

Original research article

Delivery of microbicides to the vagina: difficulties reported with the use of three devices, adherence to use and preferences

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Abstract

Purpose: A crossover study was carried out in 405 couples to compare women's difficulties with three different devices that could be used to administer a microbicide and to evaluate adherence to use and preference for any one of the devices.

Methods: Couples used a single size diaphragm, a vaginal ring or disposable applicators for 1 month each in a randomly assigned order.

Results: Few women reported difficulty using the applicators or the ring; however, almost two-thirds reported difficulty using the diaphragm. Approximately 5%, 10% and 40% of the women and a similar but slightly lower percentage of their partners reported incorrect use of the applicator, vaginal ring and diaphragm, respectively. About half the women preferred the vaginal ring, while around half the men preferred the applicator.

Conclusion: The release of microbicides from a vaginal ring is a lead worth pursuing. The diaphragm is the only one of the three devices that also offers mechanical protection, but it requires greater investment in patient education to ensure adherence to use.

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Keywords: Microbicides; Diaphragm; Vaginal ring; Applicator; Difficulties in use; Adherence to use; Preferred device

1. Introduction

Research on microbicides that would offer protection against HIV and other sexually transmitted infections has focused on vaginal formulations. Acceptance of microbicides and adherence to their use may vary according to the vehicle or device used to dispense the product into the vagina. Problems with adherence would severely compromise the effectiveness of a product as a preventive method.

Although one of the objectives in the development of microbicides is to offer women a product that can be used without male consent or cooperation, a woman may consider covert use impossible [1] or may not want to hide the use of a vaginal product from her partner [2,3]. On the other hand, the man may perceive his partner's use of the product and/or see the formulation [1] and react violently [4]. If men's values,

preferences and opinions are not taken into consideration in the development of microbicides, insurmountable barriers for their effective use by couples may be created. Therefore, the acceptability of products by both the woman and her partner should be evaluated.

The vehicle or device used to dispense the product into the vagina should be simple enough so as not to require medical intervention and be suitable for community-based distribution of microbicides. This paper presents the results of a study in which the difficulties encountered by women in the use of three different devices — applicators, a one size fit-free diaphragm and a vaginal ring — were compared. Adherence to use and the preference expressed by women and their male partners for one of the three devices were also evaluated.

2. Methods

A cross-over study was carried out in which couples successively used three different devices potentially designed to dispense microbicides. A total of 405 couples

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were recruited to the study in Campinas in the state of São Paulo and in Campo Grande in the state of Mato Grosso do Sul, Brazil. Women were selected through the “snowball” technique [5]. This method consists of identifying eligible women, recruiting them if they are willing to participate and asking each woman (whether recruited or not) to provide names and addresses or telephone numbers of female friends or relatives whom they considered to be similar to themselves. The inclusion criteria were as follows: age 18–49 years; living in Campinas or Campo Grande; having a stable sexual partner; using a nonhormonal contraceptive method (condom, copper IUD, tubal ligation or vasectomy); and having had regular menstrual cycles during the previous 3 months. Agreement of the woman’s male partner to participate in the study was also one of the inclusion criteria. The socioeconomic level of the couples recruited to the study was assessed and classified as high-middle or low socioeconomic level. Socioeconomic level was measured according to the score proposed by the Associação Nacional de Empresas de Pesquisa [6]. This score estimates the capacity of urban families to acquire certain items such as color televisions, radios, washing machines and refrigerators. Capacity is evaluated by the number of items possessed and the education level of the head of the family. The score classifies individuals into one of five levels ranging from A (the highest level) through E (the lowest). For this study, participants were of high-middle class, which included Socioeconomic Levels A and B, and low, which comprised Levels C, D and E.

Couples used a single size diaphragm (65 mm) (Semina Silicone Diaphragm; Semina Indústria & Comércio Ltda., São Paulo, SP, Brazil), a vaginal ring (NuvaRing, N.V. Organon, Oss, the Netherlands) and disposable applicators (Milfra Indústria e Comércio Ltda., Jaguariúna, SP, Brazil). The diaphragm consisted of a disk made of silicone with a flexible coil spring on the rim and subjects were instructed to insert it together with approximately 3 g of a lubricant gel that contained no spermicidal or any other active substances (Preserv Gel, Blasiegel Ind. e Com. Ltda., Cotia, SP, Brazil). The vaginal ring used is flexible, transparent and practically colorless. Its external diameter is 54 mm and it is 4 mm thick. The ring has a contraceptive effect resulting from the release of a daily amount of etonogestrel (0.120 mg) and ethinylestradiol (0.015 mg) over a period of 3 weeks and was selected for this study because placebo rings were unavailable. Applicators were dull-white, manufactured from rigid plastic, 12 cm long and 0.9 cm in diameter, and were used to administer approximately 3 g of the same gel. The devices were used by each couple in a randomly assigned order for 1 month each, one after the other. The women recruited to the study were instructed to insert the diaphragm with the gel up to 2 h before intercourse and to remove it between 8 and 24 h later. The vaginal ring had to be inserted once, between the first and fifth days of menstrual bleeding, and removed 3 weeks later. Applicators were used to insert the gel prior to each act of sexual intercourse.

The supervisor and interviewers were trained in the use of the three devices by an experienced midwife using a pelvic model. They were also trained to contact the women whose names and addresses had been provided by the women already recruited. Each new candidate was told that her name had been given by a friend or relative, who was mentioned by name. At this time, the three devices were shown to the candidate. Following the partner’s agreement to participate in the study, the interviewer made an appointment to show him the devices and obtain his informed consent. A couple was admitted to the study only after both partners had gone through the consent process and signed the informed consent form.

All women were instructed on the use of each device by practicing insertion and removal on a rubber pelvic model and were provided with written instructions. Interviewers followed up each of the women weekly by telephone to check whether they had any problems or questions. Each partner was interviewed separately in a face-to-face interview after completing 1 month of use of each device. Women were asked whether they had any difficulty inserting or removing the device and about adherence to use. Their partners were asked if their wives had had any difficulties and whether they had adhered to the instructions they had been given for use of the device (see Appendix A). After using all three devices, each member of a couple was asked which one they liked most and which they liked least.

An initial descriptive analysis was carried out. The association of difficulties and adherence with sociodemographic characteristics was tested using the chi-square statistical test. The protocol was approved by the internal review board (IRB) of the School of Medical Sciences, Universidade Estadual de Campinas and by the IRB of the Federal University of Mato Grosso do Sul.

3. Results

Women participating in this trial were evenly distributed in the various age groups: <25, 25–29, 30–34 and ≥35 years of age. One-third had only primary education, half had some high school education and only 15% of participants had some college or university education. Around half the participants were white. Participants were equally distributed between upper-middle and low socioeconomic levels. The men were slightly older than the women, had a similar education level and a similar proportion were white (data not shown in table).

Three percent of women reported difficulty using the applicator and 14.1% experienced difficulties inserting and/or removing the vaginal ring. In contrast, almost two-thirds of the women reported having had difficulties inserting or removing the diaphragm. The number of men who said they were aware of their partner’s difficulties was about half the number of women who reported having difficulty using the vaginal ring or the diaphragm (7.2% vs. 14.1% and 38.8%

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