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Effectiveness of female and male condoms in preventing exposure to semen during vaginal intercourse: a randomized trial

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Abstract

Objectives: Comparison of male condom (MC) vs. female condom (FC) with respect to self-reported mechanical and acceptability problems and semen exposure using prostate-specific antigen (PSA) as an objective biological marker and evaluation of the effect of an educational intervention on self-reported problems and semen exposure, by condom type.

Design: Randomized crossover trial.

Methods: Four hundred women attending a family planning clinic in Brazil were randomized and either received in-clinic instruction or were encouraged to read the condom package insert; all used two FCs and two MCs. We measured the rates of self-reported user problems with MC and FC use and the rates of semen exposure during use (assessed by testing vaginal fluid for PSA).

Results: The educational intervention group reported fewer problems with either condom as compared with the control group ($p=.0004$, stratified by condom type). In both groups, self-reported problems were more frequent with FC use than with MC use ($p<.0001$, stratified by intervention). The educational intervention did not significantly reduce semen exposure. Overall, semen exposure occurred more frequently with FC use (postcoital PSA, >1 ng/mL; 22%) than with MC use (15%); the difference, however, was small and nonsignificant for high PSA levels (≥150 ng/mL; 5.1% for FC vs. 3.6% for MC).

Conclusions: In this study, the FC was less effective than the MC in preventing semen exposure during use and led more frequently to self-reported user problems. Both devices were highly protective against "high-level" semen exposure, as measured by postcoital PSA levels in vaginal fluid. In-clinic education may reduce user problems and increase acceptability and use of both devices.

Keywords: Randomized trials; HIV; STD; Condoms; Educational intervention; Semen exposure; Women

1. Introduction

Barrier contraceptive methods such as the male condom (MC) and, more recently, the female condom (FC) offer protection against pregnancy as well as HIV and a number of other sexually transmitted infections (STIs). Regular condom use is associated with reduced incidence of HIV, gonorrhea, mycoplasma, chlamydia, trichomoniasis, hepatitis, cytomegalovirus and herpes [1–6]. The FC was approved by the U.S. Food and Drug Administration as a contraceptive method, which is also effective for STD

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prevention [7], and has been promoted as a woman-controlled method. The contraceptive efficacy of the FC has been adequately studied [8,9], and comparative analyses suggest that the contraceptive failure rate of the FC, if consistently and correctly used, is close to the lowest expected failure rates reported for MC [10]. However, the evaluation of the effectiveness of the FC in protecting users against STIs is more limited [11–14], and no direct comparison has been made between the efficacy of the FCs and that of the MCs.

Although previous studies have reported on both the mechanical and user problems encountered in using MCs and FCs, few studies have employed objective markers of semen exposure to measure condom effectiveness [15–18]. An objective measurement of condom failure should be based on laboratory tests that evaluate semen spillage during condom use. Suitable tests include the microscopic examination of vaginal fluid specimens to detect spermatozoa, biochemical assays to measure the enzymatic activity of acid phosphatase [19,20] and immunologic assays to detect semen components such as prostate-specific antigen (PSA, also known as P-30) [20,21] and the human seminal plasma antigen MHS-5 [22,23]. We developed a self-sampling procedure in which PSA performed better than other semen biomarkers [24].

The current study sought to compare MCs and FCs with respect to self-reported mechanical and acceptability problems and semen exposure using PSA as an objective biological marker. Another objective was to evaluate the effect of a clinic-based educational intervention on self-reported problems (such as breakage and slippage) and semen exposure, by condom type, during vaginal intercourse.

2. Methods

This was a randomized crossover trial of FC vs. MC use among 400 women attending the family planning clinic of the Universidade Estadual de Campinas (UNICAMP) in the state of São Paulo, Brazil. Women were eligible to participate if they were between 15 and 49 years old, were sexually active, had not been using condoms as their primary birth control method for 1 year or longer, were willing to try both FCs and MCs, were able to read the instruction sheet of the FC and MC packages and were willing to comply with the study protocol. The subjects were recruited from among attendees of the family planning clinic and through advertisements circulated by clinic staff. The institutional review boards (IRBs) of the Population Council and of the University of Alabama at Birmingham (UAB) in the United States reviewed and approved the study protocol and forms annually. The IRB of the UNICAMP deferred IRB review to the Population Council. Analysis of deidentified data was conducted at the Centers for Disease Control and Prevention (CDC), and the CDC IRB determined that the analysis was exempt from review.

After providing informed consent, the study participants completed a baseline questionnaire that collected basic demographic, sexual and reproductive history information. Next, they were trained by a nurse in collecting precoital and postcoital samples of vaginal fluid using a gynecologic swab protected by a cardboard tampon tube [25]. To minimize sampling error, participants were instructed to take two samples before intercourse and two samples after intercourse. The nurse emphasized the high sensitivity of the test for semen and that it was imperative that the tip of the swab be kept inside the cardboard tube until inserted and then retracted into the tube before removing the sampling device from the vagina.

Participants were randomly assigned to receive either in-clinic educational instruction on FC and MC use or the recommendation to read the condom package inserts, depending on the day the participants attended the first study visit. A trained nurse conducted in-clinic instruction on condom use, which included (1) a demonstration of the correct use of MCs using anatomical models of the penis and (2) an interactive session among participants that involved practicing the insertion of an FC initially on a model of the female pelvis and then on oneself. Participants were randomly assigned to begin the study using the FC or the MC. Depending on the randomization, study participants were provided with a free initial supply of two FCs or two latex (prelubricated) MCs. They were also trained to fill out a brief questionnaire to describe any problem encountered during intercourse for each condom used.

After participants had used the first two condoms, they came back to the clinic to return their vaginal samples and data forms and met briefly with the nurse to review their experience and the completed condom data forms, after which the participants received two condoms of the other type, two self-sampling kits, two more questionnaires and one set of written instructions. The participants subsequently repeated the process and self-sampling procedures with the new set of condoms. They then returned to the clinic for a second and final follow-up visit, in which they reviewed

Table 1
Selected baseline characteristics of 400 female participants in the study

Sociodemographic characteristics	*n*	%
Age (years)		
<20	49	12
20–29	185	46
30–39	128	32
≥40	38	10
Marital status		
Single	42	11
Married/common law	346	86
Separated/divorced/widowed	12	3
Number of live births		
0	67	17
1	128	32
2	122	30
≥3	83	21