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Acceptability of five nonoxynol-9 spermicides

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Abstract

Objective: To examine the acceptability of five nonoxynol-9 (N-9) spermicides.
Methods: We analyzed data from a randomized trial of five products, including three gels containing different amounts of N-9 per dose, a film and a suppository. In the trial, 1536 participants were asked to use the assigned spermicide for 7 months and to complete questionnaires 4 weeks after admission and at discontinuation.
Results: Overall, 43% of participants liked their spermicide "very much." This proportion was higher in the three gel groups than in the suppository and film groups. Difficulty with insertion, messiness and discontent with timing of insertion were common complaints in all groups. After adjustment for selected baseline factors, acceptability on the first questionnaire was not related to duration or consistency of subsequent spermicide use or to subsequent time to pregnancy.
Conclusions: In this study, all five spermicides were considered acceptable by most users. Acceptability did not appear to influence spermicide use or pregnancy risk.

Keywords: Spermicide; Randomized trial; Acceptability

1. Introduction

Spermicides are among the least popular of all modern contraceptive methods. In the 2002 National Survey of Family Growth, only about 0.3% of women at risk of pregnancy, or about 128,000 women, reported using spermicides alone to prevent pregnancy (James Trussell, personal communication, March 8, 2005). The limited appeal of this method may in part reflect the lower efficacy of currently available nonoxynol-9 (N-9) preparations compared to other contraceptives, such as oral contraceptive pills, injectables, IUDs and sterilization. Nevertheless, spermicides have substantial advantages over other methods: they are simple to use, have no direct serious side effects, are used only when needed, do not require a prescription and are controlled by women without the need for cooperation of a clinician or male partners. Currently, extensive international efforts are underway to develop new spermicide products that will also be microbicidal and will thus protect women from both unintended pregnancy and sexually transmitted infections (STIs), including HIV infection.

We recently completed a large randomized trial comparing the efficacy and safety of five marketed N-9 spermicides [1].

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These spermicides included three gels containing different amounts of N-9 per dose, a film and a suppository. The main findings of the trial were that the lowest dose gel (52 mg N-9) was significantly less effective than the other two gels (100 and 150 mg N-9), but no significant difference in efficacy was apparent between the 100-mg gel, the film and the suppository, which each also contained 100 mg N-9 per dose. The risk of pregnancy associated with all five spermicides was higher than would be expected among users of other modern contraceptive methods. We detected no clinically important safety problems associated with any of the spermicides.

Here we report data comparing the acceptability of these products. We hope that this information will be helpful in the future development of new spermicides, microbicides and other vaginal therapies.

2. Methods

We conducted the trial at 14 sites in the United States between June 1998 and August 2002. The study was approved by the institutional review boards at each site and at Family Health International. All participants signed written informed consent forms before enrollment.

We enrolled 1536 healthy, sexually active women aged 18–40 years who had no history suggestive of subfecundity, who were at low risk for STIs, who stated that they wished to rely on a spermicide as their only contraceptive method for 7 months and who were willing to accept a moderate risk of pregnancy. A full description of trial procedures was published elsewhere [1]; in brief, they were as follows.

After providing eligibility and other baseline data, each participant completed a questionnaire about attitudes toward contraception. She was then randomly assigned to one of the five study spermicide groups. Gels A, B and C contained 52.5, 100 and 150 mg N-9 per dose, respectively, and the film and suppository each contained 100 mg N-9 per dose. Participants were instructed to insert the gels 0–60 min, the suppository 10–60 min and the film 15–60 min before each sex act. The applicators for Gels B and C were identical but different from the applicator for Gel A. Gel group participants were not told which gel they had received. Each participant was given a supply of her assigned spermicide and a diary on which to record relevant information daily throughout the study. Follow-up visits were scheduled at 4, 17 and 30 weeks after admission. At the 4-week and final visits, each participant completed a seven-page acceptability questionnaire.

The primary measure of acceptability was the participant's response to the question: "In general, how well do you like your spermicide?" Participants were asked to check one of five possible answers: 1=*like it very much*, 2=*like it somewhat*, 3=*dislike it somewhat*, 4=*hate it* and 5=*haven't decided*. In the analysis, we grouped the responses to this question into two categories. Initially, we planned the categories as "acceptable" (answers 1, 2, 5) and "unacceptable" (answers 3, 4). However, after recognizing that only a small proportion of the population gave answer 3 or 4, we changed the groupings to "highly acceptable" (answer 1) or "not highly acceptable" (answers 2–5). Other questions asked about the most and least liked attribute of the spermicide, specific aspects of the spermicide and perceived partner acceptability. For many questions, participants could either choose precoded responses or write in answers. An analyst masked to spermicide group and to frequency of individual responses sorted answers into relevant categories.

We explored the associations between high acceptability and 17 baseline factors: geographic region, age, race, education, marital status, parity, previous spermicide use, desire for additional children, strength of desire to avoid pregnancy now, coital frequency at admission, most important reason for choosing spermicide now and importance of six characteristics of a contraceptive method (efficacy, infection prevention, side effects, acceptability to partner, whether it interrupts sex and whether it is coital-dependent). We found no evidence that any of these variables were highly correlated according to the χ^2 test. In these analyses, we first examined the association between the outcome and each factor separately with a χ^2 test or a Mantel–Haenszel test in all spermicide groups combined. We then included factors related with $p<.10$ in a logistic regression model with spermicide group. The same factor selection procedure was also applied to other regression analyses.

We assessed the association between acceptability on the first questionnaire and the proportion of subsequent coital acts using spermicide with the Wilcoxon rank-sum test. We evaluated relationships between acceptability and subsequent duration of spermicide use and pregnancy with log-rank tests. The association between knowledge of pregnancy and acceptability and the change of acceptability between two acceptability questionnaires were tested with a Cochran–Mantel–Haenszel test and McNemar's test, respectively. We used Fisher's least significant difference approach to compare the proportions of categorical outcomes of interest (e.g., participants who found the spermicide highly acceptable, or those who had specific complaints) separately among the three gel groups and among the three groups using spermicides containing 100 mg of N-9 per dose. If we found a significant result ($p<.05$) in either of these comparisons, we performed pairwise comparisons among the constituent groups.

3. Results

Of the 1536 participants enrolled in the study, 1389 (90%) completed at least one acceptability questionnaire after admission, and 938 (68%) completed two questionnaires. The first questionnaires were completed a median of 30 days after admission. The last questionnaires were completed a median of 211 days after admission and a