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Acceptability of Vaginal Film, Soft-Gel Capsule, and Tablet as Potential Microbicide Delivery Methods Among African Women

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Abstract

Background: Vaginal microbicides are in development for the prevention of HIV transmission to women via sexual intercourse. Acceptability of the microbicide delivery method in the targeted population is important to product adherence and, therefore, product effectiveness. It is anticipated that multiple delivery methods will be required to satisfy personal preferences among future microbicide users.
Methods: A total of 526 sexually active women aged 18–30 years participated in a consumer product preference study in Burkina Faso, Tanzania, and Zambia. Screened women who had given consent were instructed to use each of the three products (placebo formulations of a vaginal tablet, film, and soft-gel capsule) once daily for 7 consecutive days for a total of 21 days. Women were interviewed about their impressions of the product at the completion of each 7-day trial period.
Results: Over 80% of women reported they liked using each dosage form, and over 85% said they would definitely use it. The film and soft-gel capsule were chosen significantly more often than the tablet as the preferred dosage form (39% and 37% vs. 25%, respectively) mainly because of faster dissolving time and easier insertion. Women in Burkina Faso and Tanzania preferred the soft-gel capsule (42%–46%), whereas Zambian women preferred the film (51%). Age, socioeconomic status, and marital status did not significantly affect product preference.
Conclusions: All three dosage forms were acceptable to the women surveyed. Preferred dosage forms varied by country. These data suggest that the availability of microbicides in multiple dosage forms may increase acceptability, adherence, and, therefore, effectiveness.

Introduction

HIV/AIDS is the leading cause of death globally in women 15–44 years of age and the most important single cause of disease burden for African women aged 15–59 years.[1] Current HIV prevention options for women are limited, and new self-initiated prevention options are urgently needed.

Vaginal microbicides are designed to reduce the transmission of HIV to women during sexual intercourse. Multiple dosage forms, such as gels, rings, tablets, soft-gel capsules (SGC), and films are in development. Factors such as frequency of product use (with each sex act, daily, monthly), adaptability of product to large-scale production, and production costs vary with each dosage form.[2] Acceptability of the microbicide delivery method in the targeted population is important to product adherence and, therefore, product effectiveness. Based on experience with hormonal contraceptives,[3,4] it is anticipated that multiple dosage forms will be required to satisfy personal preferences among future microbicide users. The acceptability of three vaginal dosage forms, film, SGC, and tablet, was studied in sexually active, adult women in Burkina Faso, Tanzania, and Zambia. The results of previous acceptability studies with nonoxynol-9 (N-9) vaginal film[5–7] and the Praneem polyherbal vaginal tablet (Panacea Biotech Ltd., New Delhi, India)[8,9] have shown that these dosage forms are acceptable to the majority of female study participants and their male sexual partners.

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Materials and Methods

Study design

Sexually active women aged 18–30 participated in a consumer product preference study in Burkina Faso, Tanzania, and Zambia in 2009. By design, half of participants were 18–24 years of age and half were 25–30 years, half were married or living with a partner and half were single (including divorced or widowed), and half were of lower and half were of higher socioeconomic status (SES). SES was determined based on education, home ownership, job type, and ownership of household property.

Women were recruited door-to-door at their residences. The rationale for door-to-door recruitment was that it maximized convenience for the participants while simultaneously helping to target SES. No one was present, with the exception of small children when necessary, when the women were recruited and interviewed. Interviews were conducted inside or immediately outside of the woman's house, according to her preference. Screened women who gave consent who were not pregnant were asked to use each of three products (placebo formulations of a vaginal film, SGC, and tablet) once daily for 7 consecutive days for a total of 21 days. The order of product usage was based on a complete randomized block design.

Women received a 7-day supply (10 applications) of a single dosage form at the time of enrollment. When they met with study staff at the end of the product usage period, unused product was collected, a product evaluation survey was administered, and a 7-day supply (10 applications) of the second dosage form was provided. The procedure was repeated with the third dosage form. With the women's permission, male sexual partners who consented completed a quantitative survey at the end of the study.

The ethics committees that reviewed and approved this study were University of Zambia Biomedical Research Ethics Committee (UNZAREC), Comité d'éthique pour la recherche en santé (National Ethics Committee Burkina Faso), and National Institute for Medical Research (NIMR, Tanzania).

Materials

The placebo film was manufactured by MonoSol (Merrillville, IN) and consisted of (by weight) 25% glycerin, 25% polyvinyl alcohol, 20% hydroxypropyl methylcellulose, 20% polyethylene glycol, 5% propylene glycol, and 5% croscarmellose sodium. The translucent, off-white film measured 2.0×1.0 cm and was supplied in individual sealed wrappers (Fig. 1A). The placebo SGC was K-Y® Liquibeads™ (McNeil-PPC, Fort Washington, PA) and consisted of dimethicone, gelatin, glycerin, and dimethiconol. The clear, oval-shaped SGC measured 2.5×1.25 cm and was supplied in individual blister packs (Fig. 1B). The product dissolves in the vagina within 1–2 hours, and the dissolve rate varies from woman to woman (McNeil-PPC, personal communication). The placebo tablet was manufactured by Azopharma (Miramar, FL) and consisted of (by weight) 47.7% lactose, 15% crospovidone, 10% mannitol, 10% microcrystalline cellulose, 7.5% polyethylene oxide, 3.5% sodium bicarbonate, 3.3% tartaric acid, 2% colloidal silicon dioxide, and 1% magnesium stearate. The almond-shaped, white to off-white colored tablet measured 1.9× 0.55 cm and was supplied as 10 tablets in a bottle (Fig. 1C).

In vitro studies show that, in general, the placebo tablets used in this research dissolve in <30 minutes in water and the placebo films dissolve in <15 minutes, also in water (unpublished data). It is unknown, however, how applicable or relevant the *in vitro* data are to actual use in women.

Statistics

Standard *t* tests of statistical significance were used to assess differences between products, countries, and key subgroups. Significant differences met the 95% confidence level (95% CL) criterion, unless otherwise specified.

The study was designed such that countries were the key subgroups. Data were analyzed by age, SES, and marital status, with the understanding that country-specific results for these subgroups have limited statistical reliability because of their small size. The intent was to represent the majority of the target population under the assumption that preferences among surveyed women would be similar to those who lived

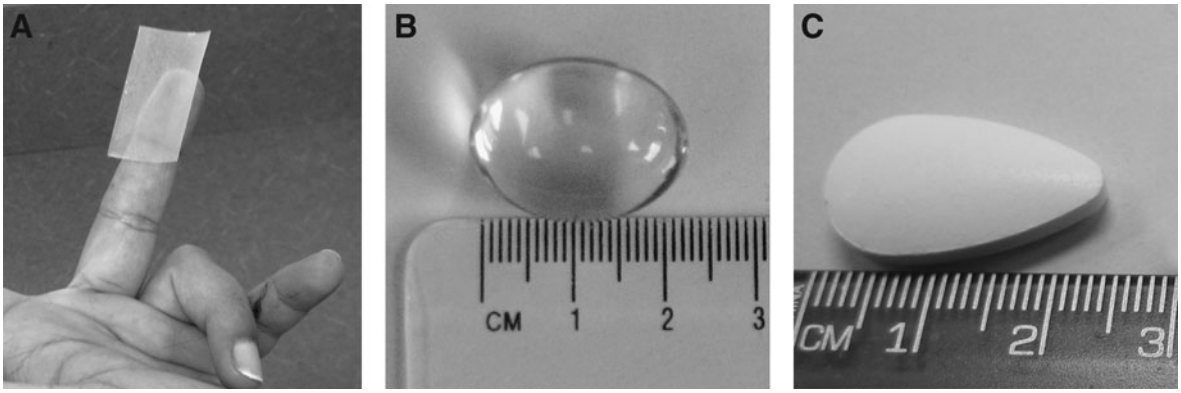

FIG. 1. Placebo dosage forms used in the study. **(A)** The translucent, off-white placebo film was manufactured by MonoSol (Merrillville, IN), measured 2.0×1.0 cm, and was supplied in individual sealed wrappers. **(B)** The clear, oval-shaped soft-gel capsule (SGC) was K-Y® Liquibeads™ (McNeil-PPC, Fort Washington, PA), measured 2.5×1.25 cm, and was supplied in individual blister packs. **(C)** The almond-shaped, white to off-white colored placebo tablet was manufactured by Azopharma (Miramar, FL), measured 1.9×0.55 cm, and was supplied as 10 tablets in a bottle.

in areas not included in the study. The study covered urban and semiurban but not rural areas, and the poorest women were underrepresented.

To achieve a 95% CL that does not exceed ±8% for key subgroups (country-specific results) and ±5% for the total sample, the goal was to have a minimum of 150 completed surveys per country. The 95% confidence intervals (CI) for $n=150$ (country-specific goal) and $n=450$ (total sample goal) are ±8% and ±4.6%, respectively. The actual sample size (526 total, 172–179 per country) exceeds these desired minimum requirements.

Results

Disposition

A total of 2329 women were screened for participation in the study, 377 at two locales in Burkina Faso, 535 at two locales in Tanzania, and 1417 at two locales in Zambia. Before the first product was placed, 1761 women were disqualified from the study: approximately 30% declined to participate, and the remaining women did not meet the enrollment criteria, mostly because their age was outside the specified age range or the quotas for their age, marital status, or socioeconomic group were already met in the particular market. Forty-two women discontinued their participation in the study after testing one or more products, usually because they did not like the product. Not counting these women, a total of 526 women participated in the study, 172 in Burkina Faso, 179 in Tanzania, and 175 in Zambia.

Demographics

Demographic characteristics (age, marital status, SES) were similar across countries (Table 1).

Product usage

Study participants were given a 7-day supply (10 applications) of each product and instructed to use one application daily for 7 days. Results include all women who used all three products three or more times and used at least two products four or more times. The majority of women in each country (89%–93% in Burkina Faso, 82%–88% in Tanzania, and 79%–86% in Zambia) used six to seven applications of each product. Participants were asked, but not required, to use at least one weekly application within 1 hour before having sexual intercourse. For each dosage form, less than half of all women (46%) followed this suggestion, especially in Burkina Faso, where the percentage was significantly lower (27%–30%) than in the other two countries (47%–62%).

Product ratings

When asked to assess each product individually, >80% of women reported that they liked using each dosage form (Fig. 2A). Using the film was liked "a lot" by significantly more women (61%) than the SGC (53%) or tablet (49%). When asked to choose their favorite dosage form, the film and SGC were chosen significantly more often than the tablet (Fig. 2B). Preferred vaginal dosage form varied by country; women in Burkina Faso and Tanzania preferred the SGC (42%–46%), whereas Zambian women preferred the film (51%) (Fig. 2C). There were no statistically significant differences in dosage form preferences between younger (18–24 years) and older (25–30 years) women in any of the three countries. Similarly, there were no significant differences in preferences for women of lower vs. higher SES. With one exception, the same was true for marital status; single women in Tanzania preferred the

Table 1. Demographic Data

Characteristic	*Burkina Faso* n=*172* n *(%)*	*Tanzania* n=*179* n *(%)*	*Zambia* n=*175* n *(%)*	*Total* n=*526* n *(%)*
Age, years[a]				
18–21	34 (19.8)	39 (21.8)	32 (18.3)	105 (20.0)
22–24	49 (28.5)	49 (27.4)	52 (29.7)	150 (28.5)
25–27	55 (32.0)[d]	40 (22.3)	43 (24.6)	138 (26.2)
28–30	34 (19.8)	51 (28.5)	48 (27.4)	133 (25.3)
Marital status[b]				
Married or living with partner	83 (48.3)	93 (52.0)	88 (50.3)	264 (50.2)
Single, divorced, widowed	89 (51.7)	86 (48.0)	87 (49.7)	262 (49.8)
Socioeconomic status[c]				
Upper	85 (49.4)	87 (48.6)	86 (49.1)	258 (49.0)
Lower	87 (50.6)	92 (51.4)	89 (50.9)	268 (51.0)
No. of children <18 in household				
None	13 (7.6)	34 (19.0)[e,f]	13 (7.4)	60 (11.4)
1–2	77 (44.8)	107 (59.8)[e,f]	78 (44.6)	262 (49.8)
3–4	54 (31.4)[d]	27 (15.1)	59 (33.7)[d]	140 (26.6)
5+	28 (16.3)[d]	11 (6.1)	25 (14.3)[d]	64 (12.2)

[a]By design, approximately half of participants in each country were 18–24 years of age and half were 25–30 years. Quotas were not set for more granular age bands.
[b]By design, approximately half of participants in each country were married/living together and half were single/divorced/widowed.
[c]Socioeconomic status was determined based on education, home ownership, job type, and ownership of household property. By design, approximately half of participants in each country were of lower and half were of higher socioeconomic status.
[d]Significantly higher than Tanzania.
[e]Significantly higher than Burkina Faso.
[f]Significantly higher than Zambia.

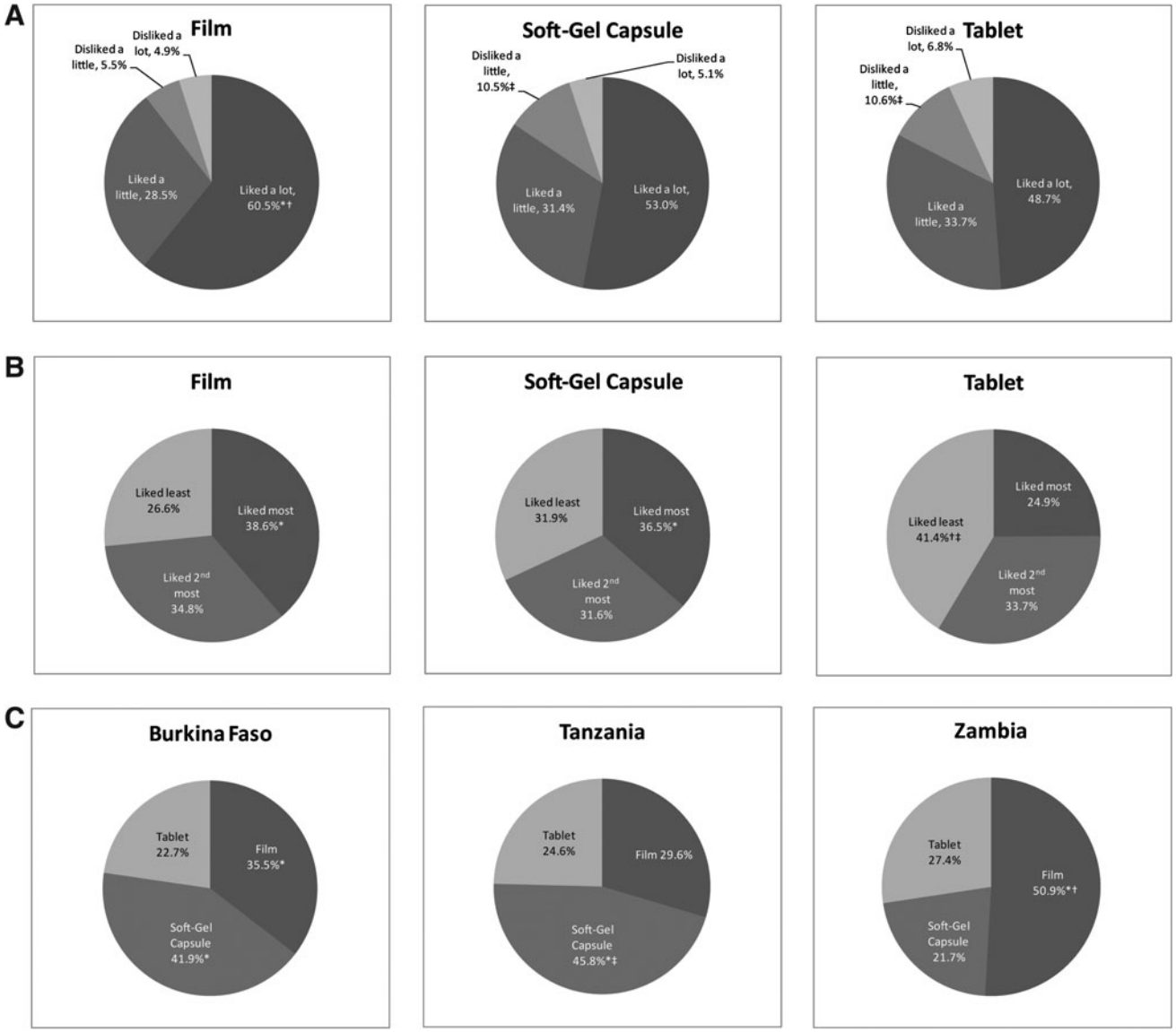

FIG. 2. Vaginal dosage form ratings and preferences. Sexually active women (172 in Burkina Faso, 179 in Tanzania, and 175 in Zambia) were instructed to use placebo formulations of each of three vaginal products (film, soft-gel capsule [SCG], and tablet) once daily for 7 consecutive days for a total of 21 days. Women were queried about their impressions of the products at the end of each 7-day trial period. Data on participants' opinions about using each dosage form are presented in **(A)**. Data on preferred dosage forms are shown for total participants in **(B)** and by country in **(C)**. *Significantly greater than tablet at the 95% CL. †Significantly greater than SGC at the 95% CL. ‡Significantly greater than film at the 95% CL.

vaginal tablet significantly more often than their married counterparts.

Product characteristics

The majority of women (64%–73%) felt that each dosage form tested was very easy to insert; the percentages were significantly greater for the SGC and tablet than for the film (Fig. 3A). Tanzanian women rated insertion "very easy" significantly less often (54%–65%) than women from Zambia (70%–77%) or Burkina Faso (67%–79%). For women who rated the dosage forms as difficult to insert (21%–28%), most agreed that insertion became easier with time (61%–66%); 70%–79% of these women thought insertion was easier after two or three applications.

Most women (84%–91%) believed that the products stayed in place every time they were inserted; the percentages were significantly lower for Tanzanian women (70%–83%) than for women in Zambia (85%–94%) or Burkina Faso (94%–98%). Although using product applicators was not an option in this study, participants were asked if they would have preferred using one with each dosage form. Over half (58%–61%) responded that they prefer inserting each dosage form by hand vs. using an applicator (28%–31%); however, a significantly greater percentage of women in Tanzania (36%–42%) than Zambia (22%–25%) or Burkina Faso (20%–28%) responded that they would prefer using an applicator with each product. Most women thought that the size of the film and tablet were just right (74% and 67%, respectively), although half (51%) indicated that the SGC was too big.

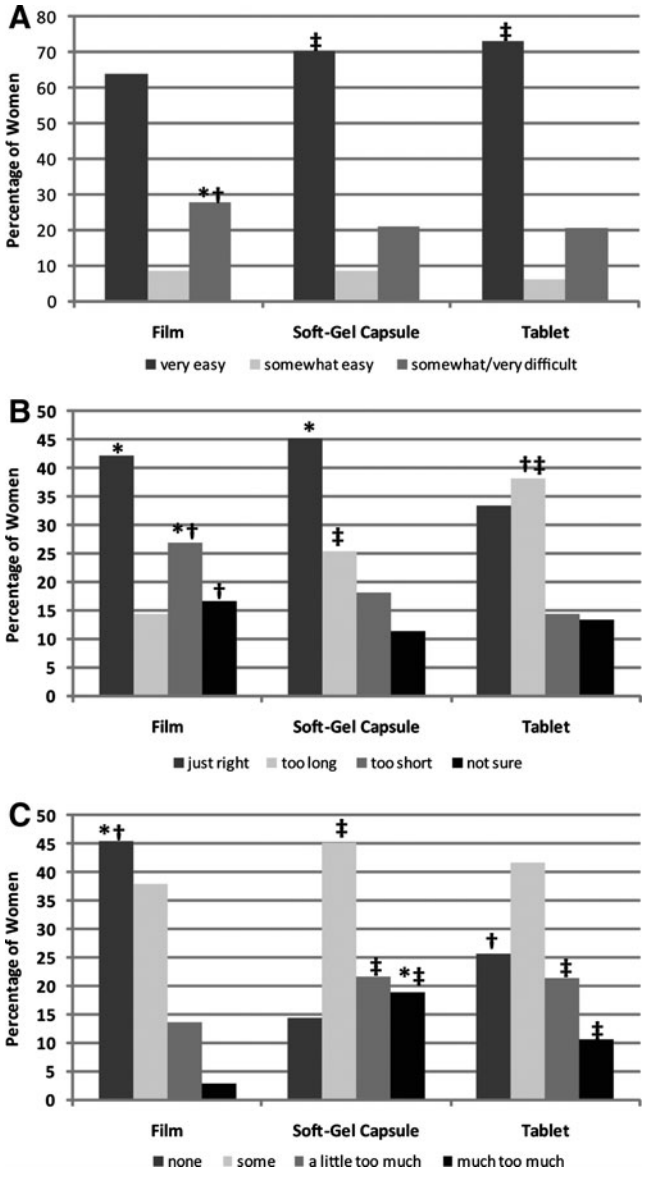

FIG. 3. Characteristics of vaginal dosage forms. After using each of three vaginal dosage forms for 7 consecutive days, sexually active women in Burkina Faso ($n=172$), Tanzania ($n=179$), and Zambia ($n=175$) were queried about their impressions of the product characteristics. Data on ease of product insertion are shown in **(A)**. Data on perceived time for product dissolution are shown in **(B)**. A perceived dissolve time ≤10 minutes was reported by 45.2% of respondents who used the film, compared with 36.9% of those who used the SGC and 29.8% of those who used the tablet. At the other end of the continuum, 22.8% of the women who used the tablet said it took >30 minutes to dissolve, compared with 12.2% of those who used the SGC and 5.1% of those who used the film. Data on product leakage are shown in **(C).** Overall, 14.4% of women using the SGC reported no leakage, compared with 25.7% of those using the tablet and 45.4% of those using the film. *Significantly greater than tablet at the 95% CL. †Significantly greater than SGC at the 95% CL. ‡Significantly greater than film at the 95% CL.

Significantly greater percentages of women felt that the dissolving time for the film and SGC were just right compared with the dissolving time of the tablet, which was considered too long by 38% of testers (Fig. 3B).

Compared with the other two dosage forms, significantly more women believed that there was no leakage with the film (45%) than with the SGC and tablet (14% and 26%, respectively) (Fig. 3C); however, significantly more women in Zambia (72%) than Burkina Faso or Tanzania (32% each) felt this way. Leakage was assessed as much too much significantly more often with the SGC than with the film or tablet (19% vs. 3%, 11%).

Significantly more women did not feel the film inside (57%) compared with the other two dosage forms (35%–38%). Most women who felt the product inside described the feeling as "not uncomfortable at all." The film was described this way significantly more often than the other two products (63% vs. 51%–54%). At least half of testers (50%–59%) claimed that the products increased their sexual pleasure, whereas 33%–43% thought the products had no impact on their sexual pleasure. Significantly more women felt the texture of the film (54%) and SGC (48%) were just right compared with the tablet (41%), which was considered too rough by 37% of women. No odor/fragrance was reported for each product by 66%–79% of responders. The color of each product was liked a lot by the majority of women (80%–85%).

Likelihood to use product

At least 85% of women in each country stated they would definitely use the film, and 87%–91% of women in Burkina Faso and Tanzania said they would definitely use the other two dosage forms as well, compared with 77%–80% of Zambian women (Fig. 4).

Among women who had sexual intercourse during the product usage period, the percentage whose male partner was aware of product use was significantly higher in Zambia (45%) than in Burkina Faso (31%) or Tanzania (27%). Partners of married women (or women living with their partners) were significantly more likely to be aware of product usage than partners of single women (45% vs. 21%). Age and SES did not significantly influence male awareness of product use.

Male partners' opinions

Women whose partners were aware of product use and had intercourse with them during the product usage period (34 of 172 women in Burkina Faso, 40 of 179 women in Tanzania, and 58 of 175 women in Zambia) were asked how much their male partners liked them using the product. Over half (54%–62%) reported that their partners liked them using the products (Fig. 5). According to participant reports, significantly more male partners in Tanzania liked them using the film (76%) and SGC (81%) than in Burkina Faso (49%, 47%) and Zambia (52%, 59%). Overall, significantly more men disliked the tablet (19%) than the film (7%) or SGC (9%).

Only 31 male sexual partners of 526 study participants completed a quantitative survey: 3 from Burkina Faso, 25 from Tanzania, and 3 from Zambia. The majority of these 31 men (71%–74%) reported that they could feel each product during sex. Significantly more men (61%) preferred the SGC over the tablet (16%) or film (19%). The SGC was reported to increase the man's sexual pleasure (71%), although 77%

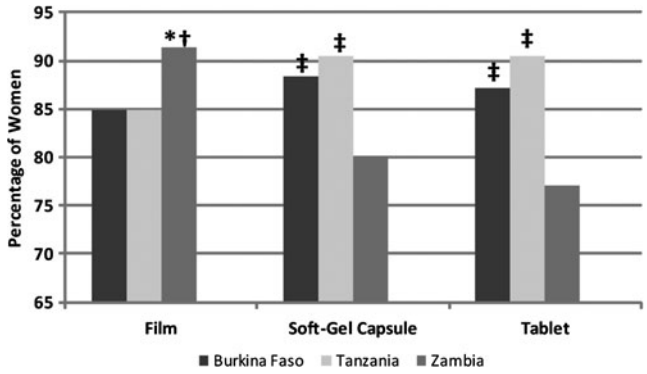

FIG. 4. Willingness to use vaginal dosage form in the future. After using each of three vaginal dosage forms for 7 consecutive days, sexually active women in Burkina Faso ($n=172$), Tanzania ($n=179$), and Zambia ($n=175$) were queried about their willingness to use a microbicide vaginal film, SGC, and tablet in the future if proven to be effective against transmission of HIV infection and affordable. The results are shown for each dosage form by country. *Significantly greater than tablet in the same country at the 95% CL. †Significantly greater than SGC in the same country at the 95% CL. ‡Significantly greater than Zambia at the 95% CL.

thought it provided too much lubrication. A lower percentage of men reported that the film increased their sexual pleasure (55%), and 42% believed that the tablet decreased their pleasure. The amount of lubrication provided by the film was considered just right by 58% of male responders; 48% reported that the tablet provided too little lubrication. In a male focus group in Morogoro, Tanzania ($n=12$), many men commented that they preferred the film because it made the vagina feel dry, which provided more pleasure for them during sexual intercourse. They also liked that the film had minimal leakage during and after sex.

Discussion

The film, SGC, and tablet were acceptable vaginal dosage forms to >80% of the women surveyed in Burkina Faso, Tanzania, and Zambia, and 77%–91% of women in each country stated they would definitely use each product if it were proven effective against HIV transmission. Favorite dosage forms varied by country: SGC and film in Burkina Faso, SGC in Tanzania, and film in Zambia. Age, SES, and marital status did not affect these preferences.

The film scored highly mainly because the size, texture, and dissolving time were considered just right, and leakage was minimal. We report that 89% of African women who used the placebo vaginal film liked using it, and 87% said they would definitely use a vaginal film for protection against HIV infection. This is similar to the percentage of American women (81% of 273),[5] South African women (75% of 20),[6] and Cameroonian women (>80% of 520)[7] who liked using the N-9 spermicidal film. In our study, 72% of African women found the placebo film easy to insert, 28% found it difficult to insert because it stuck to the fingers, and some women thought an applicator would be beneficial. In studies with the N-9 film, no South African women[6] and 76% of American women[5] reported difficulty with film insertion. Leakage was reported by 55% of placebo film users in our study compared with 23% of American N-9 film users who reported leakage or messiness.[5] Almost all (97%) users of the placebo film thought that the product increased or had no effect on their own sexual pleasure compared with 86% of American N-9 film users.[5] Seven percent of women surveyed said their male sex partners disliked them using the placebo film compared with 20% of American women who reported partner dissatisfaction with the N-9 film.[5]

Differences in acceptability ratings between the N-9 vaginal film and the placebo vaginal film tested here could have been due in part to the different chemical compositions of the products. Although both products were composed primarily of polyvinyl alcohol and glycerin,[10] the placebo film had four additional components (hydroxypropyl methylcellulose, polyethylene glycol, croscarmellose sodium, and propylene glycol). In addition, the dosing regimens varied across studies. In the American study, the N-9 film was used at the time of intercourse for 7 months; in the South African study, the N-9 film was used two to five times daily for 1 month; in the Cameroon study, the N-9 film was used at the time of intercourse for 14 months; and in the study reported here, the placebo film was used once daily for 7 days. Perceptions about the product indication (contraception vs. HIV preven-

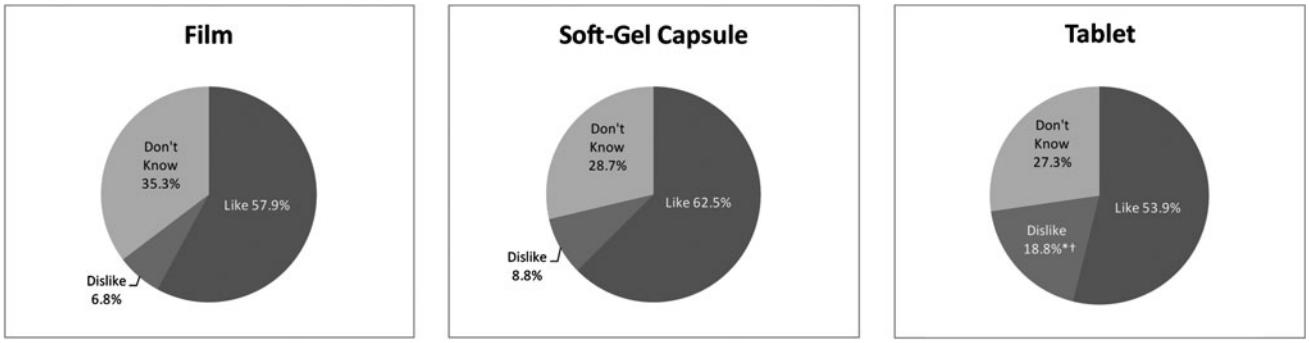

FIG. 5. Male sexual partner's opinion of woman using product as reported by participants. Women whose partners were aware of product use and had intercourse with them during the product usage period (34 of 172 women in Burkina Faso, 40 of 179 women in Tanzania, and 58 of 175 women in Zambia) were asked how much their male partners like them using the product. The results are shown by dosage form. *Significantly greater than SGC at the 95% CL. †Significantly greater than film at the 95% CL.

tion) and cultural differences between study populations also could have affected product acceptability. For example, South African N-9 film users liked the fact that the film made their vagina feel tight and dry,[6] a culturally desirable trait.[11–16]

The results of a questionnaire completed by a limited number of male sexual partners of study participants ($n = 31$) showed that the men preferred the SGC over the other two dosage forms. It is important to note, however, that 81% of these men were from Tanzania, where a greater percentage of women reported that their male partners liked the SGC (81%) than in Burkina Faso (47%) or Zambia (59%) (Fig. 5). The SCG was considered significantly easier to insert than the other two forms but was perceived by some as containing too much gel, resulting in excessive lubrication and leakage. It is important to note that the SGC used in this study (K-Y® Liquibeads™) was designed as a vaginal lubricant to last up to 4 days and, therefore, may not be directly comparable with a microbicide SGC. From the male perspective, the extra lubrication provided by the SGC was both a positive and negative characteristic. Although the majority of men (77%) thought that the SGC provided too much lubrication, 71% believed the product increased their own sexual pleasure, and significantly more men (63%) liked the SGC best when compared with the film (20%) or tablet (17%). From the female perspective, 37% liked the SGC best (vs. 39% film and 25% tablet), and 59% thought that the SGC increased their own sexual pleasure.

The major disadvantages of the tablet were the dissolution time (too long) and the texture, which was considered a little too rough by some study participants. Seventy-four percent of 526 African women reported leakage with daily use of the placebo tablet. In an acceptability study with an investigational HIV microbicide, Praneem polyherbal vaginal tablet, 45% of 20 Indian women who used the product daily for 14 days reported product leakage after sex.[8] These women and women in our study stated that product leakage would not deter them from using the vaginal tablet in the future for HIV protection. More Indian women (95%) found the Praneem tablet easy to insert than African women who used the placebo tablet (79%); neither tablet was administered with an applicator. Similar percentages of Indian women (95%) and African women (93%) believed that their own sexual pleasure was increased or not affected by use of the vaginal tablet. In a phase II study with Praneem tablet, 93% of 95 Indian women who used the active or placebo product at the time of intercourse for 6 months reported male partner acceptability of product use[9] compared with 54% of 526 African women, who reported here that their male partners liked them using the placebo tablet daily for 7 days. Differences in acceptability ratings for the two vaginal tablets could be due to the very different chemical compositions,[17] to different dosing regimens, or to cultural differences between India and Africa.

In Burkina Faso, Tanzania, and Zambia, participants preferred that their male sexual partner did not know that they were using a vaginal product. Some worried that he would not allow them to use it or would become angry with them. Most women (74%–97%) did not want their male partners contacted for an interview about product use (data not shown). Women were confident that they could use each product without their partner knowing. Nearly two thirds (66%) of the women who had sexual intercourse during product use did not tell their partners they were using the product. Male partners married to or living with the participants were more likely to know about product use than partners of single women (45% vs. 21%). When male partners knew about product use, 54%–62% of women reported that the man liked them using the product.

Similar comments were made by women who participated in earlier HIV prevention studies with the N-9 vaginal film or Praneem polyherbal vaginal tablet. Female sex workers (FSW) in Cameroon reported that they liked the ability to use the film discreetly (without their client's knowledge) and the fact that use of the product was under female control.[7] FSW in South Africa did not inform their clients about N-9 film use, but 50% informed their regular sex partner and did not experience any problems with the disclosure.[6] Indian women who used Praneem polyherbal tablet thought that other Indian women would like the fact that use of the product was female initiated; however, both Indian men and women had concerns about using HIV prevention products covertly.[8]

Conclusions

All three placebo dosage forms were acceptable to sexually active adult women surveyed in Burkina Faso, Tanzania, and Zambia. Preferred dosage forms varied by country. These data suggest that the availability of microbicides in multiple dosage forms may increase acceptability, adherence, and, therefore, effectiveness in a wide variety of women.

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Disclosure Statement

No competing financial interests exist.

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