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Review

**Vaginal Contraception –
an Update**

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Abstract

The effectiveness of available vaginal contraceptives in preventing pregnancy is reviewed. Some of the recent developments in vaginal contraception are described briefly and when available, clinical data are presented. Some of the advantages and disadvantages of vaginal contraception are discussed.

Introduction

The use of contraceptive methods to mechanically cover the cervix and the use of various spermicidal substances placed in the vagina predate Christianity. In spite of the long history of vaginal contraceptive methods, they remain the least studied and evaluated of all the presently available methods.

The beginning of the 1960s witnessed the reintroduction of the IUD following about 30 years of neglect, and the introduction of hormonal methods of contraception. At first, many researchers and contraceptive users thought IUDs and oral contraceptives provided women with an opportunity for safe and effective methods of contraception. Consequently, during the 1960s, the use of vaginal contraceptives generally declined, although in many developed and developing countries contraceptive prevalence steadily increased. However, beginning in the middle to late 1960s, numerous serious medical complications were reported in association with the use of IUDs and oral contraceptives. At one time or another, the use of oral contraceptives has been associated with increased risk of thromboembolic disease, gall-bladder disease, cerebrovascular disease and hepatic adenomas. IUDs have been associated with increased risks of pelvic inflammatory disease, impaired fertility and ectopic pregnancy, although not all investigators have found oral contraceptives and IUD users to be at an increased risk of these adverse reactions. However, the numerous reports of the increased risks of these adverse reactions in both the medical and popular literature have probably deterred many women from using these methods of contraception, and many providers of contraceptive services may become more reluctant to recommend these contraceptive methods to women.

Perhaps for these and other reasons there has been a gradual increase, during the past decade, in the proportion of women of reproductive age who elect to use vaginal contraceptives. Concomitant with this increase in the use of vaginal contraceptives has been an increase in the number of vaginal contraceptive products that are either available to the consumer or are being evaluated clinically.

Of the available vaginal contraceptives, few have been adequately evaluated to provide the consumer with adequate information on their safety and efficacy, so that the consumer may make an informed choice from among them. In Table 1, the reported effectiveness data for different vaginal contraceptives have been summarized from various sources (2, 3, 5, 6; International Fertility Research Program, unpublished data; National Institute of Child Health and Human Development, unpublished data). The data in the table show a wide range of pregnancy rates both for specific and/or different types of vaginal contraceptives. Aside from variations in the actual effectiveness of these various vaginal contraceptives in preventing pregnancy, there are many other variables that may account for the wide range of reported pregnancy rates, including the proportions of women lost-to-follow-up, methods used to collect and analyze the study data, compliance of subjects in use of the methods and the type of subjects recruited for evaluation.

In recent years, a number of new and innovative methods of vaginal contraception have been developed and are currently being evaluated. In the following sections of this paper, some of these methods are described briefly and the available data on their safety and efficacy are presented.

Vaginal contraceptive sponges

Three types of contraceptive sponges have been developed and are currently being evaluated.

Collagen sponge

The collagen sponge is a cylindrical-shaped disk, 6–7 cm wide and 2–2.5 cm thick. The sponge is made from collagen fibrous protein isolated from bovine skin. The sponge exerts its contraceptive effect by acting as a physical barrier to the sperm

Table 1 Pregnancy rates associated with the use of different types of vaginal contraceptives

| <i>Type of vaginal contraceptive</i> | <i>Pregnancy rates (per 100 woman-years of use)</i> |
|--------------------------------------|---|
| Creams | 4.7–9.1 |
| Diaphragms | 2.2–23.0 |
| Foams | 1.8–29.3 |
| Foaming tablets | 2.5–38.3 |
| Jellies | 2.7–36.1 |
| Suppositories | 0.0–21.1 |

and through its ability to absorb semen much in excess of its own weight. Clinical data from studies to evaluate the safety and efficacy of the collagen sponge are currently in progress. The preliminary data from these studies confirm the effectiveness of the sponge obtained from post-coital tests (1).

Intravaginal insert

The intravaginal insert (IVI) is made of a polyester material incorporating the spermicide nonoxynol-9. The IVI, cylindrical in shape with a diameter of 3.5 cm and a length of 4.5 cm, exerts its contraceptive effect as a physical and chemical barrier to the cervix, by its ability to absorb semen much in excess of its own weight and through the effect of nonoxynol-9. In one small clinical evaluation of the IVI, 49 women were followed up for one month. No pregnancies or unexpected adverse reactions were reported (A. Goldsmith, personal communication). The preliminary data from this study indicated that the frequency of subject complaints (vaginal odor, discharge, irritation) was higher for women who inserted a new IVI every two or three days compared to women who used a new IVI on a daily basis.

Secure sponge

The Secure sponge (formerly called Collatex) is made of polyurethane and incorporates 1 g of the spermicide nonoxynol-9. The Secure is a cup-shaped sponge, ca. 5.5 cm in diameter and 2 cm thick (Figure 1a). Its primary mode of action in preventing pregnancy is through the release of nonoxynol-9, rather than its ability to act as a physical barrier to the cervix or through its ability to absorb semen. In a multiclinic phase II evaluation of the Secure, which included 382 women, the 6-month gross life-table pregnancy rate was 3.8 ± 1.3 per 100 women; the six-month gross discontinuation rate for all reasons was 36.2 ± 3.4 per 100 women (2). Only 5.5% of the women discontinued use of the sponge because either they or their partners experienced discomfort during intercourse. In these initial phase II trials the Secure could be reused up to ten times. Following the results of these trials and other evaluations on the acceptability of the Secure, it was decided to make the Secure a single-use disposable product.

The International Fertility Research Program (IFRP) has recently undertaken clinical trials to evaluate the safety and efficacy of various vaginal contraceptives in comparative trials in which contraceptive methods are randomly assigned to subjects. The methods being evaluated include:

- (1) Secure contraceptive sponge;
- (2) Neo Sampooon (a widely used Japanese-made foaming suppository containing the spermicide menfegol);
- (3) aerosol foams;
- (4) diaphragm with spermicide; and
- (5) foaming suppositories containing 100 mg nonoxynol-9.

Sufficient data from the comparative trials of the Secure and Neo Sampooon foaming suppository studies conducted in Yugoslavia, Taiwan and Bangladesh had

been reported to the IFRP to provide a preliminary evaluation of the two contraceptive methods. The data from these trials are summarized in Tables 2 and 3. The 12-month life-table rates (Table 2) for reasons leading to discontinuation of the contraceptive methods were not significantly different ($p > 0.10$), except for the category "other personal reasons." These reasons are listed in Table 3. The results for the Secure generally agree with those obtained from the phase II trials (2), and indicate that it is a safe and effective contraceptive.

The Secure affords certain advantages over other vaginal contraceptives for any of the following reasons:

- (1) A new Secure does not have to be inserted after each coitus. The Secure can be inserted up to 24 h before intercourse, but should not be left in the vagina for more than 48 h.

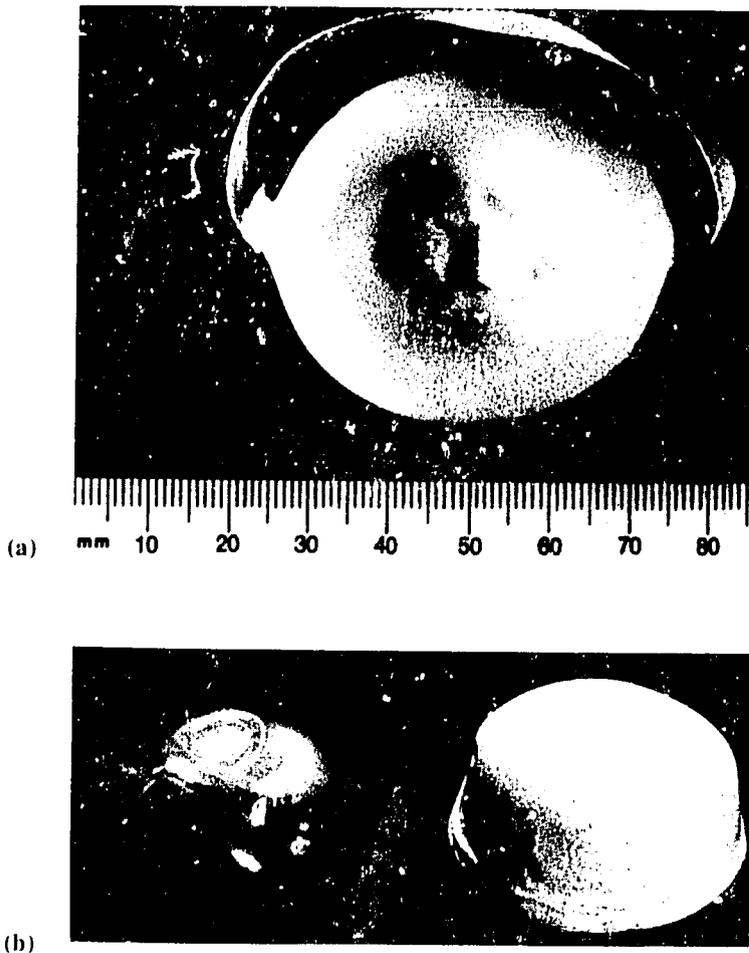


Figure 1 (a) Secure contraceptive sponge. (b) Contracap custom-fitted cervical cap and plaster mold

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Table 2 6- and 12-month life-table rates (per 100 women), by reason, for discontinuing use of the Secure and Neo Sampoo

| | <i>Secure</i> | | <i>Neo Sampoo</i> | |
|-------------------------|-------------------------------------|------------------|-------------------|--------------------------------------|
| | <i>6 Months</i> <i>(n = 549)</i> | <i>12 Months</i> | <i>6 Months</i> | <i>12 Months</i> <i>(n = 548)</i> |
| Pregnancy | 5.1 (1.2)* | 7.4 (1.8) | 6.8 (1.4) | 10.0 (2.2) |
| Discomfort | 3.2 (1.0) | 5.1 (1.7) | 4.5 (1.2) | 8.3 (2.3) |
| Other personal reasons† | 8.4 (1.5) | 24.2 (4.1) | 3.6 (1.1) | 15.7 (3.5) |
| Planned pregnancy | 1.5 (0.8) | 14.7 (3.9) | 1.1 (0.7) | 11.8 (3.2) |
| Medical reasons | 1.3 (0.7) | 2.1 (1.0) | 1.5 (0.7) | 1.5 (0.7) |

*Standard rate of error given in parentheses.

†Discontinuation for 'other personal reasons' significantly higher ($p < 0.01$) for Secure compared to Neo Sampoo**Table 3** Frequency of other personal reasons leading to discontinuation of Secure or Neo Sampoo

| <i>Personal reasons for discontinuation</i> | <i>Secure</i> | | <i>Neo Sampoo</i> | |
|---|--------------------------------|----------|--------------------------------|----------|
| | <i>No.</i> <i>(n = 548)</i> | <i>%</i> | <i>No.</i> <i>(n = 549)</i> | <i>%</i> |
| Difficulty in insertion/removal | 8 | 1.5 | 0 | 0.0 |
| No confidence in method | 5 | 0.9 | 4 | 0.7 |
| Too much trouble to use | 11 | 2.0 | 4 | 0.7 |
| Partner objects to method | 2 | 0.4 | 2 | 0.4 |
| No partner | 4 | 0.7 | 4 | 0.7 |
| Not associated with use of contraceptive | 5 | 0.9 | 0 | 0.0 |
| Specific reasons, not specified | 11 | 2.0 | 10 | 1.8 |

(2) The spermicide is immediately available after insertion of the Secure. Most vaginal contraceptive suppositories require 5–15 min to melt.

(3) It is not messy.

(4) One size can be used by all women.

Vaginal suppositories

Foaming vaginal suppositories similar to Neo Sampoo but containing 100 mg nonoxynol-9 are being developed and evaluated in the United States. Clinical data on these products are not yet available.

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Diaphragms

A non-fitted, spermicide-releasing diaphragm is currently being tested that obviates the need for a separate spermicidal supply. The diaphragm has been designed to be a one-use only product.

Cervical cap

Although the cervical cap has never been used extensively in the United States, it has a long history of use in Europe, especially in England and Germany. In recent years in the United States, there has been an increasing demand for cervical caps. Unfortunately, cervical caps for contraceptive use are not marketed in the United States. However, cervical caps imported from England are currently being evaluated there under an Investigational Device Exemption (IDE) from the Food and Drug Administration (FDA). The cervical caps used presently are only available in a limited number of sizes. To overcome some of the disadvantages of the cervical caps available, a custom-fitted cervical cap has been developed.

The custom-fitted cervical cap (Conracap) is made from a plaster mold of the cervix (Figure 1b). The cap is composed of a copolymer material that completely covers the outer surface of the cervix. The cap contains a built-in valve that opens outward when uterine pressure rises during menstruation and permits the discharge of menstrual fluids. The cap is held in place by cervical fluids that create suction between the cervix and the cap. The cap has only been evaluated in pilot studies to develop the necessary technology for an effective cervical cap. Even in these studies, which have required several design modifications to the cervical cap, the pregnancy rate was about 10 per 100 woman-years and no adverse reactions were reported. An improved model of the cap is presently being evaluated by the IFRP in a limited Phase II multiclinic trial. It is anticipated that this trial should give lower pregnancy rates because of the improvements that have been made in the design and fabrication of the cap.

Comments

It is clear that further evaluation of all vaginal contraceptives is needed so that their relative advantages and disadvantages may be assessed, as well as their efficacy in preventing pregnancy. For many of the available contraceptives, adequate safety and efficacy data are neither available to the consumers nor to the providers of these contraceptives. With the continued consumer interest in vaginal methods of contraception, it is important that appropriate safety and efficacy data be made available.

The newly developed vaginal contraceptives, such as the sponges and custom-fitted cervical cap, appear to offer a number of significant advantages over the available vaginal contraceptives. These advantages, such as their ease of use and potential not to interfere with the spontaneity of intercourse, will probably result in further increases in the numbers of women who elect to use vaginal contraceptives as their only method of contraception.

One additional benefit of the use of spermicides is that they provide a high degree of protection against some of the sexually transmitted diseases, e.g. gonorrhoea, herpes virus (types 1 and 2) (3), on the basis of *in vitro* tests and limited observational data from programs in which vaginal contraceptives have been used. Definitive clinical studies to evaluate the effectiveness of various vaginal contraceptives against the transmission of some of the common venereal diseases are urgently required.

Recently Jick and co-workers (4) reported a 2.2-fold increased risk of certain congenital malformations to the offspring of women who may have conceived while using contraceptive products containing spermicides. The fact that the study did not establish whether the women were using spermicides at the time of conception and that no single well-defined syndrome of malformations among the infants was found, throws doubt on any causal relationship between the use of spermicides and congenital malformations. Also, the frequency of malformation among offspring of the non-spermicide group was unusually low. Additional studies designed to specifically evaluate any associations between the use of spermicides and congenital malformations are required.

When used as directed, the pregnancy rate associated with the use of different types of vaginal contraceptives is acceptably low. Hopefully, new innovations in vaginal contraception will not only offer better protection against pregnancy, but will also meet with high rates of acceptability that should further reduce the likelihood of pregnancy among users of these methods.

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