GYNECOLOGY

A self-assessment efficacy tool for spermicide contraceptive users

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BACKGROUND: Easily accessible contraceptive methods, such as chemical and barrier methods, are used currently by approximately 1 in 6 women who use contraception in the United States. Even in the face of suboptimal effectiveness, coitally dependent methods likely will always have a role in fertility management. Because most contraceptive efficacy stratifications use population-based data, for women to make informed decisions about the individual fit of a contraceptive method, better evidence-based, user-friendly tools are needed.

OBJECTIVES: Spermicides are a readily available, over-the counter, woman-controlled contraceptive method, but their effectiveness is user-dependent. Patient-decision aids for spermicides and other barrier methods are not well-developed, and overall failure rates could be improved by aids that account for individual characteristics. We sought to derive a prediction rule for successful use of spermicides for pregnancy prevention and to convert those data to a point-of-care instrument that women can use when they are considering spermicide use during contraceptive decision-making.

STUDY DESIGN: We pooled local data from 3 randomized clinical trials that were published in 2004, 2007, and 2010 that tested spermicide efficacy. We constructed a prediction rule for unintended pregnancy using bootstrap validation and developed a scoring system.

RESULTS: Data from 621 women showed a mean age of 29 years; 49% of the women were African American, and 43% were white. The overall pregnancy rate was 10.3% (95% confidence interval, 7.9—12.7) over 6 months. In adjusted logistic regression, age >35 years was protective against pregnancy (odds ratio, 0.19; 95% confidence interval, 0.06—0.58; $P = .003$), and multigravidity was associated with high failure rates (odds ratio, 7.24; 95% confidence interval, 3.04—17.3; $P < .001$). These risk factors (together with frequency of unprotected sex) were used in a model that maximized sensitivity for pregnancy prediction to compute the predicted probability of unintended pregnancy for each woman. This model was 97% accurate in predicting women who had a <5% pregnancy risk while using spermicides.

CONCLUSION: Using prospectively collected data, we built a simple risk calculator for contraceptive failure that women can consult when considering spermicide use. This instrument could support patient-centered contraceptive decision-making.

Key words: contraceptive efficacy, decision, spermicide, tool

Patient-centered health care and decision-making may improve adherence to medical therapy,[1] but family planning service provisions in the United States generally do not utilize patient-centered models. The persistently high unintended pregnancy rates in the United States may be due to systemic barriers that impede patient-friendly access.[2] With the exception of some barrier methods and some emergency contraceptive methods, women must interact with a health care provider to obtain contraception; unless she has good insurance coverage, contraceptives are expensive, and several steps are often required to obtain the method. Best practices for contraceptive counseling and decision-making have not been well-established. Data suggest, however, that women may prefer more autonomy when it comes to contraceptive use than other medical interventions[3] but that we have much to learn in this domain.[4]

The most effective long-acting reversible contraceptive (LARC) methods are emphasized increasingly by providers. LARC methods are very low maintenance over time and highly effective for all women, regardless of user characteristics. But some women are deterred by the need to have the method placed and removed by a provider.[5] For these and other reasons, easily accessible contraceptive methods, such as chemical and barrier methods, currently are used by approximately 17% of US women who use contraception[6] and likely will remain a mainstay of US contraceptive use. In theory, vaginal spermicides possess many positive attributes: they are woman-controlled, are inexpensive, are available directly to the consumer over-the-counter, possess a limited side-effect profile, and are safe.[7,8] The main limitation of spermicides is that they are not highly effective. Pregnancy rates in the first year of spermicide use are estimated at 10-20%, but in typical use may be even higher.[9] To contextualize this, highly effective methods such as the LARC class are associated with <1 of 100 pregnancies annually.[10] Even in the face of suboptimal effectiveness, woman-controlled coitally dependent methods likely will always have a role in fertility management. Because most contraceptive efficacy stratifications use population-based data, for women to make informed decisions about the individual fit of a contraceptive method, better evidence-based, user-friendly tools are needed.

Our aim was to use prospectively collected data to build a user-friendly scoring system to predict individualized contraceptive efficacy for women who

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TABLE 1
Comparison of baseline demographic and clinical characteristics for the trials in the combined data set

Variable	C31G[11] (n = 138)	BufferGel[12] (n = 300)	FHI Spermicide[7] (n = 183)
Mean age, y ± standard deviation[a]	29.8 ± 6.1	27.6 ± 5.3	28.9 ± 5.9
Race/ethnicity, n (%)			
African-American	78 (56.5)	153 (51.0)	78 (42.6)
White	50 (36.2)	125 (41.7)	93 (50.8)
Other	10 (7.2)	22 (7.3)	12 (6.6)
Marital status, n (%)			
Never married	99 (71.7)	243 (81.0)	127 (69.4)
Married or living with partner	32 (23.2)	54 (18.0)	39 (21.3)
Separated, divorced, widowed	7 (5.1)	3 (1.0)	17 (9.3)
Gravidity, n (%)			
0	46 (33.3)	114 (38.0)	74 (40.4)
1	31 (22.5)	69 (23.0)	39 (21.3)
2	24 (17.4)	45 (15.0)	25 (13.7)
≥3	37 (26.8)	72 (24.0)	45 (24.6)
Parity, n (%)			
0	76 (55.1)	171 (57.0)	108 (59.0)
1	30 (21.7)	63 (21.0)	30 (16.4)
2	14 (10.1)	37 (12.3)	21 (11.5)
≥3	18 (13.0)	29 (9.7)	24 (13.1)
Mean body mass index, kg/m^2 ± standard deviation[b]	26.8 ± 6.9	N/A	27.3 ± 6.3
Mean no. of contraceptive methods used at baseline, n ± standard deviation[b]	1.6 ± 0.8	1.0 ± 1.0	1.6 ± 0.9
Used barrier method at baseline, n ± standard deviation[b]	65 (47.1)	199 (66.3)	75 (41.0)
Pregnancy during study, n (%)	16 (11.6)	29 (9.7)	19 (10.4)

C31G, a spermicide and microbicide, not commercially available; *FHI*, Family Health International; *N/A*, not available.

[a] $P < .01$; [b] $P < .001$, reflects significant statistical difference between studies (Mann-Whitney *U*-test or chi-square test).

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use vaginal spermicides. To accomplish this goal, we pooled data from clinical trials to yield estimates of a woman's risk of pregnancy while using spermicides. We included both pregnancies that were characterized as user-failures and those that were characterized as method-failures to increase the generalizability of our results.

Material and Methods

The data came from 3 recent multicenter randomized controlled trials; the methods and primary results of all the trials have been published elsewhere.[7,11,12] Briefly, 2 studies compared the efficacy, safety, and acceptability of the spermicide under study with an active placebo,[11,12] and 1 study compared 5 different doses/delivery systems of Nonoxynol-9.[7] Women who were recruited for each study met the following inclusion criteria: they were healthy, sexually active, 18-42 years of age, had no history of infertility, no sexually transmitted disease diagnosis in previous 6 months, had normal length menstrual cycles (defined as 24-35 days in 2 studies and 21-35 days in the third study), and had vaginal intercourse with regularity. The median coital act frequency was 2.3−3 times per week. Women in the trials were observed for at least 6 months or until a pregnancy occurred.

From these 3 clinical trials, we extracted the local data that were collected prospectively at the University of Pennsylvania Center for Clinical Research in Women's Health, created a new database, and analyzed these data to elucidate risk factors for pregnancy during these trials. This study was exempt from institutional review board approval, because it was a secondary data analysis of deidentified data. The overall failure rates for the 3 studies were similar (Table 1), which enabled us to pool the data. Testing for stratification by trial indicated that the studies were sufficiently homogenous to be combined.

Each clinical trial collected detailed data on menstrual cycles, intercourse timing, and contraceptive methods that had been used (or not used) during each act of intercourse. Two trials reported that 97% of coital acts used spermicide alone[7,11]; in the third trial, all the women used spermicide in conjunction with a diaphragm.[12] Pregnancies were each carefully dated by the Principal Investigator of each clinical trial who used information about last menstrual period, intercourse timing, and early pregnancy ultrasound scanning.

We characterized incident pregnancies by variables that are potential risk factors for pregnancy such as age, race, gravidity/parity, and previous contraceptive use. Because the overall pregnancy rate was 10.3%, odds ratios were used to approximate incidence rate ratios for dichotomous risk factors, and Mann Whitney *U* tests were used to compare pregnant cases and control cases, with respect to continuous variables. We used statistical software (STATA; Stata Corporation, College Station, TX) to perform descriptive analyses; logistic regression was used to construct the optimal predictive model for incident pregnancy, with emphasis given to high sensitivity. The final model