

PM-000-520/62
197-31686

Reprinted from *Advances in Planned Parenthood*, Vol. XIV, No. 4 ©Excerpta Medica, 1980

Barrier contraception—An update

DAVID A. EDELMAN, PH.D.

International Fertility Research Program, Research Triangle Park, North Carolina

1

Barrier contraception—An update

DAVID A. EDELMAN, PH.D.

International Fertility Research Program, Research Triangle Park, North Carolina

Abstract

Data on the efficacy of spermicidal foaming tablets and suppositories available in the United States are reviewed, and data on two experimental products, Neo-Sampoon foaming tablets and the Collatex sponge, are presented. Failure rates of these two methods compare favorably with that of the diaphragm. Additional data on the efficacy of most barrier contraceptives are required for providers and consumers to make informed decisions.

Introduction

During the past decade, increasing attention has been given to the adverse reactions of oral contraceptives (OCs) and intrauterine devices (IUDs), the two contraceptive methods that are used by about 80% or more of those using contraception. Both the scientific and lay presses have reported the occurrence of serious adverse side effects associated with their use, including myocardial infarction, thromboembolic disease, liver adenomas, pelvic inflammatory disease, ectopic pregnancy, and impaired fertility after discontinuing use of these methods.

Concurrent with the increased awareness of serious complications associated with the use of OCs and IUDs, there has been an increase in the number of users of barrier contraceptive methods (primarily condoms and diaphragms). Research efforts have focused on the development of improved barrier contraceptive methods with the intent of providing effective, safe, convenient, and acceptable products. Barrier contraceptive methods in use today include condoms, diaphragms, cervical caps and spermicidal creams, jellies, foams, foaming tablets, and melting suppositories. Both the cervical cap and diaphragm must be fitted by trained medical personnel. The other barrier products, however, can be obtained without prescription or any medical supervision. For this reason, it is important that adequate data on the effectiveness and safety of these products be available to the

consumer. It is also important that physicians and other providers of contraceptive services have access to such data in order to help women make an informed choice of preferred contraceptive method.

This paper examines available data relating to the efficacy of spermicidal foaming tablets and suppositories available in the United States. Data on two other barrier contraceptive products are also presented: Neo-Sampoon[®] loop tablets (Eisai Company, Tokyo, Japan) and the Collatex[®] sponge (Vorhauer Laboratories, Costa Mesa, California).

Efficacy data for spermicidal foaming tablets and suppositories

The only spermicidal foaming tablets or suppositories commercially available in the United States today are Encare Oval[®] (Eaton-Merz Laboratories, Norwich, New York), Semicid[®] (Whitehall Laboratories, New York), and S⁺positive[®] (Jordan-Simmer, Inc., Fort Lauderdale, Florida). Each consists of a relatively inert base material that may physically block the passage of sperm and that also acts as a carrier for the spermicide nonoxynol-9. Efficacy data¹⁻⁵ on these barrier contraceptives (Table 1) indicate that the products have high rates of efficacy; however, additional data are required since each of the studies is limited by one or more of the following:

1. Insufficient information on the conduct

TABLE I
Efficacy data on Encare Oval, Semicid, and S'positive.

Brand	Number of cases	Woman-months of use	Failure rate (pregnancies/100 woman-years of use)	Source
Encare Oval (Patentex Oval)	10,017	63,759	0.8	Brehm and Haase ¹
	1,652	34,506	0.3	Salomon and Haase ²
	200	2,970	2.0	Hubes ³
Semicid	326	NS*	0.3†	Jordan Simner Inc. ⁴
S'positive	200	2,682	0	Squire et al. ⁵

*NS - not stated.

†24-month cumulative life-table rate per 100 women.

of the study to assess the method(s) of subject selection, follow-up procedures and instructions given to the subjects;

2. Too few subjects for an adequate evaluation;

3. Absence of information on whether all pregnancies are included or only "method" failures are included;

4. Inadequate and/or inappropriate procedures for the selection and follow-up of subjects; or

5. The study was not specifically designed to assess safety or efficacy of the product.

None of the studies presented in Table I gives sufficient data on the frequency of allergic reactions of either women or men or the frequency of vaginal inflammations following use of these products. Such reactions have been reported by users of these and other spermicidal products.

Based on a comparative study, supported by the National Institutes of Health, of Encare and the diaphragm with spermicide, reliable data on the efficacy of Encare Oval should become available within the next two years. The study of Squire et al.⁵ on the efficacy of Semicid is not a representative study since it included "affluent, well-educated, and highly motivated" women. The single study of S'positive was a double-blind study in which S'positive and an identical placebo were randomly assigned to women. In the placebo group there were 123 pregnancies.

Neo-Sampon (Eisai Company, Tokyo, Japan), a spermicidal foaming tablet incorporating the spermicide menfegol, is available commercially and through family planning programs in many countries in Asia and Latin America. Pregnancy rates of less than five per 100 woman-years and low

rates of vaginal irritation have been reported.^{6,7}

Small-scale multiclinic studies of Neo-Sampon are being conducted by the International Fertility Research Program (IFRP) in Bangladesh, Colombia, Egypt, and Mexico. To date, 418 women have been enrolled in these studies. The six-month cumulative pregnancy rate (life-table) was 4.9 ± 2.0 per 100 women (Figure 1) or (Pearl Index) 7.6 pregnancies per 100 woman-years. The six-month cumulative discontinuation rate (life-table) was 18.2 ± 3.5 per 100 women (Figure 2).

Another barrier contraceptive currently being evaluated in multiclinic trials in Bangladesh, Colombia, Egypt, Mexico, and Yugoslavia is the Collatex sponge (Figure 3). This is made of polyurethane and incorporates the spermicide nonoxynol-9. Data from studies of 326 Collatex users give a six-month pregnancy rate (life-table) of 3.6 ± 1.6 per 100 women (Figure 1) or (Pearl Index) 8.1 pregnancies per 100 woman-years. The six-month cumulative discontinuation rate (life-table) was 11.7 ± 3.4 per 100 women (Figure 2).

To date, only two of the trials of Neo-Sampon and the Collatex sponge have been completed. In the one completed study of 150 Neo-Sampon users in Bangladesh, the six-month pregnancy rate (gross life-table) was 3.4 per 100 women. Twenty women discontinued use of Neo-Sampon for reasons that included unplanned pregnancy (5), a burning sensation (14), and inconvenience (1). In the one completed study of 100 Collatex sponge users in Yugoslavia, the six-month pregnancy rate (gross life-table) was 1.1 per 100 women. Fourteen women discontinued use of the sponge

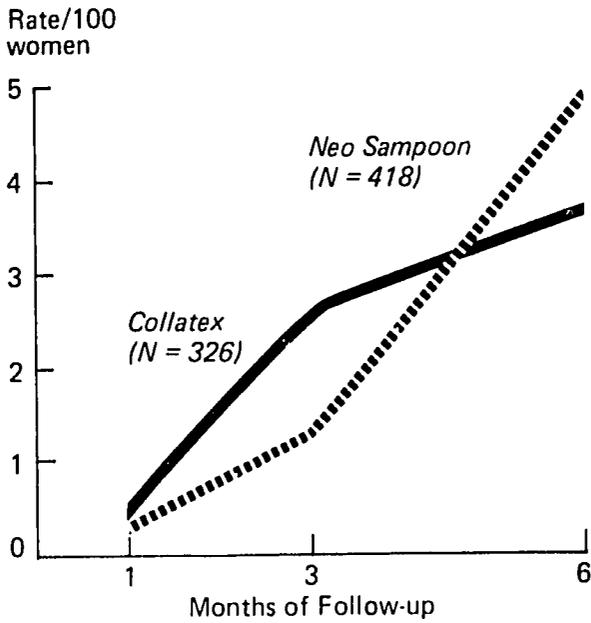


Figure 1. Six-month gross cumulative pregnancy rate for Neo-Sampoon and Collatex.

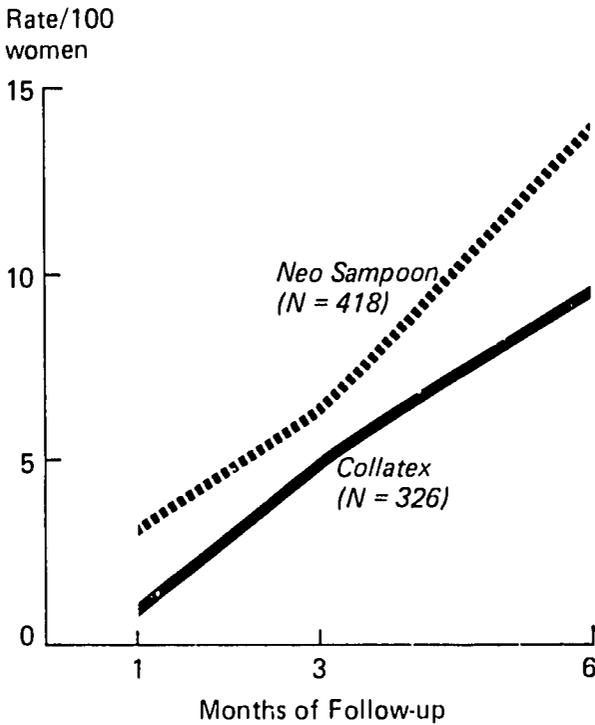


Figure 2. Six-month gross cumulative discontinuation rate for Neo-Sampoon and Collatex.

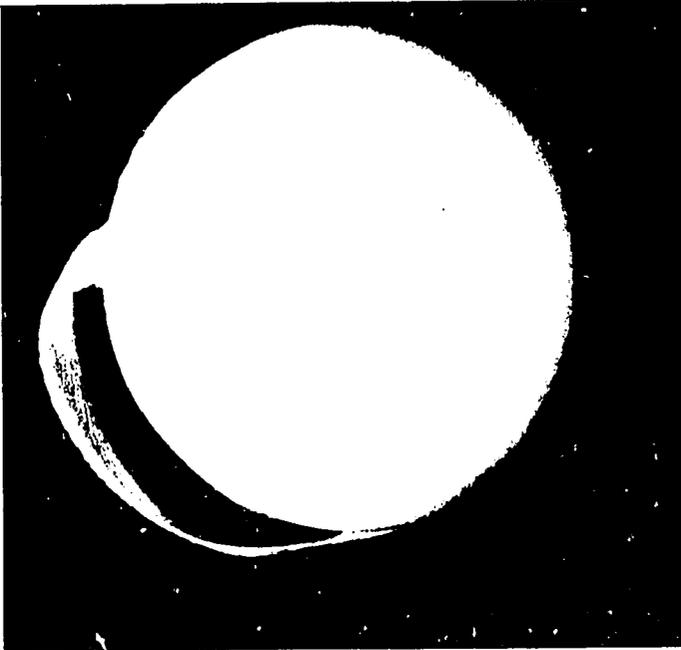


Figure 3. *The Collatex sponge.*

for reasons that included unplanned pregnancy (1), intercourse discomfort (11), vaginal infection (1), and lack of need because no longer sexually active (1).

Comment

Although there has been a resurgence in the use of barrier contraceptives during the past few years, the available data (except on condoms and diaphragms) are inadequate to judge their effectiveness in preventing pregnancy. A number of factors influence the effectiveness of barrier contraceptives, including failure of the user to use the method correctly and consistently and failure of the method to provide protection against pregnancy, even if correctly and consistently used. One added dimension influencing the effectiveness of spermicidal foaming tablets and suppositories is the time from insertion of the product into the vagina to the time the suppository has melted or foamed. This time varies among different barrier products.⁸ There are also considerable variations in the melting or foaming times among women using the

same product. Moreover, while the effectiveness of melting or foaming suppositories is necessarily dependent on the spermicide incorporated, it will also depend on the chemical content of the base material and the dispersion of the product in the vagina.

The efficacy of Neo-Sampoon and the Collatex sponge, based on the results of studies being conducted through the International Fertility Research Program (IFRP), compares favorably with the efficacy of the diaphragm. Wortman,⁹ in a review of the diaphragm and other intra-vaginal barrier contraceptives, quoted diaphragm failure rates ranging from 2.4 to 19.7 pregnancies per 100 woman-years (median failure rate, 10.6). The study with a failure rate of 2.4 included only married women, aged 25 or more years, who had successfully used the diaphragm for five or more months. In the IFRP studies, the failure rates were 7.6 and 8.1 pregnancies per 100 women-years for Neo-Sampoon and the Collatex sponge. Expanded trials of these and other barrier contraceptive methods will be required to provide reliable data on their associated failure rates.

References

1. Brehm, H. and Haase, W.: The alternative to hormonal contraception? Importance and reliability of foam ovoid for vaginal contraception. *Med. Welt* 26:1610, 1975
2. Salomon, W. and Haase, W.: Intravaginal contraception. Results of a prospective long-term study of the foam ovoid. *Sexualmedizin* 6:198, 1977
3. Hubes, A.: Problems of contraception in the teen-age girl. In: *Contraception: Practice of gynecology in Children and Teenagers*. Editors: A. Huberland and H.D. Hiersche. In press
4. Jordan Simner Inc., Miami, Florida. Unpublished data
5. Squire, J.J., Berger, G.S., and Keith, L.: A retrospective clinical study of a vaginal contraceptive suppository. *J. Reprod. Med.* 22:319, 1979
6. Eisai Company Ltd. Neo-Sampon Loop Tablets. Unpublished data
7. Ishihama, A. and Inoue, T.: Clinical field test of a new contraceptive vaginal foam tablet. *Contraception* 6:401, 1972
8. Coleman, S. and Piotrow, P.T.: Spermicides—simplicity and safety are major assets. *Popul. Rep. Ser. II (5)*, September 1979
9. Wortman, J.: The diaphragm and other intra-vaginal barriers - a review. *Popul. Rep., Ser. II (4)*, January 1976