

FEATURED RESEARCH

Acceptability of the Diaphragm in Mombasa, Kenya: A 6-month Prospective Study

Luchters S, Chersich MF, Jao I, Schroth A, Chidagaya S, Mandaliya K, Temmerman M.
The European Journal of Contraception and Reproductive Health Care. 2007;1-9.

Objectives: If proven acceptable, safe and effective, the diaphragm could be used as a female-controlled method of preventing both sexually transmitted infections (STIs) and pregnancy. This study's aim was to assess the acceptability and safety of the diaphragm among sexually-active women in Mombasa, Kenya.

Methods: We conducted a 6-month prospective study among female sex workers (FSWs), and women attending sexual and reproductive health services. Diaphragm acceptability was assessed using continuation rates and factors associated with acceptability. Safety evaluations included colposcopy findings and incidence of urinary tract infections (UTIs) and STIs.

Results: Half the 185 participants were FSWs who had less schooling and were less likely to be married than other women. After 6 months, 55% (56/102) of sexually active women reported having used the diaphragm each sex act during the preceding month. Women liked using the diaphragm (95%, 104/109), and 96% (125/130) reported willingness to continue using it. Colposcopy did not reveal significantly more vaginal or cervical lesions. Use of the diaphragm was not associated with an increase in bacterial vaginosis or UTIs. A pregnancy rate of 12 per 100 women/years was observed.

Conclusion: After 6 months of diaphragm use in this setting, continuation rates were sustained, user satisfaction was high and adverse effects were few.

Contraceptive Efficacy of a Novel Spermicidal Microbicide Used With a Diaphragm: A Randomized Controlled Trial

Barnhart KT, Rosenbuerg MJ, MacKay HT, et al.
Obstetrics and Gynecology. 2007;110(3):577-586.

Objective: Women need products that protect against both pregnancy and sexually transmitted infections, including human immunodeficiency virus (HIV). The acid buffering gel is a nondetergent spermicide that may provide this dual protection by reinforcing normal vaginal acidity to inactivate both sperm and acid-sensitive sexually transmitted pathogens. The objective of this study was to assess the gel's contraceptive effects, safety, and acceptability.

Methods: We conducted a multicenter, randomized, double-masked, noninferiority study at 11 centers, comparing 621 women who used an acid buffering gel plus diaphragm with 300 women who used a nonoxynol-9 spermicide plus diaphragm for 6 months. A double-masked study extension followed 234 women for an additional 6 months of use.

Results: The 6-month pregnancy rate per hundred women was 10.1% (95% confidence interval [CI] 7.1-13.1%) for acid buffering gel and 12.3 (95% CI 7.7-16.9) for nonoxynol-9 spermicide users. The difference in rates was -2.2% with a 95% CI -7.7 to 3.3%. Consistent and correct use 6-month pregnancy rates were 4.7% for acid buffering gel and 6.1% for nonoxynol-9 spermicide users, calculated from those cycles where diary entries indicated such use. Adverse events and acceptability were similar between the two groups. Pregnancy probabilities were similar between groups participating in the 12-month study extension.

Conclusion: An acid buffering gel used with a diaphragm is a safe, acceptable contraceptive with efficacy comparable to that of a common commercial spermicide with diaphragm.

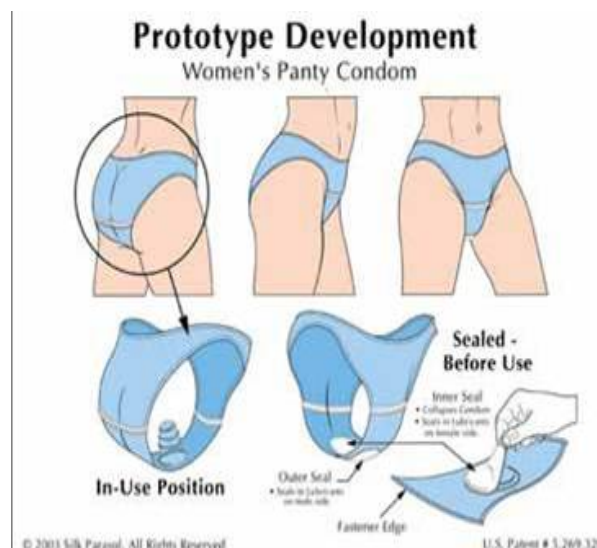
Microbicides and Cervical Barrier Methods at the 4th International AIDS Society Conference

The 4th International AIDS Society (IAS) Conference on HIV Pathogenesis, Treatment and Prevention took place this year in Sydney, Australia and covered a wide variety of HIV/health topics. For CBAS readers, we have highlighted relevant abstracts from the conference that relate to potential female-controlled methods for HIV prevention.

- Dr. Nancy Padian, Executive Director of University of California, San Francisco's Women's Global Health Imperative, delivered a plenary speech on promising new biomedical prevention technologies. She reviewed selected HIV-1 prevention methods (HSV-2 suppression, PreP, microbicides, female-initiated barrier methods), presented MIRA clinical trial results and methodological challenges, and offered recommendations for future prevention research. The full presentation is available at http://www.kaisernetwork.org/health_cast/uploaded_files/WEPL103-Padian.pdf.
- *Feasibility and acceptability of cervical barriers among vulnerable youth: a pilot study in Zimbabwe* authored by Ariane van der Straten and fellow researchers at the University of California, San Francisco assessed female youth's HIV risk perception and attitudes towards cervical barrier methods for HIV prevention. Nearly all of the participants liked the device they tried and all showed interest in participating in future studies. The authors concluded that evaluating CBs in larger studies seems feasible as all youth were willing to practice insertion and stated their interest to participate in future research.
- *Factors contributing to diaphragm size change among enrolled women at the Durban site in a phase III HIV prevention clinical trial* was authored by Sumen Govender along with fellow researchers. Information regarding the value of diaphragm fitting is limited and controversy surrounds the need for diaphragm refitting. To assess the reasons for refitting, all participants underwent checks at follow-up visits, if indicated, and at the close of the trial. Only 14 of 755 women were refit mostly due post-partum, weight changes and other, including fitting during menses and initial incorrect fitting. The authors concluded that although few women were refitted, clinicians should evaluate any complaint that suggests a refit to ensure adequate protection is provided by the diaphragm.
- *Female-controlled HIV prevention methods in Zimbabwe: how "involved" are the primary male partners?* was presented orally by Elizabeth Montgomery. To better understand male partner influence of women's acceptability and use of female-controlled methods, researchers from the MIRA Study Team explored male partner involvement among HIV-negative women in enrolled in a Phase III diaphragm trial in Zimbabwe. Nearly all women (99%) reported discussion with partners about their HIV/STI results, 85% reported that they had never used study products secretly, 95% reported that their partners were supportive of diaphragm/gel use and liked/strongly liked them, and 85% reported no difficulty negotiating product use. Women's perceptions of partner support for study participation and product use were very high. Social desirability bias may have influenced women's self-report of partner participation.

The Female Panty Condom

With the female condom gaining acceptance as a method of dual protection, Silk Parasol is currently developing a female panty condom that will put a new means of protection from both unintended pregnancy and sexually transmitted infections under women's control. The company aims for the panty condom to be a sexy fashionable and appealing barrier method tailored to women's needs. Silk Parasol Fund™, the non-profit arm of the company, has been formed to initiate pilot projects in developing countries that have been heavily affected by HIV/AIDS by: providing family planning options, establishing collaborative efforts with humanitarian agencies, communities and entrepreneurs, and encouraging the introduction of and education about the Silk Parasol Female Panty Condom™.



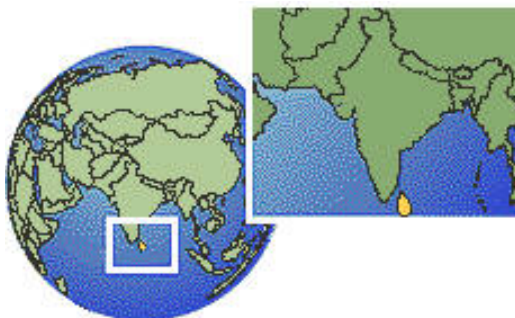
VivaGel™ Clinical Trials Under Way

Australian-based Starpharma is developing the vaginal microbicide VivaGel™ (SPL7013 Gel) to prevent transmission of HSV-2 (genital herpes) and HIV. A safety study conducted at the Melbourne Sexual Health Centers showed that VivaGel™ was safe and well tolerated, and comparable with placebo when applied to the penis of male volunteers. Participants reported the product to be acceptable if shown to be protective against sexually transmitted infections, and there were few concerns regarding the potential impact on sexual pleasure. VivaGel™ is currently being tested in healthy female volunteers in two separate expanded safety clinical trials at four sites in the U.S. and Kenya. In addition, an independent study conducted by Johns Hopkins University demonstrated VivaGel's™ potential as a contraceptive agent.

VivaGel™ is also being explored as a condom coating. A recent agreement between Starpharma and SSL International, which owns the Durex condom brand, includes a program of evaluation and development and also commercialization rights covering condoms with VivaGel™ coatings within a specified geographical region. The condom company, whose name may not be disclosed for reasons of confidentiality, holds the leading market position within that region.

International Conference on AIDS in Asia and the Pacific 2007

The World Bank-sponsored 8th International Conference on AIDS in Asia and the Pacific (ICAAP) concluded August 23 in Colombo, Sri Lanka. Over 2,500 delegates from 70 countries attended the five-day meeting. A major outcome of the meeting was the passage of the Colombo Declaration which called for "constant vigil against the epidemic." The Declaration recognized that Asia and the Pacific is a mix of countries with low and high HIV/AIDS prevalence rates; however, for low prevalence countries to maintain their status, donors should not make these countries a low priority.



Women and Girls in Hong Kong Lack Knowledge But Want Information About HPV

Cervical cancer is the seventh leading cause of death and the fourth most common type of cancer among Hong Kong Chinese women. Several studies have shown that women's knowledge about cervical cancer and preventive strategies is low. Researchers at Hong Kong University recently surveyed 1,413 women and conducted two focus groups with 113 women and girls ages 13-58 regarding their knowledge and perceptions about cervical cancer and willingness to receive a human papillomavirus (HPV) vaccine. The study found that nearly 40% of women correctly answered at least four of seven questions about HPV and that 33% correctly answered at least nine of 18 questions about cervical cancer (Benitez, *South China Morning Post*, 8/21). Over half of the respondents reported not having heard of an HPV vaccine, but 87% would consider being vaccinated if they had more information. Interestingly, more than 50% of teenage girls surveyed would be willing to receive an HPV vaccine, but many did not perceive there to be an urgent need to have one (*South China Morning Post*, 8/21).

-Adopted in part from Kaiser Daily Health Reports

IAVI-India Organized Panel Discussion at ICAAP

In collaboration with the Global Campaign for Microbicides and PATH, IAVI-India co-organised a symposium, "New HIV/STI Prevention Technologies on the Horizon." There were four expert panellists. Jeffery O'Malley, PATH-India, provided an overview of new HIV prevention technologies, the key issues and challenges in terms of introduction, access and availability. Dr. Suniti Solomon, YRG Care, addressed challenges related to HIV prevention research, including limited funding and gaps in global health research, research infrastructure and regulatory constraints, ethical and gender issues. Dr. Leela Visaria, formerly at the Gujarat Institute of Development Research, focused on the introduction and adoption of new health technologies in India, using the IAVI policy research paper on the subject to draw lessons and suggest future policies. Ms. Khartini Slamah, representing the Asia Pacific Network of Sex Workers in Bangkok, raised pertinent questions about new prevention technologies in the context of special populations such as female, male and transgender sex workers.

-Reported by Sushma Kapoor of IAVI-India

UPCOMING EVENTS

Event: International Symposium on Tropical Medicine and Hygiene

Date: December 12–15, 2007

Location: Karachi, Pakistan

Website: www.aku.edu/news/seminars/rstmh/

Description: This is an international symposium on diseases of the tropics in collaboration with the Royal Society of Tropical Medicine and Hygiene, UK, and the Infectious Diseases Society of Pakistan. The symposium will highlight important issues of relevance to tropical medicine, clinical, and public health practice in Pakistan and the developing world.

Event: 15th International Union Against Sexually Transmitted Infections Asia Pacific Congress

Date: February 3–6, 2008

Location: Dubai, United Arab Emirates

Website: www.iusti.ae

Description: The Union's objectives are to bring together all forces devoted to the fight against the sexually transmitted infections (STIs), including HIV-AIDS and the endemic treponematoses, and to promote and co-ordinate activities throughout the world aimed at research, prevention, and control of these diseases and to encourage its members to contribute to public health programs for the control of STIs.

Event: 3rd Africa Conference on Sexual Health and Rights

Date: February 4–7, 2008

Location: Abuja, Nigeria

Website: africalsexuality.org

Description: The conference seeks to bring together key actors in the field of Sexual Health and Rights to explore how sexuality has affected and can improve development in Africa, especially when working with women and youth.

Event: Microbicides 2008

Date: February 24–27, 2008

Location: New Delhi, India

Website: www.microbicides2008.com

Description: The conference will provide updates on the current state and the likely future about the research and development efforts in the area of microbicides in different parts of the world. In addition to basic research and innovative product development of novel microbicides, the progress made in areas of ethics, clinical research, socio-behavioral and epidemiological studies, accessibility and acceptability issues will be discussed.

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What are cervical barriers?

Most people think of cervical barriers primarily as the diaphragm and cervical cap but a broader definition would encompass Lea's shield, female and male condoms, the sponge and microbicides. For more information about the range of cervical barrier methods, go to www.cervicalbarriers.org/information/methods.cfm.

Mission of CBAS

Established in 2004, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods for pregnancy prevention and provide information about research on the potential of cervical barriers to prevent sexually transmitted infections, including HIV.

Membership

CBAS membership is free and open to all who are interested in joining. CBAS's goal is to create an international, professional networking organization including clinical and social science research groups, academic institutions, advocacy groups, trade associations, and pharmaceutical, biotech, and medical device companies. As a member, you will have the opportunity to network and collaborate with other professionals in the field; keep abreast of new research; share information and ideas; and receive a semi-annual newsletter.

CBAS Contact Information: For more information, contact Teresa Harrison, CBAS Executive Director, at tharrison@cervicalbarriers.org. CBAS is hosted by Ibis Reproductive Health and based in Cambridge, Massachusetts.

To comment on anything you read in the CBAS newsletter or to contribute a story, event, or news item, please email info@cervicalbarriers.org.