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Couples' acceptability of the SILCS diaphragm for microbicide delivery

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Abstract

Background: Disposable plastic applicators used in microbicide gel studies are expensive and have a negative environmental impact. The SILCS diaphragm is a barrier contraceptive that could offer a reusable delivery system.
Study Design: Thirty-six couples in this randomized, cross-over study evaluated single- and double-sided gel delivery from a SILCS diaphragm compared with gel from an applicator. Couples used each gel scenario during two acts of intercourse and completed acceptability questionnaires after each.
Results: All three scenarios received favorable ratings for ease of application, acceptability and perceived effectiveness. Both female and male participants tended to rate the gel applicator significantly more favorably than either SILCS gel delivery scenarios for all attributes except messiness/leakage and effectiveness. Additionally, about 60% of female participants and about half of male participants preferred the gel applicator to either of the gel delivery systems using SILCS. The preference for the SILCS scenario for pregnancy protection was statistically significant for both sexes. Male participants were also significantly more likely to prefer the SILCS single-sided delivery system to the gel applicator for protection from sexually transmitted infection.
Conclusions: In this study population, participants found the gel applicator to be more acceptable than either single- or double-sided gel delivery from a SILCS diaphragm. Further research of the SILCS as a microbicide delivery system should be implemented to assess its acceptability among study populations that reflect diverse potential user groups such as women and men from both low and high HIV prevalence settings including HIV-positive populations and with and without experience using female barrier methods.

Keywords: Contraception; Diaphragm; SILCS; Acceptability; Microbicide delivery

1. Introduction

Microbicide gels are being evaluated in clinical studies as protection from HIV and other sexually transmitted infections (STIs) [1]. In these clinical studies, the gels are delivered using plastic, prefilled applicators. Outside of the research setting, however, prefilled applicators may not be optimal due to cost and environmental considerations [2]. Having access to an easy-to-use, reusable diaphragm to deliver microbicide gel could offer advantages over use of a prefilled applicator, especially for women who are interested in dual protection from pregnancy and STIs [3]. The diaphragm could position the gel high in the vagina near the cervix thereby reducing messiness associated with current microbicide acceptability and offering additional protection to the cervix, considered a "hot spot" for infection [4]. First-generation microbicide gels in development are only partly effective at preventing STIs [5,6]. Combining the chemical protection for STI of the microbicide with the contraceptive barrier protection of a diaphragm may offer greater protection than either method used alone. The SILCS diaphragm is a new cervical barrier that could fit this role.

The SILCS diaphragm is designed to improve protection options for women especially in low-resource settings, such as sub-Saharan Africa, where women have significant unmet need for birth spacing and where access to additional barrier protection options could improve women's reproductive health. The acceptability and ease of use of SILCS in the United States and other countries has been reported previously [7–9]. Previous studies reported the fit of the SILCS device in women representing a range of body mass

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and parity [10]. Current clinical guidelines recommend diaphragms be used with contraceptive gel to increase effectiveness [11]. Combining a microbicide gel with a diaphragm would improve women's health by offering protection from both STIs and unwanted pregnancy.

This study is one in a series of evaluations designed to evaluate the feasibility and acceptability of using the SILCS diaphragm as a microbicide delivery system. As background, the Program for Appropriate Technology in Health (PATH) conducted bench tests to evaluate the carrying capacity of the SILCS diaphragm with various microbicide gel candidates (unpublished data, 2008). Subsequently, 19 women in Seattle evaluated the ease of handling, messiness and overall acceptability when the SILCS device was used with different gel volumes (5–10 mL) and different loading techniques (unpublished data, 2009). A recently completed exploratory study assessed the SILCS microbicide delivery system using magnetic resonance imaging to illustrate gel dispersion and retention over time and after simulated intercourse when compared with gel delivered with a vaginal applicator (K. Barnhart, unpublished data, 2010).

2. Material and methods

An open-label, randomized, cross-over assessment of SILCS as a microbicide delivery system was conducted among 36 couples who used each of three gel delivery systems during two acts of intercourse. Eligible women and men were between 18 and 45 years old, sexually active and in a self-reported monogamous heterosexual relationship for the past 6 months, willing to engage in six acts of intercourse with the study products within 1 month and willing to comply with all study procedures. In addition, female participants were using a nonbarrier method of contraception (hormonal methods excluding the vaginal ring), intrauterine device or were protected by sterilization (tubal ligation or partner had a vasectomy). Eligible women tested negative for pregnancy test at screening; had normal Pap smear within the previous 12 months, by self-report; and were judged by the clinician to have a satisfactory fitting of the SILCS diaphragm.

Couples were recruited from print media advertisements placed in a variety of community newspapers in the Los Angeles area and Internet classifieds to ensure a diverse, representative study population. Both male and female partners attended a pre-enrollment visit where informed consent and reproductive and contraceptive history was obtained and the couple received an introduction to the use of the SILCS diaphragm and gel. Only the female participants attended the subsequent enrollment visit, at which a urine pregnancy test, height and weight were taken. Women also participated in a fitting with a latex Ortho® diaphragm (Ortho-McNeil Pharmaceuticals, Raritan, NJ) to determine their baseline diaphragm size. In the clinical fitting session, the clinician provided written and verbal instructions on handling and inserting the SILCS diaphragm. The woman practiced insertion and removal with additional assistance as needed from the clinician until the woman felt confident the SILCS diaphragm was inserted correctly. The clinician confirmed the correct placement of the SILCS diaphragm by manual palpation and provided written and verbal instructions demonstrating the procedure for applying gel in this study. If the woman met eligibility criteria, could be fit with a SILCS diaphragm and was able to insert and remove the device, she was enrolled in the study.

Participants evaluated three different gel delivery systems (gel in diaphragm cup, gel split between cervical and vaginal side of diaphragm cup, gel via vaginal applicator). They engaged in a total of six acts of intercourse; two acts with each of the three gel delivery systems. They received a SILCS diaphragm and three separate, color-coded and numbered gel scenario packets. Participants used the three gel scenario packets in numerical order. Each scenario packet contained two prefilled 5-mL applicators or two 8-mL sachets of gel (one for each act of intercourse), appropriate instructions for gel application and use and an acceptability survey. See Fig. 1 for illustrations of the gel application methods used in this study. In Scenario A, the prefilled 5-mL applicator was used to fill the cervical cup of the SILCS diaphragm. In Scenario B, the 8-mL sachet of gel was split equally between the cervical and vaginal sides of the SILCS diaphragm. In Scenario C, the 5-mL gel applicators were used to apply the gel. In Scenario A, prefilled gel applicators were used because they were existing stock. A gel applicator is not necessarily the manner in which gel used with the single-side SILCS diaphragm scenario would be provided to consumers.

Both male and female participants completed an acceptability survey after they completed both acts of intercourse in the gel scenario set. Participants were instructed to wait at least 3 days between acts of sex with the study products to minimize gel run over from the last episode. Both male and female partners returned to the clinic for an exit visit after they had completed evaluating the three gel scenarios during six acts of intercourse. They returned the SILCS, any unused gel and the six acceptability surveys (three male and three female). Research staff reviewed the surveys for completeness and clarified any missing or unclear responses. Male and female participants completed a comparison survey that collected information on preference for the three gel scenarios as well as open-ended questions designed to solicit more detailed acceptability and product preference information. If a couple did not keep their scheduled exit visit, research personnel initiated a reminder telephone call and rescheduled the visit. A subset of 11 women also participated in a focus group discussion at the end of the study to further explore their perceptions of product acceptability and use. The focus group discussion was