Updated pregnancy rates for the Today contraceptive sponge

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Pregnancy rates (method and user) were evaluated for 2245 women who participated in the phase III clinical trials of the Today contraceptive sponge. User and method pregnancy rates were similar for women of different ages and parities. The 1-year method and user pregnancy rates (life table per 100 women) were 8.2 and 5.6, respectively. (Am J Obstet Gynecol 1987;157:1164-5.)

Key words: Contraceptive sponge, pregnancy rates, parity

The Today contraceptive sponge (VLI Corporation, Irvine, California) first became available to consumers in the United States in 1983. Since that time it has been approved for use and is being sold in a number of other countries including Korea, Sweden, Switzerland, and the United Kingdom. Phase III clinical trials of the Today sponge were started in 1979, and since that time data on 2245 women have been accumulated. Pregnancy data from studies conducted in the United States, the United Kingdom, and Yugoslavia have been published previously and account for only about 55% of the women included in the trials. This communication presents pregnancy rate data from the worldwide clinical trials of the contraceptive sponge and includes data from previously published studies. Since the effectiveness of vaginal contraceptives depends on whether they are correctly and consistently used, pregnancy rates were evaluated according to whether they were a result of failure of the user to use the sponge as directed (user failure) or because the method failed even though the sponge was correctly used (method failure).

Methods and material
The Today sponge is made of proprietary polyurethane and contains 1 gm of the spermicide nonoxynol 9, as well as small amounts of preservatives (citric, sorbic, and benzoic acids) that help to maintain its pH at about 4 to 5. The sponge is 2.5 cm thick and has a diameter of 5.5 cm. About 125 mg of nonoxynol 9 is eluted from the sponge during a 24-hour use period. The sponge is inserted into the vagina at any time up to 24 hours before intercourse. Repeated intercourse may occur with the sponge in place. The sponge is left in place for at least 6 hours after intercourse. The maximum recommended use time is 24 hours. Use of the sponge during menstruation is not recommended.

Pregnancy rates are based on data gathered on 2245 women from 26 clinics (Bangladesh, two; Canada, one; Israel, one; Sweden, one; Switzerland, four; Taiwan, one; United Kingdom, one; United States, 13; Yugoslavia, two). No follow-up data or incomplete records were obtained for 9.0% of the subjects. All pregnancies were classified as either user or method failures on the basis of information in the case report forms and coital logs (completed by only a subset of subjects) and from comments provided by the women and their physicians. Insufficient information was provided to classify 13 (6.7%) of the 172 pregnancies (103 method, 69 user) occurring during the 12-month follow-up period. These pregnancies were classified arbitrarily and conservatively as method failures. Pregnancy rates were computed by use of life-table methods that provide estimates of the risk of pregnancy as a function of time. Pregnancy rates were compared by means of the log rank test statistic. All of the analyses are based on the pooled data from the clinics since there were too few subjects for evaluation in all but a few clinics.

Table I. Cumulative 12-month life-table method and user pregnancy rates (per 100 women)

<table>
<thead>
<tr>
<th>Age (yr)</th>
<th>No. of women</th>
<th>Method (mean ± SEM)</th>
<th>User (mean ± SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;19</td>
<td>133</td>
<td>2.5 ± 1.4</td>
<td>4.5 ± 3.7</td>
</tr>
<tr>
<td>19-26</td>
<td>941</td>
<td>9.0 ± 1.3</td>
<td>6.2 ± 1.1</td>
</tr>
<tr>
<td>27-40</td>
<td>933</td>
<td>7.2 ± 1.1</td>
<td>5.0 ± 0.9</td>
</tr>
<tr>
<td>&gt;40</td>
<td>35</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

*Women not followed up were excluded from the table.
†Too few women for calculation of reliable life-table rate.
Results

The overall, cumulative 12-month pregnancy rate was 15.3 per 100 women (method, 8.2; user, 5.6). User and method pregnancy rates are given in Table I. Neither method nor user pregnancy rates depended on parity (nulliparous versus parous) or age of the women (p > 0.10). The same holds true for the combined pregnancy rate. At seven of the 13 clinics in the United States, 88 women volunteered to participate in the studies for a second year. The overall, cumulative pregnancy rate for these women during their second year of use was 3.4 per 100 women.

The lost-to-follow-up rates varied from clinic to clinic. However, there was no relationship between the pregnancy rates (user, method, overall) and lost-to-follow-up rates (p > 0.10). The cumulative 12-month pregnancy rates (user, method, overall) were not similar across clinics (p < 0.05).

Pregnancy rates (user, method, overall) based on the data from clinics that had women complete coital logs were similar (p > 0.10) for women who completed the coital logs and for those who did not. The principal use of these logs was to evaluate patterns of sponge use and provided no useful data for the analyses of pregnancy rates.

Comment

The presentation of method pregnancy rates is important so that women may assess their risk of pregnancy if they use the sponge consistently and correctly according to the user directions. Overall pregnancy rates do not provide this information.

The data presented in this paper include the results of previously published studies from the United States, the United Kingdom, and Yugoslavia. The data from the study of 721 subjects conducted in the United States at 13 clinics showed that the cumulative 12-month overall pregnancy rate was related to parity but not age. The report did not provide data on method or user pregnancy rates or on the pregnancy rates reported at the individual clinics. The study conducted in the United Kingdom gave higher overall pregnancy rates than did the study in the United States but no significant differences in the overall pregnancy rates for parous and nulliparous sponge users were reported. No data on either method or user pregnancy rates were reported. The study included only 126 sponge users. The Yugoslavian study included 403 subjects from two clinics and reported no significant differences between the cumulative 12-month method pregnancy rates of parous and nulliparous sponge users. No data were provided on user pregnancy rates.

If the 13 pregnancies for which there was insufficient information to classify as either method or user failures had been apportioned between method and user failures, lower method and higher user pregnancy rates would have been obtained. Failure to adequately wet the sponge before insertion may be one factor responsible for some of the method failures. When the phase III trials were initiated in 1979, the importance of adequately wetting the sponge to activate the release of spermicide was not fully appreciated. As experience was gained with use of the sponge more emphasis has been placed on adequate wetting before its insertion. This seems to have had a positive effect on the incidence of reported pregnancy.

The continued evaluation of pregnancy rates associated with use of the Today contraceptive sponge shows that it provides women with an adequate level of protection against pregnancy regardless of their age or parity.

REFERENCES