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The effects of condom choice on self-reported condom use among men in Ghana, Kenya and South Africa: a randomized trial☆

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Abstract

Background: Male condoms are readily available and affordable in many settings, but risky sexual acts still go unprotected.
Study Design: This unblinded randomized trial, conducted in Ghana, Kenya and South Africa, was designed to assess the impact of providing a choice of condoms on self-reported use and uptake over 6 months.
Results: We enrolled 1274 men. The mean subject-specific proportion of protected acts with all partners increased from baseline to 6 months by 0.07 in the control group compared to 0.03 in the choice group (p=.025). The observed results were largely consistent across all three countries. In the choice group, men clearly preferred one condom type over the others, and this preference was consistent across all three countries.
Conclusions: Providing one type of male condom in public sector programs appears justified. Programs should not focus on the number of brands available, but should encourage effective promotion and consistent and correct use of available brands.
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Keywords: Male latex condoms; Acceptability; Preference; Condom uptake

1. Introduction

Increasing condom use is a key strategy to control the spread of sexually transmitted infections (STI) and HIV. Interventions have included expanding condom distribution channels, lowering the price of condoms and providing free condoms [1]. Social marketing programs have helped promote affordable condoms [2] and have improved uptake through promoting sexual pleasure [3]. Several studies and a recent commentary in this journal have suggested that addressing concerns about condom fit and feel or providing variety in available condom types may help increase condom usage [4–9]. Other studies have explored user preferences for certain condom attributes [10,11]. Donors have increased the number of condoms distributed in many developing countries. Although condoms are now more available and affordable, many risky sexual acts still go unprotected [12].

The United States Agency for International Development (USAID) has traditionally supplied only one type of condom in developing countries (in 2004, this was a straight-walled, standard latex condom with a reservoir tip manufactured by several US suppliers). While providing one condom type simplifies procurement, common sense dictates that individual preferences could affect uptake and sustained use. To investigate whether providing a choice of condoms could increase use, FHI (formerly Family Health International), under the guidance of USAID, simultaneously designed and conducted two randomized trials, one among men seeking

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treatment at an STI clinic in Jamaica and the other among a broader population of men in Africa. Because the Jamaican men were obviously at risk for STI, the primary end point in the first study was STI incidence with self-reported condom use as secondary. However, because we anticipated that STI incidence would be rarer among a more general population and the effect of choice too small to justify the cost of including a clinical end point, the African trial was designed with self-reported condom use as the primary end point. The Jamaican trial failed to find evidence that providing a choice of condoms could reduce subsequent STI incidence or increase self-reported use [13]. Here, we report the results from the African trial.

The primary objective of our study was to assess whether providing men with a choice of condoms with varied characteristics would increase self-reported use over a 6-month period in three African settings. Secondary objectives included assessing the acceptability, preference and uptake of the various condom types.

2. Materials and methods

We conducted this unblinded, parallel-group, randomized trial from June 2002 to March 2004 at sites in Ghana, Kenya and South Africa. Prior to initiation, the protocol and informed consent process were approved by institutional review boards of FHI (which served as the board of record for the sites in Ghana and South Africa) and the Kenya Medical Research Institute. All participants provided written consent prior to enrollment. We adhere to the CONSORT guidelines in reporting our results [14].

We recruited men from different locations within each country. In Ghana, volunteers were recruited from bars, taxi stands and kiosks in the Accra metropolitan area. In Kenya, volunteers were recruited from four tea plantations. In South Africa, volunteers were recruited from student health clinics and activity centers, university dormitories, and from military bases and neighborhoods located near universities in Durban, KwaDlangezwa, Grahamstown and Johannesburg. Eligibility criteria included being at least 18 years of age, having used condoms in the previous 30 days, typically having intercourse at least once a week and agreeing to use the study condoms and participate in the study for up to 6 months. Exclusion criteria included history of adverse reactions to latex or lubricants and abstinence in the previous month.

During the enrollment visit at designated study locations, interviewers administered surveys on demographic characteristics, sexual history, number and types of sexual partners, and attitudes and practices regarding condom use. Participants were randomly allocated one to one to either the condom choice or control groups through use of sequentially numbered, opaque, sealed envelopes. A statistician at FHI generated the allocation sequences, which were stratified by country and by city within South Africa, using randomly permuted blocks of sizes four or eight.

Participants allocated to the control group received free supplies of the standard USAID condom. In addition to the USAID condom, participants allocated to the choice group received free supplies of three condom brands: Rough Rider (Ansell Healthcare Products, Dothan, AL, USA), which is straight-walled and ribbed with a reservoir tip; inSpiral (Medtech Products, Ltd., Chennai, India), which is straight-walled with a bulbous, spiral end and an elongated reservoir tip; and socially marketed (Champion) or public-sector (Red Ribbon) local brands in Ghana and South Africa, respectively, which, other than name and packaging, were identical to the USAID condoms. In Kenya, no local brand was provided due to excessive cost. All condoms were made of natural latex rubber and were lubricated with silicone. Except for inSpiral, the research condoms were available in retail outlets or health clinics throughout the study countries.

In Ghana and South Africa, choice group participants were initially given 20 condoms (five each of four types) and controls were supplied with 20 USAID condoms. In Kenya, the choice group received 21 condoms (seven each of three types), while the control group received 21 USAID condoms. The participants were instructed to return to study locations at 2, 4 and 6 months post-randomization for condom resupply and to be interviewed about sexual behaviors, condom use, acceptability and, in the choice group, condom preference. At follow-up, the choice group could select any combination of study condoms (including all of one type), but a maximum of 20 (21 in Kenya) was to be distributed in either group at any visit. All condoms were provided free of charge and participants could return between scheduled visits for condom re-supply, as needed.

The pre-specified primary outcome was change from baseline to 6 months in the subject-specific, self-reported proportion of sexual acts protected with male condoms. At each interview, participants were asked how many sexual acts they had had in the previous 7 days and in how many acts condoms had been used. Secondary condom-use outcomes included change from baseline to 2 and 4 months in the proportion of protected acts, change to each visit in number of unprotected acts and condom use at last sexual act. The primary analyses combined reported acts with both spouse/main partners and partners other than a spouse/main partner. Secondary analyses differentiated by partner type. We followed two conventions when deriving end points. First, if a participant reported using more condoms than sex acts, we assumed all acts were protected. Second, if a participant reported no sex acts in the previous 7 days, we set the proportion of acts protected by condoms to 1. To investigate the implications of this latter convention, we conducted sensitivity analyses that excluded participants with no acts in the previous 7 days.

The targeted enrollment was 1200 participants (400 per country). With pooled data across countries, this sample size would provide approximately 99.5% power to detect a 0.10 difference between groups in the mean change from baseline to the final visit in the proportion of acts protected by

condoms using a two-sided test with alpha 0.05. This calculation assumed that change-from-baseline scores are normally distributed between −1 and 1 with a standard deviation of 0.33 and that loss to follow-up would be at most 20%. Under these assumptions, this sample size would provide 80% power for separate comparisons within each country.

We analyzed every participant in the group to which he was assigned. We did not impute any missing data; thus participants who provided no follow-up data were excluded. All tests were conducted at the two-sided .05 significance level. To compare groups on the change-from-baseline outcomes, we applied Wilcoxon rank-sum tests, stratified by country (and city in South Africa) and by frequency of condom use at baseline; we designated participants as either frequent or infrequent condom users at baseline using a prespecified, but arbitrary, cut point of 70%. We used a Mantel–Haenszel test, stratified by country (and city in South Africa) and by condom use at last act prior to randomization, to compare groups on condom use in the last sexual act prior to each visit. At each visit, men in the choice group were asked to rate each condom type on a five-point scale (1=*liked very much* to 5=*disliked very much*). If a participant did not use a particular condom type at any visit, his score for that condom type was set to missing. To determine whether there were overall preferences, we used Mantel–Haenszel row mean score tests for repeated measurements with missing data [15]. If an overall test comparing all condom types was significant, all pair-wise comparisons were conducted using the least significant difference multiple comparison method. All analyses were planned prior to completion of data collection and were performed in SAS version 8 (SAS Institute, Inc., Cary, NC, USA).

3. Results

We enrolled 1274 men, 400 from Ghana, 428 from South Africa and 446 from Kenya, of whom 642 and 632 were randomly allocated to the choice and control groups, respectively (Fig. 1). We did not record data on men who were excluded or refused to participate. About 97% of all randomized participants provided data for at least one follow-up interview, 92% completed the study and 86% completed every scheduled visit. In Ghana and Kenya, there were no randomization errors and no participant ever received incorrect study condoms during follow-up. In

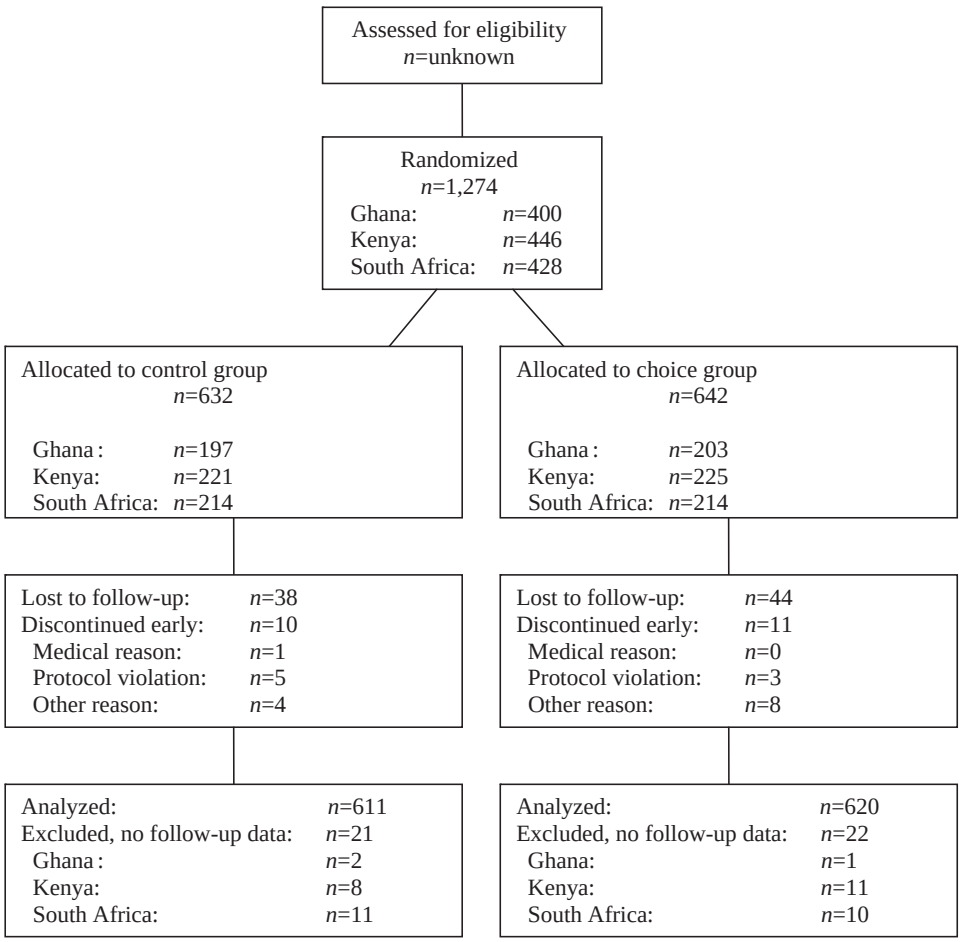

Fig. 1. Study participant flowchart.

South Africa, there were two randomization errors: one participant randomized to the control group received choice condoms and one participant randomized to the choice group received only standard condoms at baseline. Additionally, five control participants in South Africa received choice condoms at least once during follow-up.

Baseline characteristics were well balanced across randomization groups (Table 1). Participants in the choice group were slightly better educated, with 40% having more than 12 years of education compared to 35% in the standard group. Literacy was high, with about 85% of participants in both groups stating that they were easily able to read a newspaper or a letter. Men in both groups were experienced condom users, with more than 65% reporting condom use in at least seven of their 10 most recent sexual acts prior to randomization. Among men who had a spouse or main partner, about 57% in each group reported using condoms with that partner at least half the time. Among men who had other partner types, 82% in the control group and 85% in the choice group reportedly always used condoms with those partners. Participants in the control group were somewhat more likely to state that they used condoms with "other" partners either for STI or for pregnancy protection, whereas participants in the choice group were more likely

Table 1
Baseline characteristics for all randomized participants

Characteristic	Control (*n*=632)		Choice (*n*=642)	
Location, *n* (%)				
Ghana	197	(31.2)	203	(31.6)
Kenya	221	(34.9)	225	(35.0)
South Africa	214	(33.9)	214	(33.3)
Age (years); mean (range)	26.4	(18–51)	26.6	(18–66)
Education (years completed); mean (range)	11.6	(0–22)	11.8	(0–23)
Primary occupation, *n* (%)				
Construction/factory work	89	(14.1)	93	(14.5)
Office/business/clerk/sales	94	(14.9)	94	(14.6)
Student	103	(16.3)	95	(14.8)
Tea plucker	130	(20.6)	147	(22.9)
Trucker/driver	21	(3.3)	23	(3.6)
Unemployed	65	(10.3)	57	(8.9)
Other	130	(20.6)	132	(20.6)
Number of living children, mean (range)	1.0	(0–17)	1.0	(0–15)
Considers himself religious, *n* (%)	527	(83.4)	522	(81.4)
Religious beliefs affect contraceptive use, *n* (%)	69	(10.9)	56	(8.7)
Ever thought he had STI, *n* (%)	177	(28.0)	184	(28.7)
Was ever told he had STI, *n* (%)	149	(23.6)	147	(22.9)
Sexual partner types, *n* (%)				
Spouse/main partner only	113	(17.9)	113	(17.6)
Other partners in addition to spouse/main	442	(69.9)	462	(72.1)
Sexual partners but no spouse/main partner	76	(12.0)	64	(10.0)
No sexual partners	1	(0.2)	2	(0.3)
Number of sexual partners, mean (range)	2.9	(0–13)	3.0	(0–26)
Any partners are paid sex workers, *n* (%)	74	(11.7)	72	(11.2)
How often used condoms in previous 2 months with spouse/main partner, *n* (%)				
Never	87	(13.8)	90	(14.0)
Less than half the time	140	(22.2)	136	(21.2)
Half the time	48	(7.6)	47	(7.3)
More than half the time	73	(11.6)	64	(10.0)
Always	195	(30.9)	221	(34.5)
Did not have sex with spouse/main partner	12	(1.9)	17	(2.7)
Did not have spouse/main partner	77	(12.2)	66	(10.3)
How often used condoms in previous 2 months with other partners, *n* (%)				
Never	2	(0.3)	2	(0.3)
Less than half the time	29	(4.6)	19	(3.0)
Half the time	14	(2.2)	17	(2.7)
More than half the time	37	(5.9)	36	(5.6)
Always	427	(67.6)	449	(70.0)
Did not have sex with other partner(s)	9	(1.4)	3	(0.5)
No other partners	114	(18.0)	115	(17.9)
In last 10 acts prior to baseline, how many times used a condom, *n* (%)[a]				
<7 ("infrequent user")	222	(35.1)	211	(32.9)
≥7 ("frequent user")	408	(64.6)	431	(67.1)

[a] Two control participants missing responses.

to seek dual protection (75% compared to 67% in the control group).

At baseline, the most common contraceptive method used with the spouse/main partner was the male condom. Condom use for contraception with a spouse/main partner was about 70% in Kenya, 77% in South Africa, and 85% in Ghana. Other commonly-used methods included oral contraceptives (11%), injectables (9%), and withdrawal (10%).

Fig. 2 presents the percentages of all reported acts, calculated across all participants in each group, protected by condoms, by partner type and visit. Self-reported condom use with all partners combined was greater than 80% at baseline and increased in both groups post-randomization. Condom use with the main partner was greater than 65% at baseline and use with other partners was greater than 95%. Reported use with both partner types increased post-randomization. This graph depicts "population average" percentages, which estimate the likelihood that a condom would have been used in a randomly selected act. The condom use outcomes summarized below relate to subject-specific proportions, which estimate the likelihood that a randomly selected participant would have used a condom.

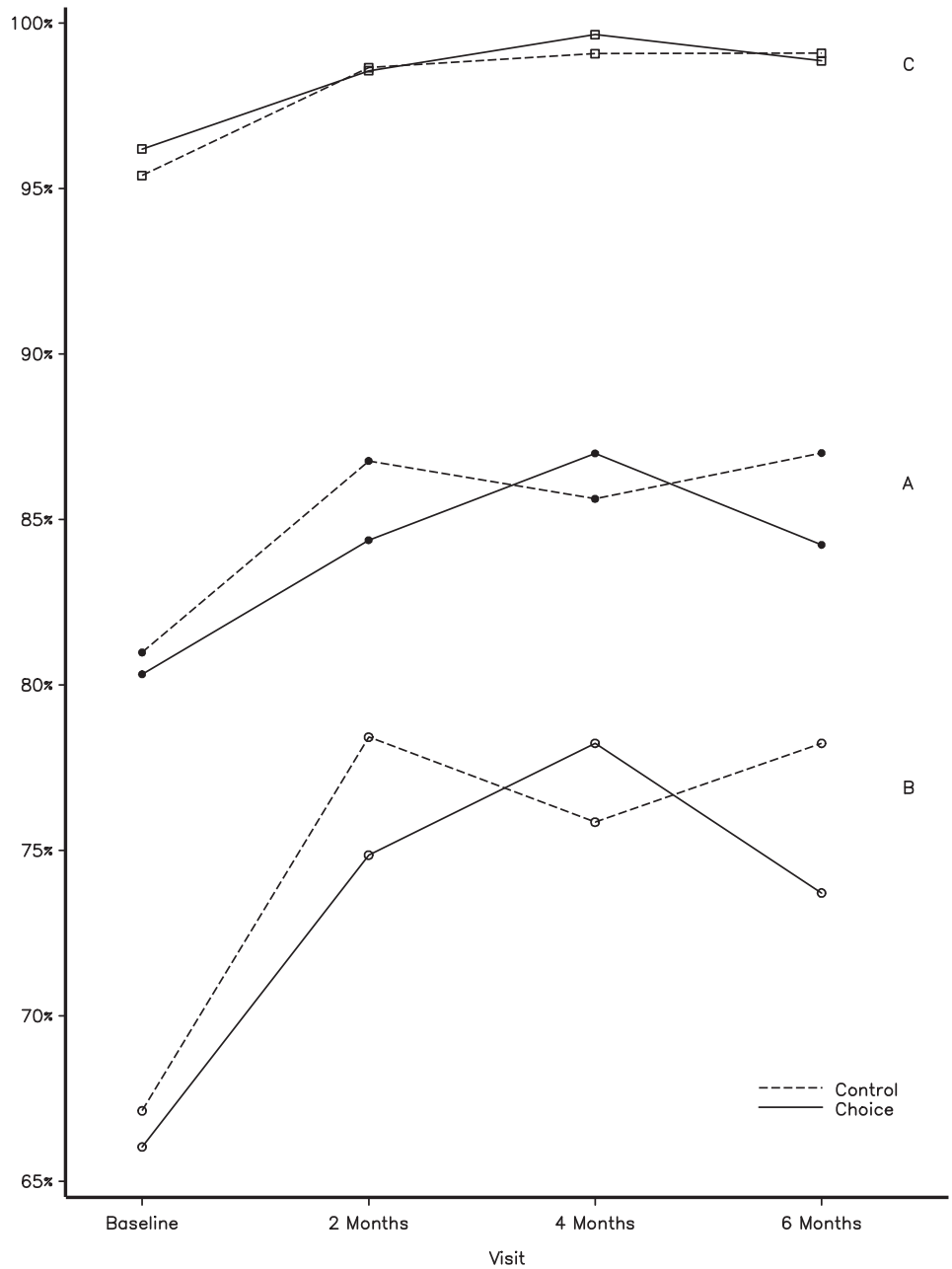

Fig. 2. Percentages of acts with (A) all partners combined, (B) a spouse/main partner and (C) partners other than a spouse/main partner who were reportedly protected by condoms, by treatment group and study visit. Lines connecting points are intended as visual aids only and not linear interpolations.

The mean subject-specific proportion of acts protected by condoms with all partners increased from baseline to the 6-month visit by 0.072 in the control group compared to 0.030 in the choice group (Table 2, p=.025). The mean proportions in the control group increased by 0.075 and 0.058 from baseline to the 2- and 4-month visits, respectively, compared with increases of 0.033 and 0.056, respectively, in the choice group, but neither difference between groups was significant at the .05 level. The mean changes-from-baseline to the 2-, 4- and 6-month visits in the numbers of unprotected acts did not differ significantly between groups either. In the sensitivity analysis excluding participants who reported no acts prior to any visit, the control group experienced a significantly greater reduction in number of unprotected acts at the 6-month visit (p=.036); otherwise, our conclusions were unaffected by this convention. Condom use at last act did not differ significantly between groups at any visit.

When analyzed separately by country, the condom-use results were notably consistent with those from the pooled analysis. Across all three countries, the control group increased their reported condom use with all partners combined, on average, more than the choice group, although only the 6-month comparison in Ghana and the 2-month comparison in South Africa were significant. Condom-use patterns with the spouse/main partner were very similar to those for all partners shown in Table 2, but the groups did not differ significantly at any visit, neither in pooled nor country-specific analyses. As is evident from Fig. 2, use with other partners had little room to increase, and there were no significant differences between groups.

Over the course of the study, participants in the control group received 58,424 condoms, or about 92.4 condoms each, while participants in the choice group received 63,976 condoms, or about 99.7 condoms each. The choice group received 39,284 Rough Rider, 10,777 USAID, 10,539 inSpiral and 3376 local brand condoms (none in Kenya). The control group almost exclusively received USAID condoms, except for 155 Rough Rider, 25 inSpiral and 20 local brand condoms provided as a result of the errors described previously.

Table 3 presents the condom ratings provided by choice group participants. Both overall comparisons indicate significant preferences across condom types (both overall

Table 2
Summary of reported condom use with all partners prior to each scheduled visit[a] among participants with at least one follow-up visit, pooled across all three countries

Visit/variable	Control		Choice		p value[b]
Baseline	*n*=611		*n*=620		
Number of sexual acts	4.9	(4.4)	5.4	(4.6)	
Number of acts protected by condoms	3.9	(4.0)	4.3	(3.9)	
Proportion protected by condoms[c]	83.9	(30.0)	85.3	(28.2)	
Used condom at last act prior to visit	520	(85.1%)	517	(83.5%)	
2-month visit	*n*=587		*n*=600		
Number of sexual acts	5.5	(3.6)	6.3	(4.2)	
Number of acts protected by condoms	4.8	(3.2)	5.4	(3.7)	
Proportion protected by condoms[c]	90.9	(22.3)	88.4	(23.6)	
Change from baseline, proportion protected[c]	7.5	(34.1)	3.3	(31.6)	0.243
Change from baseline, number unprotected	−0.2	(2.3)	−0.1	(2.9)	0.091
Used condom at last act prior to visit	538	(91.7%)	538	(89.8%)	0.336
4-month visit	*n*=580		*n*=585		
Number of sexual acts	5.8	(3.5)	6.1	(3.9)	
Number of acts protected by condoms	4.9	(3.2)	5.3	(3.6)	
Proportion protected by condoms[c]	89.4	(23.8)	90.5	(21.7)	
Change from baseline, proportion protected[c]	5.8	(36.5)	5.6	(31.4)	0.933
Change from baseline, number unprotected	−0.1	(2.6)	−0.3	(2.8)	0.358
Used condom at last act prior to visit	523	(90.2%)	528	(90.3%)	0.943
6-month visit	*n*=584		*n*=587		
Number of sexual acts	5.8	(3.4)	6.4	(3.8)	
Number of acts protected by condoms	5.0	(2.9)	5.4	(3.5)	
Proportion protected by condoms[c]	90.7	(21.5)	87.8	(24.7)	
Change from baseline, proportion protected[c]	7.2	(33.9)	3.0	(33.3)	0.025
Change from baseline, number unprotected	−0.2	(2.6)	−0.1	(2.7)	0.051
Used condom at last act prior to visit	537	(92.0%)	524	(89.3%)	0.087

Data presented as either mean (SD) or frequency (percent).

[a] All summarized variables, except for use at last act, refer to the 7 days prior to each visit; last act could have occurred any time prior to the visit.

[b] For change variables, p value from Wilcoxon rank-sum test, controlling for site and frequency of condom use at baseline. For use at last act, p value from Mantel–Haenszel test, controlling for site and whether or not a condom was used at last act prior to baseline.

[c] Proportions multiplied by 100 to aid interpretation. If a participant reported no acts in previous 7 days, proportion of acts protected was set to 100.

Table 3
Condom ratings among participants in the choice group at the 6-month visit and averaged over all visits

Ratings	Score	Condom types							
		Standard		inSpiral		Rough Rider		Local brand[a]	
		n	%	*n*	%	*n*	%	*n*	%
6-month visit									
Liked very much	(1)	60	10.2	66	11.2	528	89.9	2	0.3
Liked somewhat	(2)	136	23.2	123	21.0	34	5.8	52	8.9
Neither liked nor disliked	(3)	80	13.6	77	13.1	8	1.4	56	9.5
Disliked	(4)	48	8.2	50	8.5	3	0.5	55	9.4
Disliked very much	(5)	11	1.9	14	2.4	0	0	41	7.0
Did not use this condom	(none)	252	42.9	257	43.8	14	2.4	381	64.9
Mean score (SD)		2.4 (1.0)		2.5 (1.1)		1.1 (0.4)		3.4 (1.1)	
Average rating, when used, over all visits[b]									
Liked very much	(1)	68	11.0	70	11.3	538	86.8	4	0.6
Liked somewhat	(2)	239	38.5	201	32.4	60	9.7	75	12.1
Neither liked nor disliked	(3)	184	29.7	174	28.1	10	1.6	132	21.3
Disliked	(4)	110	17.7	119	19.2	11	1.8	107	17.3
Disliked very much	(5)	7	1.1	45	7.3	0	0	64	10.3
Did not use this condom[c]	(none)	12	1.9	11	1.8	1	0.2	238	38.4
Mean score (SD)		2.6 (1.0)		2.8 (1.1)		1.2 (0.5)		3.4 (1.0)	

Mantel–Haenszel row mean score p values for overall tests comparing all condom types were both <.001. All pairwise comparison p values were ≤.002, except for the comparison of the Standard and inSpiral condoms at the 6-month visit (p=.756).

[a] The local brands were Champion and Red Ribbon in Ghana and South Africa, respectively. No local brand condom was available for use in Kenya.

[b] Rounded average score over all completed follow-up visits in which the participant provided a response other than "did not use this condom."

[c] Participants never provided any response other than "did not use this condom."

p values <.001). At the 6-month visit, the Rough Rider scored substantially better than the other three brands. The USAID and inSpiral condoms both scored better than the local brand, but the USAID condom was not significantly preferred over the inSpiral. However, most participants who disliked the USAID and inSpiral condoms elected not to use those condoms prior to the 6-month interview. Averaged over all visits, participants ranked the condoms as follows, from favorite to least favorite: Rough Rider, USAID, inSpiral and local brand. Interestingly, the USAID condom was significantly preferred over the local brand, although the only differences were in the packaging and promotion. These results varied little by country, although participants in Ghana significantly preferred the inSpiral to the USAID condom.

Control group participants generally evaluated various attributes of the USAID condom favorably across all three countries. Regarding lubricant, 90% indicated the amount was appropriate. Acceptability was 92% for length. The condom color and scent were acceptable to about 74%, and 65% reported either that their "pleasure was increased" or that wearing the condom was the "same as having sex without a condom." One-fourth thought the condom "decreased their pleasure." Comparing the feel with condoms used previously, 63% said they liked the USAID condom "better." Preference for the USAID condom (over other brands previously used) was reported at 34% in Ghana, 68% in South Africa and 84% in Kenya. As a point of comparison, among the 511 choice group participants who stated a preference for the Rough Rider at their final visit, 93% liked the amount of lubricant, 95% liked the length, about 85% liked each of the color and scent, and all but four participants liked the feel.

4. Discussion

Over the past four decades of the AIDS epidemic, condoms have remained one of the primary means of preventing HIV acquisition through sexual intercourse. While correct and consistent condom use is important to ensuring prevention, sporadic use or discontinuation of use has been noted, especially in long-term relationships [16]. When we designed this study, we believed that men would be more likely to use condoms consistently if given a choice of condoms or condoms they preferred. We selected condoms that were available in social marketing outlets or public health facilities within the study countries, and we added private-sector "premium" condoms. Our goal was to determine whether providing "choice" would make a difference in condom uptake and use.

The results of our study were counterintuitive. Participants assigned to the choice group in each country overwhelmingly preferred the Rough Rider condom. However, such preference did not translate into increased reported protection compared to men in the control group. In fact, participants assigned to use only the standard USAID condom reported a significantly greater increase in their proportion of protected sexual acts at 6 months. Although uptake was substantially greater in the choice group, all condoms were offered free of charge and men could request

re-supply at any time during study participation. Some of the premium condoms may have been sold or given to others, rather than being used. In the Jamaican study, participants also strongly preferred the Rough Rider condom [13]. However, there again, preference did not translate into a higher proportion of reported protected acts or lower STI incidence. In another study conducted to ascertain barrier method acceptability and choice, fewer than 50% of participants who freely chose a female-controlled barrier method actually used the product, and satisfaction did not predict subsequent use [17].

We found that reported condom use with "other" partners was substantially higher than use with the spouse/main partner, a result consistent with those from other studies [18,19]. It is thus possible that the observed differences in condom use between groups could be partially explained by an imbalance in partner types. To account for such potential imbalance at baseline, we repeated the primary analysis controlling for baseline partner types, and our conclusions did not change. However, we did not assess partner progression during follow-up. Even had we been able to accurately measure such progression, controlling for post-randomization factors is problematic.

This study had limitations, primarily our inability to directly measure actual condom use over 6 months. Condom use was self-reported and thus extremely susceptible to recall and social desirability biases [20,21]. Given that this study was unblinded, it is possible that misreporting could differ by randomization group. Additionally, our analyses assumed that condom use in the 7 days prior to each visit was representative of condom use over the 2 months between visits, which may not be valid. Because all of our study condoms were of similar size (although the inSpiral condom was designed to be loose fitting), we are unable to directly address the question of whether providing condoms in a variety of sizes might increase reported use [9]. Finally, as in most randomized trials, we enrolled a convenience sample; thus our results may not generalize to any larger population [22].

Providing a choice of male condoms resulted in very clear and consistent stated preferences across multiple countries but did not increase self-reported condom use. Thus, the provision of one type of male condom in public sector programs appears justified. Programs should not focus on the number of brands available, but should encourage effective promotion of available brands together with emphasizing consistent and correct use.

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