New types of diaphragms and cervical caps versus older types of diaphragms and different gels for contraception: a systematic review

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ABSTRACT

Introduction Our primary objective was to evaluate whether new types of single-size diaphragms or cervical caps differ in prevention of pregnancy compared with older types of diaphragms, and whether different types of gels differ in their ability to prevent pregnancy. A secondary aim was to evaluate method discontinuation and complications.

Methods A comprehensive search was conducted in PubMed, Embase and the Cochrane Library. The certainty of evidence was assessed according to the GRADE system.

Results Four randomised controlled studies were included in the assessment. When comparing the new and old types of female barrier contraceptives the 6-month pregnancy rate varied between 11%–15% and 8%–12%, respectively. More women reported inability to insert or remove the FemCap device (1.1%) compared with the Ortho All-Flex diaphragm (0%) (p<0.0306). Urinary tract infections were lower when using the single-size Caya, a difference of –6.4% (95% CI –8.9 to –4.09) compared with the Ortho All-Flex diaphragm. The 6-month pregnancy rate for acid-buffering gel and spermicidal nonoxynol-9 gel varied between 10% and 12%. The discontinuation rate was lower in women who used acid-buffering gel compared with nonoxynol-9 gel (risk ratio (RR) 0.77, 95% CI 0.68 to 0.97).

Conclusions Pregnancy rates were generally high in women using female barrier contraceptives. There was no difference in the efficacy for pregnancy prevention between the new types of diaphragms and cervical caps and the older diaphragms. The new types of diaphragms and cervical caps resulted in fewer urinary tract infections. Acid-buffering gels did not differ from spermicidal nonoxynol-9 gels regarding pregnancies but seemed to be better tolerated.

Key messages

- New female barrier contraceptive methods demonstrate no better contraceptive efficacy than older methods.
- Acid-buffering gel is better tolerated compared with nonoxynol-9 gel.
- These findings are important for women who desire to use barrier contraceptive methods.

INTRODUCTION

The mode of action of all female barrier contraceptive methods is to prevent the passage of sperm into the uterus by creating a physical barrier between the sperm and the uterus, as well as to provide a reservoir that can hold the spermicidal cream or gel close to the cervical ostium.[1] The Milex diaphragm, that followed the Ortho-All-Flex diaphragm, is a silicone rubber diaphragm available in six sizes that has been on the market for many decades. Newer types are the FemCap cervical cap made of silicone rubber that is shaped like a sailor's hat and available in three sizes[2] and the single-size, reusable, non-latex diaphragm formerly known as SILCS, now branded the Caya Countered Diaphragm (Caya).[3] The recommendation in most countries has been to use the device in conjunction with a spermicide. The previously used spermicides with barrier contraceptives were all based on detergents, most commonly nonoxynol-9, which potently disrupts the sperm cell membrane, as well as those of some sexually transmitted pathogens.[1 4 5] Nowadays, acid-buffering lactate- and cellulose-based gels are currently the most used

alternatives in many countries; however, it is still possible to purchase several nonoxynol-9 products online.

Diaphragms, as a means of contraception for women, have been available for more than a century. The use of barrier methods declined following the introduction of more modern methods of contraception, for example, the combined oral contraceptive which was introduced in the 1960s.[6] In 2015 the reported prevalence of vaginal barrier methods of contraception including spermicidal foam, jelly, cream and sponges among married or in-union women aged 15–49 years was reported to be 0.1% in Europe and 0.9% worldwide.[7] However, in low-resource settings vaginal barrier methods are more common, and studies have suggested that women in low-resource settings find diaphragms acceptable as a contraceptive and for sexually transmitted infection (STI) protection.[8 9]

The World Health Organization (WHO) Family Planning Handbook classification on contraceptive effectiveness has classified the diaphragm as moderately effective.[10] According to a study by Trussell,[11] 6 pregnancies per 100 woman-years occur when diaphragms such as Ortho-All-Flex and Milex with spermicidal cream or jelly are used perfectly (defined as following the manufacturer's directions for use) compared with 12 pregnancies per 100 woman-year when they are used typically (actual use including inconsistent incorrect use).[11] Lately, interest in and demand for hormone-free contraception has increased; however, some concerns about the use of female barrier methods related to contraceptive efficacy, ease of correct use, and urinary tract infections (UTIs) have been raised.[12]

This systematic review aimed to evaluate whether new types of female barrier methods such as FemCap, Caya or equivalent products differ in their ability to prevent pregnancy compared with older types such as Milex or Ortho All-Flex, and whether different types of gels differ in prevention of pregnancy. A secondary aim was to evaluate outcomes such as method discontinuation and complications.

METHODS

Study design

We performed a systematic review according to established routines at the Regional Health Technology Assessment (HTA) Centre in the Region Västra Götaland, Sweden. Three different research questions were posed and described in the PICO (Population, Intervention, Comparison, and Outcomes) format. Is there any difference in pregnancy, discontinuation and complication rates between the new (three sizes cervical cap: FemCap (similar to the earlier Prentif Cap), single-size diaphragm: the Caya Countered Diaphragm (Caya)) and old types (six sizes diaphragm: Ortho All-Flex (nowadays called Milex)) of female barriers combined with acid-buffering gel (lactate- and cellulose-based gel), nonoxynol-9 gel or no gel at all.

Literature search

A systematic literature search in PubMed, Embase (Ovid SP, 1974 to Jan 2017) the Cochrane Library, HTA databases and Cinahl was conducted by two research librarians at the Medical Library, Sahlgrenska University Hospital, Gothenburg and Skaraborgs Hospital, Lidköping, Sweden during the period January–March 2017 with updates in February 2019. Searches were conducted using controlled vocabulary and title/abstract. A detailed description of the search strategies is available in online supplementary table 1. In addition, reference lists of review articles were scrutinised for relevant references. We included systematic reviews, randomised controlled trials (RCTs), non-randomised controlled studies and case series. No case reports or review articles were accepted for inclusion. The included publications were restricted to the English or Scandinavian (Swedish, Norwegian or Danish) languages. There was no limit for publication date.

The studies were selected and reported according to the preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines.[13] At least two authors independently selected articles for inclusion according to PICO. Any disagreement was resolved in consensus with a third author. Case series with <200 cases or case series including cervical caps that were no longer available and articles that did not fulfil the PICO were excluded.

Two investigators extracted data independently of each other, for each outcome, including study design, the number of individuals (intervention and control), type of intervention, comparison and outcome results.

Outcomes

The outcomes were categorised into critical and important but not critical for decision-making, according to the GRADE handbook.[14] The critical outcome was pregnancy rate and the important outcomes were discontinuation rate and complications.

Quality assessment

The studies were critically appraised by using a validated checklist for assessment of RCTs and cohort studies from the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU), modified by the HTA Centre.[15 16] The assessment addressed directness (external validity), study limitations (risk of bias) and precision and is presented in three levels. The certainty of evidence for each outcome across studies was assessed according to the GRADE system[14 17] by all the authors together.

Statistical analyses

When possible, data were pooled in meta-analyses, using Review Manager 5.2. A random effect model

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Table 1 Characteristics of included studies

Author, year, country	Study design	Study duration	Length of follow-up	Female barriers	Gel	Patients (n)	Mean age (years)	Civil status: (a) living or (b) not living with partner	Contraceptive use before study period	Outcome variables	Directness*	Study limitation*	Precision*
PICO 1 New vs old female barriers													
Bernstein, 1986, USA (based on data from Gallo, 2002)[18 21]	RCT	NR	6–24	Prentif cavity rim cervical cap vs Ortho All-Flex diaphragm		1529	NR Inclusion age 18–40	NR	NR	Pregnancy Complication	–	–	?
Mauck, 1999, USA[19]	RCT	1995–1999	6 months	FemCap **vs** Ortho All-Flex diaphragm		755	29	(a) 64% vs 72% (b) 36% vs 28%	Condom: 61% vs 64% Female barrier:18% vs 19% Spermicide: 13% vs 8% Other: 11% vs 10.5% None: 6.5% vs 6%	Pregnancy Discontinuation Complication	?	–	?
Schwartz, 2015 Part 2, USA[3]	Cohort	NR	NR	Caya vs Ortho All-Flex diaphragm		1055+421	NR	NR	NR	Pregnancy Complication	+	+	+
PICO 2 Acid-buffering gel vs nonoxynol-9													
Barnhart, 2007, USA[20]	RCT	2001–2004	6 months	Ortho All-Flex diaphragm	Lactate gel **vs** nonoxynol-9	1055	28	(a) 68% vs 66% (b) 33 vs 34%	Condom: 77% vs 79% Diaphragm: 8% **vs** 8% OCP: 19% **vs** 16% Spermicides: 24% vs 22% Other methods: 53% **vs** 65%	Pregnancy Discontinuation Complication	+	+	+
Schwartz, 2015 Part 1, USA[3]	RCT	2008–2009	190 days and 6 menstrual cycles	Caya	Acid-buffering gel **vs** nonoxynol-9	421	29	(a) 76% vs 75% (b) 24% vs 25%	Condom: 76% vs 69% CHC, injection: 14% **vs** 10% IUD: 2% **vs** 2% Implant: 0.7% **vs** 0% Barrier methods:19% **vs** 21%	Pregnancy Discontinuation Complication	?	+	+

*+, no or minor problems; ?, some problems; –, major problems.
†Female barriers: diaphragm, cervical cap, sponge, female condom, Lea's contraceptive or Femcap.
‡Barrier methods: spermicide alone, diaphragm, female condom, contraceptive sponge.
CHC, combined hormonal contraception; implant, progesterone implant; IUD, intrauterine device; NR, not reported; OCP, oral contraceptive pill; PICO, Population, Intervention, Comparison, and Outcomes; RCT, randomised controlled trial.

was applied. The effect estimate was expressed as risk ratios (RRs) with 95% confidence intervals (CIs).

RESULTS

The literature search identified 2220 publications after removal of duplicates. After exclusion of titles and abstracts, another 24 articles were excluded after reading the full text (online supplementary tables 2 and 3). The selection process is summarised in online supplementary figure 1.

Four RCTs[3 18–20] were included in the assessment and their characteristics are presented in table 1. One of the four RCTs[18] was not possible to retrieve from available databases, but data and quality assessment could be retrieved from a Cochrane review.[21] Another RCT[3] included a second part, which was handled as a separate cohort study. All these studies were conducted in the USA between 1986 and 2015. No other observational studies fulfilled the inclusion criteria.

New types (FemCap, Caya or equivalent products) compared with old types such as Milex or Ortho All-Flex (PICO 1)

Pregnancy

Two RCTs[18 19] and one cohort study[3] had pregnancy rate as the primary outcome (table 2). One of the RCTs,[18] that compared the Prentif Cap device with the Ortho All-Flex diaphragm, reported no difference in the cumulative pregnancy rates between the two devices (odds ratio (OR) 1.24, 95% CI 0.89 to 1.74). The other RCT[19] compared the new FemCap with the Ortho All-Flex diaphragm in a non-inferiority design. The adjusted risk ratio of pregnancy among FemCap users was 1.96 times higher that among Ortho All-Flex users, which did not meet the definition of clinical equivalence. Nonoxynol-9 gel was used in these two

Table 2 Pregnancy rate: new versus old female barriers and acid-buffering gel versus nonoxynol-9 gel

Author, year, country	Study design	Patients (n)	Lost to follow-up (n)	Intervention (I)	Control (C)	Directness*	Study limitation*	Precision*
				New female barriers	**Old female barriers**			
Bernstein,1986, USA[18]	RCT superiority	1529	305	**Prentif Cap** 87/581 (15.0%) OR 1.24 (95% CI 0.89 to 1.74)	71/572 (12.4%)	–	–	?
Mauck, 1999, USA[19]	RCT non-inferiority	I=419 C=422	I=13 C=17	**FemCap** CPP TU: 13.5% aRR 1.96 (above non-inferiority limit <1.73) PU: 11.1% (above non-inferiority limit)	**Ortho All-Flex diaphragm** CPP TU: 7.9% PU: 7.4%	?	–	?
Schwartz, 2015, USA[3]	Cohort	I=450 C=1055	I=19 C=198	**Single size Caya** 6-month CPP TU: 11.3% Δ 0.7 (95% CI–3.6 to 4.9)	**Ortho All-Flex diaphragm** 6-month CPP TU: 10.7%	+	?	+
				Acid-buffering gel	**Nonoxynol-9 gel**			
Barnhart, 2007, USA[20]	RCT non-inferiority	n=1055 I=621 C=300	I=125 C=73	6-month CPP ITT: 10.3% Δ −0.7% (95% CI −0.5 to 3.8) PP: 10.1% Δ −2.2% (95% CI −7.7 to 3.3) PU: 4.7% Δ −1.4% (95% CI −8.4 to 5.6)	6-month CPP ITT: 11.0% PP: 12.3% PU: 6.1%	+	+	+
Schwartz, 2015 USA[3]	RCT	I=299 C=151	I=11 C=8	6-month CPP TU: 9.6% (95% CI 5.5 to 13.6) 6 cycles CPP TU: 10.9% (95% CI 5.3 to 16.5) PU: 4.4% (95% CI 0 to 10.0)	6-month CPP TU: 12.5% (95% CI 5.4 to 19.5) 6 cycles CPP TU: 14.0% (95% CI 2.5 to 25.1) PU: 14.9% (95% CI 0.2 to 29.7)	?	+	+

*+, no or minor problems; ?, some problems; –, major problems.
Δ, difference; aRR, adjusted risk ratio; CPP, cumulative pregnancy probability; ITT, intent to treat; OR, odds ratio; PP, per protocol; PU, perfect use; RCT, randomised controlled trial; TU, typical use.(table 2)

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Table 3 Complications for new versus old female barriers

Author, year, country	Study design	Patients (n)	Lost to follow-up (n)	Intervention (I)	Control (C)	Directness*	Study limitations*	Precision*
				New female barriers	**Old female barriers**			
Bernstein, 1986, USA[18]	RCT superiority	1529	305	**Prentif Cap** User discomfort: 5/604 (0.8%) OR 0.31 (95% CI 0.14 to 0.71), p=0.0057 UTI: 14.8	**Ortho All-Flex diaphragm** User discomfort: 18/597 (3%) UTI: 16.5, ratio 0.9 (no data to test significance)	–	–	?
Mauck, 1999, USA[19]	RCT non-inferiority	I=419 C=422	I=13 C=17	**FemCap** User discomfort: 7/350 (2.0%) Partner discomfort: 25/350 (7.1%) Blood found in the device: 31/346 (9.0%) UTI: 26/346 (7.5%), p=0.028	**Ortho All-Flex diaphragm** User discomfort: 13/398 (3.3%) Partner discomfort: 10/398 (2.5%) Blood found in the device: 16/396 (4.0%), p=0.006 UTI: 49/396 (12.4%)	?	–	?
Schwartz, 2015, USA[3]	Cohort	I=450 C=1055	I=19 C=198	**Single-size Caya** Urogenital adverse event: Δ −23.6% (95% CI −29.1 to −18.1) Product-related adverse event: Δ −24.0% (95% CI −28.3 to −19.6) UTI: Δ −6.4% (95% CI −8.9 to −4.09)	**Ortho All-Flex diaphragm** Urogenital adverse event: Product-related adverse event: UTI:	+	+	+

*+, no or minor problems; ?, some problems; –, major problems.
Δ, difference; RCT, randomised controlled trial; UTI, urinary tract infection.

studies. Both trials had severe study limitations due to high withdrawal rates after randomisation. The cohort study[3] compared the new single-size Caya with the Ortho All-Flex diaphragm. No significant difference in the 6-month pregnancy rate between the single-size Caya (11.3%) and the Ortho All-Flex diaphragm (10.7%) was found.

In summary, there may be little or no difference in pregnancy rate when new types of barriers are compared with old ones (low certainty of evidence GRADE ⊕⊕◯◯).

Discontinuation

Only the RCT by Mauck *et al*[19] reported on discontinuation where more women reported inability to insert or remove the FemCap device (1.1%) compared with the Ortho All-Flex diaphragm (0%) (p<0.0306). In summary, the discontinuation rate was higher for the recently introduced female barrier FemCap cervical cap (low certainty of evidence GRADE ⊕⊕◯◯).

Complications

Two RCTs[18 19] and one cohort study[3] reported complications (table 3). User discomfort (vaginal ulcerations or lacerations) was reported in the RCT by Bernstein[18] to be more common among the Ortho All-Flex diaphragm users (3%) compared with the Prentif Cap users (0.8%) (p=0.0057). In the RCT by Mauck *et al*,[19] UTI was more frequently reported in the users of the Ortho All-Flex diaphragm (12.4%) compared with the newer FemCap (7.5%) (p=0.028). A similar result was reported in the cohort study by Schwartz[3] when comparing the old female barrier with the newer single-size Caya where a significant difference of −6.4% (95% CI −8.9 to −4.09) was shown. This study also reported significantly lower urogenital adverse events in the single-size Caya group (table 3).

Both RCTs had severe study limitations and the conclusions are uncertain (GRADE⊕◯◯◯), while the cohort study supports that there may be fewer complications with the new types of female barriers (GRADE⊕⊕◯◯).

Acid-buffering gel compared with nonoxynol-9 gel (PICO 2)

Pregnancy

One of two RCTs demonstrated that the acid-buffering gel was not less effective in preventing pregnancies compared with nonoxynol-9 gel.[20] The other trial[3] reported similar pregnancy rates but no statistical

Table 4 Complications for acid-buffering gel versus nonoxynol-9 gel

Author, year, country	Study design	Patients (n)	Lost to follow-up (n)	Intervention (I)	Control (C)	Directness*	Study limitations*	Precision*
				Acid-buffering gel	**Nonoxynol-9 gel**			
Barnhart, 2007, USA[20]	RCT non-inferiority	n=1055 I=621 C=300	I=125 C=73	User discomfort: 422/621 (68%), p>0.05 Symptomatic UTI: 56/621 (9%), p=0.03 Partner discomfort: 75/621 (12%), p>0.05	User discomfort: 207/300 (69%) Symptomatic UTI: 42/300 (14%) Partner discomfort: 30/300 (10%)	+	+	+
Schwartz, 2015, USA[3]	RCT	I=299 C=151	I=125 C=73	Overall: 185/278 (66.5%) User discomfort: 178/278 (64%) Symptomatic UTI: 7/278 (2.5%). p>0.05 for all comparisons	Overall: 92/137 (67.2%) User discomfort: 85/137 (62%) Symptomatic UTI: 7/137 (5.1%)	+	+	+

*+, no or minor problems; ?, some problems; –, major problems.
RCT, randomised controlled trial; UTI, urinary tract infection.

analysis was provided. Both studies had some withdrawal problems (table 2). In summary, there is probably little or no difference in the pregnancy rate between the two types of gels used with a diaphragm (moderate certainty of evidence GRADE ⊕⊕⊕◯).

Discontinuation

Each of two RCTs[3 20] independently demonstrated a lower discontinuation rate for the acid-buffering gel (39% and 51%) compared with nonoxynol-9 (43% and 53.6%). The pooled RR was 0. 77 (online supplementary figure 2). The certainty of evidence was moderate (GRADE ⊕⊕⊕◯).

Complications

User discomfort was common for both acid-buffering gel and nonoxynol-9 gel and varied between 62% and 69% (table 4). The pooled results from the two RCTs[3 20] showed that symptomatic UTIs were less frequent among users of acid-buffering gel compared with nonoxynol-9 gel (RR 0.62, 95% CI 0.44 to 0.89). In conclusion, UTIs are less frequent among users of acid-buffering gel compared with nonoxynol-9 gel (moderate certainty of evidence GRADE ⊕⊕⊕◯).

No gel compared with acid-buffering gel (lactate- and cellulose-based gel) (PICO 3)

No studies comparing the efficacy and safety of no gel and acid-buffering gels were found in the literature search.

DISCUSSION

The main finding in the present systematic review is that the newer types of barrier contraceptive methods were not found to be better than the older methods as regards contraception. The pregnancy rates were relatively high with around 8% to 15% of users conceiving after 6 months follow-up, and the discontinuation rate was higher for the recently introduced female barriers. There were, however, fewer complications with the new types of female barriers as regards UTIs and urogenital adverse events. Furthermore, we found that there is probably little or no difference in pregnancy rates between acid-buffering gel and nonoxynol-9 gel; however, women who used acid-buffering gel had lower discontinuation rates.

The risk of unplanned pregnancies is determined by many different factors. One important factor is the efficacy of the contraceptive used. When comparing the new and old types of female barriers the 6-month pregnancy rate varied between 11%–15% and 8%–12%, respectively.[3 18 19] The RCT by Mauck[19] comparing the new barrier FemCap with the Ortho All-Flex diaphragm summarised the probability of pregnancy among the FemCap users to be six percentage points higher than that of the diaphragm users but this could not be ruled out. The hypothesis of contraceptive non-inferiority was not confirmed, ie the FemCap did not perform as well as the diaphragm in preventing pregnancy. The same study reported a higher discontinuation rate with the FemCap compared with the Ortho All-Flex diaphragm due to users' inability to insert or remove the device. Similar findings were reported in a study from Canada that examined the cervical cap. Many of the women in this study were very satisfied with the cervical cap but had problems such as dislodgement and difficulty with insertion and removal.[22] The cohort study by Schwartz[3] compared the Caya with the Ortho All-Flex diaphragm and

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found no difference in the 6-month pregnancy rate. In addition, there did not appear to be any noticeable differences between the acid-buffering gel and nonoxynol-9 gel, although this was not the research aim of the study. Similar results were achieved in a non-inferiority trial[20] that demonstrated that the acid-buffering gel was not less effective. This is comparable with a postcoital test study by Mauck[23] comparing Caya used with 3% nonoxynol-9 gel, Contragel or no gel. The study concluded that Caya is safe and functions with both gels in preventing progressively motile sperm from reaching cervical mucus. There have been discussions as to whether the cervical cap would result in fewer UTIs when comparing it with diaphragms. This suggestion was due to the potential risk that a diaphragm could put pressure on the urethra. In two of the studies[3 19] there were significantly fewer UTI complications among FemCap and Caya users compared with diaphragm users.

In the Mauck study[23] the use of the Caya barrier alone without any spermicide reduced sperm penetration in cervical mucus suggesting that the barrier function of the Caya alone may be largely responsible for its contraceptive effect. Our literature search did not identify any studies that evaluated the efficacy and safety of using female barriers without any gel compared with acid-buffering gel.

The risk of unplanned pregnancy is high with these barrier methods due to dissatisfaction-related discontinuation. A study population, drawn from the 2002 National Survey of Family Growth, consisted of 6724 women (aged 15–44 years) who had ever used a reversible contraceptive method. Nearly half of the women had ever discontinued at least one method due to user dissatisfaction. The most discontinued methods were the diaphragm and cervical cap (52%).[24]

The strengths of this systematic review are the strictly applied routines including a comprehensive search and data extraction performed by several independent authors. Confidence in the results for each outcome has been evaluated across studies, and the certainty of evidence described and incorporated into the conclusions.

Limitations relate to the lack of studies reporting pregnancy as an outcome, and the fact that pooling of data in a meta-analysis for pregnancy outcome was not possible due to heterogenous reporting, for example, regarding duration of follow-up and typical use or not.

The low number of conducted and published studies may be explained by the difficulties in recruiting a sufficient number of individuals to these types of studies, since participating women will be exposed to the risk of unwanted pregnancy. A problem with these studies was also their high withdrawal rates based on low compliance. The latter was due to difficulties in inserting and removing the new barriers.[19] The results in the Schwartz study[3] suggest that if a trained provider initially could have assessed the fitness of the device for first-time users, almost all the women would be able to insert and remove the single-size diaphragm. Improved instructions have also been developed to increase the proportion of successful users and increased compliance.

CONCLUSIONS

No differences in contraceptive effect were demonstrated when comparing the new and old types of female barrier contraceptives Acid-buffering gel probably improves the discontinuation rate in comparison with nonoxynol-9 gel. These findings are important for women who desire to use barrier contraceptive methods as well as for prescribing medical professionals. Both the efficacy and safety of these different barrier methods requires evaluation.

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