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Mechanical dilatation of the cervix during elective caesarean section before the onset of labour for reducing postoperative morbidity (Review)

Liabsuetrakul T, Peeyananjarassri K

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[Intervention Review]

Mechanical dilatation of the cervix during elective caesarean section before the onset of labour for reducing postoperative morbidity

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ABSTRACT

Background

During elective (planned) caesarean sections, some obstetricians routinely dilate the cervix intraoperatively, using sponge forceps, a finger, or other instruments, because the cervix of women not in labour may not be dilated, and this may cause obstruction of blood or lochia drainage. However, mechanical cervical dilatation during caesarean section may result in contamination by vaginal micro-organisms during dilatation, and increase the risk of infection or cervical trauma.

Objectives

To determine the effects of mechanical dilatation of the cervix during elective caesarean section on postoperative morbidity.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register, [ClinicalTrials.gov](https://www.clinicaltrials.gov), the WHO International Clinical Trials Registry Platform (ICTRP) and reference lists of retrieved studies on 20 September 2017.

Selection criteria

We included all randomised, quasi-randomised, and cluster-randomised controlled trials comparing intraoperative cervical dilatation using a finger, sponge forceps, or other instruments during elective caesarean section versus no mechanical dilatation.

Data collection and analysis

Two review authors independently assessed trials for inclusion and risk of bias, extracted data and checked them for accuracy. We assessed the quality of the evidence using the GRADE approach.

Main results

We included eight studies with a total of 2227 women undergoing elective caesarean section. Of these, 1097 underwent intraoperative cervical dilatation with a double-gloved index finger or Hegar dilator inserted into the cervical canal to dilate, and 1130 did not undergo intraoperative cervical dilatation. Six of the eight included trials had high risk of bias for some of the risk of bias domains.

Very low-quality evidence suggested it was unclear whether cervical dilatation had any impact on postpartum haemorrhage (estimated blood loss greater than 1000 mL; risk ratio (RR) 1.97, 95% confidence interval (CI) 0.48 to 8.13; 5/205 versus 3/242; one study, 447 women).

Low- or very low-quality evidence showed no clear difference for the need for blood transfusion (RR 3.54, 95% CI 0.37 to 33.79; two studies, 847 women); postoperative haemoglobin (mean difference (MD) -0.05, 95% CI -0.15 to 0.06; three studies, 749 women), or haematocrit (MD 0.01%, 95% CI -0.18 to 0.20; one study, 400 women); the incidence of drop from baseline haemoglobin above 0.5 g/dL (RR 0.92, 95% CI 0.64 to 1.31; two studies, 722 women), or amount of haemoglobin drop (MD -0.01 g/dL, 95% -0.14 to 0.13; three studies, 796 women); the incidence of secondary postpartum haemorrhage within six weeks (RR 1.18, 95% CI 0.07 to 18.76; one study, 447 women); febrile morbidity (RR 1.18, 95% CI 0.76 to 1.85; seven studies, 2126 women); endometritis (RR 0.94, 95% CI 0.35 to 2.52; four studies, 1536 women); or uterine subinvolution (RR 0.34, 95% CI 0.08 to 1.36; two studies, 654 women); the results crossed the line of no effect for all of the outcomes. There were no data for cervical trauma.

We found a slight improvement with mechanical dilatation for these secondary outcomes, not prespecified in the protocol: mean blood loss, endometrial cavity thickness, retained products of conception, distortion of uterine incision, and healing ratio. The evidence for these outcomes was based on one or two studies. Cervical dilatation did not have a clear effect on these secondary outcomes, not prespecified in the protocol: wound infection, urinary tract infection, operative time, infectious morbidity, and integrity of uterine scar.

Authors' conclusions

At this time, the evidence does not support or refute the use of mechanical dilatation of the cervix during elective caesarean section for reducing postoperative morbidity.

Further large, well-designed studies are required to compare the effect of intraoperative mechanical dilatation of the cervix with no intraoperative mechanical cervical dilatation for reducing postoperative morbidity.

PLAIN LANGUAGE SUMMARY

Artificial opening of the cervix during a planned caesarean section before the start of labour for reducing postoperative problems

What is the issue?

The cervix is the narrow neck-like passage at the lower end of the uterus that enters into the vagina. A woman's cervix is firm and undilated at the beginning of pregnancy, but progressively softens, all the way to term. The progressive opening, or dilatation, of the cervix occurs with uterine contractions during labour. Mechanical dilatation of the cervix at caesarean section, before onset of labour, is the artificial opening of the cervix. It is done by the surgeon, using a gloved finger, sponge forceps, or other surgical instruments.

Why is this important?

Some obstetricians believe that dilating the cervix helps the drainage of blood from the uterus, following birth by planned caesarean section before the onset of labour. Increased drainage may reduce the risk of intrauterine infection and postpartum haemorrhage. On the other hand, mechanically opening the cervix could result in contamination of the uterus with vaginal micro-organisms, and increase the risk of infections or cervical trauma. We set out to determine the effects of mechanical dilatation of the cervix during a planned caesarean section before the onset of labour on postoperative blood loss and uterine infection, when compared with no mechanical dilatation.

What evidence did we find?

We searched for evidence from randomised controlled trials in September 2017. We identified eight studies with a total of 2227 women undergoing elective (planned) caesarean section before the onset of labour. Of these women, 1097 underwent cervical dilatation with a double-gloved index finger, or in one study with a Hegar dilator, during surgery, while 1130 did not undergo cervical dilatation during surgery.

Low- or very low-quality evidence suggested it was unclear whether cervical dilatation had any impact on postpartum haemorrhage (estimated blood loss greater than 1000 mL), the need for blood transfusion, and other measures of blood loss, postpartum haemorrhage within six weeks, febrile morbidity (infection indicated by increased temperature over a defined time period), endometritis (infection of the lining of the womb), or uterine subinvolution (uterus not returning to its normal size after childbirth). There were no data for cervical trauma.

We found a slight improvement with mechanical dilatation for some outcomes that had not been specified in our original protocol, but the evidence for these outcomes was based on one or two studies (mean blood loss, endometrial cavity thickness, retained products of conception, distortion of uterine incision, and healing ratio). Cervical dilatation did not have a clear effect on other secondary outcomes, (again not specified in our original protocol): wound infection, urinary tract infection, operative time, infectious morbidity, and integrity of uterine scar.

What does this mean?

It is uncertain whether cervical dilatation has any impact on reducing postoperative problems after caesarean section. This means there is insufficient evidence to encourage or discourage the use of mechanical dilatation of the cervix at elective caesarean section for reducing postoperative ill-health.

SUMMARY OF FINDINGS

Summary of findings for the main comparison. Cervical dilatation versus no dilatation for reducing postoperative morbidity

Manual cervical dilatation versus no dilatation for reducing postoperative morbidity

Patient or population: women with non-labour caesarean section
Settings: hospital settings in Germany, Egypt, Qatar, Turkey, and Nigeria
Intervention: manual cervical dilatation

Comparison: no dilatation

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)	Comments
	Assumed risk	Corresponding risk				
	Control	Cervical dilatation versus no dilatation				
Postpartum haemorrhage (blood loss at least 1000 mL; immediately post section or delayed, visual estimation)	Study population		RR 1.97 (0.48 to 8.13)	447 (1 study)	⊕⊕⊕⊕ very-low ^{a,b,c}	
	12 per 1000	24 per 1000 (6 to 98)				
	Medium risk population					
	12 per 1000	24 per 1000 (6 to 98)				
Need for blood transfusion (within 24 hours post caesarean section)	Study population		RR 3.54 (0.37 to 33.79)	847 (2 studies)	⊕⊕⊕⊕ very-low ^{a,d}	
	2 per 1000	7 per 1000 (1 to 68)				
	Medium risk population					
	2 per 1000	7 per 1000 (1 to 68)				
Drop from baseline haemoglobin > 0.5 g/dL	Study population		RR 0.92 (0.64 to 1.31)	722 (2 studies)	⊕⊕⊕⊕ low ^{a,c}	
	163 per 1000	150 per 1000 (104 to 214)				

	Medium risk population 223 per 1000 205 per 1000 (143 to 292)			
Secondary postpartum haemorrhage (within 6 weeks postpartum)	Study population	RR 1.18	447	⊕⊕⊕⊕
	4 per 1000 5 per 1000 (0 to 75)	(0.07 to 18.76)	(1 study)	very-low ^{a,b,c}
	Medium risk population			
	4 per 1000 5 per 1000 (0 to 75)			
Febrile morbidity (at least 38° Celsius, measured on 2/10 days postpartum)	Study population	RR 1.18	2126	⊕⊕⊕⊕
	31 per 1000 37 per 1000 (24 to 57)	(0.76 to 1.85)	(7 studies)	low ^{a,c}
	Medium risk population			
	21 per 1000 25 per 1000 (16 to 39)			
Endometritis	Study population	RR 0.94	1536	⊕⊕⊕⊕
	11 per 1000 10 per 1000 (4 to 28)	(0.35 to 2.52)	(4 studies)	very-low ^{a,d}
	Medium risk population			
	6 per 1000 6 per 1000 (2 to 15)			
Uterine subinvolution	Study population	RR 0.34	654	⊕⊕⊕⊕
	23 per 1000 8 per 1000 (2 to 31)	(0.08 to 1.36)	(2 studies)	very-low ^{a,d}
	Medium risk population			
	19 per 1000 6 per 1000			

(2 to 26)

*The basis for the **assumed risk** (e.g. the median control group risk across studies) is provided in footnotes. The **corresponding risk** (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RR:** Risk ratio;

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

^aHigh risk of bias for some of domains (-1)

^bOne study with small number of events (-1)

^cWide confidence interval crossing the line of no effect (-1)

^dSmall number of events and wide cross interval crossing the line of no effect (-2)

BACKGROUND

Description of the condition

Non-labour elective caesarean section has increased in low-, middle-, and high-income countries due to the indication of repeated caesarean or breech presentation ([Chanhasenanont 2007](#); [Lydon-Rochelle 2006](#); [Swende 2007](#); [Van Roosmalen 1995](#)). Vaginal birth after caesarean section is still a less common practice in low- and middle-income countries ([Chanrachakul 2000](#); [Van der Walt 1994](#)).

In one study on caesarean delivery for term breech, the puerperal morbidity following elective caesarean section (caesarean section before labour starts) were lower than for emergency caesarean section (after labour starts) in terms of puerperal fever or pelvic infection (1.5% versus 2.3%), and anaemia and/or haemorrhage (5.7% versus 7.0%) ([Krebs 2003](#)). Similarly, in another study, postpartum haemorrhage was reported at 4.84% in elective and 6.75% in non-elective caesarean sections ([Magann 2005](#)). Another study indicated that women undergoing caesarean section without labour were less likely to have early postpartum haemorrhage compared with women undergoing induction of labour, but they found no difference in wound infection, puerperal febrile morbidity, blood transfusion, or intraoperative trauma ([Allen 2006](#)). [Chongsuvivatwong 2010](#) found that when they evaluated complications after deliveries between vaginal delivery and caesarean section, fever, minor wound infection, peritonitis, urinary problems, and haemorrhage were more common in elective caesarean section than in vaginal delivery. In addition, [Liu 2007](#) found elective caesarean section increased the overall risk of severe morbidity, major puerperal infection, wound disruption, wound hematoma, haemorrhage requiring hysterectomy, any hysterectomy, or other complications, such as anaesthetic complications, cardiac arrest, or thromboembolism.

Description of the intervention

A woman's cervix is firm and undilated at the beginning of pregnancy, but progressive remodeling occurs during gestation, until the cervix is soft at term, especially the nulliparous cervix ([Myers 2008](#)). The progressive dilatation of the cervix needs uterine contraction during labour. A mechanical dilatation of the cervix during non-labour elective caesarean section is defined as an artificial dilatation of the cervix performed by finger, sponge forceps, or other instruments.

How the intervention might work

Some obstetricians believe that the cervix of women at non-labour caesarean section is undilated and might cause obstruction of blood or lochia drainage, leading to postpartum haemorrhage and endometritis from collection of lochia or debris. Dilatation of the cervix helps with the drainage of blood during postpartum, reducing intrauterine infection or the risk of postpartum haemorrhage. To avoid this problem, some obstetricians routinely dilate the cervix from above during an elective, non-labour caesarean section using finger, sponge forceps, or other instruments. A comparative study at Mir Hosseini Hospital in Iran, found lower incidence of postoperative endometritis in women who underwent elective caesarean section with cervical dilatation using a ring forcep (5.7%) compared with women who did not receive cervical dilatation (16.8%) ([Malkamy 1995](#)). Collection of blood in the intrauterine cavity and distended

uterus in women after elective caesarean section due to repeated sections was reported in two cases, and dilatation and evacuation were needed for treatment ([Bollapragada 2002](#)). However, this has not been proven in clinical trials. In contrast, mechanical cervical dilatation using sponge forceps or a finger during caesarean section may result in contamination by vaginal micro-organisms during dilatation, and increase the risk of infection or cervical trauma. A study found that a positive culture at the lower uterine segment predicted postpartum endometritis ([Sherman 1999](#)).

Why it is important to do this review

The information currently available about the advantages of cervical dilatation at caesarean section is inconclusive. Therefore, evidence to support the effectiveness or safety of cervical dilatation at caesarean section is needed. This is an update a review, first published in [Liabsuetrakul 2011](#).

OBJECTIVES

To determine the effects of mechanical dilatation of the cervix during elective caesarean section on postoperative morbidity.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised, quasi-randomised, or cluster-randomised controlled trials comparing cervical dilatation during caesarean section to no intervention.

Types of participants

All women underwent non-labour elective caesarean section for any indications, regardless of degree of cervical dilatation.

Types of interventions

Mechanical dilatation of the cervix using a finger, sponge forceps, or other instrument during non-labour caesarean section versus no mechanical dilatation.

Types of outcome measures

Primary outcomes

1. Postpartum haemorrhage: estimated blood loss greater than 1000 mL immediately or delayed after caesarean section

Secondary outcomes

1. Need for blood transfusion: blood transfusion given during or within 24 hours after caesarean section
2. Hematocrit or haemoglobin concentration: concentration of hematocrit or haemoglobin at postoperative period, or the change in concentration compared to preoperative or baseline level
3. Secondary postpartum haemorrhage: late vaginal bleeding, within six weeks postpartum
4. Febrile morbidity: temperature of 38 degrees Celsius or higher on any two of the first 10 days postpartum, exclusive of the first 24 hours, of unknown causes

5. Endometritis: febrile morbidity due to intrauterine infection, clinically diagnosed by fever, uterine tenderness, foul-smelling discharge, or a combination
6. Cervical trauma: signs of vaginal bleeding due to the tear of cervical tissue from mechanical dilatation
7. Uterine subinvolution: delayed or absent involution of the uterus during the postpartum period

Based on the included studies in the first version of this review, we added these secondary outcomes.

1. Blood loss: estimated blood loss recorded during and immediately after caesarean section
2. Wound infection: presence of purulent or serous wound discharge with induration, warmth, and tenderness
3. Urinary tract infection: clinical signs plus identification of micro-organisms of 10^5 on culture
4. Operative time: duration of operative time

Based on the ongoing studies identified after searching the trial registers for this update of the review, we added these secondary outcomes.

1. Infectious morbidity: rate of endometritis, wound infection, febrile morbidity, and urinary tract infection.
2. Endometrial cavity thickness: the decidual thickness and the intracavitary fluid collection measured by transabdominal ultrasound in mm
3. Retained products of conception: necessity of oxytocin administration, cervical dilatation, or curettage within six weeks
4. Integrity of uterine scar: scar thickness less than 2.3 mm
5. Distortion of uterine incision: any deviation from the full thickness apposition of the anterior uterine wall
6. Healing ratio: anterior wall thickness/anterior wall thickness + height of the wedge-shaped defect

Search methods for identification of studies

The following methods section of this review is based on a standard template used by Cochrane Pregnancy and Childbirth.

Electronic searches

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (20 September 2017).

The Register is a database containing over 24,000 reports of controlled trials in the field of pregnancy and childbirth. It represents over 30 years of searching. For full current search methods used to populate Pregnancy and Childbirth's Trials Register, including the detailed search strategies for CENTRAL, MEDLINE, Embase, and CINAHL, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the [Cochrane Pregnancy and Childbirth](#) in the Cochrane Library, and select the 'Specialized Register' section from the options on the left side of the screen.

Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

1. monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. weekly searches of MEDLINE Ovid;
3. weekly searches of Embase Ovid;
4. monthly searches of CINAHL EBSCO;
5. handsearches of 30 journals and the proceedings of major conferences;
6. weekly current awareness alerts for a further 44 journals, plus monthly BioMed Central email alerts.

Search results are screened by two people, and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set that has been fully accounted for in the relevant review sections ([Included studies](#); [Studies awaiting classification](#)).

In addition, we searched [ClinicalTrials.gov](#) and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned, and ongoing trial reports on 20 September 2017, using the terms given in [Appendix 1](#).

Searching other resources

We searched the reference lists of retrieved studies. We did not apply any language or date restrictions.

Data collection and analysis

For methods used in the previous version of this review, see [Liabsuetrakul 2011](#).

For this update, the following methods were used to assess eight reports that were identified as a result of the updated search, and searching other sources.

The following methods section of this review was based on a standard template used by Cochrane Pregnancy and Childbirth. The process of independent study selection, data extraction, and assessment of risk of bias was completed by two review authors, who used the data extraction form provided by Cochrane Pregnancy and Childbirth.

Selection of studies

Two review authors independently assessed for inclusion, all the potential studies identified as a result of the search strategy. We resolved any disagreement through discussion, or if required, we consulted a third person, a researcher from Cochrane Pregnancy and Childbirth editorial team.

Data extraction and management

Two review authors extracted the data. We resolved discrepancies through discussion or, if required, we consulted the third person. We entered the data into Review Manager 5 software, and checked for accuracy ([RevMan 2014](#)).

When information regarding any of the above was unclear, we had planned to contact authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We resolved disagreement by discussion.

(1) Random sequence generation (checking for possible selection bias)

For each included study, we described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias)

For each included study, we described the method used to conceal allocation to interventions prior to assignment, and assessed whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered, sealed, opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

For each included study, we described the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding was unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

- low, high or unclear risk of bias for participants;
- low, high or unclear risk of bias for personnel.

(3.2) Blinding of outcome assessment (checking for possible detection bias)

For each included study, we described the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

- low, high, or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

For each included study, and for each outcome or class of outcomes, we described the completeness of data, including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups, or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include missing data in the analyses that we undertook.

We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation) or greater than 20% of missing outcome;
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

For each included study, we described how we investigated the possibility of selective outcome reporting bias and what we found.

We assessed the methods as:

- low risk of bias (where it was clear that all of the study's pre-specified outcomes in the methods section and all expected outcomes of interest to the review were reported);
- high risk of bias (where not all the study's pre-specified outcomes were reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

For each included study, we described any important concerns we had about other possible sources of bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high, unclear, or low risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias, and whether it was likely to impact on the findings. We explored the impact of the level of bias through, undertaking sensitivity analyses - see [Sensitivity analysis](#).

Assessment of the quality of the evidence using the GRADE approach

For this update, we assessed the quality of the evidence using the GRADE approach, as outlined in the GRADE handbook, in order to assess the quality of the body of evidence relating to the following outcomes, for the main comparison of cervical dilatation versus no dilatation ([Schünemann 2013](#)).

1. Postpartum haemorrhage: estimated blood loss greater than 1000 mL immediately or delayed after caesarean section
2. Need for blood transfusion: blood transfusion given during or within 24 hours after caesarean section
3. Drop in baseline haemoglobin (g/dL)
4. Secondary postpartum haemorrhage: late vaginal bleeding, within six weeks postpartum
5. Febrile morbidity: temperature of 38 degrees Celsius or higher on any two of the first 10 days postpartum, exclusive of the first 24 hours, of unknown causes.
6. Endometritis: febrile morbidity due to intrauterine infection, clinically diagnosed by fever, uterine tenderness, foul-smelling discharge, or a combination
7. Uterine subinvolution: delayed or absent involution of the uterus during the postpartum period

We used GRADEpro GDT software to import data from Review Manager 5.3, to create the 'Summary of findings' table ([GRADEpro GDT](#)). A summary of the intervention effect and a measure of quality for each of the above outcomes were produced using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness, and publication bias) to assess the quality of the body of evidence for each outcome. The evidence can be downgraded from high quality by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates, or potential publication bias.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratio with 95% confidence intervals.

Continuous data

We used the mean difference, with 95% confidence intervals, if outcomes were measured in the same way between trials. In future updates, if applicable, we will use the standardised mean difference, with 95% confidence intervals, to combine trials that measure the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomised trials

Cluster-randomised trials were eligible, but none were identified in this update. In future updates, if we identify any, we will include cluster-randomised trials in the analyses along with individually randomised trials if there is little heterogeneity between the study designs, and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely. We will adjust the sample sizes of the cluster-randomised trials using the methods described in the *Cochrane Handbook for Systematic*

Reviews of Interventions, using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial, or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. We will also acknowledge heterogeneity in the randomisation unit, and perform a subgroup analysis to investigate the effects of the randomisation unit.

Cross-over trials

This study design is not eligible for inclusion.

Dealing with missing data

We noted levels of attrition for the included studies. In future updates, if we include more eligible studies, we will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect through sensitivity analyses.

For all outcomes, we conducted the analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the τ^2 , I^2 , and χ^2 statistics. We regarded heterogeneity as substantial if I^2 was greater than 30%, and either τ^2 was greater than zero, or the P value was less than 0.10 in the χ^2 test for heterogeneity. If we identified substantial heterogeneity (above 30%), we explored it through prespecified subgroup analyses.

Assessment of reporting biases

In future updates, if there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using Review Manager 5 software ([RevMan 2014](#)). If we did not find heterogeneity, we used fixed-effect meta-analysis to combine data, where it was reasonable to assume that studies were estimating the same underlying treatment effect. We had planned to use subgroup or sensitivity analyses to explore the clinical or methodological heterogeneity, respectively. If we had still detected substantial heterogeneity, we had planned to use random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. We treated the random-effects summary as the average range of possible treatment effects, and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials. If we used random-effects analyses, we presented the results as the average treatment effect with 95% confidence intervals, and the estimates of τ^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

If we identified substantial heterogeneity, we had planned to investigate it using subgroup analyses and sensitivity analyses, and reconsider whether an overall summary was meaningful. If it was, we planned to use random-effects analysis to produce it.

We had planned to carry out the following prespecified subgroup analyses, if available:

1. nulliparous woman versus multiparous woman;
2. no prior caesarean section versus repeat caesarean section;
3. no premature rupture of membrane versus premature rupture of membrane;
4. dilatation with finger versus Hegar dilator.

We had planned to assess subgroup differences by interaction tests available within RevMan 5 ([RevMan 2014](#)). We would have reported

the results of subgroup analyses, quoting the Chi^2 statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We had planned to perform the following sensitivity analysis.

Sensitivity analyses would have included:

1. omission of studies at high risk of bias;
2. repeating analyses using fixed- or random-effects;
3. omission of studies published as abstracts or non-peer reviewed publications

RESULTS

Description of studies

Results of the search

See: [Figure 1](#).

Figure 1. Study flow diagram

Figure 1. (Continued)

synthesis
(meta-analysis) =
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We included three studies previously in [Liabsuetrakul 2011](#) ([Ahmed 2005](#); [Güngördük 2009](#); [Tosun 2011](#)).

An updated search in September 2017 retrieved a further eight relevant reports. One trial registry record was an earlier report of [Tosun 2011](#). We attempted to contact the trialists involved in the [Cengiz 2013](#) study, but have received no reply to date. This study remains in [Studies awaiting classification](#). We included five new studies in this updated review ([Abdelaziz 2014](#); [Ezegwui 2015](#); [Kirscht 2017](#); [Sakinci 2015](#); [Yazicioglu 2012](#)).

Included studies

A total of 2227 women participated in the eight included studies comparing intraoperative cervical dilatation with no cervical dilatation. All studies included both nulliparous and multiparous women, as well as no prior and repeat caesarean section, except one study, which included only nulliparous with no prior caesarean section ([Yazicioglu 2012](#)). Four studies did not specify whether they included rupture of membranes ([Abdelaziz 2014](#); [Ahmed 2005](#); [Ezegwui 2015](#); [Kirscht 2017](#)), and only one study used Hegar dilatation ([Kirscht 2017](#)). Please see the 'Characteristics of included studies' table for further details.

(1) Study location and settings

The studies were conducted in Egypt ([Abdelaziz 2014](#)), Qatar ([Ahmed 2005](#)), Turkey ([Güngördük 2009](#); [Sakinci 2015](#); [Tosun 2011](#); [Yazicioglu 2012](#)), Nigeria ([Ezegwui 2015](#)), and Germany ([Kirscht 2017](#)).

(2) Participants

All participants in the included studies were undergoing non-labour elective caesarean section. Seven studies included a mixture of nulliparous and multiparous women ([Abdelaziz 2014](#); [Ahmed 2005](#); [Ezegwui 2015](#); [Güngördük 2009](#); [Kirscht 2017](#); [Sakinci 2015](#); [Tosun 2011](#)). All eight studies included women with term pregnancies; two studies also included those with gestational ages less than 37 weeks ([Kirscht 2017](#); [Tosun 2011](#)).

The included studies excluded the following categories of women: women undergoing caesarean section due to multiple pregnancies ([Abdelaziz 2014](#); [Ahmed 2005](#); [Sakinci 2015](#); [Tosun 2011](#); [Yazicioglu 2012](#)); preterm births ([Abdelaziz 2014](#); [Ahmed 2005](#); [Güngördük 2009](#); [Sakinci 2015](#); [Tosun 2011](#); [Yazicioglu 2012](#)); rupture of membranes ([Abdelaziz 2014](#); [Ezegwui 2015](#); [Güngördük 2009](#); [Sakinci 2015](#); [Tosun 2011](#); [Yazicioglu 2012](#)); evidence of infection ([Ezegwui 2015](#); [Güngördük 2009](#); [Kirscht 2017](#); [Sakinci 2015](#); [Tosun 2011](#)); placenta previa ([Abdelaziz 2014](#); [Ezegwui 2015](#); [Sakinci 2015](#)); maternal diseases such as anaemia or diabetes mellitus ([Abdelaziz 2014](#); [Ezegwui 2015](#); [Güngördük 2009](#); [Sakinci 2015](#)), and need for blood transfusion before or during caesarean section ([Güngördük 2009](#); [Sakinci 2015](#); [Tosun 2011](#)).

(3) Interventions

All included studies compared intraoperative cervical dilatation by the insertion of a double-gloved index finger ([Abdelaziz 2014](#); [Ahmed 2005](#); [Ezegwui 2015](#); [Güngördük 2009](#); [Sakinci 2015](#); [Tosun 2011](#); [Yazicioglu 2012](#)), or Hegar dilator ([Kirscht 2017](#)), into the cervical canal to dilate it (the outer glove was removed after digital dilatation), with no intraoperative cervical dilatation.

(4) Outcomes

One study reported the primary outcome of postpartum haemorrhage of at least of 1000 mL ([Kirscht 2017](#)).

Two studies measured the need for blood transfusion ([Güngördük 2009](#); [Kirscht 2017](#)). Six studies reported haematocrit or haemoglobin levels, but in various terms, as levels of haematocrit or haemoglobin at postoperative period, or the change of level compared to preoperative or baseline level ([Abdelaziz 2014](#); [Ahmed 2005](#); [Güngördük 2009](#); [Kirscht 2017](#); [Sakinci 2015](#); [Tosun 2011](#)). One study reported on secondary postpartum haemorrhage ([Kirscht 2017](#)). Seven studies measured febrile morbidity ([Abdelaziz 2014](#); [Ahmed 2005](#); [Ezegwui 2015](#); [Güngördük 2009](#); [Kirscht 2017](#); [Sakinci 2015](#); [Tosun 2011](#)). Four studies identified endometritis ([Abdelaziz 2014](#); [Güngördük 2009](#); [Kirscht 2017](#); [Tosun 2011](#)). Two studies reported uterine subinvolution ([Ezegwui 2015](#); [Kirscht 2017](#)), and no study reported on cervical trauma.

We also reported on the following outcomes that were not prespecified in our protocol: blood loss ([Güngördük 2009](#)), wound infection ([Abdelaziz 2014](#); [Ahmed 2005](#); [Güngördük 2009](#); [Kirscht 2017](#); [Tosun 2011](#)), urinary tract infection ([Güngördük 2009](#); [Kirscht 2017](#)), infectious morbidity ([Güngördük 2009](#)), operative time ([Abdelaziz 2014](#); [Güngördük 2009](#); [Kirscht 2017](#); [Sakinci 2015](#)), endometrial cavity thickness ([Sakinci 2015](#); [Tosun 2011](#)), retained products of conception ([Kirscht 2017](#)), integrity of uterine scar ([Abdelaziz 2014](#)), and distortion of uterine incision and healing ratio ([Yazicioglu 2012](#)).

(5) Dates of study, funding sources and declarations of interest

Dates when the studies were conducted were reported as: 16 November 2002 to 25 February 2003 ([Ahmed 2005](#)); December 2002 to March 2005 ([Yazicioglu 2012](#)); June 2007 to December 2007 ([Güngördük 2009](#)); 22 July 2008 to 15 September 2009 ([Tosun 2011](#)); November 2011 to July 2013 ([Kirscht 2017](#)); February 2013 to September 2014 ([Abdelaziz 2014](#)); and March 2013 to February 2014 ([Sakinci 2015](#)). Study dates were not reported in one study ([Ezegwui 2015](#)).

One study declared there was no funding ([Kirscht 2017](#)). Funding sources were not reported for the remaining seven studies.

Declarations of interest of trial authors were reported that 'all authors declare no conflict of interest' in four studies ([Ezegwui 2015](#); [Kirscht 2017](#); [Sakinci 2015](#); [Tosun 2011](#)). There was no

information on declarations of interest in four studies ([Abdelaziz 2014](#); [Ahmed 2005](#); [Güngördük 2009](#); [Yazicioglu 2012](#)).

Please see the '[Characteristics of included studies](#)' table for further details.

Excluded studies

There were no excluded studies.

Risk of bias in included studies

A summary of the risk of bias judgements that we made for each included study is presented in [Figure 2](#) and [Figure 3](#). In conclusion, one study had a high overall risk of bias ([Ahmed 2005](#)), two studies we judged to be unclear risk of bias ([Abdelaziz 2014](#); [Ezegwui 2015](#)), and five studies at low risk of bias ([Güngördük 2009](#); [Kirscht 2017](#); [Sakinci 2015](#); [Tosun 2011](#); [Yazicioglu 2012](#)).

Figure 2. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Abdelaziz 2014	?	?	+	?	+	+	-
Ahmed 2005	-	-	+	?	?	+	-
Ezegwui 2015	?	?	+	?	+	+	+
Güngördük 2009	+	?	+	-	+	+	+
Kirsch 2017	+	+	+	+	+	+	-
Sakinci 2015	+	+	+	+	-	+	+
Tosun 2011	+	?	+	?	+	+	+
Yazicioglu 2012	+	?	+	+	-	+	+

Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies

Allocation

Five of eight studies had adequate random sequence generation, and we rated them as having a low risk of bias for random sequence (Güngördük 2009; Kirscht 2017; Sakinci 2015; Tosun 2011; Yazicioglu 2012). Random sequence was unclear in two studies (Abdelaziz 2014; Ezegwui 2015). Ahmed 2005 used alternation, in which the sequence was predictable and unconcealed, leading to a high risk of bias for selection bias.

We rated allocation concealment as being of unclear risk of bias for five studies (Abdelaziz 2014; Ezegwui 2015; Güngördük 2009; Tosun 2011; Yazicioglu 2012). Güngördük 2009 used sealed envelopes, but did not state whether they were opaque or consecutively numbered. Two studies had adequate allocation concealment, and we rated them as a low risk of bias (Kirscht 2017; Sakinci 2015).

Blinding

All studies compared the intervention to no intervention. It was not feasible to blind the intervention, but the outcome was not likely to be influenced by lack of blinding; thus we rated all studies as low risk of performance bias.

We rated three of the eight studies as a low risk of detection bias, because the outcomes were assessed in a blinded manner (Kirscht 2017; Sakinci 2015; Yazicioglu 2012). We rated one study as high risk, as procedure allocation was recorded in the women's charts (Güngördük 2009). The other four studies had insufficient information to permit judgement (Abdelaziz 2014; Ahmed 2005; Ezegwui 2015; Tosun 2011).

Incomplete outcome data

Five of the eight studies reported no or low losses to follow-up (Abdelaziz 2014; Ezegwui 2015; Güngördük 2009; Kirscht 2017; Tosun 2011), but Ahmed 2005 did not mention whether any data were missing. Two studies had a high risk of bias due to losses to follow-up greater than 20%, or reasons for missing an outcome was likely to be related to the true outcome (Sakinci 2015; Yazicioglu 2012).

Selective reporting

All included studies were judged to be at low risk. For a study, all outcomes were reported as in the study protocol published (Kirscht 2017). For the remaining seven studies, the study protocols were not found, but the prespecified outcomes mentioned in the methods section were reported thus they were also judged as low risk (Abdelaziz 2014; Ahmed 2005; Ezegwui 2015; Güngördük 2009; Sakinci 2015; Tosun 2011; Yazicioglu 2012).

Other potential sources of bias

Five studies did not appear to be at risk of other sources of bias (Ezegwui 2015; Güngördük 2009; Sakinci 2015; Tosun 2011; Yazicioglu 2012), but three studies had substantial discrepancies in numbers of participants reported (Abdelaziz 2014; Ahmed 2005; Kirscht 2017). Abdelaziz 2014 presented unbalanced samples without details of allocation ratio, including 299 cases with cervix opened, and other 240 cases with unopened cervix. The number of samples in the abstract and methods showing 67 and 64 in cervical dilatation and no dilatation, but in the results, they presented 62 and 121 in cervical dilatation and no dilatation for the outcome of febrile morbidity (Ahmed 2005). Kirscht 2017 described the randomisation of 1:1 allocation but the results showed 205 women with cervical dilatation and 242 women without dilatation.

Effects of interventions

See: [Summary of findings for the main comparison Cervical dilatation versus no dilatation for reducing postoperative morbidity](#)

Cervical dilatation versus no dilatation

Primary outcomes

One study reported on postpartum haemorrhage (estimated blood loss greater than 1000 mL (Kirscht 2017)). It was uncertain whether mechanical dilatation during caesarean section had any impact on the risk of postpartum haemorrhage (risk ratio (RR) 1.97, (95% confidence interval (CI) 0.48 to 8.13; 5/205 versus 3/242; one study, 447 women; very low-quality evidence; [Analysis 1.1](#)). The quality of

the evidence was downgraded due to limitations in study design and imprecision.

Secondary outcomes

Note that infectious morbidity was reported differently in seven included studies (febrile morbidity, endometritis, wound infection, urinary tract infection, infectious morbidity; see [Characteristics of included studies](#)); we included these outcomes at different stages of the review process, as explained below.

1. It was uncertain whether cervical dilatation increased the need for blood transfusions during or within 24 hours following caesarean section (RR 3.54, 95% CI 0.37 to 33.79; two studies, 847 women; very low-quality evidence; [Analysis 1.2](#) (Güngördük 2009; Kirscht 2017)). The quality of the evidence was downgraded for limitations in study design and imprecision (small number of events and wide CIs crossing the line of no effect).
2. There was no clear effect seen in postoperative haemoglobin concentrations (MD -0.05 g/dL, 95% CI -0.15 to 0.06; three trials, 749 women; [Analysis 1.3](#) (Güngördük 2009; Sakinci 2015; Tosun 2011)); postoperative hematocrit concentrations (MD 0.01%, 95% CI -0.18 to 0.20; one trial, 400 women; [Analysis 1.4](#) (Güngördük 2009)); incidence of postoperative drop from baseline in haemoglobin > 0.5 g/dL (RR 0.92, 95% CI 0.64 to 1.31; two studies, 722 women; low-quality evidence; [Analysis 1.5](#) (Abdelaziz 2014; Ahmed 2005)); or postoperative drop from baseline in mean haemoglobin (MD -0.01, 95% CI -0.14 to 0.13; three studies, 796 women; [Analysis 1.6](#) (Kirscht 2017; Sakinci 2015; Tosun 2011)).
3. In one study of 447 women, cervical dilatation did not have a clear effect on secondary postpartum haemorrhage, measured within six weeks postpartum (RR 1.18, 95% CI 0.07 to 18.76; very low-quality evidence; [Analysis 1.7](#) (Kirscht 2017)).
4. There was no clear effect of dilatation on febrile morbidity: RR 1.18, 95% CI 0.76 to 1.85; seven studies, 2126 women; low-quality evidence; [Analysis 1.8](#) (Abdelaziz 2014; Ahmed 2005; Ezegwui 2015; Güngördük 2009; Kirscht 2017; Sakinci 2015; Tosun 2011);
5. There was no clear effect of dilatation on endometritis: RR 0.94, 95% CI 0.35 to 2.52; four studies, 1536 women; very low-quality evidence; [Analysis 1.9](#) (Abdelaziz 2014; Güngördük 2009; Kirscht 2017; Tosun 2011);
6. No study reported the outcome of cervical trauma.
7. Cervical dilatation did not have a clear impact on uterine subinvolution (RR 0.34, 95% CI 0.08 to 1.36; two studies, 654 women; very low-quality evidence; [Analysis 1.10](#) (Ezegwui 2015; Kirscht 2017)).

Based on the included studies in the first version of this review, we added these secondary outcomes.

1. In one study of 400 women, blood loss was reduced in the dilatation group compared with the no dilatation group (mean difference (MD) -48.49 mL, 95% CI -88.75 to -8.23; [Analysis 1.11](#) (Güngördük 2009)).
2. There was no clear difference in wound infection between groups: RR 1.13, 95% CI 0.44 to 2.90; random-effects, $\tau^2 = 0.49$, $I^2 = 71\%$; 37/841 versus 33/878; [Analysis 1.12](#) (Abdelaziz 2014; Ahmed 2005; Güngördük 2009; Kirscht 2017; Tosun 2011)).

3. There was no clear difference in urinary tract infection between groups: RR 0.92, 95% CI 0.34 to 2.53; two studies, 847 women; [Analysis 1.13](#) (Güngördük 2009; Kirscht 2017);
4. Cervical dilatation did not have a clear effect on the operative time of 1585 women in four studies (MD -0.05 minutes, 95% CI -2.62 to 2.53; random-effects, $\tau^2 = 6.23$, $I^2 = 95\%$; [Analysis 1.14](#) (Abdelaziz 2014; Güngördük 2009; Kirscht 2017; Sakinci 2015)).

Based on the new and ongoing studies identified during the searches for this update of the review, we added these secondary outcomes.

1. There was no clear difference in infectious morbidity between groups: RR 0.91, 95% CI 0.51 to 1.61; one study, 400 women; [Analysis 1.15](#) (Güngördük 2009).
2. Endometrial cavity thickness was slightly reduced in the dilatation group compared to the no dilatation group (MD -1.89, 95% CI -3.30 to -0.48; random-effects, $\tau^2 = 0.84$, $I^2 = 81\%$; two studies, 349 women; [Analysis 1.16](#) (Sakinci 2015; Tosun 2011)).
3. There was lower rate of retained product of conception in the dilatation group than in the no dilatation group (RR 0.04, 95% CI 0.00 to 0.63; 0/205 versus 15/242; one study, 447 women; [Analysis 1.17](#) (Kirscht 2017)).
4. There was no clear difference seen in the integrity (or thickness) of the uterine scar (RR 2.68, 95% CI 0.74 to 9.61; one trial, 539 women; [Analysis 1.18](#) (Abdelaziz 2014)).
5. In the dilatation group, there was lower rate of distortion of the uterine incision (RR 0.35, 95% CI 0.14 to 0.88; one study, 67 women; [Analysis 1.19](#) (Yazicioglu 2012)).
6. In the dilatation group, there was a higher healing ratio (MD 0.35, 95% CI 0.14 to 0.88; one study, 67 women; [Analysis 1.20](#) (Yazicioglu 2012)).

We could not perform subgroup analysis in this review, since nulliparous and multiparous women who underwent primary and repeat caesarean section were included as a total population in all seven studies, except the study by Yazicioglu 2012.

DISCUSSION

Summary of main results

We included eight studies, with a total of 2227 women undergoing elective caesarean section; 1097 with intraoperative cervical dilatation using finger or Hegar dilator, and 1130 without cervical dilatation. Low- or very low-quality evidence suggested it was unclear whether cervical dilatation had any impact on postpartum haemorrhage (estimated blood loss greater than 1000 mL), the need for blood transfusion, postoperative haemoglobin or hematocrit, the incidence or amount of drop from baseline haemoglobin above 0.5 g/dL, secondary postpartum haemorrhage (within six weeks), febrile morbidity, endometritis, or uterine subinvolution; the results crossed the line of no effect for all of the outcomes. There were no data for cervical trauma.

We found a slight improvement with mechanical dilatation for these secondary outcomes, not prespecified in the protocol: mean blood loss, endometrial cavity thickness, retained products of conception, distortion of uterine incision, and healing ratio. The evidence for these outcomes was based on one or two studies. Cervical dilatation did not have a clear effect on these secondary outcomes, not prespecified in the protocol: wound infection,

urinary tract infection, operative time, infectious morbidity, and integrity of uterine scar.

Overall completeness and applicability of evidence

Although there were five studies added in this update to the three already included studies, only one included study reported the primary outcome of postpartum haemorrhage with blood loss at least 1000 mL ([Kirscht 2017](#)). Secondary outcomes not pre-specified in the protocol were reported in this review. Due to substantial heterogeneity, random-effects model on the outcomes of wound infection, operative time and endometrial thickness was performed, but the finding of wound infection from a sensitivity analyses by omission of a study at high risk of bias ([Ahmed 2005](#)) was not changed.

One study showed that a positive culture at the lower uterine segment increased an incidence of endometritis ([Sherman 1999](#)). However, we could not determine whether cervical dilatation was associated with febrile morbidity and endometritis. Further well-designed randomised controlled studies with sufficient sample sizes and adequate methodological quality are needed.

Quality of the evidence

A summary of the 'Risk of bias' judgements that we made for each included study is presented in [Figure 2](#) and [Figure 3](#). In this update, we assessed the quality of evidence considering the study limitations, consistency of effect, imprecision, indirectness, and publication bias for the primary and main secondary outcomes. The quality of the evidence for the seven outcomes presented in [Summary of findings for the main comparison](#) varied from low to very low. We based our downgrading decisions on limitations in study design, small numbers of events, and wide confidence intervals that crossed the line of no effect.

Potential biases in the review process

Two authors independently selected studies, reviewed risks of bias, and extracted data. TL conducted the GRADE quality assessments, and KP reviewed them; there were no discrepancies. None of the authors of this review have any conflict of interest on this issue. We were unable to formally assess publication bias because the number of studies for each outcome was less than 10 studies. We

performed a comprehensive search of the literature in an attempt to identify all relevant published and unpublished randomised trials.

Agreements and disagreements with other studies or reviews

Two descriptive studies reported a lower risk of postoperative endometritis and collection of blood in the intrauterine cavity among women undergoing cervical dilatation with elective caesarean section ([Bollapragada 2002](#); [Malkamy 1995](#)).

A retrospective study showed that cervical dilatation was performed in 34% of women undergoing elective caesarean section, during 2008 to 2011, in a university hospital in Germany ([Berlit 2013](#)). However, strong evidence of the benefits of this procedure is needed before it can be recommended for routine use.

AUTHORS' CONCLUSIONS

Implications for practice

At this time, the evidence does not support or refute the use of mechanical dilatation of the cervix at non-labour elective caesarean section for reducing postoperative morbidity.

Implications for research

Further large, well-designed studies are required to compare the effect of intraoperative mechanical dilatation of the cervix with no intraoperative mechanical cervical dilatation for reducing postoperative morbidity.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Abdelaziz 2014

Methods	Study design: randomised
Participants	Inclusion criteria: all term primigravidas and women undergoing repeat elective caesarean delivery without prior vaginal delivery and with a closed cervix Exclusion criteria: those with emergency caesarean section, preterm deliveries, placenta previa, polyhydramnios, anaemia with haemoglobin below 9 gm/dL, multiple pregnancy, medical diseases, or rupture of membranes Total no. of women: 539 Setting: A Kasr El Aini Hospital, Cairo, Egypt Total study duration: 11 months

Abdelaziz 2014 (Continued)

Interventions	Intervention: opening of the cervical canal was done by the surgeon's double gloved index finger (N = 299). Control: opening of the cervical canal was not done (N = 240).
Outcomes	1. Decreased haemoglobin > 0.5 gm/mL or hematocrit change more than 1.6%. 2. Fever (temperature above 38 degree Celsius). 3. Wound infection (wound swelling, erythema, tenderness, or purulent or serous discharge at 1 week postoperative) 4. Endometritis (uterine tenderness and foul smelling discharge) 5. Integrity of uterine scar (scar thickness below 2.3 mm)
Notes	Dates of study: February 2013 to September 2014 Funding sources: no details given Declarations of interest of trial authors: no details given

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "Five hundred and thirty-nine women undergoing elective caesarean section were included in this randomized controlled trial but process of sequence generation was not described". Comment: insufficient information to permit judgement of low or high risk
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to permit judgement of low or high risk
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "In 299 cases, opening of the cervical canal was done by the surgeon's double gloved index finger and then the outer glove was removed while in 240 cases, this step was omitted." Comment: not blinded for the personnel, but the outcomes were not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: insufficient information to permit judgement of low or high risk
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "Same number of women included and outcomes presented were shown". Comment: no missing outcome data
Selective reporting (reporting bias)	Low risk	Comment: all outcomes prespecified in the methods section were reported.
Other bias	High risk	Quote: "Five hundred and thirty-nine women undergoing elective caesarean section were included in this randomized controlled trial. ....In 299 cases, opening of the cervical canal was done by the surgeon's double gloved index finger.....240 cases, this step was omitted". Comment: the ratio of randomisation was not described and number of samples in both groups were very different

Ahmed 2005

Methods	Study design: quasi-randomised
Participants	Inclusion criteria: all women with an even number admitted for primary or repeat elective caesarean section and use of antibiotic prophylaxis Exclusion criteria: women undergoing emergency lower segment caesarean section, elective caesarean section for multiple pregnancies or preterm caesarean section Total no. of women: 183 Setting: women's hospital in Doha, Qatar Total study duration: 3 months
Interventions	Intervention: intraoperative cervical dilatation by insertion of double-gloved index digit in cervical canal then removed outer gloves (N = 62) Control: no intraoperative cervical dilatation (N = 121)
Outcomes	1. Blood loss: drop in haemoglobin within 48 hours after operation as 0 to 0.5, 0.6 to 1.5 and > 1.5 g/dL 2. Febrile morbidity: body temperature of 38 degree Celsius or over, measured at least twice by sublingual digital devices every 4 hours 3. Wound infection: clinically detected by presence of smelly discharge or bacteriological evidence on a swab of suspicious area of the wound
Notes	In the abstract and method section, the number of women in the intervention and control groups was 67 and 64, respectively. However, the results showed 62 and 121 for febrile morbidity and 63 and 120 for drop in haemoglobin, respectively. We contacted the authors to clarify this inconsistency. The authors replied that 62 and 121 women were randomised into the intervention and control, respectively Dates of study: 16 November 2002 to 25 February 2003 Funding sources: no details given Declarations of interest of trial authors: no details given

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Quote: "Women were randomly allocated....Depending on the senior operator, he or she used dilatation in every second case". Comment: alternate allocation was used
Allocation concealment (selection bias)	High risk	Quote: "Depending on.....second case". Comment: not concealed
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: not blinded for the personnel, but the outcomes were not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: insufficient information to permit judgement of low or high risk

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Ahmed 2005 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Comment: losses to follow-up were not reported
Selective reporting (reporting bias)	Low risk	Comment: all outcomes prespecified in the methods section were reported.
Other bias	High risk	Comment: numbers of participants were reported inconsistently in the trial report (see notes above).

Ezegwui 2015

Methods	Study design: randomised
Participants	Inclusion criteria: nulliparous and multiparous women with term pregnancies who had clear indications for elective caesarean delivery Exclusion criteria: anaemic pregnant women with a packed cell volume < 30%; women who had an intrauterine infection before surgery, e.g. chorioamnionitis; women with prolonged premature rupture of membranes; women with febrile conditions of unknown aetiology; and those women at term who had risk factors for postpartum haemorrhage, e.g. placenta previa Total no. of women: 208 Setting: Enugu, Nigeria Total study duration: no information
Interventions	Intervention: intraoperative cervical dilation with gloved finger index (N = 104) Control: no dilatation (N = 104)
Outcomes	1. Postoperative maternal infection (postoperative pyrexia after 24 hours of surgery, offensive lochia, tenderness over the uterus in those with no fibroids and haematoma) 2. Postoperative blood loss 3. Mean haemoglobin difference between the preoperative and postoperative haemoglobin levels 4. Duration of hospitalisation 5. Rate of uterine involution
Notes	All the participants had prophylactic antibiotics. Dates of study: no details given Funding sources: no details given Declarations of interest of trial authors: all authors declare no conflict of interest

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Quote: "This was a multicentre, double blind, randomised controlled study of two sample groups selected on a ratio of 1:1 but process of sequence generation was not described".

Ezegwui 2015 (Continued)

		Comment: insufficient information to permit judgement of low or high risk
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to permit judgement of low or high risk
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "This was a multicentre, double blind, randomised controlled study of two sample groups selected on a ratio of 1:1". Comment: it was impossible to be blinded because intervention was intraoperative cervical dilation and control was no dilatation. So, no blinding or incomplete blinding, but the review authors judged that the outcomes were not likely to be influenced by lack of blinding.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: insufficient information to permit judgement of low or high risk
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "No missing outcome data". Comment: no missing outcome data
Selective reporting (reporting bias)	Low risk	Comment: all outcomes prespecified in the methods section were reported.
Other bias	Low risk	Comment: the study settings were not clearly defined.

Güngördük 2009

Methods	Study design: randomised
Participants	Inclusion criteria: nulliparous and multiparous women with gestational age > 37 weeks undergoing elective caesarean section Exclusion criteria: use of antibiotics during the last 24 hours, pathology needing to be treated with antibiotics, pre-existing maternal diseases, chorioamnionitis, fever on admission, need of transfusion before or during caesarean section, ruptured membrane, emergency caesarean section, and preterm caesarean section. Total no. of women: 400 Setting: Bakirkoy Women's and Children's teaching hospital, Istanbul, Turkey Total study duration: 7 months
Interventions	Intervention: intraoperative cervical dilatation by insertion of double-gloved index digit into cervical canal to dilate, and removed outer gloves after digital dilatation (N = 200) Control: no intraoperative cervical dilatation (N = 200)
Outcomes	1. Estimated blood loss 2. Hematocrit or haemoglobin level postoperatively and drop 3. Febrile morbidity: body temperature of 38 degree Celsius or over, measured at least 24 hours after caesarean section, and not associated with lower abdominal or pelvic tenderness, and no signs of infection elsewhere. 4. Endometritis: body temperature > 38.5 degree Celsius with concomitant foul smelling discharge or abnormal tendered uterus on bimanual examination

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Güngördük 2009 (Continued)

5. Wound infection: partial or total dehiscence or presence of purulent or serious wound discharge with induration, warmth, and tenderness
6. Urinary tract infection: clinical signs plus urinary analysis showing organisms of $> 10^5$ on culture
7. Infectious morbidity: febrile morbidity, endometritis, wound infection, and urinary tract infection
8. Operative time

Notes

Abstract of this paper reported that operative time was significantly longer in the dilatation group, whereas the text of the paper indicated the reverse. We contacted the authors about this inconsistency, but were unable to resolve the discrepancy. Therefore, we used what was reported in table 2 (main paper and erratum).

Dates of study: June 2007 to December 2007

Funding sources: no details given

Declarations of interest of trial authors: no details given

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Patients were randomised in computer-generated random numbers". Comment: random sequence generation
Allocation concealment (selection bias)	Unclear risk	Quote: "Patient ....in sealed envelopes...allocated enveloped was opened by the clinician just before surgery". Comment: not stated if envelopes were sequentially numbered and opaque
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The investigator was not blinded to the procedure allocation". Comment: personnel not blinded, but the outcomes were not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	Quote: "The procedure allocation was recorded in women's charts". Comment: blinding of outcome assessment probably not done because procedure allocation was recorded in women's charts.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "In both groups, no subjects were lost at two and six weeks of postpartum follow up". Comment: no missing outcome data
Selective reporting (reporting bias)	Low risk	Comment: all outcomes prespecified in the methods section were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Kirscht 2017

Methods

Study design: randomised

Participants

Inclusion criteria: all pregnant women with elective caesarean section

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Kirscht 2017 (Continued)

Exclusion criteria: women with current antibiotic therapy, chorioamnionitis, onset of labour with dilatation of the cervix, and gestational age under 24 weeks of gestation

Total no. of women: 447

Setting: 1 university hospital in Germany

Total study duration: 9 months

Interventions	Intervention: cervix was dilated using a Hegar dilator (N = 205) Control: no dilatation (N = 242)
Outcomes	1. Postpartum haemorrhage (PPH, defined as blood loss of at least 1000 mL) within 6 weeks 2. Retained products of conception (defined as necessity of oxytocin administration, cervical dilatation, or curettage within 6 weeks) 3. Wound infections 4. Puerperal endometritis 5. Haemorrhage with the need of blood transfusions 6. Haemoglobin changes after the operation 7. Uterine subinvolution 8. Puerperal fever 9. Urinary tract infections 10. Operating time 11. Secondary postpartum haemorrhage
Notes	Dates of study: November 2011 to July 2013 Funding sources: there was no funding Declarations of interest of trial authors: all authors declared they had no conflict of interest

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants were randomly allocated by a computer-generated randomization scheme with 1:1 allocation for each arm of the study". Comment: randomised
Allocation concealment (selection bias)	Low risk	Quote: "The author of study replied on this issue "The physician that was responsible for the enrolment did not know the randomization group". Comment: probably concealed
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The women were blinded to the intervention, but due to the nature of the intervention, it was not possible to blind the staff". Comment: no blinding or incomplete blinding, but the review authors judged that the outcomes were not likely to be influenced by lack of blinding.

Kirscht 2017 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The author of study replied on this issue "For outcomes, such as PPH and retained products of conception, they were blinded (patient and physician did not know whether the cervix was dilated or not)". Comment: probably blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "No missing outcome data".
Selective reporting (reporting bias)	Low risk	Comment: the study protocol was available and all of the study's prespecified outcomes were reported
Other bias	High risk	Quote: "Randomization scheme with 1:1 allocation....but the analysis and results showed imbalance of samples as 205 women (dilatation group) and 242 (no dilation group)". Comment: the details of randomisation ratio and number of sample sizes in both groups were different, without reasons described.

Sakinci 2015

Methods	Study design: randomised.
Participants	Inclusion criteria: women having scheduled caesarean delivery (nulliparous women who would undergo their first elective caesarean section and multiparous women who had undergone caesarean section in all the previous pregnancies without any labour pain) Exclusion criteria: multiple pregnancies, emergency caesarean, preterm labour, ruptured membranes, age younger than 18 years, prepregnancy diabetes mellitus, ongoing infection, placenta previa, daily use of immunosuppressive, alcohol and drug abuse, chronic pelvic pain, body mass index (BMI, calculated as weight (kg)/[height (m)]²) more than 35, and need for blood transfusion before or during the caesarean section Total no. of samples: 206 Setting: A Kanuni Sultan Suleyman Teaching and Research Hospital, Istanbul, Turkey Total study duration: 12 months
Interventions	Intervention: the surgeon performed the cervical dilatation by inserting the double-gloved index finger into the cervical canal of the patients after the extraction of placenta and membranes (N = 104) Control: no cervical dilatation (N = 102)
Outcomes	1. Operative time 2. Postoperative haemoglobin level 3. Drop in haemoglobin 4. Endometrial cavity thickness 5. Puerperal fever 6. Days from caesarean to discharge 7. Pain score at 8 hours, 30 hours and 48 hours

Sakinci 2015 (Continued)

Notes

Intravenous 3 g cefuroxime prophylaxis was given (1.5 g before skin incision and 1.5 g 12 hours after the operation). Pain score was an outcome of study, but we did not include it in this systematic review.

Dates of study: March 2013 to February 2014

Funding sources: no details given

Declarations of interest of trial authors: all authors declare no conflict of interest

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Randomisation was computer-generated and the allocation list was stored in a locked room by third parties not otherwise involved in the trial". Comment: randomised
Allocation concealment (selection bias)	Low risk	Quote: "The allocation was concealed in 206 identical, opaque, sequentially numbered sealed envelopes. The appropriately numbered envelope was opened soon before the incision of caesarean delivery and the allocation was shown to the surgeon". Comment: concealed
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Comment: no blinding or incomplete blinding, but the review authors judged that the outcomes were not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The nursing staff and the patients were blinded to the intervention throughout the postoperative period". Comment: probably done for all outcomes assessed
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "Two cases in cervical dilatation group and five cases in non-dilated group were excluded from analysis. The reasons were cervical dilatation not performed in two cases, which were randomized into dilatation group. One case in non-dilated group had dilatation performed, and four cases were lost to follow-up". Comment: reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups
Selective reporting (reporting bias)	Low risk	Comment: all outcomes prespecified in the methods section were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Tosun 2011

Methods	Study design: randomised
Participants	Inclusion criteria: nulliparous women who would undergo their first elective caesarean section at term without any labour pain and multiparous women who had undergone caesarean section in all the previous pregnancies without any labour pain

Tosun 2011 (Continued)

Exclusion criteria: emergency caesarean section, multiple pregnancy, preterm labour, rupture of membrane, repeat caesarean section with labour pain, women felt labour pain before caesarean section, fever on admission, need of blood transfusion before or during caesarean section

Total no. of samples: 150

Setting: Ondokuz Mayıs University Medical Faculty Obstetrics and Gynecology Department, Turkey

Total study duration: 15 months

Interventions	Intervention: intraoperative cervical dilatation by inserting double-gloved index finger into the cervical canal of patients after the extraction of placenta and membrane; the outer glove was removed after the procedure (N = 75) Control: no intraoperative cervical dilatation (N = 75)
Outcomes	1. Haemoglobin concentration in the postoperative period (and drop from baseline) 2. Puerperal fever: body temperature elevations over 38 degree Celsius taken from the axillary region, on 2 occasions more than 6 hours apart, after the first postpartum day 3. Endometritis: foul smelling vaginal discharge, uterine tenderness, fever 4. Wound infection: swelling, erythema, induration, discharge, and tenderness 5. Endometrial cavity thickness: endometrial cavity thickness measured by transabdominal ultrasound
Notes	Intravenous 1 g cefazolin was administered to all patients for prophylaxis half an hour before the operation. Dates of study: 22 July 2008 to 15 September 2009 Funding sources: no details given Declarations of interest of trial authors: all authors declared they had no conflict of interest

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "For randomization, we used random number tables.....". Comment: randomised
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to permit judgement of low or high risk
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "The investigator was not blinded to the procedure allocation". Comment: no blinding or incomplete blinding, but the outcomes were not likely to be influenced by lack of blinding
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Comment: insufficient information to permit judgement of low or high risk
Incomplete outcome data (attrition bias) All outcomes	Low risk	Quote: "One patient was lost to follow-up in both of the groups". Comment: missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups

Tosun 2011 (Continued)

Selective reporting (reporting bias)	Low risk	Comment: all outcomes prespecified in the methods section were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Yazicioglu 2012

Methods	Study design: randomised
Participants	Inclusion criteria: nulliparous patients with term pregnancy scheduled for elective caesarean Exclusion criteria: women with a dilated cervix of > 1 cm, multiparity, active labour, multiple pregnancy, premature rupture of membranes, and prematurity Total no. of women: 94 Setting: a Suleymaniye Maternity Hospital for Research and Training in Istanbul, Turkey Total study duration: 28 months
Interventions	Intervention: digital dilatation of the internal cervical ostium was performed by introducing the forefinger into the cervical canal to form an open passage to the vagina, after the delivery of the fetus and removal of the placenta (N = 48) Control: no cervical dilatation (N = 46)
Outcomes	1. Distortion of uterine incision defined as any deviation from the full thickness apposition of the anterior uterine wall. 2. Healing ratio defined as anterior wall thickness/(anterior wall thickness + height of the wedge-shaped defect)
Notes	Every patient received a prophylactic dose of antibiotics (cefazolin sodium 1 g intramuscular) Dates of study: December 2002 to March 2005 Funding sources: no details given Declarations of interest of trial authors: no details given

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote: "Participants were randomized into 2 groups by using a computer program (Random Number Generator Version 1.0, Segobit software, ...". Comment: randomised
Allocation concealment (selection bias)	Unclear risk	Comment: insufficient information to permit judgement of low or high risk
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Quote: "One group received cervical dilatation, and no dilatation was performed in other group". Comment: no blinding or incomplete blinding, but the outcomes were not likely to be influenced by lack of blinding

Yazicioglu 2012 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Quote: "The ultrasound examination was performed by the same expert physician (H.F.Y.) blinded to the operative procedure". Comment: probably done
Incomplete outcome data (attrition bias) All outcomes	High risk	Quote: "13 in group I (27%) and 14 in group II (30%) were lost to follow-up as patients were referred to our maternity hospital from different cities in our region". Comment: high proportion of patients lost to follow-up
Selective reporting (reporting bias)	Low risk	Comment: all outcomes prespecified in the methods section were reported.
Other bias	Low risk	Comment: the study appeared to be free of other sources of bias

Characteristics of studies awaiting assessment *[ordered by study ID]*
Cengiz 2013

Methods	Study design: randomised
Participants	Inclusion criteria: pregnant women at more than 37 weeks of gestation who had elective caesarean delivery Exclusion criteria: women who received antibiotics during the last 24 hours and had pathology that should be treated with antibiotics, pre-existing maternal diseases, chorioamnionitis, fever on admission, need of transfusion before or during the caesarean section, ruptured membranes, emergency caesarean section, and preterm caesarean section Total no. of women: 400 Setting: Turkey Total study duration: 15 months
Interventions	Intervention: cervix dilated after surgery (N = 200) Control: cervix not dilated after surgery (N = 200)
Outcomes	1. Postpartum endometritis 2. Wound infection 3. Febrile morbidity 4. Urinary tract infection 5. Vaginal discharge 6. Uterine consistency 7. Peritoneal reaction for peritonitis
Notes	This is a protocol from the Clinical Trial Register. The contact person who registered was contacted via email on 7 November 2016, but we have not yet received a response.

DATA AND ANALYSES

Comparison 1. Manual cervical dilatation versus no dilatation

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Postpartum haemorrhage (blood loss at least 1000 mL)	1	447	Risk Ratio (M-H, Fixed, 95% CI)	1.97 [0.48, 8.13]
2 Need for blood transfusion	2	847	Risk Ratio (M-H, Fixed, 95% CI)	3.54 [0.37, 33.79]
3 Postoperative haemoglobin (g/dL)	3	749	Mean Difference (IV, Fixed, 95% CI)	-0.05 [-0.15, 0.06]
4 Postoperative haematocrit (%)	1	400	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.18, 0.20]
5 Drop from baseline haemoglobin > 0.5 g/dL	2	722	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.64, 1.31]
6 Drop from baseline haemoglobin (g/dL)	3	796	Mean Difference (IV, Fixed, 95% CI)	-0.01 [-0.14, 0.13]
7 Secondary postpartum haemorrhage (within 6 weeks)	1	447	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.07, 18.76]
8 Febrile morbidity	7	2126	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.76, 1.85]
9 Endometritis	4	1536	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.35, 2.52]
10 Uterine subinvolution	2	654	Risk Ratio (M-H, Fixed, 95% CI)	0.34 [0.08, 1.36]
11 Blood loss (mL)	1	400	Mean Difference (IV, Fixed, 95% CI)	-48.49 [-88.75, -8.23]
12 Wound infection	5	1719	Risk Ratio (M-H, Random, 95% CI)	1.13 [0.44, 2.90]
13 Urinary tract infection	2	847	Risk Ratio (M-H, Fixed, 95% CI)	0.92 [0.34, 2.53]
14 Operative time (min)	4	1585	Mean Difference (IV, Random, 95% CI)	-0.05 [-2.62, 2.53]
15 Infectious morbidity	1	400	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.51, 1.61]
16 Endometrial cavity thickness (mm)	2	349	Mean Difference (IV, Random, 95% CI)	-1.89 [-3.30, -0.48]
17 Retained products of conception	1	447	Risk Ratio (M-H, Fixed, 95% CI)	0.04 [0.00, 0.63]
18 Integrity of uterine scar	1	539	Risk Ratio (M-H, Fixed, 95% CI)	2.68 [0.74, 9.61]
19 Distortion of uterine incision	1	67	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.14, 0.88]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
20 Healing ratio	1	67	Mean Difference (IV, Fixed, 95% CI)	0.08 [0.03, 0.13]

Analysis 1.1. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 1 Postpartum haemorrhage (blood loss at least 1000 mL).

Analysis 1.2. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 2 Need for blood transfusion.

Analysis 1.3. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 3 Postoperative haemoglobin (g/dL).

Analysis 1.4. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 4 Postoperative haematocrit (%).

Analysis 1.5. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 5 Drop from baseline haemoglobin > 0.5 g/dL.

Analysis 1.6. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 6 Drop from baseline haemoglobin (g/dL).

Analysis 1.7. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 7 Secondary postpartum haemorrhage (within 6 weeks).

Analysis 1.8. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 8 Febrile morbidity.

Analysis 1.9. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 9 Endometritis.

Analysis 1.10. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 10 Uterine subinvolution.

Analysis 1.11. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 11 Blood loss (mL).

Analysis 1.12. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 12 Wound infection.

Analysis 1.13. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 13 Urinary tract infection. **Analysis 1.14. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 14 Operative time (min).** **Analysis 1.15. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 15 Infectious morbidity.** **Analysis 1.16. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 16 Endometrial cavity thickness (mm).**

Analysis 1.17. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 17 Retained products of conception.

Analysis 1.18. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 18 Integrity of uterine scar.

Analysis 1.19. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 19 Distortion of uterine incision.

Analysis 1.20. Comparison 1 Manual cervical dilatation versus no dilatation, Outcome 20 Healing ratio.

APPENDICES

Appendix 1. Search terms for ClinicalTrials.gov and ICTRP

dilatation AND c(a)esarean

WHAT'S NEW

Date	Event	Description
8 November 2018	Amended	Typo in the title corrected.

HISTORY

Protocol first published: Issue 4, 2009

Review first published: Issue 11, 2011

Date	Event	Description
20 September 2017	New search has been performed	Search updated and five new studies included (Abdelaziz 2014 ; Ezegwui 2015 ; Kirscht 2017 ; Sakinci 2015 ; Yazicioglu 2012).
20 September 2017	New citation required and conclusions have changed	The conclusions on prespecified outcomes of the updated version have not changed. Based on the new included studies, we added new, non-prespecified outcomes; cervical dilation appeared to improve healing ratio, and reduce endometrial cavity thickness, retained products of conception, and distortion of uterine incision. There was no clear effect on infectious morbidity or integrity of uterine scar.

CONTRIBUTIONS OF AUTHORS

Tippawan Liabsuetrakul (TL), is guarantor of the review and prepared the first draft of review. Krantarat Peeyanjarassri reviewed and commented on the review. TL revised the final version which was approved by both authors.

DECLARATIONS OF INTEREST

Tippawan Liabsuetrakul: none known

Krantarat Peeyanjarassri: none known

SOURCES OF SUPPORT

Internal sources

- Faculty of Medicine, Prince of Songkla University, Thailand.

External sources

- Senior Research Scholarship, Thailand Research Fund, Thailand.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Only postpartum haemorrhage was retained as a primary outcome. The remaining primary outcomes in the protocol were moved to secondary outcomes. The included studies reported on additional outcomes, which we had not prespecified in the protocol for our review, but we considered to be clinically relevant, and therefore, we added them as secondary outcomes. These additional outcomes were as follows.

- Blood loss: estimated blood loss recorded during and immediately after caesarean section
- Wound infection: presence of purulent or serous wound discharge with induration, warmth, and tenderness
- Urinary tract infection: clinical signs plus identification of micro-organisms of 10^5 on culture
- Operative time: duration of operative time

The methods have been updated to reflect the latest *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011).

In September 2017, we added a search of ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). Based on these results, we added these outcomes.

- Infectious morbidity: rate of endometritis, wound infection, febrile morbidity, and urinary tract infection.
- Endometrial cavity thickness: the decidual thickness and the intracavitary fluid collection measured by transabdominal ultrasound in mm
- Retained products of conception: necessity of oxytocin administration, cervical dilatation, or curettage within six weeks
- Integrity of uterine scar: scar thickness less than 2.3 mm
- Distortion of uterine incision: any deviation from the full thickness apposition of the anterior uterine wall
- Healing ratio: anterior wall thickness/anterior wall thickness + height of the wedge-shaped defect

Subgroup analysis

We added the following subgroup to the methods for this update.

- Dilatation with finger versus Hegar dilator

Sensitivity analysis

In the previous version of the review, we reported that we would use the following outcomes in sensitivity analyses:

- postpartum haemorrhage;
- need of blood transfusion;
- secondary postpartum haemorrhage;
- hematocrit or haemoglobin level;
- febrile morbidity;
- endometritis.

In this update, we changed this to report that 'we will perform sensitivity analyses for all outcomes where substantial heterogeneity is evident'.

A 'Summary of findings' table has been incorporated in this update (2017).

INDEX TERMS

Medical Subject Headings (MeSH)

*Cervix Uteri; *Cesarean Section; Dilatation [*adverse effects] [methods]; Elective Surgical Procedures [adverse effects] [methods]; Endometritis [epidemiology]; Labor Stage, First; Postoperative Complications [epidemiology] [prevention & control]; Postpartum Hemorrhage [epidemiology]; Randomized Controlled Trials as Topic; Surgical Wound Infection [epidemiology]; Urinary Tract Infections [epidemiology]

MeSH check words

Female; Humans; Pregnancy