

CBAS Newsletter: Volume 3, Number 3

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FEATURED RESEARCH

Baseline dimensions of the human vagina.

Barnhart KT, Izquierdo A, Pretorius ES, Shera DM, Shabbout M, Shaunik A. *Human Reproduction*. 2006; 21(6):1618-1622.

Fallopian Tube

Ovaries

Uterus

BACKGROUND: Vaginal anatomy has been poorly studied. This study aimed to measure baseline dimensions of the undistended vagina of women of reproductive age. METHODS: We combined

baseline information collected from five clinical trials using magnetic resonance imaging (MRI) to quantify distribution of a vaginal gel. Seventy-seven MRI scans were performed on 28 women before gel application to establish baseline vaginal measurements. Average dimensions were calculated for each woman and for

the population. The influence of potential covariates (age, height, weight and parity) on these dimensions was assessed. RESULTS: MRI measurements are reproducible. The SD surrounding the mean at each anatomical site,

and with summary measurements, was significantly smaller with each subject compared with the population. Mean vaginal length from cervix to introitus was 62.7 mm. Vaginal width

was largest in the proximal vaginal vagina (32.5 mm), decreased as it passed through the pelvic diaphragm (27.8 mm) and smallest at the introitus (26.2 mm). Significant positive associations were parity with vaginal fornix length, age with pelvic flexure width and the height with width at the pelvic flexure. CONCLUSION: No one

description characterized the shape of the human vagina. Although there is variation among women, variables such as parity, age and height are positively associated with differences in baseline dimensions.

A polyherbal vaginal pessary with spermicidal and antimicrobial action: evaluation of its safety.

Bagga R, Raghuvanshi P, Gopalan S, Das SK, Baweja R, Suri S, Malhotra D, Khare S, Talwar GP. *Transactions of the Royal Society of Tropical Medicine and Hygiene*. Available online June 2006.

A polyherbal vaginal pessary (Praneem) has been formulated that has antimicrobial properties against genital pathogens in addition to spermicidal action. Thus, it has dual potential as a barrier method for contraception and for providing protection against some sexually transmitted infections. The present study reports the findings of a multicentre trial that was conducted to evaluate the safety of this product. Trials were carried out in 23 women in three centres in India: the Postgraduate Institute of Medical Education and Research, Chandigarh; Safdarjang Hospital, New Delhi; and Kamla Nehru Memorial Hospital, Allahabad. Thorough clinical and pelvic examinations were carried out as well as cervical cytology, blood biochemistry and haematology before and after use of the polyherbal pessary intravaginally once daily for 7 consecutive days. No toxicity was observed on clinical examination or by laboratory investigations. Daily intravaginal use of this pessary for 7 days had no adverse effects on cervical cytology or on metabolic and organ functions.

Could reducing medical restrictions on contraceptives increase use?

In the article, "Barriers to Contraceptive Use in Product Labeling and Practice Guidelines," published in the May 2006 issue of the American Journal of Public Health (p. 791-99), Grossman et al. argue that simplifying contraceptive provision based on existing data could reduce costs and improve access to contraception. Contraceptive labels often did not reflect available clinical evidence and contained unnecessary restrictions to use. In addition to identifying access barriers to intrauterine hormonal methods and devices (IUDs), the authors make the case that sizing, spermicidal use, and length-of-wear limits burden users of cervical barriers and may be unnecessary.

Highlighting the potential of cervical barriers to serve as female-controlled methods for HIV prevention, Grossman et al. advocate that improving user access to cervical barriers methods will be critical. Some current requirements, such as fitting by clinicians, may be necessary for cervical caps but little evidence supports this standard for the diaphragm. In fact, some limited data suggest that a standard size diaphragm (70 mm) may be as effective as a fitted one.

Although not evidence-based, diaphragm labeling recommends use with spermicide and removal within 24 hours. Women's complaints of the messiness of spermicide, research indicating that nonoxynol-9 spermicide should not be used by women at high HIV risk, and evidence suggesting the use of spermicide does not affect efficacy all point to the need for further research to confirm whether spermicide for contraceptive efficacy of the diaphragm is indeed necessary. The authors also note that continuous use of the diaphragm could simplify use and increase the popularity of this method.

CBAS/Ibis participate at Global Health Council Conference

CBAS and Ibis Reproductive Health co-hosted an exhibition booth at the Global Health Council conference. Many conference participants were not familiar with the range of available cervical barrier methods and asked a range of questions about acceptability, cost and usage. Attendees were excited about the information offered and signed up to receive the quarterly CBAS newsletter.

Pictured right: Teresa Harrison, Senior Project Manager, Ibis Reproductive Health.

Condom use shown to reduce risk of HPV infection

In a study among newly sexually active women, researchers demonstrated that consistent use of male condoms effectively reduced the risk of male-to-female genital transmission of the human papillmoa virus (HPV), the sexually transmitted virus that causes cervical cancer. Cervical cancer kills more than 288,000 women each year worldwide and disproportionately affects the poorest, most vulnerable women.

For eight months, researchers followed 82 female college students ages 18-22 who were virgins or had first intercourse with one male partner within the previous three months. Participants completed a web-based diary every two weeks detailing the number of instances of vaginal intercourse, how often condoms were used by male partners and number of new partners. The women also underwent gynecological exams every four months. Results showed that women whose partners always wore a condom during vaginal sex were 70 percent less likely to become infected with HPV than those women whose partners used a condom less than five percent of the time. Women whose partners wore a condom even half the time reduced their risk of infection by 50 percent compared to the women whose partners used condoms less than five percent of the time.

This study differed from previous research in that it was a longitudinal study and evaluated more accurately the temporal relationship between condom use and HPV infection. This finding adds to the evidence on the importance of condom use in preventing cervical cancer. These results come at an exciting time with the recent approval by the U.S. Food and Drug Administration of an HPV vaccine and the recommendation by the Centers for Disease Control and Prevention that the vaccine should be given to girls at 11 and 12 years of age.

Winer RL et al. Condom use and the risk of genital Human Papillomavirus infection in young women. *The New England Journal of Medicine.* 2006; 354(25): 2645-2654.



Cervical Barriers featured at Global Health Council Partner's Forum

The Global Health Council featured a series, "Female-controlled methods for HIV Prevention" during the month of June including separate panel presentations on female condoms, cervical barriers and microbicides. The cervical barrier methods presentation was held on June 22. Julia Matthews from CBAS/Ibis Reproductive Health provided an introduction on cervical barrier methods and re-



viewed the evidence for why cervical barriers are being researched as potential methods for HIV prevention. Marianne Callahan of CONRAD described two cervical barriers recently approved by the U.S. Food and Drug Administration, FemCap

Julia Matthews and Shannon Cali

and Lea's Shield. She also discussed three studies which CONRAD is undertaking to test the diaphragm with candidate microbicides in Madagascar, South Africa and Zimbabwe. Shannon Cali, representing PATH, updated the audience on SILCS, a modified diaphragm that was developed with user input from women in the U.S., South Africa, Thailand and the Dominican Republic.

Photos: Global Health Council



The Microbicides 2006 (M2006) conference, held in Cape Town, South Africa from April 23-26, highlighted the enormity of the HIV/AIDS epidemic in developing countries and drew attention

to the important role that gender inequities continue to play in advancing the epidemic. This was the fourth bi-annual meeting and the most heavily attended with 1,300 participants from around the world. Nearly 30 of this year's presentations reported on research related to the potential of cervical barriers for HIV prevention and issues relevant to cervical barrier methods.

The panel presentation, *Barrier Methods and Dual Protection for HIV Prevention*, provided an update on several cervical barrier studies. One study among U.S. women found that two candidate microbicides, Acidform[™] and BufferGel[™], were safe when used with a diaphragm. Researchers at the University of California San Francisco and University of Zimbabwe found that Cellulose Sulfate gel, another potential microbicide, when used with the SILCS is currently undergoing contraceptive trials; results will be available in 2008. Thomas Moench from ReProtect, Inc. introduced the BufferGel Duet[™], a reusable one-size-fits-all diaphragm-like device made of clear polyurethane that delivers and distributes BufferGel[®], a candidate microbicide and contraceptive, to the opening and interior of the vagina and cervix. A contraceptive efficacy

study is planned for the near future. The audience of providers, advocates, researchers, staff from nongovernmental organizations, product manufacturers and others posed a range of questions from how these products will be made



Marianne Callahan and Thomas Moench

available in developing countries to what providers' perceptions are toward prescribing the diaphragm to clients. Rachel Wilson, Communications Director of the Global Health Council closed the session with an urgent call for bringing more attention to female-controlled methods for HIV prevention, including cervical barriers, female condoms and microbicides.

Microbicides 2006

diaphragm was shown to be safe. Another research trial demonstrated that the BufferGel Duet[™], a cervical barrier that is combined with the candidate microbicide BufferGel[®], was easy to insert and remove, validating the idea



BufferGelDuet™

that a cervical barrier can be prepackaged with a microbicide. (See photo of the BufferGel Duet[™].) One of the most exciting pieces of news from the panel were the results presented by Kurt Barnhart of the University of Pennsylvania showing that BufferGel[™] used with the diaphragm is as effective as the diaphragm used with nonoxynol-9 spermicide for contraception.

CBAS and Ibis Reproductive Health also co-hosted an exhibition booth. Participants expressed a great deal of interest in the various cervical barrier methods and over 100 joined the CBAS newsletter mailing list. To review all of the abstracts on cervical barrier studies that were presented at M2006, go to <u>www.cervicalbarriers.org/information/</u> microbicides2006.cfm.

UPCOMING EVENTS

Event: International Federation of Professional Abortion and Contraception Associates (FIAPAC) Meeting

Date: October 13 - 14, 2006 Location: Rome, Italy Website: <u>http://www.fiapac.org/e/</u> RomePrelProgr2.html

Description: This conference is sponsored by FIAPAC and this year's theme is "Freedom and Rights in Reproductive Health."

Event: Global Forum for Health Research Date: October 29 – November 2, 2006 Location: Cairo, Egypt Website: <u>http://www.globalforumhealth.org/</u> Site/000__Home.php

Description: A forum to transform research into policy, this conference is co-hosted by WHO's Global Forum for Health Research and India MOH, Indian Council of Medical Research and National Institute for Research in Reproductive Health in Mumbai. **Event:** American Public Health Association Annual Meeting

Date: November 4 – 8, 2006 **Location:** Boston, MA

Website: http://www.apha.org/meetings/

Description: This yearly conference is hosted by the American Public Health Association and attracts more than 13,000 national and international physicians, administrators, nurses, educators, researchers, epidemiologists, and related health specialists. This year's theme is "Public Health and Human Rights."

Event: World Congress of Gynecology and Obstetrics

Date: November 5 – 10, 2006 Location: Kuala Lumpur, Malaysia Website: <u>http://www.figo2006kl.com/</u> marketroot/figo2006kl/index.html

Description: This conference sponsored by the International Federation of Gynecology and Obstetrics (FIGO) focuses on new practices and lowcost, low-tech solutions. It is the largest international meeting of obstetricians and gynecologists.

CBAS Steering Committee

Marianne Callahan: CONRAD

Tsungai Chipato: <u>University of Zimbabwe-University of</u> California San Francisco Collaborative Research Programme in Women's Health Patricia Coffey: <u>PATH</u>

Natalya Dinat: Perinatal HIV Research Unit

Katy Backes Kozhimannil: Harvard PhD Program in Health Policy

Nancy Padian: <u>Women's Global Health Imperative</u>, <u>University of California San Francisco</u> Gita Ramjee: <u>Medical Research Council of South Africa</u>

Helen Rees: Reproductive Health Research Unit

Kelley Ryan: Duke Clinical Research Institute

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 <u>http://www.cervicalbarriers.org/information/methods.cfm</u>.

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 Julia Matthews, CBAS Executive Director at <u>jmatthews@cervicalbarriers.org</u>. 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.