INTERNAL FEMALE CONDOM RESEARCH


BACKGROUND: Female (internal) condoms could be viable alternatives to male (external) condoms. Our objective was to describe barriers and facilitators of adolescent maternal caregivers experiencing when trying to access female condoms in US pharmacies.

METHODS: In mid-2016, university students seeking contraception purchased counterfeit and non-counterfeit retail pharmacies in Arizona, California, New Mexico, and Utah. We evaluated differences in product availability and callers’ experiences by pharmacy type.

RESULTS: Out of our final sample (n=1475), eight outlets (0.5%), all national chains, definitely stocked female condoms. Of those not (or probably not) stocking female condoms, 11% tried to be helpful (e.g., referred to special order), 59% made no substantive comment, and 30% were unhelpful (e.g., dismissive, rude, gave wrong information). National chain employees were significantly more unhelpful (34% vs 23%, p <0.01).

CONCLUSION: Almost no pharmacies in four southwestern states stocked female condoms in mid-2016. Pharmacy staff frequently were unhelpful, which could deter adolescent use of female condoms even if new types become available.


OBJECTIVE: To investigate whether rates of self-reported Woman’s Condom (WC) clinical failure and semen exposure from a functionality study are comparable to results from a contraceptive efficacy study.

STUDY DESIGN: We structured our comparative analysis to assess whether functionality studies might credibly supplant contraceptive efficacy studies when evaluating new female condom products. Couples at risk of pregnancy in the functionality (breakage/slippage/ripping/navigating/penile retraction) study and women in the contraceptive efficacy study completed condom self-reports and collected precollect and postcollect vaginal samples for up to four uses of the WC. Both studies used nearly identical sexual scenarios and self-sampling procedures and laboratory for prostaglandin specific antigen (PSA), a well-studied semen biomarker. We compared condom failure and exposure propensities using generalized estimating equations methods accounting for within-couple correlation.

RESULTS: Ninety-five (95) efficacy suitability participants used 334 WC and 408 functionality participants used 1572 WC. Based on self-report, 19.2% WC (94 condoms) clinically failed in the efficacy suitability study compared to 12.3% WC (194 condoms) in the functionality study (p<0.05). Of the 207 WC efficacy uses with evaluable PSA tests, 14.1% resulted in semen exposure compared to 14.2% (134 uses) of the 1203 evaluable WC functionality studies use.

CONCLUSIONS: When evaluating the effectiveness of condom to prevent semen exposure, the rate of clinical condom failure reported by participants risking pregnancy in an efficacy suitability study was significantly higher then the rate reported by participants not risking pregnancy in a functionality study at a rate of semen exposure assessed, by an objective biomarker was nearly identical for the two studies.

IMPLICATIONS: Our results suggest that an objective marker of semen exposure in functionality studies could provide a reasonable alternative to contraceptive-efficacy studies evaluating in risk of unintentional pregnancy and informing protection from sexually transmitted infection than condom failure rates based on self-report.

BARRIER METHODS UPDATE

On February 10, 2020, Reuters published an in-depth story on barrier methods of contraception, specifically highlighting Ovaprene, a non-hormonal barrier contraceptive method developed by Dardi Bioscience. The device consists of a plastic vault and polymer mesh that, in conjunction with ferrous glucuronate, acts to prevent sperm from entering the cervix. In contrast to other available barrier methods that require removal after sexual activity, Ovaprene is designed for monthly use.

An initial FDA trial of the device was completed in November 2019 in collaboration with an Idaho Falls, ID company called Ovaprene, as COMBAR, Oregon Health & Science University, and the University of Pennsylvania. Thirty-eight healthy women ages 18-40 years old who had undergone tubal sterilization and thus not at risk for pregnancy, enrolled in the study launched in May 2018. The researchers gave the participant the test kit to measure sperm and mid-cycle cervical mucus after sexual activity across multiple menstrual cycles. Twenty-three study participants reportedly attended 21 visits each for postpartum testing. Although the full results of the study have not yet been published, topline findings reported by Dardi in a recent press release indicate that sperm were effectively blocked from entering the cervical canal across all participants in all cycles of use. In addition, they report that 90% of participants would recommend the device to others. Dardi plans to apply for investigational device exemption from the United States Food and Drug Administration (FDA), the regulatory agency that reviews and provides approval for medical devices in the United States, and will conduct additional testing in support of an application for market approval.

As reported in Economist.com in January 2020, Dardi has entered into an agreement with Bayer Pharmaceuticals to license Ovaprene for entry into the US market, pending the outcome of the Clinical trial of the device and approval from the FDA. As of the time of that announcement, they anticipated entry of the product into the US market as early as 2023.

ABOUT US

Mission of CBAS

Established in 2014, the Cervical Barrier Advancement Society (CBAS) aims to raise the profile of cervical barrier methods, including diaphragms, caps, female condoms, and other devices, and to share the latest news and resources related to these methods.

CBAS contact information

More information, contact Laura Fox, CBAS Executive Director, at lfox@cbas.org.

CBAS is coordinated by Ibis Reproductive Health.

www.ibisreproductivehealth.org