A STUDY OF THE VAGINAL CONTRACEPTIVE SPONGE USED WITH AND WITHOUT THE FERTILITY AWARENESS METHOD

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ABSTRACT

The actual effectiveness rates of natural and barrier methods of family planning are lower than the theoretical ones. If couples accurately defined the limits of the fertile phase and used barriers at that time, then actual effectiveness might increase. A randomized, controlled clinical trial was initiated to determine the effectiveness of the contraceptive sponge used only during the fertile time and to compare this with sponge use at every intercourse. Recruitment problems and discontinuation forced the early termination of this study, but qualitative information about compliance and acceptability was collected. Common sponge problems were reported as were misuses of the sponge, but problems and misuse were not related. Determination of the fertile phase was reportedly easy, but complaints of and discontinuation for inconvenience occurred. For unplanned pregnancies, contraceptive behaviors around the time of conception are presented.

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INTRODUCTION

The actual effectiveness rates of all temporary contraceptives are generally not as great as their theoretical rates would predict.[1] For barrier methods, the difference is presumably due to either the failure to use the method according to instruction or the failure to use them at every intercourse. In actual practice, barrier users frequently risk unprotected intercourse. Possibly such users think they are in an infertile time of the menstrual cycle or desire more spontaneous relations. The effectiveness of barrier methods might be enhanced if their use was vigilant yet restricted to the fertile days. This would enable the user to have days of contraception-free intercourse during the infertile phases of the menstrual cycle.

The theoretical or method effectiveness rates of natural methods of family planning (NFP) are among the highest for non-permanent methods, but the actual effectiveness rates are among the lowest.[1,2] NFP consists of interpreting one or more of the woman's natural signs of fertility (changes in cervical mucus, basal body temperature or a combination of these with cervical and other changes) to determine the beginning and the end of the fertile time. NFP requires abstinence during the fertile phase of the cycle, and actual effectiveness of NFP is generally low because couples do not always abstain for the entire fertile phase. For couples who find periodic abstinence to be inappropriate for them, barrier use during the fertile phase could represent a viable contraceptive option. This combination of methods can be considered a fertility awareness based method (FAM). While the option of mixing FAM with barriers is intriguing, it has not been studied clinically before.

This article discusses qualitative observations made in the course of a randomized, controlled clinical trial that was intended to compare the effectiveness of the TODAY vaginal contraceptive sponge used only during the fertile phase (as defined by two FAM rules), with the effectiveness of the sponge used in the conventional manner (used at every intercourse throughout the cycle.) The study itself was unable to recruit enough subjects for valid tests of the difference in effectiveness. Nevertheless, qualitative information has been gathered about compliance, acceptability and contraceptive behavior around the time of conception which, we feel, merits presentation.

METHODOLOGY

The specific FAM for determining the fertile phase that was taught in this study involved the use of two principles: (1) the "21-day rule" from the calendar rhythm method for

determining the end of the preovulatory infertile phase and the onset of the fertile phase, and (2) the "thermal shift rule" for determining the end of the fertile phase and the onset of the postovulatory infertile phase.*

It has not been established that interpretation of cervical mucus is reliable while using the vaginal contraceptive sponge. In theory, mucus could be either confused with the spermicide of the sponge or absorbed by the sponge itself. Therefore, mucus symptoms were not evaluated in this study. Condoms presumably would not interfere with the mucus symptom, but there was concern that partner compliance could not be assured. Thus the TODAY sponge was chosen because of its convenience and presumed appeal to potential study participants.

Participants were sought among clients at several family planning clinics in the Los Angeles area and through a limited multi-media campaign in the vicinity. Generally healthy, sexually active women aged 18 to 40 with a history of regular menstrual cycles of 24 to 42 days were eligible for the study if they had had at least one complete cycle within this range since the end of the last pregnancy; did not take hormonal contraception within the past three months; had a normal pelvic examination and PAP smear, and a negative urinary pregnancy test. Volunteers were asked to remain in follow-up using their assigned method for a full 12 months.

Those women randomly assigned to the sponge-only group were initially given 30 sponges, 12 monthly menstrual/coital diaries and oral and written instructions for use of the sponge. Pre-addressed envelopes were provided for the monthly diaries to be mailed back to the clinic. Return visits to the clinic occurred as needed to receive additional sponges.

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* Use of the "21-day rule" required knowledge of the length of the previous six cycles. Substracting 21 from the length of the shortest of the six cycles results in the number of the cycle day that begins the fertile phase. In the FAM group, the sponge was not used until this day. The thermal shift was defined as the time when basal body temperature (BBT) rose at least 0.2°F above the highest of the previous six low normal preovulatory temperatures. Once this rise occurred, a coverline was drawn 0.1°F above the highest of these six temperatures. After three consecutive temperatures were recorded above the coverline, the fertile phase was considered to be ended, and sponge use discontinued for women in the FAM group.

Those assigned to the FAM group were given 15 sponges; a BBT thermometer; a FAM diary for recording menses, intercourse and BBT; written and oral instructions for use of the sponge; and an appointment to return within two weeks for FAM instruction. FAM users also returned to the clinic at the end of the first cycle and for a maximum of three follow-up visits to ensure proper understanding of the FAM rules.

All volunteers were instructed not to leave the sponge in the vagina for more than 24 hours nor to use the sponge during menses. If so desired, intercourse without the sponge was advised for women in both study groups for the first four days of the cycle if the previous cycle appeared normal. Abstinence was advised for any remaining days of menses. After the end of menses the usual study group conditions applied regarding the use of the sponge.

Monthly diaries were reviewed throughout the study for women in both groups. Follow-up about experiences with the study methods occurred at approximately 6 and 12 months after admission to the study (or at termination from the study if it occurred at some other time). For women who gave more than one interview, only the most recent one was selected for this report since it reflected the maximum experience with the study method.

RESULTS

Fifty-three women were admitted into the study between October 1984 and November 1985 and randomly assigned to the two method groups. It was subsequently determined that one woman in each group was pregnant at the time of admission, leaving 24 women in the sponge-only group and 27 in the FAM group. This paper presents observations on these 51 women.

Despite twice extending the recruitment period, only one-quarter of the expected number of volunteers were enrolled. The obstacles to recruitment are discussed later in this paper. Since the drop-out rate was high, recruitment was ended and all women followed-up as long as possible, for up to 12 months. Due to the small numbers, it is not possible to compare the contraceptive effectiveness between the groups. The remainder of the results are therefore given in descriptive terms.

Volunteer Characteristics

There were no differences between the two groups across the general socioeconomic and obstetric parameters (Table I). The majority were white, college graduates, employed full-time and not Catholic. There was a full range of

Table I: Selected Characteristics of the Volunteers - Numbers

	Sponge-Only	FAM	Total
Mean age (years):	28.2	29.6	
Race:			
Caucasian	19	22	41
other	5	5	10
Education:			
≤ high school	7	3	10
some college	6	8	14
≥ college degree	11	16	27
Employment:			
unemployed	3	4	7
part-time	7	7	14
full-time	14	16	30
Monthly income(dollars):			
<400	7	4	11
400-750	5	5	10
750-1500	7	7	14
>1500	11	5	16
Religion:			
none	9	10	19
Catholic	3	3	6
other	12	14	26
Marital status:			
never married	15	11	26
married/POSSLQ*	6	10	16
separated/divorced	3	6	9
Number of livebirths:			
0	21	21	42
1	3	4	7
2	0	1	1
3	0	1	1
Number of abortions:			
0	8	12	20
1	7	9	16
2	6	4	10
3	1	1	2
4	2	1	3

*Persons of opposite sex sharing living quarters.

incomes represented in each group. About half were ever-married and half were single and not living with their partners.

Most women had never had a livebirth. Most had experienced at least one induced abortion, hence the last pregnancy was terminated for the majority. Most women had previous experience with oral contraceptive pills (N=45), the sponge (N=33), and the diaphragm (N=28). About a third of the women had ever used NFP or a FAM. A FAM pretest was given upon admission to the study in which more than three-quarters of the volunteers answered most of the questions correctly. Immediately prior to the study, most women were using the sponge, diaphragm, condoms or withdrawal for family planning. The only difference between the groups is that more in the sponge-only group (7 vs. 1) were using withdrawal upon entering the study.

Reason for Termination from the Study

About one-quarter of the volunteers completed 12 months of follow-up in the study. The main reason for terminating the study involved a problem or dissatisfaction with the assigned study method (Table II). Women in the FAM group who terminated the study because of problems with the method had reported complaints with FAM, with the sponge or with both (Table III). Problems with FAM in women who discontinued included: difficulty or inconvenience with BBT (N=7) and the fear that FAM is ineffective (N=2). Sponge problems included: vaginal infection, irritation, dryness and/or odor attributed by the women to the sponge; difficulty in removal; penile irritation or dislike of the sponge by the partner; and fear of side effects and/or ineffectiveness. (More than one complaint was sometimes offered).

Description of the Pregnancies

Six volunteers experienced unintended pregnancies in this study--two volunteers in the sponge-only group and four in the FAM group. Careful examination of the available coital logs, FAM charts and interviews with the women have permitted the classification of the pregnancies as either probable user failures or probable sponge failures. Three pregnancies fell into each category.

In the sponge-only group, a probable sponge failure occurred in a woman who used the sponge as directed, leaving the sponge in place for a maximum of 10 hours after intercourse, and who often (12 to 20 times) used the sponge for multiple episodes of intercourse during the six months before the conception. A probable user failure occurred in

Table II: Reason for Termination from the Study

	Sponge-Only	FAM	Total
No longer eligible:			
not sexually active	3	2	5
menstrual abnormalities	2	2	4
Moved	0	1	1
Lost to follow-up	3	1	4
Pregnant	2	4	6
Problem with assigned method*	8	11	19
Completed 12-month follow-up	6	6	12
TOTAL	24	27	51

* In some cases, other reasons in addition to complaints about the assigned method were given, eg., two women disliked their assigned method but also wished to use oral contraceptives or condoms. It is not known whether preference for another method or dislike of the study method was more important, but a problem with the study method was at least partially implicated in discontinuation.

Table III: Volunteers in Whom Problem with the Assigned Method was the Reason for Discontinuation

Problem	Study Group		
	Sponge-Only	FAM	Total
Problem with sponge only	8	2	10
Problem with FAM only	NA	3	3
Problem with both	NA	6	6
TOTAL*	8	11	19

*Volunteers who terminated the study for other reasons also had problems with the sponge and/or FAM. They are not included here.

Table IV: Problems and Practices Regarding Sponge Use in the Past Six Months

	Yes	No	Total*
Problems with sponge in last six months:			
vaginal infection	13	24	37
tearing of the sponge	9	28	37
odor from the sponge	13	24	37
irritation from the sponge	12	25	37
trouble removing the sponge	18	19	37
needed assistance to remove sponge	6	31	37
Practices regarding sponge in last six months:			
used sponge for more than one intercourse	23	14	37
left sponge in vagina for more than 24 hours	7	30	37
used sponge during menses	8	29	37

* All women who answered these questions at follow-up.

a volunteer who left the sponge in place not more than 16 hours, used the sponge for multiple intercourse "several times", but who put the sponge in place after having sexual relations.

In the FAM group, probable user failures occurred in two women who reported that they did not use the sponge for multiple coital episodes. Both had unprotected intercourse during the fertile phase. One probable sponge failure occurred in a woman who followed the 21-day rule, did not use the sponge during menses, and did use the sponge at the time of probable conception for multiple acts of intercourse. She reported a history of removing the sponge after intercourse no more than 10 hours later and often (8 to 10 times) used the sponge for multiple intercourse. The other probable sponge failure occurred in a woman whose record did not indicate multiple intercourse around conception, but she could not remember how long she had left the sponge in place. She had a history,during the study,of sponge use during menses and twice reported leaving the sponge in place for two days. Although she may not have always used the sponge as directed, she appeared to have used the sponge correctly around the time of conception.

Use of the Sponge as Reported at Follow-Up

Thirty-seven of the 51 women answered questions at follow-up about whether they had experienced specific problems with the sponge, or if they had engaged in specific recommended and discouraged uses of the sponge in the past six months (Table IV). Eighteen of the 37 respondents reported difficulty removing the sponge, six of whom needed the help of another person to remove it. Vaginal infection, odor and irritation from the sponge were each reported by about one-third of the respondents. Over three-quarters (29/37) reported at least one problem with the sponge with a mean of 1.9 out of six possible problems per respondent.

Close to two-thirds of the respondents reported using one sponge for more than one episode of intercourse. This practice was endorsed by the manufacturer and the research protocol and staff. One-third (13/37) of the women reported at least one contraindicated sponge use behavior. Seven of the 37 women reported leaving the sponge in place for more than 24 hours and eight used the sponge during menses. There was no difference in the number or type of sponge problem(s) reported according to whether the sponge was reportedly misused. There was also little clustering of reported sponge problems, except that those who reported tearing more often reported odor. The presence/absence of sponge problems was not related to the ever-use of the sponge or spermicides or

with the frequency of sexual relations. Women who had ever-used the diaphragm, however, were more likely to report sponge problems than never-users.

Attitudes about FAM

Follow-up interview questions about FAM were asked only of those volunteers in the FAM group. Twelve of 19 respondents said that they liked using FAM with the sponge. When asked on a five-point scale whether some particular aspects of FAM were easy or difficult, 14 of 18 said it was easy to tell the beginning of the fertile phase by using the 21-day rule; and 15 of 18 said it was easy to tell the beginning of the postovulatory infertile phase by using the thermal shift rule.

DISCUSSION

The idea of using a barrier method only during the fertile phase seems intuitively reasonable, and is assumed to be commonly practiced (e.g. as reported in the Philippines[4] and Sri Lanka), so it was both surprising and disappointing that it was not possible to recruit enough volunteers to report effectiveness. However, the study does provide detailed insights from a small number of users. The remainder of this discussion is not intended to argue for or against the use of the sponge, FAM or the combination, but rather to present a summary of contraceptive behaviors that were observed.

Obstacles to Recruitment

To recruit users of an over-the-counter method was found to be difficult. Recruitment was initially thought to be easiest in the Los Angeles area where family planning clinics already offered fertility awareness orientation as a routine part of clinical practice, and where barriers and spermicides are popular. However, several extraordinary circumstances surrounding the implementation of this study may have caused the poor recruitment outcome. Recruitment began at precisely the time that the clinics saw a dramatic decrease in appointments, presumably due to the end of the spring semester at the universities and the beginning of the 1984 Olympic Games in Los Angeles. Reports of toxic shock syndrome possibly associated with the sponge were currently in the popular media, and this may also have dampened willingness to try the sponge.

Four months into the original six-month recruiting period, 52 consecutive women were interviewed at two separate clinic sessions to better understand why they were not interested in

participating in the study. It was learned that approximately 60% had heard about or personally experienced vaginal irritation, dryness, itching, infection, difficulty removing the sponge or pregnancy attributed to the sponge. The other 40% were satisfied users of other methods of family planning or were not sexually active. It is also presumed that some satisfied users of the sponge did not volunteer for the study to avoid being randomly allocated to the FAM group and vice-versa. Although the clinics dispensed sponges along with other barrier methods, the sponge is also widely available in drug stores and supermarkets without medical prescription, and satisfied sponge users may simply not appear at a clinic. Strict clinical protocols were found to be difficult to apply to these do-it-yourself methods.

Over 125 women who volunteered did not meet the eligibility criteria, mainly because they either had not experienced a normal menstrual cycle since the end of the last pregnancy, had irregular cycles (often coming off oral contraceptive pills), or had a class II PAP smear. Multi-media advertising efforts resulted in 230 telephone inquiries, but most callers were not eligible or would not accept random allocation.

Multiple Acts of Intercourse

According to both the sponge package insert and the instructions given to the study subjcts, one vaginal contraceptive sponge may be used for multiple acts of intercourse as long as the sponge is not removed from the vagina until at least six hours after the last intercourse. Among the 37 volunteers who answered follow-up questions about sponge use, 23 reported using the sponge for multiple episodes of intercourse, and among these 23, four became pregnant during the study. Among the 14 who did not report multiple use, two became pregnant but both reported unprotected intercourse at mid-cycle. In one case of probable sponge failure, multiple use had occurred around the time of conception. In a second pregnancy, multiple use was possible, and in the third case the woman could not remember, the latter case being the most dubious sponge failure.

Sponge Problems and Misuse

Many of the same problems with the sponge reported by others have been found in this study.[5-9] Consistent with these studies, difficult removal of the sponge was the most frequent complaint. Fewer persons discontinued this study because of problems (16/51) than actually reported problems (29/51). The variety of complaints offered --from vaginal dryness to penile irritation to lack of confidence in the method--also confirm other reports and suggest that it is difficult to determine what kind of users will be most likely

to discontinue. The reporting of a sponge problem could only be associated with prior diaphragm use.

Opinions about FAM

Nine of the 27 FAM users in this study had serious problems with FAM, having discontinued the study--at least in part--due to lack of faith in the method or the "inconvenience" of using it. On the other hand, at least 12 of the 27 liked using it and found FAM use to be "easy".

FAM and NFP program managers often face disappointing continuation rates and could benefit from better ways of predicting which clients are likely to be compatible with family planning methods that involve (1) detection of the fertile phase and (2) unprotected intercourse during parts of the cycle. This study suggests that screening tools should be developed and evaluated to determine how important "convenience" is to the client and the extent to which the couple feels comfortable in adhering to the rules for extra protection (or abstinence) as well as in having unprotected relations.

One of the main concerns of promoters of NFP and FAM has been the ease of use of the methods. This study suggests that a natural method may be considered "easy" but still "inconvenient". This study was conducted in a major U.S. metropolitan area where the pace of life is quick, and more "convenient" methods of modern family planning are readily available. Apparently the motivations for using FAM must somehow outweigh the value of the time needed to attend to measuring the signs of fertility--or at least the perception that the attention devoted to the method takes a great deal of time and constitutes an inconvenience.

CONCLUSION

In this study, volunteers kept logs of their coital activity, menses, and sponge and FAM use. Thus contraceptive use around the time of unintended pregnancy was described. Common sponge use problems were reported as well as misuse of the sponge, despite both written and oral instruction. Reported problems with the sponge were apparently not related to misuse. The variety of sponge complaints makes predicting user satisfaction difficult.

Problems with FAM were overwhelmingly related to the inconvenience of using BBT. Since FAM was found to be "easy" yet "inconvenient", screening for the importance of convenience may be of use to NFP and FAM program managers.

This study could be replicated using another barrier method, and a non-clinical recruitment base. The AIDS epidemic has increased the general acceptability of condoms, so the time may be more appropriate for a successful study using condoms. Alternatively, a study could be conducted in a setting where many family planning users are already trying to combine periodic abstinence and barrier methods, such as in Sri Lanka and Japan.

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