

The diaphragm with and without spermicide for contraception: a Cochrane review

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BACKGROUND: The diaphragm is usually used with a spermicide. However, some practitioners have suggested that spermicides offer no additional contraceptive protection and have advocated alternative guidelines for the use of diaphragms. The objective of this review was to compare the effectiveness, safety and acceptability of the diaphragm with and without spermicide. **METHODS AND RESULTS:** We searched Medline, Embase, Popline, CINAHL, the Cochrane Controlled Trials Register and reference lists of relevant articles. In addition, we contacted experts in the field to identify unpublished studies. Randomized controlled trials comparing women of reproductive age using the diaphragm with and without spermicide as the sole contraceptive method that reported clinical outcomes were selected. Two reviewers independently extracted data on outcomes and trial characteristics and any discrepancies were resolved by consensus or by consultation with the third reviewer. The results of the one identified study are presented descriptively. We identified only one study. No significant difference was found in the pregnancy rates (with typical use or consistent use) or discontinuation rates between the diaphragm-with-spermicide and diaphragm-without-spermicide groups. There was a trend towards higher pregnancy rates in the diaphragm-without-spermicide group. However, this study failed to recruit the planned number of participants and was consequently underpowered. **CONCLUSIONS:** As only one underpowered study was identified, we cannot distinguish between the contraceptive effectiveness of the diaphragm with and without spermicide. We cannot draw any conclusion at this point; further research is needed.

Key words: contraception/Cochrane review/diaphragm/spermicide

Introduction

The diaphragm used in conjunction with a spermicide is an important woman-controlled, immediately reversible, low-risk method of contraception. However, the proportion of women using this method is low and has been falling, with an estimated 1% of women using vaginal contraception worldwide (Department for Economic and Social Information and Policy Analysis, 1996). The diaphragm's limited acceptance is due to several factors, in particular the availability of more effective forms of contraception. Another factor deterring use may be the adjunctive use of spermicide. Many women find spermicides inconvenient and messy. In addition, spermicides may increase the risk of cystitis by altering normal vaginal flora and allowing overgrowth of pathogenic strains of *E.coli* (Fihn, 1985; Hooton, 1991).

As a response to this, some practitioners have advocated use of the diaphragm without spermicide, suggesting that spermicides offer no additional contraceptive protection (Stim,

1980; Ferreira, 1993). These authors have also advocated other variations on standard diaphragm use, such as continuous wearing of the diaphragm (Ferreira, 1993) or a one-size fits all 'free-fit' diaphragm (Stim, 1980). However, the reported pregnancy rates of women using this method have been widely variable (Stim, 1980; Ferreira, 1993; Smith, 1995).

Clarification of the contribution of spermicides to the contraceptive effectiveness of the diaphragm would aid women and practitioners in the decision concerning adjunctive use of spermicides.

The purpose of this review is to compare the effectiveness, safety and acceptability of the diaphragm with and without spermicide.

Materials and methods

Types of studies

Only randomized controlled trials comparing the diaphragm with and without spermicide that reported clinical outcomes were considered for inclusion.

Types of participants

Participants were women of reproductive age currently using or willing to use the diaphragm (any type) as their sole contraceptive method.

Types of interventions

Interventions were the use of the diaphragm with and without spermicide as the sole contraceptive method.

Types of outcome measures

The review focused on clinical outcome measures. The primary outcome measure was the observed probability of pregnancy. The full list of outcomes was: (i) observed probability of pregnancy in 'typical use'; (ii) observed probability of pregnancy in 'perfect use'/'consistent use'; (iii) uro-genital tract irritation or infection; (iv) method continuation; (v) method-related discontinuation (as a measure of acceptability); (vi) lost to follow-up rates.

Search strategy for identification of studies

We conducted computerized searches of Medline, Embase, Popline and CINAHL and searched reference lists of relevant articles. In addition, we attempted to find unpublished randomized controlled trials through personal communication with experts. We set no limits about language, date, or other restrictions.

Medline was searched using the following strategy: (diaphragm* OR diaphragm OR contraceptive devices, female OR (barrier AND (method* OR contraceptive* OR device*)) AND (spermatocidal agents OR nonoxynol OR 26027-38-3 OR octoxynol OR 9002-93-1 OR spermicid*) AND (randomized controlled clinical trial OR randomized controlled trial OR (random* AND (trial* OR allocation)) OR double blind method OR single blind method OR placebos OR placebo* OR research design OR comparative stud* OR comparative study OR evaluation studies OR follow-up studies OR prospective studies OR clinical trials OR multicenter studies OR random* OR multicentre).

Embase was searched using the search strategy: (diaphragm? OR (barrier AND (method? OR contracept? OR device?)) AND (spermatocidal agents OR nonoxynol OR 26027-38-3 OR octoxynol OR 9002-93-1 OR spermicid?).

Popline was searched using the search strategy: (diaphra* OR female contraception OR barrier methods) AND (spermicid* OR spermatici* OR nonoxynol OR octoxynol) AND (random* OR multicent* OR placebo* OR blind* OR clinical trial* OR comparative studies OR follow-up studies OR prospective studies).

CINAHL was searched using the search strategy: 1 (diaphragm or contraceptive devices, female or (barrier and (method or contraceptive or device))).mp. (mp=title, cinahl subject heading, abstract, instrumentation) 2 (spermatocidal agents or nonoxynol or octoxynol or spermicid).mp. (mp=title, cinahl subject heading, abstract, instrumentation) 3 1 and 2 4 from 3 keep 1-3 5 from 3 keep 1-3.

The Cochrane Controlled Trial Register was searched using the search strategy: diaphragm OR diaphragms OR female barrier methods OR female barrier method.

Methods of the review

Two reviewers (L.A.C. and K.N.) reviewed titles and abstracts from our literature search. We obtained copies of all possibly relevant articles. After a preliminary review of the single identified trial (Bounds *et al.*, 1995), we developed and field-tested an inclusion checklist and data collection form, as described in Cochrane Collaboration manuals (Mulrow and Oxman, 1997). Two reviewers (L.A.C. and K.N.) each independently applied inclusion criteria and extracted data. Differences were resolved by discussion. We contacted authors

of the one identified trial to supplement information. In addition to the clinical outcomes, we systematically extracted data on the following variables: (i) methodology: random allocation techniques, blinding, post-randomization exclusions and loss to follow-up; (ii) demographics: type of health care setting, city, country, total number of women included, parity and inclusion/exclusion criteria.

Description of studies

Only one trial was identified which fulfilled the criteria for inclusion in this review (Bounds *et al.*, 1995). Its characteristics are given in Table I. No trials were excluded.

The objective of this trial was to compare the contraceptive effectiveness of three methods: diaphragm-without-spermicide versus diaphragm-with-spermicide versus spermicide-only over a 12 month period of use. Randomization to the spermicide-only arm was discontinued early in the course of the study, as it was identified as a hindrance to recruitment. Instead, potential participants were given the option to choose the spermicide-alone intervention before randomization. Randomization codes were generated for the two remaining groups. Only the diaphragm-without-spermicide and the diaphragm-with-spermicide arms are considered in this review. The planned study size was 144 women per group, which would have yielded adequate power (0.80) to detect a 14% absolute difference in pregnancy rates between the two arms. The trial was terminated early due to recruitment difficulties. The trial recruited 164 participants (84 in the diaphragm-without-spermicide arm and 80 in the diaphragm-with-spermicide arm).

Methodological quality of included studies

The allocation sequence was computer-generated and allocation concealment was by sequentially numbered, sealed, opaque envelopes (author communication). The participants, investigators and the outcome assessors were not masked. An *a priori* power calculation was reported. There were no known exclusions after randomization. The loss to follow-up was low (0.5% at 12 months).

Results

The trial found no significant differences in pregnancy or discontinuation rates between the two arms. The 12 month cumulative pregnancy rate per 100 women for typical use for diaphragm-without-spermicide was 28.6 (95% CI, 17.4-39.8) and diaphragm-with-spermicide was 21.2 (95% CI, 11.0-31.4). The 12-month cumulative pregnancy rate per 100 women for consistent use (defined as no unprotected intercourse and use of only assigned method) for diaphragm-without-spermicide was 19.3 (95% CI, 7.5-31.1) and diaphragm-with-spermicide was 12.3 (95% CI, 2.8-21.8). Three related adverse events were reported; all described as vaginal/vulvar irritation attributed to candida. All were in the diaphragm-without-spermicide arm. The discontinuation rates were high, but there was no significant difference between the arms. The 12 month cumulative total discontinuation rate per 100 women for the diaphragm-without-spermicide group was 57.2 (95% CI, 46.6-67.8) and for the diaphragm-with-spermicide group 49.2 (95% CI, 38.2-60.2). The loss to follow-up was low (0.5% at 12 months).

Discussion

Only one trial was identified and it was underpowered. The effectiveness of the diaphragm in this trial was poor, with or without concomitant use of a spermicide. These failure rates (21-29%) were higher than those commonly reported in other

Table I. Characteristics of included studies

Study	Methods	Participants	Interventions	Outcomes	Notes	Allocation concealment
Bounds 1995	Computer-generated randomization list No masking Recruitment period of 5 years Post-randomization exclusions Undescribed	Groups similar in all respects. Average age 29.5 years. 99% white. Averaging 2.6 acts of intercourse per week at study entry. 65% of participants had previous diaphragm experience. Nulliparous—55% of women in diaphragm-without-spermicide and 60% in diaphragm-with-spermicide	1. Diaphragm-without-spermicide. 2. Diaphragm-with-spermicide. 3. Spermicide alone.	Pregnancy rates in typical use. Pregnancy rates in consistent use. Discontinuation rates. Side-effects	Spermicide-only arm discontinued as it was identified as a hindrance to recruitment. Conducted in a family planning clinic, London, UK.	A

clinical studies (13–17%) or with common use (2–21%) (Trussell, 1994). Proposed reasons for these high rates included the study's high follow-up rate.

This study did not find a significant difference in pregnancy rates (with typical or consistent use) or discontinuation rates between the diaphragm-with-spermicide and diaphragm-without-spermicide groups. There was a trend towards higher pregnancy rates in the diaphragm-without-spermicide group. However, this study failed to recruit the planned number of participants and was consequently underpowered. Therefore, no firm conclusions can be drawn about the relative contraceptive effectiveness of the diaphragm-with-spermicide compared with diaphragm-without-spermicide.

In the absence of sufficient data, health care professionals and women will need to consider several factors when deciding whether or not to use the diaphragm with or without spermicide. Consideration should be given to the non-significant trend towards higher pregnancy rates in the diaphragm-without-spermicide group in the one identified study, possible benefits of spermicides (STI prevention) and personal preference.

Randomized controlled trials with adequate numbers of participants would be required to establish whether or not a diaphragm without spermicide is as effective a contraceptive method as a diaphragm used with spermicide. However, further trials may not only be logistically difficult, particularly as the prevalence of diaphragm use is low worldwide, but may also be ethically questionable considering the magnitude and direction of the difference observed in the one identified study.

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References

- Bounds, W., Guillebaud, J., Dominik, R. and Dalberth, B.T. (1995) The diaphragm with and without spermicide. A randomized, comparative efficacy trial. *J. Reprod. Med.*, 40, 764–774.
- Department for Economic and Social Information and Policy Analysis (1996) New York, United Nations.
- Ferreira, A.E., Araujo, M.J., Regina, C.H., Diniz, S.G. and Faundes, A. (1993) Effectiveness of the diaphragm, used continuously, without spermicide. *Contraception*, 48, 29–35.
- Fihn, S.D., Latham, R.H., Roberts, P., Running, K. and Stamm, W.E. (1985) Association between diaphragm use and urinary tract infections. *JAMA*, 254, 240–245.
- Hooton, T.M., Hillier, S., Johnson, C., Roberts, P.L. and Stamm, W.E. (1991) *Escherichia coli* bacteriuria and contraceptive method. *JAMA*, 265, 64–69.
- Mulrow, C.D. and Oxman, A.D. (eds) (1997) Cochrane Collaboration Handbook. In *The Cochrane Library* (database on disk and CDROM). The Cochrane Collaboration, Oxford Update Software, (updated 1 March 1997).
- Smith, C., Farr, G., Feldblum, P.J. and Spence, A. (1995) Effectiveness of the non-spermicidal fit-free diaphragm. *Contraception*, 51, 289–291.
- Stim, E.M. (1980) The nonspermicide fit-free diaphragm: a new contraceptive method. *Advance in Planned Parenthood*, 15, 88–98.
- Trussell, J. (1994) Contraceptive efficacy of barrier contraceptive. In Mauck, C.K., Cordero, M., Gabelnick, H.L., Spieler, J.M. and Rivera, R. (eds) *Barrier Contraceptives. Current Status and Future Prospects*. Wiley-Liss, NY, USA, pp. 17–51.