (4% and 7%, respectively). Most thought that a choice of condoms would lead them to use more condoms (81% and 88%, respectively).

Participants assigned to the choice group expressed a strong preference for the Rough Rider condoms (Fig. 2). During each follow-up visit, approximately 80% of participants reported using the Rough Rider since their last visit, whereas use of the other 3 types of condoms dropped off sharply from interval to interval with only 24% of participants in the choice group reporting using the USAID condom during the last study interval (Unidus 31% and Inspirial 33%). Participants in the choice group ranked the Rough Rider significantly higher ($P = <0.01$) on a 5-point scale for all 7 acceptability attributes (feel during intercourse, ease of putting on, lubrication, length, width, smell, strength). For example, the Rough Rider's mean score for "feel during intercourse" after the first month of use was 1.7 (vs. Inspirial = 2.6; Unidus = 2.4, and USAID condom = 2.4). Participants in the choice group received over twice as many Rough Rider condoms (6831 condoms) than the other 3 types (Unidus = 2467; Inspirial = 2783; USAID = 2164). Overall, the choice group received slightly more condoms than the control group (14,245 vs. 13,035).

However, the strong preference for the Rough Rider did not translate into higher condom use in the choice group compared

TABLE 1. Baseline Characteristics

	Choice N = 208	Control N = 206
Age/yrs, median (range)	26 (16–57)	26 (16–55)
Education/yrs, median (range)	12 (0–20)	13 (1–20)
Union status, n (%)		
Married	4 (2)	10 (5)
Common law	43 (21)	45 (22)
Single	47 (23)	54 (26)
Visiting relationship	114 (55)	97 (47)
Sexually transmitted infection in past, median (range)	2 (1–20)	2 (0–17)
Ever used condom, n (%)	198 (95)	202 (98)
How often used condoms in past 6 mo, n (%)		
Never	30 (15)	23 (11)
Less than half the time	67 (34)	60 (30)
Half the time	27 (14)	23 (11)
More than half the time, but not always	66 (33)	81 (40)
Always	8 (4)	15 (7)
How many times sex in past 7 d, mean, (SD)	1.0 (1.4)	1.0 (1.5)
Having a choice of condoms will lead me to use more condoms, n (%)	169 (81)	181 (88)
Prevalent sexually transmitted infection		
Gonorrhea, n (%)	76 (36)	79 (38)
Chlamydia, n (%)	50 (24)	47 (23)
Trichomoniasis, n (%)	14 (7)	9 (4)
Two positives	27 (13)	20 (10)
Three positives	0 (0)	1 (<1)

with the control group. The Wilcoxon rank sum test on the difference scores comparing change from screening with final visit between groups was not significant ($P = 0.16$); over half of participants reported always using condoms during the study

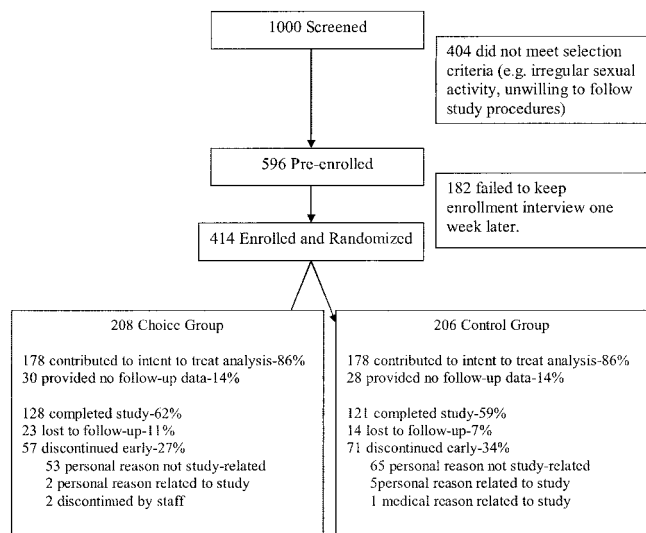


Fig. 1. Study participant flowchart.

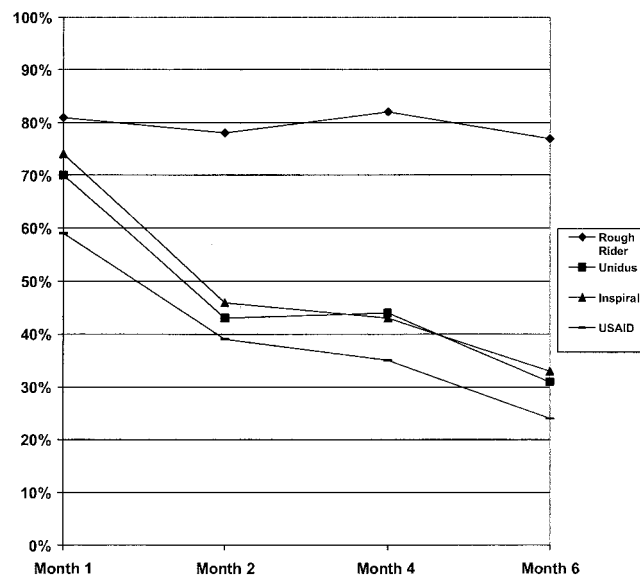


Fig. 2. Proportion of participants using condom type since last visit—choice group. (Participants in the choice group had access to all 4 condom types.)

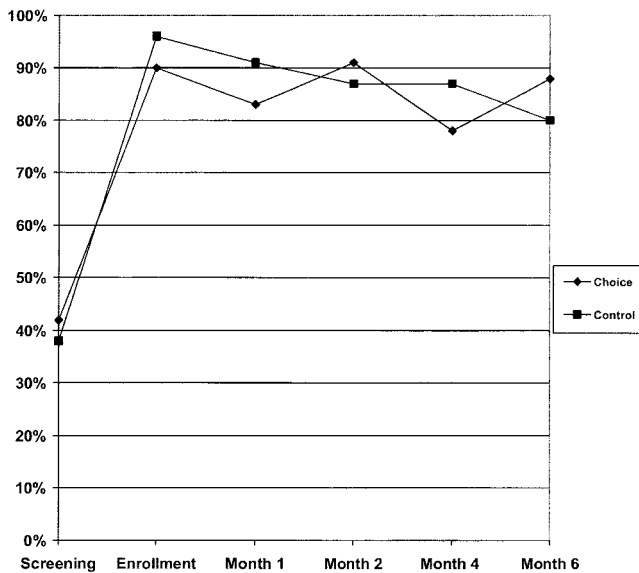


Fig. 3. Proportion of acts protected—all partners (last 7 days before visit).

(choice = 56%; control = 54%). Only 2% in both groups reported never using condoms during the trial.

At the screening visit, participants reported using condoms less than half the time in the previous 7 days (choice = 42%; control = 38%), and during the enrollment visit a week later, the proportion protected increased significantly in both groups ($P < 0.01$; choice = 90%; control = 96%) and stayed similarly high throughout the study (Fig. 3). Mean number of acts of unprotected intercourse throughout the study, as measured in the 7-day interval before each follow-up visit, was the same (0.2 coital acts unprotected) in the 2 groups. We also conducted these analyses stratified by partner type and results were very similar (data not shown).

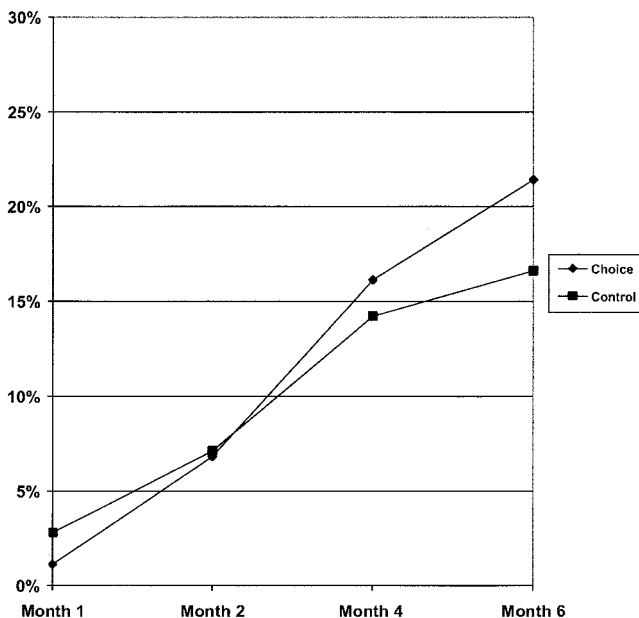


Fig. 4. Cumulative incidence of sexually transmitted infection (first infection—gonorrhea, chlamydia, or trichomoniasis).

The 6-month cumulative probability of first incidence of gonorrhea, chlamydia, or trichomoniasis was slightly higher in the choice group (21%; 95% confidence interval [CI], 15–28%) than in the control group (17%; 95% CI, 11–23%) (relative risk [RR], 1.3; 95% CI, 0.8–2.1), and the difference in the unadjusted survival curves was not significant ($P = 0.35$) (Fig. 4). Similarly, no individual STI outcome alone was associated with group assignment (chlamydia $P = 0.46$; gonorrhea $P = 0.64$; and trichomoniasis $P = 0.54$), although our power for determining comparisons for the separate STIs was low.

Discussion

Our study provides evidence that a choice of male condoms will not lead to increased condom use and subsequently lower STI rates. Participants provided a choice of condoms expressed a strong preference for the Rough Rider condom and reported using that type of condom more frequently than the other 3 types. Our study provides evidence that participants in the choice group simply substituted what they perceived to be less acceptable condoms with the more acceptable Rough Rider condoms with no net increase in condom use. Although providing a choice of condoms may increase the perceived pleasure of intercourse with condoms, our intervention did not impact the most relevant public health outcome—STI rates.

Our findings are consistent with 3 parallel studies conducted in Ghana, Kenya, and South Africa looking at the impact of condom choice on self-reported measures without biologic outcomes (Joanis et al., unpublished data). At all 3 sites, participants preferred the Rough Rider condom, but providing a choice of condoms had no impact on self-reported levels of use. Although in the related field of contraception, providing a choice of widely different methods increases overall contraceptive use,^{22,23} our studies suggest that within the narrow range of a single barrier method (male condoms), offering a choice has no impact. Offering a range of different barrier methods (e.g., male condoms, female condoms, diaphragms) may in some instances increase self-reported overall acts protected²⁶ as well as decrease STI rates;²⁶ but because these devices cost substantially more than male condoms, the cost-effectiveness of providing different types of barrier methods is still under study.²⁷

Being enrolled in our study appeared to have more than doubled self-reported condom use (Fig. 1). We do not know how much this reported increase is the result of: 1) the increased access to condoms, 2) the condom counseling provided to all participants, and/or 3) the social desirability of overreporting condom use. Without knowing the exact exposure risk in this population, it is difficult to evaluate whether this relatively high reinfection rate with these highly infectious pathogens is possible given the high level of self-reported condoms use. Future modeling may shed light on the veracity of self-reported condom use in our study.

Strengths of our study include the randomized design using biologic outcome measures and a relatively low loss to follow up rate (9%). The major weakness of the study was almost one third (31%) discontinued early, mainly for personal reasons not related to the study. However, the combined loss to follow up and early discontinuation was not different between groups (log-rank of the difference in survival curves $P = 0.65$) and is unlikely to have introduced confounding that influenced our conclusions. A second weakness was that we fell well short of recruiting our planned study size of 1000 participants. Although the site treated close to the anticipated number of males with urethral discharge, a large proportion was not interested in learning more about the study after initial contact. Our planned study size would have provided 80% power for the *a priori* hypothesis that a choice of condoms

would decrease STI incidence (one-sided $\alpha = 0.05$). With only 414 participants recruited and a high early discontinuation rate, our study power was reduced to approximately 50% given our original assumptions. However, because the incidence of STIs was actually higher in the choice group than the control group (RR, 1.3; 95% CI, 0.8–2.1), we can confidently conclude that among our participants, a choice of condoms did not have the desired impact of lowering STI rates. Whether our results are generalizable outside this study population or might apply to a different choice of male condoms is not known. That the 3 studies in Ghana, Kenya, and South Africa using similar protocols produced similar results lends confidence to our findings.

For public sector programs in which resources are often limited, our study supports the current general practice of providing a low-cost male condom. Globally, ensuring that all current demand for condoms is met must be the highest public health priority. Moreover, we must scale up interventions that have been shown to increase condom use and rigorously evaluate new approaches. With HIV vaccines and microbicides not available in the foreseeable future, we must make better use of the male condom, which is one of the main currently available approaches shown to decrease HIV transmission.²⁸

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