Preferred Characteristics of Vaginal Microbicides in Women with Bacterial Vaginosis

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Abstract

Background: Vaginal microbicides have the potential to reduce HIV/STD acquisition when used consistently. Our objectives were to determine product attributes associated with willingness to use a vaginal microbicide and whether product preferences varied according to participant characteristics.

Methods: Women ($n = 408$) with bacterial vaginosis (BV) were recruited as part of a randomized trial to prevent BV. Participants completed a survey interview that assessed demographic information, sexual history, and douching behavior. To assess microbicide preferences, women rated whether specific product attributes would make them more or less likely to use a vaginal microbicide. Principal components analyses revealed two major groupings for the product attribute items. We determined the relative importance of each group of product attributes and whether the importance of the different groupings varied among subgroups of women.

Results: The participants' mean age was 24 years (range 14–45), 64% were black, and 74% were unmarried. Overall, participants reported being most likely to use a vaginal product with protection properties (2.54), whereas they were nearly neutral regarding side effects (0.56). The individual product attributes, could prevent BV, could prevent vaginal odor (2.72), and could prevent vaginal itching and burning (2.61), were rated similarly or slightly higher than could reduce the risk of getting an STD (2.58) or could reduce the risk of getting HIV (2.44). In multivariate analyses, protection attributes were rated significantly higher among older women and marginally higher in women with a greater number of lifetime sexual partners. Younger women were most likely to report that side effects would affect their likelihood of using the product.

Conclusions: Women with BV rated potential protection features of a vaginal microbicide higher than side effects. A product's personal hygiene aspects were rated equally or more important than the product's ability to prevent HIV/STD infections. Younger women may respond to different factors that influence product acceptability and adherence.

Introduction

WOMEN'S OPTIONS TO PREVENT sexual acquisition of HIV infection are limited. For the past decade, there has been a growing effort to develop effective vaginal microbicides, in the form of cream, gel, suppository, or other product that can be applied to the vagina and can protect against HIV/STDs and other sexual and reproductive health

conditions.^{1,2} Many microbicides are currently in phase III clinical studies.^{1,2} Even if microbicides are proven effective, however, women must choose to use them consistently prior to sexual intercourse in order to prevent HIV and STD acquisition. Therefore, it is of critical importance to understand factors related to acceptability of vaginal microbicides, especially in women at greatest risk for HIV and other STDs.

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Previous studies have assessed women's perspectives and interest in using several types of microbicides, many involving preliminary product trials.³⁻¹⁵ These studies suggest that several factors may influence microbicide acceptability, including a woman's sociodemographic characteristics, personal risk (real or perceived), cultural norms and practices, side effects, and the smell or taste of a product.³⁻¹⁵ An increased understanding of which attributes of a microbicide are most appealing to women at increased risk for STDs may help ensure that effective products are used.

Women with a history of bacterial vaginosis (BV) are an important group to consider. BV is very common in the United States, with prevalence ranging from 7% to 49% in various settings.^{16,17} Not only are women with BV at increased risk for HIV and STDs,¹⁸ but they might also be more motivated to seek and use a vaginal product for BV if it also provided an additional, BV-related benefit. It is also important to know if different attributes of microbicides are most appealing to specific groups of women at increased risk for HIV/STDs, including adolescents, women of color, women with a previous STD, women with multiple partners, and women who douche. Identification of attributes most important to women at higher risk for HIV/STDs may help shape product development to maximize overall utilization once an effective microbicide is available.

A previous study in the same population evaluated women's satisfaction with an intravaginal *Lactobacillus* capsule for the treatment of bacterial vaginosis.¹⁹ The objective of this study is to determine the potential microbicide attributes most associated with willingness to use a vaginal microbicide product among women with BV and whether certain attributes are more critical in women at greatest risk for HIV/STD.

Materials and Methods

Participants

Data for these analyses were obtained from 408 women participating in a randomized clinical trial that was designed to evaluate the efficacy of a vaginal suppository containing human *Lactobacillus crispatus* to prevent recurrent BV. Women were informed that the product might prevent recurrent BV and possibly STDs, but the product was not specifically identified as a microbicide. Details of the recruitment and data collection have been reported previously.¹⁹ In brief, we recruited women aged 14-45 years who had been diagnosed with BV within clinical settings in Pittsburgh and Seattle. Exclusions to enrollment included pregnancy, current meneses, concomitant vulvovaginal candidiasis or trichomoniasis, use of antimicrobials or any investigational drug in the prior month, hypersensitivity to metronidazole, presence of an intrauterine device, spontaneous or surgical menopause, concurrent anticoagulation therapy, and ingestion of alcohol within the previous 8 hours. All participants provided written informed consent as approved by IRBs at affiliated institutions. For minor participants, parental consent and participant assent were obtained.

Measures

At the time of enrollment, women completed an interviewer-administered questionnaire. The questionnaire assessed demographic characteristics, such as age, race, marital

status, and employment. The number of sexual partners was assessed by asking an open-ended question: During the past 30 days, how many sexual partners have you had? The question was repeated to assess the number of sexual partners in one's lifetime and in the past year. Participants were also asked about frequency of sexual activity with the item: During the past 30 days, how many times were you the recipient of vaginal sex from a man? To assess past STDs, women were asked: In the past year, have you ever been told by a doctor/nurse that you had any of these infections? The response options included trichomoniasis, genital warts, pelvic inflammatory disease (PID), genital herpes, *Chlamydia*, gonorrhea, and HIV disease. Women also indicated whether they had ever douched and, if so, how many times in the past 30 days.

In addition, women responded to 16 items that we developed to assess acceptability and preferences related to a microbidental product. At the time that the survey was developed, there were no existing validated instruments to measure microbicide acceptability. Therefore, survey items addressed issues found to be related to microbicide acceptability in other studies, including those that might increase or decrease microbicide acceptability.^{3,5} For these items, women were asked: Suppose a new vaginal capsule was available for women to use. For each of the following characteristics, please indicate whether you would be more likely to use the product, less likely to use, or neutral. Participants responded on a 7-point scale ranging from much less likely to use to much more likely to use. Because some items were inherently positive (e.g., reducing risk) and others were inherently negative (e.g., having a bad taste), most items were distributed almost entirely on one side of the neutral midpoint of 4. To make responses more interpretable, responses were shifted to range from -3 to +3, with 0 representing the midpoint, which was labeled Neutral on the scale. Responses to deterrent attributes were reverse scored to make the magnitude of their impact comparable to that of the positive attributes.

Analysis

Many of the variables were highly skewed, with a large number, sometimes even a majority, of people choosing the most extreme value. We performed inverse transformations (reversed to keep the original directionality) for the most highly skewed variable and logarithmic transformations for those that had a more moderate skew. To simplify interpretation of the acceptability and preference items, we conducted a principal components analysis on the 16 characteristics (transformed variables, where appropriate). We then used the averaged item scores from the resulting two components as a within-subjects factor in a repeated measures analysis of variance (ANOVA) to compare these components of product attributes in terms of their relative overall importance to women in this study. The ANOVAs thus describes the statistical differences between the two microbicide product attribute components in terms of their acceptability.

Then, to determine if specific subgroups of women were more likely to favor each of these product characteristics, we conducted a separate multiple regression analysis on each product attribute with the following predictors: age, race (white vs. nonwhite), number of current and prior sexual partners (each subject to an inverse transformation to nor-

malize distribution), douching behavior (at least monthly vs. less or none), and history of BV infections. Correlations between predictors were examined to guard against multicollinearity. None of the predictor variables used in the model correlated with any other predictors above our conservative threshold of $r = 0.5$, even though some are closely related conceptually.

Results

The mean age of participants was 24 years (range 14–45 years); 64% were African American. Of those over the age of 18, 67% had never been married, 91% had completed high school, and 62% were currently employed (47% full-time). Most (61%) had douched in the past. Eighty-one percent of participants reported having had sex at least once in the past month, with a median of 4 times. The median number of lifetime male sexual partners was 8, with 2 in the past year. Twelve percent of participants had 2 or more sexual partners in the past month. Many participants reported a history of STDs, including *Chlamydia* (13%), trichomoniasis (11%), gonorrhea (6%), genital herpes (4%), genital warts (2%), and HIV (1%).

Two major groupings related to microbicide acceptability emerged from the principal components analysis. The first, accounting for 34% of the variance, could be described as protection. It included 7 items focused on reducing the risk of disease (STDs, BV, and HIV), promoting vaginal health (promoting cleanliness and healthy bacteria), and preventing symptoms (preventing vaginal odor and burning or itching). The second grouping, with 3 items, accounted for 13% of the variance and can be identified as side effects (being sticky, having a bad taste, and causing slight discharge). The remaining items did not fit well into any category. We summed the untransformed variable values to create two index scores corresponding to these groupings: protection (Cronbach's $\alpha = 0.83$) and side effects (Cronbach's $\alpha = 0.73$). Because the index variable of protection was not normally distributed, an inverse transformation for this item was performed.

Preferences

Women rated properties associated with protection as having the greatest impact on their decision (mean $[M] = 2.54$), whereas they were nearly neutral regarding side effects ($M = 0.56$). These preferences for the different groupings were significantly different from one another, $F(1,407) = 611.61, p < 0.001$. Table 1 presents the means for the individual product characteristics that were included within each category. Within the protection category, along with BV prevention, women rated two aspects related to personal hygiene the highest overall: could prevent vaginal odor and could prevent vaginal burning and itching. Also highly rated were a product's ability to prevent STDs and HIV infection, the promotion of healthy bacteria, and vaginal cleanliness (Table 1).

Predictors of product attributes

We next examined which groups of women were most interested in each of the two groupings of product attributes (Table 2). In multivariable analyses, the most significant pre-

TABLE 1. RATING GIVEN BY 408 WOMEN ABOUT HOW STRONGLY EACH GROUP OF PRODUCT ATTRIBUTES WOULD INFLUENCE THEIR WILLINGNESS TO USE (OR NOT TO USE) A VAGINAL PRODUCT

<i>Characteristic of microbicide</i>	<i>Mean impact on use (SD)^a</i>
Protection	2.54 (0.72)
Could prevent BV	2.77 (0.62)
Could prevent vaginal odor	2.72 (0.79)
Could prevent vaginal burning and itching	2.61 (0.89)
Could reduce risk of getting an STD	2.58 (0.97)
Could reduce risk of getting HIV through sex	2.44 (1.10)
Promotes growth of healthy bacteria	2.44 (1.12)
Could promote cleanliness in vagina	2.33 (1.26)
Side effects (reverse scored)	0.56 (1.35)
Had a bad taste	0.73 (1.66)
Was sticky	0.64 (1.73)
Caused a slight vaginal discharge the day after using it	0.32 (1.63)
Other attributes, which did not load together into any grouping	
Could prevent vaginal discharge	2.20 (1.28)
Can use with a condom	2.01 (1.37)
Prevents pregnancy	1.66 (1.78)
Could be used without partner's knowledge	1.50 (1.60)
Could increase physical pleasure during sex	1.50 (1.66)

^aScores range from -3 (much less likely to use) to 0 (neutral) to 3 (much more likely to use). This scoring is reversed for items in the Side effects grouping.

dictor of an increased interest in protection was age, such that the rating score for protection increased steadily with increasing age. A greater number of lifetime sexual partners was also marginally predictive of increased interest in prevention. In the regression predicting side effects, age was the only significant predictor, such that younger women rated side effects as more likely to affect their behavior compared with older women.

Discussion

Overall, women with a history of BV indicated that the protective features of a vaginal microbicide would be more likely than its side effects to influence their use of a product. Interestingly, within the overall category of protection, women rated a product's personal hygiene aspects (i.e., vaginal health) to be equally important or more important than the product's ability to prevent HIV/STD infections. This finding is important because vaginal microbicides will only be effective if women choose to use them on a consistent basis. Therefore, from a public health perspective, understanding factors that will influence consistent use of microbicides among high-risk women is of utmost importance.

The overall level of interest in using vaginal products for personal hygiene may be attributed, at least in part, to the diagnosis of BV in all our participants. BV is often associated

TABLE 2. FACTORS ASSOCIATED WITH PREFERENCES FOR THREE ATTRIBUTES OF VAGINAL MICROBICIDES AMONG 408 WOMEN WITH BACTERIAL VAGINOSIS^a

	<i>Microbicide attributes</i>	
	<i>Protection</i>	<i>Side effects</i>
Age (older)	$\beta = 0.16, t(382) = 2.76^{**}$	$\beta = -0.14, t(382) = -2.42^{**}$
White race	$\beta = -0.02, t(382) = -0.28$	$\beta = 0.07, t(382) = 1.27$
Current douching	$\beta = 0.07, t(382) = 0.91$	$\beta = 0.01, t(382) = 0.23$
More sex partners (past 30 days)	$\beta = 0.05, t(382) = 1.05$	$\beta = -0.01, t(382) = -0.19$
More sex partners (lifetime)	$\beta = 0.11, t(382) = 1.74^{*}$	$\beta = -0.10, t(382) = -1.78$
More prior BV infections	$\beta = 0.02, t(382) = 0.64$	$\beta = 0.09, t(382) = 1.74$

* $p < 0.10$; ** $p < 0.01$.

^aMultivariable analysis. A β value >0 indicates that the personal characteristic is positively associated with the microbicide attribute, whereas a β value <0 indicates that the personal characteristic is negatively associated.

with a vaginal discharge or unusual odor, and these women may have had a stronger preference for this type of preventive benefit. Of note, women rated the prevention of specific symptoms of BV more important than prevention of BV *per se*. Vaginal hygiene has also been mentioned as an ideal microbicide attribute in other studies,^{14,20} and women who douche regularly often mention that hygiene is their primary reason for douching.²¹ Future research should consider the ways in which beliefs about the body and vaginal cleansing intersect with hopes for product effectiveness and acceptability.

Our results also demonstrate that a woman's age influenced specific microbicidal preferences. Specifically, women who were older placed more emphasis on protection. Also, as in other studies, we found that younger women were more likely to report that side effects would affect their likelihood of using the product.^{11,15} Previous research suggests that women may not attempt, may reduce the amount, or may discontinue product use if the microbicide causes irritation, excessive leakage, or wetness.⁶ The results also suggest that women who had a greater lifetime number of sex partners were more interested in protection features, although this finding was marginally significant.

Our results have somewhat limited generalizability, as participants all had a diagnosis of BV and had agreed to participate in a clinical trial involving a vaginal product that was designed to prevent recurrent BV. Thus, these women may value products that prevent symptoms of BV more than do women in the general population. Also, the acceptability measures were somewhat limited because they had not been validated previously and because participants stated how these factors would influence their use of a hypothetical product, whereas actual use may differ. On the other hand, our participants were mostly young, single, minority women, who, in general, represent a population of women who might benefit most from vaginal microbicides. Conducting microbicide and other HIV/STD research with higher-risk populations is necessary for meeting the needs of those who will benefit most from future interventions.

Microbicide use will be most effective if used on a regular and consistent basis. As new microbicides become available, public health and HIV/STD prevention experts need to consider how to best motivate women with risk of HIV/STDs to use them. An understanding of factors influencing acceptability is crucial to achieving adherence to these products in the most vulnerable women. Our research suggests that various public health marketing strategies be considered and that

many women may be more motivated to use a product that offers personal hygiene in addition to HIV/STD prevention. Adolescents may have different preferences,^{22,23} and future research is needed to clarify specific motivators and barriers to use of microbicides in younger samples of women.

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Disclosure Statement

The authors have no conflicts of interest to report.

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