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Mechanical methods for induction of labour (Review)

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TABLE OF CONTENTS

[Intervention Review]

Mechanical methods for induction of labour

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ABSTRACT

Background

Mechanical methods were the first methods developed to ripen the cervix and induce labour. During recent decades they have been substituted by pharmacological methods. Potential advantages of mechanical methods, compared with pharmacological methods may include reduction in side effects that could improve neonatal outcomes. This is an update of a review first published in 2001, last updated in 2012.

Objectives

To determine the effectiveness and safety of mechanical methods for third trimester (> 24 weeks' gestation) induction of labour in comparison with prostaglandin E2 (PGE2) (vaginal and intracervical), low-dose misoprostol (oral and vaginal), amniotomy or oxytocin.

Search methods

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register, ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP), and reference lists of retrieved studies (9 January 2018). We updated the search in March 2019 and added the search results to the awaiting classification section of the review.

Selection criteria

Clinical trials comparing mechanical methods used for third trimester cervical ripening or labour induction with pharmacological methods.

Mechanical methods include: (1) the introduction of a catheter through the cervix into the extra-amniotic space with balloon insufflation; (2) introduction of laminaria tents, or their synthetic equivalent (Dilapan), into the cervical canal; (3) use of a catheter to inject fluid into the extra-amniotic space (EASI).

This review includes the following comparisons: (1) specific mechanical methods (balloon catheter, laminaria tents or EASI) compared with prostaglandins (different types, different routes) or with oxytocin; (2) single balloon compared to a double balloon; (3) addition of prostaglandins or oxytocin to mechanical methods compared with prostaglandins or oxytocin alone.

Data collection and analysis

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

Main results

This review update includes a total of 113 trials (22,373 women) contributing data to 21 comparisons. Risk of bias of trials varied. Overall, the evidence was graded from very-low to moderate quality. All evidence was downgraded for lack of blinding and, for many comparisons, the effect estimates were too imprecise to make a valid judgement.

Balloon versus vaginal PGE2: there may be little or no difference in **vaginal deliveries not achieved within 24 hours** (average risk ratio (RR) 1.01, 95% confidence interval (CI) 0.82 to 1.26; 7 studies; 1685 women; I^2 = 79%; low-quality evidence) and there probably is little or no difference in **caesarean sections** (RR 1.00, 95% CI 0.92 to 1.09; 28 studies; 6619 women; moderate-quality evidence) between induction of labour with a balloon catheter and vaginal PGE2. A balloon catheter probably reduces the risk of uterine **hyperstimulation with fetal heart rate (FHR) changes** (RR 0.35, 95% CI 0.18 to 0.67; 6 studies; 1966 women; moderate-quality evidence), **serious neonatal morbidity or perinatal death** (RR 0.48, 95% CI 0.25 to 0.93; 8 studies; 2757 women; moderate-quality evidence) and may slightly reduce the risk of a**neonatal intensive care unit (NICU) admission** (RR 0.82, 95% CI 0.65 to 1.04; 3647 women; 12 studies; low-quality evidence). It is uncertain whether there is a difference in **serious maternal morbidity or death** (RR 0.20, 95% CI 0.01 to 4.12; 4 studies; 1481 women) or **five-minute Apgar score < 7** (RR 0.74, 95% CI 0.49 to 1.14; 4271 women; 14 studies) because the quality of the evidence was found to be very low and low, respectively.

Balloon versus low-dose vaginal misoprostol: it is uncertain whether there is a difference in **vaginal deliveries not achieved within 24 hours** between induction of labour with a balloon catheter and vaginal misoprostol (RR 1.09, 95% CI 0.85 to 1.39; 340 women; 2 studies; low-quality evidence). A balloon catheter probably reduces the risk of **uterine hyperstimulation with FHR changes** (RR 0.39, 95% CI 0.18 to 0.85; 1322 women; 8 studies; moderate-quality evidence) but may increase the risk of a **caesarean section** (average RR 1.28, 95% CI 1.02 to 1.60; 1756 women; 12 studies; I^2 = 45%; low-quality evidence). It is uncertain whether there is a difference in **serious neonatal morbidity or perinatal death** (RR 0.58, 95% CI 0.12 to 2.66; 381 women; 3 studies), **serious maternal morbidity or death** (no events; 4 studies, 464 women), both very low-quality evidence, and **five-minute Apgar score < 7** (RR 1.00, 95% CI 0.50 to 1.97; 941 women; 7 studies) and **NICU admissions** (RR 1.00, 95% CI 0.61 to 1.63; 1302 women; 9 studies) both low-quality evidence.

Balloon versus low-dose oral misoprostol: a balloon catheter probably increases the risk of a **vaginal delivery not achieved within 24 hours** (RR 1.28, 95% CI 1.13 to 1.46; 782 women, 2 studies, and probably slightly increases the risk of a **caesarean section** (RR 1.17, 95% CI 1.04 to 1.32; 3178 women; 7 studies; both moderate-quality evidence) when compared to oral misoprostol. It is uncertain whether there is a difference in **uterine hyperstimulation with FHR changes** (RR 0.81, 95% CI 0.48 to 1.38; 2033 women; 2 studies), **serious neonatal morbidity or perinatal death** (RR 1.11, 95% CI 0.60 to 2.06; 2627 women; 3 studies), both low-quality evidence, **serious maternal morbidity or death** (RR 0.50, 95% CI 0.05 to 5.52; 2627 women; 3 studies), very low-quality evidence, **five-minute Apgar scores < 7** (RR 0.71, 95% CI 0.38 to 1.32; 2693 women; 4 studies) and **NICU admissions** (RR 0.82, 95% CI 0.58 to 1.17; 2873 women; 5 studies) both low-quality evidence.

Authors' conclusions

Low- to moderate-quality evidence shows mechanical induction with a balloon is probably as effective as induction of labour with vaginal PGE2. However, a balloon seems to have a more favourable safety profile. More research on this comparison does not seem warranted.

Moderate-quality evidence shows a balloon catheter may be slightly less effective as oral misoprostol, but it remains unclear if there is a difference in safety outcomes for the neonate. When compared to low-dose vaginal misoprostol, low-quality evidence shows a balloon may be less effective, but probably has a better safety profile.

Future research could be focused more on safety aspects for the neonate and maternal satisfaction.

PLAIN LANGUAGE SUMMARY

Mechanical methods for induction of labour

We set out to determine from randomised controlled trials the effectiveness and safety of mechanical methods to bring on labour in the third trimester of pregnancy (> 24 weeks' gestation). Use of a balloon to stretch the cervix (the lower end of the uterus) was compared with prostaglandin E2 (PGE2), low-dose misoprostol or oxytocin.

What is the issue?

Induction is carried out generally when the risk of continuing pregnancy outweighs the benefits, or at the request of pregnant women.

Mechanical methods for induction promote cervical ripening and onset of labour by stretching the cervix. They are amongst the oldest methods used to initiate labour. During the last decades, medication such as PGE2, misoprostol and oxytocin have partly replaced mechanical methods.

Why is this important?

More and more women have labour induced and indications are often not urgent. This means that the safety aspects of induction methods become more important, although this could be at the expense of effectiveness. Mechanical methods could have advantages over pharmacological methods as they are widely available, low in cost and may have fewer side effects, such as excessive contractions of the uterus (uterine hyperstimulation). This could potentially be safer for the baby because if contractions are too long or very close together, the baby may not receive sufficient oxygen.

What evidence did we find?

For this review we included a total of 113 randomised controlled trials involving 22,373 women who were scheduled for induction of labour for different indications. The data contributed to 21 different comparisons and 20 subgroup comparisons. Overall, the evidence was graded from very low to moderate quality. For many comparisons there were too few women in the trials to determine any clear differences in serious illness for mothers and babies.

Twenty-eight trials (6619 women) showed mechanical induction with a balloon is as effective as vaginal PGE2 as there may be little or no difference in vaginal deliveries within 24 hours and there probably is little or no difference in caesarean sections between groups. However, a balloon appears to be safer for the neonate as it probably reduces the risk of uterine hyperstimulation with an abnormal heart rate of the baby, serious illness or death of the baby and may slightly reduce the risk for a neonatal intensive care unit admission. It was unclear if there was a difference in serious illness or death of the mother or in the five-minute Apgar score less than seven.

Thirteen trials (1818 women) compared induction of labour with a balloon with vaginal misoprostol and showed a balloon probably reduces the risk of uterine hyperstimulation with an abnormal heart rate of the baby, but may increase the risk of a caesarean section. It was unclear if there was a difference in vaginal deliveries within 24 hours, serious illness or death of the baby, serious illness or death of the mother, five-minute Apgar score less than seven or neonatal intensive care unit admissions.

Seven trials (3178 women) showed a balloon may be less effective than oral misoprostol as a balloon probably increases the risk of a vaginal delivery not achieved within 24 hours and probably slightly increases the risk of a caesarean section. Data on safety are still unclear as it is uncertain whether there is a difference in uterine hyperstimulation with an abnormal heart rate of the baby, serious illness or death of the baby, serious illness or death of the mother, five-minute Apgar score less than seven or neonatal intensive care unit admissions.

What does this mean?

Mechanical induction with a balloon is probably as effective as induction of labour with vaginal PGE2. However, a balloon seems to have a more favourable safety profile for the baby. More research on this comparison does not seem warranted.

A balloon catheter may be slightly less effective as oral misoprostol, but It remains unclear if there is a difference in safety outcomes for the baby. When compared to low-dose vaginal misoprostol, a balloon catheter may be less effective, but probably has a better safety profile for the baby.

Future research could focus more on safety aspects for the baby and maternal satisfaction.

Summary of findings for the main comparison. Balloon (Foley or ATAD) compared to vaginal prostaglandin E2 for third trimester labour induction in women with a viable fetus

Balloon (Foley or ATAD) compared to vaginal prostaglandin E2 for third trimester labour induction in women with a viable fetus

Patient or population: third trimester labour induction in women with a viable fetus
Setting: Australia, China, Denmark, Iran, Jordan, India, Italy, Israel, Nigeria, Pakistan, Singapore, Sweden, the Netherlands, USA, UK
Intervention: balloon (Foley or ATAD)
Comparison: vaginal prostaglandin E2

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with vaginal prostaglandin E2	Risk with balloon (Foley or ATAD)				
Vaginal delivery not achieved in 24 hours	Study population		RR 1.01 (0.82 to 1.26)	1685 (7 RCTs)	⊕⊕⊖⊖ LOW [1,2]	
	528 per 1000	533 per 1000 (433 to 665)				
Uterine hyperstimulation with FHR changes	Study population		RR 0.35 (0.18 to 0.67)	1966 (6 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	31 per 1000	11 per 1000 (6 to 21)				
Caesarean section	Study population		RR 1.00 (0.92 to 1.09)	6619 (28 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	238 per 1000	238 per 1000 (219 to 260)				
Serious neonatal morbidity or perinatal death	Study population		RR 0.48 (0.25 to 0.93)	2757 (8 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	20 per 1000	9 per 1000 (5 to 18)				
Serious maternal morbidity or death	Study population		RR 0.20 (0.01 to 4.12)	1481 (4 RCTs)	⊕⊖⊖⊖ VERY LOW [1,3]	
	3 per 1000	1 per 1000 (0 to 11)				
Apgar score < 7 at 5 minutes	Study population		RR 0.74 (0.49 to 1.14)	4271 (14 RCTs)	⊕⊕⊖⊖ LOW [1,4]	

	22 per 1000	16 per 1000 (11 to 25)			
Neonatal intensive care unit admission	Study population		RR 0.82 (0.65 to 1.04)	3647 (12 RCTs)	⊕⊕⊝⊝ LOW [1 4]
	74 per 1000	60 per 1000 (48 to 77)			

*__The risk in the intervention group__ (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 certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]We downgraded (1) level for serious limitation in study design due to lack of blinding (although not feasible due to nature of event)
[2]We downgraded (1) level for serious inconsistency due to evidence of statistical heterogeneity (I^2 = >30%)
[3]We downgraded (2) levels for very serious imprecision due to wide CI crossing the line of no effect and small number of events
[4]We downgraded (1) level for serious imprecision due to wide CI crossing the line of no effect

Summary of findings 2. Balloon (Foley or ATAD) compared to low-dose vaginal misoprostol for third trimester induction of labour in women with a viable fetus

Balloon (Foley or ATAD) compared to low-dose vaginal misoprostol for third trimester induction of labour in women with a viable fetus

Patient or population: third trimester induction of labour in women with a viable fetus
Setting: Brazil, Egypt, India, Iran, Nigeria, the Netherlands, Sweden
Intervention: balloon (Foley or ATAD)
Comparison: low-dose vaginal misoprostol

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with low-dose vaginal misoprostol	Risk with balloon (Foley or ATAD)				
Vaginal delivery not achieved in 24 hours	Study population		RR 1.09 (0.85 to 1.39)	340 (2 RCTs)	⊕⊕⊝⊝ LOW [1 2]	

	412 per 1000	449 per 1000 (350 to 573)				
Uterine hyperstimulation with FHR changes	Study population		RR 0.39 (0.18 to 0.85)	1322 (8 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	33 per 1000	13 per 1000 (6 to 28)				
Caesarean section	Study population		RR 1.28 (1.02 to 1.60)	1756 (12 RCTs)	⊕⊕⊖⊖ LOW [1 3]	
	243 per 1000	311 per 1000 (247 to 388)				
Serious neonatal morbidity or perinatal death	Study population		RR 0.58 (0.12 to 2.66)	381 (3 RCTs)	⊕⊖⊖⊖ VERY LOW [1 4]	
	21 per 1000	12 per 1000 (2 to 55)				
Serious maternal morbidity or death	Study population		not estimable	464 (4 RCTs)	⊕⊖⊖⊖ VERY LOW [1 5]	no events occurred in included studies
	0 per 1000	0 per 1000 (0 to 0)				
Apgar score < 7 at 5 minutes	Study population		RR 1.00 (0.50 to 1.97)	941 (7 RCTs)	⊕⊕⊖⊖ LOW [1 2]	
	30 per 1000	30 per 1000 (15 to 59)				
Neonatal intensive care unit admission	Study population		RR 1.00 (0.61 to 1.63)	1302 (9 RCTs)	⊕⊕⊖⊖ LOW [1 2 6]	
	47 per 1000	47 per 1000 (29 to 77)				

*__The risk in the intervention group__ (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 certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]We downgraded (1) level for serious limitation in study design due to lack of blinding (although not feasible due to nature of event)
[2]We downgraded (1) level for serious imprecision due to wide CI crossing the line of no effect
[3]We downgraded (1) level for serious inconsistency due to evidence of statistical heterogeneity (I^2 = >30%)
[4]We downgraded (2) levels for very serious imprecision due to wide CI crossing the line of no effect and small number of events
[5] We downgraded (2) levels for very serious imprecision due to wide CI crossing the line of no effect and no events reported in included studies
[6] Although there was some evidence suggesting small-study effect we did not downgrade for publication bias because individual studies did not reach statistical significance and there was low heterogeneity across all studies for this outcome. Also, no difference was found between fixed-effect or random-effect analyses

Summary of findings 3. Balloon (Foley or ATAD) compared to low-dose oral misoprostol for third trimester induction of labour in women with a viable fetus

Balloon (Foley or ATAD) compared to low-dose oral misoprostol for third trimester induction of labour in women with a viable fetus

Patient or population: third trimester induction of labour in women with a viable fetus
Setting: Finland, India, Pakistan, Sri Lanka, the Netherlands
Intervention: balloon (Foley or ATAD)
Comparison: low-dose oral misoprostol

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with low-dose oral misoprostol	Risk with balloon (Foley or ATAD)				
Vaginal delivery not achieved within 24 hours	Study population		RR 1.28 (1.13 to 1.46)	782 (2 RCTs)	⊕⊕⊕⊖ MODERATE [1]	
	476 per 1000	609 per 1000 (538 to 695)				
Uterine hyperstimulation with FHR changes	Study population		RR 0.81 (0.48 to 1.38)	2033 (2 RCTs)	⊕⊕⊖⊖ LOW [1 2]	
	29 per 1000	24 per 1000 (14 to 40)				
Caesarean section	Study population		RR 1.17 (1.04 to 1.32)	3178 (7 RCTs)	⊕⊕⊕⊖ MODERATE [1 3]	
	222 per 1000	259 per 1000 (230 to 293)				
Serious neonatal morbidity or perinatal death	Study population		RR 1.11 (0.60 to 2.06)	2627 (3 RCTs)	⊕⊕⊖⊖ LOW [1 2 4]	
	14 per 1000	16 per 1000 (9 to 30)				

Serious maternal morbidity or death	Study population		RR 0.50 (0.05 to 5.52)	2627 (3 RCTs)	⊕⊖⊖⊖ VERY LOW [1 5]
	2 per 1000	1 per 1000 (0 to 8)			
Apgar score < 7 after 5 minutes	Study population		RR 0.71 (0.38 to 1.32)	2693 (4 RCTs)	⊕⊕⊖⊖ LOW [1 2 4]
	18 per 1000	13 per 1000 (6 to 28)			
Neonatal intensive care unit admission	Study population		RR 0.82 (0.58 to 1.17)	2873 (5 RCTs)	⊕⊕⊖⊖ LOW [1 2 4]
	46 per 1000	37 per 1000 (26 to 53)			

*__The risk in the intervention group__ (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 certainty: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate certainty: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low certainty: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low certainty: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1]We downgraded (1) level for serious limitation in study design due to lack of blinding (although not feasible due to nature of event)
[2]We downgraded (1) level for serious imprecision due to wide CI crossing the line of no effect
[3] Trial of Mundle 2017 did not meet the pre-specified population as pregnancies with a non viable fetus were included. Sensitivity analyses did not alter the estimated effect size. Therefore we did not downgrade
[4] Trial of Mundle 2017 did not meet the pre-specified population as pregnancies with a non viable fetus were included. Sensitivity analysis did not change the direction of the effect size and numbers of events were not higher compared to other trials. Therefore we did not downgrade.
[5] We downgraded (2) levels for very serious imprecision due to wide CI crossing the line of no effect and small number of events

BACKGROUND

The previous version of this review formed one of a series of reviews of methods for induction of labour that followed a standardised published 'generic' protocol (Hofmeyr 2009). These reviews were initially developed to help inform the recommendations of the National Institute for Health and Care Excellence (NICE) clinical practice guidelines on induction of labour (NICE 2008). This review no longer strictly follows the original protocol and has been updated with the intention of being a stand-alone review. This is an update of a review first published in 2001 (Boulvain 2001), and last updated in 2012 (Jozwiak 2012).

Description of the condition

Labour induction is a common obstetric procedure, which is generally carried out when the risk of continuing pregnancy outweighs the benefits. Also, induction of labour is being used more and more at the request of pregnant women to shorten the duration of pregnancy or to time the birth of the baby according to the convenience of the mother and/or healthcare workers (WHO 2011). In the USA, approximately one in four women are induced and in the last decade, the induction rate in the UK has risen up to almost 30% (NICE 2008; NHS 2017). Although rates are generally lower in developing countries, in some settings they can be as high as those observed in developed countries (WHO 2011). To maximise the success of induction of labour in women with an unfavourable cervix, various ripening methods are available.

Description of the intervention

Mechanical methods were the first methods developed to ripen the cervix and induce labour (Thiery 1989). Devices that were used in this context include various type of catheters and laminaria tents, introduced into the cervical canal or through the cervix into the extra-amniotic space. During recent decades they were partly substituted by pharmacological methods, including various prostaglandin E2 (PGE2) preparations (vaginal gel, tablets, inserts, intracervical gel), prostaglandin E1 (PGE1; misoprostol tablets, applied either orally or vaginally) and oxytocin. Pharmacological methods however, have a variety of effects at different sites and receptors in the body that can lead to unwanted side effects when used, such as uterine hyperstimulation (excessive contractions of the uterus) and as result, fetal distress. Therefore, mechanical induction methods are gaining in popularity as it has the potential to have a better safety profile compared to pharmacological methods, however possibly at the cost of a longer duration of labour. These factors need to be considered to determine the most appropriate methods depending on the clinical situation, with impact on labour duration possibly being of secondary importance as more women have labour induced for less urgent indications.

How the intervention might work

The goal of mechanical induction methods is to ripen the cervix, which can be achieved directly through dilatation of the canal, indirectly by increasing prostaglandin or oxytocin secretion, or both (Keirse 1983). In addition to the local effect, mechanisms which involve neuro-endocrine reflexes (the Ferguson reflex) may promote the onset of contractions, leading to labour onset (Krammer 1995b).

The standard Foley urinary catheter can be used, as well as a specially developed 'Atad' double-balloon catheter (Atad 1996) or Cook balloon. The catheter is introduced through the cervical canal to reach the extra-amniotic space. The balloon is then inflated to keep the catheter in place. Traction is applied to the catheter in some cases. Another method involving catheters consists of infusing saline solution or prostaglandins through a catheter inserted, via the cervical canal, in the extra-amniotic space (EASI).

Laminaria tents, made from sterile sea-weed or synthetic hydrophilic materials (e.g. Lamicel), are introduced into the cervical canal. These devices increase in diameter because of their hydrophilic properties. This achieves a gradual stretching of the cervix.

Digital stripping or sweeping of the membranes is evaluated in a different review (Boulvain 2005).

Why it is important to do this review

Mechanical methods were never completely abandoned, but were substituted by pharmacological methods in recent decades. However, as induction rates rise and indications are often less urgent, the safety aspects of induction methods become more important, although this could be at the expense of effectiveness. Apart for being widely available and low in cost, potential advantages of mechanical methods over pharmacological ones may include a reduction in side effects, such as uterine hyperstimulation, thereby having the potential to improve neonatal outcomes.

OBJECTIVES

To determine the effectiveness and safety of mechanical methods for third trimester (> 24 weeks' gestation) induction of labour in comparison with prostaglandin E2 (PGE2) (vaginal and intracervical), low-dose misoprostol (oral and vaginal), amniotomy or oxytocin.

METHODS

Criteria for considering studies for this review

Types of studies

Clinical trials, comparing mechanical methods for cervical ripening or labour induction with other induction methods. Quasi-randomised controlled trials and trials only reported as abstract were eligible for inclusion. Cluster-randomised trials are unlikely to be conducted in this area, however, if identified by a future search, they will be handled with appropriate methods.

Types of participants

Pregnant women due for third trimester induction of labour, carrying a viable fetus.

Predefined subgroup comparisons were: previous caesarean section or not, nulliparity or multiparity. Only those outcomes with data appear in the analyses tables.

Types of interventions

Different types of intervention have been considered as mechanical methods: (1) the introduction of a catheter (Foley single balloon, Atad/Cook double balloon or other type), through the cervix into the extra-amniotic space, either with or without traction; (2) introduction of laminaria tents, or their synthetic equivalent

(Dilapan), into the cervical canal; (3) use of a catheter to inject fluids, usually saline water, in the extra-amniotic space (EASI).

Mechanical methods were compared with other induction methods (i.e. vaginal PGE2, intracervical PGE2, intravenous oxytocin, amniotomy, vaginal and oral misoprostol). For this update, the comparison with placebo/no treatment was left out. When the protocol for reviews of induction methods was designed, it was relevant to know if cervical ripening before actual induction of labour (rupturing the membranes, and if needed, administer of oxytocin) was beneficial. Since we already know the advantages of cervical ripening in case of an unfavourable cervix, no future trials will be done to study the effect of cervical ripening with a mechanical method versus no ripening. Also, in the case of pharmacological methods, it is possible to perform a placebo-controlled study, but with mechanical methods of labour, this is not possible. Studies which do make this comparison between mechanical induction and no treatment, explore other objectives rather than the ones relevant for his review (induction of labour versus expectant management to improve birth outcome). Therefore, the choice was made to depart from the original research protocol and leave out this pre-specified comparison. For this update, we also chose only to include low-dose misoprostol (defined as ≤ 50 mcg every ≥ 4 hours) as evidence suggests low-dose misoprostol is superior to high-dose misoprostol regarding safety outcomes and being equally effective (Alfirevic 2014; Hofmeyr 2010).

In addition, other comparisons were made: (1) a single balloon compared to a double balloon; (2) laminaria tent compared to other hygroscopic dilatators; (3) addition of prostaglandins or oxytocin to mechanical methods compared with prostaglandins or oxytocin alone. These comparisons were not pre-specified in the generic protocol of induction of labour reviews (Hofmeyr 2009).

Types of outcome measures

We included all clinically relevant outcomes for trials of methods of cervical ripening/labour induction as had been pre-specified by two authors of the generic protocol for labour induction reviews (Justus Hofmeyr and Zarko Alfirevic). We added six more outcomes to the list of the original protocol. Differences were settled by discussion.

Primary outcomes

Five primary outcomes were chosen as being most representative of the clinically important measures of effectiveness and complications. Subgroup comparisons were limited to the primary outcomes:

1. vaginal delivery not achieved within 24 hours (from start cervical ripening);
2. uterine hyperstimulation with fetal heart rate (FHR) changes;
3. caesarean section;
4. serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood);
5. serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia).

Perinatal and maternal morbidity and mortality are composite outcomes. This is not an ideal solution because some components are clearly less severe than others. It is possible for one intervention to cause more deaths but less severe morbidity. However, in the context of labour induction in mainly term pregnancies, this is unlikely. All these events are rare, and a modest change in their incidence will be easier to detect if composite outcomes are presented. The incidence of individual components were explored as secondary outcomes (see below).

Secondary outcomes relate to measures of effectiveness, complications and satisfaction.

Measures of effectiveness:

1. cervix unfavourable/unchanged after 12 to 24 hours;
2. oxytocin augmentation.

Complications:

1. uterine hyperstimulation without FHR changes;
2. uterine rupture;
3. epidural analgesia;
4. instrumental vaginal delivery;
5. meconium-stained liquor;
6. Apgar score less than seven at five minutes;
7. neonatal intensive care unit (NICU) admission;
8. neonatal encephalopathy;
9. perinatal death;
10. disability in childhood;
11. maternal side effects (all);
12. maternal nausea;
13. maternal vomiting;
14. maternal diarrhoea;
15. other maternal side effects;
16. postpartum haemorrhage (as defined by the trial authors);
17. serious maternal complications (e.g. intensive care unit admission, septicaemia but excluding uterine rupture);
18. maternal death.

Measures of satisfaction:

1. woman not satisfied;
2. caregiver not satisfied.

The terminology of uterine hyperstimulation is problematic (Curtis 1987). In the review, we use the term 'uterine hyperstimulation without FHR changes' to include uterine tachysystole (more than five contractions per 10 minutes for at least 20 minutes) and uterine hypersystole/hypertonus (a contraction lasting at least two minutes) and 'uterine hyperstimulation with FHR changes' to denote uterine hyperstimulation syndrome (tachysystole or hypersystole with FHR changes such as persistent decelerations, tachycardia or decreased short-term variability).

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 (9 January

2018). We updated this search on 19 March 2019 and added the results to Studies awaiting classification for consideration in the next update.

The Register is a database containing over 25,000 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.

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, Excluded, Awaiting Classification or Ongoing).

In addition, we searched ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing trial reports (19 March 2019) using the search methods detailed 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* Jozwiak 2012.

For this update, the following methods were used for assessing the 247 reports that were identified as a result of the updated search. The following methods section of this review is based on a standard template used by Cochrane Pregnancy and Childbirth.

Selection of studies

Two review authors (Marieke de Vaan and Mieke ten Eikelder) independently assessed all potential studies identified as a result of the search strategy for inclusion. Any disagreement was resolved through discussion, or if required, by involving a third review author (Marta Jozwiak).

Data extraction and management

We designed a form to extract data. For eligible studies, two groups of two review authors (Marieke de Vaan, Marta Jozwiak, Ben Willem Mol and Kirsten Palmer) extracted the data using the agreed form. We resolved discrepancies through discussion or, if required, we consulted a third review author. Data were entered into Review Manager software (RevMan 2014) and checked by a second review author for accuracy.

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

Assessment of risk of bias in included studies

Two review authors (Marieke de Vaan and Mieke ten Eikelder) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). Any disagreement was resolved by discussion or by involving a third assessor (Marta Jozwiak).

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

We described for each included study 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)

We described for each included study 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)

We described for each included study 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 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)

We described for each included study 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)

We described for each included study, and for each outcome or class of outcomes, 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 which 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);
- unclear risk of bias.

(5) Selective reporting (checking for reporting bias)

We described for each included study 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 is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest are reported incompletely and so cannot be used; study fails 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)

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

Assessment of the quality of the evidence using the GRADE approach

For this update, the quality of the evidence was assessed for the comparisons relating to the most frequently used methods of cervical ripening (i.e. vaginal prostaglandin E2 (PGE2), vaginal misoprostol, and oral misoprostol) 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.

1. Vaginal delivery not achieved within 24 hours
2. Uterine hyperstimulation with FHR changes
3. Caesarean section
4. Serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood)
5. Serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia)
6. Neonatal intensive care unit admission
7. Apgar score less than seven at five minutes

For the main comparisons we used GRADEpro Guideline Development Tool to import data from Review Manager 5.3 (RevMan 2014) in order to create 'Summary of findings' tables. A summary of the intervention effect and a measure of quality for each of the above outcomes was 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

No continuous data were analysed in this update. If outcomes using continuous data are included in future versions of this review, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome but use different methods.

Unit of analysis issues

Cluster-randomised trials

Cluster-randomised trials are eligible for inclusion in the analyses along with individually-randomised trials. None have currently been identified. If in the future such trials are identified, we will adjust their standard errors using the methods described in the Handbook (Higgins 2011) 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. If we identify both cluster-randomised trials and individually-

randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both 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 also acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Cross-over trials

Cross-over trials were not eligible for inclusion.

Other unit of analysis issues

Trials in pregnancy and childbirth may include outcomes for multiple pregnancies, but the trials identified to date have included singleton pregnancies only. Trials with multiple pregnancy will be included, but the outcomes relating to the babies will have to take account of clustering of events, as outlined in the Pregnancy and Childbirth Group Methodological Guidelines and the *Handbook* (Higgins 2011).

Some trials are multi-arm studies, where this occurs only the intervention arms relevant to this review were included and this is noted in the Characteristics of included studies table.

Dealing with missing data

For included studies, levels of attrition were noted. In future updates, if more eligible studies are included, we will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

For all outcomes, analyses were carried out, 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 Tau^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if an I^2 was greater than 30% and either a Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity. In the case of substantial heterogeneity (above 30%), if possible, we explored it by subgroup analyses.

Assessment of reporting biases

When there were 10 or more studies in the meta-analysis, we investigated reporting biases (such as publication bias) using funnel plots. We assessed funnel plot asymmetry visually. If asymmetry was suggested by a visual assessment, we performed exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2014). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar.

If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and the clinical implications of treatment effects differing between trials is discussed. If the average treatment effect was not clinically meaningful, we did not combine trials. When random-effects analyses were used, the results were presented as the average treatment effect with 95% confidence intervals, and the estimates of Tau^2 and I^2.

Subgroup analysis and investigation of heterogeneity

We did not carry out formal subgroup analysis to investigate heterogeneity, but carried out additional analyses of subgroups of trials based on the following.

1. Previous caesarean section or not
2. Nulliparity or multiparity

The following outcomes were used in the subgroups.

1. Vaginal delivery not achieved within 24 hours
2. Uterine hyperstimulation with FHR changes
3. Caesarean section
4. Serious neonatal morbidity or perinatal death (e.g. seizures, birth asphyxia defined by trialists, neonatal encephalopathy, disability in childhood)
5. Serious maternal morbidity or death (e.g. uterine rupture, admission to intensive care unit, septicaemia)

Sensitivity analysis

We carried out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, high attrition rates, or both, with poor quality studies being excluded from the analyses in order to assess whether this made any difference to the overall result.

RESULTS

Description of studies

Results of the search

See: Figure 1.

Figure 1. Study flow diagram.

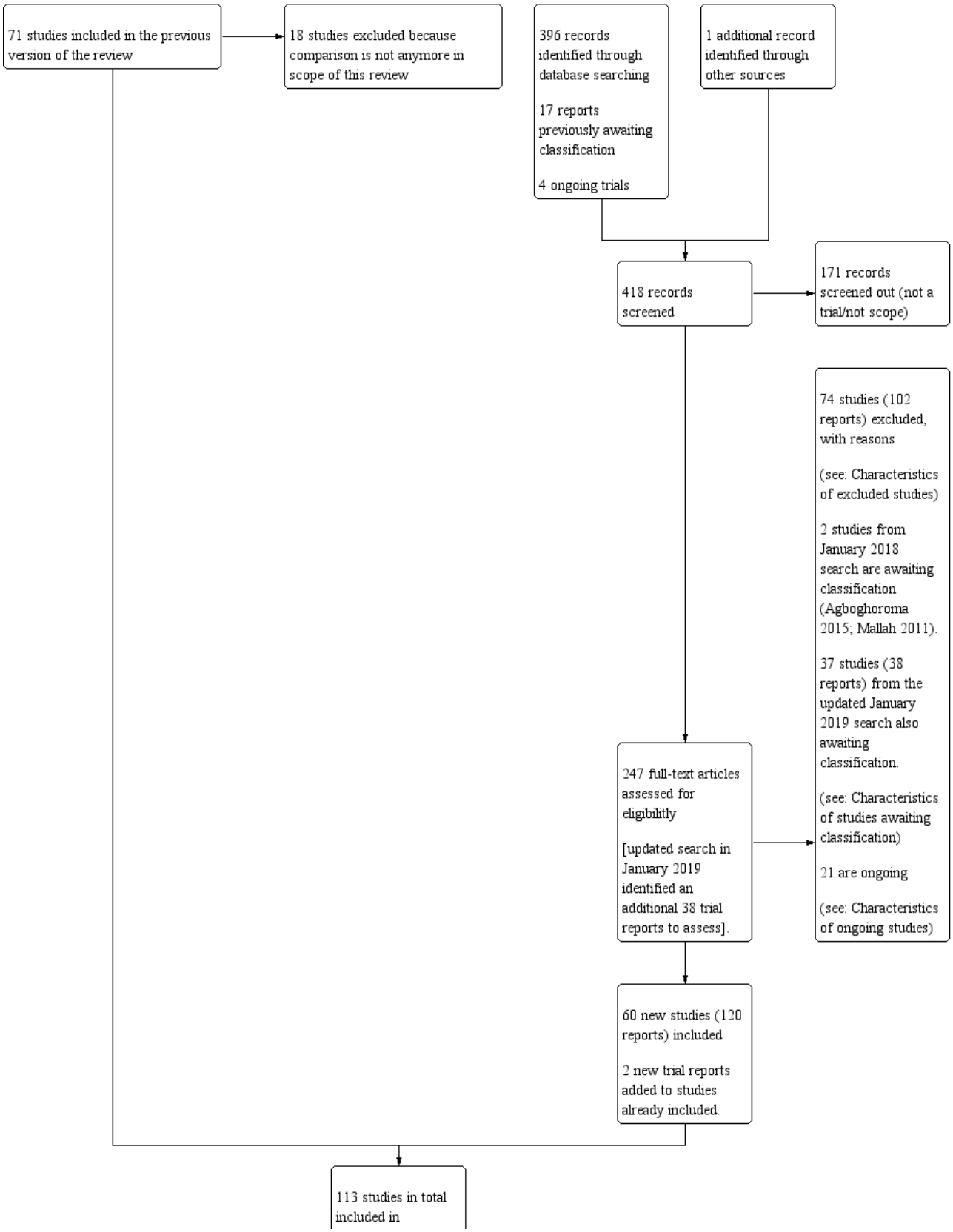
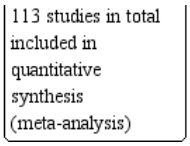


Figure 1. (Continued)



For this update, we identified 418 trial reports to assess in the search of 9 January 2018. One study (Pineda Rivas 2016) was retrieved through other sources. When exploring the included trial registration of this study, we found out that an abstract of this study was published.

We also reassessed the 17 reports awaiting classification and the four ongoing studies in the previous version of the review (Jozwiak 2012). One hundred and seventy-one reports were screened out because they did not meet the scope for this review or were not randomised controlled trials. We then assessed trial reports which related to 166 new trials (247 reports). We included 60 new trials (120 reports), added two trial reports to already included studies and excluded 74 trials (102 reports). Two trials from the January 2018 search are awaiting classification (Agboghoroma 2015; Mallah 2011), and 21 are ongoing (Argilagos 2016; Beckmann 2013; Bekele 2017; Berndl 2016; Bhide 2017; Eser 2016; Goli 2017; Goonewardene 2016; Gupta 2016; Hassanzadeh 2017; Igwe 2017; Lacarin 2017; Lauterbach 2017; Levy 2016; Osoti 2016; Park 2012; Perrotin 2016; Tagore 2015; Viteri 2015; Wise 2016; Yildirim 2017).

Of the 71 previous included studies, we excluded 18 trials because they were no longer within the scope of this review. Four studies were excluded because they compared a mechanical method with a placebo or no cervical ripening (De Oliveira 2003; Gilson 1996; Gower 1982; Lackritz 1979), 11 studies because of the use of high-dose misoprostol (Adeniji 2005b; Barrilleaux 2002a; Buccellato 2000; Chung 2003; Greybush 2001; Hill 2009; Kashanian 2006; Owolabi 2005; Rust 2001; Sciscione 2001; Vengalil 1998), two studies compared extra-amniotic space infusion (EASI) versus induction with a balloon or laminaria (El-Torkey 1995; Lin 1995), and one study compared a balloon versus prostaglandin F2alpha (Mawire 1999).

In the updated search of 19 March 2019, we identified an additional 38 trial reports which were added to Studies awaiting classification for consideration in the next update. The references have been assessed but not incorporated into the review. Only seven of these trials are likely to contribute data for this review and are mainly small trials (Khatib 2019; Lim 2018; Osoti 2018; Souizi 2018; ten Eikelder 2017; Tulek 2018; Viteri 2019). We imputed the data for these trials and this resulted in no changes in terms of the direction or strength of the evidence. We will incorporate these studies fully at the next update.

Included studies

Altogether, this review now comprises 113 included studies, 105 of which contributed data. The studies that contributed data involved 22,373 women (see Characteristics of included studies). Trials with more than two arms may be included in more than one comparison. No cluster-randomised trials were identified by the search.

Eight studies did not contribute any data to this review because the outcomes of interest were not reported, or reported in a format that could not be included in this review (Biron-Shental 2004; Deo 2013; Hughes 2002; Jalilian 2011; Peedicayil 1998; Qamar 2012; Thiery 1981; Zahoor 2014). These studies are therefore not included in the descriptions of study details and 'Risk of bias' assessment below.

Design

All included studies were randomised controlled trials although the randomisation method was not always well described and in three studies the allocation process was not truly random (Jagani 1982; Kandil 2012; Roztocil 1998). All studies involved two trial arms except for Aduloju 2016, Allouche 1993, Atad 1996, Browne 2011, Cromi 2011, Deo 2012, Dionne 2011, El Khouly 2017, Guinn 2000, Matonhodze 2003, Lewis 1983, Orhue 1995, Pennell 2009, Prager 2008, Saleem 2006, Sheikher 2009 and Yuen 1996, which had three arms. Gelisen 2005, Lyndrup 1989 and Roberts 1986 had four arms, and Jagani 1982 had five arms. Not all comparisons in these studies were relevant for this review and therefore one or more arms in the studies of Gelisen 2005, Jagani 1982, Lewis 1983 and Roberts 1986 were excluded.

Setting

Nine studies were multicentre studies (Edwards 2014c; Guinn 2000; Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; Lokkegaard 2015; Mundle 2017; Sarreau 2016; ten Eikelder 2016), the remaining studies were single-centre studies.

All studies took place in a hospital setting, except for Henry 2013, in which the period of cervical ripening took place in an outpatient setting.

The included studies were conducted in the following countries: Australia (Henry 2013; Pennell 2009), Brazil (Filho 2002; Oliveira 2010, Canada (Lemyre 2006; Pineda Rivas 2016; St Onge 1995), Czech Republic (Roztocil 1998), China (Wang 2012; Wang 2014; Wu 2017; Yuen 1996), Denmark (Lokkegaard 2015; Lyndrup 1989; Lyndrup 1994), Egypt (Ahmed 2016; El Khouly 2017; Kandil 2012), Finland (Kruit 2016), France (Allouche 1993; Sarreau 2016;), India (Chavakula 2015; Dalui 2005; Deo 2012; Deshmukh 2011; Goonewardene 2014; Gunawardena 2012; Joshi 2016; Kuppulakshmi 2016; Laddad 2013; Lanka 2014; Meetei 2015; Mundle 2017; Sheikher 2009), Iran (Moini 2003; Niromanesh 2003; Roudsari 2011; Sharami 2005) Italy (Cromi 2011; Cromi 2012), Israel (Atad 1996; Barda 2018; Ophir 1992; Shechter-Maor 2015; Salim 2011; Solt 2009), Jordan (Al-Taani 2004; Khamaiseh 2012), the Netherlands (Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; ten Eikelder 2016), Nigeria (Aduloju 2016; Garba 2016; Orhue 1995; Tabowei 2003), Norway (Haugland 2012), Pakistan (Husain 2017; Matonhodze 2003; Mazhar 2003; Saleem 2006), Russia (Glagoleva 1999), Rwanda (Gilson 2017), South Africa (Bagratee 1990; Jeeva 1982; Ntsaluba 1997), Singapore (Chua 1997), Sri Lanka (Rudra 2012; Somirathne 2017; Tan 2015), Sweden (Hemlin 1998; Prager 2008), Tunis (Benzineb 1996), Turkey (Gelisen 2005), the UK (Dionne 2011; Guinn 2000; Hay 1995; Johnson 1985; Lewis 1983), the USA (Al-Ibraheemi 2018; Amorosa 2017; Blumenthal 1990; Browne 2011; Carbone 2013; Casey 1995; Culver 2004; Edwards 2014c;

Hibbard 1998; Hoppe 2016; Hudon 1999; Jagani 1982; Krammer 1995a; Mackeen 2018; Mullin 2002; Perry 1998; Ridgway 1991; Roberts 1986; Rouben 1993; Sanchez-Ramos 1992; Sciscione 1999; Suffecool 2014; Sullivan 1996; Tita 2006; Turnquest 1997).

Dates

The study of Blumenthal 1990 and Sanchez-Ramos 1992 took place between 1980 and 1989; the studies of Allouche 1993, Guinn 2000, Hemlin 1998, Hibbard 1998, Khamaiseh 2012, Lyndrup 1994, Orhue 1995, Perry 1998, Roudsari 2011, Roztocil 1998, Sciscione 1999, St Onge 1995, Sullivan 1996 and Turnquest 1997 between 1990 and 1999; the studies of Tabowei 2003, Culver 2004 and Mullin 2002 between 1998 and 2001; the studies of Al-Taani 2004, Cromi 2011, Deshmukh 2011, Dionne 2011, Filho 2002, Joshi 2016, Jozwiak 2012, Jozwiak 2013, Krammer 1995a, Lokkegaard 2015, Matonhodze 2003, Mazhar 2003, Moini 2003, Niromanesh 2003, Oliveira 2010, Pennell 2009, Prager 2008, Roudsari 2011, Rudra 2012, Saleem 2006, Sharami 2005 and Tita 2006 between 2000 and 2009; the studies of Jozwiak 2014 and Salim 2011 between 2008 and 2011; and the studies of Aduloju 2016, Ahmed 2016, Al-Ibraheemi 2018, Amorosa 2017, Barda 2018, Browne 2011, Carbone 2013, Chavakula 2015, Cromi 2012, Edwards 2014c, El Khouly 2017, Garba 2016, Goonewardene 2014, Haugland 2012, Henry 2013, Hoppe 2016, Husain 2017, Kandil 2012, Kruit 2016, Kuppulakshmi 2016, Laddad 2013, Mundle 2017, Noor 2015, Sarreau 2016, Somirathne 2017, Suffecool 2014, ten Eikelder 2016, Wang 2014 and Wu 2017 between 2010 and the present day.

For the remaining studies, no study period was reported (Atad 1996; Bagratee 1990; Benzineb 1996; Casey 1995; Chua 1997; Dalui 2005; Deo 2012; Gelisen 2005; Gilson 2017; Glagoleva 1999; Gunawardena 2012; Hay 1995; Hudon 1999; Jagani 1982; Jeeva 1982; Johnson 1985; Lanka 2014; Lanka 2014; Lewis 1983; Lyndrup 1989; Ntsaluba 1997; Ophir 1992; Pineda Rivas 2016; Ridgway 1991; Roberts 1986; Rouben 1993; Solt 2009; Shechter-Maor 2015; Sheikher 2009; Tan 2015; Wang 2012; Yuen 1996).

Participants

Most studies included both nulliparous and multiparous women. Nine studies included only nulliparous women (Culver 2004; Deshmukh 2011; Gunawardena 2012; Johnson 1985; Kandil 2012; Pennell 2009; Sharami 2005; Suffecool 2014; Wang 2012) and two studies included only multiparous women (Al-Taani 2004; Garba 2016).

Thirteen studies included women with a specific indication for labour induction or specific patient groups, i.e. women with a hypertensive disease (Mundle 2017), women with a body mass index (BMI) greater than 30 (Pineda Rivas 2016), post-date pregnancies (Gelisen 2005; Goonewardene 2014; Gunawardena 2012; Kandil 2012; Somirathne 2017), oligohydramnios (Shechter-Maor 2015; Wang 2014) or pre labour rupture of membranes (PROM; Amorosa 2017; Kruit 2016; Mackeen 2018; Tita 2006). Most authors specified that only women with intact membranes were included, except for Prager 2008, in which this was not an exclusion criteria. Orhue 1995, Roudsari 2011 and Roztocil 1998 reported nothing on membrane status, so it was not clear if women with ruptured membranes could be included.

Most studies excluded women with a past history of caesarean section, although four studies only included women with a past history of caesarean section (Joshi 2016; Meetei 2015; Sarreau 2016; Tabowei 2003). Three studies did not exclude women with a past history of caesarean section, but did not specify the outcomes for this subgroup of women separately (Mackeen 2018; Tabowei 2003; Tita 2006). Benzineb 1996, Cromi 2011, Deo 2012, Guinn 2000, Haugland 2012, Lyndrup 1994, Pineda Rivas 2016, Rouben 1993, and Wu 2017 reported nothing on previous caesarean section in their inclusion and exclusion criteria.

The majority of studies included women with a gestational age beyond 37 weeks, except for Edwards 2014c and Hemlin 1998 who reported a minimal gestational age of 36 weeks, Amorosa 2017, Chavakula 2015, Cromi 2011, Cromi 2012, Mackeen 2018 Matonhodze 2003, Pennell 2009; Roudsari 2011 and Sharami 2005 of 34 weeks, Dalui 2005 of 33 weeks, Lokkegaard 2015 of 32 weeks, Culver 2004, Lanka 2014 and El Khouly 2017 of 28 weeks, Browne 2011 of 26 weeks, Carbone 2013 of 24 weeks and Mundle 2017 of 20 weeks, although in this last study, no women with a gestational age below 28 weeks were included.

Twenty-four studies were not clear on their inclusion and exclusion criteria: Gilson 2017, Jeeva 1982 and Kuppulakshmi 2016 reported no inclusion or exclusion criteria. Jagani 1982, Rudra 2012 and Turnquest 1997 only reported that women with intact membranes were included. Glagoleva 1999 only reported that women with a previous caesarean section were excluded. Bagratee 1990, Dionne 2011, Johnson 1985, Lyndrup 1989, Ridgway 1991, Solt 2009; Sullivan 1996 reported that only women with an indication for labour induction with an unfavourable cervix were included. Hemlin 1998 reported nothing on membrane status or previous caesarean section. Casey 1995, Garba 2016, Hudon 1999, Krammer 1995a, Lemyre 2006, Lewis 1983 and Saleem 2006 reported nothing on fetal presentation, membrane status or previous caesarean section. Chua 1997 and Ophir 1992 reported nothing on gestational age, fetal presentation, membrane status or previous caesarean section.

Interventions and comparisons

The protocol of administration in the intervention and in the control groups varied between studies. Different mechanical devices were evaluated (i.e. balloon catheter, laminaria tents, and extra-amniotic infusion). Prostaglandins (intracervical or intravaginal PGE2, and oral or vaginal misoprostol) were used with different protocols of administration. We regrouped these protocols as follows: (1) balloon catheter versus other interventions; (2) laminaria tent versus other interventions: (3) extra-amniotic infusion versus other interventions; (4) any mechanical method combined with other (non-mechanical) intervention versus other interventions. For this last group of comparisons, we considered both PGE2 (intracervical or intravaginal PGE2) and misoprostol (oral or vaginal misoprostol) as a single intervention. The information on comparisons made in each trial, used device and balloon size is summarised below.

Studies evaluating laminaria or Dilapan were considered together, irrespective of the number of devices inserted. Similarly, evaluations of a Foley catheter (regardless of sizes and amount of liquid used to inflate the balloon and traction applied on the catheter) and a specially designed double-balloon catheter (ATAD or Cook catheter), we considered as similar interventions. However, when a catheter was used to perform extra-amniotic saline infusion (EASI), we considered these studies separately. Despite having regrouped similar interventions, this review still includes a large number of comparisons.

Most of the studies included in the review examined a balloon and compared it with either vaginal PGE2 or with vaginal or oral misoprostol. A smaller number of studies examined a balloon versus either intracervical PGE2 or oxytocin. Since the last update, no more studies have been published about induction of labour with a Laminaria tent or with EASI. None of the included studies examined the combination of a mechanical method with amniotomy.

The following comparisons were made in this review.

1. Balloon comparisons

Balloon (Foley or ATAD) versus vaginal prostaglandin E2

PGE2 tablets: Al-Taani 2004 (50 cc); Atad 1996 (double balloon); Barda 2018 (80 cc); Khamaiseh 2012 (50 cc to 60 cc); Lokkegaard 2015 (double balloon); Niromanesh 2003 (30 cc); Ophir 1992 (40 cc); Pennell 2009 (30 cc and double balloon); Tan 2015 (double balloon).

PGE2 gel: Browne 2011 (40 cc); Deo 2012 (30 cc); Deshmukh 2011 (balloon size unknown); Henry 2013 (30 cc); Jozwiak 2012 (30 cc); Orhue 1995 (30 cc); Prager 2008 (30 cc); Rouben 1993 (30 cc); Rudra 2012 (40 cc).

PGE2 vaginal insert: Cromi 2011 (50 cc; for this comparison the two groups of Foley catheter (12 hours and 24 hours) were combined); Cromi 2012 (double balloon); Edwards 2014c (30 cc); Jozwiak 2013 (30 cc); Lewis 1983 (30 cc); Lyndrup 1994 (30 cc); Pineda Rivas 2016 (balloon size unknown); Saleem 2006 (40 cc to 50cc); Shechter-Maor 2015 (double balloon); Suffecool 2014 (double balloon); Wang 2012 (80 cc); Wang 2014 (double balloon); Yuen 1996 (double balloon).

Balloon (Foley or ATAD) versus intracervical prostaglandin E2

PGE2 intracervical gel: Allouche 1993 (50 cc); gel: Benzineb 1996 (40 cc); Dalui 2005 (30 cc); Gunawardena 2012 (balloon size unknown); Hudon 1999 (40 cc); Kuppulakshmi 2016 (30 cc); Laddad 2013: (balloon size unknown); Moini 2003 (30 cc); Ntsaluba 1997 (30 cc); Sciscione 1999 (30 cc); St Onge 1995 (30 cc); Yuen 1996 (double balloon).

Balloon (Foley or ATAD) versus low-dose vaginal misoprostol

Misoprostol tablets: Aduloju 2016 (30 cc); Chavakula 2015 (30 cc); Filho 2002 (30 cc); Jozwiak 2014 (30 cc); Kandil 2012 (30 cc); Lemyre 2006 (balloon size unknown); Noor 2015 (50 cc); Oliveira 2010 (30 cc); Prager 2008 (30 cc); Roudsari 2011 (50 cc); Sheikher 2009 (30 cc); Tabowei 2003 (50 cc).

Balloon (Foley or ATAD) versus low-dose oral misoprostol

Misoprostol tablets: Goonewardene 2014 (balloon size unknown); Kruit 2016 (50 cc to 60 cc); Mundle 2017 (30 cc); Saleem 2006 (40 cc to 50 cc); Sheikher 2009 (30 cc); Somirathne 2017 (60 cc);ten Eikelder 2016 (30 cc). *misoprostol solution:* Matonhodze 2003 (50 cc).

Balloon (Foley or ATAD) versus oxytocin

Amorosa 2017 (60 cc); Atad 1996 (double balloon); El Khouly 2017 (30 cc); Gelisen 2005 (50 cc); Jagani 1982 (70 to 80 cc); Joshi 2016; (30 cc); Meetei 2015 (30 cc); Orhue 1995 (30 cc); Sarreau 2016 (50 cc).

Balloon (Foley or ATAD) versus amniotomy

Jagani 1982 (70 cc to 80 cc).

Single balloon (Foley versus double balloon (ATAD)

Ahmed 2016 (50 cc); Haugland 2012 (size unknown); Hoppe 2016 (30 cc); Pennell 2009 (30 cc); Salim 2011 (60 cc); Solt 2009 (balloon size unknown).

No studies were found for the comparison of a balloon versus oxytocin with amniotomy.

2. Laminaria comparisons

Laminaria tent versus vaginal prostaglandin E2

PGE2 tablets: Bagratee 1990 (Lamicel); Hay 1995 (Dilapan); Jeeva 1982; (laminaria).

PGE2 gel: Johnson 1985 (Lamicel); Roudsari 2011 (Dilapan); Sanchez-Ramos 1992 (Dilapan).

Laminaria tent versus intracervical prostaglandin E2

PGE2 intracervical gel: Chua 1997 (Dilapan); Glagoleva 1999 (Dilapan); Krammer 1995a; (Dilapan); Roztocil 1998 (Dilapan).

Laminaria tent versus oxytocin

Jagani 1982 (70 to 80 cc); Roberts 1986 (Lamicel).

Laminaria tent versus amniotomy

Jagani 1982 (70 to 80 cc).

Laminaria tent versus other hygroscopic dilator

Blumenthal 1990 (Dilapan versus laminaria tent).

No studies were found for the comparison of laminaria tent versus oxytocin with amniotomy or laminaria tent versus vaginal or oral misoprostol.

3. EASI comparisons

The only studies which were found compared EASI with PGE2.

EASI versus vaginal prostaglandin E2

Vaginal insert: Mazhar 2003.

EASI versus intracervical prostaglandin E2

Intracervical gel: Hemlin 1998.

4. Any mechanical combined with prostaglandin E2 comparisons

Any mechanical method combined with prostaglandin E2 versus prostaglandin E2 alone

PGE2 intracervical gel: Allouche 1993 (50 cc); Casey 1995 (50 cc); Ridgway 1991 (Lamicel); Sullivan 1996 (50 cc).

PGE2 vaginal gel: Browne 2011 (40 cc); Hibbard 1998 (Dilapan); Lyndrup 1989; (Lamicel); Turnquest 1997 (Laminaria)

Any mechanical method combined with prostaglandin E2 versus low-dose misoprostol alone

Vaginal misoprostol: Perry 1998.

Any mechanical method combined with prostaglandin E2 versus oxytocin alone

Lyndrup 1989 (Lamicel).

No studies were found which compared a mechanical method combined with PGE2 with amniotomy or oxytocin with amniotomy

5. Any mechanical combined with low-dose misoprostol comparisons

Any mechanical method combined with low-dose misoprostol versus prostaglandin E2 alone

Oral misoprostol: Matonhodze 2003.

Any mechanical method combined with low-dose misoprostol versus low-dose misoprostol alone

Vaginal misoprostol: Aduloju 2016 (30 cc); Al-Ibraheemi 2018 (60 cc); Carbone 2013 (60 cc); Dionne 2011 (balloon size and dosage of misoprostol unknown); Lanka 2014 (30 cc).

Oral misoprostol: Husain 2017 (30 cc); Matonhodze 2003 (50 cc).

No studies were found which compared a mechanical method combined with low-dose misoprostol with amniotomy, oxytocin or oxytocin with amniotomy.

6. Any mechanical method combined with oxytocin comparisons

Any mechanical method combined with oxytocin versus prostaglandin E2 alone

PGE2 intracervical gel: Guinn 2000 (laminaria + oxytocin and EASI + oxytocin); Lyndrup 1989 (Lamicel); Sharami 2005 (EASI).

Any mechanical method combined with oxytocin versus low-dose misoprostol alone

Vaginal misoprostol: Culver 2004 (30 cc); Dionne 2011 (balloon size unknown); Gilson 2017 (30 cc); Garba 2016 (balloon size and dosage of misoprostol unknown); Mullin 2002.

Any mechanical method combined with oxytocin versus oxytocin alone

El Khouly 2017 (30 cc); Lyndrup 1989 (Lamicel); Mackeen 2018 (30 cc); Tita 2006 (balloon size unknown); Wu 2017 (double balloon).

No studies were found which compared a mechanical method combined with oxytocin to amniotomy or oxytocin with amniotomy.

Outcomes

The study authors frequently reported on continuous outcome measures such as change in the cervical status or time to onset of labour, but also mean Apgar score after five minutes and mean pH in the umbilical artery. As these were not pre-specified in our protocol, we have not included these results in the review. In several studies, the only pre-specified result available was the number of women delivered by caesarean section. Maternal or neonatal death were infrequently pre-specified by the authors and therefore not specifically reported. Therefore, these outcomes could not be included in this review.

Maternal satisfaction was reported in seven studies (Ahmed 2016; Chavakula 2015; Gilson 2017; Henry 2013; Lyndrup 1994; Mundle 2017; Shechter-Maor 2015). Of these seven studies, only three studies contributed data for the meta-analysis (Gilson 2017; Lyndrup 1994; Mundle 2017). The other four studies reported on maternal satisfaction with continuous data. Because of the importance of this outcome, we decided to report these results in narrative form.

Source of trial funding

Only 14 trials provided details for their funding sources: Filho 2002 received financial support from CAPES. Guinn 2000 reported that UpJohn Pharmaceuticals provided funds to purchase study drugs. Kruit 2016 received a grand from the Finnish medical society Duodecim and Helsinky university central hospital. Lokkegaard 2015 reported the randomisation procedure was funded by Snedkermester Sophus Jacobsen & Astrid Jacobsens fond and the Danish Toyota Foundation. Mackeen 2018 received a small internal grant to assist with the conduct and statistical analyses for the entire study. Mundle 2017 received funding from the Department for International Development, Medical Research Council, and Wellcome Trust Joint Global Health Trials Scheme. The study of Pennell 2009 was supported by a grant from the Women and Infants Research Foundation and Adeza Biomedical Corporation contributed support for the fetal fibronectin test kits. Roberts 1986 and Sullivan 1996 stated they were supported by the Vicksburg hospital medical foundation. Salim 2011 received funding from the Emek medical centre. Tan 2015 reported that the double balloons were provided by Cook medical. ten Eikelder 2016 received funding from Fonds Nuts Ohra. Wang 2014 received financial support of The People's Liberation Army. Wu 2017 received a grant from the Nature Science Foundation of China.

Thirteen studies reported they received no funding (Aduloju 2016; El Khouly 2017; Garba 2016; Hoppe 2016; Husain 2017; Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; Laddad 2013; Lanka 2014; Meetei 2015; Shechter-Maor 2015; Somirathne 2017). All other studies did not provide information on received funding.

Declarations of interest

Thirty-five studies declared no conflict of interest (Aduloju 2016; Ahmed 2016; Al-Ibraheemi 2018; Amorosa 2017; Barda 2018; Chavakula 2015; Cromi 2012; Edwards 2014c; El Khouly 2017; Filho 2002; Garba 2016; Goonewardene 2014; Henry 2013; Hoppe 2016; Husain 2017; Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; Kandil 2012; Kruit 2016; Laddad 2013; Lanka 2014; Lewis 1983; Lokkegaard 2015; Mackeen 2018; Meetei 2015; Noor 2015; Pennell 2009; Salim 2011; Shechter-Maor 2015; Somirathne 2017;Tan 2015; ten Eikelder 2016; Wang 2014; Wu 2017).

Two studies reported they had conflicts of interest. Atad 1996 stated that the first author has a patent licensing arrangement for Atad ripening device and thus has the potential gain from its sales. Mundle 2017 reported that one of the authors was a scientific adviser to Azanta, a Danish pharmaceutical company.

The remaining studies did not report whether any conflicts of interest were present.

Excluded studies

In total, 138 studies were excluded (see Characteristics of excluded studies), 74 studies (102 reports) in this update. In this update, most of the excluded trials (54 studies) made comparisons not within the scope of this review (Ahmad 2015; Arsenijevic 2012; Arshad 2016; Caughey 2007; Connolly 2016; Connolly 2017; Demirel 2015; Edwards 2017; El-Khayat 2016; El Sharkwy 2017; Forgie 2016; Forooshani 2011; Fruhman 2017; Gadel 2015; Ghanaei 2009; Ghanaie 2013; Gibson 2013; Gu 2015; Haghighi 2015; Hallak 2008; He 2000; Hill 2013; Hussein 2012; Ifnan 2006; Jonsson 2011; Kehl 2012; Kehl 2015; Lam 2006; Leong 2017; Levine 2016; Lutgendorf 2012; Manish 2016; Mattingly 2015; McGee 2016; Mei-Dan 2012a; Mei-Dan 2014; Movahed 2016; Mullin 2014; Neethurani 2013; Rameez 2007; Rezk 2014; Saad 2016; Salmeen 2012; Sandberg 2017; Schoen 2017; Sharma 2015a; Sharma 2017; Siddiqui 2013; Torbenson 2015;Walfisch 2015; Wickramasinghe 2014; Wilkinson 2015; Yaddehige 2015; Zakaria 2017). Four studies were not randomised trials (Du 2015; Miller 2015; Naseem 2007; Nasir 2012) and one study did a cross-over after 24 hours (Ugwu 2013). Thirteen trial registration were excluded because they exceeded the participated end date by more than two years and it was presumed the trial was terminated before enrolment (Anabosy 2014; Baacke 2006; Behrashi 2013; Cullimore 2009; Dias 2008 EUCTR 2012; Kamilya 2011; Mei-Dan 2012; Park 2011 Pathiraja 2014; Reif 2012; Yazdani 2011; Zhang 2014). For more information, see Characteristics of excluded studies.

Risk of bias in included studies

The quality assessments are graphically summarised in Figure 2 and Figure 3.

Figure 2. 'Risk of bias' graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

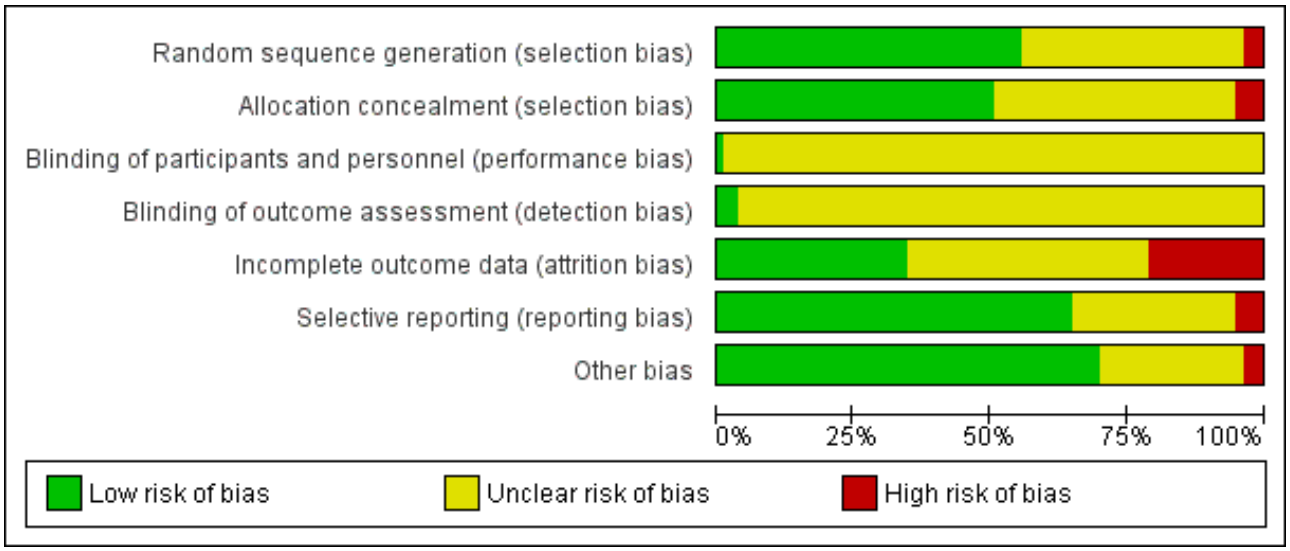


Figure 3. 'Risk of bias' summary: review authors' judgements about each risk of bias item for each included study.

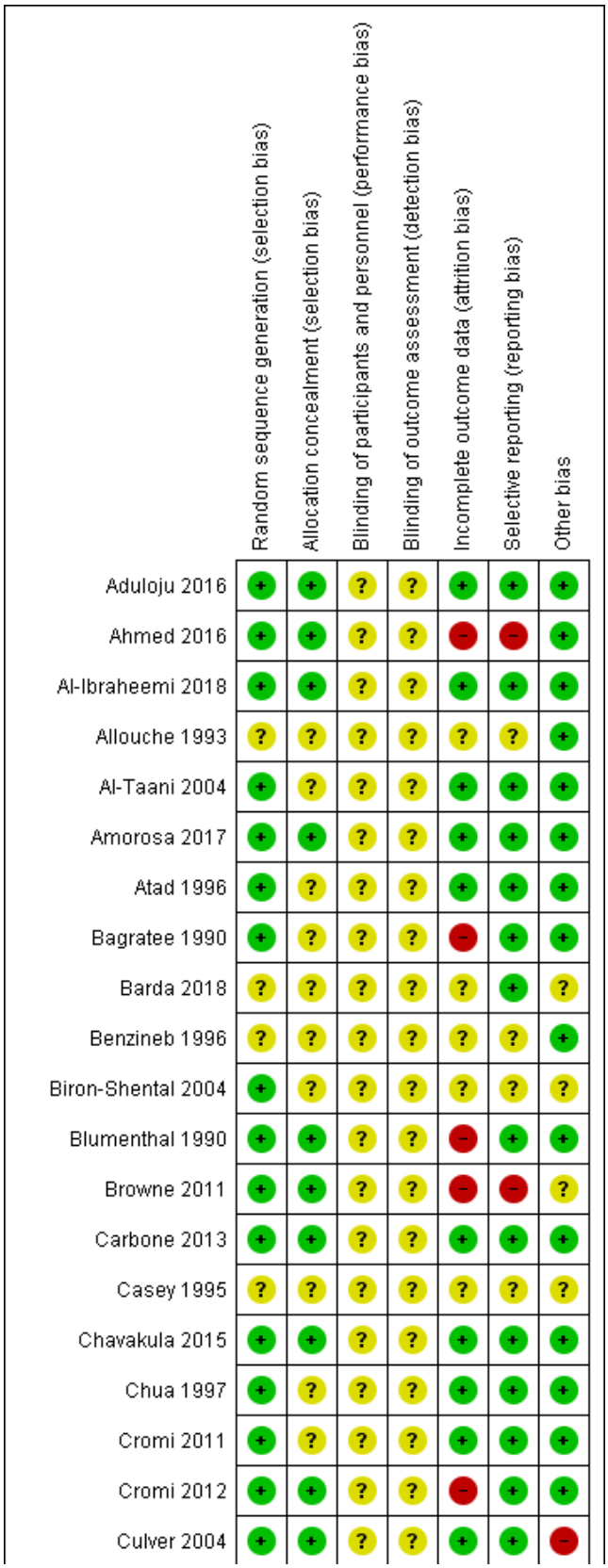


Figure 3. (Continued)

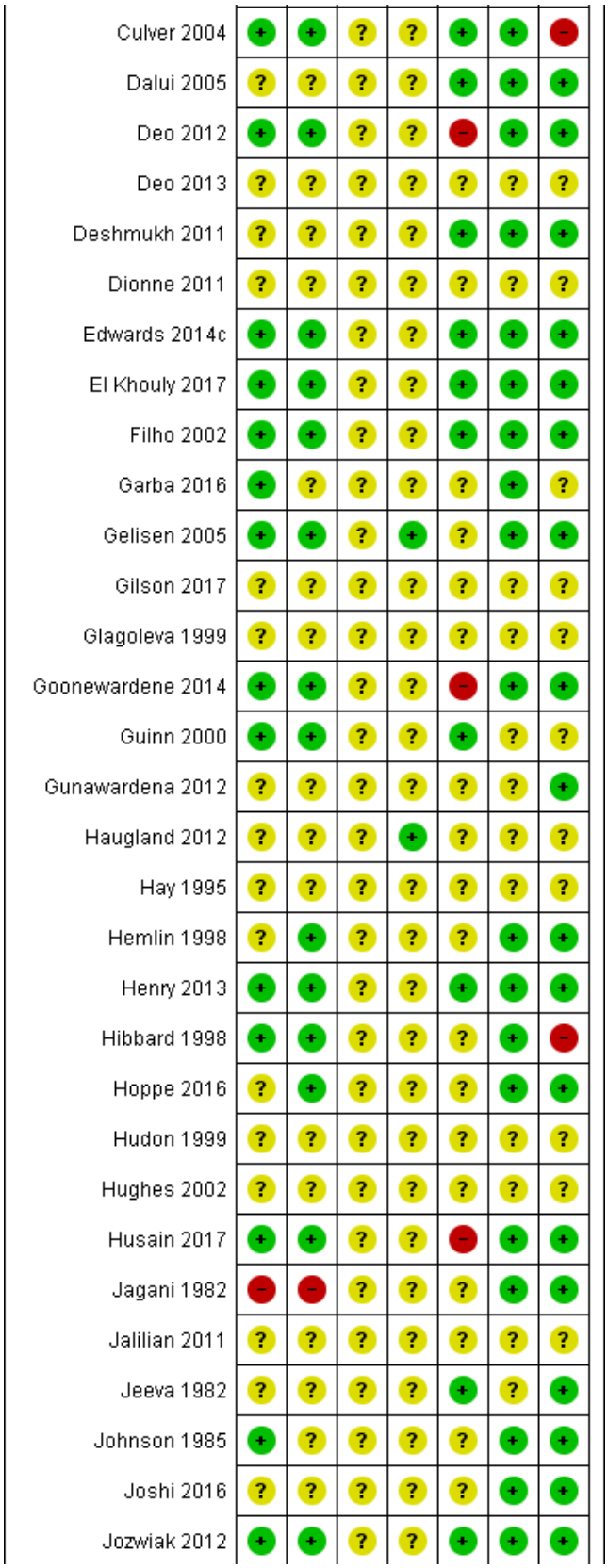


Figure 3. (Continued)

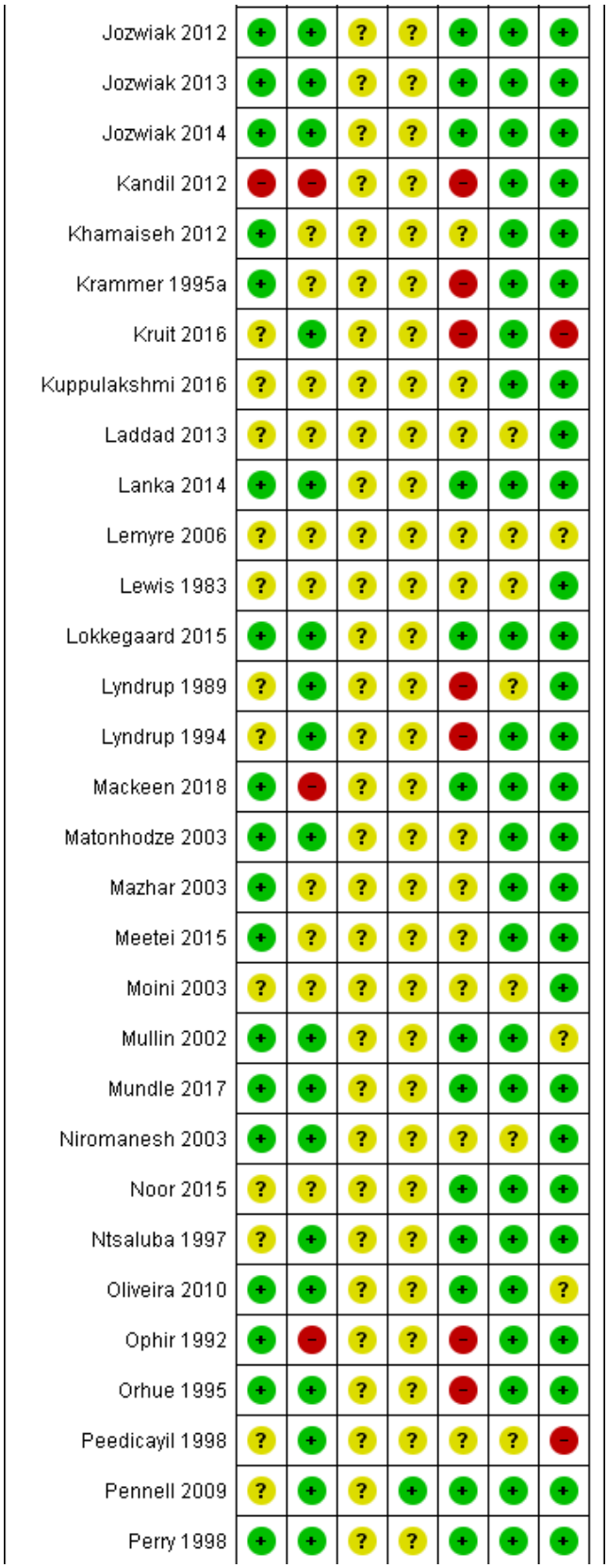


Figure 3. (Continued)

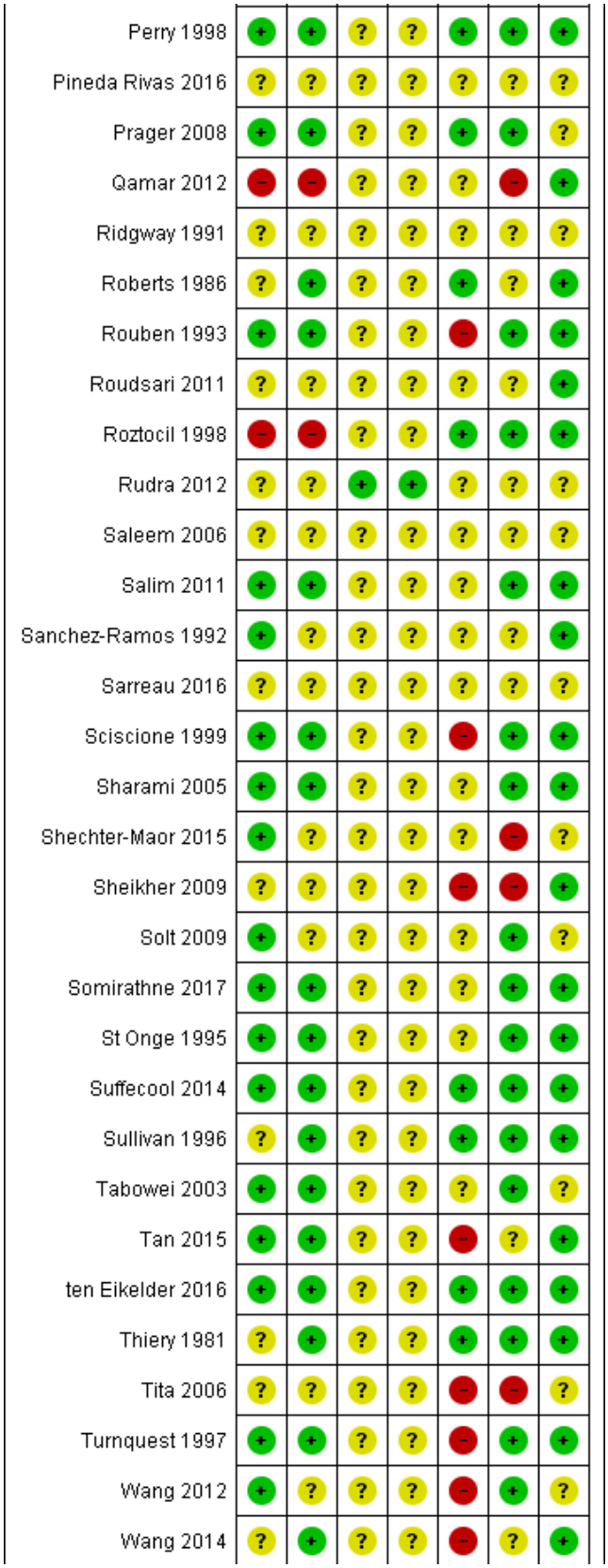
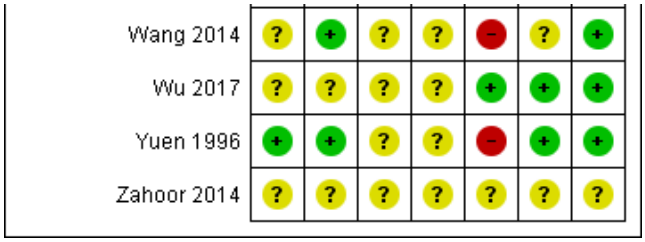


Figure 3. (Continued)



This review update includes nine comparisons with more than 10 studies, of which we constructed funnel plots (Figure 4; Figure 5; Figure 6; Figure 7; Figure 8; Figure 9; Figure 10; Figure 11; Figure 12). Visual inspection of one funnel plot (Figure 5) was somewhat asymmetrical suggesting some form of publication bias for this outcome (oxytocin augmentation) for the comparison of a balloon versus vaginal PGE2. Visual assessment of the other funnel plots did not show asymmetry, suggesting there is no publication bias for these comparisons.

Figure 4. Funnel plot of comparison: 1 Balloon (Foley or ATAD) versus vaginal Prostaglandin E2: all women, outcome: 1.3 Caesarean section.

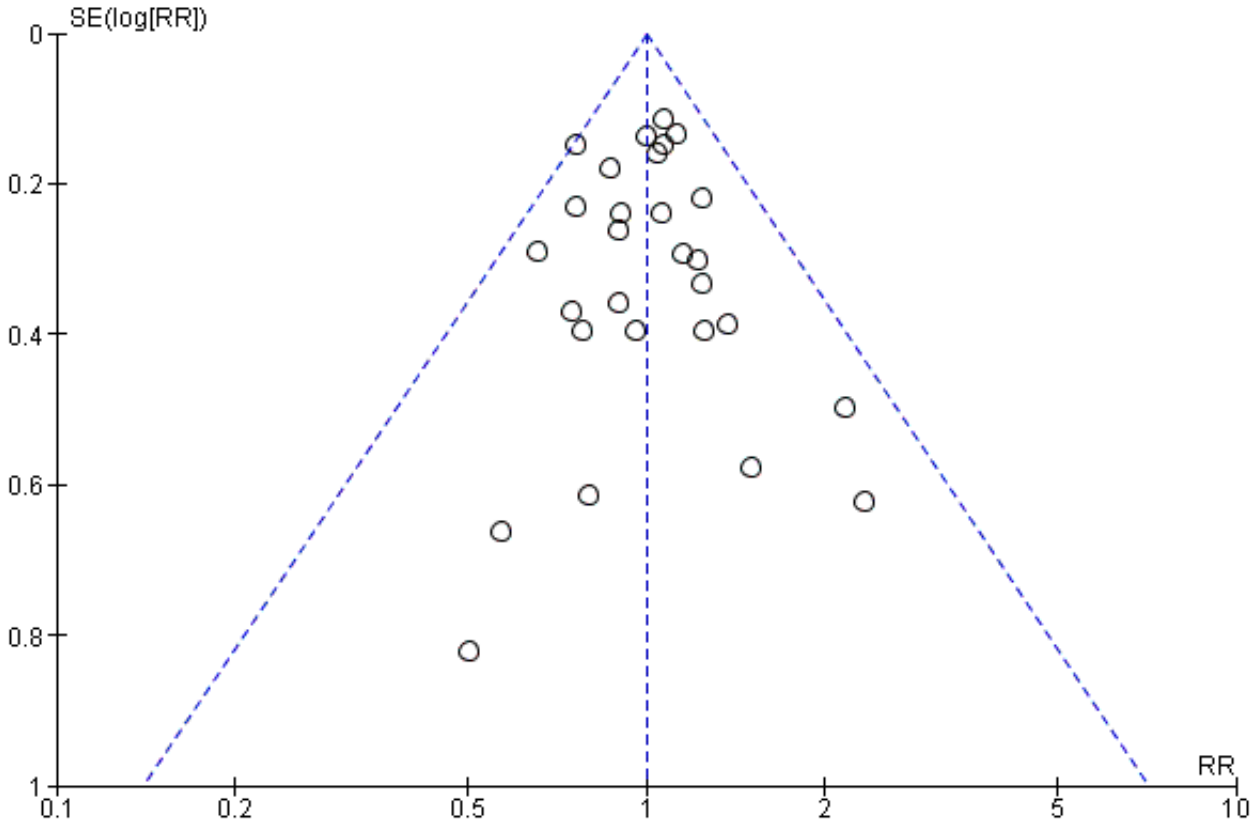


Figure 5. Funnel plot of comparison: 1 Balloon (Foley or ATAD) versus vaginal Prostaglandin E2: all women, outcome: 1.6 Oxytocin augmentation.

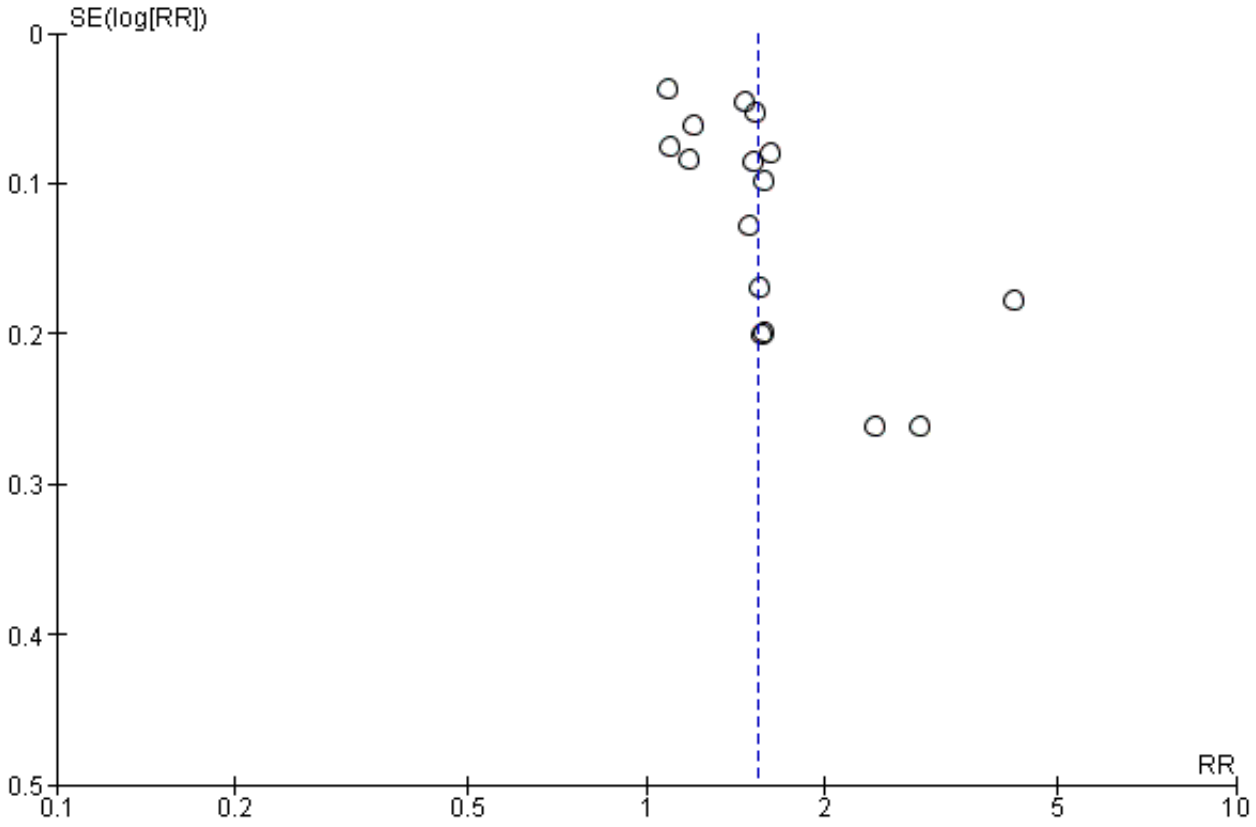


Figure 6. Funnel plot of comparison: 1 Balloon (Foley or ATAD) versus vaginal Prostaglandin E2: all women, outcome: 1.7 Uterine hyperstimulation without fetal heart rate changes.

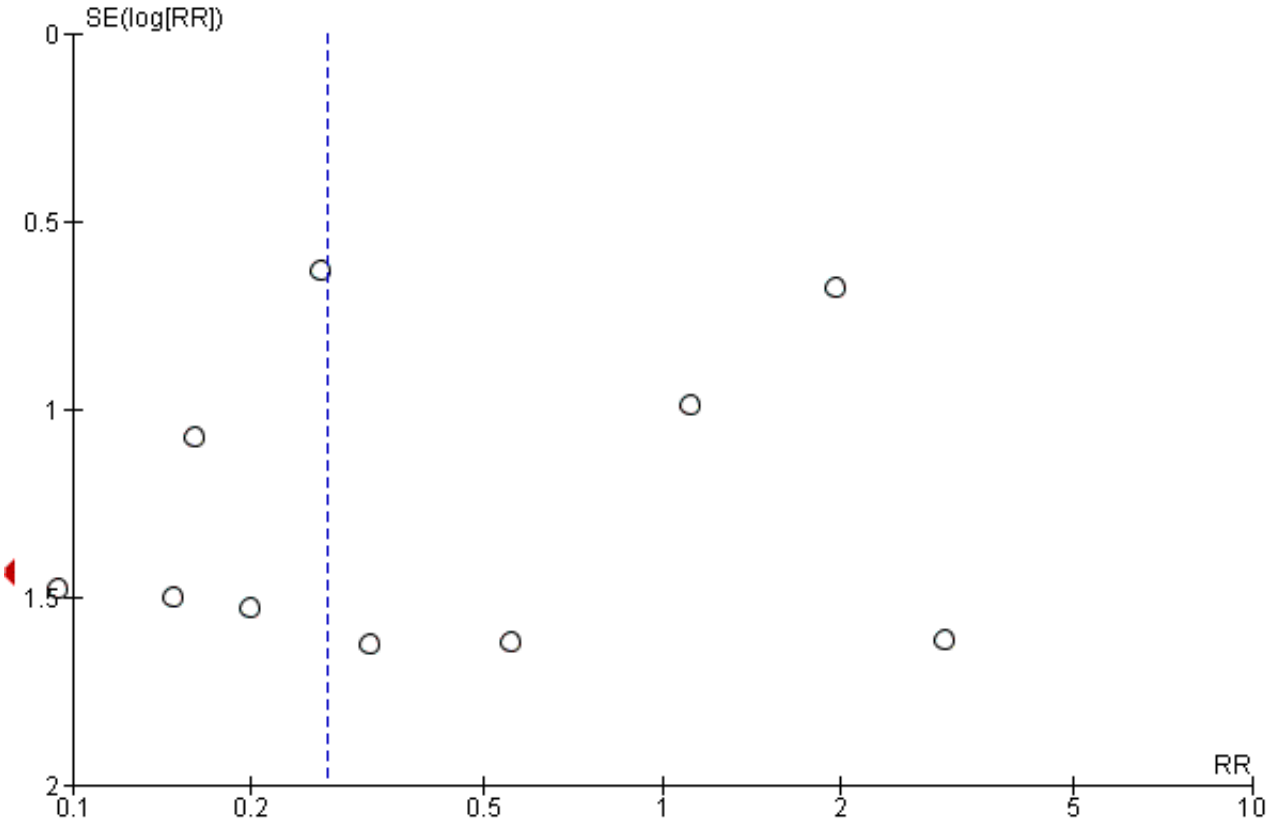


Figure 7. Funnel plot of comparison: 1 Balloon (Foley or ATAD) versus vaginal Prostaglandin E2: all women, outcome: 1.10 Instrumental vaginal delivery.

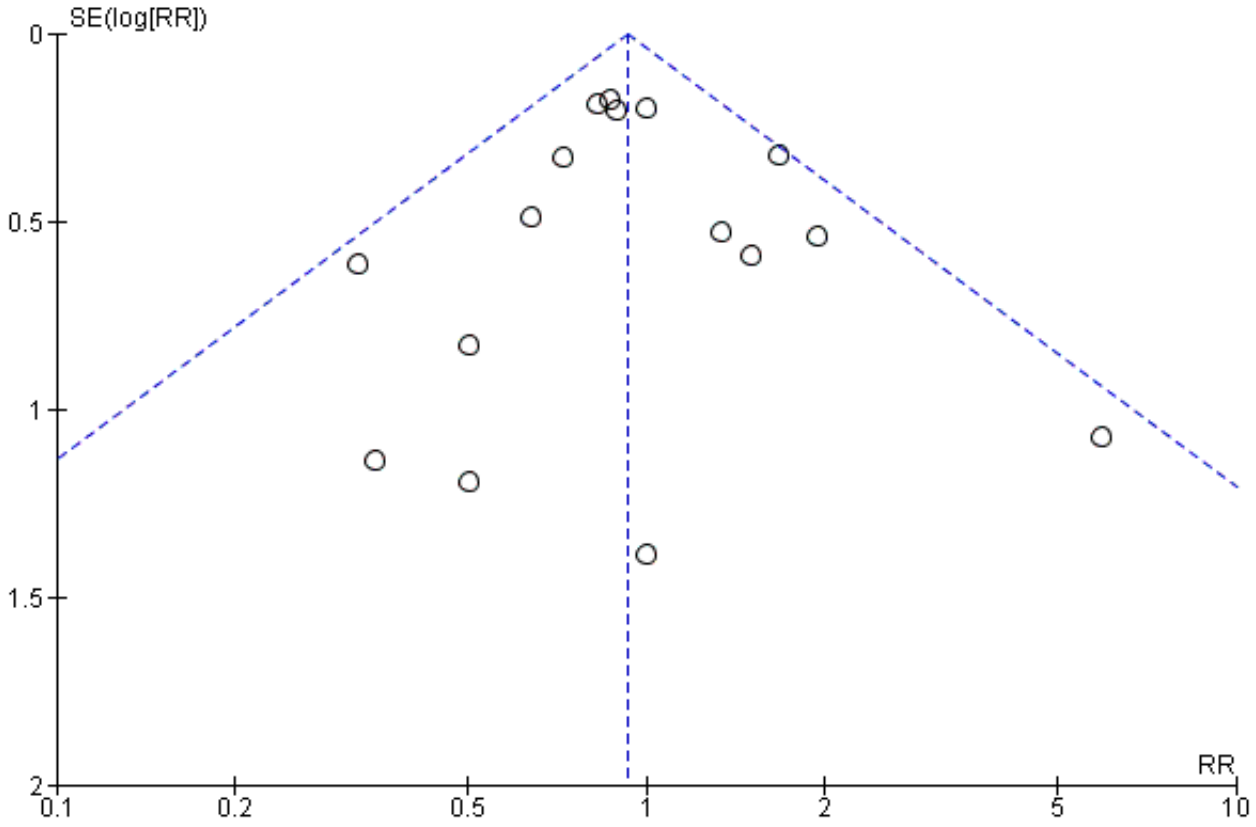


Figure 8. Funnel plot of comparison: 1 Balloon (Foley or ATAD) versus vaginal Prostaglandin E2: all women, outcome: 1.12 Apgar score < 7 at 5 minutes.

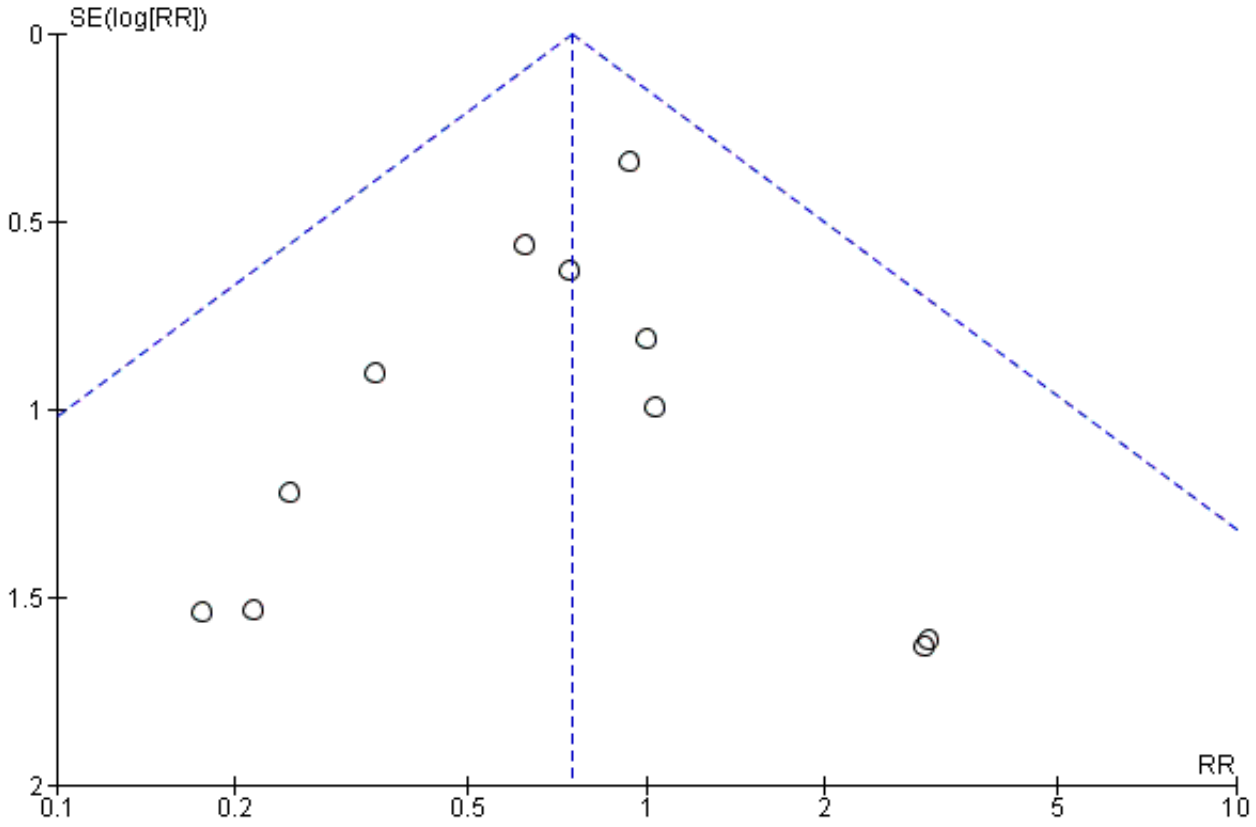


Figure 9. Funnel plot of comparison: 1 Balloon (Foley or ATAD) versus vaginal Prostaglandin E2: all women, outcome: 1.13 Neonatal intensive care unit admission.

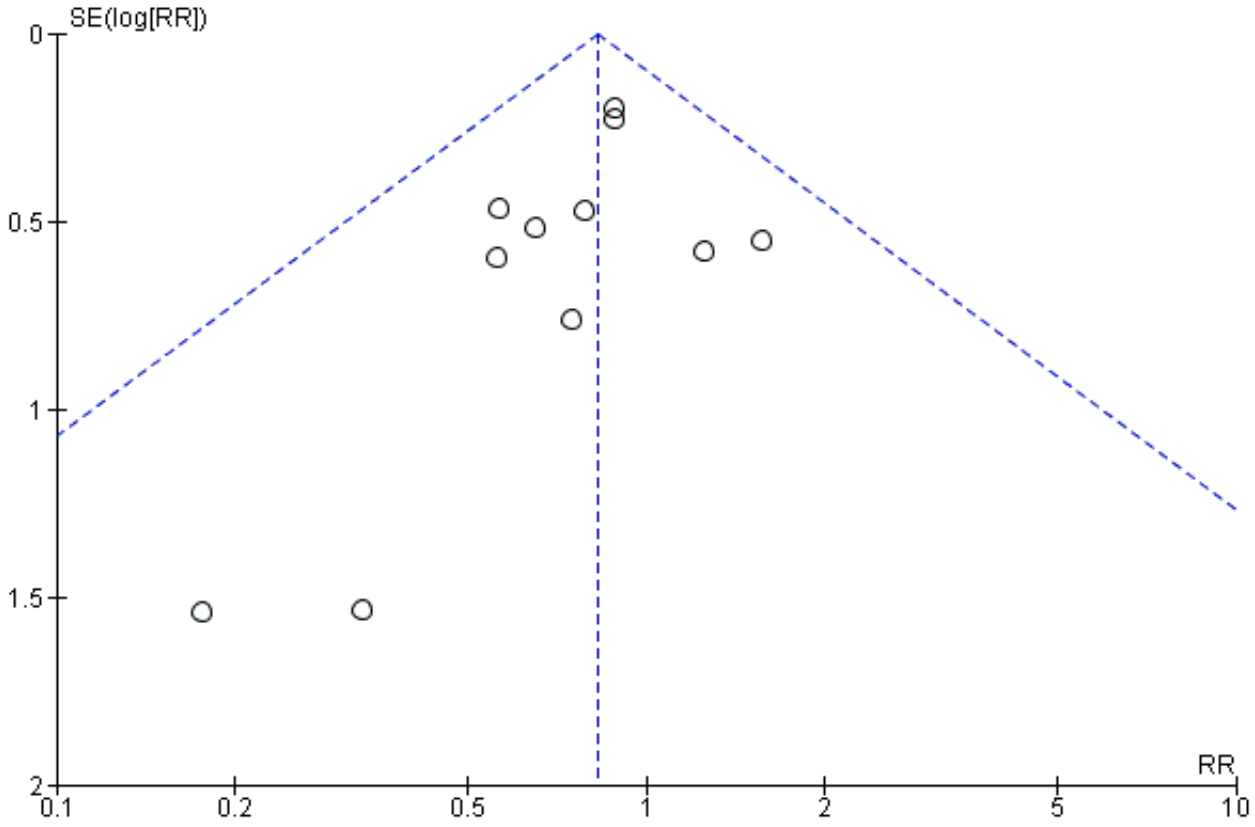


Figure 10. Funnel plot of comparison: 1 Balloon (Foley or ATAD) versus vaginal Prostaglandin E2: all women, outcome: 1.21 Fetal distress.

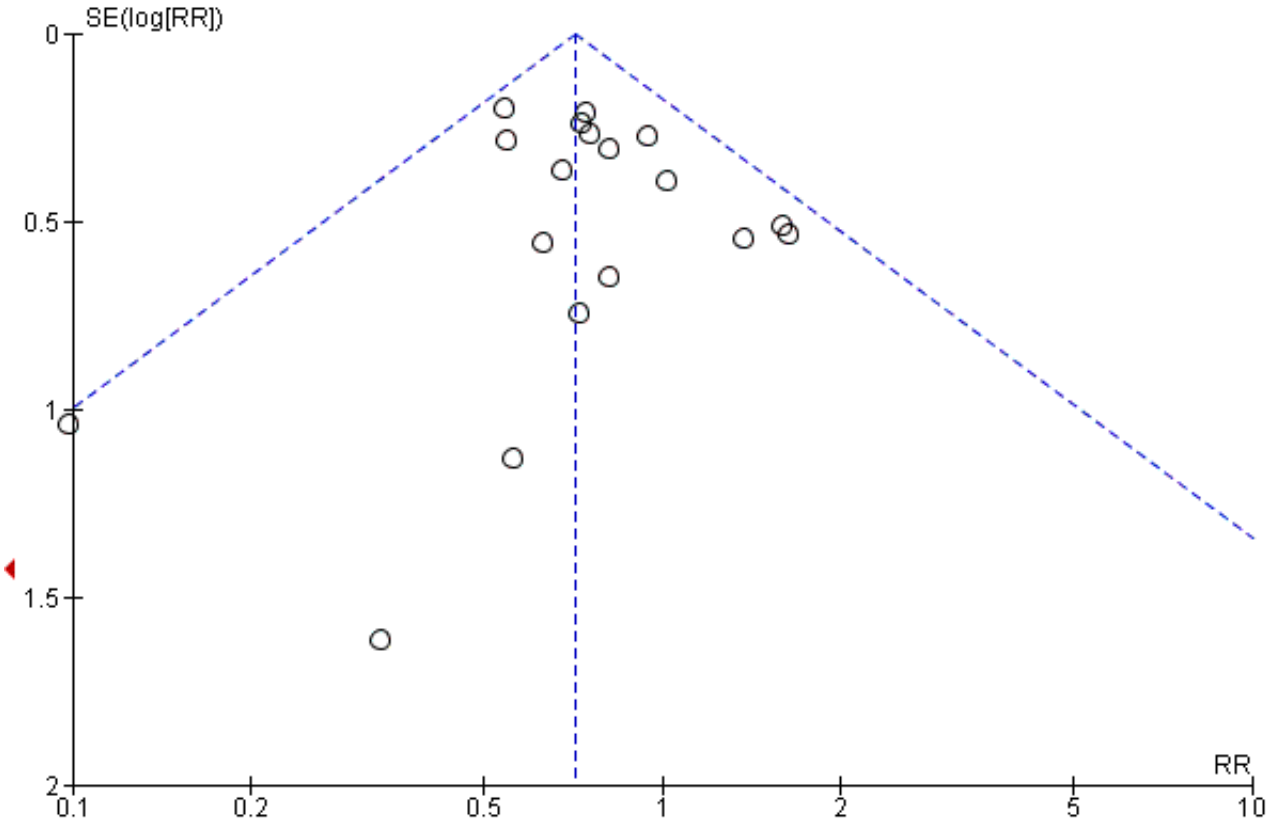


Figure 11. Funnel plot of comparison: 4 Balloon (Foley or ATAD) versus intracervical Prostaglandin E2: all women, outcome: 4.3 Caesarean section.

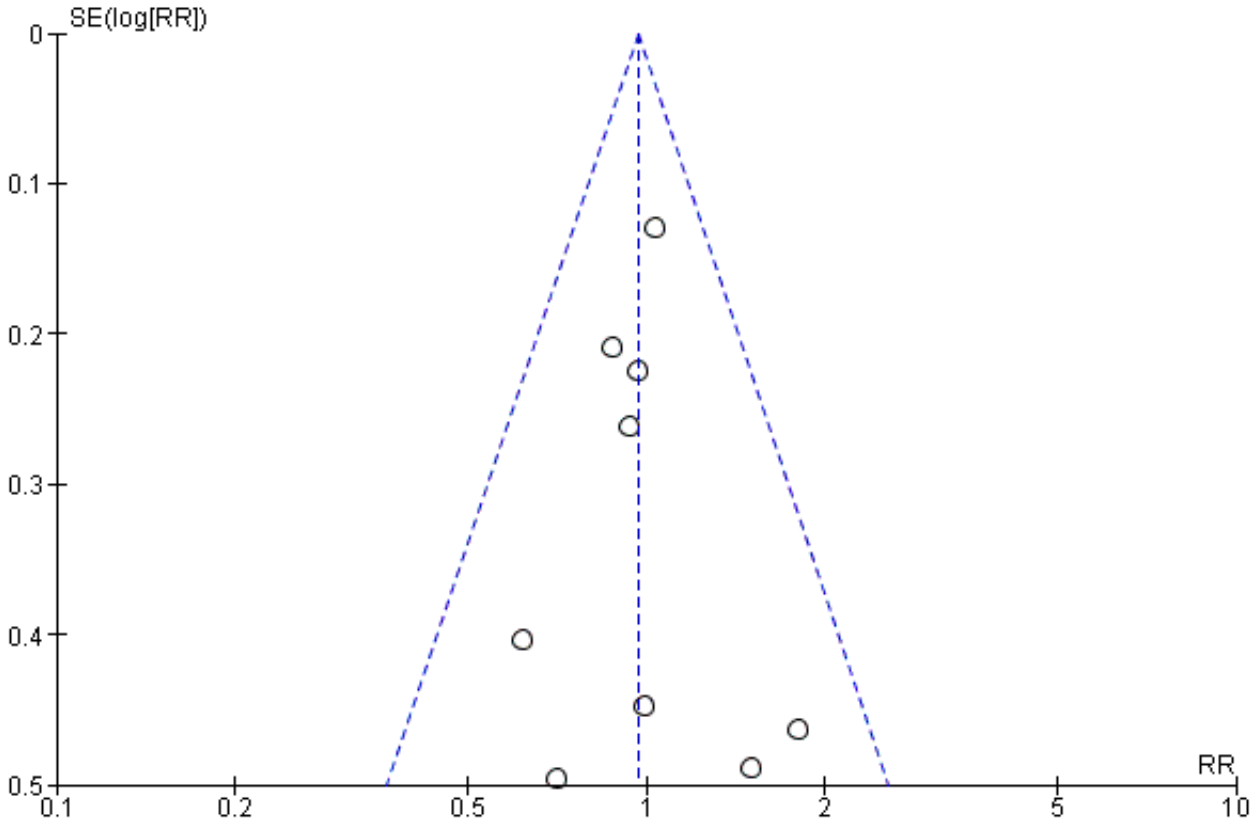
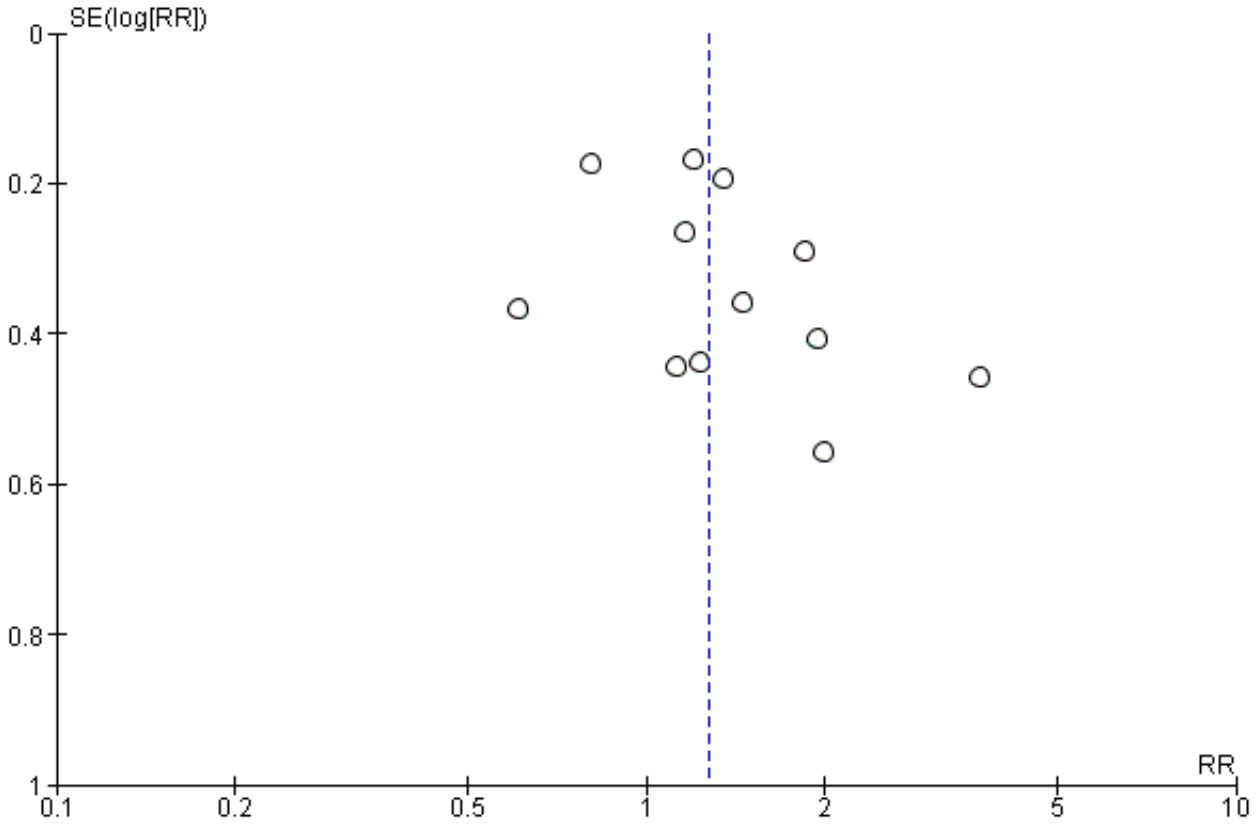


Figure 12. Funnel plot of comparison: 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, outcome: 7.3 Caesarean section.



Allocation

Sequence generation

We judged 62 trials to be at low risk of selection bias, reporting some form of adequate random sequencing such as a computer-generated sequence or a list of random numbers (Aduloju 2016; Ahmed 2016; Al-Ibraheemi 2018; Al-Taani 2004; Amorosa 2017; Atad 1996; Bagratee 1990; Blumenthal 1990; Browne 2011; Carbone 2013; Chavakula 2015; Chua 1997; Cromi 2011; Cromi 2012; Culver 2004; Deo 2012; Edwards 2014c; El Khouly 2017; Filho 2002; Garba 2016; Gelisen 2005; Goonewardene 2014; Guinn 2000; Henry 2013; Hibbard 1998; Husain 2017; Johnson 1985; Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; Khamaiseh 2012; Krammer 1995a; Lanka 2014; Lokkegaard 2015; Mackeen 2018; Matonhodze 2003; Mazhar 2003; Meetei 2015; Mullin 2002; Mundle 2017; Niromanesh 2003; Oliveira 2010; Ophir 1992; Orhue 1995; Perry 1998; Prager 2008; Rouben 1993; Salim 2011; Sanchez-Ramos 1992; Sciscione 1999; Sharami 2005; Shechter-Maor 2015; Solt 2009; Somirathne 2017; St Onge 1995; Suffecool 2014; Tabowei 2003; Tan 2015; ten Eikelder 2016; Turnquest 1997; Wang 2012; Yuen 1996).

Three trials were classified as high risk because they were quasi-randomised trials. Jagani 1982 randomised by last digit of the chart number, Kandil 2012 randomised by odd or even admission date and Roztocil 1998 randomised by week of admission.

We judged the remaining 40 trials to be at unclear risk of selection bias, as they did not report on how a random sequence was generated (Allouche 1993; Barda 2018; Benzineb 1996; Casey 1995; Dalui 2005; Deshmukh 2011; Dionne 2011; Gilson 2017; Glagoleva 1999; Gunawardena 2012; Haugland 2012; Hay 1995; Hemlin 1998; Hoppe 2016; Hudon 1999; Jeeva 1982; Joshi 2016; Kruit 2016; Kuppulakshmi 2016; Laddad 2013; Lemyre 2006; Lewis 1983; Lyndrup 1989; Lyndrup 1994; Moini 2003; Noor 2015; Ntsaluba 1997; Pennell 2009; Pineda Rivas 2016; Ridgway 1991; Roberts 1986; Roudsari 2011; Rudra 2012; Saleem 2006; Sarreau 2016; Sheikher 2009; Sullivan 1996;Tita 2006; Wang 2014; Wu 2017).

Allocation concealment

Fifty-five studies reported a method of allocation concealment likely to have a low risk of bias, either by central randomisation or sequentially numbered, sealed, opaque envelopes (Aduloju 2016; Ahmed 2016; Al-Ibraheemi 2018; Amorosa 2017; Blumenthal 1990; Browne 2011; Carbone 2013; Chavakula 2015; Cromi 2012; Culver 2004; Deo 2012; Edwards 2014c; El Khouly 2017; Filho 2002; Gelisen 2005; Goonewardene 2014; Guinn 2000; Hemlin 1998; Henry 2013; Hibbard 1998; Hoppe 2016; Husain 2017; Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; Kruit 2016; Lanka 2014; Lokkegaard 2015; Lyndrup 1989; Lyndrup 1994; Matonhodze 2003; Mullin 2002; Mundle 2017; Niromanesh 2003; Ntsaluba 1997; Oliveira 2010; Orhue 1995; Pennell 2009; Perry 1998; Prager 2008; Roberts 1986; Rouben 1993; Salim 2011; Sciscione 1999; Sharami 2005; Somirathne 2017; St Onge 1995; Suffecool 2014; Sullivan 1996; Tabowei 2003; Tan 2015; ten Eikelder 2016; Turnquest 1997; Wang 2014; Yuen 1996).

Five studies were judged to be high risk. In the quasi-randomised trials of Jagani 1982, Kandil 2012 and Roztocil 1998 no measures were taken to conceal the allocation; Mackeen 2018 stated that the allocation was not concealed and Ophir 1992 allocated women by odd or even randomisation number.

The remaining 45 studies did not report a method for concealing allocation and were judged as being at unclear risk of bias (Allouche 1993; Al-Taani 2004; Atad 1996; Bagratee 1990; Barda 2018; Benzineb 1996; Casey 1995; Chua 1997; Cromi 2011; Dalui 2005; Deshmukh 2011; Dionne 2011; Garba 2016; Gilson 2017; Glagoleva 1999; Gunawardena 2012; Haugland 2012; Hay 1995; Hudon 1999; Jeeva 1982; Johnson 1985; Joshi 2016; Khamaiseh 2012; Krammer 1995a; Kuppulakshmi 2016; Laddad 2013; Lemyre 2006; Lewis 1983; Mazhar 2003; Meetei 2015; Moini 2003; Noor 2015; Pineda Rivas 2016; Ridgway 1991; Roudsari 2011; Rudra 2012; Saleem 2006; Sanchez-Ramos 1992; Sarreau 2016; Shechter-Maor 2015; Sheikher 2009; Solt 2009; Tita 2006; Wang 2012; Wu 2017).

Blinding

Performance bias

Given the nature of the intervention (mechanical methods for induction of labour) and comparison (pharmacological methods for induction of labour), it was not possible for women or clinicians to be blinded to the treatment group in any of the trials. For the more objective outcomes such as perinatal death, the lack of blinding is unlikely to be a major source of bias. Therefore, risk of performance bias was judged as unclear in all studies, but was a reason to downgrade the quality of evidence from high to moderate.

Detection bias

It would have been possible for outcome assessment to have been undertaken by someone blinded to allocation groups. However, only four trials reported blinded outcome assessment (rated as low risk of bias). Gelisen 2005 blinded only for the outcome of hyperstimulation. In the studies of Pennell 2009 and Gelisen 2005, data were collected by research midwives who were blinded to the intervention. Rudra 2012 and Haugland 2012 both stated they performed a double blind-trial but provided too little information to assess how this was done. The remaining 101 trials did not detail whether outcome assessment was blinded, and thus we judged risk of detection bias to be unclear. Measurement of outcomes such as perinatal death are unlikely to be biased by lack of blinding.

Incomplete outcome data

We considered 38 studies to be at low risk of attrition bias with data analyses according to intention- to-treat and minimal/no loss to follow-up or exclusion of women (Aduloju 2016; Al-Ibraheemi 2018; Al-Taani 2004; Amorosa 2017; Atad 1996; Carbone 2013; Chavakula 2015; Chua 1997; Cromi 2011; Culver 2004; Dalui 2005; Deshmukh 2011; Edwards 2014c; El Khouly 2017; Filho 2002; Guinn 2000; Henry 2013; Jeeva 1982; Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; Lanka 2014; Lokkegaard 2015; Mackeen 2018; Mullin 2002; Mundle 2017; Noor 2015; Ntsaluba 1997; Oliveira 2010; Pennell 2009; Perry 1998; Prager 2008; Roberts 1986; Roztocil 1998; Suffecool 2014; Sullivan 1996; ten Eikelder 2016; Wu 2017).

Forty-three studies were judged to be at unclear risk of attrition bias, mainly because it was not clear if intention-to-treat analyses was used (Allouche 1993; Benzineb 1996; Garba 2016; Gelisen 2005; Hemlin 1998; Hibbard 1998; Hoppe 2016; Jagani 1982; Johnson 1985; Joshi 2016; Khamaiseh 2012; Laddad 2013; Lewis 1983; Matonhodze 2003; Meetei 2015; Niromanesh 2003; Roudsari 2011; Salim 2011; Sanchez-Ramos 1992; Sharami 2005; Shechter-Maor 2015; Somirathne 2017; St Onge 1995), or there was too little information to judge attrition bias (Barda 2018; Casey 1995; Dionne 2011; Gilson 2017; Glagoleva 1999; Gunawardena 2012; Haugland 2012; Hay 1995; Hudon 1999; Kuppulakshmi 2016; Lemyre 2006; Mazhar 2003; Moini 2003; Pineda Rivas 2016; Ridgway 1991; Rudra 2012; Saleem 2006; Sarreau 2016; Solt 2009; Tabowei 2003).

Twenty-four studies were classified as high risk for attrition bias. In the studies of Ahmed 2016, Cromi 2012 and Wang 2014, women were excluded because of failed placement of the balloon. Kandil 2012 also excluded nine patients because of failed placement of the Foley catheter, but replaced them with women who did receive a Foley catheter. Deo 2012 analysed data as treated and also four cases went missing without a given explanation. Husain 2017, Kruit 2016, Lyndrup 1989, Sciscione 1999, Tan 2015, Turnquest 1997, Wang 2012 and Yuen 1996 excluded cases because of protocol violation and Krammer 1995a reported they analysed intention-to-treat, but eventually excluded women because of protocol violation or if they delivered within six hours after induction had started. Goonewardene 2014 also excluded women if they went into spontaneous labour after the intervention. Lyndrup 1994 excluded women if they delivered after 48 hours of induction had started. Orhue 1995 excluded women if they had an unfavourable cervix after 12 hours of induction. Rouben 1993 excluded women after failed induction. The studies of Bagratee 1990, Blumenthal 1990, Browne 2011, Ophir 1992, Sheikher 2009, Tita 2006 were judged to be of high risk for attrition bias because cases were missing without a given explanation.

Selective reporting

Seventy-two studies were judged to be at low risk of reporting bias as all pre-specified outcomes were reported (Aduloju 2016; Al-Ibraheemi 2018; Al-Taani 2004; Amorosa 2017; Atad 1996; Bagratee 1990; Barda 2018; Blumenthal 1990; Carbone 2013; Chavakula 2015; Chua 1997; Cromi 2011; Cromi 2012; Culver 2004; Dalui 2005; Deo 2012; Deshmukh 2011; Edwards 2014c; El Khouly 2017; Filho 2002; Garba 2016; Gelisen 2005; Goonewardene 2014; Guinn 2000; Hemlin 1998; Henry 2013; Hibbard 1998; Hoppe 2016; Husain 2017; Jagani 1982; Johnson 1985; Joshi 2016; Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; Kandil 2012; Khamaiseh 2012; Krammer 1995a; Kruit 2016; Kuppulakshmi 2016; Lanka 2014; Lokkegaard 2015; Lyndrup 1994; Mackeen 2018; Matonhodze 2003; Mazhar 2003; Meetei 2015; Mullin 2002; Mundle 2017; Noor 2015; Ntsaluba 1997;Oliveira 2010; Ophir 1992; Orhue 1995; Pennell 2009; Perry 1998; Prager 2008; Rouben 1993; Roztocil 1998; Salim 2011; Sciscione 1999; Sharami 2005; Solt 2009; Somirathne 2017; St Onge 1995; Suffecool 2014; Sullivan 1996; Tabowei 2003; ten Eikelder 2016; Turnquest 1997; Wang 2012;Wu 2017; Yuen 1996). It is important to note that not all studies had a trial protocol available and therefore it was not possible to check if there were other pre-specified outcomes not reported in the method section of the article.

Twenty-eight studies were judged to be of unclear risk of reporting bias. In 10 studies no outcomes were pre-specified in the methods section (Allouche 1993; Benzineb 1996; Jeeva 1982; Laddad 2013; Lewis 1983; Lyndrup 1989; Roberts 1986; Sanchez-Ramos 1992; Tan 2015; Wang 2014 and in 18 studies there was too little information to judge reporting bias (Casey 1995; Dionne 2011; Gilson 2017;

Glagoleva 1999; Guinn 2000; Gunawardena 2012; Haugland 2012; Hay 1995; Hudon 1999; Lemyre 2006; Moini 2003; Niromanesh 2003; Pineda Rivas 2016; Ridgway 1991; Roudsari 2011; Rudra 2012; Saleem 2006; Sarreau 2016).

The studies of Ahmed 2016, Browne 2011, Shechter-Maor 2015, Sheikher 2009 and Tita 2006 were judged as high risk as not all pre-specified outcomes were reported in the results section.

Other potential sources of bias

For 24 studies it was not clear if there was another source of bias and these were therefore judged as unclear. For one study (Barda 2018), only a manuscript with no tables was available. Two trials (Browne 2011; Tita 2006) were not published, but the results of the primary outcome and adverse events were reported in the trial registration. Guinn 2000 stopped recruiting women for one arm of the study without an explanation. Mullin 2002 calculated a sample size of 140 women but included 200 women without explanation. Prager 2008 included patients who did not meet inclusion criteria. Eighteen studies were only published as abstracts, or there was too little information provided and so it was not possible to judge the risk of bias (Casey 1995; Dionne 2011; Garba 2016; Gilson 2017; Glagoleva 1999; Haugland 2012; Hay 1995; Hudon 1999; Lemyre 2006; Oliveira 2010; Pineda Rivas 2016; Ridgway 1991; Rudra 2012; Sarreau 2016; Shechter-Maor 2015; Solt 2009; Tabowei 2003; Wang 2012).

The studies of Culver 2004, Hibbard 1998, and Kruit 2016 were judged as high risk for other potential sources of bias as they were terminated early before the required sample size was recruited.

Effects of interventions

See: **Summary of findings for the main comparison** Balloon (Foley or ATAD) compared to vaginal prostaglandin E2 for third trimester labour induction in women with a viable fetus; **Summary of findings 2** Balloon (Foley or ATAD) compared to low-dose vaginal misoprostol for third trimester induction of labour in women with a viable fetus; **Summary of findings 3** Balloon (Foley or ATAD) compared to low-dose oral misoprostol for third trimester induction of labour in women with a viable fetus

Balloon (single or double) versus vaginal prostaglandin E2 (28 trials involving 6619 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

There may be little or no difference in vaginal deliveries not achieved within 24 hours between induction of labour with a balloon catheter and vaginal PGE2 (average risk ratio (RR) 1.01, 95% confidence interval (CI) 0.82 to 1.26; 7 studies; 1685 women; low-quality evidence; Analysis 1.1), although there was substantial heterogeneity for this outcome (Tau^2 = 0.06; Chi^2 = 29.06, df = 6 (P =< 0.0001); I^2 = 79%).

A sensitivity analysis, after eliminating the two trials assessed as having a potentially higher risk of concealment or attrition bias (Cromi 2012; Wang 2014), did not change the effect observed, despite the result becoming less precise (average RR 1.10, 95% CI 0.86 to 1.41; 1351 women; 5 studies; I^2 = 82%).

The same result was seen on a subgroup comparison for primiparous women (RR 1.01, 95% CI 0.83 to 1.23; 330 women; 1 study; Analysis 2.1). While for multiparous women, a balloon catheter may increase the risk of a vaginal delivery not being achieved within 24 hours (RR 4.38, 95% CI 1.74 to 10.98; 147 women; 1 study; Analysis 3.1).

Uterine hyperstimulation with fetal heart rate (FHR) changes

A balloon catheter probably reduces the risk of uterine hyperstimulation with FHR changes when compared to vaginal PGE2 (RR 0.35, 95% CI 0.18 to 0.67; 6 studies; 1966 women; moderate-quality evidence; Analysis 1.2), the absolute effect being 21 less per 1000 deliveries.

The same result was seen on a subgroup comparison for primiparous women (RR 0.05, 95% CI 0.00 to 0.85; 330 women; 1 study; Analysis 2.2). For multiparous women, no outcomes were reported.

Caesarean section

There probably is little or no difference in caesarean sections between both induction methods (RR 1.00, 95% CI 0.92 to 1.09; 28 studies; 6619 women; moderate-quality evidence; Analysis 1.3). Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 4).

It is uncertain whether there is a difference in caesarean sections between both induction methods on subgroups for both primiparous women (average RR 0.89, 95% CI 0.59 to 1.33; 828 women; 5 studies; Analysis 2.3) and multiparous women (RR 1.31, 95% CI 0.65 to 2.63; 180 women; 2 studies; Analysis 3.2) as the results of these outcomes were imprecise. Furthermore, for the primiparous group, there was also substantial heterogeneity (Tau^2 = 0.11; Chi^2 = 10.01, df = 4 (P = 0.04); I^2 = 60%).

Serious neonatal morbidity or perinatal death

A balloon catheter probably reduces the risk of serious neonatal morbidity or perinatal death when compared to vaginal PGE2 (RR 0.48, 95% CI 0.25 to 0.93; 8 studies; 2757 women; moderate-quality evidence; Analysis 1.4). However, numbers are low (12/1483 versus 25/1274, respectively) and almost all of these numbers were cases of birth asphyxia. Only two perinatal deaths were reported, both in the PGE2 group (Edwards 2014c). No heterogeneity was seen for this outcome.

For primiparous women, it is uncertain whether there is a difference in effect as the result for this outcome was imprecise (RR 0.17, 95% CI 0.01 to 4.24; 330 women; 1 study; Analysis 2.4). For multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (RR 0.20, 95% CI 0.01 to 4.12; 4 studies; 1481 women; very low-quality evidence; Analysis 1.5). Of all the 28 studies included for this comparison, only four studies reported on this composite outcome. No events were reported in the balloon group. One author (Jozwiak 2012) reported two events in the PGE2 group, both events being uterine rupture.

Only one study (60 women) reported on this outcome in primiparous women, in which no events were seen (Analysis 2.5). For multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

Induction of labour with a balloon catheter may increase the risk of oxytocin augmentation when compared to vaginal PGE2 (average RR 1.54, 95% CI 1.35 to 1.76; 4828 women; 16 studies; Analysis 1.6), although there was substantial heterogeneity for this outcome (Tau^2 = 0.05; Chi^2 = 141.47, df = 15 (P = < 0.0001); I^2 = 89%). Visual inspection of the funnel plot was somewhat asymmetrical, suggesting some form of publication bias (Figure 5).

A sensitivity analysis, after eliminating the five trials assessed as having a potentially higher risk of allocation or attrition bias (Cromi 2012; Deo 2012; Tan 2015; Wang 2012; Wang 2014), did not alter the result, nor did it lower heterogeneity (average RR 1.37, 95% CI 1.21 to 1.54; 4005 women; 11 studies; I^2 = 87%).

Uterine hyperstimulation without FHR changes

A balloon catheter may reduce the risk of uterine hyperstimulation without FHR changes when compared to vaginal PGE2 (average RR 0.27, 95% CI 0.11 to 0.66; 2444 women; 15 studies; Analysis 1.7), although there was moderate heterogeneity for this outcome (Tau^2 = 1.13; Chi^2 = 22.28, df = 12 (P = 0.03); I^2 = 46%). Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 6).

A sensitivity analysis, after eliminating the seven trials assessed as having a potentially higher risk of allocation or attrition bias (Deo 2012; Orhue 1995; Shechter-Maor 2015; Tan 2015; Wang 2012; Wang 2014; Zahoor 2014), made this result less precise and therefore raises uncertainty as to whether there is a difference in uterine hyperstimulation without FHR changes (average RR 0.26, 95% CI 0.06 to 1.05; 1694 women; 8 studies; I^2 = 62%).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (RR 0.20, 95% CI 0.01 to 4.12; 1045 women; 2 studies; Analysis 1.8). Only two cases of uterine rupture were reported, both in the PGE2 group in the study of Jozwiak 2012. Uterine rupture was defined by the authors as a separation of the uterine wall, and in one case this was caused by inserting an intrauterine pressure catheter.

Epidural analgesia

A balloon catheter may slightly increase the use of epidural analgesia during labour when compared to vaginal PGE2 (average RR 1.14, 95% CI 1.00 to 1.29; 2828 women; 8 studies; Analysis 1.9). However, there was substantial heterogeneity for this outcome (Tau^2 = 0.02; Chi^2 = 32.09, df = 7 (P = < 0.0001); I^2 = 78%).

A sensitivity analysis, after eliminating the two trials assessed as having a potentially higher risk of allocation or attrition bias (Cromi 2012; Tan 2015), did not alter the result, nor did it lower heterogeneity (average RR 1.11, 95% CI 0.97 to 1.28; 2537 women; 6 studies; I^2 = 80%).

Instrumental vaginal delivery

There probably is little or no difference in instrumental vaginal deliveries between both induction methods (RR 0.93, 95% CI 0.79 to 1.09; 4514 women; 16 studies; Analysis 1.10). Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 7).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 0.89, 95% CI 0.67 to 1.19; 964 women; 4 studies; Analysis 1.11).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar score less than seven at five minutes between both induction methods (RR 0.74, 95% CI 0.49 to 1.14; 4271 women; 14 studies; low-quality evidence; Analysis 1.12). Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 8).

Neonatal intensive care unit (NICU) admission

A balloon catheter may reduce the risk of a NICU admission when compared to vaginal PGE2 (RR 0.82, 95% CI 0.65 to 1.04; 3647 women; 12 studies; low-quality evidence; Analysis 1.13), the absolute effect being 15 fewer NICU admission per 1000 deliveries. Although it should be noted that there is a wide range of treatment effects that are compatible with the data, from a very small increase in risk to very large decrease. Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 9).

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is a difference in perinatal death between both induction methods (RR 0.21, 95% CI 0.01 to 4.27; 1036 women; 5 studies; Analysis 1.14). Only two cases of perinatal death were reported by Edwards 2014c, both being cases of neonatal death and born to women randomised to vaginal PGE2. The authors describe that in both cases the neonates died as a result of complications related to a congenital diaphragmatic hernia and were unrelated to the induction method.

Disability in childhood

Not reported.

Maternal side effects (all)

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (RR 0.82, 95% CI 0.63 to 1.06; 2215 women; 8 studies; Analysis 1.15).

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

A balloon catheter may reduce the amount of women not being satisfied with the induction method when compared to prostaglandin E2 (RR 0.61, 95% CI 0.39 to 0.97; 93 women; 1 study; Analysis 1.16), the absolute effect being 224 fewer women not satisfied per 1000 deliveries. This outcome was reported by Henry 2013 by asking the women if they would choose the randomised induction method again. Patient satisfaction was also reported by Shechter-Maor 2015, but could not be included in the meta-analysis. In this study women were asked to score their satisfaction with the induction process on a five-point Likert scale. No difference in satisfaction was seen between both induction methods (3.41 (± 1.3) versus 3.33 (± 1.2), respectively; P = 0.860).

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

It is uncertain whether there is a difference in maternal fever during labour between both methods (RR 0.87, 95% CI 0.65 to 1.17; 2362 women; 7 studies; Analysis 1.17).

Antibiotics during labour

It is uncertain whether there is a difference in antibiotics during labour between both methods (RR 1.43, 95% CI 0.89 to 2.29; 330 women; 1 study; Analysis 1.18).

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 0.69, 95% CI 0.32 to 1.49; 376 women; 1 study; Analysis 1.19).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 0.49, 95% CI 0.19 to 1.27; 706 women; 2 studies; Analysis 1.20).

Fetal distress

A balloon catheter probably reduces the risk of fetal distress for which a caesarean section is indicated when compared to vaginal PGE2 (RR 0.71, 95% CI 0.60 to 0.83; 4753 women; 20 studies; Analysis 1.21). Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 10).

Umbilical artery pH < 7.10

A balloon catheter probably reduces the risk of an umbilical artery pH less than 7.10 directly postpartum when compared to vaginal PGE2 (RR 0.65, 95% CI 0.44 to 0.94; 2675 women, 8 studies; Analysis 1.22). However, numbers occurred infrequently in both groups (35 per 1000 versus 56 per 1000, respectively).

Balloon (single or double) versus cervical prostaglandin E2 (10 trials involving 1428 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

It is uncertain whether there is a difference in vaginal deliveries achieved within 24 hours between induction of labour with a balloon catheter and cervical PGE2 (average RR 1.01, 95% CI 0.35 to 2.91; 200 women; 2 studies; Analysis 4.1). There also was substantial heterogeneity for this outcome (Tau^2 = 0.53; Chi^2 = 10.35, df = 1 (P = 0.001); I^2 = 90%). Even though data were pooled, both studies may be incompatible as no overlap of CIs is present. No sensitivity analysis was conducted as no potential high-risk studies were included for this outcome.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between both induction methods (RR 0.37, 95% CI 0.02 to 8.90; 447 women; 4 studies; Analysis 4.2).

Only one small study (53 women) reported this outcome for the subgroups of primiparous and multiparous women. No events were reported in primiparous women (Analysis 5.1). For multiparous women, it is uncertain whether there is a difference for this outcome between both induction methods (RR 0.30, 95% CI 0.01 to 7.02; 53 women; 1 study; Analysis 6.1).

Caesarean section

There probably is little or no difference in caesarean sections between both induction methods (RR 0.97, 95% CI 0.81 to 1.15; 1309 women; 9 studies; Analysis 4.3). Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 11).

It is uncertain whether there is a difference in caesarean sections between both induction methods on subgroup comparisons for both primiparous women (RR 1.30, 95% CI 0.86 to 1.95; 245 women; 3 studies; Analysis 5.2) and multiparous women (average RR 0.66, 95% CI 0.16 to 2.78; 136 women; 3 studies; Analysis 6.2) as the results for both comparisons were imprecise. For the multiparous group, there also was substantial heterogeneity (Tau^2 = 0.90; Chi^2 = 4.78, df = 2 (P = 0.09); I^2 = 58%).

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 0.78, 95% CI 0.29 to 2.05; 500 women; 2 studies; Analysis 4.4). Of the 10 studies included for this comparison, two studies (Benzineb 1996; Laddad 2013) reported on this composite outcome. All reported events in these studies were cases of perinatal death.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

Not reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

It is uncertain whether there is a difference in an unfavourable cervix after 24 hours between both induction methods (RR 0.96, 95% CI 0.70 to 1.34; 219 women; 2 studies; Analysis 4.5).

Oxytocin augmentation

There may be little or no difference in oxytocin augmentation between both induction methods (RR 1.08, 95% CI 0.93 to 1.26; 400 women; 1 study; Analysis 4.6).

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (average RR 0.99, 95% CI 0.09 to 10.38; 654 women; 5 studies; Analysis 4.7). Also, there was substantial heterogeneity for this outcome ($Tau^2 = 2.92$; $Chi^2 = 6.33$, df = 2 (P = 0.04); $I^2 = 68\%$).

A sensitivity analysis, after eliminating the two trials assessed as having a potentially higher risk of allocation or attrition bias (Sciscione 1999; Yuen 1996) did not alter the result, nor did it lower heterogeneity (average RR 0.56, 95% CI 0.01 to 39.31; 430 women; 3 studies; $I^2 = 76\%$).

Uterine rupture

Not reported.

Epidural analgesia

There may be little or no difference in epidural analgesia during labour between both induction methods (RR 0.91, 95% CI 0.81 to 1.02; 149 women; 1 study; Analysis 4.8).

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 1.18, 95% CI 0.68 to 2.05; 337 women; 3 studies; Analysis 4.9).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 1.17, 95% CI 0.42 to 3.26; 118 women; 1 study; Analysis 4.10).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes (RR 0.79, 95% CI 0.41 to 1.53; 475 women; 2 studies; Analysis 4.11).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both methods (RR 0.88, 95% CI 0.60 to 1.31; 400 women; 1 study; Analysis 4.12).

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is difference in perinatal death between both induction methods (RR 0.78, 95% CI 0.29 to 2.05; 500 women; 2 studies. Analysis 4.13). Noteworthy, there was a relatively high number of neonatal deaths reported in the study of Laddad 2013 for the balloon group (6/200), as well as in the cervical PGE2 group (8/200), for which no explanation was given by the authors.

Disability in childhood

Not reported.

Maternal side effects

It is uncertain whether there is a difference in maternal side effects (RR 0.15, 95% CI 0.02 to 1.24; 211 women; 2 studies; Analysis 4.14). The nature of the side effects was not specified in both included studies.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (RR 0.20, 95% CI 0.01 to 4.06; 100 women; 1 study; Analysis 4.15).

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 1.00, 95% CI 0.21 to 4.75; 118 women; 1 study; Analysis 4.16).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 1.00, 95% CI 0.06 to 15.61; 118 women; 1 study; Analysis 4.17).

Fetal distress

A balloon catheter probably reduces the risk of fetal distress for which a caesarean section is indicated when compared to cervical PGE2 (RR 0.61, 95% CI 0.42 to 0.89; 1023 women; 6 studies; Analysis 4.18).

Umbilical artery pH < 7.10

Not reported.

Balloon (single or double) versus low-dose vaginal misoprostol (13 trials involving 1818 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

It is uncertain whether there is a difference in vaginal deliveries not achieved within 24 hours between induction of labour with a balloon catheter and vaginal misoprostol (RR 1.09, 95% CI 0.85 to 1.39; 340 women; 2 studies; low-quality evidence; Analysis 7.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Uterine hyperstimulation with FHR changes

A balloon catheter probably reduces the risk of uterine hyperstimulation with FHR changes when compared to vaginal misoprostol (RR 0.39, 95% CI 0.18 to 0.85; 1322 women; moderate-quality evidence; 8 studies; Analysis 7.2), the absolute effect being 22 fewer cases per 1000 deliveries.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

A balloon catheter may increase the risk of a caesarean section when compared to vaginal misoprostol (average RR 1.28, 95% CI 1.02 to 1.60; 1756 women; 12 studies; low-quality evidence; Analysis 7.3), the absolute effect being 53 more caesarean sections per 1000 deliveries. However, there was moderate heterogeneity for this outcome (Tau^2 = 0.06; Chi^2 = 19.86, df = 11 (P = 0.05); I^2 = 45%).

A sensitivity analysis, after eliminating the three trials assessed as having a potentially higher risk of allocation or attrition bias (Deo 2012; Kandil 2012; Sheikher 2009), did not alter the result, nor did it lower heterogeneity (average RR 1.34, 95% CI 1.05 to 1.71; 1492 women; 10 studies; I^2 = 48%). Visual inspection of the funnel plot associated with this outcome does not suggest any evidence of publication bias (Figure 12).

For the subgroup of primiparous women, it is uncertain whether there is a difference in caesarean sections between both induction methods (RR 0.82, 95% CI 0.59 to 1.13; 255 women; 1 study; Analysis 8.1). For multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 0.58, 95% CI 0.12 to 2.66; 381 women; 3 studies; very low-quality evidence; Analysis 7.4). All of the cases included for this composite outcome were cases of perinatal asphyxia (2/187 versus 4/194, respectively).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (very low-quality evidence; Analysis 7.5). Of the 13 studies included for this comparison, four studies (464 women) reported on this composite outcome. No events of maternal morbidity or death occurred in one of these studies.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 12 hours

It is uncertain whether there is a difference in an unfavourable cervix after 12 hours between both induction methods (average RR 2.66, 95% CI 0.60 to 11.89; 200 women; 2 studies; Analysis 7.6). Also, there was moderate heterogeneity for this outcome (Tau^2 = 0.63; Chi^2 = 1.56, df = 1 (P = 0.21); I^2 = 36%). No studies reported on a time period of 24 hours.

A sensitivity analysis, after eliminating one trial assessed as having a potentially higher risk of allocation or attrition bias (Sheikher 2009), did not change the result, but did narrow the CI (RR 1.82, 95% CI 0.94 to 3.51; 1 study).

Oxytocin augmentation

A balloon catheter probably increases the risk of oxytocin augmentation when compared to vaginal misoprostol (average RR 1.62, 95% CI 1.38 to 1.90; 911 women; 9 studies; Analysis 7.7), although there was substantial heterogeneity for this outcome (Tau^2 = 0.03; Chi^2 = 21.93, df = 8 (P = 0.005); I^2 = 64%).

In the sensitivity analysis, after eliminating two trial assessed as having a potentially higher risk of allocation or attrition bias (Kandil 2012 and Sheikher 2009), heterogeneity was lost without altering the effect observed (average RR 1.50, 95% CI 1.36 to 1.64; 751 women, 7 studies; I^2 = 0%).

Uterine hyperstimulation without FHR changes

A balloon catheter probably reduces the risk of uterine hyperstimulation without FHR changes when compared to vaginal misoprostol (RR 0.25, 95% CI 0.14 to 0.44; 1139 women; 9 studies; Analysis 7.8).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (Analysis 7.9). Of the 13 studies

included for this comparison, only three studies (364 women) reported on this outcome. No events of uterine rupture occurred in one of these studies.

Epidural analgesia

A balloon catheter probably slightly increases the use of epidural analgesia during labour when compared to vaginal misoprostol (RR 1.22, 95% CI 1.06 to 1.41; 517 women; 2 studies; Analysis 7.10).

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.72, 95% CI 0.50 to 1.05; 721 women; 4 studies; Analysis 7.11).

Meconium-stained liquor

A balloon catheter probably reduces the risk of meconium-stained liquor when compared to vaginal misoprostol (RR 0.64, 95% CI 0.48 to 0.87; 1268 women; 7 studies; Analysis 7.12).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 1.00, 95% CI 0.50 to 1.97; 941 women; 7 studies; low-quality evidence; Analysis 7.13).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both induction methods (RR 1.00, 95% CI 0.61 to 1.63; 1302 women; 9 studies; low-quality evidence; Analysis 7.14).

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is difference in perinatal death between both induction methods (Analysis 7.15). Of the 13 studies included for this comparison, only one study (121 women) pre-specified this outcome. No cases of perinatal death were reported in this study.

Disability in childhood

Not reported.

Maternal side effects (all)

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

It is uncertain whether there is difference in maternal vomiting between both induction methods (Analysis 7.16). Of all the 13 studies included for this comparison, only one study (60 women) pre-specified this outcome. No cases of maternal vomiting were reported in this study.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is difference in postpartum haemorrhage between both induction methods (RR 1.14, 95% CI 0.24 to 5.44; 120 women; 1 study; (Analysis 7.17).

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

One study (Chavakula 2015) reported on patient satisfaction, but could not be included in the meta-analysis. In this study, satisfaction was assessed by a visual analogue score ranging from zero to five (0 = very poor; 5 = very good), in which no difference between both induction methods was seen (100 women; 4.5 [4-5] versus 4.45 [3-5], respectively; P = 0.488).

Caregiver not satisfied

Not reported.

Not pre-specified outcomes

Maternal fever during labour

It is uncertain whether there is a difference in maternal fever during labour between both methods (average RR 1.84, 95% CI 0.22 to 15.62; 617 women; 3 studies; Analysis 7.18). Also, there was substantial heterogeneity for this outcome ($Tau^2 = 1.86$; $Chi^2 = 3.95$, df = 1 (P = 0.05); $I^2 = 75\%$). No sensitivity analysis was performed as no potential high-risk studies were included for this outcome.

Antibiotics during labour

Not reported.

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 1.24, 95% CI 0.31 to 4.88; 200 women; 2 studies; Analysis 7.19).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 2.95, 95% CI 0.12 to 71.72; 240 women; 1 study; Analysis 7.20).

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated (RR 0.84, 95% CI 0.67 to 1.05; 1127 women; 7 studies; Analysis 7.21).

Umbilical artery pH < 7.10

It is uncertain whether there is a difference in umbilical artery pH less than 7.10 directly postpartum between both induction methods (RR 1.14, 95% CI 0.35 to 3.74; 120 women; 1 study; Analysis 7.22).

Balloon (single or double) versus low-dose oral misoprostol (seven trials involving 3178 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

A balloon catheter probably increases the risk of a vaginal delivery not achieved within 24 hours when compared to oral misoprostol (RR 1.28, 95% CI 1.13 to 1.46; 782 women, 2 studies. moderate-quality evidence, Analysis 9.1), the absolute effect being 133 more per 1000 deliveries.

The same results were seen on parity subgroup comparisons for primiparous women (RR 1.19, 95% CI 1.04 to 1.37; 573 women; 2 studies; Analysis 10.1) and multiparous women (RR 1.55, 95% CI 1.17 to 2.06; 209 women; 2 studies; Analysis 11.1).

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between both induction methods (RR 0.81, 95% CI 0.48 to 1.38; 2033 women; 2 studies; low-quality evidence; Analysis 9.2).

The same results were seen on parity subgroup comparisons for primiparous women (RR 0.81, 95% CI 0.45 to 1.46; 1206 women; 1 study; Analysis 10.2 and multiparous women (RR 1.45, 95% CI 0.24 to 8.61; 639 women; 1 study; Analysis 11.2).

Caesarean section

A balloon catheter probably slightly increases the risk of a caesarean section when compared to oral misoprostol (RR 1.17, 95% CI 1.04 to 1.32; 3178 women; 7 studies; moderate-quality evidence; Analysis 9.3), the absolute effect being 37 more caesarean sections per 1000 deliveries.

The same result was seen on the subgroup of primiparous women (RR 1.21, 95% CI 1.06 to 1.38; 1778 women; 3 studies; Analysis 10.3). For multiparous women, it is uncertain whether there is a difference in caesarean sections between both methods (RR 1.22, 95% CI 0.79 to 1.87; 848 women; 3 studies; Analysis 11.3).

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 1.11, 95% CI 0.60 to 2.06; 2627 women; 3 studies; low-quality evidence; Analysis 9.4).

The same results were seen on parity subgroup comparisons for primiparous women (RR 4.49, 95% CI 0.77 to 26.14; 1296 women; 2 studies; Analysis 10.4) and multiparous women (RR 0.98, 95% CI 0.14 to 6.86; 729 women; 2 studies; Analysis 11.4).

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (RR 0.50, 95% CI 0.05 to 5.52; 2627 women; 3 studies; very low-quality evidence; Analysis 9.5).

The same results were seen on parity subgroup comparisons for primiparous women (RR 0.51, 95% CI 0.05 to 5.63; 1296 women; 2 studies; Analysis 10.5) and multiparous women (Analysis 11.5). In the latter group, no events of maternal morbidity or death were reported (2 studies; 729 women).

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

It is uncertain whether there is a difference in an unfavourable cervix after 24 hours between both induction methods (average RR 0.98, 95% CI 0.61 to 1.56; 994 women; 4 studies; Analysis 9.6). Also, there was moderate heterogeneity for this outcome (Tau^2 = 0.06; Chi^2 = 2.96, df = 2 (P = 0.23); I^2 = 33%).

A sensitivity analysis, after eliminating the two trials assessed as having a potentially higher risk of allocation or attrition bias (Goonewardene 2014; Sheikher 2009), did not change the result, although heterogeneity was lost (RR 1.31, 95% CI 0.81 to 2.15; 782 women; 2 studies; I^2 = 0%).

Oxytocin augmentation

A balloon catheter may increase the risk of oxytocin augmentation when compared to oral misoprostol (average RR 1.28, 95% CI 1.09 to 1.49; 2847 women; 5 studies; Analysis 9.7) although there was substantial heterogeneity for this outcome (Tau^2 = 0.03; Chi^2 = 31.32, df = 4 (P < 0.000001); I^2 = 87%).

A sensitivity analysis, after eliminating the three trials assessed as having a potentially higher risk of allocation or attrition bias (Goonewardene 2014; Kruit 2016; Sheikher 2009), did not change this result, nor did it lower heterogeneity (average RR 1.35, 95% CI 1.02 to 1.79; 2447 women; 2 studies; I^2 = 95%).

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (average RR 0.50, 95% CI 0.12 to 2.07; 2838 women; 5 studies; Analysis 9.8). Also, there was substantial heterogeneity for this outcome (Tau^2 = 1.26; Chi^2 = 8.12, df = 4 (P = 0.09); I^2 = 51%).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias (Sheikher 2009), did not change the effect observed, nor did it lower heterogeneity (average RR 0.49, 95% CI 0.09 to 2.64; 2778 women; 4 studies; I^2 = 60%).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (Analysis 9.9). Of the seven studies included for this comparison, three studies (2627 women) pre-specified this outcome. No events of uterine rupture occurred in any of these studies.

Epidural analgesia

A balloon catheter may slightly increase the risk for epidural analgesia when compared to oral misoprostol (average RR 1.08, 95% CI 0.96 to 1.22; 2635 women; 3 studies; Analysis 9.10). However, the result is still too imprecise to make a valid judgement on this outcome. Also, there was substantial heterogeneity for this outcome (Chi^2 = 4.73, df = 2 (P = 0.09); I^2 = 58%).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias (Kruit 2016), did not change this result, but did lower heterogeneity for this outcome (RR 1.13, 95% CI 1.03 to 1.24; 2447; 2 studies; I^2 = 5%).

Instrumental vaginal delivery

A balloon catheter probably reduces the risk of an instrumental vaginal delivery when compared to oral misoprostol (RR 0.71, 95% CI 0.55 to 0.92; 2627 women; 3 studies; Analysis 9.11).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (average RR 0.77, 95% CI 0.44 to 1.35; 2627 women; 3 studies; Analysis 9.12). Also, there was moderate heterogeneity for this outcome ($Tau^2 = 0.11$; $Chi^2 = 3.09$, df = 2 (P = 0.21); $I^2 = 35\%$). No sensitivity analysis was conducted as no potential high-risk studies were included for this outcome.

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 0.71, 95% CI 0.38 to 1.32; 2693 women; 4 studies; low-quality evidence; Analysis 9.13).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both induction methods (RR 0.82, 95% CI 0.58 to 1.17; 2873 women; 5 studies; low-quality evidence; Analysis 9.14).

Neonatal encephalopathy

It is uncertain whether there is a difference in neonatal encephalopathy between both induction methods (RR 0.81, 95% CI 0.32 to 2.03; 600 women; 1 study; Analysis 9.15).

Perinatal death

It is uncertain whether there is difference in perinatal death between both induction methods (RR 1.28, 95% CI 0.49 to 3.30; 2627 women; 3 studies; Analysis 9.16) as the result was imprecise and events occurred infrequently (9/1310 versus 7/1317, respectively). In the balloon group, two cases of perinatal death were related to asphyxia, compared to one case in the misoprostol group.

Disability in childhood

Not reported.

Maternal side effects (all)

It is uncertain whether there is a difference in maternal side effects between both induction methods (RR 0.61, 95% CI 0.33 to 1.13; 662 women; 2 studies; Analysis 9.17).

Maternal nausea

Not reported.

Maternal vomiting

It is uncertain whether there is a difference in maternal vomiting between both induction methods (RR 0.73, 95% CI 0.37 to 1.46; 662 women; 2 studies; Analysis 9.18).

Maternal diarrhoea

It is uncertain whether there is a difference in maternal diarrhoea between both induction methods (RR 0.29, 95% CI 0.06 to 1.37; 602 women; 1 study; Analysis 9.19).

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is difference in postpartum haemorrhage between both induction methods (RR 1.03, 95% CI 0.79 to 1.34; 2966 women; 5 studies; Analysis 9.20).

Serious maternal complications

Not reported.

Maternal death

It is uncertain whether there is a difference in maternal death between both induction methods (Analysis 9.21). Of the 13 studies included for this comparison, three studies (2627 women) pre-specified this outcome. No events of maternal death occurred in one of these studies.

Woman not satisfied

A balloon catheter may increase the risk of women not being satisfied when compared to oral misoprostol (RR 1.70, 95% CI 1.15 to 2.50; 602 women; 1 study; Analysis 9.22), the absolute effect being 80 more women not satisfied per 1000 deliveries. In the one study included for this outcome, women were asked if they would choose the same induction method again in a future induction of labour.

Caregiver not satisfied

Not reported.

Not pre-specified outcomes

Maternal fever during labour

There probably is little or no difference in maternal fever during labour between both induction methods (RR 0.98, 95% CI 0.78 to 1.24; 2033 women; 2 studies; Analysis 9.23).

Antibiotics during labour

It is uncertain whether there is a difference in antibiotics during labour between both induction methods (RR 1.22, 95% CI 0.75 to 2.00; 2033 women; 2 studies; Analysis 9.24).

Chorioamnionitis

Not reported.

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 0.56, 95% CI 0.05 to 6.03; 188 women; 1 study; Analysis 9.25).

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 0.82, 95% CI 0.61 to 1.09; 2966 women; 5 studies; Analysis 9.26).

Umbilical artery pH < 7.10

It is uncertain whether there is a difference in umbilical artery pH less than 7.10 directly postpartum between both induction methods (RR 0.77, 95% CI 0.53 to 1.12; 1535 women; 2 studies; Analysis 9.27).

Balloon (single or double) versus oxytocin (eight trials involving 781 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

Not reported.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between induction of labour with a balloon and oxytocin (RR 0.20, 95% CI 0.01 to 4.11; 200 women; 1 study; Analysis 12.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

A balloon catheter probably reduces the risk of a caesarean section when compared to oxytocin (RR 0.68, 95% CI 0.56 to 0.83; 781 women; 8 studies; Analysis 12.2), the absolute effect being 126 fewer caesarean sections per 1000 deliveries.

For women with a previous caesarean section, a balloon catheter may slightly reduce the risk of a caesarean section when compared to oxytocin (RR 0.80, 95% CI 0.64 to 1.00; 364 women; 3 studies; Analysis 13.1). However, the result is still too imprecise to make a valid judgement on this outcome.

For primiparous women, it is uncertain whether there is a difference in effect as the result of this outcome was imprecise (RR 0.43, 95% CI 0.12 to 1.50; 60 women; 1 study; Analysis 14.1). For multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (Analysis 12.3). Of the eight studies included for this comparison, one study (100 women) reported on this composite outcome. No events of neonatal morbidity or perinatal death occurred in this study.

The same result was seen on a subgroup of women with a previous caesarean section. One study (100 women) reported on this outcome, in which no events of serious neonatal morbidity of perinatal death occurred (Analysis 13.2).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (Analysis 12.4). Of the eight studies included for this comparison, two studies (160 women) reported on this composite outcome. No events of serious maternal morbidity or death occurred in these studies.

The same result was seen on a subgroup of women with a previous caesarean section. One study (100 women) reported on this outcome, in which no events of serious maternal morbidity of death occurred (Analysis 13.3).

On parity subgroup comparisons, one study (60 women) reported on this outcome in primiparous women, in which no events were seen (Analysis 14.2). For multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

It is uncertain whether there is a difference in an unfavourable cervix after 24 hours between both induction methods (RR 0.56, 95% CI 0.20 to 1.54; 100 women; 1 study; Analysis 12.5).

Oxytocin augmentation

Not a relevant outcome because all women in the comparison group received oxytocin.

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (RR 1.00, 95% CI 0.23 to 4.29; 192 women; 3 studies; Analysis 12.6).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (Analysis 12.7). Of the eight studies included for this comparison, one study (100 women) pre-specified this outcome. No events of uterine rupture occurred in this study.

Epidural analgesia

Not reported.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 1.19, 95% CI 0.55 to 2.57; 220 women; 3 studies; Analysis 12.8).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 0.53, 95% CI 0.23 to 1.21; 272 women; 2 studies; Analysis 12.9).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 0.71, 95% CI 0.14 to 3.53; 300 women; 2 studies; Analysis 12.10).

Neonatal intensive care unit admission

It is uncertain whether there is difference in NICU admissions between both induction methods (RR 0.80, 95% CI 0.32 to 1.98; 372 women; 3 studies; Analysis 12.11).

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is a difference in perinatal death between both induction methods (Analysis 12.12). Of the eight studies included for this comparison, one study (100 women) pre-

specified this outcome. No cases of perinatal death occurred in this study.

Disability in childhood

Not reported.

Maternal side effects (all)

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is difference in postpartum haemorrhage between both induction methods (RR 1.26, 95% CI 0.51 to 3.11; 396 women; 4 studies; Analysis 12.13).

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

It is uncertain whether there is difference in maternal fever during labour between both induction methods (RR 0.20, 95% CI 0.01 to 4.00; 60 women; 1 study; Analysis 12.14).

Antibiotics during labour

Not reported.

Chorioamnionitis

Not reported.

Endometritis

Not reported.

Fetal distress

A balloon catheter probably reduces the risk of fetal distress for which a caesarean section is indicated when compared to oxytocin (RR 0.43, 95% CI 0.19 to 0.98; 332 women; 3 studies; Analysis 12.15).

Umbilical artery pH < 7.10

Not reported.

Balloon (single or double) versus amniotomy (one trial involving 20 women)

The only outcome of interest reported for this comparison was caesarean section. Other outcomes were not reported.

Caesarean section

It is uncertain whether there is difference in caesarean sections between induction of labour with a balloon and amniotomy (RR 0.25, 95% CI 0.03 to 1.86; 20 women; 1 study; Analysis 15.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Singe balloon (Foley) versus double balloon (ATAD/Cook) (five trials involving 826 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

There may be little or no difference in vaginal deliveries not achieved within 24 hours between induction of labour with a single balloon and a double balloon (average RR 0.97, 95% CI 0.75 to 1.25; 608 women; 3 studies; Analysis 16.1), although there was substantial heterogeneity for this outcome (Chi^2 = 5.64, df = 2 (P = 0.06); I^2 = 65%). No sensitivity analysis was performed as no high-risk studies were included for this outcome.

It is uncertain whether there is a difference in vaginal deliveries not achieved within 24 hours between both induction methods on subgroups for both primiparous women (RR 1.14, 95% CI 0.95 to 1.38; 50 women; 1 study; Analysis 17.1) and multiparous women (RR 1.24, 95% CI 0.80 to 1.93; 48 women; 1 study; Analysis 18.1) as the results for these outcomes were imprecise.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes (Analysis 16.2), as events seem to occur infrequently after the use of both induction methods. Of the five studies included for this comparison, one study (217 women) reported on this outcome. No events of uterine hyperstimulation with FHR occurred in this study.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (average RR 0.97, 95% CI 0.71 to 1.33; 862 women; 5 studies; Analysis 16.3). Also, there was moderate heterogeneity for this outcome (Chi^2 = 6.99, df = 4 (P = 0.14); I^2 = 43%).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of concealment or attrition bias (Ahmed 2016), did not change the effect observed, nor did it lower heterogeneity (average RR 0.92, 95% CI 0.65 to 1.32; 788 women; 5 studies; I^2 = 50%).

The same result was seen on parity subgroup comparisons for primiparous women (average RR 1.30, 95% CI 0.76 to 2.22; 374 women; 4 studies; Analysis 17.2) and multiparous women (RR 0.74, 95% CI 0.30 to 1.84; 186 women; 2 studies; Analysis 18.2).

Furthermore, for the primiparous group, there was also substantial heterogeneity ($Tau^2 = 0.18$; $Chi^2 = 7.96$, df = 3 (P = 0.05); $I^2 = 62\%$).

Serious neonatal morbidity or perinatal death

Not reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (Analysis 16.4). Of the five studies included for this comparison, one study (217 women) reported on this composite outcome. No events of serious maternal morbidity or death occurred in this study.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

There probably is little or no difference in oxytocin augmentation between both induction methods (RR 0.94, 95% CI 0.82 to 1.08; 278 women; 2 studies; Analysis 16.5).

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes (Analysis 16.6), although events seem to occur infrequently after the use of both induction methods. Of the five studies included for this comparison, one study (217 women) reported on this outcome. No events of uterine hyperstimulation without FHR occurred in this study.

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (Analysis 16.7). Of the five studies included for this comparison, one study (217 women) reported on this outcome. No events of uterine rupture occurred in this study.

Epidural analgesia

There probably is little or no difference in epidural analgesia between both induction methods (RR 0.93, 95% CI 0.83 to 1.03; 608 women; 3 studies; Analysis 16.8).

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.86, 95% CI 0.61 to 1.20; 690 women; 3 studies; Analysis 16.9).

Meconium-stained liquor

A single balloon may reduce the risk of meconium-stained liquor when compared to a double balloon (RR 0.40, 95% CI 0.15 to 1.04; 98 women; 1 study; Analysis 16.10). However, the result is still too imprecise to make a valid judgement on this outcome.

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 0.84, 95% CI 0.25 to 2.79; 608 women; 3 studies; Analysis 16.11).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both induction methods (RR 1.67, 95% CI 0.71 to 3.93; 391 women; 2 studies; Analysis 16.12).

Neonatal encephalopathy

Not reported.

Perinatal death

Not reported.

Disability in childhood

Not reported.

Maternal side effects (all)

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects: pain after insertion

It is uncertain whether there is a difference in pain after insertion of the catheter between both induction methods (RR 0.67, 95% CI 0.20 to 2.17; 74 women; 1 study; Analysis 16.13).

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (RR 0.83, 95% CI 0.27 to 2.52; 291 women; 2 studies; Analysis 16.14).

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

It is uncertain whether there is a difference in maternal fever during labour between both induction methods (average RR 0.61, 95% CI 0.16 to 2.34; 584 women; 3 studies; Analysis 16.15). Also, there was substantial heterogeneity for this outcome ($Chi^2 = 2.85$, df = 1 (P = 0.09); $I^2 = 65\%$).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias

(Ahmed 2016), did not alter the result, nor did it lower heterogeneity (average RR 0.61, 95% CI 0.16 to 2.34; 510 women; 2 studies; I^2 = 65%).

Antibiotics during labour

It is uncertain whether there is a difference in antibiotics during labour between both induction methods (RR 0.97, 95% CI 0.61 to 1.56; 217 women; 1 study; Analysis 16.16).

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 1.56, 95% CI 0.47 to 5.20; 98 women;1 study; Analysis 16.17).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 1.95, 95% CI 0.18 to 21.14; 217 women; 1 study; Analysis 16.18).

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated (RR 0.98, 95% CI 0.70 to 1.36; 682 women; 4 studies; Analysis 16.19).

Umbilical artery pH < 7.10

It is uncertain whether there is a difference in umbilical artery pH less than 7.10 directly postpartum between both induction methods (RR 0.42, 95% CI 0.11 to 1.57; 217 women; 1 study; Analysis 16.20).

Laminaria tent versus vaginal prostaglandin E2 (five trials involving 263 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

Not reported.

Uterine hyperstimulation with FHR changes

A laminaria tent probably reduces the risk of uterine hyperstimulation with FHR changes when compared to vaginal prostaglandin E2 (RR 0.11, 95% CI 0.02 to 0.60; 188 women; 3 studies; Analysis 19.1), the absolute effect being 118 fewer per 1000 deliveries.

For primiparous women, it is uncertain whether there is a difference in effect as the result of this outcome was imprecise (RR 0.33, 95% CI 0.01 to 7.95; 80 women; 1 study; Analysis 20.1). For multiparous women, this outcome was not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (RR 0.91, 95% CI 0.56 to 1.48; 263 women; 5 studies; Analysis 19.2).

The same result was seen on parity subgroup comparisons for primiparous women (average RR 1.07, 95% CI 0.24 to 4.89; 90 women; 2 studies; Analysis 20.2) and multiparous women (RR 0.50, 95% CI 0.06 to 3.91; 10 women; 1 study; Analysis 21.1). Furthermore, for the primiparous group, there was also substantial heterogeneity (Chi^2 = 2.25, df = 1 (P = 0.13); I^2 = 56%).

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (Analysis 19.3). Of the five studies included for this comparison, one study (80 women) reported on this composite outcome. No events of neonatal morbidity or perinatal death occurred in this study.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (Analysis 19.4). Of the five studies included for this comparison, one study (28 women) reported on this composite outcome. No events of serious maternal morbidity or death occurred in this study.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

Not reported.

Uterine hyperstimulation without FHR changes

A laminaria tent may reduce the risk of uterine hyperstimulation without FHR changes when compared to vaginal PGE2 (RR 0.22, 95% CI 0.09 to 0.49; 180 women; 3 studies; Analysis 19.5).

Uterine rupture

Not reported.

Epidural analgesia

It is uncertain whether there is a difference in epidural analgesia between both induction methods (RR 0.91, 95% CI 0.74 to 1.13; 80 women; 1 study; Analysis 19.6).

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.71, 95% CI 0.43 to 1.17; 80 women; 1 study; Analysis 19.7).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 0.14, 95% CI 0.01 to 2.68; 80 women; 1 study; Analysis 19.8).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (Analysis 19.9). Of the five studies included for this comparison, two studies (160 women) reported on this outcome. No events of Apgar scores less than seven at five minutes occurred in these studies.

Neonatal intensive care unit admission

Not reported.

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is a difference in perinatal death between both induction methods (Analysis 19.10). Of the five studies included for this comparison, one study (80 women) reported on this outcome. No events of perinatal deaths occurred in this study.

Disability in childhood

Not reported.

Maternal side effects (all)

It is uncertain whether there is a difference in maternal side effects between both induction methods (RR 0.29, 95% CI 0.01 to 6.60; 28 women; 1 study; Analysis 19.11).

Maternal nausea

It is uncertain whether there is a difference in maternal nausea between both induction methods (RR 0.29, 95% CI 0.01 to 6.60; 28 women; 1 study; Analysis 19.12).

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

Not reported.

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

Not reported.

Endometritis

Not reported.

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 0.62, 95% CI 0.34 to 1.15; 188 women; 3 studies; Analysis 19.13).

Umbilical artery pH < 7.10

Not reported.

Laminaria tent versus cervical prostaglandin E2 (five trials involving 920 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

Not reported.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between induction of labour with a laminaria tent and cervical PGE2 (RR 0.17, 95% CI 0.02 to 1.42; 350 women; 2 studies; Analysis 22.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (RR 1.16, 95% CI 0.93 to 1.45; 920 women; 5 studies; Analysis 22.2).

The same results were seen on parity subgroup comparisons for primiparous women (RR 1.15, 95% CI 0.62 to 2.13; 116 women; 1 study; Analysis 23.1) and multiparous women (RR 1.28, 95% CI 0.45 to 3.65; 69 women; 1 study; Analysis 24.1).

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 3.16, 95% CI 0.13 to 76.70; 185 women; 1 study; Analysis 22.3). One event, a case of perinatal death, was reported in the laminaria group. No events occurred in the cervical PGE2 group.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (RR 0.35, 95% CI 0.01 to 8.52; 185 women; 1 study; Analysis 22.4). No events occurred in the laminaria group. One event, a uterine rupture, was reported in the cervical PGE2 group.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

It is uncertain whether there is a difference in an unfavourable cervix after 24 hours between both induction methods (average RR 0.46, 95% CI 0.11 to 1.96; 218 women; 2 studies; Analysis 22.5). Also, there was substantial heterogeneity for this outcome ($Tau^2 = 0.62$; $Chi^2 = 1.98$, df = 1 (P = 0.16); $I^2 = 50\%$).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias (Roztocil 1998), did not alter the result (RR 0.16, 95% CI 0.02 to 1.24; 53 women; 1 study; $I^2 = 0\%$).

Oxytocin augmentation

A laminaria tent probably increases the risk of oxytocin augmentation when compared to cervical PGE2 (RR 1.41, 95% CI 1.21 to 1.64; 185 women; 1 study; Analysis 22.6).

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (RR 0.17, 95% CI 0.02 to 1.36; 601 women; 2 studies; Analysis 22.7).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (RR 0.35, 95% CI 0.01 to 8.52; 185 women; 1 study; Analysis 22.8). One study reported on this outcome in which one uterine rupture occurred in the PGE2 group. No uterine ruptures were seen in the laminaria group.

Epidural analgesia

Not reported.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 1.05, 95% CI 0.65 to 1.69; 424 women; 3 studies; Analysis 22.9).

Meconium-stained liquor

Not reported.

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 5.28, 95% CI 0.63 to 44.30; 185 women; 1 study; Analysis 22.10).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both induction methods (RR 1.58, 95% CI 0.58 to 4.33; 259 women; 2 studies; Analysis 22.11).

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is a difference in perinatal death between both induction methods (RR 3.16, 95% CI 0.13 to 76.70; 185 women; 1 study; Analysis 22.12). One study reported on this outcome, in which one perinatal death occurred in the laminaria group. No perinatal death were seen in the cervical PGE2 group.

Disability in childhood

Not reported.

Maternal side effects (all)

It is uncertain whether there is a difference in maternal side effects between both induction methods (RR 0.20, 95% CI 0.01 to 4.15; 165 women; 1 study; Analysis 22.13). The one study included for this outcome reported on gastro-intestinal symptoms without specifying what the symptoms were.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (RR 1.14, 95% CI 0.46 to 2.81; 239 women; 2 studies; Analysis 22.14).

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 3.17, 95% CI 0.35 to 29.06; 74 women; 1 study; Analysis 22.15).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (average RR 0.30, 95% CI 0.08 to 1.09; 490 women; 2 studies; Analysis 22.16). Also, there was substantial

heterogeneity for this outcome (Tau^2 = 0.54; Chi^2 = 2.54, df = 1 (P = 0.11); I^2 = 61%).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias (Krammer 1995a), did not alter the result (RR 0.63, 95% CI 0.16 to 2.46; 74 women; 1 study; I^2 = 0%).

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 0.44, 95% CI 0.07 to 2.90; 128 women; 2 studies; Analysis 22.17).

Umbilical artery pH < 7.10

Not reported.

Laminaria tent versus oxytocin (two trials involving 73 women)

The only outcomes of interest reported for this comparison were caesarean section and fetal distress. Other outcomes were not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between induction of labour with a laminaria tent and oxytocin (RR 0.83, 95% CI 0.36 to 1.89; 73 women; 2 studies; Analysis 25.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 2.69, 95% CI 0.11 to 63.18; 53 women; 1 study; Analysis 25.2).

Laminaria tent versus amniotomy (one trial involving 20 women)

The only outcome of interest reported for this comparison was caesarean section. Other outcomes were not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between induction of labour with a laminaria tent compared to amniotomy (RR 0.75, 95% CI 0.22 to 2.52; 20 women; 1 study; Analysis 26.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Laminaria tent versus other hygroscopic dilators (one trial involving 41 women)

The only outcome of interest reported for this comparison was caesarean section. Other outcomes were not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between induction of labour with a laminaria tent and other hygroscopic dilators (RR 1.70, 95% CI 0.44 to 6.66; 41 women; 1 study; Analysis 27.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Extra amniotic saline infusion (EASI) versus vaginal prostaglandin E2 (two trials involving 221 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

EASI probably increases the risk of a vaginal delivery not achieved within 24 hours when compared to vaginal PGE2 (RR 1.74, 95% CI 1.21 to 2.49; 109 women; 1 study; Analysis 28.1).

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between both induction methods (RR 0.23, 95% CI 0.03 to 2.07; 221 women; 2 studies; Analysis 28.2).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (average RR 1.35, 95% CI 0.94 to 1.96; 221 women; 2 studies; Analysis 28.3). Also, there was substantial heterogeneity for this outcome (Chi^2 = 5.24, df = 1 (P = 0.02); I^2 = 81%). No sensitivity analysis could be done as both included studies were assessed as having a potentially higher risk of allocation or attrition bias.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

Not reported.

Serious maternal morbidity or death

Not reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

EASI may increase the risk of oxytocin augmentation when compared to vaginal PGE2 (RR 12.71, 95% CI 3.20 to 50.57; 109 women; 1 study; Analysis 28.4).

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (RR 0.23, 95% CI 0.03 to 2.07; 221 women; 2 studies; Analysis 28.5).

Uterine rupture

Not reported.

Epidural analgesia

There may be little or no difference in epidural analgesia between both induction methods (RR 1.00, 95% CI 0.97 to 1.04; 112 women; 1 study; Analysis 28.6).

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.58, 95% CI 0.30 to 1.14; 109 women; 1 study; Analysis 28.7).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 3.00, 95% CI 0.12 to 72.10; 112 women; 1 study; Analysis 28.8).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 4.25, 95% CI 0.21 to 86.51; 109 women; 1 study; Analysis 28.9).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both induction methods (RR 1.50, 95% CI 0.45 to 5.03; 112 women; 1 study; Analysis 28.10).

Neonatal encephalopathy

Not reported.

Perinatal death

Not reported.

Disability in childhood

Not reported.

Maternal side effects (all)

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

Not reported.

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

It is uncertain whether there is a difference in women not being satisfied between both induction methods (RR 0.56, 95% CI 0.10 to 3.25; 109 women; 1 study; Analysis 28.11). For this outcome, women in the included study were asked to comment on the induction method, for which they could choose between recommendable, satisfactory and unsatisfactory.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

Not reported.

Endometritis

Not reported.

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 1.20, 95% CI 0.39 to 3.71; 112 women; 1 study; Analysis 28.12).

Umbilical artery pH < 7.10

Not reported.

Extra amniotic saline infusion versus cervical prostaglandin E2 (two trials involving 155 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

Not reported.

Uterine hyperstimulation with FHR changes

Not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (average RR 0.73, 95% CI 0.10 to 5.12; 155 women; 2 studies; Analysis 29.1). Also, there was substantial heterogeneity for this outcome (Tau^2 = 1.60; Chi^2 = 5.11, df = 1 (P = 0.02); I^2 = 80%). As the results for both included studies show no overlap of CI, this makes the pooled result for this outcome less meaningful. No sensitivity analysis was performed as no potential high-risk studies were included for this outcome.

The same result was seen on a subgroup comparison for primiparous women (RR 0.25, 95% CI 0.06 to 1.09; 70 women; 1 study; Analysis 30.1). For multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

Not reported.

Serious maternal morbidity or death

Not reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

EASI may reduce the risk of an unfavourable cervix after 24 hours when compared to cervical PGE2 (RR 0.06, 95% CI 0.00 to 0.97; 85 women; 1 study; Analysis 29.2).

Oxytocin augmentation

It is uncertain whether there is a difference in oxytocin augmentation between both induction methods (RR 1.10, 95% CI 0.54 to 2.25; 70 women; 1 study; Analysis 29.3).

Uterine hyperstimulation without FHR changes

Not reported.

Uterine rupture

Not reported.

Epidural analgesia

Not reported.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.33, 95% CI 0.04 to 3.01; 85 women; 1 study; Analysis 29.4).

Meconium-stained liquor

Not reported.

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (Analysis 29.5). One study (85 women) pre-specified this outcome in which no Apgar scores less than seven after five minutes were reported.

Neonatal intensive care unit admission

Not reported.

Neonatal encephalopathy

Not reported.

Perinatal death

Not reported.

Disability in childhood

Not reported.

Maternal side effects (all)

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

Not reported.

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

Not reported.

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (Analysis 29.6). One study (85 women) pre-specified this outcome in which no cases of endometritis were reported.

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 0.29, 95% CI 0.06 to 1.28; 70 women; 1 study; Analysis 29.7).

Umbilical artery pH < 7.10

Not reported.

Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone (eight trials involving 639 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

It is uncertain whether there is a difference in vaginal deliveries not achieved within 24 hours between induction of labour with a mechanical method combined with PGE2 and PGE2 alone (RR 0.84, 95% CI 0.53 to 1.33; 39 women; 1 study; Analysis 31.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between both induction methods (RR 0.26, 95% CI 0.01 to 5.12; 122 women; 2 studies; Analysis 31.2).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (average RR 0.96, 95% CI 0.66 to 1.40; 517 women; 7 studies; Analysis 31.3). Also, there was moderate heterogeneity for this outcome ($Tau^2 = 0.11$; $Chi^2 = 11.16$, df = 6 (P = 0.08); $I^2 = 46\%$).

A sensitivity analysis, after eliminating three trials assessed as having a potentially higher risk of allocation or attrition bias (Browne 2011; Lyndrup 1989; Turnquest 1997), did not alter the result nor did it lower heterogeneity (average RR 1.02, 95% CI 0.56 to 1.84; 364 women; 4 studies; $I^2 = 70\%$).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

Not reported.

Serious maternal morbidity or death

Not reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

A mechanical method combined with PGE2 may reduce the risk of an unfavourable cervix after 24 hours when compared to PGE2 alone (RR 0.52, 95% CI 0.31 to 0.85; 122 women; 1 study; Analysis 31.4).

Oxytocin augmentation

It is uncertain whether there is a difference in oxytocin augmentation between both induction methods (RR 0.95, 95% CI 0.64 to 1.41; 44 women; 1 study; Analysis 31.5).

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (Analysis 31.6). Of the eight studies included for this comparison, three studies (239 women) pre-specified this outcome. No events of uterine hyperstimulation without FHR changes occurred in these studies.

Uterine rupture

Not reported.

Epidural analgesia

There may be little or no difference in epidural analgesia during labour between both induction methods (RR 0.98, 95% CI 0.77 to 1.24; 39 women; 1 study; Analysis 31.7).

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.56, 95% CI 0.22 to 1.45; 78 women; 2 studies; Analysis 31.8).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 0.97, 95% CI 0.33 to 2.83; 120 women; 1 study; Analysis 31.9).

Apgar score less than seven at five minutes

Not reported.

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both methods (RR 0.26, 95% CI 0.01 to 5.12; 44 women; 1 study; Analysis 31.10).

Neonatal encephalopathy

Not reported.

Perinatal death

Not reported.

Disability in childhood

Not reported.

Maternal side effects

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (Analysis 31.11). Of the eight studies included for this comparison, one study (39 women) pre-specified this outcome. No events of postpartum haemorrhage occurred in this study.

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 1.56, 95% CI 0.45 to 5.45; 122 women; 2 studies; Analysis 31.12).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 1.07, 95% CI 0.41 to 2.78; 237 women; 3 studies; Analysis 31.13).

Fetal distress

It is uncertain whether there is a difference fetal distress for which a caesarean section is indicated between both induction methods (RR 2.28, 95% CI 0.54 to 9.69; 140 women; 2 studies; Analysis 31.14).

Umbilical artery pH < 7.10

Not reported.

Any mechanical method and prostaglandin E2 versus low-dose misoprostol alone (one trial involving 127 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

A mechanical method combined with PGE2 probably reduces the risk of a vaginal delivery not achieved within 24 hours when compared to misoprostol (RR 0.32, 95% CI 0.12 to 0.82; 127 women; 1 study; Analysis 32.1). the absolute effect being 165 less per 1000 deliveries.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Uterine hyperstimulation with FHR changes

Not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (RR 1.09, 95% CI 0.58 to 2.04; 127 women; 1 study; Analysis 32.2).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 0.19, 95% CI 0.01 to 3.90; 127 women; 1 study; Analysis 32.3). Two events occurred in the misoprostol group, both being cases of perinatal death.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

Not reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

A mechanical method combined with PGE2 probably reduces the risk of an unfavourable cervix after 24 hours when compared to misoprostol (RR 0.41, 95% CI 0.25 to 0.67; 127 women; 1 study; Analysis 32.4).

Oxytocin augmentation

A mechanical method combined with PGE2 probably slightly increases the risk of oxytocin augmentation when compared to misoprostol (RR 1.21, 95% CI 1.01 to 1.46; 127; 1 study; Analysis 32.5).

Uterine hyperstimulation without FHR changes

A mechanical method combined with PGE2 probably increases the risk of uterine hyperstimulation without FHR changes when compared to misoprostol (RR 4.05, 95% CI 1.44 to 11.38; 127; 1 study; Analysis 32.6).

Uterine rupture

Not reported.

Epidural analgesia

Not reported.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 1.26, 95% CI 0.77 to 2.04; 127 women; 1 study; Analysis 32.7).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 0.56, 95% CI 0.23 to 1.32; 127 women; 1 study; Analysis 32.8).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 1.91, 95% CI 0.18 to 20.51; 127 women; 1 study; Analysis 32.9).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both methods (RR 0.64, 95% CI 0.31 to 1.31; 127 women; 1 study; Analysis 32.10).

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is a difference in perinatal death between both methods (RR 0.19, 95% CI 0.01 to 3.90; 127 women; 1 study; Analysis 32.11). Two cases of neonatal death were reported by Perry 1998, both were born to women randomised to

misoprostol. The authors describe that in both cases the neonates died as a result of complications of congenital malformations and were unrelated to the induction method.

Disability in childhood

Not reported.

Maternal side effects

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

Not reported.

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 1.91, 95% CI 0.18 to 20.51; 127 women; 1 study; Analysis 32.12).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 1.91, 95% CI 0.36 to 10.05; 127 women; 1 study; Analysis 32.13).

Fetal distress

Not reported.

Umbilical artery pH < 7.10

Not reported.

Any mechanical method and prostaglandin E2 versus oxytocin alone (one trial involving 44 women)

The only outcomes of interest reported for this comparison were caesarean section, instrumental vaginal delivery and endometritis. Other outcomes were not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between induction of labour with a mechanical method combined with PGE2 versus oxytocin (RR 0.30, 95% CI 0.04 to 2.47; 44 women; 1 study; Analysis 33.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.60, 95% CI 0.12 to 2.94; 44 women; 1 study; Analysis 33.2).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 3.57, 95% CI 0.15 to 83.14; 44 women; 1 study; Analysis 33.3).

Any mechanical method and low-dose misoprostol versus prostaglandin E2 alone (one trial involving 350 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

It is uncertain whether there is a difference in vaginal deliveries not achieved within 24 hours between induction of labour with a mechanical method combined with misoprostol and prostaglandin E2 (RR 1.14, 95% CI 0.89 to 1.46; 350 women; 1 study; Analysis 34.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between both induction methods (RR 0.75, 95% CI 0.27 to 2.13; 327 women; 1 study; Analysis 34.2).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (RR 0.85, 95% CI 0.57 to 1.25; 350 women; 1 study; Analysis 34.3).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 2.04, 95% CI 0.19 to 22.24; 345 women; 1 study; Analysis 34.4).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (Analysis 34.5). No events of maternal morbidity or death occurred in the one included study (350 women).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

A mechanical method combined with misoprostol probably reduces the risk of oxytocin augmentation when compared to PGE2 (RR 0.54, 95% CI 0.34 to 0.86; 350 women; 1 study; Analysis 34.6).

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (RR 0.54, 95% CI 0.22 to 1.32; 327 women; 1 study; Analysis 34.7).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (Analysis 34.8). No events of uterine rupture occurred in the one included study (350 women).

Epidural analgesia

Not reported.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 1.01, 95% CI 0.26 to 3.98; 350 women; 1 study; Analysis 34.9).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 1.15, 95% CI 0.60 to 2.23; 339 women; 1 study; Analysis 34.10).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 0.68, 95% CI 0.25 to 1.88; 346 women; 1 study; Analysis 34.11).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both methods (RR 0.68, 95% CI 0.12 to 4.03; 346 women; 1 study; Analysis 34.12).

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is a difference in perinatal death between both induction methods (RR 1.02, 95% CI 0.06 to 16.14; 345 women; 1 study; Analysis 34.13). Two cases of perinatal death were reported by Matonhodze 2003, one in each group. No further information was given on timing or cause of the demise.

Disability in childhood

Not reported.

Maternal side effects

It is uncertain whether there is a difference in maternal side effects between both induction methods (RR 1.16, 95% CI 0.95 to 1.43; 314 women; 1 study; Analysis 34.14).

Maternal nausea

A mechanical method combined with misoprostol may increase the risk of maternal nausea when compared to PGE2 (RR 1.65, 95% CI 0.98 to 2.79; 300 women; 1 study; Analysis 34.15). However, the result is still too imprecise to make a valid judgement on this outcome.

Maternal vomiting

Not reported.

Maternal diarrhoea

A mechanical method combined with misoprostol probably increases the risk of maternal diarrhoea when compared to PGE2 (RR 3.72, 95% CI 1.53 to 9.00; 313 women; 1 study; Analysis 34.16).

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (RR 0.98, 95% CI 0.67 to 1.41; 348 women; 1 study; Analysis 34.17).

Serious maternal complications

It is uncertain whether there is a difference in serious maternal complications between both induction methods (Analysis 34.18). One study (350 women) was included for this outcome in which no cases of septicaemia or intensive care unit admission were reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

It is uncertain whether there is a difference in maternal fever during labour between both induction methods (RR 1.53, 95% CI 0.26 to 9.02; 347 women; 1 study; Analysis 34.19).

Antibiotics during labour

Not reported.

Chorioamnionitis

Not reported.

Endometritis

Not reported.

Fetal distress

Not reported.

Umbilical artery pH < 7.10

Not reported.

Any mechanical method and low dose misoprostol versus misoprostol alone (seven trials involving 1422 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

It is uncertain whether there is a difference in vaginal deliveries not achieved within 24 hours between any mechanical method combined with misoprostol and misoprostol alone (average RR 0.70, 95% CI 0.25 to 1.95; 668 women; 2 studies; Analysis 35.1). Also, there was substantial heterogeneity for this outcome (Tau^2 = 0.51; Chi^2 = 14.00, df = 1 (P = 0.0002); I^2 = 93%).

A sensitivity analysis, after eliminating one trial assessed as having a potentially higher risk of allocation or attrition bias (Husain 2017), did not alter the result (average RR 1.14, 95% CI 0.89 to 1.46; 350 women; 1 study).

The same results were seen on a subgroup comparison for primiparous women (RR 0.83, 95% CI 0.23 to 2.96; 53 women; 1 study; Analysis 36.1). For multiparous women, a mechanical method combined with misoprostol may reduce the risk of a vaginal delivery not achieved within 24 hours (RR 0.37, 95% CI 0.21 to 0.63; 265 women; 1 study; Analysis 37.1).

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between both induction methods (average RR 0.54, 95% CI 0.20 to 1.45; 707 women; 4 studies; Analysis 35.2). Also, there was substantial heterogeneity for this outcome (Tau^2 = 0.57; Chi^2 = 7.40, df = 2 (P = 0.02); I^2 = 73%). No sensitivity analysis was performed as no potential high-risk studies were included for this outcome.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (average RR 0.87, 95% CI 0.66 to 1.15; 1422 women; 7 studies; Analysis 35.3). Also, there was substantial heterogeneity for this outcome (Tau^2 = 0.07; Chi^2 = 13.33, df = 6 (P = 0.04); I^2 = 55%).

A sensitivity analysis, after eliminating one trial assessed as having a potentially higher risk of allocation or attrition bias (Husain 2017), showed there probably is little or no difference in caesarean sections between both induction methods (RR 0.96, 95% CI 0.79 to 1.17; 1104 women; 6 studies; I^2 = 5%).

The same results were seen on a subgroup comparison for primiparous women (RR 0.62, 95% CI 0.15 to 2.51; 53 women; 1 study; Analysis 36.2). For multiparous women, a mechanical method combined with misoprostol may reduce the risk a caesarean section (RR 0.35, 95% CI 0.18 to 0.68; 265 women; 1 study; Analysis 37.2).

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 1.25, 95% CI 0.34 to 4.55; 487 women; 2 studies; Analysis 35.4).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (Analysis 35.5). Of the seven studies included for this comparison, two studies (490 women) reported on this composite outcome. No events of serious maternal morbidity or death occurred in these studies.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

A mechanical method combined with misoprostol probably reduces the risk of an unfavourable cervix after 24 hours when compared to misoprostol alone (RR 0.27, 95% CI 0.08 to 0.94; 140 women; 1 study; Analysis 35.6).

Oxytocin augmentation

It is uncertain whether there is a difference in oxytocin augmentation between both induction methods (average RR 0.94, 95% CI 0.70 to 1.25; 1051 women; 5 studies; Analysis 35.7). Also, there was substantial heterogeneity for this outcome (Tau^2 = 0.07; Chi^2 = 16.91, df = 4 (P = 0.002); I^2 = 76%).

A sensitivity analysis, after eliminating one trial assessed as having a potentially higher risk of allocation or attrition bias (Husain 2017), did not alter the result nor did it lower heterogeneity (average RR 0.98, 95% CI 0.66 to 1.48; 733 women; 4 studies; I^2 = 82%).

Uterine hyperstimulation without FHR changes

A mechanical method combined with misoprostol probably reduces the risk of uterine hyperstimulation without FHR changes when compared to misoprostol alone (RR 0.53, 95% CI 0.32 to 0.90; 982 women; 4 studies; Analysis 35.8).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (Analysis 35.9). Of the seven studies included for this comparison, two studies (490 women) reported on this outcome. No events of uterine rupture occurred in one of these studies.

Epidural analgesia

There may be little or no difference in epidural analgesia between both induction methods (average RR 1.00, 95% CI 0.91 to 1.10; 443 women; 3 studies; Analysis 35.10), although there was moderate heterogeneity for this outcome ($Tau^2 = 0.00$; $Chi^2 = 3.52$, df = 2 (P = 0.17); 43%).

No sensitivity analysis was performed as no potential high-risk studies were included for this outcome.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.93, 95% CI 0.58 to 1.51; 676 women; 3 studies; Analysis 35.11).

Meconium-stained liquor

A mechanical method combined with misoprostol may reduce the risk of meconium-stained liquor when compared to misoprostol alone (average RR 0.61, 95% CI 0.35 to 1.04; 1243 women; 6 studies; Analysis 35.12). However, the result is still too imprecise to make a valid judgement on this outcome. Also, there was substantial heterogeneity for this outcome ($Tau^2 = 0.24$; $Chi^2 = 11.55$, df = 5 (P = 0.04); $I^2 = 57\%$).

A sensitivity analysis, after eliminating one trial assessed as having a potentially higher risk of allocation or attrition bias (Husain 2017), did not alter the result nor did it lower heterogeneity (average RR 0.55, 95% CI 0.26 to 1.14; 925 women; 5 studies; $I^2 = 64\%$).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar score less than seven at five minutes between both induction methods (average RR 0.71, 95% CI 0.37 to 1.36; 802 women; 3 studies; Analysis 35.13). Also, there was substantial heterogeneity for this outcome ($Tau^2 = 0.11$; $Chi^2 = 2.89$, df = 2 (P = 0.24); $I^2 = 31\%$).

A sensitivity analysis, after eliminating one trial assessed as having a potentially higher risk of allocation or attrition bias (Husain 2017), did not alter the result, although heterogeneity was lost (RR 1.10, 95% CI 0.50 to 2.44; 484 women; 2 studies; $I^2 = 0\%$).

Neonatal intensive care unit admission

A mechanical method combined with misoprostol may reduce the risk of NICU admission when compared to misoprostol alone (RR 0.57, 95% CI 0.36 to 0.91; 1246 women; 6 studies; Analysis 35.14), the absolute effect being 30 fewer NICU admissions per 1000 deliveries.

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is difference in perinatal death between both induction methods (RR 3.09, 95% CI 0.13 to 75.26; 347 women; 1 study; Analysis 35.15). One case of perinatal death was reported by Matonhodze 2003, which occurred in the combined method group. No further information was given on timing or cause of the demise.

Disability in childhood

Not reported.

Maternal side effects (all)

It is uncertain whether there is a difference in maternal side effects between both induction methods (RR 1.06, 95% CI 0.87 to 1.30; 300 women; 1 study; Analysis 35.16).

Maternal nausea

It is uncertain whether there is a difference in maternal nausea between both induction methods (RR 1.37, 95% CI 0.84 to 2.23; 300 women; study; Analysis 35.17).

Maternal vomiting

Not reported.

Maternal diarrhoea

A mechanical method combined with misoprostol probably increases the risk of maternal diarrhoea when compared to misoprostol alone (RR 3.38, 95% CI 1.40 to 8.17; 298 women; 1 study; Analysis 35.18).

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is difference in postpartum haemorrhage between both induction methods (RR 0.93, 95% CI 0.65 to 1.33; 466 women; 2 studies; Analysis 35.19).

Serious maternal complications

It is uncertain whether there is a difference in serious maternal complications between both induction methods (Analysis 35.20). One study (350 women) was included for this outcome in which no cases of septicaemia or intensive care unit admissions were seen.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 0.63, 95% CI 0.28 to 1.38; 443 women; 3 studies; Analysis 35.21).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 0.41, 95% CI 0.08 to 2.08; 435 women; 2 studies; Analysis 35.22).

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 0.78, 95% CI 0.53 to 1.14; 784 women; 4 studies; Analysis 35.23).

Umbilical artery pH < 7.10

Not reported.

Any mechanical method and oxytocin versus prostaglandin E2 alone (four trials involving 713 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

Not reported.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between a mechanical method combined with oxytocin and PGE2 (RR 1.48, 95% CI 0.55 to 3.95; 151 women; 1 study; Analysis 38.1).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (RR 0.93, 95% CI 0.72 to 1.20; 713 women; 4 studies; Analysis 38.2).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious neonatal morbidity or perinatal death

Not reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (Analysis 38.3). One study (200 women) was included for this composite outcome in which no events of maternal morbidity or death occurred.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

A mechanical method combined with oxytocin probably increases the risk of oxytocin augmentation when compared to PGE2 (RR 2.48, 95% CI 1.95 to 3.15; 200 women; 1 study; Analysis 38.4).

Uterine hyperstimulation without FHR changes

A mechanical method combined with oxytocin probably increases the risk of uterine hyperstimulation without FHR changes when compared to PGE2 (RR 2.19, 95% CI 1.39 to 3.46; 151 women; 1 study; Analysis 38.5).

Uterine rupture

Not reported.

Epidural analgesia

Not reported.

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.35, 95% CI 0.08 to 1.58; 41 women; 1 study; Analysis 38.6).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 1.13, 95% CI 0.43 to 2.95; 151 women; 1 study; Analysis 38.7).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 2.96, 95% CI 0.12 to 71.55; 151 women; 1 study; Analysis 38.8).

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both methods (RR 0.85, 95% CI 0.30 to 2.40; 151 women; 1 study; Analysis 38.9).

Neonatal encephalopathy

Not reported.

Perinatal death

Not reported.

Disability in childhood

Not reported.

Maternal side effects

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (RR 0.14, 95% CI 0.01 to 2.68; 151 women; 1 study; Analysis 38.10).

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

Not reported.

Chorioamnionitis

Not reported.

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (Analysis 38.11). One study (41 women) reported on this outcome. No events of endometritis occurred in this study.

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (average RR 0.97, 95% CI 0.61 to 1.56; 498 women; 3 studies; Analysis 38.12). Also, there was moderate heterogeneity for this outcome ($Tau^2 = 0.06$; $Chi^2 = 2.93$, df = 2 (P = 0.23); $I^2 = 32\%$).

No sensitivity analysis was performed as no potential high-risk studies were included for this outcome.

Umbilical artery pH < 7.10

Not reported.

Any mechanical method and oxytocin versus misoprostol alone (six trials involving 1779 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

A mechanical method combined with oxytocin probably reduces the risk of a vaginal delivery not being achieved within 24 hours when compared to misoprostol (RR 0.48, 95% CI 0.37 to 0.63; 362 women; 2 studies; Analysis 39.1), the absolute effect being 285 fewer per 1000 deliveries.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Uterine hyperstimulation with FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation with FHR changes between both induction methods (RR 0.43, 95% CI 0.17 to 1.11; 1463 women; 3 studies; Analysis 39.2).

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Caesarean section

There probably is little or difference in caesarean sections between both induction methods (RR 0.95, 95% CI 0.80 to 1.12; 1779 women; 5 studies; Analysis 39.3).

For the subgroup of primiparous women, no outcomes were reported. For multiparous women, it is uncertain whether there is a difference in caesarean sections between both induction methods (RR 0.45, 95% CI 0.19 to 1.11; 136 women; 1 study; Analysis 40.1).

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 0.82, 95% CI 0.18 to 3.65;1263 women; 2 studies; Analysis 39.4). All the events included for this composite outcome were cases of neonatal death.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

Not reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

It is uncertain whether there is a difference in oxytocin augmentation between both induction methods (average RR 3.89, 95% CI 0.70 to 21.72; 336 women; 2 studies; Analysis 39.5). Also, there was substantial heterogeneity for this outcome ($Tau^2 = 1.46$; $Chi^2 = 18.47$, df = 1 (P < 0.0001); $I^2 = 95\%$).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias (Garba 2016), changed the result in favour of misoprostol as it showed a mechanical method combined with oxytocin may increase the risk of oxytocin augmentation (RR 1.91, 95% CI 1.59 to 2.31; 200 women; 1 study).

Uterine hyperstimulation without FHR changes

A mechanical method combined with oxytocin probably reduces the risk of uterine hyperstimulation without FHR changes when compared to misoprostol (RR 0.52, 95% CI 0.30 to 0.92; 498 women; 3 studies; Analysis 39.6).

Uterine rupture

Not reported.

Epidural analgesia

It is uncertain whether there is a difference in epidural analgesia between both induction methods (RR 1.07, 95% CI 0.90 to 1.27; 162 women; 1 study; Analysis 39.7).

Instrumental vaginal delivery

Not reported.

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 0.72, 95% CI 0.43 to 1.19; 362 women; 2 studies; Analysis 39.8).

Apgar score less than seven at five minutes

It is uncertain whether there is a difference in Apgar scores less than seven at five minutes between both induction methods (RR 0.95, 95% CI 0.20 to 4.58; 162 women; 1 study; Analysis 39.9).

Neonatal intensive care unit admission

A mechanical method combined with oxytocin probably reduces the risk of a NICU admission when compared to misoprostol (RR 0.66, 95% CI 0.49 to 0.90; 1599 women; 4 studies; Analysis 39.10), the absolute effect being 37 fewer NICU admissions per 1000 deliveries.

Neonatal encephalopathy

Not reported.

Perinatal death

It is uncertain whether there is a difference in perinatal death between both induction methods (RR 0.82, 95% CI 0.18 to 3.65; 1263 women; 2 studies; Analysis 39.11). Perinatal death occurred in one of the included studies (Gilson 2017). All were cases of neonatal death. No further information was given on cause of the demise.

Disability in childhood

Not reported.

Maternal side effects

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

Not reported.

Serious maternal complications

Not reported.

Maternal death

Not reported.

Woman not satisfied

A mechanical method combined with oxytocin may increase the risk of women not being satisfied when compared to misoprostol (RR 1.68, 95% CI 1.47 to 1.93; 866 women; 1 study; Analysis 39.12), the absolute effect being 260 more women not satisfied per 1000 deliveries. For this outcome, women in the study of Gilson 2017 were asked if they would choose the same method again if induction of labour was needed in a future pregnancy.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

A mechanical method combined with oxytocin may reduce the risk of maternal fever during labour when compared to misoprostol (RR 0.13, 95% CI 0.04 to 0.50; 298 women; 2 studies; Analysis 39.13).

Antibiotics during labour

Not reported.

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (RR 0.65, 95% CI 0.32 to 1.31; 200 women; 1 study; Analysis 39.14).

Endometritis

Not reported.

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 0.55, 95% CI 0.25 to 1.21; 362 women; 2 studies; Analysis 39.15).

Umbilical artery pH < 7.10

Not reported.

Any mechanical method and oxytocin versus oxytocin alone (six trials involving 718 women)

Primary outcomes

Vaginal delivery not achieved within 24 hours

It is uncertain whether there is a difference in a vaginal delivery not being achieved within 24 hours between induction of labour with a mechanical method combined with oxytocin and oxytocin alone (average RR 0.71, 95% CI 0.21 to 2.40; 321 women; 2 studies; Analysis 41.1). Also, there was substantial heterogeneity for this outcome ($Tau^2 = 0.72$; $Chi^2 = 19.17$, df = 1 (P,0.0001); $I^2 = 95\%$).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias (Mackeen 2018), changed the result in favour of a mechanical method combined with oxytocin as it showed it may reduce the risk

of vaginal delivery not being achieved within 24 hours (RR 0.39, 95% CI 0.27 to 0.55; 120 women; 1 study), the absolute effect being 550 fewer per 1000 deliveries.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Uterine hyperstimulation with FHR changes

Not reported.

Caesarean section

It is uncertain whether there is a difference in caesarean sections between both induction methods (average RR 0.68, 95% CI 0.39 to 1.20; 718 women; 6 studies; Analysis 41.2). Also, there was substantial heterogeneity for this outcome (Tau^2 = 0.32; Chi^2 = 17.15, df = 5 (P = 0.004); I^2 = 71%).

A sensitivity analysis, after eliminating the three trials assessed as having a potentially higher risk of allocation or attrition bias (Lyndrup 1989; Mackeen 2018; Tita 2006), did not alter the result nor did it lower heterogeneity (average RR 0.57, 95% CI 0.21 to 1.52; 319 women; 3 studies; I^2 = 82%).

Serious neonatal morbidity or perinatal death

It is uncertain whether there is a difference in serious neonatal morbidity or perinatal death between both induction methods (RR 0.71, 95% CI 0.12 to 4.13; 321 women; 2 studies; Analysis 41.3). All the events included for this composite outcome were cases of asphyxia.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Serious maternal morbidity or death

It is uncertain whether there is a difference in serious maternal morbidity or death between both induction methods (Analysis 41.4). Of the six included studies for this comparison, two studies (321 women) reported on this composite outcome. No events of maternal morbidity or death occurred in these studies.

For the subgroups of primiparous and multiparous women, no outcomes were reported.

Secondary outcomes

Cervix unfavourable/unchanged after 24 hours

Not reported.

Oxytocin augmentation

Not reported.

Uterine hyperstimulation without FHR changes

It is uncertain whether there is a difference in uterine hyperstimulation without FHR changes between both induction methods (RR 0.85, 95% CI 0.34 to 2.09; 199 women; 2 studies; Analysis 41.5).

Uterine rupture

It is uncertain whether there is a difference in uterine rupture between both induction methods (Analysis 41.6). Of the six included studies for this comparison, one study (120 women) reported on this outcome. No events of uterine rupture occurred in this study.

Epidural analgesia

There probably is little or no difference in epidural analgesia between both induction methods (RR 1.03, 95% CI 0.98 to 1.09; 127 women; 1 study; Analysis 41.7).

Instrumental vaginal delivery

It is uncertain whether there is a difference in instrumental vaginal deliveries between both induction methods (RR 0.99, 95% CI 0.48 to 2.02; 293 women; 3 studies; Analysis 41.8).

Meconium-stained liquor

It is uncertain whether there is a difference in meconium-stained liquor between both induction methods (RR 0.72, 95% CI 0.32 to 1.63; 319 women; 3 studies; Analysis 41.9).

Apgar score less than seven at five minutes

Not reported.

Neonatal intensive care unit admission

It is uncertain whether there is a difference in NICU admissions between both induction methods (RR 0.98, 95% CI 0.61 to 1.58; 400 women; 3 studies; Analysis 41.10).

Neonatal encephalopathy

Not reported.

Perinatal death

Not reported.

Disability in childhood

Not reported.

Maternal side effects

Not reported.

Maternal nausea

Not reported.

Maternal vomiting

Not reported.

Maternal diarrhoea

Not reported.

Other maternal side effects

Not reported.

Postpartum haemorrhage

It is uncertain whether there is a difference in postpartum haemorrhage between both induction methods (RR 1.18, 95% CI 0.44 to 3.18; 319 women; 3 studies; Analysis 41.11).

Serious maternal complications

It is uncertain whether there is a difference in serious maternal complications between both induction methods (Analysis 41.12). Of the six included studies for this comparison, one study (201

women) reported on maternal sepsis. No events occurred in this study.

Maternal death

Not reported.

Woman not satisfied

Not reported.

Caregiver not satisfied

Not reported.

Other outcomes (not pre-specified)

Maternal fever during labour

Not reported.

Antibiotics during labour

It is uncertain whether there is a difference in antibiotics during labour between both induction methods (RR 2.32, 95% CI 0.82 to 6.55; 201 women; 1 study; Analysis 41.13).

Chorioamnionitis

It is uncertain whether there is a difference in chorioamnionitis between both induction methods (average RR 4.34, 95% CI 0.55 to 34.01; 328 women; 2 studies; Analysis 41.14). Also, there was moderate heterogeneity for this outcome ($Tau^2 = 1.19$; $Chi^2 = 1.92$, df = 1 (P = 0.17); $I^2 = 48\%$).

A sensitivity analysis, after eliminating the one trial assessed as having a potentially higher risk of allocation or attrition bias (Mackeen 2018), did not alter the result (RR 2.16, 95% CI 0.57 to 8.28; 127 women; 1 study).

Endometritis

It is uncertain whether there is a difference in endometritis between both induction methods (RR 1.08, 95% CI 0.16 to 7.45; 374 women; 3 studies; Analysis 41.15).

Fetal distress

It is uncertain whether there is a difference in fetal distress for which a caesarean section is indicated between both induction methods (RR 1.37, 95% CI 0.68 to 2.77; 400 women; 3 studies; Analysis 41.16).

Umbilical artery pH < 7.10

Not reported.

DISCUSSION

We set out to explore the effectiveness of mechanical methods for labour induction and their adverse effects for women and their babies in comparison to different pharmacological methods. We included a total of 113 studies, with 105 studies contributing data involving 22,373 women. This updated review now consists of 21 different comparisons (and 20 subgroup comparisons), where in most of the comparisons a mechanical method (balloon, laminaria or extra-amniotic space infusion (EASI)) was compared with prostaglandin E2 (PGE2), misoprostol or oxytocin. We explored the combination of a mechanical method combined with a pharmacological method, as well as a single versus a double balloon.

Summary of main results

Balloon

Balloon versus PGE2

A balloon catheter is probably as effective for inducing labour as vaginal PGE2, as there was little or no difference in a vaginal delivery not achieved within 24 hours (low-quality evidence) and caesarean sections (moderate-quality evidence) between both induction methods. However, oxytocin augmentation is probably more often required when labour is induced with a balloon catheter. As for perinatal outcomes, a balloon catheter appears to have a more favourable safety profile compared to vaginal PGE2, as it probably reduces the risk of uterine hyperstimulation with and without fetal heart rate (FHR) changes (moderate-quality evidence), fetal distress for which a caesarean section is required and an umbilical artery pH less than 7.10. Also, a balloon catheter may slightly reduce the risk of a neonatal intensive care unit (NICU) admission (low-quality evidence), although conventional statistical significance was not reached as the result was still too imprecise to make a valid judgement. Of note, a balloon catheter probably reduces the risk of serious neonatal morbidity or perinatal death (moderate-risk evidence). However, this outcome should be interpreted with caution as only a few studies (eight out of 28 studies), reported on this composite outcome and therefore a bias for this result could exist. Most of the serious perinatal adverse events in this composite outcome were cases of perinatal asphyxia. Regarding our other main outcomes for this comparison, it was unclear if there is a difference in five-minute Apgar score less than seven (low-quality evidence) or serious maternal morbidity or death (very low-quality evidence).

There was no evidence of a difference in outcomes between induction of labour with a balloon compared to cervical PGE2, although the risk of fetal distress for which a caesarean section is indicated is probably reduced when a balloon is used.

Balloon versus misoprostol

A balloon catheter may be less effective for induction of labour when compared to low-dose oral misoprostol, as a balloon probably increases the risk of a vaginal delivery not achieved within 24 hours (moderate-quality evidence), oxytocin augmentation and probably slightly increases the risk of a caesarean section (moderate-quality evidence). Regarding safety outcomes for the neonate, which are hyperstimulation with (low-quality evidence) and without FHR changes, serious neonatal morbidity or perinatal death (low-quality evidence), NICU admission (low-quality evidence), five-minute Apgar score less than seven (low-quality evidence), fetal distress and umbilical artery pH less than 7.10, it is unclear if there is a difference between both methods as results were too imprecise to make a valid judgement. This was also the case for the composite outcome serious maternal morbidity or death (very low-quality evidence).

When compared to low-dose vaginal misoprostol, a balloon catheter may increase the risk of a caesarean section and oxytocin augmentation (low-quality evidence). However, there was substantial heterogeneity for both outcomes. For the outcome caesarean section, heterogeneity was not reduced after sensitivity analysis. The risk of hyperstimulation, with and without FHR changes, is probably reduced when a balloon catheter is used, as well as the risk of meconium-stained liquor (moderate-quality

evidence). Regarding our other main outcomes for this comparison, it was unclear if there was a difference between serious neonatal morbidity or perinatal death (very low-quality evidence), serious maternal morbidity or death (very low-quality evidence), NICU admission (low-quality evidence) and five-minute Apgar score less than seven (low-quality evidence) as these results were too imprecise to make a valid judgement.

Epidural analgesia is probably used slightly more after induction of labour with a balloon compared to low-dose oral misoprostol, as well as vaginal misoprostol.

Balloon versus oxytocin

In women with an unfavourable cervix, cervical ripening with a balloon seems to be more effective than induction with oxytocin as it probably reduces the risk of caesarean section and the risk of fetal distress for which a caesarean section is indicated. For women with a previous caesarean section, a balloon catheter may slightly reduce the risk of a caesarean section when compared to oxytocin. However, the result is too imprecise to make a valid judgement on this outcome.

Single balloon versus double balloon

There is no evidence of benefit of a double balloon over a single balloon. There is little or no difference in vaginal deliveries not achieved within 24 hours and in oxytocin augmentation. No clear difference in caesarean section rate was seen between these induction methods. However, the result was still too imprecise to make a valid judgement. Hyperstimulation seems to occur infrequently with either balloons, as no events of uterine hyperstimulation with or without FHR changes were reported in the one study (217 women) which reported on these outcomes.

Laminaria tent

There was no evidence of a difference in outcomes between a laminaria tent compared to vaginal PGE2. However, results were too imprecise to make a valid judgement. Compared to cervical PGE2, a laminaria tent probably reduces the risk uterine hyperstimulation both with and without FHR changes.

EASI

Only a few small studies compared EASI with other methods. When compared to vaginal PGE2, EASI may increase the risk of a vaginal delivery not achieved within 24 hours and oxytocin augmentation.

Mechanical method combined with a pharmacological method

There was no evidence of clear benefit for a mechanical method combined with PGE2 compared to PGE2 alone or to oxytocin. When compared to low-dose misoprostol, a mechanical method combined with PGE2 may reduce the risk of a vaginal delivery not achieved within 24 hours. However, only one study (127 women) reported on this comparison. When a mechanical method is combined with misoprostol or with oxytocin, it may reduce the risk of a NICU admission when compared to misoprostol alone. However, regarding other perinatal outcomes for both comparisons, there was no evidence for a difference in serious neonatal morbidity or perinatal death, Apgar scores less than seven at five minutes or fetal distress.

Infection

Risk of infection may theoretically be associated with the insertion of foreign material in the cervix. Most studies did not report on this outcome, resulting in limited data, reported as various outcomes (maternal fever during labour, antibiotic use during labour, chorioamnionitis and endometritis). According to the limited data available, there is no evidence of an increased risk of infectious morbidity with mechanical methods. These data should however be cautiously interpreted as results were imprecise.

Women's view

Data on patient satisfaction or patient preferences are sparse and not all data could be included in the meta-analyses. When a balloon catheter was compared to vaginal PGE2, more women who were randomised to a balloon would choose the allocated induction method again in a subsequent pregnancy, as compared to women who were randomised to PGE2. However, when a balloon catheter was compared to oral misoprostol, more women would choose misoprostol in a subsequent pregnancy. For both outcomes, only one study was included.

Overall completeness and applicability of evidence

This review was previously one of a series of Cochrane Reviews examining various methods for induction of labour and now serves as a stand-alone review. Other reviews have examined pharmacological and non-pharmacological methods including vaginal prostaglandins (Thomas 2014); intracervical prostaglandins (Boulvain 2008); intravenous oxytocin (Alferivic 2009); amniotomy (Bricker 2000); intravenous oxytocin with amniotomy (Howarth 2001); vaginal misoprostol (Hofmeyr 2010); oral misoprostol (Alfirevic 2014), and other methods.

Despite including 113 studies and including data from 105 studies, there were relatively few clear results. Only for the comparison of a balloon versus vaginal prostaglandin E2, including 28 studies involving 6619 women, were there enough data to make a valid judgement on effectiveness and adverse events between these methods.

Most of the outcomes of interest were poorly reported in the included studies, especially serious maternal or perinatal morbidity or death. Also, for some outcomes such as duration from start of induction to vaginal delivery, Apgar score or umbilical cord pH, only continuous data were reported and therefore were not included in this review. Outcomes should therefore be interpreted with caution. Caesarean section on the other hand, was reported in almost every study. Therefore, caesarean section may be the most reliable outcome by which to assess the effectiveness of mechanical methods for cervical ripening and induction of labour.

The external validity of our results can be questioned as the policy of labour induction varies across the different settings in which trials took place. There was a difference seen in maximum ripening time (e.g. the maximum time cervical ripening was awaited, ranging from six hours to 96 hours) and for when induction of labour was declared as failed. As it may take longer to achieve successful cervical ripening when a balloon is used, this could influence the outcome measures of effectiveness used, such as caesarean section. Also, the caesarean rate differs according to the setting in which trials took place, ranging from 9% (Deshmukh 2011) to 70% (Hudon 1999).

Studies ranged in date of publication from 1982 to 2018. While we did not consider the potential influence of date on our results, it is possible that changes in management of labour can mean that for some comparisons, in which relatively older studies were included, may not be generalisable to the current clinical context.

Quality of the evidence

Risk of bias varied throughout the included trials (see Figure 2 and Figure 3). A great proportion of the trial methods were not well reported and were assessed to be at unclear risk of bias in many domains. Three trials were assessed as using inadequate random sequence generation, and in five trials no measures were taken to conceal allocation. In almost all studies, no blinding was done due to the nature of the intervention. However, blinding of the research personnel would have been possible, but was only described in four studies. Two studies reported to have performed a double-blind study, but did not describe how this was achieved. We rated many trials at unclear risk of attrition bias, mainly because it was not clear if intention-to-treat was performed. Although we did attempt to assess reporting bias, lack of trial protocols for most of the older studies, meant this assessment relied on information available in the published trial report.

The outcomes were assessed using the GRADE approach. We determined the evidence to be moderate-quality, low-quality or very low-quality. All evidence was downgraded for lack of blinding. Other reasons for downgrading were predominately for imprecision (uncertain effect estimates, small sample sizes and low event rates) and inconsistencies (heterogeneity). For our three main comparisons (balloon versus vaginal PGE2; balloon versus vaginal misoprostol; balloon versus oral misoprostol), a 'Summary of findings' table was produced (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3).

Although no publication bias was detected for our main outcomes, there is still a possibility of publication bias. Most comparisons had less than 10 studies included and therefore, a funnel plot could not be produced. Also, for 11 trial registrations the anticipated end date was overdue by two years and it was not clear if the trials had started, were ongoing or finished recruiting (Baacke 2006; Behrashi 2013; Cullimore 2009; Dias 2008; EUCTR 2012; Kamilya 2011; Park 2011; Pathiraja 2014; Reif 2012; Yazdani 2011; Zhang 2014). Therefore, a potential risk exists as results from these studies were not published.

We acknowledge that with so many comparisons within the review, there is also a risk of statistical type 1 error, meaning a false-positive result. The results where there are very few studies included, moderate or substantial heterogeneity, or those where the meta-analysis result is of borderline statistical significance must therefore be treated with caution.

Potential biases in the review process

We are aware that the possibility of introducing bias was present at every stage of the reviewing process. We attempted to minimise bias in a number of ways; two review authors assessed studies for eligibility, assessed risk of bias and carried out data extraction. Each review author worked independently. We resolved discrepancies through discussion, or if required we consulted a third review author. Nevertheless, the process of assessing risk of bias, for example, is not an exact science and includes many personal judgements. Four review authors, Mieke ten Eikelder, Marta Jozwiak , Kitty Bloemenkamp and Ben Willem Mol are also trial authors for the following included studies: Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; ten Eikelder 2016. Data extraction and risk of bias assessments were conducted by other review authors for these studies (Marieke de Vaan; Kirsten Palmer).

Agreements and disagreements with other studies or reviews

This review is one the most extensive reviews on mechanical methods of labour induction as most reviews on this subject only contain one or two of the comparisons included in this review. We found eight recent systematic reviews covering one or more of our main comparisons, being balloon versus vaginal PGE2, balloon versus vaginal misoprostol or balloon versus oral misoprostol.

Our review was in line with other systematic reviews on induction of labour with a balloon versus vaginal PGE2. Liu 2018 compared a double balloon with a vaginal PGE2 insert and they found no difference in vaginal deliveries achieved within 24 hours or caesarean section rate. They also found a reduction in uterine hyperstimulation and umbilical artery pH < 7.10 when a balloon was used. All of the five studies included in the review of Liu 2018, were also included in our review. Du 2017 compared a double balloon with PGE2 (vaginal as well as cervical) and produced the same results as described in our review and the review of Liu 2018. However, they found no difference in fetal distress for which a caesarean section was indicated. All eight studies were also included in this review. Zhu 2018 compared a Foley catheter with a vaginal PGE2 and included eight studies of which one (Ghanaie 2013) was excluded in our review because oxytocin was administered concurrent to both induction methods. Just as the other reviews, Zhu 2018 found no difference in caesarean section rate. They also looked at the induction to delivery interval on a continuous level and found no difference between both induction methods. Wang 2016 however, found a longer induction to delivery interval when a Foley catheter was used in comparison to PGE2 vaginal insert. The authors did not compare vaginal delivery rates within 24 hours.

Chen 2016 performed a network meta-analysis in which direct and indirect comparisons between different induction agents, including Foley catheter, vaginal PGE2, vaginal misoprostol and oral misoprostol were made. Studies with high-dose misoprostol were included in the review of Chen 2016 as opposed to our review and only indirect comparisons could be made between a Foley catheter and oral misoprostol in the review of Chen 2016. The outcomes of interest were vaginal delivery not achieved within 24 hours, uterine hyperstimulation with FHR changes and caesarean section. Not all results were in line with our results. In the network meta-analysis, a Foley catheter increased the risk of vaginal delivery not achieved within 24 hours compared to vaginal misoprostol, where in our review the outcome was uncertain. When compared to oral misoprostol, no clear difference in vaginal deliveries within 24 hours was seen by Chen 2016 compared to an increased risk in our review. In our review no clear difference was seen in uterine hyperstimulation with FHR changes, but in the network analysis of Chen 2016, a reduced risk was seen when a Foley catheter was used compared to oral misoprostol. For the outcome of caesarean section, the network meta-analyses of Chen 2016 showed the same results as our review. They found that a Foley catheter may slightly increase the risk of a caesarean section

when compared to vaginal or oral misoprostol, with moderate heterogeneity for the comparison with vaginal misoprostol.

Alfirevic 2016 performed a extensive systematic review on induction of labour. The authors included 34 active treatment types/regimens including different dose regimens and routes of administration, and performed a network meta-analysis in which all different treatments were ranked in relation to each other, including direct as well as indirect comparisons. Ranking was done on absolute risks for all pre specified outcomes. Mechanical induction with a balloon was divided in a single or double balloon. Alfirevic 2016 used other cut-off points in dividing oral and vaginal tablets in dose regimens. In our review low dose was defined as ≤ 50 mcg every ≥ four hours, opposed to the cut-of point of ≥ 50 mcg in the review of Alfirevic 2016. Vaginal PGE2 was divided into tablets, gel, slow-release and normal-release inserts. For the outcome of a vaginal delivery not achieved within 24 hours, low-dose vaginal misoprostol scored better, as well as all different regimens of vaginal PGE2 compared to induction with a balloon (single as well as double). For the outcome caesarean section, a single balloon and vaginal PGE2 gel had a similar mean ranking in the mid regions. Noteworthy is that low-dose titrated oral misoprostol had one of the lowest mean rankings, as compared to oral misoprostol < 50 mcg, which was ranked relatively high. The same high ranking for this outcome was seen for a double balloon. In line with our review, all mechanical methods had a low ranking regarding uterine hyperstimulation with FHR changes. Alfirevic 2016 also looked at neonatal and maternal mortality and severe morbidity, but for these composite outcomes no network meta-analysis was possible as events were rare and poorly reported in studies. For the outcomes of NICU-admission as well as five-minute Apgar score less than seven, there was considerable uncertainty on the probability of the mean ranking as the 95% confidence intervals (CIs) for these rankings were relatively broad.

Ten Eikelder 2016 looked at safety outcomes between induction of labour with a Foley catheter and misoprostol (any route, any dose) and found less uterine hyperstimulation with FHR changes and less fetal distress for which a caesarean section was indicated when a Foley was used. They found that a Foley catheter may slightly increase the caesarean section rate, although conventional statistical significance was not reached and there was moderate heterogeneity for this outcome. Studies with high-dose misoprostol were not excluded in the review of Ten Eikelder 2016. In subgroup analyses for 25 mcg and 50 mcg vaginal misoprostol, no evidence for a difference in safety outcomes were found.

In our review, there was no evidence for a difference in outcomes related to infection between mechanical induction and other methods for induction of labour. However, the results of outcomes covering infection were still too imprecise to make a valid judgement. McMaster 2015 addressed this question by comparing induction of labour with a balloon versus locally-applied prostaglandin and included 26 trials. Their results were in line with our results and found no evidence for a difference in chorioamnionitis, endometritis and neonatal infection. When infection outcomes were pooled, little or no difference was seen, suggesting a Foley catheter does not increase the risk of infection compared to locally-applied prostaglandin.

AUTHORS' CONCLUSIONS

Implications for practice

Mechanical induction with a balloon is probably as effective as induction of labour with vaginal PGE2 with little or no difference in vaginal deliveries not achieved within 24 hours and caesarean section rate between the two methods. However, a balloon seems to have a more favourable safety profile compared to vaginal PGE2, as it probably reduces the risk of uterine hyperstimulation with and without fetal heart rate (FHR) changes, fetal distress for which a caesarean section is indicated and serious neonatal morbidity or perinatal death.

A balloon catheter may be less effective for induction of labour when compared to low-dose oral misoprostol as a balloon probably increases the risk of a vaginal delivery not achieved within 24 hours and probably slightly increases the risk of a caesarean section. It is unclear if there is a difference in hyperstimulation with FHR changes. When compared to low-dose vaginal misoprostol, a balloon catheter may increase the risk of a caesarean section but probably reduces the risk of hyperstimulation, with and without FHR change as well as the risk of meconium-stained liquor.

Cervical ripening with a balloon seems to be more effective than induction with oxytocin as it probably reduces the risk of caesarean section and the risk of fetal distress. For women with a previous caesarean section, a balloon catheter may slightly reduce the risk of a caesarean section when compared to oxytocin.

There is no evidence of a benefit of a double balloon over a single balloon. For the comparisons of a laminaria tent or extra-amniotic space infusion (EASI) with other induction methods, results were mostly too imprecise to make a valid judgement.

There was no evidence of clear benefit for a mechanical method combined with PGE2 to PGE2 alone or to oxytocin. When a mechanical method is combined with misoprostol or with oxytocin, it may reduce the risk of neonatal intensive care unit (NICU) admissions when compared to misoprostol alone. However, regarding other perinatal outcomes for both comparisons, there was no evidence for a difference in serious neonatal morbidity or perinatal death, Apgar scores less than seven at five minutes or fetal distress.

The advantages of mechanical methods are their wide availability and the low cost of the devices, especially Foley catheters. Storage and preservation of mechanical devices is less problematic than PGE2, which should be kept refrigerated. However, special attention should be paid to contraindications (e.g. low-lying placenta) when inserting these devices.

Implications for research

There seems to be sufficient data to make a valid judgement on the safety and effectiveness of balloon in comparison to vaginal PGE2. More research on this comparison does not seem warranted as moderate-quality evidence suggests a balloon is equally effective, but has a better safety profile. GRADE assessment for important outcomes for this comparison can never be assessed as 'high quality' because blinding is not possible and this is the reason the evidence being downgraded from high-quality evidence to moderate-quality evidence for key outcomes. Future research could focus on comparing a balloon with low-dose misoprostol or

a combination of mechanical methods with low-dose misoprostol. More studies evaluating mechanical methods for induction of labour in women with a history of prior caesarean section could be of benefit.

To facilitate future meta-analyses of labour induction, we recommend the standardisation of outcomes through core outcome sets. This would minimise the reporting challenges experienced in this review, where many included studies reported outcomes in a highly varied manner, resulting in many being excluded from analyses. Also, while there were many large randomised trials included in this review, only a few reported on rare but serious adverse events or included women's views regarding induction methods. As safety aspects and maternal satisfaction become more and more important with rising induction rates, large multicentre studies focusing on safety aspects for the neonate and maternal satisfaction, could help clinicians make a more carefully balanced choice when arranging an induction of labour.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Aduloju 2016

Methods	RCT
Participants	Inclusion: life singleton pregnancy, cephalic presentation, intact membranes, > 37 weeks, indication for IOL, reactive non stress test. unfavourable cervix (BS < 6) Exclusion: IFD, no prenatal care in study centre, contraindication for vaginal delivery
Interventions	A: Foley catheter: 16F, 30 mL (n = 70), max 12 hours, if necessary another Foley for 12 hours (n = 70) B: Foley catheter (16F, 30 cc) + vaginal misoprostol 25 ug every 6 hours(n = 70), max dose 100 ug (4 gifts) (n = 70) C: Vaginal misoprostol alone 25 ug every 6 hours (n = 70) max dose 100 ug (4 gifts) (n = 70) Max induction time all groups: 24 hours
Outcomes	Vaginal delivery rate, time interval to achieve favourable cervix, induction delivery interval, oxytocin use, AS at 1 and 5 minutes, asphyxia, NICU admission, uterine tachysystole, uterine hypertonus, hyperstimulation, uterine rupture, FHR abnormalities
Notes	Setting: Ekiti State University Teaching tertiary healthcare institution; referral centre for primary and secondary healthcare facilities, 2400 deliveries annually, Nigeria Study period: 1 September, 2014 and 31 August, 2015. Funding: no grant or fund was received Declaration of interest: no conflict of interest

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Blocked randomisation using random table computer-generated numbers
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not mentioned

Aduloju 2016 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not mentioned, but is probably the case looking at Figure 1. no missing data or cases.
Selective reporting (reporting bias)	Low risk	All pre-specified outcome measures were reported,
Other bias	Low risk	No other bias detected

Ahmed 2016

Methods	RCT
Participants	Inclusion: postdate pregnancy (> 40 weeks) singleton gestation, intact membranes, cephalic fetal BS ≤ 4 Exclusion: previous caesarean deliveries, EFW > 4000 g, non-reassuring fetal conditions, ruptured membranes, placenta previa, malpresentation
Interventions	Foley catheter (n = 39), 18 F, filled with 50 mL Cook balloon (n = 39), filled with 80/80 mL Max of 12 hours of priming
Outcomes	Cervical ripening and BS after 12 hours, VAS for catheter insertion, catheter insertion (easy, moderate or difficult), VAS for patient satisfaction after birth, insertion expulsion time, insertion amniotomy time, insertion delivery time and mode of delivery. Abnormal fetal presentation, cord prolapse, bleeding related to catheter insertion that required removal of the catheter and AS
Notes	Setting: Gynaecology, Suez Canal University Hospital, Egypt Study period: March 2013 to April 2014 Funding: not mentioned Declaration of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Shuffling 78 envelopes, 1:1
Allocation concealment (selection bias)	Low risk	Sealed envelopes, opaque?
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described

Ahmed 2016 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not mentioned, 2 women excluded because of failed placement. no missing data mentioned
Selective reporting (reporting bias)	High risk	Pre-specified outcomes bleeding after insertion, cord prolapse and abnormal fetal presentation not described in results
Other bias	Low risk	No other bias detected

Al-Ibraheemi 2018

Methods	RCT
Participants	Inclusion: > 37 weeks, singleton fetus, cephalic, BS ≤ 6 Exclusion: rupture of membranes, regular uterine contractions (3 or more contractions per 10 minutes), prior uterine surgery, multiple gestations, malpresentation, contraindication to PGs, non-reassuring FHR tracing, vaginal bleeding, fetal demise, anomalous fetus, or any contraindication to vaginal delivery
Interventions	Foley catheter + misoprostol: (n = 100) 30 mL balloon, filled with 60 mL, gentle traction, max 24 hours and misoprostol vaginal 4-hourly with a max of 6 doses, Misoprostol (n = 100) 25 ug vaginally, 4-hourly with a max of 6 doses
Outcomes	Time from placement of the first misoprostol dose to delivery, time to active phase (6 cm or greater), time from active phase to delivery, caesarean delivery rate, uterine tachysystole, estimated blood loss, chorioamnionitis, cord blood pH, 5-minute AS, NICU admission.
Notes	Setting: from the Department of Obstetrics and Gynecology, Mount Sinai West Hospital, New York Study period: September 2015 to July 2016 Funding: not described Declaration of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated sequence
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Al-Ibraheemi 2018 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis, no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Al-Taani 2004

Methods	Randomised trial, random number table, blinding unclear.
Participants	Grand multiparous women, BS 5 or less, singleton term pregnancy, intact membranes, cephalic presentation, good fetal condition. Exclusion: previous CS, contraindications for vaginal birth, suspected cephalopelvic disproportion, unexplained antenatal haemorrhage.
Interventions	Foley catheter 50 mL (72). (PGE2) tablet 3 mg (75), 6-hourly.
Outcomes	Route of delivery, change in BS, intrapartum complications, need for augmentation.
Notes	Setting: Queen Alia military hospital, Amman, Jordan Dates of study:September 2001 - August 2003 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Unclear risk	No information provided.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT nor reported, bu seems reasonable as the numbers in both groups are equal to randomised numbers. missing outcome data mentioned.

Al-Taani 2004 *(Continued)*

Selective reporting (reporting bias)	Low risk	All primary and secondary outcomes are reported as pre-specified.
Other bias	Low risk	No other bias detected

Allouche 1993

Methods	RCT. No details were given on the method for concealment of the allocation.
Participants	BS < 6, vertex, singleton, no previous CS.
Interventions	PGE2 (Prepidil 0.5 mg) intracervical (59 women); Foley 50 mL (60 women); PGE2 (Prepidil 0.5 mg) and Foley 50 mL extra-amniotic (63 women).
Outcomes	Uterine hyperstimulation, discomfort during the procedure, maternal and neonatal infection.
Notes	Setting: not reported Dates of study:between April and December 1992 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Only stated women were randomly allocated
Allocation concealment (selection bias)	Unclear risk	Unclear
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, no missing data or cases reported
Selective reporting (reporting bias)	Unclear risk	No outcomes pre-specified
Other bias	Low risk	No other bias detected

Amorosa 2017

Methods	RCT
Participants	Inclusion: PROM, age ≥ 18 years, viable fetus, cephalic, singleton, GA > 34 weeks, < 3 cm dilation Exclusion: multifetal gestation, a known anomalous fetus, malpresentation, latex allergy, unexplained vaginal bleeding or contraindication to vaginal delivery (such as a placenta previa), antibiotics, previous uterine surgery, spontaneous labour
Interventions	Foley catheter (n = 61) 16F, 30 mL balloon filled with 60 mL saline, traction applied (no max time described), oxytocin started after 1 hour Oxytocin alone directly (n = 68) Oxytocin in both groups, started 2 mU/minute, max 30 mU/minute
Outcomes	The primary outcome measure was time from start of induction to delivery. Secondary outcomes included mode of delivery, tachysystole, chorioamnionitis, postpartum haemorrhage, neonatal AS, and admission to the NICU.
Notes	Setting: Mount Sinai Hospital, New York, USA Study period: August 2014 to September 2016 Funding: not reported Declaration of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated numbers
Allocation concealment (selection bias)	Low risk	Sequential numbered sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Modified ITT, (1 woman excluded who afterwards did not met the inclusion criteria), no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcome measures were reported in results
Other bias	Low risk	No other bias detected

Atad 1996

Methods	RCT. Computer-generated sequence. No details were given on the method for concealment of the allocation.
Participants	Singleton vertex term pregnancies with intact membranes, BS < 5 without previous CS.
Interventions	Atad ripening device (35 women); PGE2 intravaginal tablets 3 mg (30 women); oxytocin (30 women).
Outcomes	Need for another method, CS, change in BS.
Notes	Also reported as abstract (Abramovici 1994). Setting: Israel Study period: not reported Funding: not reported Declarations of interest: J Atad has a patent licensing arrangement for Atad ripening device and thus has the potential gain from its sales

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer random-generated allocation list
Allocation concealment (selection bias)	Unclear risk	Unclear
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No ITT reported, but seems reasonable as numbers in tables are equal to randomised numbers, no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Bagratee 1990

Methods	RCT. Random number tables, stratified for parity. No details were given on the method for concealment of the allocation.
Participants	Women with unfavourable cervix (BS < 7).
Interventions	Lamicel (40 women);

Bagratee 1990 *(Continued)*

	(PGE2) (2 mg tablet) (40 women). After 6 hours, oxytocin was started in both groups.
Outcomes	CS, hyperstimulation, fetal distress, perinatal death.
Notes	No outcome reported in subgroups. setting: king Edward VIII hospital, Durban, South Africa Study period: for 6 months, no exact dates reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number tables
Allocation concealment (selection bias)	Unclear risk	Unclear, not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	No ITT mentioned, in table 4 cases missing, not clear why.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Barda 2018

Methods	RCT
Participants	Inclusion criteria: GA ≥ 37 weeks, parity 1 to 3, singleton pregnancy with a vertex presentation, BS less than 5) and intact membranes. Exclusion criteria: previous CS, lack of prenatal care, contraindication for vaginal delivery
Interventions	Foley catheter (n = 150): 22 F, 80 mL balloon (max 18 hours) Dinoproston (n = 150): 3 mg tablets (every 8 hours, max 2 gifts)

Barda 2018 *(Continued)*

Outcomes	Start induction to active labour (4 cm dilatation and 80% effacement), labour within 24 hours, CS rate, excessive haemorrhage, chorioamnionitis, non-reassuring FHR, fetal pH, NICU admission, early neonatal sepsis
Notes	Setting: Edith Wolfson Medical Centre, Holon, Israel Study period: June 2015 - July 2016 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random assigned; not described how this was done. In trial registration => parallel assignment.
Allocation concealment (selection bias)	Unclear risk	Random assigned; not described how this was done. In trial registration => parallel assignment.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT, no tables available, so incomplete data can not be judged, no missing data described
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Unclear risk	Full text is an accepted manuscript without tables, therefore risk of bias cannot properly be determined

Benzineb 1996

Methods	RCT. Blocks of 10 women. No other details were given on the method for randomisation and on concealment of the allocation.
Participants	Singleton vertex term pregnancies with intact membranes, BS < 6.
Interventions	Foley catheter inflated with 40 mL of water (50 women); PGE2 intracervical gel 0.5 mg every 24 hours. (n = 50?)
Outcomes	Vaginal delivery not achieved within 24 hours, CS, perinatal deaths, cervix unchanged after 24 hours, postpartum haemorrhage.
Notes	Setting: Charles Nicolle Hospital, Tunis Dates of study: not reported

Benzineb 1996 *(Continued)*

	Funding: not reported
	Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported women were random allocated in blocks of 10
Allocation concealment (selection bias)	Unclear risk	Unclear. not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, no missing data or cases reported
Selective reporting (reporting bias)	Unclear risk	Outcomes not pre-specified
Other bias	Low risk	No other bias detected

Biron-Shental 2004

Methods	Randomised trial.
Participants	Term, singleton pregnancy BS 4 or less, medical indication for labour induction.
Interventions	PGE 2 gel 2 mg (27). Double balloon catheter (26) combined (24)
Outcomes	Change in BS, need for oxytocin augmentation.
Notes	Outcomes of interest not reported. Setting: Israel Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Biron-Shental 2004 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence.
Allocation concealment (selection bias)	Unclear risk	Not mentioned.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Brief communication, for the reported data no missing. Incomplete outcome data not further mentioned in this report.
Selective reporting (reporting bias)	Unclear risk	Our outcomes of interest are not reported here, main outcome is change in BS.
Other bias	Unclear risk	Hard to say, very short report, our outcomes of interest not mentioned, not clear how sample size was calculated.

Blumenthal 1990

Methods	RCT. Randomisation by drawing a blank envelope from a stack of 50 identical envelopes containing the group allocation.
Participants	Vertex, intact membranes, BS < 5, no previous CS.
Interventions	Dilapan (polyacrilonitrile hydrogel) inserted in the cervix, up to 6 sticks (23 women); Laminaria inserted in the cervix, as many as possible (18 women).
Outcomes	CS.
Notes	Results for a 3rd group of women with favourable cervix treated with oxytocin are presented. These women are not be included in the analysis, as they were not randomly allocated to the intervention. Setting: Michael Reese hospital, Chicago, USA Study period:January 1987 to January 1988 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Shuffling envelopes

Blumenthal 1990 *(Continued)*

Allocation concealment (selection bias)	Low risk	Women choose from stack of all blank, identical envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not reported. no explanation what happened to the rest of the randomised women
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Browne 2011

Methods	RCT
Participants	Inclusion criteria: single, live fetus, cephalic, presentation,reassuring fetal health assessment, GA between 26 and 42 weeks, Maternal age 18 and above, BS less than 5 Exclusion criteria: multiple gestation (twins, triplets, quadruplets), fetal demise Fetal malpresentation, EFW less than 500 g or more than 4000 g, placenta previa, non-reassuring fetal health assessment Maternal asthma, Latex allergy, spontaneous labour, other contraindication to vaginal delivery
Interventions	Balloon: (n = 34): 40 mL, under traction, max 6 hours. PGE2 vaginal (36): prepidil gel in fornix posterior, no oxytocin in 6 hours after gel is applied balloon and PGE2 (31): 40 mL, under traction. prepidil gel inserted through catheter.
Outcomes	CS
Notes	Grey literature: not published. primary outcomes reported in trial registration Setting: USA Study period: July 2010 - February 2013 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Browne 2011 *(Continued)*

Random sequence generation (selection bias)	Low risk	Randomisation envelopes prepared by statisticians at the University of South Carolina Arnold School of Public Health. The investigator was given the next sequentially-numbered study envelope by the patient's nurse.
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not reported. case missing for relevant outcome (CS)
Selective reporting (reporting bias)	High risk	Only primary outcome en adverse events reported
Other bias	Unclear risk	Study not published, not clear why.

Carbone 2013

Methods	RCT
Participants	Inclusion: singleton, viable gestation (≥ 24 weeks), cephalic, intact membranes, BS < 7 Exclusion: malpresentation, multifetal gestation, spontaneous labour, contraindication to PGs, fetal growth restriction, anomalous fetus, fetal demise, previous CS, or other uterine surgery.
Interventions	Foley + misoprostol (n = 56): 25 mcg vaginal misoprostol every 4 hours AND Foley catheter filled with 60 mL saline; taped to the inner thigh under gentle traction. misoprostol alone (n = 61): 25 mcg vaginal misoprostol every 4 hours Not mentioned for how long misoprostol and/or Foley was given in total.
Outcomes	Induction to delivery time, mode of delivery, tachysystole, postpartum haemorrhage (> 500 cc), chorioamnionitis, neonatal AS and NICU admission.
Notes	Setting: USA Study period: January 2011 to April 2012 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement

Carbone 2013 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated sequence
Allocation concealment (selection bias)	Low risk	Opaque envelopes, not stated if these were sequential numbered
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Casey 1995

Methods	RCT. No details were given on the method for concealment of the allocation.
Participants	Singleton term pregnancies, BS < 6.
Interventions	PGE2 intracervical gel and intracervical Foley catheter inflated with 50 cc (78 women); PGE2 intracervical gel (68 women).
Outcomes	CS.
Notes	Abstract only. Setting: USA Study period: not reported, 11-month period Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Only reported it was a RCT
Allocation concealment (selection bias)	Unclear risk	Not reported

Casey 1995 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Too little information to judge
Selective reporting (reporting bias)	Unclear risk	Too little information to judge
Other bias	Unclear risk	Abstract only

Chavakula 2015

Methods	RCT
Participants	Inclusion: singleton, cephalic, fetal growth restriction, ≥ 34 weeks. Exclusion: previous caesarean deliveries, uterine surgery, a multiple pregnancy, ruptured membranes, a BS > 6, severe fetal growth restriction, abnormal FHR prior to induction, pre-partum haemorrhage.
Interventions	1. Foley catheter (n = 54) 16F, 30 mL, catheter was removed after 12 hours. 2. Vaginal misoprostol (n = 46) every 6 hours, 25 mcg, max 3 doses
Outcomes	Hyperstimulation with FHR changes, BS at AROM, duration of induction to delivery, vaginal delivery within 12 hours and 24 hours, CS, oxytocin, chorioamnionitis, antibiotics, NICU admission, AS < 7 at 5 minutes, patients and caregiver satisfaction (VAS score)
Notes	Setting: tertiary care teaching hospital in South India with approximately 13,000 deliveries per year. Study period:December 2011 to June 2012. Funding: not stated Declarations of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated sequence, block randomisation
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias)	Unclear risk	Not feasible due to nature of intervention

Chavakula 2015 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis, no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Chua 1997

Methods	RCT. Random number table, no details on the method of concealment of the allocation.
Participants	Singleton vertex presentation, unfavourable cervix (BS < 6). 185 women recruited (90 in Dilapan group, 95 in PGE2 group).
Interventions	Dilapan group: 4 dilators. PGE2 Gel (Prepidil): 0.5 mg. In both groups, ripening was followed by rupture of membranes and oxytocin after 12 hours.
Outcomes	Need for oxytocin, CS, instrumental delivery, uterine rupture, uterine hyperstimulation, admission to NICU, perinatal death.
Notes	Setting: National University hospital, Singapore Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Chua 1997 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not mentioned but seems reasonable as numbers in tables are equal to randomised numbers, no reporting of missing cases or outcomes
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Cromi 2011

Methods	RCT
Participants	Inclusion: singleton gestation, vertex presentation, BS ≤ 6, intact membranes, GA ≥ 34 weeks, reassuring FHR tracing Exclusion: Women with antepartum bleeding, intrauterine fetal death, previous uterine scars, known allergy to latex, placenta previa, contraindication to vaginal delivery
Interventions	24-hour Foley (n = 133): 18F, 50cc, 24 hours 12-hour Foley (n = 132): 18F, 50cc, 12 hours PGE2 vaginal insert 10 mg (n = 132): vaginal fornix, 24 hours
Outcomes	vaginal delivery within 24 hours, improvement in BS after ripening, caesarean delivery, ripening-to-delivery interval, oxytocin administration, epidural request, neonatal outcomes.
Notes	Setting:Obstetrics Department of University of Insubria, Varese, Italy. Study period: July 2008 to June 2010 Funding: none reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated block randomisation
Allocation concealment (selection bias)	Unclear risk	Allocation not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Low risk	ITT, no missing data or cases.

Cromi 2011 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Cromi 2012

Methods	RCT
Participants	210 patients. Inclusion: singleton gestation, vertex presentation, BS ≤ 6, intact membranes, GA > 34 weeks, and reassuring fetal heart tracing on admission. Exclusion:antepartum bleeding, intrauterine fetal death, prior uterine scars, positive vaginal or rectal group B streptococcus screening cultures, placenta previa, other contraindication to vaginal delivery.
Interventions	Double-balloon catheter (n = 105): inflated with 50 mL in either balloon. The double-balloon device was left in place for approximately 12 hours. Dinoprostone vaginal insert 10-mg controlled-release (n = 105): in the vaginal fornix, max 24 hours
Outcomes	Vaginal delivery within 24 hours, improvement in the BS after ripening, caesarean delivery rates, ripening-to-delivery interval, oxytocin administration, epidural request, NICU admission, AS < 7 at 5 minutes, umbilical artery pH < 7.00.
Notes	Setting: University of In-subria, Varese, Italy Study period: October 2010 to October 2011 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation scheme
Allocation concealment (selection bias)	Low risk	Concealment by keeping random allocation sequence in a file cabinet with access restricted to research staff?
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Not an ITT analysis, women excluded after failed placement balloon or need for PGE2 gel after suppository expulsion.

Cromi 2012 *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in result
Other bias	Low risk	No other bias detected

Culver 2004

Methods	RCT, computer-generated block randomisation 4 and 6, consecutively numbered envelopes.
Participants	Nulliparous women GA 28 or more weeks, BS < 6, intact membranes, singleton, cephalic presentation, Exclusion: previous uterine surgery, non-reassuring FHR, latex allergy, contraindication to vaginal birth.
Interventions	Foley 30 cc + concurrent oxytocin (83 patients analysed). Misoprostol 25 mcg intravaginally 4-hourly, oxytocin augmentation after ripening. (79 patients analysed.)
Outcomes	Primary: CS Secondary: tachysystole, hyperstimulation, abnormal FHR tracing, intrapartum and postpartum fever, use of antibiotics, estimated blood loss, blood transfusions, AS, neonatal resuscitation, admission to ICU, meconium aspiration, sepsis, death.
Notes	Power analysis showed 266 patients were to be included, 173 were randomised. Study was stopped because principle investigator moved to other hospital. 11 patients were excluded from analysis, either received other treatment, or incomplete data. Setting: North Caroline Women's hospital and WakeMed hospital, North Carolina, USA Study period: June 1999 to April 2001 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence.
Allocation concealment (selection bias)	Low risk	Consecutively numbered envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	9 patients had incomplete records (4 and 5 in both groups), they were excluded.

Culver 2004 *(Continued)*

		2 patients (1 in every group) who did not receive the treatment were excluded, but otherwise ITT.
Selective reporting (reporting bias)	Low risk	All pre-specified outcome measures are reported.
Other bias	High risk	Recruitment goal was not reached, because PI moved to another institution.

Dalui 2005

Methods	Randomised prospective study, randomisation method unclear.
Participants	Singleton live fetus in cephalic presentation, 33-42 weeks GA, intact membranes, BS < 4 Exclusion: APH, scarred uterus, low-located placenta, cervicovaginal infection, history of cardiac disease, glaucoma, convulsive disorder, asthma, jaundice.
Interventions	Foley catheter 30 mL 12 hours, followed by oxytocin (n = 50). PGE2 gel 0.5 mg endocervically oxytocin augmentation after 12 hours (n = 50).
Outcomes	Bischop score after 12 hours, percentage of subjects entering spontaneous labour, insertion-expulsion interval Foley, induction-delivery interval, amount of oxytocin used, mode of delivery, side effects.
Notes	No power calculation, BS lower than most studies, no notes on method of randomisation Setting: Nehru Hospital, PGIMER, Chandigarh, India Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	'Randomised' method not described.
Allocation concealment (selection bias)	Unclear risk	'Randomised' method not described.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	Although ITT not mentioned, it seems ITT was used. no missing cases or data

Dalui 2005 *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre=specified data are reported, except for expulsion interval of Foley catheter (this is not an outcome of interest for this review).
Other bias	Low risk	No other bias detected

Deo 2012

Methods	RCT
Participants	Inclusion: full-term singleton gestation, cephalic presentation, indication for IOL. BS < 6. Exclusion: rupture of membranes, antepartum bleeding, placenta praevia, previous induction or pre-induction agent during the pregnancy.
Interventions	Foley catheter (n = 50): 16 F with 30 mL balloon, traction applied. no max hours described. Misoprostol vaginal (n = 54): 25 ug post fornix, every 4 hours max 8 doses. Dinoprostone vaginal gel (n = 52), 2 mg, once every 6 hours, max of 3 doses
Outcomes	Change in BS, total time for induction, delivery route, uterine tachysystole (defined as 6 contractions in 10 minutes, in 2 consecutive 10 minutes periods), uterine hypertonus (contraction lasting longer than 3 minutes), subject comfort as women were asked to evaluate their discomfort on a visual scale from 0 to 10.
Notes	Setting: CSM Medical University (India). Study period: not reported, 1 year duration Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated random allocation numbers
Allocation concealment (selection bias)	Low risk	Consecutive, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	As treated analysis (2 or 4 exclusions? (158 cases analysed, but total of included patients makes 156) Primary outcome: unclear how many women in Foley were analysed, in comparison groups 4 cases missing without explanation

Deo 2012 *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Deo 2013

Methods	RCT
Participants	Inclusion: full-term singleton gestation, cephalic presentation, indication for IOL. BS < 6. Exclusion: rupture of membranes, antepartum bleeding, placenta praevia, previous induction or pre-induction agent during the pregnancy.
Interventions	Foley catheter (n = 100): 16 F with 30 mL balloon, traction applied. no max hours described. dinoprostone vagina gel (n = 104), 2 mg, once every 6 hours, max of 3 doses
Outcomes	post induction BS at 6 and 13 hours,
Notes	Abstract only, no outcomes of interested reported Setting: KGMU Lucknow India Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only described women were randomly allocated, no more information available
Allocation concealment (selection bias)	Unclear risk	Only described women were randomly allocated, no more information available
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not reported, too little information to judge
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge
Other bias	Unclear risk	Abstract only, too little information to judge risk of bias

Deshmukh 2011

Methods	RCT
Participants	Inclusion: primigravida > 37 weeks of gestation, singleton pregnancy, cephalic presentation BS ≤ 3, Intact membranes Exclusion: multiple pregnancy, malpresentation, absent membranes, APH, medical disease, e.g. heart disease, renal disease
Interventions	Intracervical Foley (n = 200): if BS < 7 after 6 hours, PGE2 was given PGE2 gel vaginal (n = 200), dose repeated after 6 hours Failure of induction was declared if patient failed to go in active phase of labour within 24 hours of induction
Outcomes	Improvement of BS, induction-delivery interval, mode of delivery and feto-maternal outcomes
Notes	Setting: India Study period:July 2005 to January 2008 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported women were randomly assigned
Allocation concealment (selection bias)	Unclear risk	Allocation concealment not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT. no missing cases or data. no women excluded
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Dionne 2011

Methods	RCT, stratified for parity
Participants	Inclusion: indication for induction, BS < 6
Interventions	Foley catheter with oxytocin (n = 93) Foley catheter with intravaginal misoprostol (n = 84) Intravaginal misoprostol (n = 87)
Outcomes	Delivery within 24 hours, CS rate, maternal or fetal complications
Notes	Abstract only, no information about dosage misoprostol Setting: UK Study period: October 2001 to October 2004 Funding: no information Declaration of interest: no information

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation not described
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, too little information to judge
Selective reporting (reporting bias)	Unclear risk	Pre-specified outcome CS reported, too little information to judge
Other bias	Unclear risk	Abstract only, too little information to judge risk of bias

Edwards 2014c

Methods	RCT
Participants	Inclusion criteria: GA > 36 weeks, live singleton fetus in cephalic presentation, unfavourable cervix (less than 3 cm dilated; if 2 cm dilated, less than 80% effaced).

Edwards 2014c *(Continued)*

	Exclusion criteria: < 18 years, no informed consent in English, > 1 contraction/5 minutes, ruptured membranes, a prior caesarean delivery or any other prior uterine incision, a temperature of 38°C or higher, lethal fetal anomalies, placenta previa, other contraindication to vaginal delivery, suspected placental abruption or undiagnosed bleeding, a category II or III FHR pattern, HIV infection or any other immune dysfunction, an allergy to latex or dinoprostone, previous attempt of cervical ripening.
Interventions	Foley catheter (n = 185): 16F, 30 mL, minimal tension, removed after 12 hours Dinoprostone vaginal insert (n = 191): removed after 12 hours
Outcomes	Induction to delivery time, (vaginal) delivery within 12 hours, (vaginal) delivery within 24 hours, tachysystole, clinical chorioamnionitis, endometritis, other postpartum complications, caesarean delivery, early neonatal outcomes
Notes	Setting: multicentre, USA period: July 2010 to February 2013 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocated by an online randomisation system 1 to 1
Allocation concealment (selection bias)	Low risk	Allocation web-based
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analyses reported, but women who did not deliver and went home were excluded (5 to 77. Patients with missing values for arterial cord pH level. properly described how this was dealt with
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

El Khouly 2017

Methods	RCT
Participants	Inclusion criteria: singleton pregnancy, cephalic presentation, GA > 28 weeks and the BS < 6.

El Khouly 2017 *(Continued)*

	Exclusion criteria: contraindication vaginal delivery, EFW > 4500 g, a previous uterine scar, clinically significant cervical or vaginal infection, chorioamnionitis, unexplained vaginal bleeding, low-lying placenta, abnormal cervical anatomy or cervical cerclage.
Interventions	Foley catheter (n = 36): 18F, 30 mL, max of 12 hours Foley catheter + oxytocin (n = 36): 18F, 30 mL balloon, oxytocin, Foley max of 12 hours) Oxytocin alone (n = 36): increased by 2 mU/minute at 30-minute intervals until adequate uterine activity was maintained, max dose 32 mU/minute, AROM at 3 cm
Outcomes	Duration and dose of required oxytocin, induction to delivery interval, mode of delivery and reason (in case of CS), maternal and neonatal complications
Notes	Setting: Menoufia University Hospital, Egypt Study period: between January 2015 and February 2016. Funding: no funding Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Although ITT is not mentioned, figure 1 and results are plausible for ITT, all cases analysed, no missing data described
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Filho 2002

Methods	RCT.
Participants	Term or post-term, live, singleton fetus in cephalic presentation, intact membranes, BS < 6, not in labour, medically indicated for labour induction.

Filho 2002 *(Continued)*

	Exclusion criteria: multiple gestations, non-cephalic presentation, previous caesarean delivery or uterine scar, rupture of membranes, antepartum bleeding, genital herpes infection, fetal death, placenta previa or previous attempts to induce labour.
Interventions	Misoprostol (n = 119): 25 mcg 6-hourly, max 4 doses. Foley (n = 121): 30cc traction applied 24 hours followed by oxytocin.
Outcomes	Induction-to-vaginal delivery time, deliveries within 24 hours, mode of delivery, uterine contraction abnormalities, puerperal infection or neonatal outcomes.
Notes	Setting: Maternidade Monteiro de Morais, Recife, Brazil Dates of study: between September 2000 and December 2001 Funding sources: financial support from CAPES Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence.
Allocation concealment (selection bias)	Low risk	Consecutively numbered sealed opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not described
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow up, analysis ITT.
Selective reporting (reporting bias)	Low risk	All pre-specified data reported.
Other bias	Low risk	No other bias detected

Garba 2016

Methods	RCT
Participants	Inclusion: multiparae, postdate (41+3), singleton, unfavourable cervix Exclusion: not mentioned
Interventions	Foley catheter + oxytocin (n = 66) (no more info available)

Garba 2016 *(Continued)*

	Vaginal misoprostol (n = 70), (no more information available
Outcomes	Mode of delivery, maternal and perinatal outcomes, induction to delivery interval, AS, maternal vital signs, estimated blood loss.
Notes	Setting: antenatal clinic at Aminu Kano Teaching Hospital, Nigeria Study period: February to May, 2015 Funding: no funding Declaration of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not reported, in table 4 there are cases missing, not reported why. no missing data reported
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Unclear risk	All eligible patients where randomised. Inclusion rate of 100% of all eligible patients is doubtful

Gelisen 2005

Methods	RCT, randomisation by sealed opaque envelopes, no mentioning of sequence.
Participants	Singleton live pregnancy, GA 41 completed weeks, BS < 5, no contractions, AFI > 5, estimated fetal body weight < 4500 g. Exclusion: known hypersensitivity to PG, previous caesarean delivery or other uterine surgery, MBI > 30, parity > 4, low-lying placenta.
Interventions	Foley catheter 50 mL (n = 100). Vaginal misoprostol 50 mcg 6-hourly, max 24 hours (n = 100). (group excluded because of high dose) Oxytocin low dose protocol (n = 100).

Gelisen 2005 *(Continued)*

	Spontaneous follow-up (n = 300). (not in analyses)
Outcomes	CS rate, neonatal outcomes: meconium, arterial pH, acidaemia, admissions to NICU secondary, tachysystole, hyperstimulation, fetal distress.
Notes	Primary goals of study is to compare induction versus expectant management. Setting: tertiary training centre in Turkey Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	600 opaque envelopes, 1 was drawn every time.
Allocation concealment (selection bias)	Low risk	Opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Blinded assessment of fetal monitor strips. (to assess hyperstimulation).
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not addressed, seems like all data complete.
Selective reporting (reporting bias)	Low risk	All pre-specified outcome measures are reported.
Other bias	Low risk	No other bias detected

Gilson 2017

Methods	RCT
Participants	Patients eligible for medical induction
Interventions	Foley catheter + oxytocin (n = 526) Low dose titrated oral misoprostol (n = 575) dose not mentioned in abstract
Outcomes	Effectiveness, safety
Notes	Abstract only

Gilson 2017 *(Continued)*

	Setting: Rwanda Study period: not reported Funding: not reported Declaration of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation not described
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT mentioned, not clear why groups are different in size.
Selective reporting (reporting bias)	Unclear risk	Insufficient information
Other bias	Unclear risk	Abstract only, to little information to judge risk of bias

Glagoleva 1999

Methods	RCT. No details were given on the method for concealment of the allocation.
Participants	BS < 5. Women with a past history of CS were excluded.
Interventions	Dilapan (4 tents) removed after 12 hours (27 women). PGE2 intracervical gel 0.5 mg (1-2 doses) (26 women).
Outcomes	CS.
Notes	Abstract only Setting: Russia Dates of study: not reported Funding sources: not reported Declarations of interest: not reported

Glagoleva 1999 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported women were randomly assigned.
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to judge
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge
Other bias	Unclear risk	Abstract only, insufficient information to judge risk of bias

Goonewardene 2014

Methods	RCT
Participants	Inclusion: singleton pregnancy, cephalic, cervix unfavourable (MBS < 6), 40 weeks and 6 days Exclusion: multiple pregnancies, malpresentation, previous CS or any contraindication for normal delivery or misoprostol, prior intervention for ripening of the cervix, non-reactive CTG after fetal acoustic stimulation test.
Interventions	Oral misoprostol (n = 74) 25 ug, every 4 hours, max of 2 gifts Foley catheter (n = 78) max 24 hours
Outcomes	Modified BS ≥ 6 day 2 after the intervention; Induction to delivery interval, mode of delivery, side effects of misoprostol (only reported in trial register)
Notes	Setting: Academic Obstetric Unit, Teaching Hospital, Mahamodara, Galle, India Study period: January 2011 to March 2012 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement

Goonewardene 2014 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated sequence, block randomisation, stratified for parity
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not mentioned, no FIgure 1, cases excluded for some selective outcomes because of spontaneous labour after intervention, no missing data reported.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results, except secondary outcome 'side effects misoprostol' not reported.
Other bias	Low risk	No other bias detected

Guinn 2000

Methods	RCT. Computer-generated sequence. Opaque, sealed, sequentially numbered envelopes.
Participants	Singleton, vertex presentation, intact membranes. Unfavourable cervix (< 2 cm dilated and effacement < 75%). Exclusion: bleeding, labour, asthma. prior vertical uterine incision, acute fetal compromise
Interventions	Laminaria and IV oxytocin: as many laminaria as possible were kept for 12 hours, unless expelled or membranes ruptured. IV oxytocin was simultaneously given (165 women); EASI + IV oxytocin: Foley catheter balloon filled with 30 mL of water followed by saline infusion 30 mL/hour. IV oxytocin was simultaneously given (169 women); PGE2 intracervical gel 0.5 mg/6H, max 2 doses. IV oxytocin was started if not in labour after 2 doses of PGE2 (110 women).
Outcomes	CS, delay to delivery, delivery within 24 hours, infections, haemorrhage.
Notes	After interim analysis, the authors stopped recruiting in the PGE2 group. 68 protocol violations, but ITT analysis was conducted. Setting: University of Alabama and Cooper Green Hospitals Birmingham, Alabama Dates of study: January 1994 to August 1997 Funding sources: UpJohn Pharmaceuticals provided funds to purchase study drugs Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**

Guinn 2000 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated random number table
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT
Selective reporting (reporting bias)	Unclear risk	All pre-specified outcomes reported for laminaria and EASI
Other bias	Unclear risk	After interim analysis, the authors stopped recruiting in the PGE2 group.

Gunawardena 2012

Methods	RCT
Participants	Uncomplicated primipara with singleton pregnancies who underwent IOL at 40 weeks + 5 days
Interventions	PGE2 intracervical (72) Foley (73)
Outcomes	Change in mean MBS, uterine hyper-stimulation, Broncho-constriction, nausea and vomiting, postpartum haemorrhage and maternal fever, meconium at membrane rupture, AS at 5 minutes and PBU admission
Notes	Abstract only Setting: Ward 5, Teaching Hospital, Kandy, India Study period: not reported Funding: not reported Declaration of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported

Gunawardena 2012 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, no missing data or cases reported
Selective reporting (reporting bias)	Unclear risk	Maternal and neonatal adverse outcomes were not given in numbers
Other bias	Low risk	No other bias detected

Haugland 2012

Methods	RCT
Participants	Inclusion: singleton pregnancy, > 37 weeks, indication to induce birth, BS < 2 cm, term date set by US before week 21 Exclusion: IUFD, fetal malformations, low lying placenta, rupture of membranes, no understanding of Norwegian language
Interventions	Foley catheter (n = 90), 16-19 hours Cook double balloon (n = 88), 16-19 hours
Outcomes	Cervix dilatation ≥ 3 cm after removal or active labour
Notes	Abstract only Setting: Haukeland university hospital, Bergen, Norway Study period: March 2010 - January 2011 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Randomisation not described
Allocation concealment (selection bias)	Unclear risk	No information

Haugland 2012 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Double-blind, says in the protocol that participants and outcome assessor will be blind to allocated treatment, but not clinicians
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Double-blind, in the study protocol says participant and outcome assessor will be blind to allocated treatment
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not described mentioned, to little information to judge
Selective reporting (reporting bias)	Unclear risk	Insufficient information
Other bias	Unclear risk	Abstract only, too little information to judge risk of bias

Hay 1995

Methods	RCT. No details were given on the method for concealment of the allocation.
Participants	28 women in the comparison between Dilapan and PGE2, with a total of 39 women recruited (15 Dilapan group, 13 PGE2 group, 11 amniotomy).
Interventions	Dilapan versus PGE2, no details on dosage provided.
Outcomes	CS, hyperstimulation, nausea.
Notes	Abstract only. Setting: UK Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported

Hay 1995 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to judge
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge
Other bias	Unclear risk	Abstract only

Hemlin 1998

Methods	RCT
Participants	Singleton vertex term pregnancies, BS < 5
Interventions	EASI 30 to 60 mL/hour infusion (43 women) PGE2 0.5 mg intracervical (42 women)
Outcomes	CS, instrumental delivery, painful contractions, vaginal delivery achieved within 12 to 24 h0urs.
Notes	Setting: County hospital of Ekinstuna, Sweden Study period: November 1990 to November 1995 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported women were randomised using sealed envelopes
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, women delivered by CS and women with quote: " unsuccessful" treatment were excluded for some of the outcome measures. no missing cases of missing data for outcomes of interest.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported

Hemlin 1998 *(Continued)*

Other bias	Low risk	No other bias detected

Henry 2013

Methods	RCT
Participants	Inclusion: women ≥ 18 years gestational > 37 weeks requiring IOL with a cervical preparation procedure Exclusion: unsuitable for outpatient management, unsuitable for randomisation to either PGE2 (e.g. previous CS) or catheter use (e.g. latex allergy), or prior attempted IOL in this pregnancy, ruptured membranes, regular uterine contractions, multiple pregnancy or non-vertex presentation, unable to give informed consent
Interventions	Foley catheter (n = 50): 30 mL, slight traction, spigot inserted to occlude the lumen, PCM 1 g/60 mg codeine, 20 mg temazepam., went home. *N*ext morning AROM or priming by choice of clinician (n = 50) PG gel (n = 51): (2 mg nulliparous – 1 mg multi parous), fornix posterior, repeated if necessary after 6 hours (1 mg), PCM 1 g/60 codeine, temazepam 20 mg, next morning AROM or priming by choice of clinician
Outcomes	Delivering vaginally within 12 hours of admission to Delivery Unit; total inpatient hours from induction to delivery, syntocinon for induction or augmentation of labour, mode of delivery, vaginal delivery within 24 hours of insertion of Foley catheter or first dose PGE2 gel, Induction to delivery interval, i.e. time from commencement of cervical ripening to delivery, delivery within 24 hours of insertion of Foley catheter or first dose PGE2 gel, requirement for second method of cervical ripening or (in Prostin group) 3rd dose of PG, patient satisfaction using questionnaire created for purposes of this study, return to hospital (Foleys group) prior to planned readmission and not in labour, maternal febrile morbidity, non-reassuring FHR trace, CS or instrumental delivery for fetal distress, Admission to newborn care, AS 1 and 5 minutes, epidural.
Notes	Setting: Australian metropolitan tertiary teaching hospital, Australia Time period: June 2009 to December 2010 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table was performed prior to trial commencement.
Allocation concealment (selection bias)	Low risk	Sealed in sequentially-numbered, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Henry 2013 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, no missing data reported, no missing cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results, except secondary outcome 'epidural' (pre specified in trial registration)
Other bias	Low risk	No other bias detected

Hibbard 1998

Methods	RCT. Computer-generated sequence. Opaque, sequentially-numbered envelopes.
Participants	Vertex, > 34 weeks, intact membranes, BS < 5. Exclusion of previous CS, cervicitis, macrosomia.
Interventions	PGE2 (Prepidil) gel (17 women); PGE2 (Prepidil) and Dilapan (22 women).
Outcomes	CS, instrumental delivery, painful contractions, vaginal delivery not achieved in 24 hours, uterine hyperstimulation, infection.
Notes	Setting: University of Chicago, USA Study period: August 1994 - May 1995 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation chart
Allocation concealment (selection bias)	Low risk	Sequential opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, no missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported
Other bias	High risk	Study ended prematurely (before power was reached) as Dilapan was removed of the USA market

Hoppe 2016

Methods	RCT
Participants	Inclusion: ≥ 18 years, singleton, vertex, BS of ≤ 5, < 4 contractions in 10 minutes, category I fetal monitoring. Exclusion: contraindication for vaginal delivery, planned or received exogenous PG administration, unexplained vaginal bleeding, active herpes simplex, previous caesarean delivery, previous attempt at IOL, non-English speaking
Interventions	Single balloon 18F Foley, 30 mL, traction applied, max 12 hours Double balloon, Cook 80 mL/80 mL, max 12 hours
Outcomes	BS of > 6 at time of catheter removal, change in BS, time from catheter insertion to spontaneous expulsion or removal, mean time from catheter insertion to vaginal delivery, vaginal delivery in 24 hours, the use of pharmacologic methods for further cervical ripening or augmentation of labour, AROM, epidural use, mode of delivery, indications for CS, chorioamnionitis, AS at 5 minutes < 7, meconium, NICU admissions
Notes	Setting: University of Washington Medical Center Labor and Delivery, USA Study period: January 2010 and November 2013 Funding: no funding by Cook Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Block randomisation, stratified for parity, not clear how this was done.
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No ITT reported, most likely per protocol, missing data in baseline characteristic, not in outcomes, no cases missing
Selective reporting (reporting bias)	Low risk	All pre-specified outcome data reported
Other bias	Low risk	No other bias detected

Hudon 1999

Methods	RCT. No details on the method of randomisation or on concealment of the allocation.
Participants	Term, unfavourable cervix (BS < 5).
Interventions	Foley catheter placed above the internal os and inflated with 40 mL left in place for a max of 16 hours (56 women); intracervical PGE2 (0.5 mg), repeated if BS unfavourable (55 women). Oxytocin was given after achievement of cervical ripening.
Outcomes	CS.
Notes	Setting: USA Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported women were randomised
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information to judge
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge
Other bias	Unclear risk	Abstract only

Hughes 2002

Methods	Randomised trial.
Participants	Singleton gestation, cephalic presentation, intact membranes, GA 36-42, indicated labour induction.
Interventions	PGE 2 pessary (n = 34).

Hughes 2002 *(Continued)*

	Foley + EASI + oxytocin (n = 33).
Outcomes	Change in BS, induction-delivery time.
Notes	Outcomes of interest not reported in this abstract. Setting: USA Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly assigned, no further details
Allocation concealment (selection bias)	Unclear risk	Randomly assigned, no further details
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	2 patients excluded after randomisation in Foley group, unclear
Selective reporting (reporting bias)	Unclear risk	Study protocol/predefined outcomes not available
Other bias	Unclear risk	Only reported as abstract

Husain 2017

Methods	RCT
Participants	Inclusion: age 20 to 40 years, singleton pregnancy, cephalic presentation ≥ 37 weeks Exclusion: BS of > 4, cephalopelvic disproportion on examination, history of placenta previa or unexplained vaginal bleeding, history of previous CS or other uterine surgery, active herpes simplex infection, chorioamnionitis, contraindication to use of PGs, acute pelvic inflammatory disease, contraindication to vaginal delivery, a non reassuring FHR pattern prior to induction.
Interventions	Oral misoprostol (n = 157): 50 mcg, every 4 hours, max 4 gifts

Husain 2017 *(Continued)*

	Foley catheter + oral misoprostol (n = 161): 16 or 18F, filled with 30 mL + oral misoprostol (50 mcg) every 4 hours, max 4 gifts both groups: if labour was not established within 4 hours of the 4th dose of misoprostol, induction was considered to have failed and such cases were then delivered by CS.
Outcomes	Failure to achieve vaginal delivery after 24 hours, induction-to-delivery interval, mode of delivery, reason for CS maternal complications, NICU admissions
Notes	Setting: Abbasi Shaheed Hospital in Karachi, Pakistan, tertiary care centre Study period: May 2016 to October 2016. Funding: no funding reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence, block randomisation
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT analysis not reported, cases excluded because of protocol violation. no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Jagani 1982

Methods	RCT. Randomisation based on case number. No measure taken to conceal the allocation.
Participants	Intact membranes.
Interventions	5 groups: no treatment (n = 10; exclude); laminaria n = 10 (as many as possible); Foley catheter n = 10 (inflated with 70 - 80 mL water) under traction; amniotomy (n = 10); oxytocin (n = 10) increased by 5 mU/minute every 10 -15 minutes. In all groups, each of 10 women, an extraovular catheter with a 5 mL balloon was used to record uterine activity.
Outcomes	CS.
Notes	Setting: USA

Jagani 1982 *(Continued)*

	Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Method selected by last digit of the chart number
Allocation concealment (selection bias)	High risk	Inadequate.No measure taken to conceal the allocation.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, not clear how many women were actually included.
Selective reporting (reporting bias)	Low risk	All outcome measures were reported
Other bias	Low risk	No other bias detected

Jalilian 2011

Methods	RCT
Participants	Inclusion criteria: singleton gestation, cephalic presentation, reactive FHR pattern, intact membranes and GA between 37-41 weeks Exclusion criteria: BS at least 7 or cervical dilatation greater than 3 cm, EFW > 4500 g or < 2000 g, evidence of cephalopelvic disproportion, placenta previa or unexplained vaginal bleeding, previous section caesarean or uterine surgery and contraindications to PG
Interventions	Intravaginal dinoprostone (n = 20), 3 mg every 6 hours, max 4 doses Foley catheter, 16F, 30 mL (n = 20), removed after 12 hours
Outcomes	Not mentioned in method section
Notes	Article is submitted as letter to the editor. no relevant outcomes reported Setting: Iran Study period: not reported Funding: not reported

Jalilian 2011 *(Continued)*

	Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only described women were randomly allocated, no more info available
Allocation concealment (selection bias)	Unclear risk	Only described women were randomly allocated, no more info available
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not reported, too little information to judge
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge
Other bias	Unclear risk	Abstract only (letter to editor), too little information to judge risk of bias

Jeeva 1982

Methods	RCT. No details on the method of randomisation or on concealment of the allocation.
Participants	No description of inclusion/exclusion criteria. 10 primigravidas and 10 multigravidas.
Interventions	Laminaria tents (2 - 3 tents) (10 women); (PGE2) 4 mg tablets vaginally.
Outcomes	Change in BS after 16 hours, CS.
Notes	Setting: South Africa Dates of study: not reported Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported women were randomised

Jeeva 1982 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not mentioned, but seems reasonable as numbers in tables are equal to randomised numbers, no cases missing
Selective reporting (reporting bias)	Unclear risk	Insufficient information as no outcome measures were pre-specified in report
Other bias	Low risk	No other bias detected

Johnson 1985

Methods	RCT. Sequence based on a random number table. No details were given on the method for concealment of the allocation.
Participants	Term, primiparas, BS < 6.
Interventions	Lamicel (40 women); PGE2 vaginal gel (4 mg) (40 women).
Outcomes	Epidural analgesia, CS, instrumental delivery, uterine hyperstimulation, fetal distress.
Notes	Setting: UK Dates of study: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention

Johnson 1985 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT unclear, no missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Joshi 2016

Methods	RCT
Participants	Inclusion criteria: 1 previous low transverse CS, singleton live pregnancy with cephalic presentation, reassuring fetal status, > 37 weeks and BS < 6 Exclusion criteria: placenta praevia, CPD, various mal presentations, short interconceptional period of 18 months, previous 2 caesareans, in a case of previous myomectomy or hysterectomy, patient demands repeat elective CS
Interventions	Foley catheter (n = 100), 16F, 30 mL, max 24 hours in situ Oxytocin (n = 100): starting from 1 mU/minute, increased to 2 mU/minute and max up to 32 mU/minute
Outcomes	Induction delivery interval, indications for CS, mode of delivery, neonatal outcome and NICU admissions were studied in both groups
Notes	Setting: Swami Dayanand Hospital Dilshad Garden New Delhi, India Study period: January 2015 - June 2015 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Only stated that women were randomly allocated
Allocation concealment (selection bias)	Unclear risk	Only stated that women were randomly allocated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias)	Unclear risk	Not reported

Joshi 2016 *(Continued)*

All outcomes		
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not reported, no figure 1 to check allocation, all cases analysed, no missing data described
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Jozwiak 2012

Methods	RCT
Participants	Inclusion criteria: pregnant women scheduled for IOL beyond 37 weeks of gestation with a vital singleton pregnancy in cephalic presentation, intact membranes, and an unfavourable cervix (BS < 6). Exclusion criteria: women younger than 18 years, with a previous CS, placenta praevia, lethal fetal congenital anomaly, or known hypersensitivity for one of the products used for induction were ineligible
Interventions	Foley catheter (n = 411): 18F, 30 cc sterile saline. PG E2 gel (408): 1 mg, followed by 1 mg after 6 hours, with a max of 2 doses per 24 hours inserted into the posterior vaginal fornix. An initial dose of 2 mg was allowed in nulliparous women. 2 days of induction, 1 day of " rest" followed by 2 more days of induction in case of BS < 6
Outcomes	CS, maternal and neonatal morbidity and time from start induction to birth.
Notes	Setting: multicentre, the Netherlands Study period: Feb 2009 - May 2010 Funding: none Declarations of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	Web-based
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Jozwiak 2012 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, missing outcome data (pH and BMI) balanced in numbers across intervention groups, with similar reasons for missing data across groups. no missing cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Jozwiak 2013

Methods	RCT
Participants	Women > 18 years with term pregnancy and unfavourable cervix, requiring IOL. Exclusion criteria were previous CS, non-vertex presentation of the fetus, ruptured membranes, hypersensitivity for one of the products used for induction, or a lethal congenital anomaly of the fetus
Interventions	Foley catheter (107),18F 30 cc sterile saline. 10 mg slow release PG vaginal insert (n = 119). Removed after 12 hours, if BS < 6, after 24 hours new PG vaginal insert was used 2 days of induction, 1 day of " rest" followed by 2 more days of induction in case of BS < 6
Outcomes	CS, maternal and neonatal morbidity and time from start induction to birth.
Notes	Setting: multicentre, the Netherlands Study period: February 2009 - May 2010 Funding: none Declarations of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation
Allocation concealment (selection bias)	Low risk	Web-based
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis, missing outcome data (pH and BMI) balanced in numbers across intervention groups, with similar reasons for missing data across groups. no missing cases

Jozwiak 2013 *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Jozwiak 2014

Methods	Pilot study within RCT
Participants	Women > 18 years, ≥ 37 weeks, BS < 6, planned for IOL. Exclusion:previous CS, non vertex presentation, ruptured membranes, hypersensitivity for one of the products used for induction, lethal congenital anomaly
Interventions	Foley catheter (n = 56), 16 or 18F, 30 mL Vaginal misoprostol (n = 64) 25 mcg tablets every 4 hours, max 3 doses in 24 hours. In both groups, if the cervix was still unfavourable for amniotomy after 48 hours of treatment, women were generally assigned a day of rest followed by another 48 hours of induction
Outcomes	CS, instrumental vaginal delivery, reasons for operative delivery, time from induction to delivery, uterine hyperstimulation, uterine rupture, analgesics, antibiotics, maternal suspected intrapartum infection, maternal postpartum infection, postpartum haemorrhage (> 1000 cc) postpartum blood transfusion, AS of < 7 at 1 minute and 5 minutes, arterial cord blood pH < 7·10, neonatal admissions neonatal ward/NICU
Notes	Setting:multicenter, the Netherlands Study period: February 2009 and May 2010 Funding: no funding reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence, block randomisation
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis, missing data reported, but even distributed over groups and likely for the same reasons. no missing cases

Jozwiak 2014 *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results, except secondary outcome maternal postpartum infection
Other bias	Low risk	No other bias detected

Kandil 2012

Methods	Prospective quasi-RCT
Participants	Inclusion criteria: 41 weeks or more, primigravida, BS < 4, singleton living fetus, vertex presentation, no evidence of active labour, a reassuring FHR pattern, no evidence of intrauterine infection. Exclusion criteria: contra-indication for vaginal delivery, previous uterine surgery, non-reassuring FHR, IUFD, ruptured membranes, vaginal infection, malpresentation, macrosomic fetus, cephalopelvic disproportion, history of APH, contra-indication to PGs
Interventions	1. 18F Foley catheter, 30 cc sterile saline. Taped to the inner thigh. Each patient received 1 g of ampicillin/6 hours. Removed after 12 hours. (N = 50) 2. 25 ug misoprostol vaginally every 4 hours (N = 50)
Outcomes	Induction to delivery time, oxytocin use, route of delivery, occurrence of chorioamnionitis, AS, admission to NICU, tachysystole, hypertonus, hyperstimulation
Notes	9 patients were insertion of Foley was not possible were replaced by 9 other patients! Setting: Menofyia University Hospital, Egypt Study period: from January 2010 to October 2010 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Randomisation by odd or even admission date
Allocation concealment (selection bias)	High risk	Randomisation by odd or even admission date
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT was not mentioned. 9 patients in Foley group were replaced by 9 others because insertion of Foley was not possible. No flow chart, no description of lost to follow-up.

Kandil 2012 *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre-described outcome measures were mentioned.
Other bias	Low risk	No other bias detected

Khamaiseh 2012

Methods	RCT
Participants	Inclusion criteria: age 15 years or more, term, singleton, live fetus in vertex presentation, intact membranes and BS < 6. Exclusion criteria: previous CS or history of other uterine surgery, history of ante partum haemorrhage, cephalopelvic disproportion, acute fetal distress revealed by a non stress test prior to induction, signs of infection, ruptured membranes, EFW > 4300, or known allergy to PG
Interventions	PG E2 (n = 204) tablets 3 mg, max 2 dose. AROM performed if labour did not commence after 2 doses Foley catheter (n = 210): 22/24F, 50-60 mL in balloon.Removed after 24 hours and AROM if possible
Outcomes	Mode of delivery, time interval between the start of induction and delivery, oxytocin requirement, the indications for CS and adverse neonatal and maternal reactions to the cervical ripening agent. Hyperstimulation with and without FHR changes, failed induction.
Notes	Setting: King Hussein Medical Centre and Prince Ali Bin Al-Hussein hospital, Jordan Study period: July 2009 - July 2010 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random sequence generated by computer
Allocation concealment (selection bias)	Unclear risk	Not described, only description: Randomisation was done by a computer-generated list of random numbers
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT analysis not reported and not clear if used, no missing data or cases

Khamaiseh 2012 *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Krammer 1995a

Methods	RCT. Computer-generated sequence. No details were given on the method for concealment of the allocation.
Participants	Term women with a BS < 9, absence of contraindication for labour and fetal distress. 441 women (224 in the Dilapan group and 217 in the PGE2 group).
Interventions	Dilapan, as many dilators as possible (224 randomised, 214 analysed); intracervical PGE2 0.5 mg (217 women randomised, 202 analysed). In both groups, ripening was followed 6 hours later by oxytocin.
Outcomes	CS, uterine hyperstimulation, fetal and neonatal infection.
Notes	25 women excluded: 10 in the Dilapan group (8 protocol violations, 2 entered spontaneous labour before insertion) and 15 in the PG group (10 protocol violations, 3 entered labour before ripening and 2 delivered before the 6-hour interval). Authors stated that including these excluded women do not alter the results. Numbers of CS derived from Williams 1997. Setting: Tampa general hospital, USA Dates of study: June 1991 - December 1993 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated sequence
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT was performed, but 25 women excluded: 10 in the Dilapan group (8 protocol violations, 2 entered spontaneous labour before insertion) and 15 in the PG group (10 protocol violations, 3 entered labour before ripening and 2 delivered before the 6-hour interval)

Krammer 1995a *(Continued)*

Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Kruit 2016

Methods	RCT
Participants	Inclusion: PROM > 18 hours, ≥ 37 weeks, BS < 6, vital singleton pregnancy, cephalic Exclusion: previous CS, placenta previa, vaginal bleeding, HIV, hepatitis B or C, maternal infection, fetal anomaly
Interventions	Foley (n = 89): 22ch Rush balloon, traction, 40-50 cc, max 8 hours. if unripe, further management by discretion of clinician oral misoprostol (n = 99): 50 mcg misoprostol every 4 hours, after 3 gifts dosis increased to 100 mcg or 25 to 50 mcg vaginal every 3-4 hours
Outcomes	CS rate, maternal and neonatal infections. Reason for CS (fetal distress, suspected infection, prolonged labour, failed induction, postpartum infection, postpartum haemorrhage, uterine hyperstimulation, fetal tachycardia, use of analgesics, AS, umbilical arterial pH, admission to neonatal care, induction to delivery interval.
Notes	Trial stopped prematurely due to insufficient patient enrolment Setting: multicentre, Finland Study period: March 2012 to September 2014 Funding: grant from the Finnish medical society duodecim and Helsinky University Central Hospital research grant Declarations of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported how this was done (only that they used sealed envelopes)
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	High risk	Seems to be per protocol analysis. Patients excluded after enrolment for cross-over during analysing data, 3rd arm formed

Kruit 2016 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	High risk	Trial stopped prematurely due to insufficient patient enrolment

Kuppulakshmi 2016

Methods	RCT
Participants	Not mentioned
Interventions	intracervical dinoprostone (n = 100): 0.5 mg, 6-hourly, max 2 doses Foley catheter (n = 100), 30 mL, max 12 hours in place.
Outcomes	Vaginal delivery within 24 hours, improvement in BS, induction to onset of active labour and induction to delivery interval, mode of delivery, occurrence of maternal complications and fetal outcome, cost-effectiveness
Notes	Setting: India Study period: June 2015 - July 2016 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only described that patients were randomly allocated
Allocation concealment (selection bias)	Unclear risk	Only described that patients were randomly allocated
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No missing data described, difficult to judge how selection of patients was done, if there was ITT, if patients were excluded. no numbers of analysed patient in result section
Selective reporting (reporting bias)	Low risk	Pre specified outcomes reported in method section were all reported
Other bias	Low risk	No other bias detected

Laddad 2013

Methods	RCT
Participants	Inclusion criteria: primigravida, > 37 weeks of gestation, singleton pregnancy, cephalic presentation, BS < 4, Intact membranes Exclusion criteria: multiple pregnancy, mal-presentation, absent membranes, APH, medical disease e.g. heart disease, renal disease, previous LSCS
Interventions	Foley catheter (n = 200): PGE2 gel intracervical (n = 200), max 2 doses, failed induction declared if patient was not in active labour after 48 hours
Outcomes	Not mentioned in method section
Notes	PGE2 dose not described Setting: KIMSDU; India, Study period: January 2011 - December 2012 Funding: none Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only stated that women were randomly assigned
Allocation concealment (selection bias)	Unclear risk	Only stated that women were randomly assigned
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear if analysis was ITT, (no figure 1) all cases analysed, no missing data described
Selective reporting (reporting bias)	Unclear risk	No pre -specified outcome measures reported, so cannot be determined
Other bias	Low risk	No other bias detected

Lanka 2014

Methods	RCT
Participants	Inclusion: GA > 28 weeks, singletons, intact membranes, absence of labour, cephalic presentation, BS < 5. Exclusion: multifetal gestations, congenital malformations, Gravidity > 4, non-reassuring FHR trace, ruptured membranes, active genital infection, previous uterine surgery (including CS), low-lying placenta, chorioamnionitis, EFW > 4000 g, IUFD, known allergies to latex or PGs
Interventions	Foley + misoprostol (n = 63): 16F Foley catheter, 30 cc, traction applied, max 12 hours - 25 mcg vaginal misoprostol, every 4 hours up to a max of 8 doses. vaginal misoprostol (n = 63): 25 mcg vaginal misoprostol every 4 hours, with a max of 8 doses
Outcomes	induction to delivery interval, rate of vaginal deliveries, hyperstimulation, CS rate, neonatal outcome, chorioamnionitis, oxytocin use
Notes	Setting: tertiary care centre, India Study period: 2-year period Funding: no funding Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence, block randomisation
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT analysis, no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Lemyre 2006

Methods	RCT.

Lemyre 2006 *(Continued)*

Participants	Term pregnancy requiring cervical ripening.
Interventions	Foley catheter for 12 hours (n = 31). Vaginal misoprostol 25 mcg 4-hourly (n = 31).
Outcomes	Induction-active labour, induction-delivery, delivery within 12 and 20 hours, oxytocin, obstetric outcome, maternal and neonatal morbidity
Notes	Reported as abstract, only outcome of interest reported is oxytocin infusion. Setting: Canada Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly assigned, no details on sequence generation.
Allocation concealment (selection bias)	Unclear risk	No details on allocation concealment given.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported in this abstract.
Selective reporting (reporting bias)	Unclear risk	In this abstract from the outcomes of interest only oxytocin infusion reported, other outcomes not reported.
Other bias	Unclear risk	Only abstract available.

Lewis 1983

Methods	RCT. No details were given on the method for concealment of the allocation.
Participants	Singleton vertex term pregnancy, unfavourable cervix.
Interventions	Vaginal pessary 3 mg PGE2 (22 women); Foley catheter in the extra-amniotic space 30 mL (22 women); Control group with no treatment (22 women; exclude)

Lewis 1983 *(Continued)*

Outcomes	Change in BS, CS, uterine hyperstimulation, AS.
Notes	Data on induction-delivery intervals not interpretable to derive proportion of women with vaginal delivery not achieved in 24 hours. Setting: Manchester, UK Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random allocation, no more details reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear if ITT was performed. no missing cases or data reported
Selective reporting (reporting bias)	Unclear risk	No specific pre specified outcomes reported in method section.
Other bias	Low risk	No other bias detected

Lokkegaard 2015

Methods	RCT
Participants	Inclusion criteria: intact membranes, cephalic position, BS ≤ 6, indication of IOL. Exclusion criteria: ruptured membranes, spontaneous labour, placenta praevia, acute fetal distress, asthma, glaucoma, latex allergy, infections (acute herpes, GBS, condylomata), previous CS
Interventions	1. Double balloon catheter (n = 412); 80 mL, max 12 hours, thereafter either AROM or start of oxytocin. 2. PGE2 3 mg tablet (n = 413), 2 dose a day (4-5 hourly), max 2 days
Outcomes	Failed inductions, time interval from induction to delivery, mode of delivery, neonatal outcome as assessed by the AS after 5 minutes and referral to a neonatal care unit, subgroups by parity and indica-

Lokkegaard 2015 *(Continued)*

	tion for induction. Post hoc analyses included the percentage of women who gave birth within 24 hours and the need for additional oxytocin stimulation
Notes	Setting: multicentre, Denmark Study period: September 2002 to December 2005 Funding: the randomisation procedure was funded by ' Snedkermester Sophus Jacobsen & Astrid Jacobsens fond and the Danish Toyota Foundation. Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated and was stratified for parity and department.
Allocation concealment (selection bias)	Low risk	Central allocation by telephone
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, missing data reported, but evenly distributed.
Selective reporting (reporting bias)	Low risk	All pre-specified outcome measures were reported
Other bias	Low risk	No other bias detected

Lyndrup 1989

Methods	RCT.
Participants	Woman with unfavourable cervix.
Interventions	4 groups: 1. oxytocin without Lamicel (according to a fixed schedule, with a max of 32 mU per minute) (24 women); 2. oxytocin with Lamicel (1 unit) (22 women); 3. PGs without Lamicel (2.5 mg PGE2) (19 women); 4. PGs with Lamicel (1 unit) (20 women).
Outcomes	CS, forceps or vacuum extraction, endometritis.
Notes	Setting: Denmark

Lyndrup 1989 *(Continued)*

	Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported women were randomised by sealed envelope method
Allocation concealment (selection bias)	Low risk	Sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	6 women excluded for protocol violation.
Selective reporting (reporting bias)	Unclear risk	No outcomes were pre specified in method section.
Other bias	Low risk	No other bias detected

Lyndrup 1994

Methods	RCT
Participants	Singleton vertex pregnancy, intact membranes with unfavourable cervix.
Interventions	Foley extra-amniotic 30 mL (59 women) PGE2 2.5 mg pessaries (50 women)
Outcomes	Vaginal delivery not achieved within 24 hours, CS, instrumental delivery, women not satisfied, caregiver not satisfied, pH, AS.
Notes	Setting: Denmark Study:period: June 1990 - March 1993 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Lyndrup 1994 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	No details on the method of generation of the sequence.
Allocation concealment (selection bias)	Low risk	Concealment of allocation by sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT reported, but 4 women were lost to follow-up. Women were excluded if delivered after 48 hours
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Mackeen 2018

Methods	RCT
Participants	Inclusion criteria: women with a live, singleton gestation in cephalic presentation at 34 weeks of gestation or greater with PROM (at least 60 minutes prior to randomisation), an unfavourable cervical examination (less than 2 cm or 80% effaced), and no contraindication to labour. English speaking with a plan for vaginal delivery. Exclusion criteria: active labour and those with suspected intra-amniotic infection, abruption or significant haemorrhage, latex allergy, greater than 1 prior caesarean delivery, any contraindication to vaginal delivery, or human immunodeficiency virus or acquired immunodeficiency syndrome, multifetal gestations, lethal fetal anomalies, intrauterine fetal demise, and category II or III FHR tracings.
Interventions	Oxytocin only (n = 108): start 2 mUh/minute, increase 2 mUh/minute every 30 minute, max 30 mUh/minute Foley catheter + oxytocin (n = 93): 16F, 30 mL, traction applied, max 12 hours, oxytocin concurrent (as above) If not in labour after 24 hours, management per discretion of clinician
Outcomes	Interval from induction to delivery, interval from induction to vaginal delivery, induction to delivery excluding patients with PPROM before 34 weeks of GA, CS rate, rate of vaginal delivery within 12 or 24 hours, indication for CS, infection complications, maternal LOS, 5-minute AS < 5, neonatal infectious evaluation and diagnosis of sepsis, maternal and neonatal length of stay, NICU admission, chorioamnionitis, fetal tachycardia, endomyometritis,
Notes	Setting: multicentre, USA Study period: March 2014 to July 2016 Funding: small internal grants to assist with the conduct and statistical analyses for the entire study.

Mackeen 2018 *(Continued)*

Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated schema in random-sized blocks stratified by multiparity or primiparity, preterm or term gestation, and hospital site.
Allocation concealment (selection bias)	High risk	Not concealed.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Matonhodze 2003

Methods	RCT: Computer-generated random sequence, sealed opaque envelopes.
Participants	Inclusion: completed 34 weeks GA, intact membranes Exclusion: uterine scar, uncontrolled medical complication, non-vertex presentation, multiple pregnancy, fetal distress, APH.
Interventions	Foley catheter + misoprostol (n = 174): 50 mL, traction, max 24 hours, followed by oral misoprostol solution 20 mcg every 2 hours, 40 mcg 2-hourly after 3 doses, until active labour had started. If after established labour contractions became inadequate: augmentation with misoprostol solution 5-20 mcg hourly. If ineffective: oxytocin. Titrated oral misoprostol (n = 176): as described above Dinoprostone vaginal (n = 176). 2 mg in posterior fornix, repeated after 6 hours. If no active labour after 12 hours: oxytocin
Outcomes	Failed vaginal delivery within 24 hours, augmentation, tachysystole, hypersystole, hyperstimulation syndrome, tocolysis, analgesia, meconium, CS, instrumental delivery, maternal side effects, AS < 7, NICU admission, perinatal death, neonatal sepsis.
Notes	It is not clear if all patients had an unfavourable cervix (not mentioned in baseline characteristics. Data reported for different numbers of subjects depending on outcome (selective reporting or missing outcome data?).

Matonhodze 2003 *(Continued)*

	Setting: Pakistan Study period: October 2000 - December 2001 Funding: not reported Declaration of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random sequence,
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque, sealed envelopes out of a dispenser. intact membranes/unfavourable cervix, intact membranes/favourable cervix
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT analysis, data reported for different numbers of subjects depending on outcome. not clear why
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Mazhar 2003

Methods	RCT randomisation: computer-generated random numbers, concealed.
Participants	Inclusion: singleton pregnancy, cephalic presentation, reassuring fetal status, GA 37 completed weeks, BS 6 or lower. Exclusion: placenta praevia, chorioamnionitis, polyhydramnios, parity > 5, SROM, previous CS, contraindication to labour induction.
Interventions	(PGE2) vaginal pessary max 2 x 6 hours (dose not mentioned) followed by ARM and oxytocin infusion (n = 100). Foley catheter 45 mL + EASI for 12 hours followed by ARM and oxytocin infusion (n = 100).
Outcomes	Primary: time from insertion to delivery, mode of delivery. secondary: change is BS after 6 hours, neonatal AS.
Notes	No sample size calculation.

Mazhar 2003 *(Continued)*

	4 patients were excluded (1 left against medical advice, 1 had SROM, 2 failed inductions were induced at later stage). Setting: Pakistan Dates of study: October 2000 to December 2001 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence.
Allocation concealment (selection bias)	Unclear risk	Randomised numbers concealed in the delivery suite?
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of incomplete data, however unlikely due to nature of outcome measures.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported.
Other bias	Low risk	No other bias detected

Meetei 2015

Methods	RCT
Participants	Inclusion: 1 previous low transverse CS, singleton live pregnancy, cephalic presentation, > 28 weeks and BS < 5. Exclusion: previous classical or T-shaped incision, unknown scar, transfundal uterine surgery, medical or obstetric complications that preclude vaginal delivery, placenta previa, low-lying placenta undiagnosed vaginal bleeding, maternal heart disease, rupture of membranes, interval between previous CS and present pregnancy/conception < 6 months, cervico-vaginal infection, unclean vaginal examination, infection in previous CS
Interventions	1. Foley catheter (n = 30): 16F, 30 mL balloon, max 12 hours, thereafter start of oxytocin augmentation 2. Oxytocin (n = 30): 1 mUh/minute, after 1 hour 2/mUh/minute, after 1 hour 4 mUh/minute (max 12 hours). oxytocin augmentation as above

Meetei 2015 *(Continued)*

Outcomes	Change in BS before and after 12 hours of ripening, percentage and time interval of spontaneous labour, insertion and expulsion interval of Foley catheter, route of delivery/outcome of delivery, time required from the beginning of cervical ripening to delivery, hyperstimulation, fetal distress, scar dehiscence, uterine rupture
Notes	Setting: Department of Obstetrics and Gynecology, PGIMER, Chandigarh, India Study period: July 2004 and November 2005, Funding: no funding Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by Tippet's table
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Analysing method not reported and not clear, no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Moini 2003

Methods	RCT: quote: "randomly assigned".
Participants	Singleton gestation, cephalic presentation, GA between 37 and 42 weeks, BS < 6. Exclusion: malpresentation, ruptured membranes, active genial herpes, antepartum bleeding, fetal death, cephalopelvic disproportion, indication for emergency termination of pregnancy, history of infertility or CS, women who had undergone induction before presenting.
Interventions	Dinoprostone intracervical 0.5 mg, oxytocin infusion after 6 hours (n = 35). Foley catheter 30 mL + EASI (n = 35).

Moini 2003 *(Continued)*

Outcomes	Change in BS (after 6 hours), induction-delivery interval, need for oxytocin, mode of delivery, fetal complications, maternal complications.
Notes	No sample size calculation. Setting: Roointan-Arash Maternity Hospital, Iran Dates of study: April 2000 - April 2001 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information about sequence generation process quote: "randomly assigned".
Allocation concealment (selection bias)	Unclear risk	Insufficient information.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not mentioned.
Selective reporting (reporting bias)	Unclear risk	All pre-specified outcomes are reported, it is however unclear what is meant by 'fetal complications', and it is likely that there were more outcomes noted.
Other bias	Low risk	No other bias detected

Mullin 2002

Methods	RCT: randomisation by computerised random number generator, consecutively-numbered sealed envelopes.
Participants	Singleton gestation, cephalic presentation intact membranes, BS 4 or less, < 8 contractions per hour, reactive FHR tracing. EFW > 4500 g or < 1800 g, low-lying placenta, placenta praevia, unexplained vaginal bleeding, active genital herpes, vasa praevia, chorioamnionitis, contraindication for PGs, previous uterine surgical procedure, parity > 5.
Interventions	Foley 30 mL+ EASI (max 12 hours) + IV oxytocin infusion (n = 100). Vaginal misoprostol 25 mcg every 4 hours max 24 hours (n = 100).

Mullin 2002 *(Continued)*

Outcomes	Primary: mean time from start induction to delivery. Secondary: route of delivery, success of induction (vaginal delivery within 24 hours), uterine contraction abnormalities, chorioamnionitis, route of delivery, AS < 7, NICU admission, neonatal resuscitation.
Notes	Power calculation states that 140 patients were necessary, yet 200 were included Setting: Los Angeles County–University of Southern California Medical Center, USA Dates of study: February 1999 to July 2001 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computerised random number generator.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No withdrawals from protocol, no mention of incomplete data.
Selective reporting (reporting bias)	Low risk	All predefined outcomes are reported.
Other bias	Unclear risk	Unclear why 200 patients were included, while 140 were calculated in the power calculation.

Mundle 2017

Methods	RCT
Participants	Inclusion: age ≥ 18 years, ≥ 20 weeks' gestation or later with a live fetus, decision made to induce vaginal birth because of pre-eclampsia or hypertension Exclusion: unable to give informed consent, previous CS, multiple pregnancy, ruptured membranes, chorioamnionitis, allergy to misoprostol.
Interventions	1. Foley catheter (n = 300): 18F, 30 mL balloon, traction applied, max 12 hours, afterward start oxytocin or AROM

Mundle 2017 *(Continued)*

	2. Oral misoprostol (n = 302) 25 mcg, 2-hourly, max of 12 dose (24 hours). In primigravid women the dose could be increased to 50 mcg 2-hourly after the first 2 doses oxytocin administered through gravity infusion set
Outcomes	Vaginal birth within 24 hours, induction to birth interval (vaginal births, CSs, and all births), vaginal births within 12 hours, cervix unchanged at 12 hours and 24 hours, need for oxytocin augmentation, time from randomisation to start of induction and birth, total dose of misoprostol used and the number of participants given a 50 µg dose. Maternal complications, satisfaction, fetal/neonatal complications
Notes	Fetal surveillance with doptone Setting: 2 public hospitals in Nagpur, India Study period: December 2013 to June 2015 Funding: Department for International Development, Medical Research Council, and Wellcome Trust Joint Global Health Trials Scheme. The funder of the study had no role in data collection Declarations of interest: ADW is a scientific adviser to Azanta, a Danish pharmaceutical company, MAT has provided consultancy services to Chiesi, Bristol–Myers Squibb, Novartis, Shire, Janssen, and Grunenthal. both authors received no personal payment,

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated pseudo-random numbers, block randomisation, stratified by centre
Allocation concealment (selection bias)	Low risk	Sequentially-numbered, sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, missing data reported, but small numbers and not in outcomes of interest for this review, no cases missing
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Niromanesh 2003

Methods	Quote:"randomly assigned".
Participants	BS < 5, maternal age 20 to 30 years, gravidity 1 - 3, parity 1 - 2, < 6 contractions per hour, singleton pregnancy.

Niromanesh 2003 *(Continued)*

	Exclusion: history of preterm labour, antepartum bleeding, low-lying placenta, history of caesarean deliveries, active herpes infection, acute poly or oligohydramnios, high blood pressure, IUFD, GA < 40 weeks, chronic condition or contraindication for use of PGs.
Interventions	Foley catheter 30 mL max 8 hours (n = 45). (PGE2) tablet 6-hourly, max 6 doses (n = 44).
Outcomes	Primary: BS (after ripening). Secondary: ripening time, induction time, total time, delivery route, uterine hyperstimulation, adverse side effects, non-reassuring FHR tracing, AS.
Notes	No sample size calculation. 1 patient withdrew due to 'complications'. Time of ripening in Foley group 8 hours, PG group 12 hours Setting: Mirza Kochkhan Hospital, Tehran, Iran. Study period: March 2000 to May 2001 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelope.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No mention of incomplete data, insufficient information to permit judgment.
Selective reporting (reporting bias)	Unclear risk	1 patient was withdrawn due to 'complications', data for this patient not reported, other than this, data reported for all patients on the prespecified outcomes.
Other bias	Low risk	No other bias detected

Noor 2015

Methods	RCT
Participants	Singleton pregnancies, cephalic presentation, > 37 weeks, intact membranes, BS ≤ 4 Exclusion: rupture of the membranes, chorioamnionitis, APH, cervical dilatation > 2.5 cm, temperature > 38 degrees Celsius, contracted pelvis, fetal distress, polyhydramnios, indication for immediate delivery previous CS or other uterine surgeries.
Interventions	1. Vaginal misoprostol (n = 60): 25 mcg, 4-hourly, with a max of 6 doses. no effective uterine contractions after the 6th dose, then it was considered as failure of induction. 2. Foley catheter (n = 44): 18F Foley 50 mL, traction applied, no max time period reported
Outcomes	induction to delivery interval, uterine tachysystole, uterine hypertonus, uterine hyperstimulation (tachysystole + FHR changes), meconium-stained liquor, mode of delivery, maternal and neonatal outcome, AS.
Notes	Setting: Department of Obstetrics and Gynaecology in collaboration with the Department of Paediatrics, JNMCH,AMU, Aligarh (UP), India Study period: May 2013–August 2014. Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Only reported they were randomly assigned, unequal numbers in groups? (60 vs 44)
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not reported, although this is likely as numbers are equal to randomised numbers. no missing data or cases
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Ntsaluba 1997

Methods	RCT
Participants	Singleton vertex presentation with intact membranes, BS < 6, no previous CS.
Interventions	Intracervical PGE2 (0.5 mg) (59 women) Foley catheter with a 30 mL balloon extra-amniotic (53 women)
Outcomes	Change in BS, CS, uterine hyperstimulation, fever, neonatal sepsis, fetal distress.
Notes	Setting: KIng Henry 8th hospital, Durban, South Africa Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No other details on the randomisation process.
Allocation concealment (selection bias)	Low risk	Sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No ITT reported (although it's likely as numbers are equal as randomised numbers), no missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported.
Other bias	Low risk	No other bias detected

Oliveira 2010

Methods	RCT
Participants	Inclusion: singletons in cephalic presentation, GA > 37 weeks, live fetus, BS ≤ 4. Exclusion: ruptured membranes, uterine scar, placenta praevia, chorioamnionitis, EFW > 4000 g, hypersensitivity for products used in intervention
Interventions	1. Foley catheter (n = 80): 14 or 16F, 30 cc, max 48 hours

Oliveira 2010 *(Continued)*

	2. Misoprostol (n = 80) 25 mcg a 6 hours, with a max dose of 200 mcg max 48 hours of induction
Outcomes	Oxytocin use, tachysystole, hypertonus of the uterus, BS > 6, total time until cervical modification, delivery route, FHR abnormalities, meconium stained liquor, AS
Notes	In Portuguese, but translated Setting: Maternidade Escola de Vila Nova Cachoeirinha, public institution which is administrated by the Secretaria Municipal da Saúde de São Paulo, Brazil Study period:January 2006 to January 2008. Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number sequence.
Allocation concealment (selection bias)	Low risk	Sequentially-numbered, sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, no missing data or cases reported
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Unclear risk	Based on translated article

Ophir 1992

Methods	RCT
Participants	Singleton vertex presentation, BS 0-4.
Interventions	PGE2 (6 tablets 0.5 mg) intravaginally (27 women); Foley catheter with a balloon filled with 40 mL water (27 women).
Outcomes	CS
Notes	Setting: Israel

Ophir 1992 *(Continued)*

	Study period: not reported
	Funding: not reported
	Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation sequence from a random numbers table
Allocation concealment (selection bias)	High risk	Allocation by odd and even number
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not reported, 8 women missing in Foley group and 7 in PGE2 group. not clear why.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Orhue 1995

Methods	RCT
Participants	Singleton, vertex, term fetus, adequate pelvis, maternal height > 155 cm, BS < 5. Exclusion if previous uterine scar, placenta praevia or abruptio, age > 35 years.
Interventions	(PGE2) 3 mg every 6 hours, max 3 doses (34 women randomised, 30 women analysed) oxytocin (2 mU/minute, doubled every 30 minutes, max 32 mU/minute) and ARM (30 women) Foley 30 mL (30 women)
Outcomes	CS, instrumental delivery, uterine hyperstimulation, fetal distress, postpartum haemorrhage.
Notes	4 women excluded in PG group were re-included for CS results only. Setting: University of Benin Teaching Hospital, Benin City, Nigeria Study period: April 1990 - October 1991 Funding: not reported Declarations of interest: not reported

Orhue 1995 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation sequence from a table of random numbers
Allocation concealment (selection bias)	Low risk	Concealment of allocation by sequentially numbered, sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not reported, 4 women excluded in PG group were because of unripe cervix after 12 hours
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Peedicayil 1998

Methods	Randomised equivalence trial
Participants	Primigravid, requiring IOL, BS < 5
Interventions	n = 60 'randomised into 2 groups' Foley 12 hours PGE2 intracervically
Outcomes	Change in BS, ripening to delivery interval
Notes	None of our outcomes of interest were reported Setting: tertiary level teaching hospital, India Dates of study: not reported Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Peedicayil 1998 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Not described.
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Person assessing BS was blinded to what agent was used (after 12 hours and removal of agent I presume).
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not reported how many women were randomised to which group, thus unclear.
Selective reporting (reporting bias)	Unclear risk	The methods section states that only BS and ripening to delivery interval were the outcomes of interest, which is questionable.
Other bias	High risk	Retrospective power calculation, unclear how many women in which group.

Pennell 2009

Methods	RCT: generation of sequence unclear, sealed opaque envelopes, patient chose from a selection of 12.
Participants	Inclusion: primipara, GA > 36 weeks, intact membranes, BS < 4.singleton fetus, cephalic presentation, intact membranes. Exclusion criteria were age < 16 years, previous uterine surgery, low-lying placenta, any active or purulent infection of the lower vaginal tract, or an abnormal pre-induction FHR tracing
Interventions	Foley catheter 30cc. (110). Atad catheter 80 cc. (107). PGE 2 gel 2 mg, 6-hourly. (113).
Outcomes	Vaginal delivery within 24 hours, uterine hyperstimulation with/without FHR changes, CS, epidural analgesia, instrumental vaginal delivery, antibiotics during labour, postpartum haemorrhage, maternal fever during labour, pH < 7.10, placental abruption, endometritis, wound infection.
Notes	Data for Foley catheter and double balloon catheter were entered in 1 comparison (any mechanical method versus PG). Setting: King Edward Memorial Hospital (KEMH) in Perth, Western Australia Dates of study: July 2001 to December 2003 Funding sources: supported by a grant from the Women and Infants Research Foundation, King Edward Memorial Hospital, Perth, Australia. Adeza Biomedical Corporation contributed support for the fetal fibronectin test kits. Declarations of interest: none declared

Pennell 2009 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Insufficient information about sequence generation process in the paper.
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes (but why selection of 12??).
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention.
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Research midwives were blinded to treatment allocation, especially important for satisfaction questionnaires.
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, loss to follow-up is described, incomplete data not mentioned.
Selective reporting (reporting bias)	Low risk	All outcomes prespecified in methods were reported, report includes all expected outcomes.
Other bias	Low risk	No other bias detected.

Perry 1998

Methods	RCT.
Participants	Inclusion: singleton gestation, cephalic presentation, BS of ≤ 4. Exclusion: spontaneous uterine contractions, rupture of membranes, placenta previa, unexplained vaginal bleeding, a non-reactive nonstress test, an EFW > 4500 g, a prior vertical uterine incision, parity of > 5, active genital herpes infection, or a contraindication to receiving PGs
Interventions	Vaginal misoprostol 25 mcg every 4 hours (65 women) intracervical Foley of 50cc and PGE2 (4 mg) every 4 hours (62 women)
Outcomes	CS, instrumental delivery, uterine hyperstimulation, AS, NICU admission, chorioamnionitis, perinatal death.
Notes	Setting: University of Mississippi Medical Center Labor and Delivery Unit, Jackson, USA Study period: August 1996 - April 1997 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Perry 1998 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated random schedule.
Allocation concealment (selection bias)	Low risk	The allocation of assignment was concealed by placement in a numbered, opaque, sealed envelope
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not reported, although this is likely as numbers are equal to randomised numbers. No missing cases or data in outcomes of interest
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported
Other bias	Low risk	No other bias detected

Pineda Rivas 2016

Methods	RCT
Participants	Inclusion criteria: obese (BMI > 30 before 20 weeks' GA). Singleton pregnancy. Vertex presentation, BS < 6, Intact membranes,GA 37 + 0 to 42 + 0. Normal fetal heart tracing on admission for ripening Exclusion: IOL for intrauterine fetal demise, Intrauterine growth restriction, Suspected abruption at the start of induction, contraindication for a vaginal delivery
Interventions	Foley catheter (n = 20): PGE2 (n = 21): dinoprostone 10 mg slow release for 24 hours
Outcomes	Time from initiation of IOL to vaginal delivery, number of vaginal deliveries within 24 hours in each group, CS operative vaginal deliveries chorioamnionitis oxytocin administration, epidural, ICU (NICU) admission, arterial pH < 7, AS < 7 at 5 minutes
Notes	Abstract only Setting: Canada Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Pineda Rivas 2016 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	insufficient information to judge
Selective reporting (reporting bias)	Unclear risk	insufficient information to judge
Other bias	Unclear risk	Abstract only

Prager 2008

Methods	RCT, not blinded.
Participants	Term pregnancy, BS 6 or less, different indication for IOL, including PROM Exclusion criteria: previous CS, malpresentation, immediate delivery indicated, contraindication to vaginal delivery, contraindication to PGs.
Interventions	Foley catheter 30 cc (199). Dinoproston 2 mg 6-hourly (191). Misoprostol 25 mcg vaginally 4-hourly (199).
Outcomes	Uterine hyperstimulation, CS, epidural analgesia, instrumental delivery, meconium, AS, NICU admissions, fever during delivery.
Notes	Hyperstimulation is not further specified (with of without FHR changes). Patients who did not meet inclusion criteria were not excluded retrospectively Setting: Karolinska university Hospital, Sweden Dates of study: December 2004 to March 2008 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Prager 2008 *(Continued)*

Random sequence generation (selection bias)	Low risk	Computer-generated sequence.
Allocation concealment (selection bias)	Low risk	Opaque numbered envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Missing data described: 3 dinoprostone and 1 catheter. these were excluded.
Selective reporting (reporting bias)	Low risk	All outcomes prespecified in methods were reported, report includes all expected outcomes.
Other bias	Unclear risk	Patients who did not meet inclusion criteria were not excluded retrospectively (n = 32).

Qamar 2012

Methods	Quasi-experimental
Participants	Inclusion: singleton alive fetus, cephalic presentation, gestation at or beyond 37 weeks, para 4 or less, BS less than 5, obstetric and medical indication for induction Exclusion: congenital anomalies, multiple pregnancies, mal-presentation, CPD, placenta praevia or APH, previous CS, and PROM
Interventions	PGE2 pessary (80) dosage not known, failure of improvement of modified BS after 6 hours (< 5), a second PG E2 gel/pessary was applied and patient reassessed again after 6 hours. If still there was no improvement in BS (< 5) a 3rd PG E2 gel/pessary was applied. PGE2 intracervical (80): as above EASI with oxytocin IV (80) Foleys catheter of 24 or 26 Fr, inflated with 45 mL of distilled water. Traction applied and then saline infusion was started extra-amniotically at 30 mL per hour for 12 hours. oxytocin infusion was started at 2 mU/minute and the dose was doubled at half-hourly interval up to the max dose of 40 mU/minute
Outcomes	induction labour interval, induction delivery interval, mode of delivery, AS at 1 and 5 minutes, and neonatal morbidity and mortality including ICU admission.
Notes	No relevant outcomes reported in article Setting: Pakistan Study period: not reported Funding: not reported

Qamar 2012 *(Continued)*

	Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation in order of admission
Allocation concealment (selection bias)	High risk	Method of induction could be foreseen as a rotation was used
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear if ITT was used, missing cases or outcomes not reported
Selective reporting (reporting bias)	High risk	Neonatal mortality not reported in numbers, only reported they dit not differ. neonatal morbidity not reported in results
Other bias	Low risk	No other bias detected

Ridgway 1991

Methods	RCT. No details were given on the method for generating the allocation sequence or for the concealment of the allocation.
Participants	BS < 5.
Interventions	Intracervical PGE2 (0.5 mg) and Lamicel (52 women); intracervical PGE2 (0.5 mg) alone (49 women).
Outcomes	CS.
Notes	Setting: San Antonio, USA Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Ridgway 1991 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomisation not described
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not mentioned, insufficient information to judge
Selective reporting (reporting bias)	Unclear risk	Insufficient information to judge
Other bias	Unclear risk	Abstract only, insufficient information to judge risk of bias

Roberts 1986

Methods	RCT
Participants	Unfavourable cervix (BS < 5). Women with previous history of uterine surgery, fetal malpresentation or multiple gestation were excluded.
Interventions	4 groups: PGE1 in Tylose gel 3 mg (27 women) (exclude); laminaria tents (28 women); oxytocin 1 mU/minute (25 women); no treatment (24 women exclude). Then oxytocin was given in all groups.
Outcomes	CS.
Notes	Successful IOL and fetal distress not defined. Setting: Jackson, USA Dates of study: not reported Funding: supported by the Vicksburg hospital medical foundation: Declarations of interest: not reported
Risk of bias	

Roberts 1986 *(Continued)*

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomly ordered envelopes, not clear how
Allocation concealment (selection bias)	Low risk	Drawing a sealed envelope by a third party
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not reported, although this is likely as numbers are equal to randomised numbers. no missing cases or data
Selective reporting (reporting bias)	Unclear risk	No outcomes pre specified in method section
Other bias	Low risk	No other bias detected

Rouben 1993

Methods	RCT. Allocation sequence from a table of random numbers. Blocks of 6 women. Concealment of allocation by sequentially-numbered, sealed, opaque envelopes.
Participants	Singleton vertex term pregnancies, intact membranes, BS < 6. Excluded if non-reassuring FHR, placenta praevia.
Interventions	Foley catheter inflated with 30 mL water and extra-amniotic infusion of 1 mL/minute saline during up to 8 hours (56 women); PGE2 vaginal gel 2.85 mg (56 women).
Outcomes	BS change, CS, uterine hyperstimulation, NICU admission, chorioamnionitis, spontaneous labour, failure of induction, endometritis.
Notes	Also reported as abstract (Arias 1993). Setting: St. Louis, USA Dates of study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Rouben 1993 *(Continued)*

Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Low risk	Consecutively-numbered, opaque, sealed envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not reported, women with failed induction excluded from further analysis
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Roudsari 2011

Methods	RCT
Participants	Indication for IOL, GA > 37 weeks, BS < 7, singleton, gestational diabetes mellitus, reassuring FHR tracing, cephalic presentation, intact membranes, low-located placenta (no definition), and mild pre-eclampsia. Excluded hypersensitivity to PG, temp > 38, previous CS delivery or other uterine surgery, placenta previa, chorioamnionitis, vaginal bleeding, fetal distress, macrosomia and polyhydramnios.
Interventions	Low-dose vaginal misoprostol: 25 mcg, repeated up to 6 doses every 4 hours. If no BS > 7 after 24 hours, oxytocin was started Foley catheter (n = 59) 18 F, 50 mL. After 12 hours oxytocin was started.
Outcomes	interval time from the first intervention to the time of delivery. Uterine tachysystole, uterine hyperstimulation
Notes	Setting: Department of Obstetrics, teaching hospitals, Mashhad University of Medical Sciences, Iran Study period: September 2007 to March 2008 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported how

Roudsari 2011 *(Continued)*

Allocation concealment (selection bias)	Unclear risk	Not reported how
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No ITT mentioned, no missing data, 1 woman excluded because of bad participation?
Selective reporting (reporting bias)	Unclear risk	Time to delivery: not clear from when till delivery, most likely from active phase. primary outcome was for first intervention to delivery. other pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Roztocil 1998

Methods	Allocation according to the week of admission. No concealment of allocation.
Participants	Singleton vertex term pregnancies, BS < 5. Excluded if labour, fetal hypoxia, previous CS.
Interventions	Dilapan S 4 units, removed after 14 hours (82 women); PGE2 intracervical gel 0.5 mg, 1 dose (83 women). In both groups, PGE2 vaginal tablets were administered after 14 hours for labour induction.
Outcomes	CS, hyperstimulation with FHR changes, instrumental vaginal delivery, AS < 7, GI side effects, haemorrhage.
Notes	Inadequate method of random allocation and of concealment of allocation. Setting: obstetrics department Brno, Chech Republic Study period: January 1994 to December 1996 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation according to the week of admission.
Allocation concealment (selection bias)	High risk	No concealment of allocation

Roztocil 1998 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not reported, but seems reasonable as numbers are equal to randomised numbers. no missing cases or data
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Rudra 2012

Methods	RCT
Participants	Inclusion criteria: low BS, AROM not possible Exclusion criteria: grande multiparas, preterm induction
Interventions	1. Foley catheter (n = 200), 40 mL, 24 hours 2. PGE2 vaginal; 2 mg
Outcomes	Duration of labour, mode of delivery, postpartum infection and haemorrhage and perinatal, AS
Notes	Abstract only Setting: Batticaloa General Hospital, Sri Lanka Study period: 18 months from 2004 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Double-blind? Not clear how this is possible

Rudra 2012 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Low risk	Double-blind? Not clear how this is possible
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Too little information to judge
Selective reporting (reporting bias)	Unclear risk	Too little information to judge
Other bias	Unclear risk	Abstract only

Saleem 2006

Methods	Patients randomly selected, randomisation method not described.
Participants	Singleton live pregnancy BS 5 or lower, requiring induction between 37 and 42 weeks of gestation.
Interventions	Foley catheter 40-45 mL, after 8-10 hours oxytocin infusion was started (n = 78). Dinoprostone pessary 3 mg 6-hourly max 2 doses, followed by oxytocin infusion (n = 75). Oral misoprostol 50 mcg 4-hourly, max 4 doses, followed by oxytocin infusion (n = 73).
Outcomes	Vaginal delivery rate, Induction to delivery interval < 12 hours, postpartum haemorrhage, tachysystole.
Notes	Methods describe random selection of patients, not randomisation. No neonatal outcomes. Setting: Hamdard University Hospital and Patel Hospital, Pakistan Dates of study: July 2005 - June 2005 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	'Random selection' of patients, insufficient information for judgement.
Allocation concealment (selection bias)	Unclear risk	'Random selection' of patients, insufficient information for judgement.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported

Saleem 2006 *(Continued)*

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	It is unclear how many patients were assessed for randomisation or randomised, therefore it is also unclear if incomplete data were reported. There is no mention of this in the paper.
Selective reporting (reporting bias)	Unclear risk	All outcomes mentioned in the methods section are reported, it is however interesting why they did not report any neonatal data.
Other bias	Unclear risk	No sample size calculated

Salim 2011

Methods	RCT
Participants	Inclusion: viable singleton pregnancy, cephalic presentation, intact membranes, BS of ≤ 6. Exclusion: contraindication for vaginal delivery, previous caesarean delivery, a low-lying placenta, fetal malformations that were incompatible with postpartum life, intrauterine fetal death, clinical amnionitis, carriers of hepatitis B/C, HIV, allergy to latex.
Interventions	1. Foley: (n = 145) 24 F, 60 mL, max 12 hours 2. Double balloon (n = 148), 80/80 mL, max 12 hours
Outcomes	Time from insertion of the catheter to delivery, mode of delivery, vaginal deliveries within 24 hours, abnormal fetal presentation, cord prolapse, intrapartum fever more than 38°C, bleeding related to catheter insertion, AS.
Notes	Setting: Emek medical centre, Afula, Israel. (teaching medical centre) Study period: June 2008 and December 2010 Funding: Department of obstetrics, Emek medical centre Declarations of interest: none reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated numbers, block randomisation
Allocation concealment (selection bias)	Low risk	Sequentially-numbered allocation, stored in a box.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias)	Unclear risk	ITT not reported and not clear if done, no missing data or cases.

Salim 2011 *(Continued)*

All outcomes		
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Sanchez-Ramos 1992

Methods	RCT. Computer-generated allocation sequence. No details on concealment of allocation.
Participants	Singleton vertex term pregnancies, intact membranes, BS < 6. Excluded if non-reassuring FHR, placenta praevia, previous uterine scar, cervicitis.
Interventions	Hygroscopic cervical dilators (as many as possible) (36 women); (PGE2) 4 mg gel applied to the cervical os (n = 38). After 8-12 hours, repeat in both groups if cervix unfavourable. Followed by oxytocin and amniotomy.
Outcomes	CS, instrumental vaginal delivery, haemorrhage, admission to NICU, infection.
Notes	Unclear whether PG was intracervical or intravaginal. Setting: Univerity medical Center of Jacksonville, USA. largely high risk, low income obstetric population Study period: June 1988 to July 1989 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated randomisation list
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not reported and not clear if done, no missing data or cases reported
Selective reporting (reporting bias)	Unclear risk	No outcomes pre specified in method section

Sanchez-Ramos 1992 *(Continued)*

Other bias	Low risk	No other bias detected

Sarreau 2016

Methods	RCT
Participants	Inclusion: indication for IOL, vertex, singleton, > 37 weeks of GA, previous CS (transverse incision), BS < 5, no premature rupture of membranes, singleton in vertex presentation. Exclusion: < 18 years, placenta praevia, cervical infection, malpresentation, latex allergy, induction for CS
Interventions	1. Foley catheter (n = 101): 50 mL, max 12 hours (N = 101) 2. oxytocin (N = 103), low-dose perfusion
Outcomes	Vaginal birth rate, maternal and neonatal complications
Notes	Abstract only (awaiting publication) Setting: France, multicentre Study period: December 2010 tot December 2013 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT, too little information to judge incomplete outcome data
Selective reporting (reporting bias)	Unclear risk	Too little information to judge
Other bias	Unclear risk	Abstract only

Sciscione 1999

Methods	RCT. Computer-generated allocation sequence. Concealment of allocation by opaque, sealed, consecutively-numbered envelopes.
Participants	Singleton vertex pregnancies with intact membranes, BS < 6. Term > 28 weeks. Inclusion of women with previous CS.
Interventions	Intracervical PGE2 (0.5 mg) every 6 hours (72 women). Intracervical Foley catheter inflated with 30 mL (77 women).
Outcomes	Spontaneous onset of labour, nausea, maternal discomfort measured with an analogue scale 0-10, non-reassuring FHR, hyperstimulation, use of epidural, use of oxytocin, shoulder dystocia, vaginal delivery.
Notes	12 women excluded (6 women in PGE2 group because of use of Foley catheter, 2 removed consent, 1 pre-eclampsia, 1 BS of 7 and 2 breech). Setting: Medical centre of Delaware, USA. tertiary referral centre, Study period: July 1995 to July 1996 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random allocation.
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	No ITT, women excluded because of protocol violation. no missing data.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Sharami 2005

Methods	Randomised trial: computer-generated random number table, blocks of 4, sequentially-numbered opaque sealed envelopes.
Participants	Nulliparous women, admitted for induction, between 34 and 42 weeks GA, singleton in cephalic presentation, BS < 4, intact membranes, reassuring FHR tracing, < 6 contractions per hour Exclusion: significant vaginal bleeding, fetal chorioamnionitis, any contraindication to vaginal delivery, previous uterine scar, FHR abnormalities, severe pre-eclampsia, contraindication to PG.
Interventions	Foley 30 mL + EASI + concurrent IV oxytocin for 12 hours (n = 76). PGE2 gel 0.5 mg intracervical 6-hourly, max 3 doses (n = 75).
Outcomes	Interval from start induction to active phase, abnormal FHR tracing, tachysystole, hyperstimulation, meconium passage, caesarean delivery, chorioamnionitis, endometritis, AS < 7, admission NICU Secondary: start induction to delivery, change in dilation at 1, 6, 12 hours, CS for failed induction.
Notes	No sample size calculation. Prophylactic antibiotics after 12 hours of start induction Setting: Prenatal Clinic in Al-Zahra Maternity Hospital, Iran Dates of study: March 2002 - September 2003 Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated sequence.
Allocation concealment (selection bias)	Low risk	Sequentially-numbered opaque sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Good description of excluded patients, quite evenly spread over the groups. There is no information about missing/incomplete outcome data.
Selective reporting (reporting bias)	Low risk	It seems that all outcomes prespecified in methods were reported, report includes all expected outcomes.
Other bias	Low risk	No other bias detected

Shechter-Maor 2015

Methods	RCT
Participants	Inclusion criteria: singleton, GA 37 weeks or more, cephalic presentation, intact membranes, unfavourable cervix (BS =/< 6), oligohydramnios (AFI =/< 5) Exclusion criteria: multifetal gestation, fetal malpresentation, spontaneous labour, contraindication to PGs or a vaginal delivery (e.g. placenta previa), non-reassuring FHR tracing, a fetus with major anomalies or previous CS
Interventions	1. Propess (10 mg slow release PGE), n = 26 2. Double balloon (Cook), n = 26
Outcomes	Time from induction to active labour (defined as cervical dilation of at least 5 cm), induction to delivery time, CS and operative delivery rates, oxytocin augmentation, uterine tachysystole (defined as greater than 5 uterine contractions in 5 minutes), meconium passage, FHR changes, AS and maternal satisfaction
Notes	Setting: Israël Study period: not reported Funding: none received Declarations of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Using computer-generated, random sequences
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not reported, no missing data described. No figure 1, all women analysed
Selective reporting (reporting bias)	High risk	All pre-specified outcomes reported but secondary outcome 'AS'
Other bias	Unclear risk	Not mentioned in method section how long balloon/dinoprostone was given and what happened after ripening process.

Sheikher 2009

Methods	RCT
Participants	Inclusion: 1st or 2nd gravida, single, live fetus, cephalic, indication for IOL, GA 37-42 weeks, BS ≤ 5, absence of uterine contractions. Exclusion: previous uterine surgery, non reassuring FHR tracing, IUGR, oligohydramnios, placenta praevia, multifetal pregnancy, chorioamnionitis, active herpes, EFW > 4 kg, renal or hepatic disease
Interventions	1. Oral misoprostol (n = 30):, 50 mcg, repeated every 4 hours to a max of 5 doses. 2. Vaginal misoprostol (n = 30): 25 mcg, repeated every 4 hours to a max of 5 dosis. n = 30 3. Foley catheter (n = 30): 16 or 18 F, 35 mL. max of 16 hours In all 3 groups after 16 hours oxytocin was started.
Outcomes	interval from induction to birth, mode of delivery, maternal complication, neonatal outcome, failed induction
Notes	Setting: SMGS hospital, Jammu, India Study period: over 1 year Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random assigned, no more information reported
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	No ITT reported, cases missing in table 2, not clear why
Selective reporting (reporting bias)	High risk	No outcome measures were mentioned in the method section, induction to delivery interval is given but no SDs,
Other bias	Low risk	No other bias detected

Solt 2009

Methods	RCT
Participants	100 primiparae and 100 multiparae women with an unfavourable BS
Interventions	Foley catheter:(nulliparae n = 50) Double balloon:(nulliparae n = 45)
Outcomes	Primary outcomes were BS increment, time from catheter withdrawal to delivery, CS rate and post caesarean febrile morbidity.
Notes	Abstract only, numbers only given for nulliparae Setting: Israel Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated numbers
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Reported it was a single-blinded study, not how blinding was performed.
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	20 women excluded from analyses, not clear why
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Unclear risk	Abstract only

Somirathne 2017

Methods	RCT
Participants	Inclusion criteria: not delivered by 40 weeks + 5 days gestation, having uncomplicated pregnancies with a singleton fetus, longitudinal lie and cephalic presentation.

Somirathne 2017 *(Continued)*

	Exclusion criteria were pregnancy-induced hypertension, gestational diabetes mellitus, multiple pregnancies, planned CS, fetal growth restriction and scarred uterus
Interventions	1. Foley catheter, (n = 89), 60 mL, max 24 hours 2. Low dose oral misoprostol (n = 91), 50 mcg, 3 gifts, 4 hourly (N = 91) In both groups, if cervix is unfavourable after 24 hours Foley group PGE2, oral misoprostol group Foley catheter)
Outcomes	The induction delivery interval following IOL, the mode of delivery, the reasons for operative delivery, maternal morbidity, hyperstimulation, uterine rupture, peripartum hysterectomy, postpartum blood transfusion or crystalloid transfusion, IV antibiotics, maternal pyrexia of > 38°C, fetal and neonatal outcome and morbidity, suspicious or pathological CTG according NICE guidelines, meconium-stained liquor, birthweight, 1 minute AS, NICU and reason for admission
Notes	Setting: University Unit of the THMG, Sri Lanka Study period: September 2014 to April 2015. Funding: none Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated numbers, block randomisation,stratified by parity
Allocation concealment (selection bias)	Low risk	Sequentially-numbered, sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	ITT not reported, no missing data or cases. referred to Figure 1, but not available
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

St Onge 1995

Methods	RCT. Computer-generated allocation sequence. Concealment of allocation by sealed envelopes.

St Onge 1995 *(Continued)*

Participants	Singleton vertex term pregnancies with intact membranes, BS < 5. Exclusion of women with previous CS, low-lying placenta.
Interventions	Intracervical PGE2 (0.5 mg) (30 women). Intracervical Foley catheter inflated with 30 mL (36 women).
Outcomes	CS, instrumental delivery, maternal side effects, maternal pyrexia, fetal distress.
Notes	2 women excluded in each group. Also reported as abstract (Lange 1994). Setting: Foothills Hospital in Calgary, Alberta, Canada Study period: October 1991 to November 1993 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated allocation sequence.
Allocation concealment (selection bias)	Low risk	Concealment of allocation by sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	2 women in each group excluded (not meeting inclusion criteria or in labour directly after randomisation). no missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Suffecool 2014

Methods	RCT
Participants	Inclusion criteria: nulliparous, 18 years or older, GA 37 weeks or more, singleton, cephalic presentation, intact membranes, BS < 6, admission for IOL. Exclusion criteria: contraindication for vaginal delivery (placenta praevia, non vertex presentation), ruptured membranes, severe pre-eclampsia, suspected fetal growth restriction with abnormal dopplers, presence of a uterine scar, non reassuring FHR trace requiring medical intervention.

Suffecool 2014 *(Continued)*

Interventions	1. 10 mg dinoprostone vaginal insert (n = 31), max 12 hours, if after 12 hours unfavourable cervix start with oxytocin 2. Double balloon (Cook) (n = 31), 80 mL, oxytocin started 6 hours after placement. Balloon removed after max 12 hours.
Outcomes	Time from insertion of ripening method until delivery, delivery rate < 24 hours, CS rate, time to active labour, rate of operative vaginal delivery, maternal or fetal adverse events
Notes	Setting: USA Study period: February 2011 - September 2012 Funding: not reported Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated numbers
Allocation concealment (selection bias)	Low risk	The allocation assignment was sealed in sequentially-numbered, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, no missing data or cases.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Sullivan 1996

Methods	RCT. Concealment of allocation by opaque, sealed envelopes.
Participants	BS < 6 and indication/no contraindication for IOL.
Interventions	Intracervical PGE2 (0.5 mg) and Foley catheter inflated with 50 mL of water (41 women); intracervical PGE2 (0.5 mg) repeated after 4 to 6 hours if needed (37 women).
Outcomes	CS, uterine hyperstimulation with and without FHR changes, infection.
Notes	Setting: Jackson, USA

Sullivan 1996 *(Continued)*

	Study period: October 1993 - May 1994 Funding: supported by the Vicksburg hospital medical foundation Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not reported
Allocation concealment (selection bias)	Low risk	Concealment of allocation by opaque, sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not reported, but is reasonable as numbers are equal to randomised numbers, no missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcome reported.
Other bias	Low risk	No other bias detected

Tabowei 2003

Methods	Random number table, opaque sealed envelopes.
Participants	Term pregnancy, singleton fetus in cephalic presentation, BS < 4. Exclusion: ruptured membranes, placenta praevia, non-reactive non-stress test, EFW > 4000 g, prior uterine incision, parity > 4, contraindication to PGs.
Interventions	Foley 50 mL max 12 hours (n = 61). Vaginal misoprostol 25 mcg every 4 hours, max 6 doses (n = 60).
Outcomes	Failure to achieve ripening within 12 hours, vaginal delivery within 24 hours, need for oxytocin augmentation, CS rate, tachysystole, hypertonus, meconium, maternal and neonatal complications, AS < 7, NICU admissions, febrile morbidity.
Notes	Prior uterine incision is exclusion criterion, but 18 women with previous CS included. Setting: Zonal general hospital, Nigeria Study period: June 1998 to May 2001 Funding: not reported

Tabowei 2003 *(Continued)*

Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random number table.
Allocation concealment (selection bias)	Low risk	Opaque sealed envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Incomplete outcome data were not mentioned in the report.
Selective reporting (reporting bias)	Low risk	All outcomes prespecified in methods were reported, report includes all expected outcomes.
Other bias	Unclear risk	Prior uterine incision is exclusion criterion, but 18 women with previous CS included, they were evenly divided between the groups.

Tan 2015

Methods	RCT
Participants	Inclusion criteria: pregnant women aged 21 to 40 years old with a singleton pregnancy with no major fetal anomaly who were suitable for vaginal delivery and scheduled for a planned IOL at 37-41 + 6 weeks of gestation. Exclusion criteria: spontaneous labour, had a cervical dilatation of 3 cm or more, confirmed rupture of membrane, had abnormal cardiotocogram, a scarred uterus such as previous CS, malpresentation in labour, or if CS delivery was indicated
Interventions	1. Double balloon (80 mL, balloon started with 40 mL, every following hour 20 mL inserted until 80 mL total), max 12 hours (N = 31) 2. PG 3 mg tablet, repeat once after 6 hours (N = 54) If not in labour or AROM possible after 12 hours, further management by local physician.
Outcomes	Not clearly mentioned in method section
Notes	Setting: tertiary referral maternity unit in Singapore. Study period: not reported Funding: double balloons provided by Cook Medica

Tan 2015 *(Continued)*

	Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Shuffling of 150 envelopes with equal numbers of chance for intervention or control, labelled sequentially
Allocation concealment (selection bias)	Low risk	Sealed envelope, next allocated number of envelope
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	ITT not described, seems per protocol as woman in pain and breech during labour were excluded; no missing data described
Selective reporting (reporting bias)	Unclear risk	No pre specified outcomes reported, so cannot be judged
Other bias	Low risk	No other bias detected

ten Eikelder 2016

Methods	RCT
Participants	Inclusion: singleton, scheduled for labour induction, GA ≥ 37 wk; BS < 6, vertex presentation, intact membranes. Exclusion: placenta previa, previous uterine scar. contraindication to receive or known allergy to latex or PG.
Interventions	1. Foley catheter (n = 921): 30 mL, no traction, replaced after 48 hours, max 4 days 2. Low dose oral misoprostol (n = 924): 50 mg every 4 hours, max 3 times a day, max 4 days
Outcomes	Primary outcome for safety was composite of fluxus postpartum and asphyxia, and for effectiveness CS rate. Secondary outcomes included maternal and neonatal outcomes, total induction time, interval between randomisation and active phase
Notes	Setting: multicentre, 6 tertiary-care and 23 secondary-care hospitals, the Netherlands Study period: July 2012 to October 2013, Funding: FondsNutsOhra, no role in study design, data collection, data analysis, data interpretation, writing of the report or publication Declarations of interest: none declared

ten Eikelder 2016 *(Continued)*

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated numbers, block randomisation, stratified by parity and centre
Allocation concealment (selection bias)	Low risk	Web-based allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT, no missing cases. missing data in primary outcome (pH in umbilical artery). similar reasons for missing data across groups, pre-specified in protocol, anticipated on as followed: data missing for umbilical artery pH and a 5-minute AS of less than 7, the outcome was classified as abnormal; for patients with missing data for umbilical artery pH and a 5-minute AS of 7 or more, the neonatal outcome was classified as normal.
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported in results
Other bias	Low risk	No other bias detected

Thiery 1981

Methods	RCT. Concealment of allocation by envelopes.
Participants	Singleton vertex term pregnancies. Favourable cervix (BS > 5).
Interventions	Foley catheter with a balloon inflated with 30 mL saline and PGE2 0.5 mg extra-amniotic (48 women); PGE2 0.5 mg extra-amniotic (43 women); amniotomy and oxytocin if needed (52 women).
Outcomes	No outcomes reported.
Notes	No relevant outcomes reported. Setting: Belgium Study period: not reported Funding: received free PGE2. not clear if this gift is related to a pharmaceutical company Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Thiery 1981 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Prepared envelopes with numbers
Allocation concealment (selection bias)	Low risk	Concealment of allocation by envelopes.
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	Unclear if ITT was performed, but is reasonable as numbers are equal to randomised numbers), no missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Low risk	No other bias detected

Tita 2006

Methods	RCT
Participants	Inclusion: preterm rupture of membranes, cervix ≤ 2 cm GA ≥ 34 weeks, singleton gestation, cephalic, Exclusion: regular uterine contractions (contractions more frequent than every 5 minutes), 2 prior transverse uterine incisions/vertical uterine incision/transmural myomectomy or any obstetric contraindication to labour, evidence of chorioamnionitis, lethal fetal anomalies, intrauterine fetal demise, placenta previa, suspected abruption/significant haemorrhage, non-reassuring FHR pattern
Interventions	Foley + oxytocin (n = 87) oxytocin only (n = 82)
Outcomes	Reported outcomes: hours from placement of Foley or initiation of oxytocin to delivery, rate of delivery (vaginal or caesarean) within 24 hours caesarean rate, induction to vaginal delivery interval.
Notes	Grey literature: study terminated, primary outcomes reported in trial registration. Setting; USA Study period: December 2005 - May 2008 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement

Tita 2006 *(Continued)*

Random sequence generation (selection bias)	Unclear risk	Randomisation process unclear
Allocation concealment (selection bias)	Unclear risk	Unclear
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Unclear if ITT analyses was used. for CS there are missing cases
Selective reporting (reporting bias)	High risk	Only primary outcomes were reported in trial registration
Other bias	Unclear risk	Study was terminated (not clear why)

Turnquest 1997

Methods	RCT
Participants	Term women with unfavourable cervix (BS < 5), intact membranes.
Interventions	Laminaria (as many as possible) and (PGE2) vaginal gel (4 mg) (21 women); (PGE2) vaginal gel (4 mg) alone (27 women).
Outcomes	Need for oxytocin, CS, uterine hyperstimulation, admission to NICU, chorioamnionitis.
Notes	Setting: memorial hospital Indianapolis, USA Study period: October 1994 to May 1995 Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated allocation sequence.
Allocation concealment (selection bias)	Low risk	Concealment of allocation by consecutively-numbered, opaque, sealed envelopes.
Blinding of participants and personnel (performance bias)	Unclear risk	Not feasible due to nature of intervention

Turnquest 1997 *(Continued)*

All outcomes		
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	4 women excludes because of protocol violation, no missing cases or data
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	No other bias detected

Wang 2012

Methods	RCT
Participants	Inclusion criteria: primiparae, full-term, singleton with cephalic presentation; indication for labour induction; intact membranes; BS < 6; no contra indication for vaginal delivery
Interventions	Foley catheter (n = 138); 16F Foley, 80cc fluid, max 24 hours Propess: (n = 124), 10 mg slow release dinoprostone, fornix posterior, max 24 hours afterwards started with oxytocin. if after 3 days labour did not started, IOL was declared failed
Outcomes	The duration of placement (of Propess or catheter, mode of delivery and time from IOL to delivery; usage of oxytocin, postpartum haemorrhage; meconium-stained amnion fluid, AS, post-delivery temperature monitoring (for a total of 10 days); 42 days after delivery follow-up interview to check for lochia appearance or signs of infection.
Notes	Article in Chinese => translated by native speaker Setting: China Study period; not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Random number table
Allocation concealment (selection bias)	Unclear risk	Not reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention

Wang 2012 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	No ITT, women were excluded for different reasons during the trial (n = 8)
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes reported
Other bias	Unclear risk	Judged from a translated article

Wang 2014

Methods	RCT
Participants	Inclusion: oligohydramnios (AFI < 5 cm). GA beyond 37 0/7 weeks', singleton pregnancy, vertex presentation, BS ≤ 6, intact membranes, the absence of documented uterine contractions, the absence of prior CS delivery, reassuring antenatal fetal testing (non-stress test) active, and oxytocin challenge test negative upon study entry. Exclusion: antepartum bleeding, chorioamnionitis, placenta previa, or any other contraindication to vaginal delivery, women with documented PG allergy, maternal asthma history, vaginitis or cervicitis at presentation, and/or glaucoma history were not eligible for the pharmacological treatment arm
Interventions	Double balloon (n = 67): 80/80cc, no traction, max 12 hours. After 24 hours unsuccessful ripening start oxytocin 10 mg dinoprostone insert (n = 59), fornix posterior, max 24 hours, After 24 hours unsuccessful ripening start oxytocin
Outcomes	Pregnancy outcomes and success of induction
Notes	Setting: The People's Liberation Army 174th Hospital, Xiamen, China, Study period: April 2010 - February 2011 Funding: financial support of The People's Liberation Army Nanjing Military Area Command Medicine Health Department in China. Declarations of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not described how random sequence was generated.
Allocation concealment (selection bias)	Low risk	Sealed envelope randomisation, opaque?
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention

Wang 2014 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	No ITT => 5 woman reassigned after randomisation (non re-assuring FHR, failed placement) no missing data or cases
Selective reporting (reporting bias)	Unclear risk	No pre specified outcomes reported, so can't be judged
Other bias	Low risk	No other bias detected

Wu 2017

Methods	RCT
Participants	Inclusion: 18–40 years old; 37 + 0-41 + 6 gestational weeks; BS ≤ 6; single alive fetus with cephalic presentation; in cephalopelvic proportion; without premature rupture of membrane; NST reaction type before labour induction. The indications of labour induction included delayed pregnancy, oligohydramnios (AFI = 3.0–8.0 cm), gestational diabetes mellitus, intrahepatic cholestasis of pregnancy, good control of gestational hypertension, with vaginal trial production condition and required pregnancy termination. Exclusion: placenta previa, vasa previa and APH; invasive cervical carcinoma; untreated HIV infection; allergic to induction drugs.
Interventions	Double-balloon combined with IV drip of oxytocin (n = 60) AROM after 12 hours. IV drip of oxytocin at a concentration of 0.5% (n = 60); AROM after 12 hours If the patients did not enter the stage of active labour within 48 hours, the labour induction was regarded as failing, and other methods for pregnancy termination were used
Outcomes	Postpartum haemorrhage, cervical laceration, uterine rupture, puerperal infection, neonatal asphyxia, neonatal infection and meconium aspiration syndrome
Notes	Setting: China Study period: January 2014 - June 2015 Funding: grants received from the Nature Science Foundation of China, the Science and Technology Project of Special Funds of Guangzhou, Guangdong Science and Technology Project, the Natural Science Foundation of Guangdong Province and Guangzhou Science and Technology Project Declarations of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Women randomly divided, no information given
Allocation concealment (selection bias)	Unclear risk	No information reported on allocation concealment

Wu 2017 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	ITT not mentioned, but is reasonable as numbers are equal to randomised numbers. no missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcomes were reported
Other bias	Low risk	No other bias detected

Yuen 1996

Methods	RCT
Participants	Singleton vertex presentation, intact membranes, BS < 5, no previous CS.
Interventions	Atad device (100 mL) (36 women); intracervical PGE2 (0.5 mg) (39 women); vaginal pessary 0.5 mg PGE2 (39 women).
Outcomes	Change in BS, vaginal delivery achieved within 12 and 24 hours, CS, instrumental delivery, vaginal bleeding, uterine hyperstimulation, AS.
Notes	5 women were excluded (2, 2 and 1, respectively). Setting: Prince of Wales Hospital, Honkong teaching hospital, China Dates of study: period of 18 months Funding sources: not reported Declarations of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Computer-generated number
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention

Yuen 1996 *(Continued)*

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not reported
Incomplete outcome data (attrition bias) All outcomes	High risk	5 women excluded because of protocol violation, no other missing cases or data
Selective reporting (reporting bias)	Low risk	All pre-specified outcome reported
Other bias	Low risk	No other bias detected

Zahoor 2014

Methods	RCT
Participants	Women requiring IOL for common indications, no previous CS
Interventions	PGE2 tablets (n = 100) dosage of 2 mg, every 6 hours, max of 4 doses transcervical balloon catheter(n = 100) filled with 60 mL of saline.
Outcomes	Induction to delivery interval, mode of delivery, meconium staining, CTG abnormalities, admission in NICU, low AS
Notes	No relevant outcomes were reported in the abstract Setting: Pakistan Study period: not reported Funding: not reported Declarations of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Randomisation not described
Allocation concealment (selection bias)	Unclear risk	No information
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not feasible due to nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No information
Incomplete outcome data (attrition bias)	Unclear risk	ITT not reported, insufficient information.

Zahoor 2014 *(Continued)*
All outcomes

Selective reporting (reporting bias)	Unclear risk	Insufficient information.
Other bias	Unclear risk	Abstract only, too little information to judge risk of bias

AFI: amniotic fluid index
APH: antepartum haemorrhage
ARM/AROM: artificial rupture of membranes
AS: Apgar score
BMI: body mass index
BS: Bishop score
CPD: cephalopelvic disproportion
CS: caesarean section
CTG: Cardiotocography
EASI: extra-amniotic saline infusion
EFW: estimated fetal weight
FHR: fetal heart rate
GA: gestational age
GBS: group B Streptococcus
GI: gastrointestinal
ICU: intensive care unit
IOL: induction of labour
IFD/IUFD intrauterine fetal death
ITT: intention-to-treat
IV: intravenous
LSCS: lower segment caesarian section
max: maximum
Mbs: modified Bishop Score
mcg: microgram
mL: millilitre
mg: milligram
mU: milliunits
NICU: neonatal intensive care unit
NST: non-stress test
PBU: premature baby unit
PCM:
PG: prostaglandin
PGE2: prostaglandin E2
PROM: pre labour rupture of membranes
RCT: randomised controlled trial
SROM: spontaneous rupture of membranes
US: ultrasound

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Abramovici 1999	It is unclear whether all women had Foley catheter (included as 'intention to ripe the cervix' with Foley catheter). Women only received a Foley catheter when they had no dilation at the start of induction (for this study this was the control group), and concurrent oxytocin was started. It is unclear how many women received a Foley catheter.
Adeniji 2005a	Primary outcome fibronectin, other outcomes not mentioned.
Adeniji 2005b	High-dose misoprostol

Study	Reason for exclusion
Adeniji 2006	Outcome cervical scores, other outcomes not mentioned.
Afolabi 2005	Only reports outcomes for the successfully induced, thus not useful.
Ahmad 2015	laminaria vs Foley => not within scope of review
Anabosy 2014	Trial stopped before start patient inclusion because of technical issues
Arsenijevic 2012	No dilatator vs hegar vs continues, controlled, balloon dilator => not within scope of review
Arshad 2016	Laminaria prior to PGE2 vs nothing prior to PGE2 => not within scope of review
Atad 1991	No randomised comparison of mechanical methods. A subgroup of women were randomised to receive PGE2 or placebo.
Atad 1999	Compares 2 mechanical regimens.
Baacke 2006	Trial registration, expected end date expired > 2 years. no information could be obtained (authors were contacted)
Barrilleaux 2002a	High-dose misoprostol
Behrashi 2013	Trial registration with no publication. anticipated end date 2013 => no information could be obtained (authors were contacted)
Ben-Aroya 2001	There is no mention of randomisation in the abstract. Retrospective cohort study.
Buccellato 2000	High-dose misoprostol
Cahill 1988	Alternate randomisation.
Caughey 2007	Balloon high vs low volume => not within scope of review
Chipato 1997	2 regimens of extra-amniotic infusion compared.
Chung 2003	High-dose misoprostol
Connolly 2016	Foley+ oxytocin vs Foley => not within scope of review
Connolly 2017	Foley + oxytocin vs Foley (multiparae) => not within scope of review
Cross 1978	Randomisation based on the last digit of the hospital chart number. 6 women were excluded in the laminaria group, and 1 in the control group. No clinical outcomes were reported.
Cullimore 2009	Trial registration. study terminated after n = 5).no information could be obtained (authors were contacted)
De Oliveira 2003	Foley vs no ripening => not in scope
Delaney 2010	Comparison of 2 mechanical methods.
Demirel 2015	Nipple stimulation, no mechanical method included
Dias 2008	Trial registration, expected end date expired > 2 years. no information could be obtained (authors were contacted)

Study	Reason for exclusion
Du 2015	Not randomised. women could choose induction method
Edwards 2017	Foley + PGE2 vs Foley => not within scope of review
El Sharkwy 2017	Foley + miso vs Foley (and miso after 12 hours) => not within scope of review
El-Khayat 2016	Foley + isorbide mononitrate vs misoprostol => not within scope of review
El-Torkey 1995	Foley + EASI vs Foley => not in scope
Emery 1988	No information.
EUCTR 2012	Trial registration, expected end date expired > 2 years. no information obtained (authors were contacted)
Filshie 1992	Insufficient information.
Forgie 2016	Placement stylette vs no stylette => not within scope of review
Forooshani 2011	Foley vs laminaria => not within scope of review
Fruhman 2017	Tension vs no tension => not within scope of review
Gadel 2015	Cervical ripening in case of stillbirth
Garebedian 2016	Foley vs expectative management
Ghanaei 2009	Foley + oxytocin vs EASI + oxytocin
Ghanaie 2013	Foley +oxytocin vs EASI + oxytocin vs PGE2 + oxytocin => not within scope of review
Gibson 2013	different kind of traction applied => not within scope of review
Gilson 1996	Dilapan vs no treatment => not in scope
Gonsoulin 1989	No clinical outcome reported.
Gower 1982	Laminaria vs placebo => not in scope
Greybush 2001	High-dose misoprostol
Gu 2015	Low- vs high-volume balloon => not within scope of review
Guinn 2004	Compares 2 mechanical regimens.
Haghighi 2015	EASI vs isoniazide => not within scope of review
Hallak 2008	Foley vs Foley + EASI vs ATAD + EASI => not in scope
He 2000	Air vesicle odinopoeia => not within scope of review
Hill 2009	High-dose misoprostol
Hill 2013	Balloon + miso vs balloon + placebo => not within scope of review

Study	Reason for exclusion
Hussein 2012	Induction for fetal demise or early PE (begin third trimester), so no viable fetus
Ifnan 2006	Hydrostatic membrane sweeping vs Foley => not within scope of review
Jagani 1984	An extra-amniotic catheter is used in all groups to record the uterine activity. This catheter uses a 5 mL balloon, which is much lower than the volume used by the other authors (30 mL to 40 mL). Thus, this study is a comparison between oxytocin and PG, with a control group without intervention.
Jasper 2000	No clinical outcome reported (reported as abstract).
Jindal 2007	Methods are interchanged after 24 hours, outcomes are given for the totals.
Jonsson 2011	Digital vs manual placement Foley => not within scope of review
Kamilya 2011	Trial registration, expected end date expired > 2 years. no information could be obtained (authors were contacted)
Karjane 2006	Compares 2 mechanical regimens.
Kasdaglis 2007	The randomisation scheme is unclear and the numbers in both groups are very different (32 and 24).
Kashanian 2006	High-dose misoprostol
Kashanian 2009a	Comparison of 2 mechanical regimens.
Kehl 2012	2 hours cook balloon before vaginal miso vs no balloon before vaginal miso => not within scope of review
Kehl 2015	Balloon before oral misoprostol vs no balloon before oral misoprostol => not within scope of review
Keirse 1983	No clinical outcome reported.
Lackritz 1979	Laminaria vs no treatment => not in scope
Lam 2006	Foley +oxytocin vs EASI + oxytocin => not within scope of review
Leiberman 1977	Alternate inclusion in each group. Imbalance between groups in numbers and prognostic factors.
Leong 2017	Menbrane sweeping vs Foley => not within scope of review
Levine 2016	High-dose misoprostol
Levy 2000	Comparison between early and late amniotomy.
Levy 2004	Comparison between 2 mechanical regimens.
Lin 1995	Laminaria vs EASI => not in scope
Lin 2006	Trial registration only, study terminated.
Lin 2007	Compares 2 mechanical regimens.

Study	Reason for exclusion
Lutgendorf 2012	Traction vs no traction => not within scope of review
Macpherson 1983	No clinical outcomes mentioned.
Mahomed 1988	Foley catheter under traction compared with Foley catheter with extra-amniotic PGE2.
Manabe 1985	No clinical outcomes.
Manish 2016	High- vs low-volume balloon
Manyonda 2007	Balloon vs expectant management => not in scope
Martin 1989	Comparison of induction of labour vs surveillance in post-term pregnancy.
Mattingly 2015	Double balloon 12 hours vs double balloon 24 hours
Mawire 1999	EASI vs PGE f2 alpha => not in scope
McGee 2016	Foley silicone vs Foley latex
Mei-Dan 2009	Comparison of 2 mechanical regimens.
Mei-Dan 2012	Trial terminated before start.
Mei-Dan 2012a	Foley +EASI vs Cook balloon
Mei-Dan 2014	Single balloon + EASI vs double balloon + EASI
Miller 2015	Induction vs expectant management. (choice of induction method was up to clinician.)
Moise 1991	Duplicate information, already included.
Morrison 1993	Insufficient information.
Movahed 2016	Foley vs laminaria vs isorbide mononitrate
Mullin 2014	Direct removal of Foley or not
Naseem 2007	Quasi-experimental, every second patient gets Foley
Nasir 2012	Quasi-experimental
Neethurani 2013	Foley + EASI followed by miso vs miso
Owolabi 2005	High-dose misoprostol
Park 2011	Trial registration, expected end date expired > 2 years. No information could be obtained (authors were contacted)
Pathiraja 2014	Trial registration, anticipated end date (2014) has expired > 2 years. No information could be obtained (authors were contacted)
Pedersen 1981	Comparison of the addition or not of estradiol to Foley catheter.
Pettker 2008	Comparison of 2 mechanical regimens.

Study	Reason for exclusion
Rameez 2007	Nitric oxide vs vitamin C
Reif 2012	Trial registration, anticipated end date (2015) has expired > 2 years. No information could be obtained (authors were contacted)
Rezk 2014	Foley vs isorbide mononitrate
Rust 2001	High-dose misoprostol
Saad 2016	Foley vs laminaria
Saito 1999	Comparison of 2 mechanical regimens.
Salmeen 2012	Outpatient, pre-induction Foley before pharmacological hospital induction
Sanchez-Ramos 1990	Insufficient information.
Sandberg 2017	High vs low volume
Schoen 2017	Foley + oxytocin vs Foley
Schreyer 1989	Allocation of women was performed according to alternate weeks.
Sciscione 2001	High-dose misoprostol
Sharma 2015a	Foley: direct removal or not.
Sharma 2017	Foley vs mifepristone => not in scope
Sherman 2001	Comparison of PGE2 infusion vs saline infusion extra-amniotically. This comparison is not included in this review.
Siddiqui 2013	Placement Foley: stylette vs no stylette
Suri 2000	No clinical outcome reported (reported only as abstract).
Thigpen 2004	Compares a mechanical method with very high dose misoprostol (250 mcg).
Thomas 1986	Randomisation by odd and even numbers of hospital charts
Torbenson 2015	Outpatient Foley vs inpatient miso or Foley. Choice of inpatient method by clinician, so no RCT
Ugwu 2013	Balloon vs misoprostol, crossover after 24 hours
Vengalil 1998	High-dose misoprostol
Walfisch 2014	Foley vs expectative management
Walfisch 2015	Balloon + EASI vs balloon
Welt 1987	Insufficient information.
Wickramasinghe 2014	Foley 24 hours vs Foley 48 hours
Wilkinson 2015	Inpatient vs outpatient double balloon

Study	Reason for exclusion
Yaddehige 2015	Membrane sweeping vs massage => not in scope
Yazdani 2011	Trial registration of which anticipated end date (2008) has expired > 2 years. Trial was registered in retrospect. not clear why there is no publication. no information could be obtained (author contacted)
Zakaria 2017	Different charriere Foley catheter
Zhang 2014	Trial registration, anticipated end date (2015) has expired > 2 years. No information could be obtained (authors contacted)
Zimmer 1996	No outcomes reported. The authors focused on breathing movements of the fetus.

EASI: extra-amniotic space infusion
PG: prostaglandin
PGE2: prostaglandin E2
RCT: randomised controlled trial
vs: versus

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

ACTRN12618000510246 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Agboghoroma 2015

Methods	
Participants	
Interventions	
Outcomes	
Notes	Publication could not be obtained. To try again in next update

Amorosa 2017a

Methods	
Participants	

Amorosa 2017a *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Bauer 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Chai 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Cherian 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

CTRI/2018/01/011574

Methods	
Participants	

CTRI/2018/01/011574 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

de Vaan 2019

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

DeCesare 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Diguisto 2017

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

EUCTR2017-001914-27-GB 2018

Methods	
Participants	

EUCTR2017-001914-27-GB 2018 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

IRCT20170326033142N2 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

IRCT20170513033941N39 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

IRCT20181123041731N1 2019

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Khatib 2019

Methods	
Participants	

Khatib 2019 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Leigh 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Lim 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Mallah 2011

Methods	
Participants	
Interventions	
Outcomes	
Notes	Authors contacted. outcomes reported in Iranian magazine, asked authors for reference

McGee 2018

Methods	
Participants	

McGee 2018 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Mohamad 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03172858 2017

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03399266 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03435458 2018

Methods	
Participants	

NCT03435458 2018 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03588585 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03629548

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03629548 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03670836 2018

Methods	
Participants	

NCT03670836 2018 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03682718 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03744078 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03752073 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

NCT03866772 2019

Methods	
Participants	

NCT03866772 2019 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Oskei 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Osoti 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Saad 2019

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Sanmugam 2018

Methods	
Participants	

Sanmugam 2018 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Souizi 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

ten Eikelder 2017

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Tulek 2018

Methods	
Participants	
Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Viteri 2019

Methods	
Participants	

Viteri 2019 *(Continued)*

Interventions	
Outcomes	
Notes	Found in search update of March 2019 => classification will be done in next update

Characteristics of ongoing studies *[ordered by study ID]*

Argilagos 2016

Trial name or title	Comparison of vaginal misoprostol plus supracervical balloon versus vaginal misoprostol alone for induction of labor
Methods	RCT
Participants	
Interventions	Foley + vaginal misoprostol Vaginal misoprostol
Outcomes	
Starting date	Unknown
Contact information	
Notes	Author contacted: still recruiting

Beckmann 2013

Trial name or title	Prostaglandin Inpatient iNduction of labour Compared with BALLOon Outpatient iNduction of labour: a randomised controlled trial - The PINC BALLOON Study
Methods	RCT
Participants	
Interventions	Foley Vaginal PGE2
Outcomes	
Starting date	Unknown
Contact information	
Notes	Author contacted: recruiting

Bekele 2017

Trial name or title	A randomised controlled trial of sequential versus simultaneous use of Foley balloon and oxytocin for induction of labour in nulliparous pregnant women
Methods	
Participants	Foley + oxytocin Foley
Interventions	
Outcomes	
Starting date	9 August 2017
Contact information	
Notes	Status unknown. author contacted

Berndl 2016

Trial name or title	High volume Foleys increasing vaginal birth (high 5 birth) pilot trial
Methods	
Participants	
Interventions	Balloon Prostaglandin
Outcomes	
Starting date	December 2016
Contact information	
Notes	Recruiting (estimated end date: September 2019)

Bhide 2017

Trial name or title	Prostaglandin insert (propess) versus trans-cervical balloon catheter for out-patient labour induction: a randomised controlled trial of feasibility
Methods	
Participants	
Interventions	Foley Vaginal PGE2
Outcomes	

Bhide 2017 *(Continued)*

Starting date	September 2017
Contact information	
Notes	Recruiting (anticipated end date: August 2018)

Eser 2016

Trial name or title	Compare prostaglandin e2 against to combined transcervical Foley catheter balloon and vaginal prostaglandin e2 for induction of labour at term: a randomised study
Methods	
Participants	
Interventions	Foley + vaginal PGE2 Vaginal PGE2
Outcomes	January 2016
Starting date	
Contact information	
Notes	Recruitment completed in January 2018

Goli 2017

Trial name or title	Comparison the results of induction of vaginal misoprostol with Foley catheter in prolonged pregnancy with unripe cervix
Methods	
Participants	
Interventions	Foley Vaginal misoprostol
Outcomes	
Starting date	March 2017
Contact information	
Notes	Estimated end date: June 2017 => author contacted. status unknown

Goonewardene 2016

Trial name or title	Oral misoprostol for 48 hours versus an intracervical Foley catheter for 48 hours for induction of labour in post dated pregnancies: a randomised control trial
Methods	
Participants	
Interventions	Foley catheter Oral misoprostol
Outcomes	
Starting date	October 2016
Contact information	
Notes	Recruitment completed

Gupta 2016

Trial name or title	A randomised controlled trial of a synthetic osmotic cervical dilator for induction of labour in comparison to dinoprostone vaginal insErt: the SOLVE Trial
Methods	
Participants	
Interventions	Laminaria Vagina PGE2
Outcomes	
Starting date	
Contact information	
Notes	Not yet recruiting

Hassanzadeh 2017

Trial name or title	Misoprostol versus Foley catheter for cervical ripening in women with pre-eclampsia or gestational hypertension
Methods	
Participants	
Interventions	Foley Misoprostol

Hassanzadeh 2017 *(Continued)*

Outcomes	
Starting date	February 2017
Contact information	
Notes	Authors contacted. Still recruiting?

Igwe 2017

Trial name or title	Comparison between intravaginal misoprostol tablet and intracervical Foley's catheter in a low resource setting
Methods	
Participants	
Interventions	Foley Vaginal misoprostol (dosage unclear)
Outcomes	
Starting date	
Contact information	
Notes	Recruitment completed in April 2018

Lacarin 2017

Trial name or title	Comparison between two strategies of induction in case of unfavourable cervix after 12 hours of premature rupture of membranes (prom) at term: cook cervical ripening + oxytocine from 6 hours versus dinoprostone vaginal insert
Methods	
Participants	
Interventions	Foley Vaginal PGE2
Outcomes	
Starting date	October 2017
Contact information	
Notes	Expected end date: July 2020

Lauterbach 2017

Trial name or title	A comparison between labour induction with dinoprostone and a cervical ripening balloon in women with a BMI > 30 as oppose with a BMI < 30
Methods	
Participants	
Interventions	Balloon PGE2
Outcomes	
Starting date	January 2017
Contact information	
Notes	Expected end date: January 2019

Levy 2016

Trial name or title	A randomised controlled study comparing cervical Foley catheter, vaginal dinoprostone and a combination of the two methods for induction of labor
Methods	
Participants	
Interventions	Foley + PGE2 PGE2
Outcomes	
Starting date	February 2016
Contact information	
Notes	Not yet recruiting

Osoti 2016

Trial name or title	A combination of Foley balloon and misoprostol versus misoprostol alone for induction of labour at Kenyatta national hospital, a randomised controlled trial
Methods	
Participants	
Interventions	Foley + misoprostol Misoprostol

Osoti 2016 *(Continued)*

Outcomes	
Starting date	March 2016
Contact information	
Notes	Recruitment completed

Park 2012

Trial name or title	Foley catheter versus dinoprostone vaginal insert for induction of labour in parous women at term: a randomised trial
Methods	
Participants	
Interventions	
Outcomes	
Starting date	May 2012
Contact information	
Notes	Trial status unclear. expected end date 2017 => authors contacted

Perrotin 2016

Trial name or title	Propess® versus double balloon for cervical ripening of prolonged pregnancies: a randomised controlled trial
Methods	
Participants	
Interventions	Double balloon Vaginal PGE2
Outcomes	
Starting date	September 2016
Contact information	
Notes	Expected end date: January 2020

Tagore 2015

Trial name or title	Cervical ripening balloon in induction of labour at term (crbii) - a prospective randomised controlled trial
Methods	
Participants	
Interventions	PGE2 Balloon
Outcomes	
Starting date	December 2015
Contact information	
Notes	Expected end date: March 2018 => recruiting

Viteri 2015

Trial name or title	The efficacy of transcervical Foley balloon plus vaginal misoprostol versus vaginal misoprostol alone for cervical ripening in nulliparous obese women: a randomised, comparative effectiveness trial
Methods	
Participants	
Interventions	Foley + misoprostol Misoprostol
Outcomes	
Starting date	December 2015
Contact information	
Notes	Recruiting

Wise 2016

Trial name or title	Comparison of low-risk pregnant women undergoing induction of labour at term by outpatient balloon or inpatient prostaglandin in order to assess vaginal birth rate; a randomised controlled trial
Methods	
Participants	
Interventions	Balloon

Wise 2016 *(Continued)*

	PGE2
Outcomes	
Starting date	March 2016
Contact information	
Notes	Not yet recruiting

Yildirim 2017

Trial name or title	Dinoprostone vaginal insert versus double balloon catheter for preinduction cervical ripening
Methods	
Participants	
Interventions	Double balloon PGE2
Outcomes	
Starting date	January 2017
Contact information	
Notes	Recruitment completed

BMI: body, mass index
PGE2: prostaglandin E2
RCT: randomised controlled trial

DATA AND ANALYSES

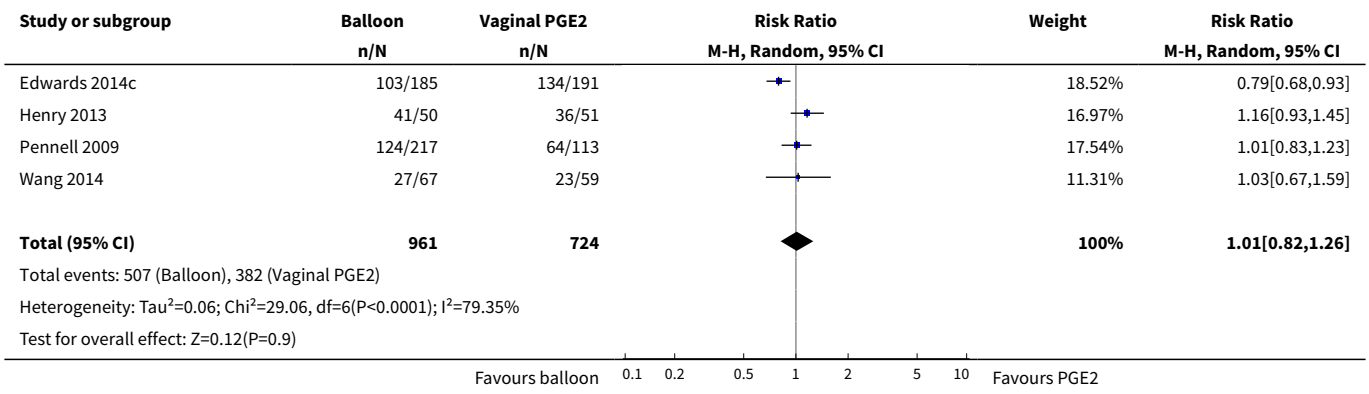
Comparison 1. Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	7	1685	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.82, 1.26]
2 Uterine hyperstimulation with FHR changes	6	1966	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.18, 0.67]
3 Caesarean section	28	6619	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.92, 1.09]
4 Serious neonatal morbidity/perinatal death	8	2757	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.25, 0.93]

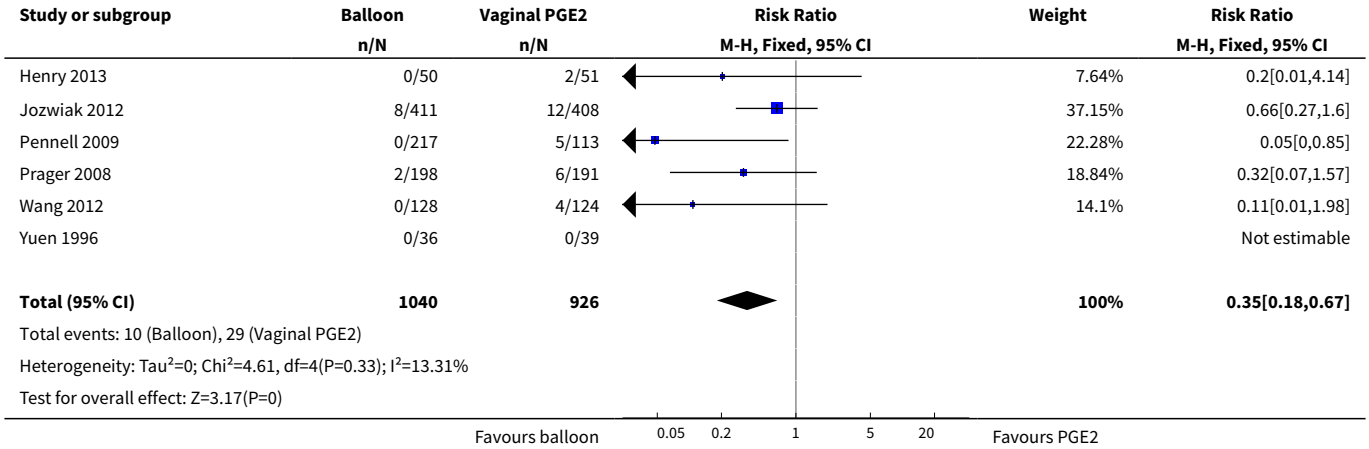
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Serious maternal morbidity or death	4	1481	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.12]
6 Oxytocin augmentation	16	4828	Risk Ratio (M-H, Random, 95% CI)	1.54 [1.35, 1.76]
7 Uterine hyperstimulation without fetal heart rate changes	15	2444	Risk Ratio (M-H, Random, 95% CI)	0.27 [0.11, 0.66]
8 Uterine rupture	2	1045	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.12]
9 Epidural analgesia	8	2828	Risk Ratio (M-H, Random, 95% CI)	1.14 [1.00, 1.29]
10 Instrumental vaginal delivery	16	4514	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.79, 1.09]
11 Meconium-stained liquor	4	964	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.67, 1.19]
12 Apgar score < 7 at 5 minutes	14	4271	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.49, 1.14]
13 Neonatal intensive care unit admission	12	3647	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.65, 1.04]
14 Perinatal death	5	1036	Risk Ratio (M-H, Fixed, 95% CI)	0.21 [0.01, 4.27]
15 Postpartum haemorrhage	8	2215	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.63, 1.06]
16 Women not satisfied	1	93	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.39, 0.97]
17 Maternal fever during labour	7	2362	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.65, 1.17]
18 Antibiotics during labour	1	330	Risk Ratio (M-H, Fixed, 95% CI)	1.43 [0.89, 2.29]
19 Chorioamnionitis	1	376	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.32, 1.49]
20 Endometritis	2	706	Risk Ratio (M-H, Fixed, 95% CI)	0.49 [0.19, 1.27]
21 Fetal distress	20	4753	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.60, 0.83]
22 Umbilical artery pH < 7.10	8	2675	Odds Ratio (M-H, Fixed, 95% CI)	0.65 [0.44, 0.94]

Analysis 1.1. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.

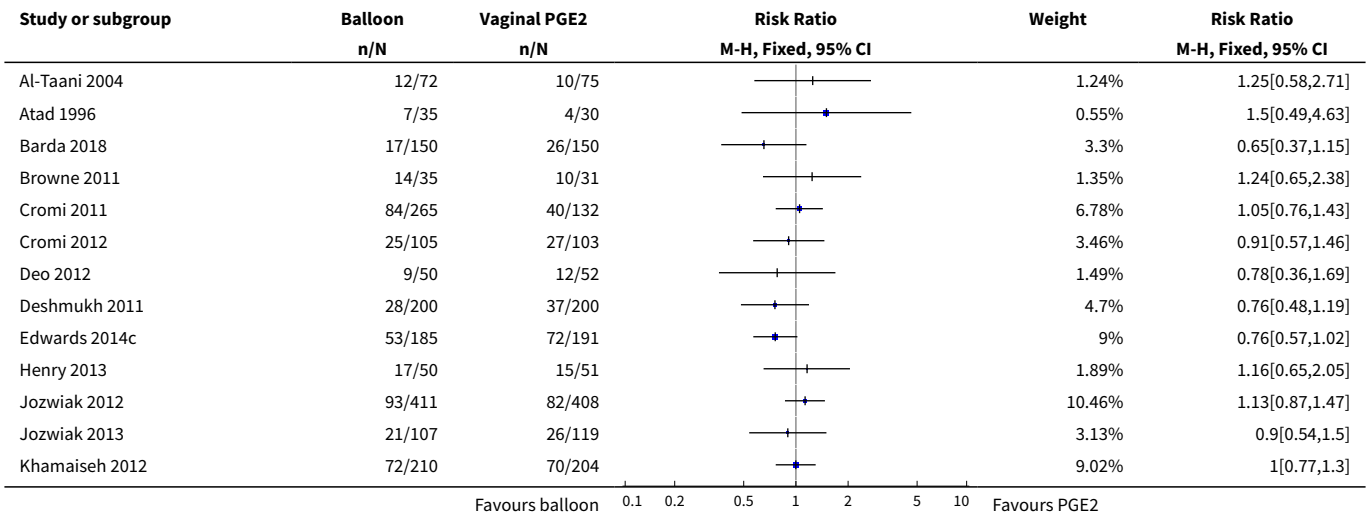
Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Al-Taani 2004	21/72	5/75		4.37%	4.38[1.74,10.98]
Cromi 2011	158/265	68/132		17.67%	1.16[0.95,1.4]
Cromi 2012	33/105	52/103		13.62%	0.62[0.44,0.88]

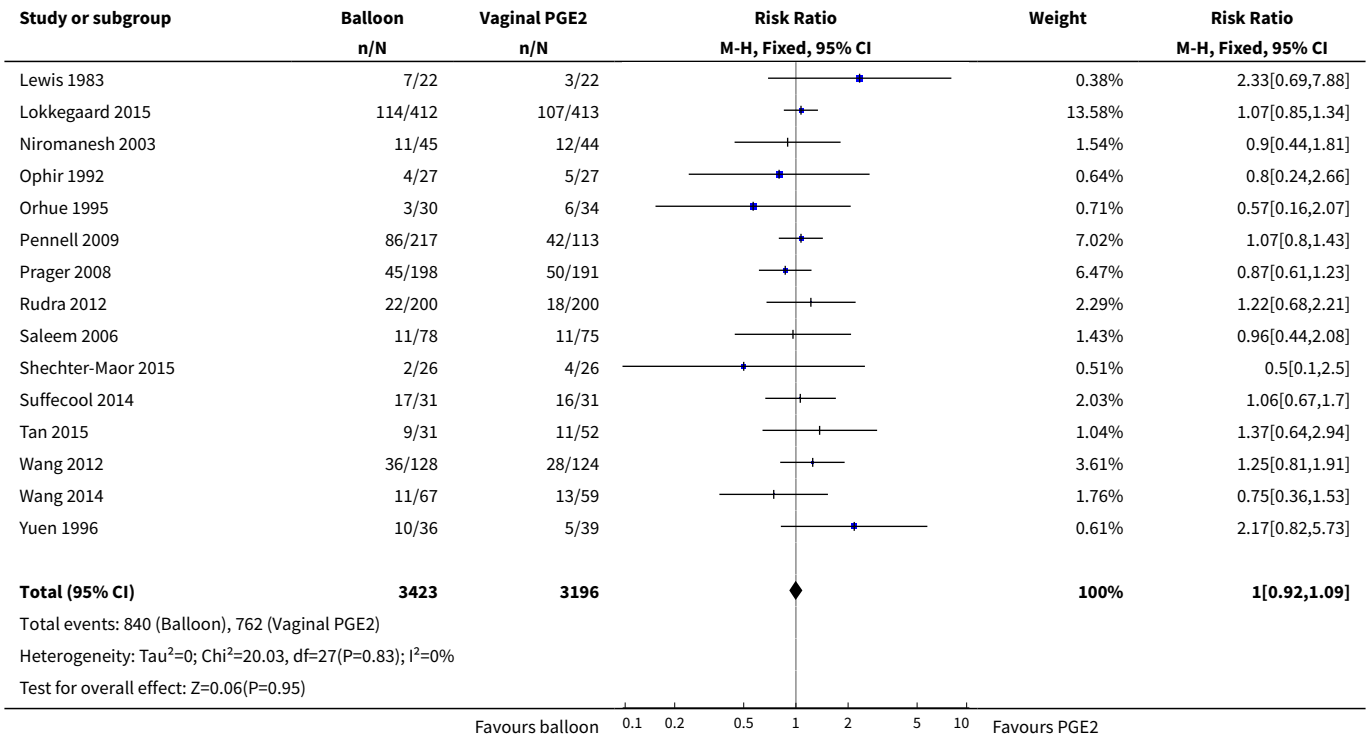


Analysis 1.2. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 2 Uterine hyperstimulation with FHR changes.

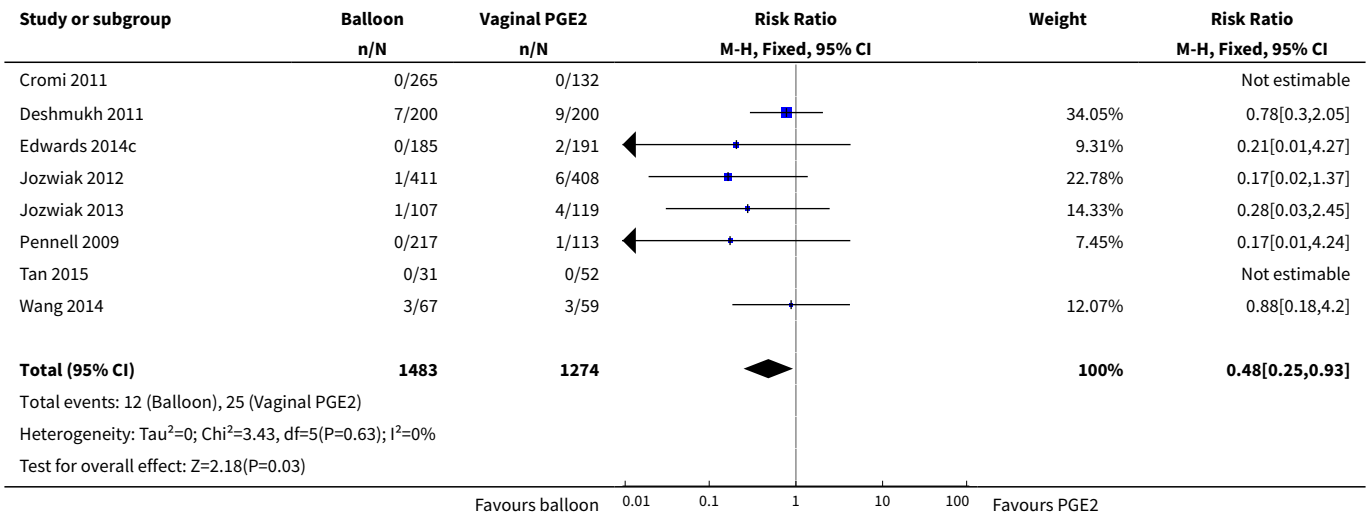


Analysis 1.3. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 3 Caesarean section.



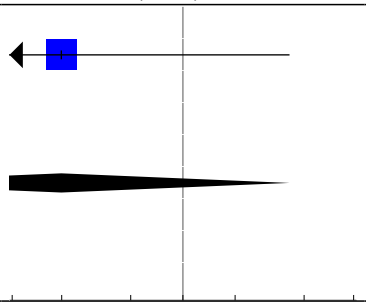


Analysis 1.4. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 4 Serious neonatal morbidity/perinatal death.



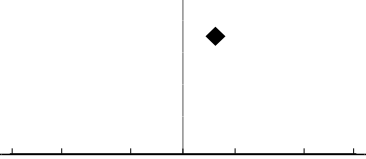
Analysis 1.5. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 5 Serious maternal morbidity or death.

Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Edwards 2014c	0/185	0/191			Not estimable
Jozwiak 2012	0/411	2/408		100%	0.2[0.01,4.12]
Jozwiak 2013	0/107	0/119			Not estimable
Orhue 1995	0/30	0/30			Not estimable
Total (95% CI)	**733**	**748**		**100%**	**0.2[0.01,4.12]**
Total events: 0 (Balloon), 2 (Vaginal PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.04(P=0.3)					



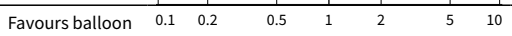
Analysis 1.6. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 6 Oxytocin augmentation.

Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Al-Taani 2004	35/72	15/75		3.59%	2.43[1.46,4.05]
Barda 2018	133/150	82/150		7.26%	1.62[1.39,1.9]
Cromi 2011	216/265	71/132		7.14%	1.52[1.28,1.79]
Cromi 2012	90/105	56/103		6.88%	1.58[1.3,1.91]
Deo 2012	32/50	21/52		4.68%	1.58[1.07,2.34]
Deshmukh 2011	134/200	122/200		7.35%	1.1[0.95,1.27]
Edwards 2014c	171/185	162/191		7.91%	1.09[1.01,1.17]
Henry 2013	44/50	30/51		6.22%	1.5[1.16,1.92]
Jozwiak 2012	353/411	239/408		7.81%	1.47[1.34,1.61]
Jozwiak 2013	83/107	78/119		7.17%	1.18[1,1.4]
Khamaiseh 2012	165/210	134/204		7.58%	1.2[1.06,1.35]
Lokkegaard 2015	329/412	215/413		7.71%	1.53[1.38,1.7]
Shechter-Maor 2015	22/26	14/26		4.67%	1.57[1.06,2.33]
Tan 2015	24/31	26/52		5.31%	1.55[1.11,2.16]
Wang 2012	112/128	26/124		5.13%	4.17[2.95,5.91]
Wang 2014	43/67	13/59		3.59%	2.91[1.75,4.86]
Total (95% CI)	**2469**	**2359**		**100%**	**1.54[1.35,1.76]**
Total events: 1986 (Balloon), 1304 (Vaginal PGE2)					
Heterogeneity: Tau^2=0.05; Chi^2=141.47, df=15(P<0.0001); I^2=89.4%					
Test for overall effect: Z=6.53(P<0.0001)					



Analysis 1.7. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 7 Uterine hyperstimulation without fetal heart rate changes.

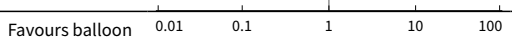
Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Deo 2012	0/50	3/52		6.13%	0.15[0.01,2.8]
Edwards 2014c	0/185	5/191		6.28%	0.09[0.01,1.69]
Jozwiak 2013	2/107	2/119		9.81%	1.11[0.16,7.76]
Khamaiseh 2012	1/210	6/204		9.06%	0.16[0.02,1.33]
Lewis 1983	0/22	0/22			Not estimable
Niromanesh 2003	6/45	3/44		13.09%	1.96[0.52,7.34]
Orhue 1995	1/30	0/30		5.55%	3[0.13,70.83]
Pennell 2009	0/217	11/113		6.47%	0.02[0,0.38]
Saleem 2006	0/78	1/75		5.49%	0.32[0.01,7.75]
Shechter-Maor 2015	0/26	2/26		5.99%	0.2[0.01,3.97]
Suffecool 2014	0/31	8/31		6.5%	0.06[0,0.98]
Tan 2015	0/31	1/52		5.53%	0.55[0.02,13.15]
Wang 2012	0/128	18/124		6.54%	0.03[0,0.43]
Wang 2014	3/67	10/59		13.55%	0.26[0.08,0.91]
Yuen 1996	0/36	0/39			Not estimable
Total (95% CI)	**1263**	**1181**		**100%**	**0.27[0.11,0.66]**
Total events: 13 (Balloon), 70 (Vaginal PGE2)					
Heterogeneity: Tau^2=1.13; Chi^2=22.28, df=12(P=0.03); I^2=46.13%					
Test for overall effect: Z=2.88(P=0)					



Favours balloon — Favours PGE2

Analysis 1.8. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 8 Uterine rupture.

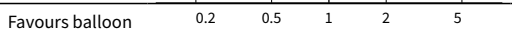
Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Jozwiak 2012	0/411	2/408		100%	0.2[0.01,4.12]
Jozwiak 2013	0/107	0/119			Not estimable
Total (95% CI)	**518**	**527**		**100%**	**0.2[0.01,4.12]**
Total events: 0 (Balloon), 2 (Vaginal PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.04(P=0.3)					



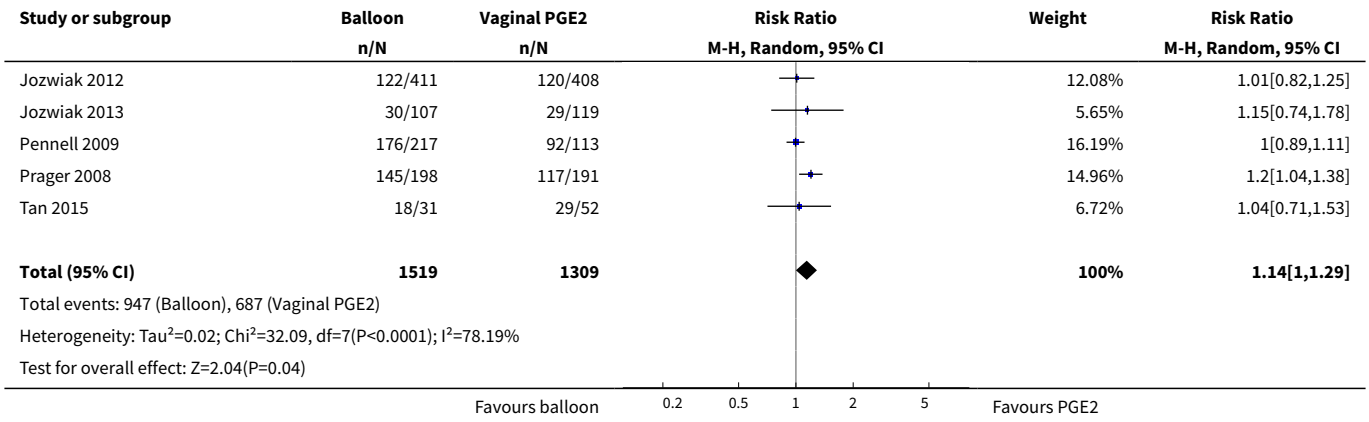
Favours balloon — Favours PGE2

Analysis 1.9. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 9 Epidural analgesia.

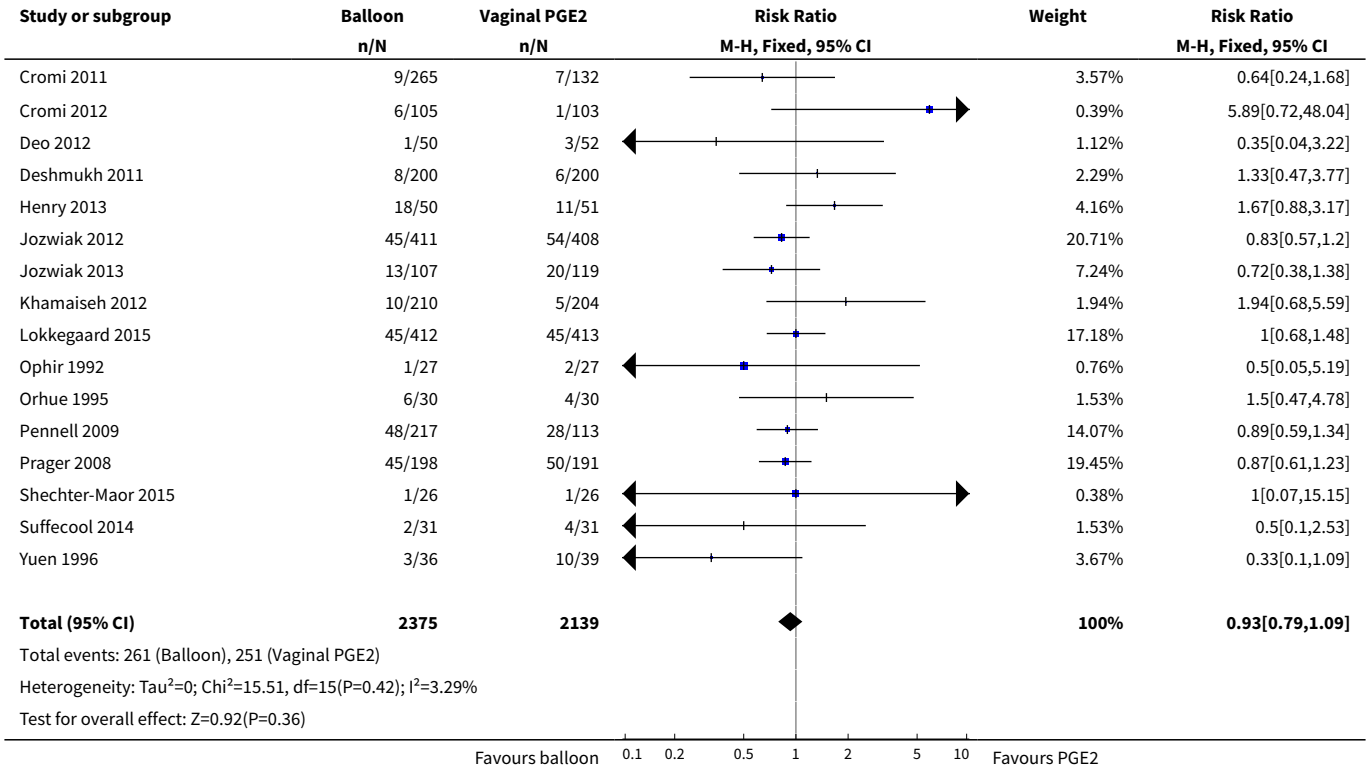
Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Cromi 2011	211/265	71/132		13.79%	1.48[1.25,1.75]
Cromi 2012	87/105	63/103		13.49%	1.35[1.14,1.62]
Edwards 2014c	158/185	166/191		17.13%	0.98[0.91,1.07]



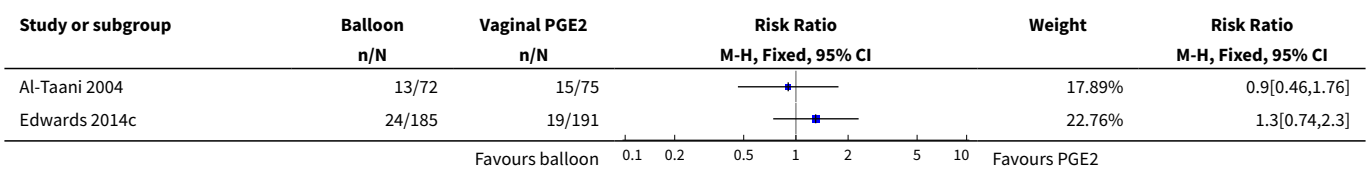
Favours balloon — Favours PGE2

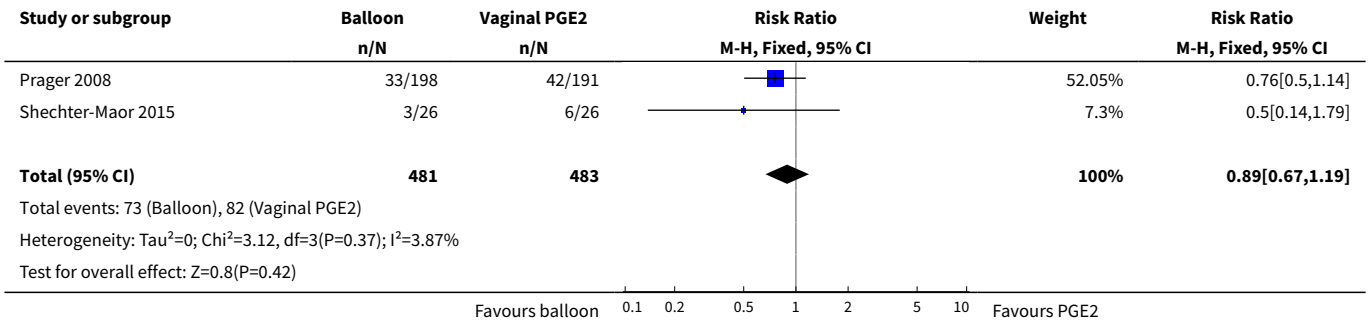


Analysis 1.10. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 10 Instrumental vaginal delivery.

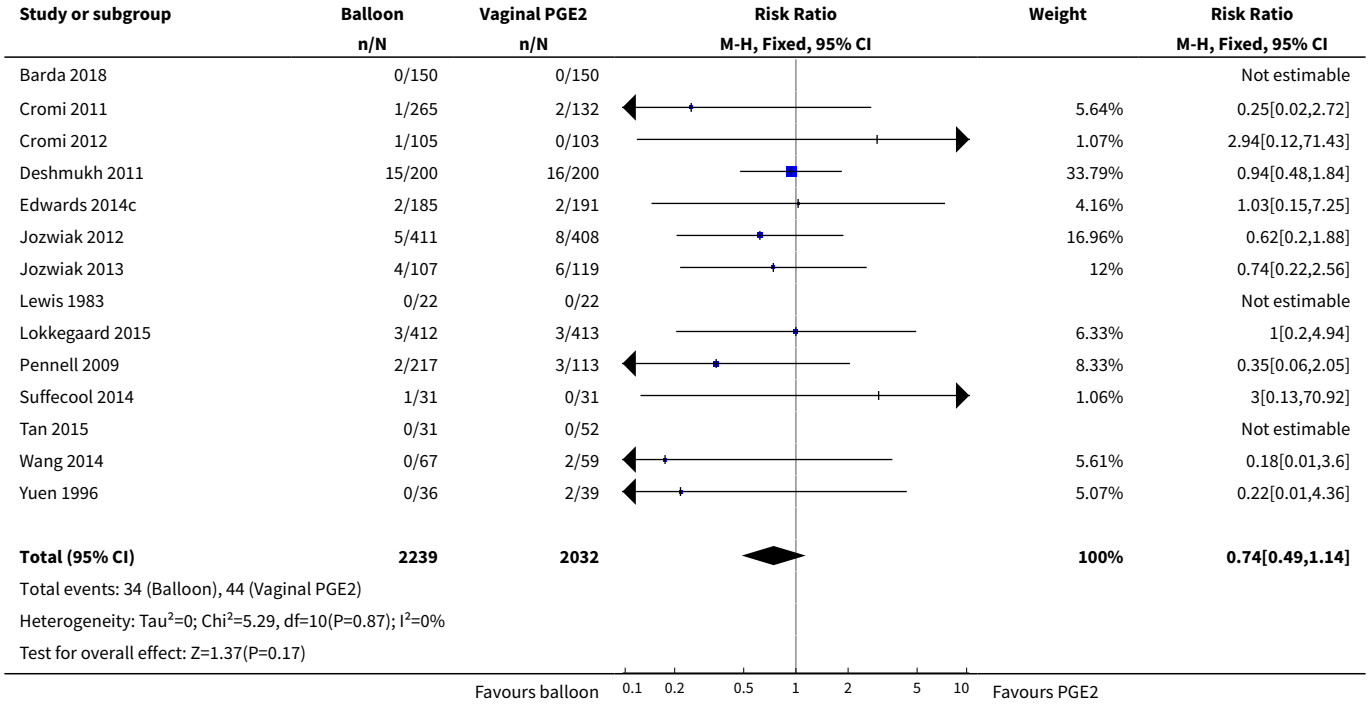


Analysis 1.11. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 11 Meconium-stained liquor.

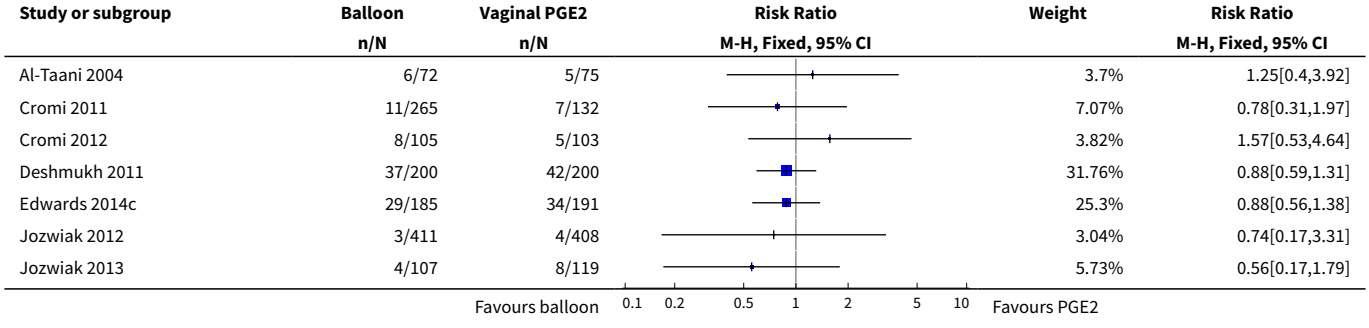


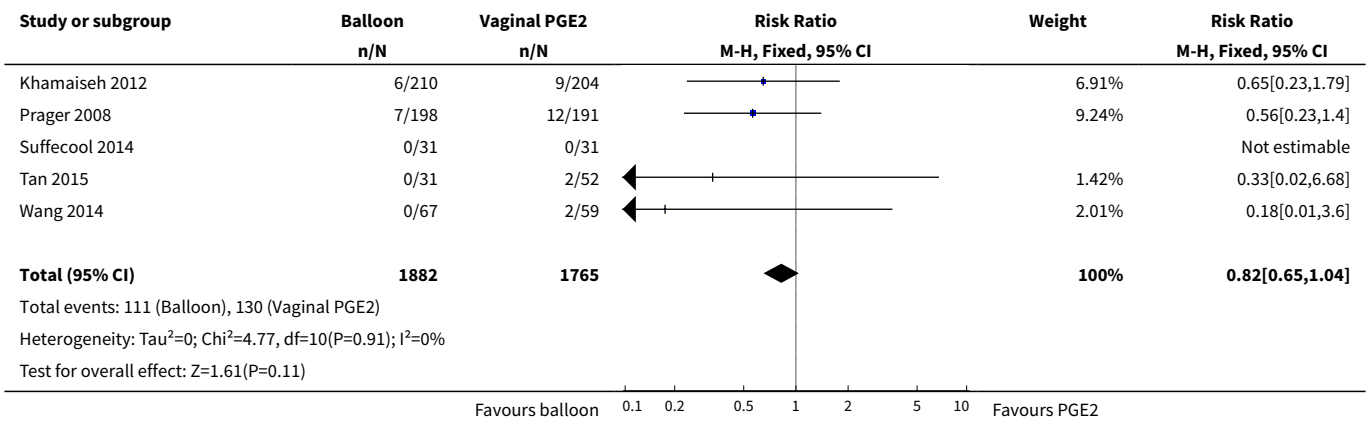


Analysis 1.12. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 12 Apgar score < 7 at 5 minutes.

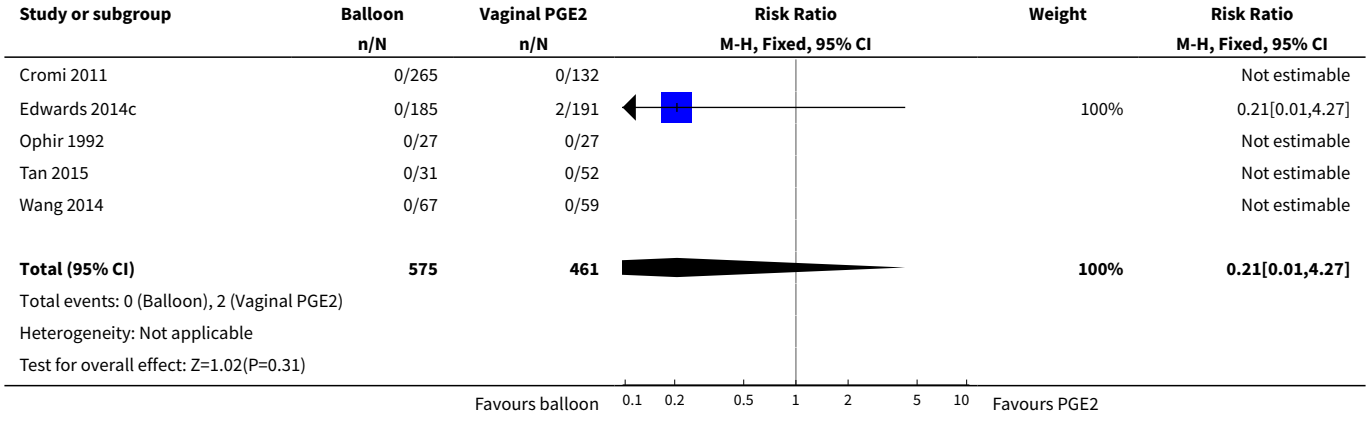


Analysis 1.13. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 13 Neonatal intensive care unit admission.

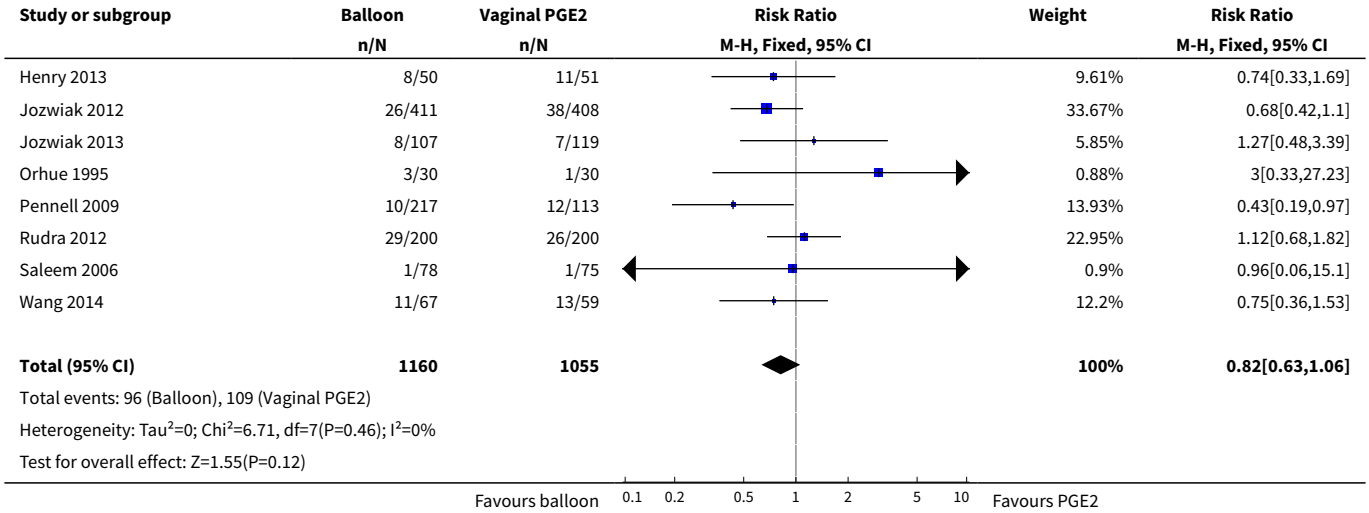




Analysis 1.14. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 14 Perinatal death.

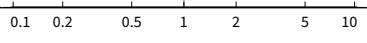


Analysis 1.15. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 15 Postpartum haemorrhage.



Analysis 1.16. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 16 Women not satisfied.

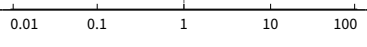
Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Henry 2013	17/48	26/45		100%	0.61[0.39,0.97]
Total (95% CI)	**48**	**45**		**100%**	**0.61[0.39,0.97]**
Total events: 17 (Balloon), 26 (Vaginal PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.1(P=0.04)					



Favours balloon — Favours PGE2

Analysis 1.17. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 17 Maternal fever during labour.

Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Henry 2013	5/50	4/51		4.63%	1.27[0.36,4.48]
Jozwiak 2012	12/411	18/408		21.11%	0.66[0.32,1.36]
Jozwiak 2013	5/107	8/119		8.85%	0.7[0.23,2.06]
Khamaiseh 2012	12/210	14/204		16.6%	0.83[0.39,1.76]
Pennell 2009	37/217	20/113		30.73%	0.96[0.59,1.58]
Prager 2008	13/198	13/191		15.46%	0.96[0.46,2.03]
Tan 2015	2/31	3/52		2.62%	1.12[0.2,6.33]
Total (95% CI)	**1224**	**1138**		**100%**	**0.87[0.65,1.17]**
Total events: 86 (Balloon), 80 (Vaginal PGE2)					
Heterogeneity: Tau^2=0; Chi^2=1.41, df=6(P=0.97); I^2=0%					
Test for overall effect: Z=0.9(P=0.37)					



Favours balloon — Favours PGE2

Analysis 1.18. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 18 Antibiotics during labour.

Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Pennell 2009	52/217	19/113		100%	1.43[0.89,2.29]
Total (95% CI)	**217**	**113**		**100%**	**1.43[0.89,2.29]**
Total events: 52 (Balloon), 19 (Vaginal PGE2)					
Heterogeneity: Tau^2=0; Chi^2=0, df=0(P<0.0001); I^2=100%					
Test for overall effect: Z=1.47(P=0.14)					

Favours balloon — Favours PGE2

Analysis 1.19. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 19 Chorioamnionitis.

Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Edwards 2014c	10/185	15/191		100%	0.69[0.32,1.49]
Total (95% CI)	**185**	**191**		**100%**	**0.69[0.32,1.49]**
Total events: 10 (Balloon), 15 (Vaginal PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.95(P=0.34)					

Favours balloon — Favours PGE2

Analysis 1.20. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 20 Endometritis.

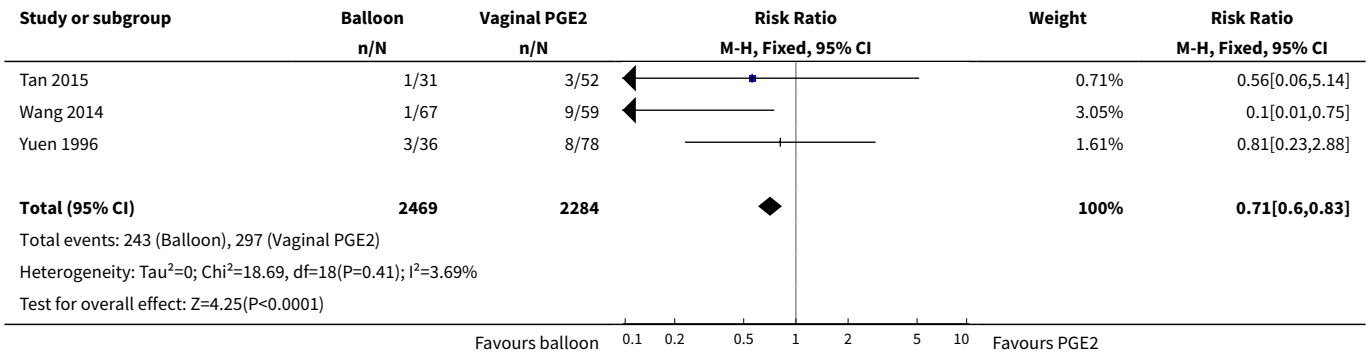
Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Edwards 2014c	4/185	10/191		78.91%	0.41[0.13,1.29]
Pennell 2009	3/217	2/113		21.09%	0.78[0.13,4.61]
Total (95% CI)	**402**	**304**		**100%**	**0.49[0.19,1.27]**
Total events: 7 (Balloon), 12 (Vaginal PGE2)					
Heterogeneity: Tau^2=0; Chi^2=0.35, df=1(P=0.55); I^2=0%					
Test for overall effect: Z=1.47(P=0.14)					

Favours balloon — Favours PGE2

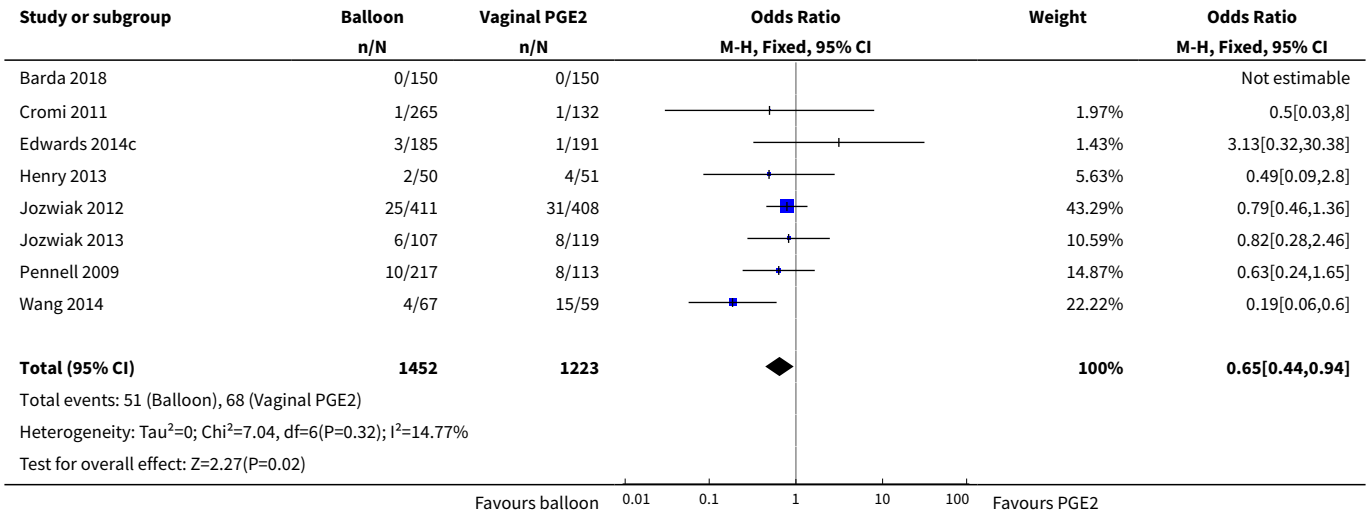
Analysis 1.21. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 21 Fetal distress.

Study or subgroup	Balloon n/N	Vaginal PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Barda 2018	5/150	8/150		2.55%	0.63[0.21,1.87]
Cromi 2011	40/265	37/132		15.73%	0.54[0.36,0.8]
Cromi 2012	11/105	16/103		5.14%	0.67[0.33,1.38]
Deshmukh 2011	17/200	21/200		6.69%	0.81[0.44,1.49]
Edwards 2014c	22/185	24/191		7.52%	0.95[0.55,1.63]
Henry 2013	8/50	5/51		1.58%	1.63[0.57,4.65]
Jozwiak 2012	28/411	38/408		12.14%	0.73[0.46,1.17]
Jozwiak 2013	11/107	12/119		3.62%	1.02[0.47,2.21]
Khamaiseh 2012	32/210	42/204		13.57%	0.74[0.49,1.12]
Niromanesh 2003	7/45	5/44		1.61%	1.37[0.47,3.99]
Ophir 1992	0/27	1/27		0.48%	0.33[0.01,7.84]
Orhue 1995	0/30	0/30			Not estimable
Pennell 2009	29/217	20/113		8.37%	0.76[0.45,1.27]
Prager 2008	17/198	30/191		9.72%	0.55[0.31,0.96]
Saleem 2006	3/78	4/75		1.3%	0.72[0.17,3.11]
Shechter-Maor 2015	0/26	9/26		3.02%	0.05[0,0.86]
Suffecool 2014	8/31	5/31		1.59%	1.6[0.59,4.35]

Favours balloon — Favours PGE2



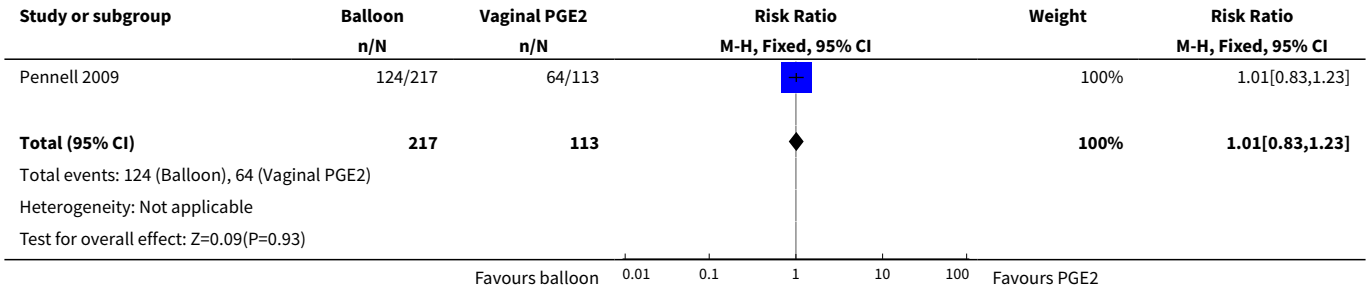
Analysis 1.22. Comparison 1 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all women, Outcome 22 Umbilical artery pH < 7.10.



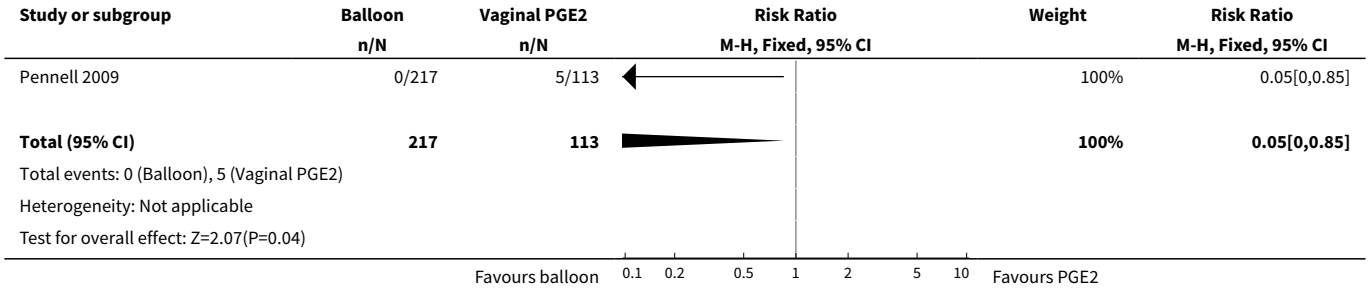
Comparison 2. Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	330	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.83, 1.23]
2 Uterine hyperstimulation with FHR changes	1	330	Risk Ratio (M-H, Fixed, 95% CI)	0.05 [0.00, 0.85]
3 Caesarean section	5	828	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.59, 1.33]
4 Serious neonatal morbidity/perinatal death	1	330	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.01, 4.24]
5 Serious maternal morbidity or death	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

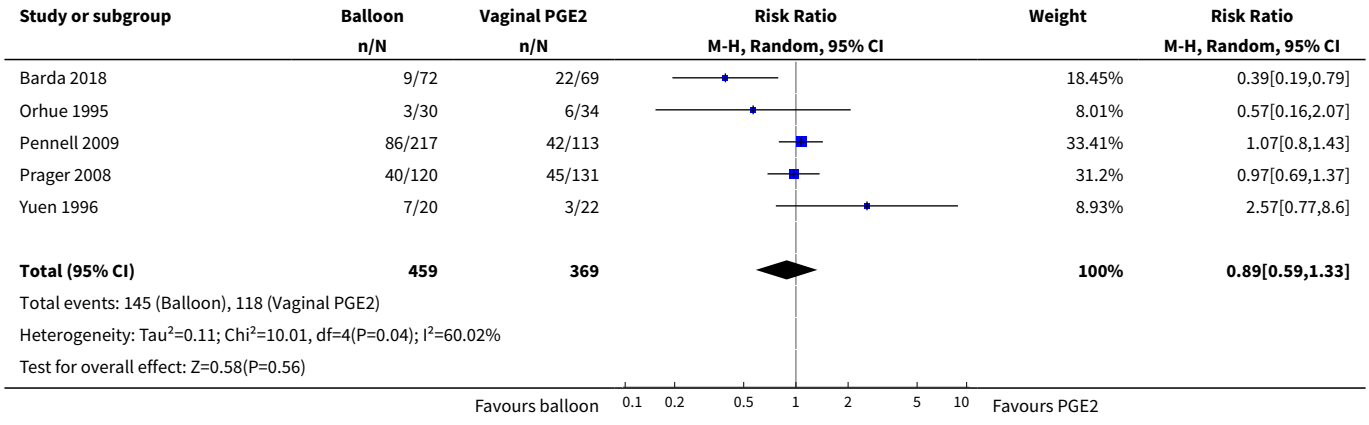
Analysis 2.1. Comparison 2 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all primiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



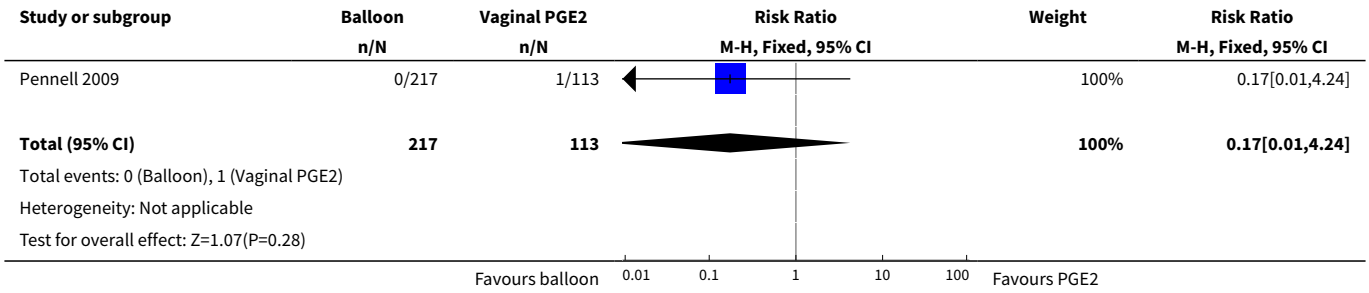
Analysis 2.2. Comparison 2 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all primiparae, Outcome 2 Uterine hyperstimulation with FHR changes.



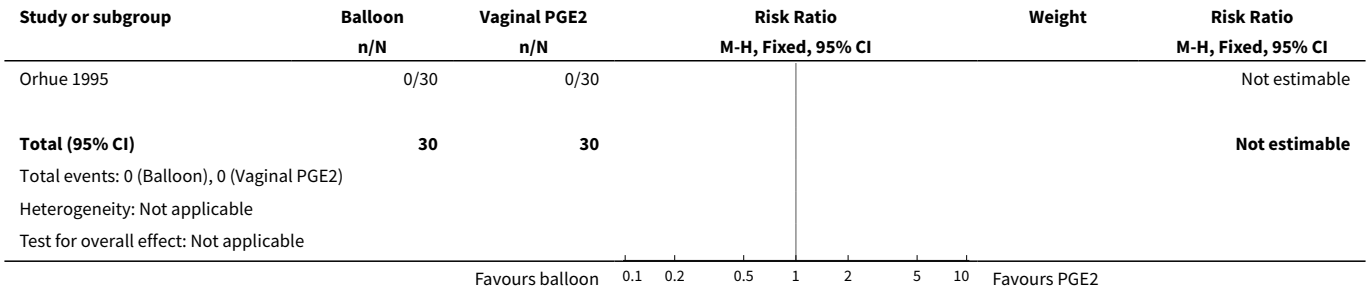
Analysis 2.3. Comparison 2 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all primiparae, Outcome 3 Caesarean section.



Analysis 2.4. Comparison 2 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all primiparae, Outcome 4 Serious neonatal morbidity/perinatal death.



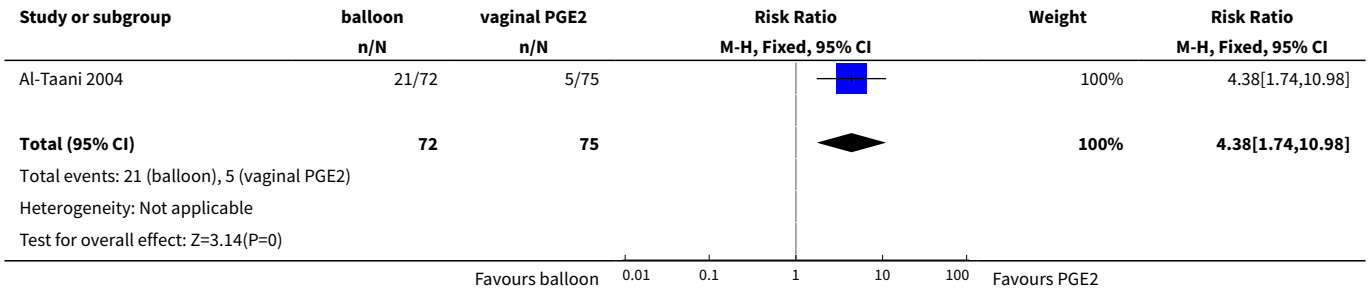
Analysis 2.5. Comparison 2 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all primiparae, Outcome 5 Serious maternal morbidity or death.



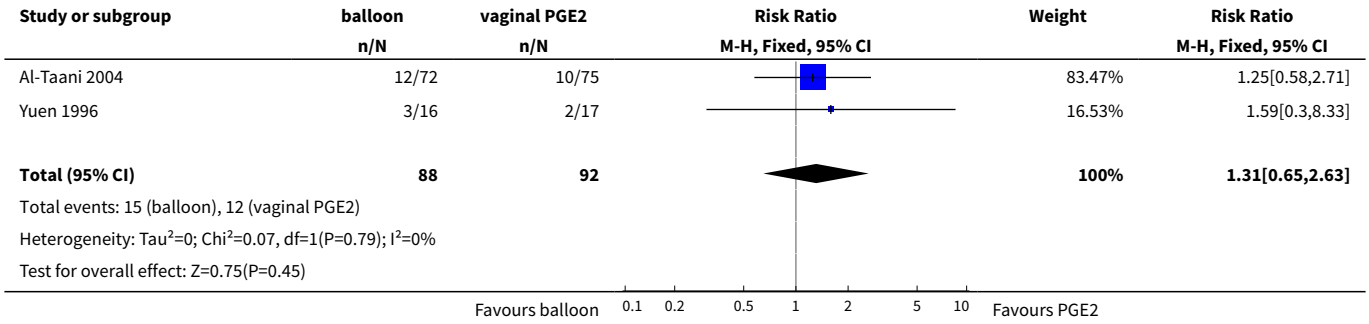
Comparison 3. Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all multiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	147	Risk Ratio (M-H, Fixed, 95% CI)	4.38 [1.74, 10.98]
2 Caesarean section	2	180	Risk Ratio (M-H, Fixed, 95% CI)	1.31 [0.65, 2.63]

Analysis 3.1. Comparison 3 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all multiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



Analysis 3.2. Comparison 3 Balloon (Foley or ATAD) versus vaginal prostaglandin E2: all multiparae, Outcome 2 Caesarean section.

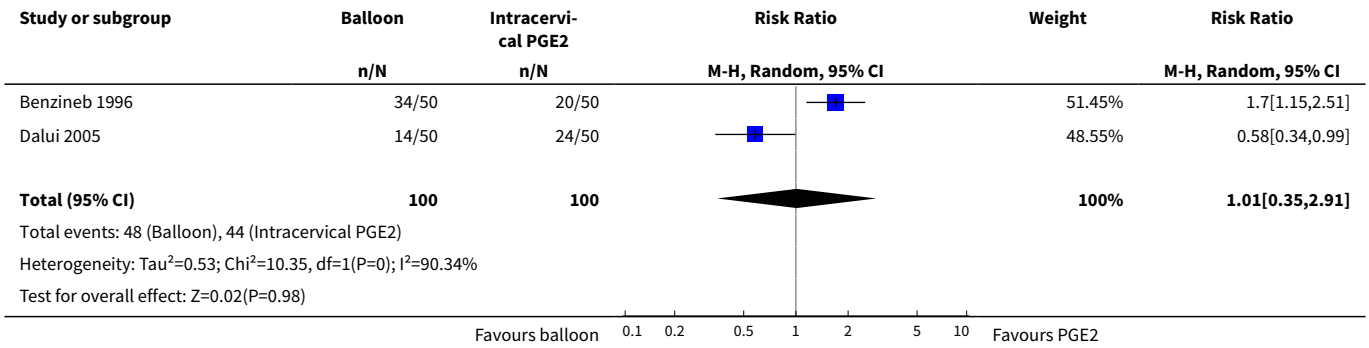


Comparison 4. Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women

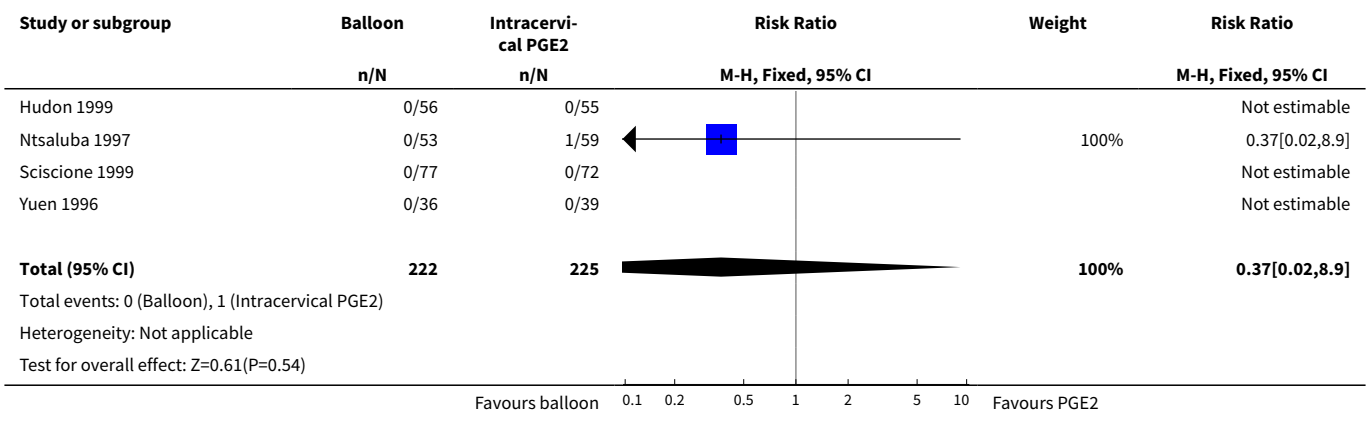
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	2	200	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.35, 2.91]
2 Uterine hyperstimulation with FHR changes	4	447	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.02, 8.90]
3 Caesarean section	9	1309	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.81, 1.15]
4 Serious neonatal morbidity/perinatal death	2	500	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.29, 2.05]
5 Cervix unfavourable/unchanged after 24 hours	2	219	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.70, 1.34]
6 Oxytocin augmentation	1	400	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.93, 1.26]
7 Uterine hyperstimulation without FHR changes	5	654	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.09, 10.38]
8 Epidural analgesia	1	149	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.81, 1.02]
9 Instrumental vaginal delivery	3	337	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.68, 2.05]
10 Meconium-stained liquor	1	118	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [0.42, 3.26]
11 Apgar score < 7 at 5 minutes	2	475	Risk Ratio (M-H, Fixed, 95% CI)	0.79 [0.41, 1.53]
12 Neonatal intensive care unit admission	1	400	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.60, 1.31]
13 Perinatal death	2	500	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.29, 2.05]
14 Maternal side effects	2	211	Risk Ratio (M-H, Fixed, 95% CI)	0.15 [0.02, 1.24]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15 Postpartum haemorrhage	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.2 [0.01, 4.06]
16 Chorioamnionitis	1	118	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.21, 4.75]
17 Endometritis	1	118	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.06, 15.61]
18 Fetal distress	6	1023	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.42, 0.89]

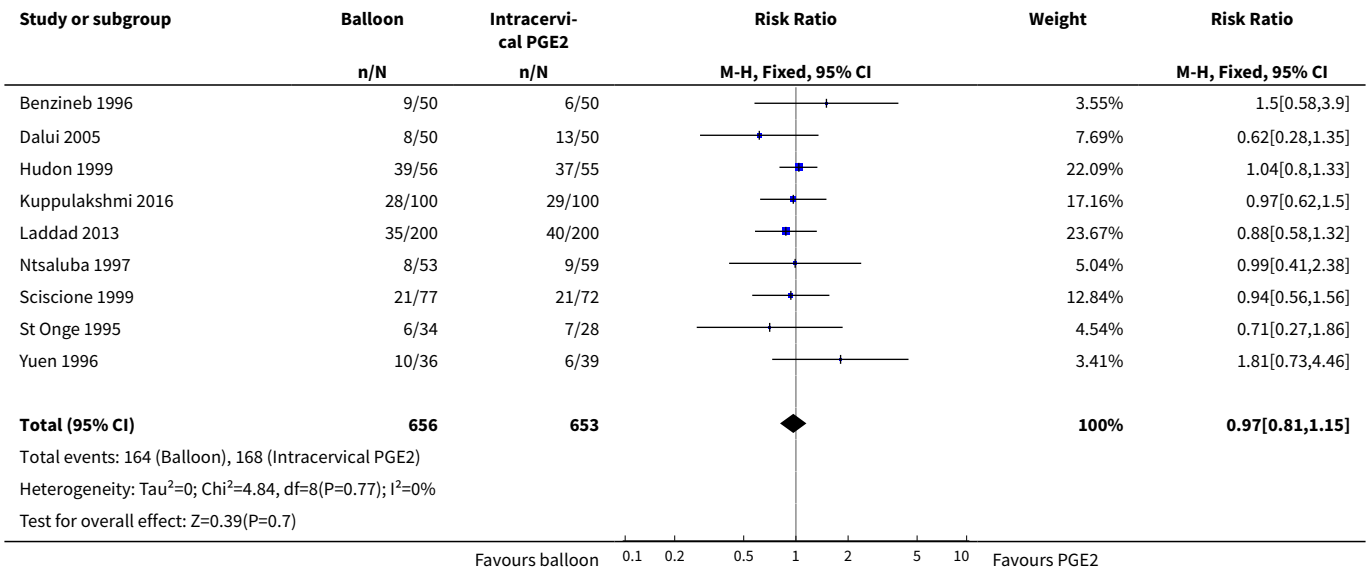
Analysis 4.1. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.



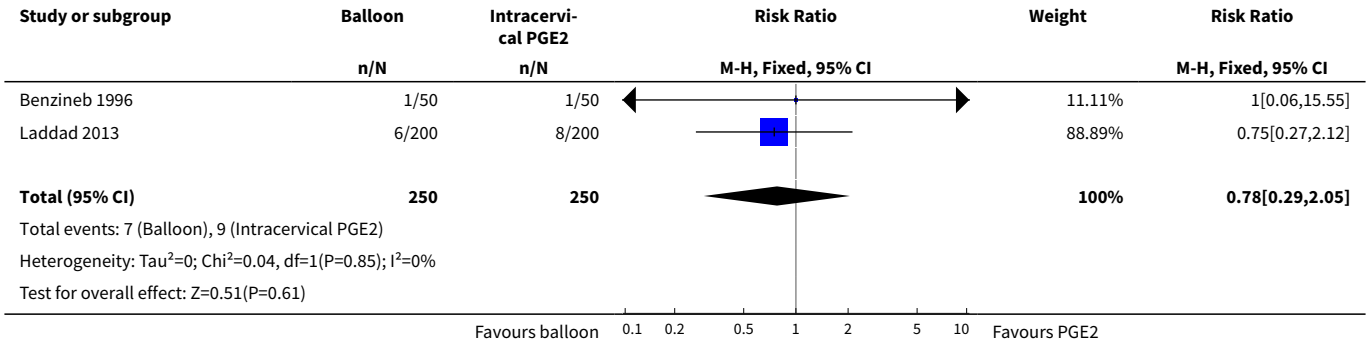
Analysis 4.2. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 2 Uterine hyperstimulation with FHR changes.



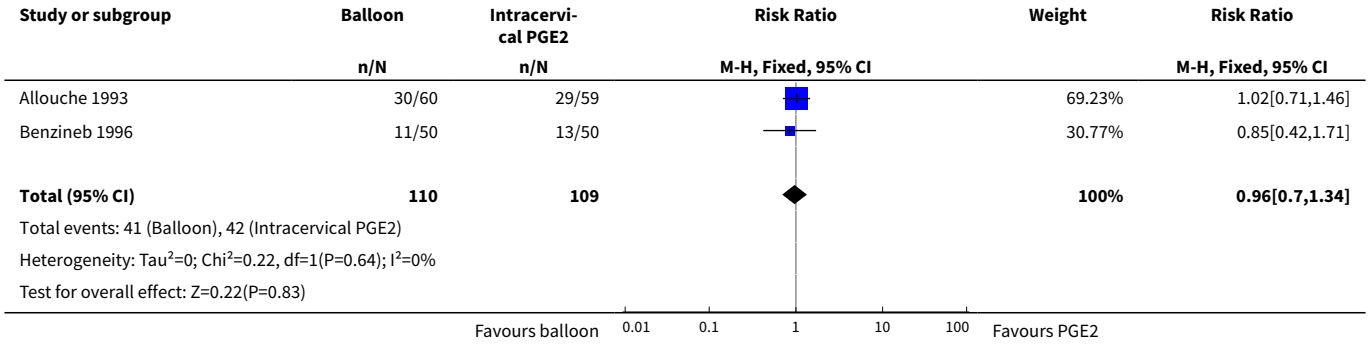
Analysis 4.3. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 3 Caesarean section.



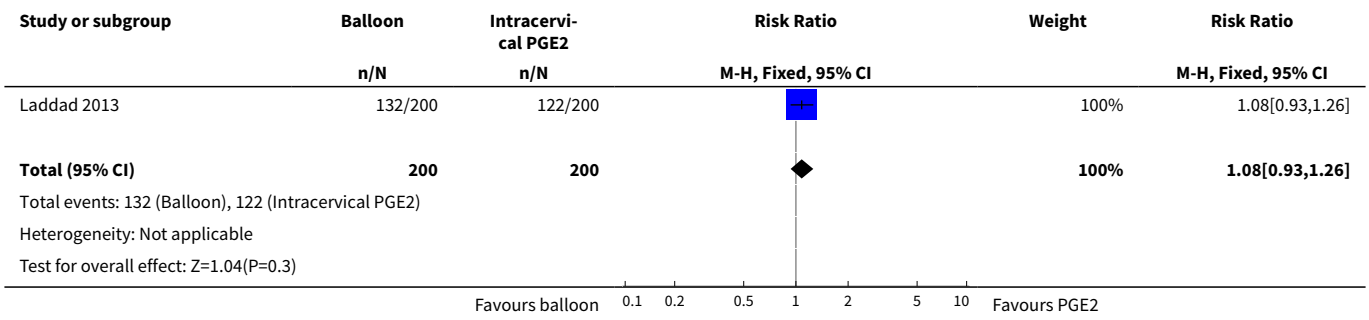
Analysis 4.4. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 4 Serious neonatal morbidity/perinatal death.



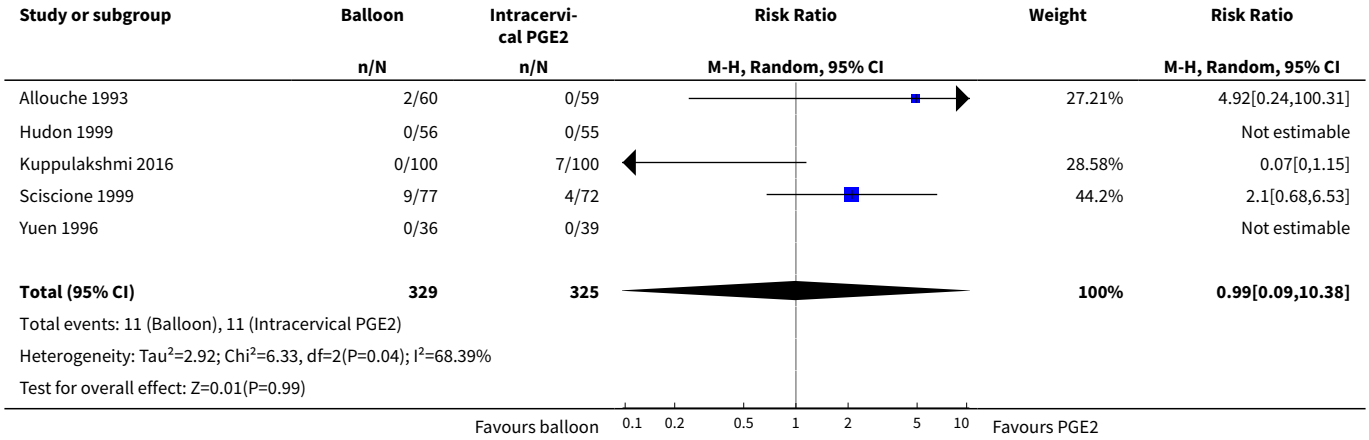
Analysis 4.5. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 5 Cervix unfavourable/unchanged after 24 hours.



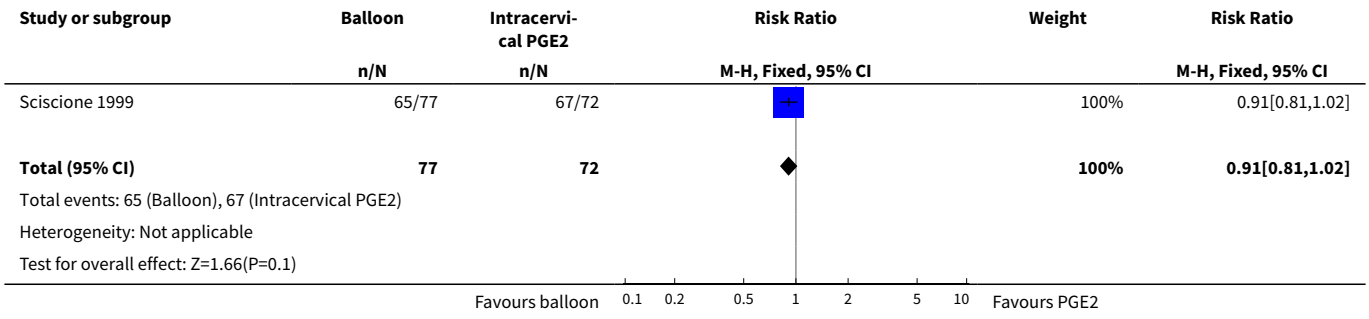
Analysis 4.6. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 6 Oxytocin augmentation.



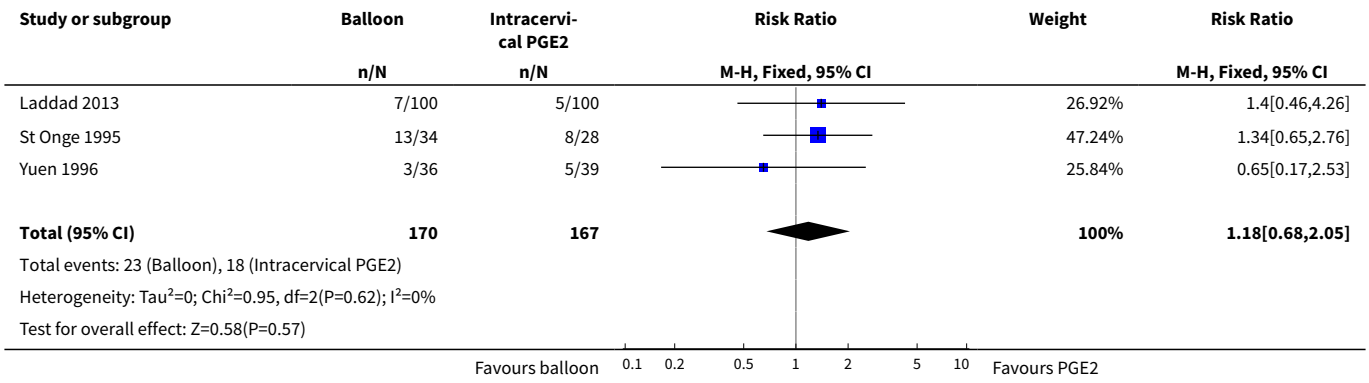
Analysis 4.7. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 7 Uterine hyperstimulation without FHR changes.



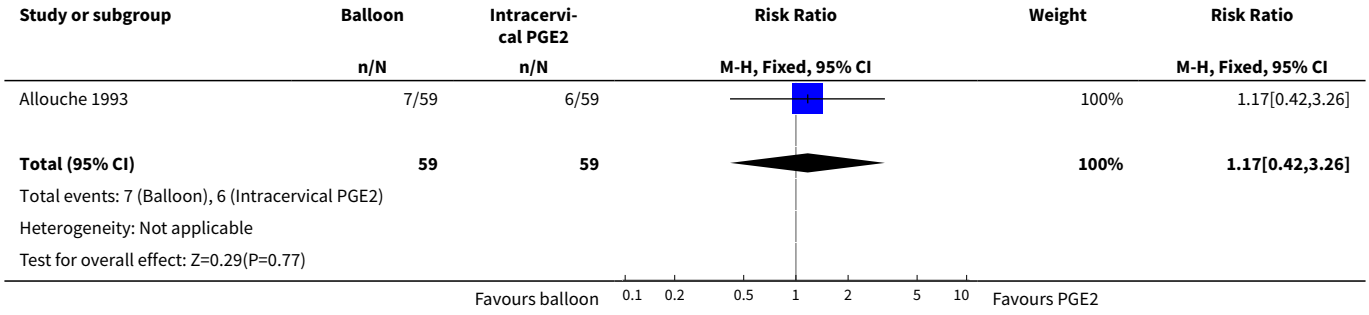
Analysis 4.8. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 8 Epidural analgesia.



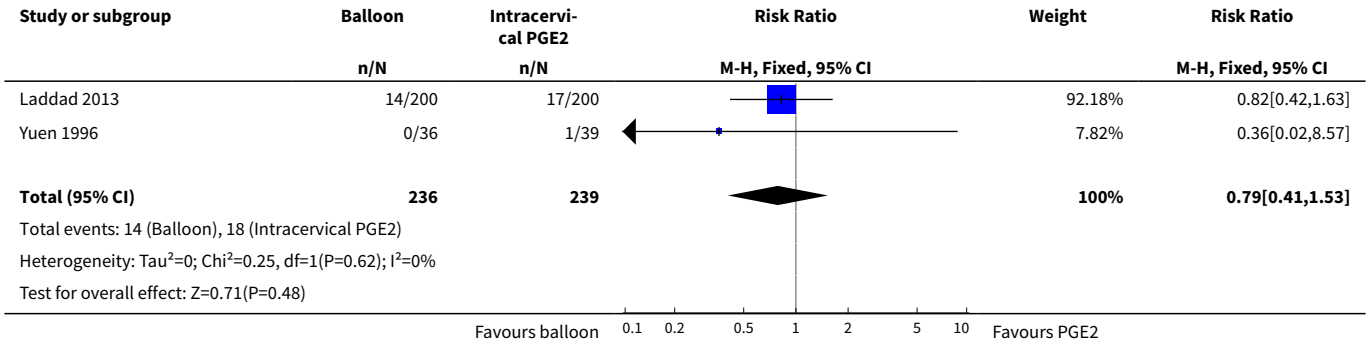
Analysis 4.9. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 9 Instrumental vaginal delivery.



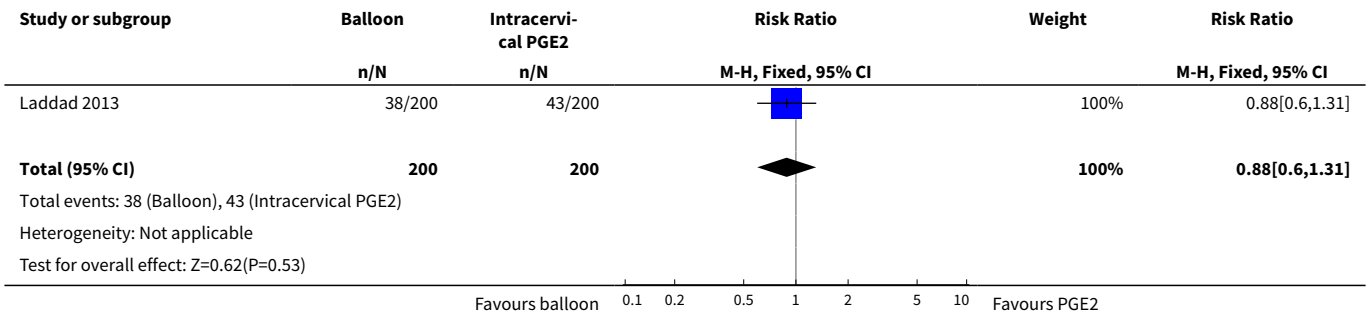
Analysis 4.10. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 10 Meconium-stained liquor.



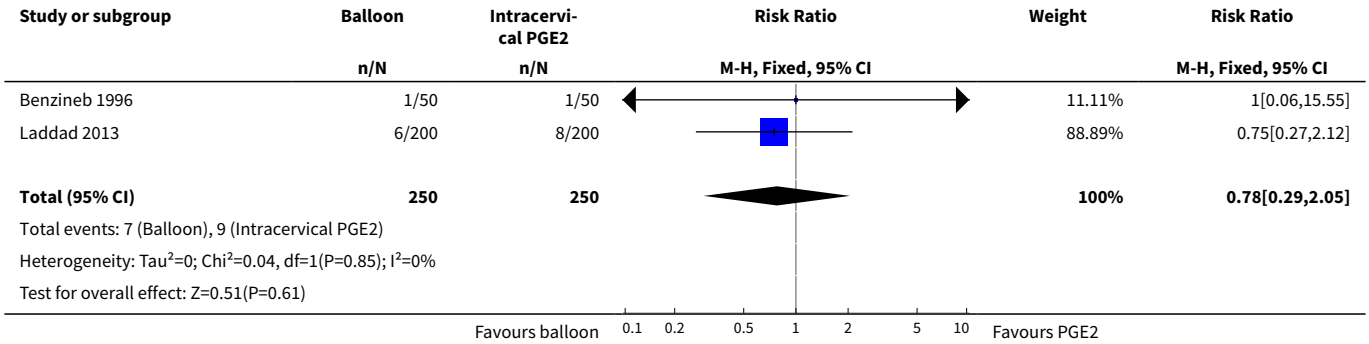
Analysis 4.11. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 11 Apgar score < 7 at 5 minutes.



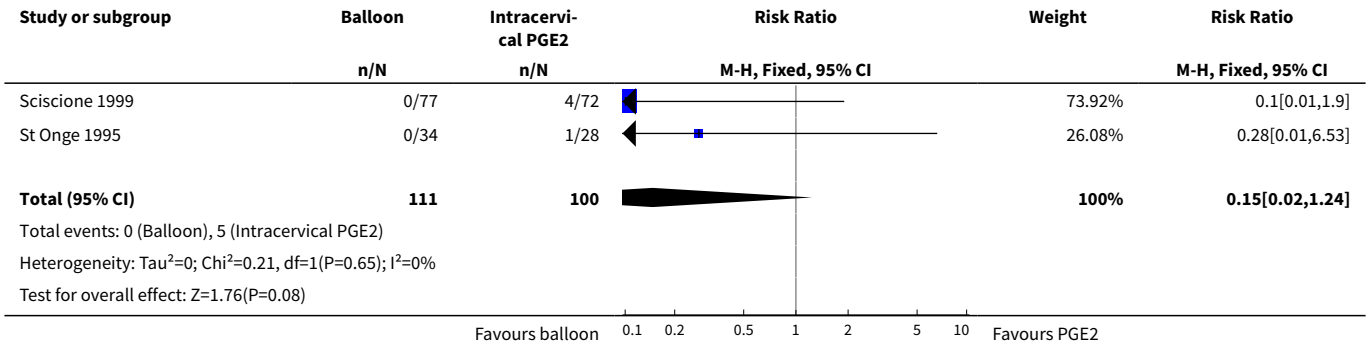
Analysis 4.12. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 12 Neonatal intensive care unit admission.



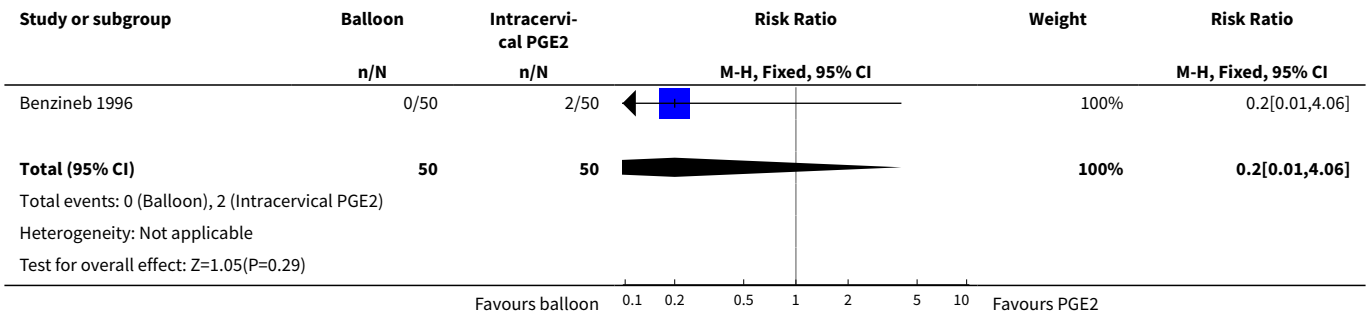
Analysis 4.13. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 13 Perinatal death.



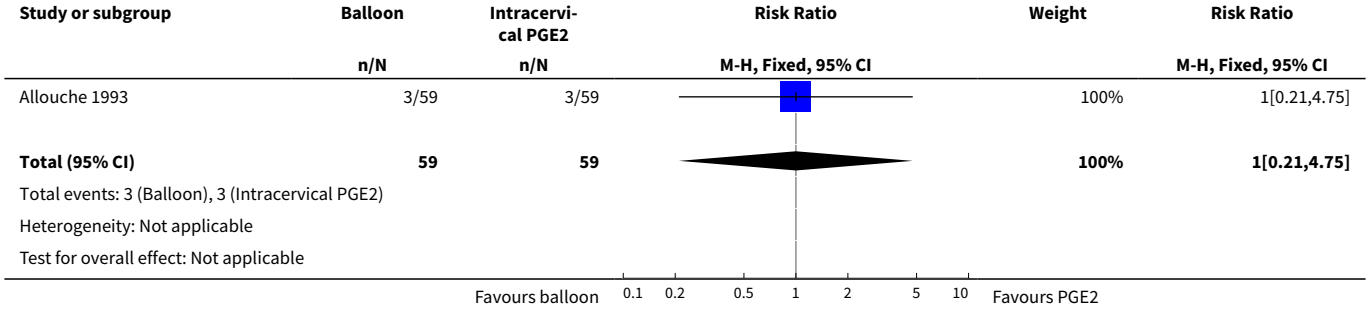
Analysis 4.14. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 14 Maternal side effects.



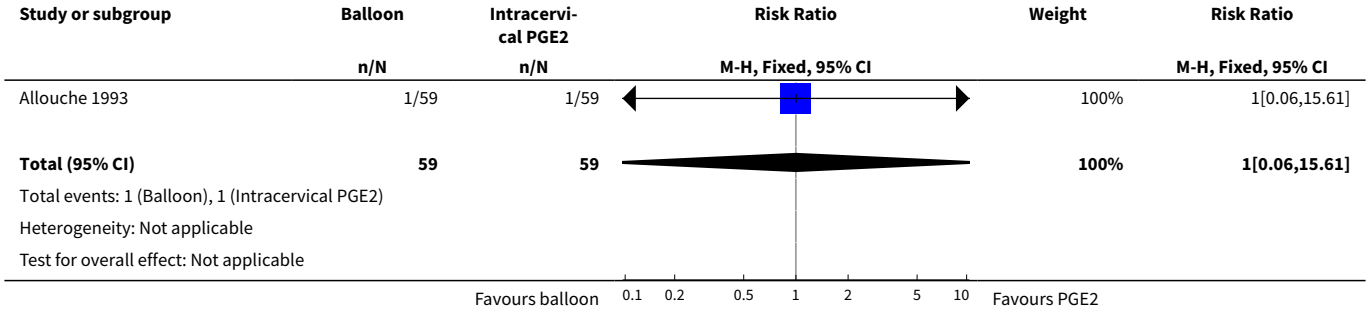
Analysis 4.15. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 15 Postpartum haemorrhage.



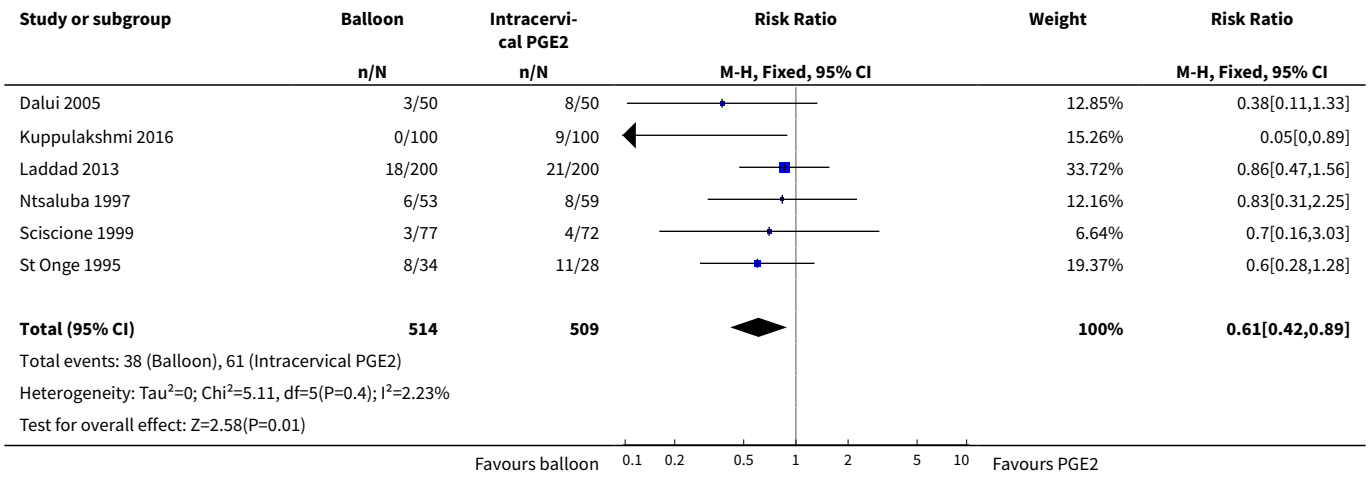
Analysis 4.16. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 16 Chorioamnionitis.



Analysis 4.17. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 17 Endometritis.



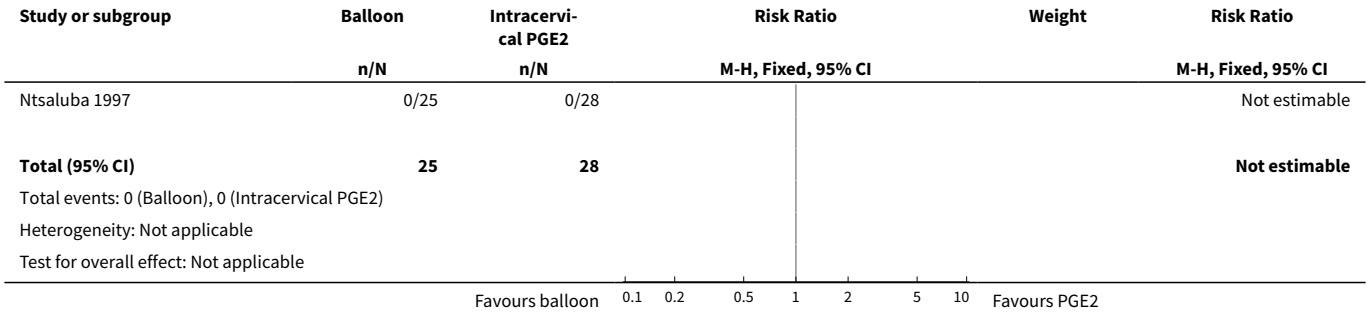
Analysis 4.18. Comparison 4 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all women, Outcome 18 Fetal distress.



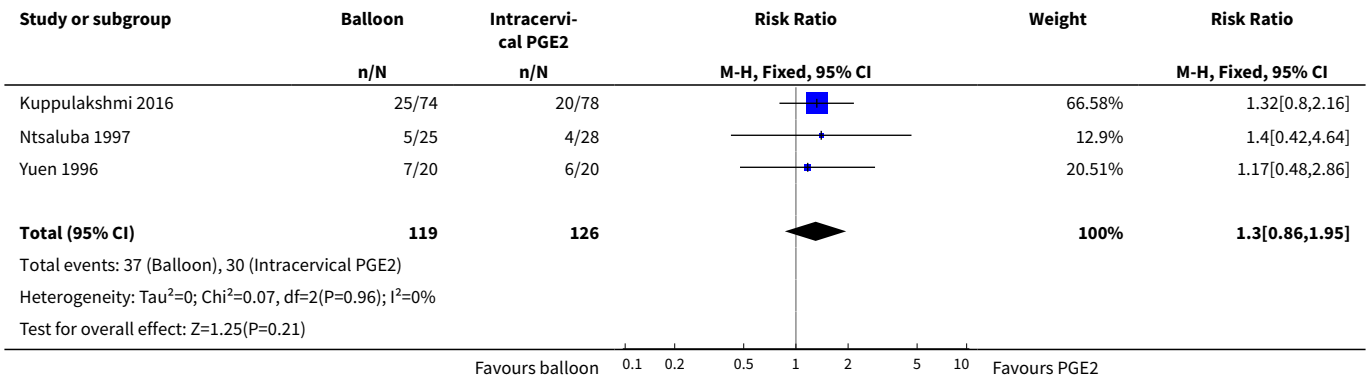
Comparison 5. Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Uterine hyperstimulation with FHR changes	1	53	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Caesarean section	3	245	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.86, 1.95]

Analysis 5.1. Comparison 5 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all primiparae, Outcome 1 Uterine hyperstimulation with FHR changes.



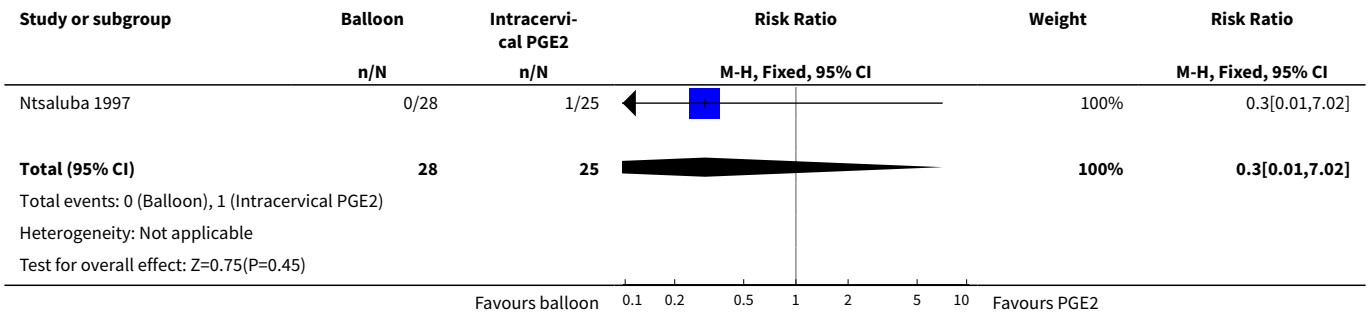
Analysis 5.2. Comparison 5 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all primiparae, Outcome 2 Caesarean section.



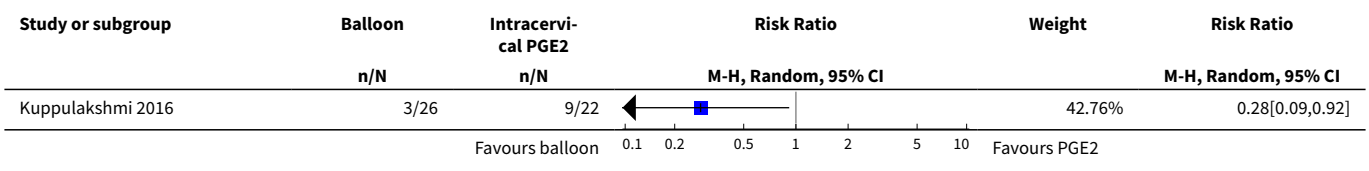
Comparison 6. Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all multiparae

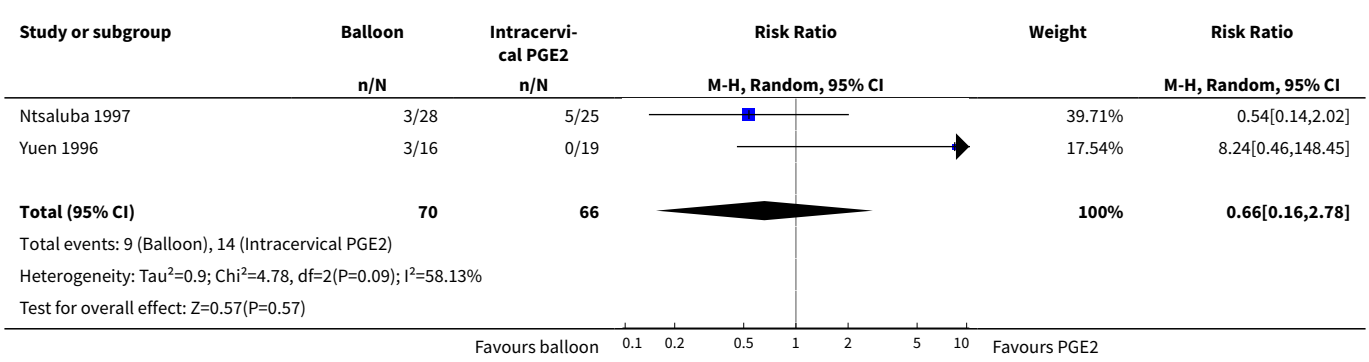
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Uterine hyperstimulation with FHR changes	1	53	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.01, 7.02]
2 Caesarean section	3	136	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.16, 2.78]

Analysis 6.1. Comparison 6 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all multiparae, Outcome 1 Uterine hyperstimulation with FHR changes.



Analysis 6.2. Comparison 6 Balloon (Foley or ATAD) versus intracervical prostaglandin E2: all multiparae, Outcome 2 Caesarean section.





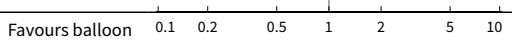
Comparison 7. Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	2	340	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.85, 1.39]
2 Uterine hyperstimulation with FHR changes	8	1322	Risk Ratio (M-H, Fixed, 95% CI)	0.39 [0.18, 0.85]
3 Caesarean section	12	1756	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.02, 1.60]
4 Serious neonatal morbidity/perinatal death	3	381	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.12, 2.66]
5 Serious maternal morbidity or death	4	464	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Cervix unfavourable/unchanged after 12 hours	2	200	Risk Ratio (M-H, Random, 95% CI)	2.66 [0.60, 11.89]
7 Oxytocin augmentation	9	911	Risk Ratio (M-H, Random, 95% CI)	1.62 [1.38, 1.90]
8 Uterine hyperstimulation without FHR changes	9	1139	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.14, 0.44]
9 Uterine rupture	3	364	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Epidural analgesia	2	517	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [1.06, 1.41]
11 Instrumental vaginal delivery	4	721	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.50, 1.05]
12 Meconium-stained liquor	7	1268	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.48, 0.87]
13 Apgar score < 7 at 5 minutes	7	941	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.50, 1.97]
14 Neonatal intensive care unit admission	9	1302	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.61, 1.63]
15 Perinatal death	1	121	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Maternal vomiting	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
17 Postpartum haemorrhage	1	120	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.24, 5.44]
18 Maternal fever during labour	3	617	Risk Ratio (M-H, Random, 95% CI)	1.84 [0.22, 15.62]
19 Chorioamnionitis	2	200	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.31, 4.88]
20 Endometritis	1	240	Risk Ratio (M-H, Fixed, 95% CI)	2.95 [0.12, 71.72]
21 Fetal distress	7	1127	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.67, 1.05]
22 Umbilical artery pH <7.10	1	120	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.35, 3.74]

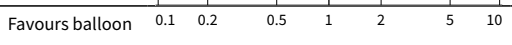
Analysis 7.1. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Chavakula 2015	21/54	17/46		26.31%	1.05[0.64,1.74]
Filho 2002	57/121	51/119		73.69%	1.1[0.83,1.46]
Total (95% CI)	**175**	**165**		**100%**	**1.09[0.85,1.39]**
Total events: 78 (Balloon), 68 (vaginal misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=0.02, df=1(P=0.88); I^2=0%					
Test for overall effect: Z=0.66(P=0.51)					



Analysis 7.2. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 2 Uterine hyperstimulation with FHR changes.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	0/70	0/70			Not estimable
Chavakula 2015	0/54	1/46		7.2%	0.28[0.01,6.83]
Filho 2002	2/121	3/119		13.47%	0.66[0.11,3.85]
Jozwiak 2014	2/56	1/64		4.16%	2.29[0.21,24.54]
Kandil 2012	0/50	1/50		6.68%	0.33[0.01,7.99]
Noor 2015	0/44	7/60		28.36%	0.09[0.01,1.54]
Prager 2008	2/198	6/199		26.65%	0.34[0.07,1.64]
Tabowei 2003	1/61	3/60		13.47%	0.33[0.04,3.06]
Total (95% CI)	**654**	**668**		**100%**	**0.39[0.18,0.85]**
Total events: 7 (Balloon), 22 (vaginal misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=3.6, df=6(P=0.73); I^2=0%					
Test for overall effect: Z=2.38(P=0.02)					



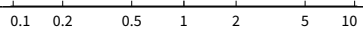
Analysis 7.3. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 3 Caesarean section.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Aduloju 2016	22/70	19/70		10.1%	1.16[0.69,1.94]
Chavakula 2015	16/54	7/46		5.89%	1.95[0.88,4.32]
Deo 2012	9/50	16/54		6.77%	0.61[0.3,1.25]
Filho 2002	44/121	32/119		13.3%	1.35[0.93,1.97]
Jozwiak 2014	14/56	11/64		6.99%	1.45[0.72,2.94]
Kandil 2012	9/50	8/50		5.19%	1.13[0.47,2.68]
Noor 2015	19/44	14/60		9.07%	1.85[1.05,3.27]
Oliveira 2010	41/80	34/80		14.52%	1.21[0.86,1.68]
Prager 2008	45/198	56/199		14.33%	0.81[0.58,1.13]
Roudsari 2011	22/60	5/50		4.95%	3.67[1.5,8.98]
Sheikher 2009	8/30	4/30		3.62%	2[0.67,5.94]
Tabowei 2003	10/61	8/60		5.27%	1.23[0.52,2.9]
Total (95% CI)	**874**	**882**		**100%**	**1.28[1.02,1.6]**
Total events: 259 (Balloon), 214 (vaginal misoprostol)					
Heterogeneity: Tau^2=0.06; Chi^2=19.86, df=11(P=0.05); I^2=44.61%					
Test for overall effect: Z=2.11(P=0.03)					

Favours balloon — Favours misoprostol

Analysis 7.4. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 4 Serious neonatal morbidity/perinatal death.

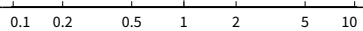
Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	2/70	3/70		68.16%	0.67[0.11,3.87]
Jozwiak 2014	0/56	1/64		31.84%	0.38[0.02,9.15]
Tabowei 2003	0/61	0/60			Not estimable
Total (95% CI)	**187**	**194**		**100%**	**0.58[0.12,2.66]**
Total events: 2 (Balloon), 4 (vaginal misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=0.09, df=1(P=0.76); I^2=0%					
Test for overall effect: Z=0.71(P=0.48)					



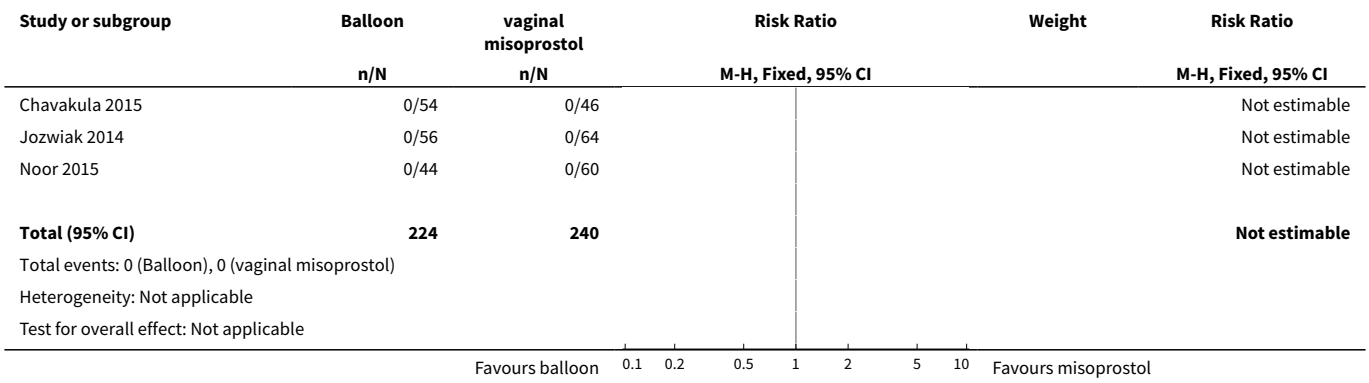
Favours balloon — Favours misoprostol

Analysis 7.5. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 5 Serious maternal morbidity or death.

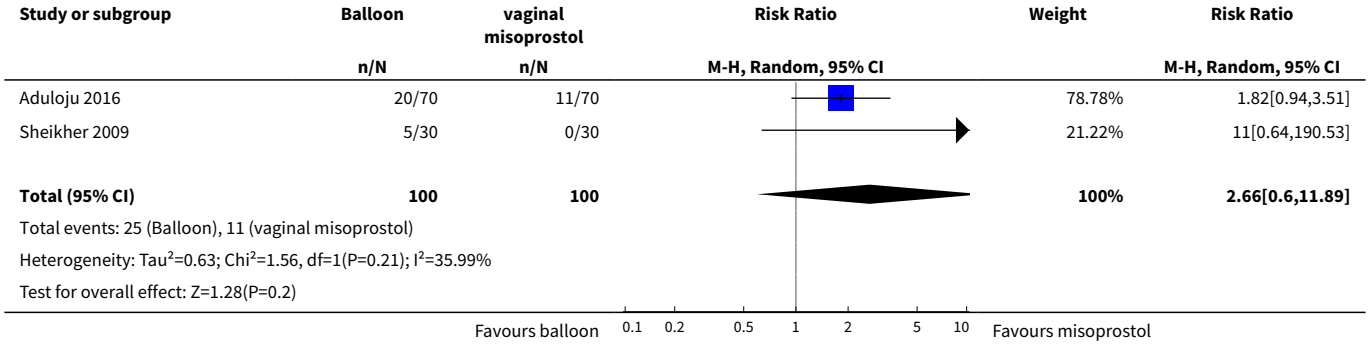
Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	0/70	0/70			Not estimable



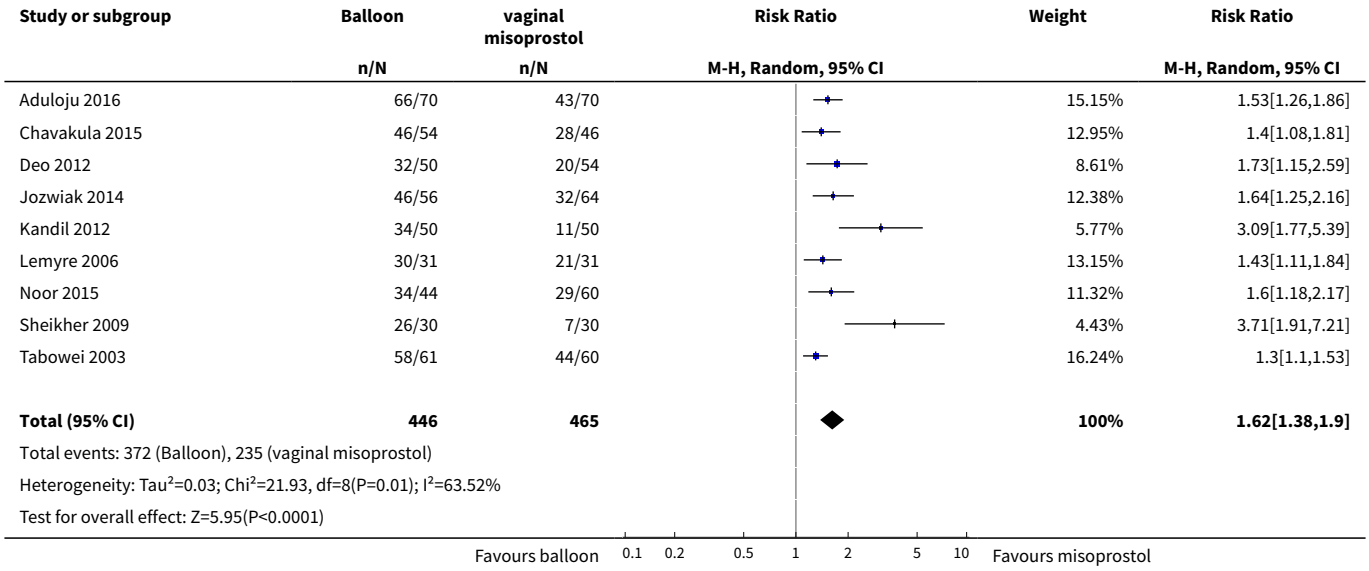
Favours balloon — Favours misoprostol



Analysis 7.6. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 6 Cervix unfavourable/unchanged after 12 hours.

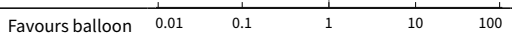


Analysis 7.7. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 7 Oxytocin augmentation.



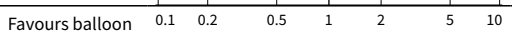
Analysis 7.8. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 8 Uterine hyperstimulation without FHR changes.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	0/70	0/70			Not estimable
Deo 2012	0/50	6/54		11.13%	0.08[0,1.44]
Filho 2002	3/121	6/119		10.77%	0.49[0.13,1.92]
Kandil 2012	0/50	2/50		4.45%	0.2[0.01,4.06]
Noor 2015	0/44	0/60			Not estimable
Oliveira 2010	5/80	18/80		32.04%	0.28[0.11,0.71]
Roudsari 2011	0/60	2/50		4.85%	0.17[0.01,3.4]
Sheikher 2009	0/30	1/30		2.67%	0.33[0.01,7.87]
Tabowei 2003	4/61	19/60		34.1%	0.21[0.07,0.57]
Total (95% CI)	**566**	**573**		**100%**	**0.25[0.14,0.44]**
Total events: 12 (Balloon), 54 (vaginal misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=1.83, df=6(P=0.93); I^2=0%					
Test for overall effect: Z=4.85(P<0.0001)					



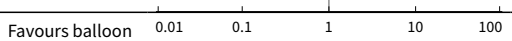
Analysis 7.9. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 9 Uterine rupture.

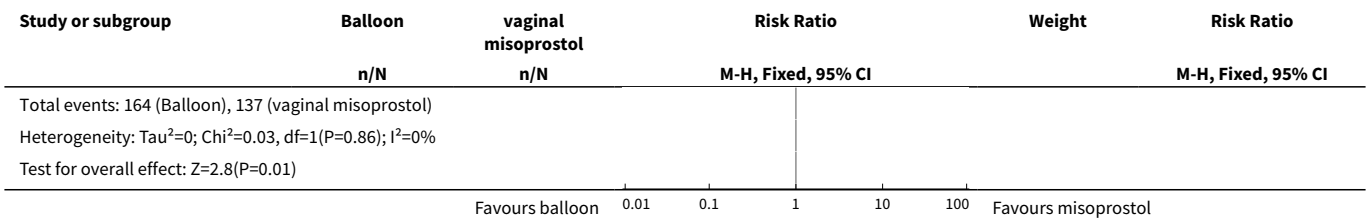
Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	0/70	0/70			Not estimable
Jozwiak 2014	0/56	0/64			Not estimable
Noor 2015	0/44	0/60			Not estimable
Total (95% CI)	**170**	**194**			**Not estimable**
Total events: 0 (Balloon), 0 (vaginal misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



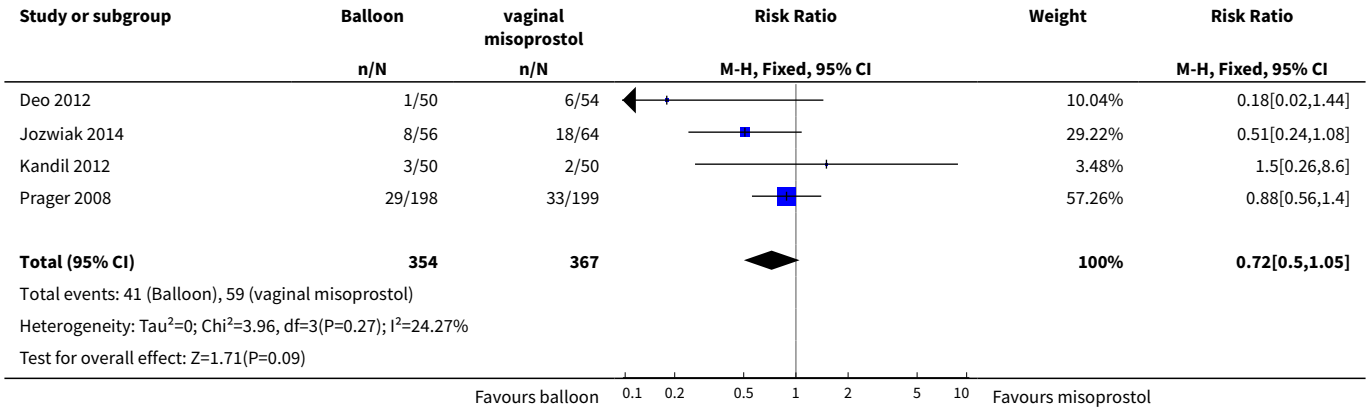
Analysis 7.10. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 10 Epidural analgesia.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Jozwiak 2014	19/56	17/64		11.7%	1.28[0.74,2.21]
Prager 2008	145/198	120/199		88.3%	1.21[1.06,1.4]
Total (95% CI)	**254**	**263**		**100%**	**1.22[1.06,1.41]**

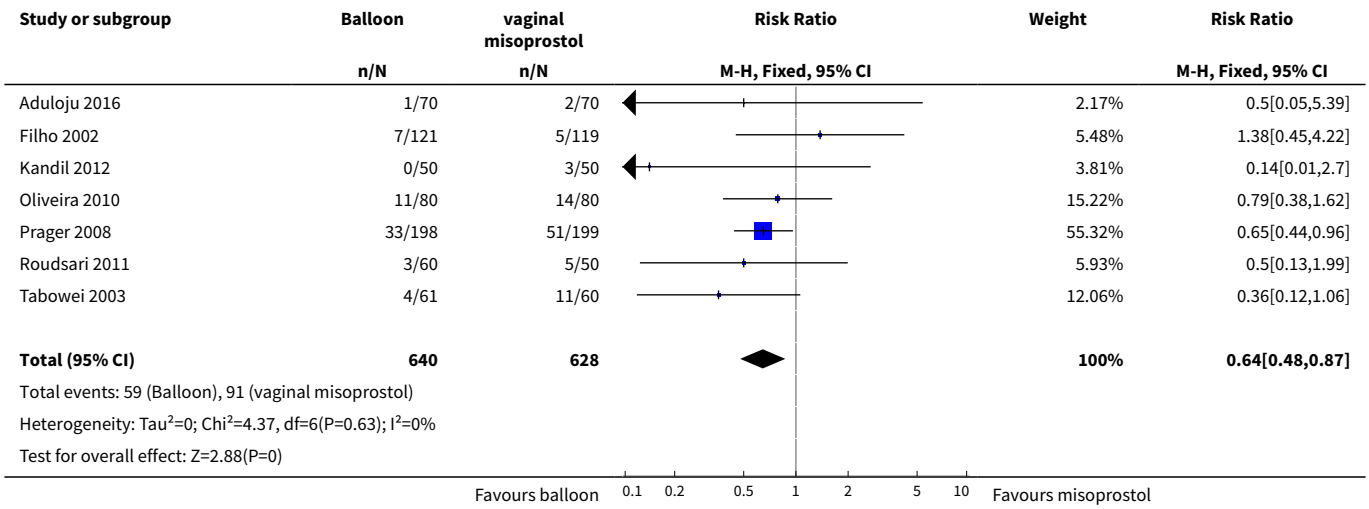




Analysis 7.11. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 11 Instrumental vaginal delivery.



Analysis 7.12. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 12 Meconium-stained liquor.



Analysis 7.13. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 13 Apgar score < 7 at 5 minutes.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	5/70	5/70		31.42%	1[0.3,3.3]
Chavakula 2015	1/54	0/46		3.39%	2.56[0.11,61.45]
Filho 2002	1/121	0/119		3.17%	2.95[0.12,71.72]
Jozwiak 2014	0/56	2/64		14.68%	0.23[0.01,4.65]
Oliveira 2010	3/80	3/80		18.85%	1[0.21,4.81]
Sheikher 2009	1/30	0/30		3.14%	3[0.13,70.83]
Tabowei 2003	3/61	4/60		25.35%	0.74[0.17,3.16]
Total (95% CI)	**472**	**469**		**100%**	**1[0.5,1.97]**
Total events: 14 (Balloon), 14 (vaginal misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=2.33, df=6(P=0.89); I^2=0%					
Test for overall effect: Z=0.01(P=1)					

Analysis 7.14. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 14 Neonatal intensive care unit admission.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	3/70	5/70		16.5%	0.6[0.15,2.41]
Chavakula 2015	4/54	1/46		3.56%	3.41[0.39,29.42]
Jozwiak 2014	2/56	1/64		3.08%	2.29[0.21,24.54]
Kandil 2012	0/50	0/50			Not estimable
Noor 2015	6/44	8/60		22.34%	1.02[0.38,2.74]
Oliveira 2010	3/80	5/80		16.5%	0.6[0.15,2.43]
Prager 2008	7/198	7/199		23.05%	1.01[0.36,2.81]
Sheikher 2009	1/30	0/30		1.65%	3[0.13,70.83]
Tabowei 2003	3/61	4/60		13.31%	0.74[0.17,3.16]
Total (95% CI)	**643**	**659**		**100%**	**1[0.61,1.63]**
Total events: 29 (Balloon), 31 (vaginal misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=3.37, df=7(P=0.85); I^2=0%					
Test for overall effect: Z=0.01(P=0.99)					

Analysis 7.15. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 15 Perinatal death.

Study or subgroup	Balloon n/N	vaginal misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Tabowei 2003	0/61	0/60			Not estimable

Study or subgroup	Balloon	vaginal misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Total (95% CI)	**61**	**60**			**Not estimable**
Total events: 0 (Balloon), 0 (vaginal misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

Favours balloon 0.1 0.2 0.5 1 2 5 10 Favours misoprostol

Analysis 7.16. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 16 Maternal vomiting.

Study or subgroup	Balloon	vaginal misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Sheikher 2009	0/30	0/30			Not estimable
Total (95% CI)	**30**	**30**			**Not estimable**
Total events: 0 (Balloon), 0 (vaginal misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

Favours balloon 0.1 0.2 0.5 1 2 5 10 Favours misoprostol

Analysis 7.17. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 17 Postpartum haemorrhage.

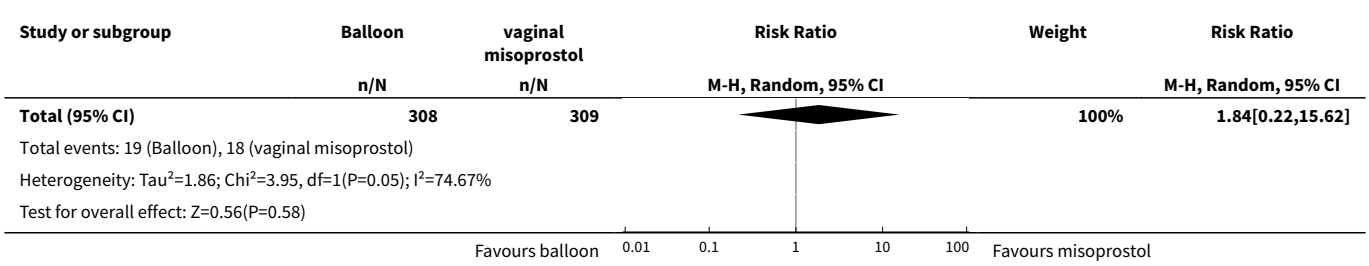
Study or subgroup	Balloon	vaginal misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Jozwiak 2014	3/56	3/64		100%	1.14[0.24,5.44]
Total (95% CI)	**56**	**64**		**100%**	**1.14[0.24,5.44]**
Total events: 3 (Balloon), 3 (vaginal misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.17(P=0.87)					

Favours balloon 0.1 0.2 0.5 1 2 5 10 Favours misoprostol

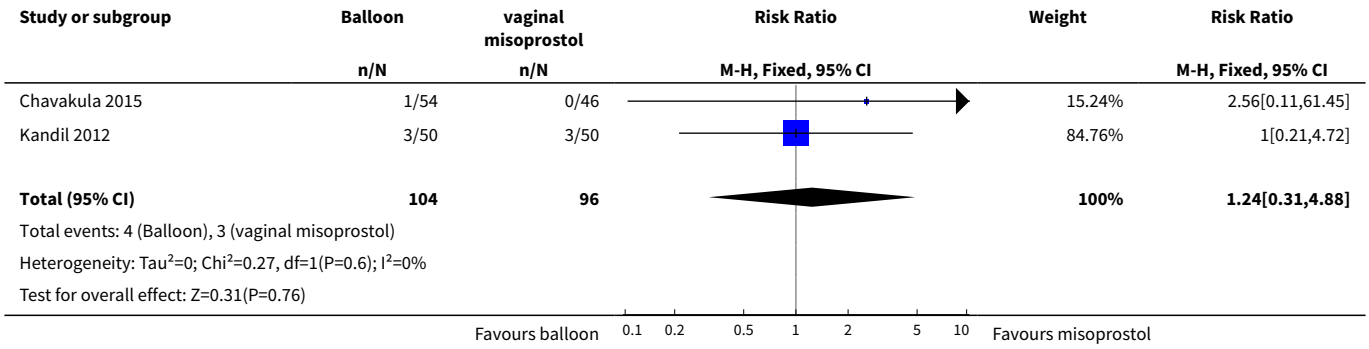
Analysis 7.18. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 18 Maternal fever during labour.

Study or subgroup	Balloon	vaginal misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Chavakula 2015	0/54	0/46			Not estimable
Jozwiak 2014	6/56	1/64		39.86%	6.86[0.85,55.24]
Prager 2008	13/198	17/199		60.14%	0.77[0.38,1.54]

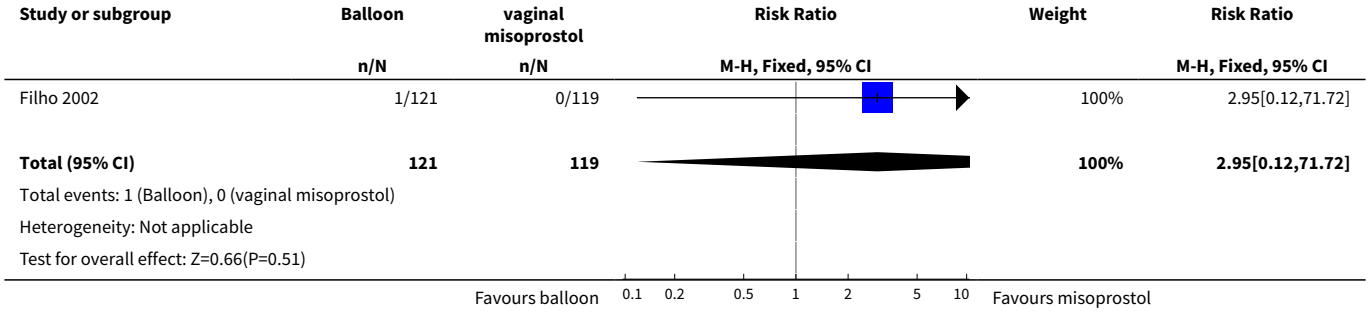
Favours balloon 0.01 0.1 1 10 100 Favours misoprostol



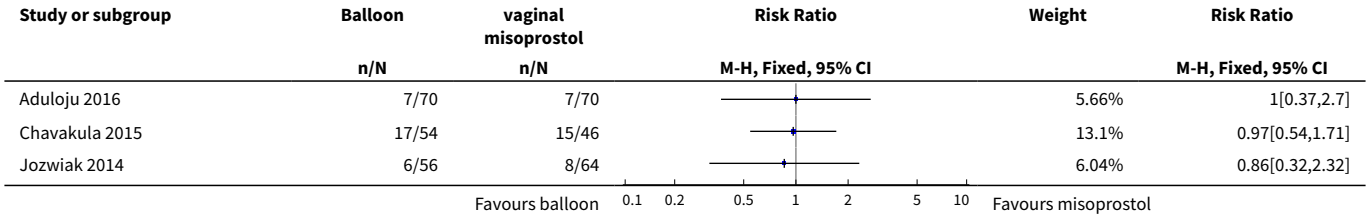
Analysis 7.19. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 19 Chorioamnionitis.

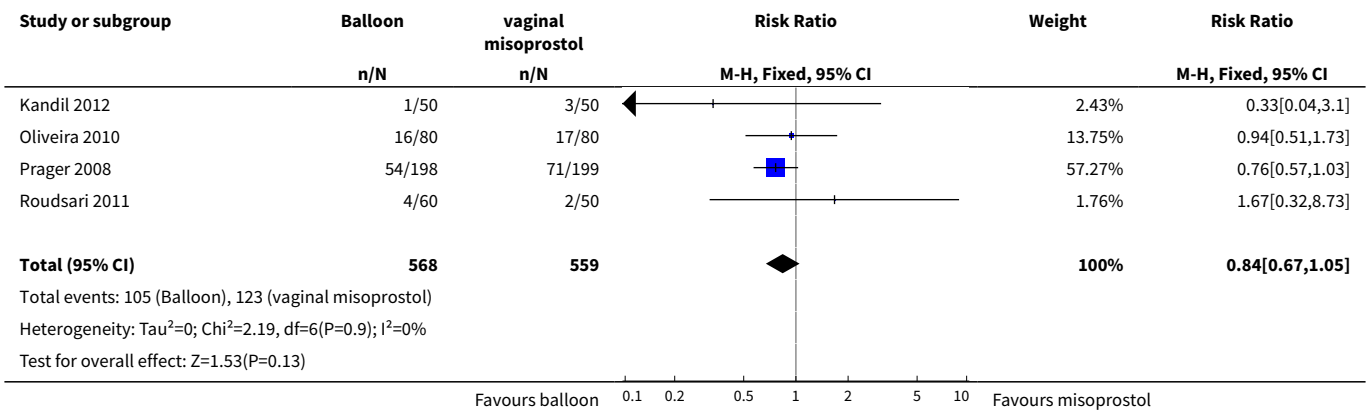


Analysis 7.20. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 20 Endometritis.

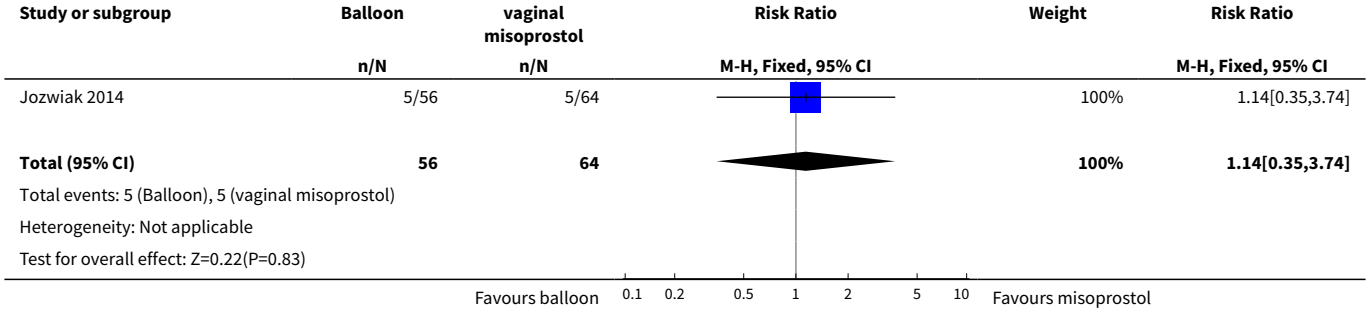


Analysis 7.21. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 21 Fetal distress.





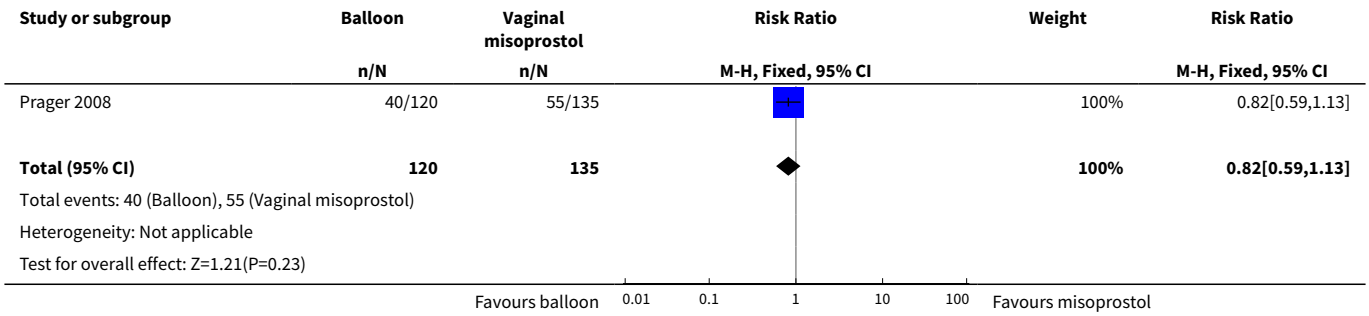
Analysis 7.22. Comparison 7 Balloon (Foley or ATAD) versus low dose vaginal misoprostol: all women, Outcome 22 Umbilical artery pH <7.10.



Comparison 8. Balloon (Foley or ATAD versus low dose vaginal misoprostol: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	255	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.59, 1.13]

Analysis 8.1. Comparison 8 Balloon (Foley or ATAD versus low dose vaginal misoprostol: all primiparae, Outcome 1 Caesarean section.

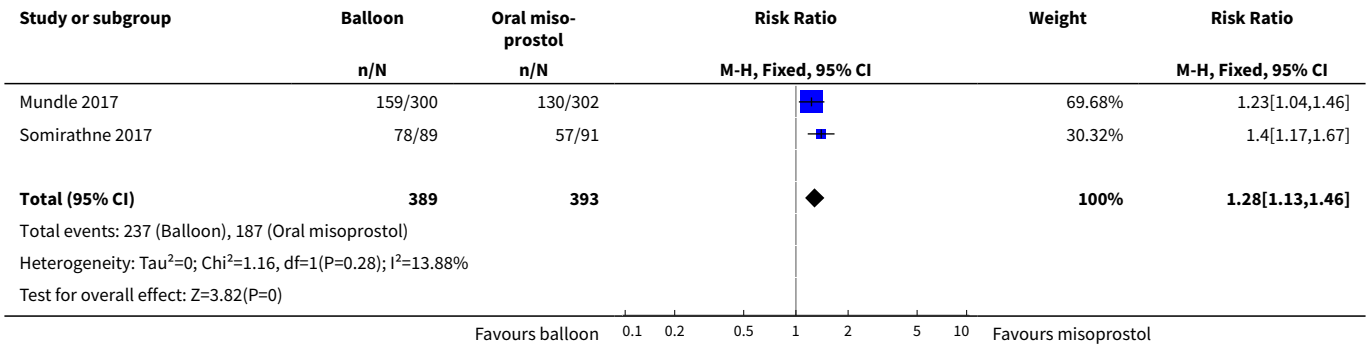


Comparison 9. Balloon (Foley or ATAD) versus low dose oral misoprostol: all women

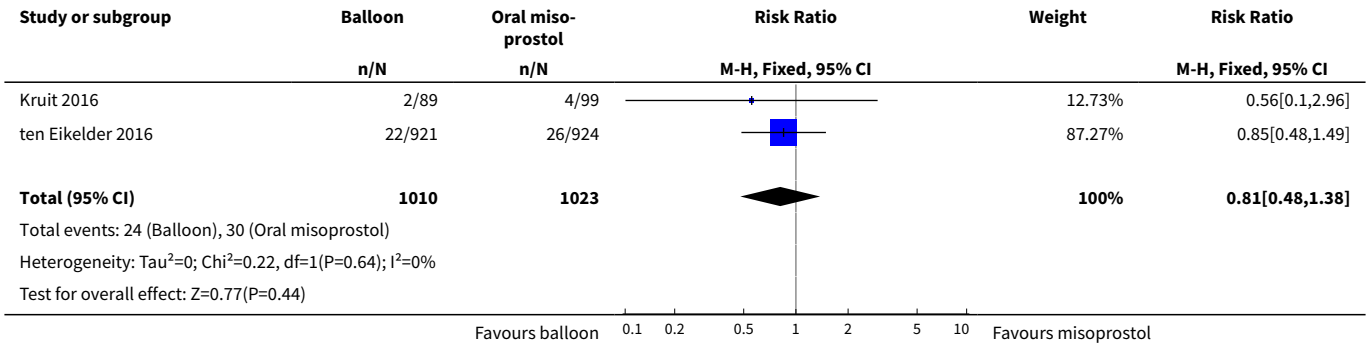
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved within 24 hours	2	782	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [1.13, 1.46]
2 Uterine hyperstimulation with FHR changes	2	2033	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.48, 1.38]
3 Caesarean section	7	3178	Risk Ratio (M-H, Fixed, 95% CI)	1.17 [1.04, 1.32]
4 Serious perinatal morbidity/perinatal death	3	2627	Risk Ratio (M-H, Fixed, 95% CI)	1.11 [0.60, 2.06]
5 Serious maternal morbidity or death	3	2627	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.05, 5.52]
6 Cervix unfavourable after 24 hours	4	994	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.61, 1.56]
7 Oxytocin augmentation	5	2847	Risk Ratio (M-H, Random, 95% CI)	1.28 [1.09, 1.49]
8 Uterine hyperstimulation without FHR changes	5	2838	Risk Ratio (M-H, Random, 95% CI)	0.50 [0.12, 2.07]
9 Uterine rupture	3	2627	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Epidural	3	2635	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.96, 1.22]
11 Instrumental vaginal delivery	3	2627	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.55, 0.92]
12 Meconium-stained liquor	3	2627	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.44, 1.35]
13 Apgar score < 7 after 5 minutes	4	2693	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.38, 1.32]
14 Neonatal intensive care unit admission	5	2873	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.58, 1.17]
15 Neonatal encephalopathy	1	600	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.32, 2.03]
16 Perinatal death	3	2627	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [0.49, 3.30]
17 Maternal side effects (all)	2	662	Risk Ratio (M-H, Fixed, 95% CI)	0.61 [0.33, 1.13]
18 Maternal vomiting	2	662	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.37, 1.46]
19 Maternal diarrhoea	1	602	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.06, 1.37]
20 Postpartum haemorrhage	5	2966	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.79, 1.34]
21 Maternal death	3	2627	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
22 Women not satisfied	1	602	Risk Ratio (M-H, Fixed, 95% CI)	1.70 [1.15, 2.50]
23 Maternal fever during labour	2	2033	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.78, 1.24]
24 Antibiotics during labour	2	2033	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.75, 2.00]
25 Endometritis	1	188	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.05, 6.03]
26 Fetal distress	5	2966	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.61, 1.09]
27 Umbilical artery pH < 7.10	2	1535	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.53, 1.12]

Analysis 9.1. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 1 Vaginal delivery not achieved within 24 hours.



Analysis 9.2. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 2 Uterine hyperstimulation with FHR changes.



Analysis 9.3. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 3 Caesarean section.

Study or subgroup	Balloon n/N	Oral misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Goonewardene 2014	17/78	24/74		6.99%	0.67[0.39,1.15]
Kruit 2016	21/89	18/99		4.84%	1.3[0.74,2.27]
Mundle 2017	151/300	124/302		35.1%	1.23[1.03,1.46]
Saleem 2006	11/78	9/73		2.64%	1.14[0.5,2.6]
Sheikher 2009	8/30	8/30		2.27%	1[0.43,2.31]
Somirathne 2017	18/89	15/91		4.21%	1.23[0.66,2.28]
ten Eikelder 2016	185/921	155/924		43.94%	1.2[0.99,1.45]
Total (95% CI)	**1585**	**1593**		**100%**	**1.17[1.04,1.32]**
Total events: 411 (Balloon), 353 (Oral misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=4.76, df=6(P=0.57); I^2=0%					
Test for overall effect: Z=2.57(P=0.01)					

Favours balloon — Favours misoprostol

Analysis 9.4. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 4 Serious perinatal morbidity/perinatal death.

Study or subgroup	Balloon n/N	Oral misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Mundle 2017	8/300	11/302		57.88%	0.73[0.3,1.79]
Somirathne 2017	4/89	1/91		5.22%	4.09[0.47,35.88]
ten Eikelder 2016	9/921	7/924		36.9%	1.29[0.48,3.45]
Total (95% CI)	**1310**	**1317**		**100%**	**1.11[0.6,2.06]**
Total events: 21 (Balloon), 19 (Oral misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=2.3, df=2(P=0.32); I^2=13.21%					
Test for overall effect: Z=0.34(P=0.73)					

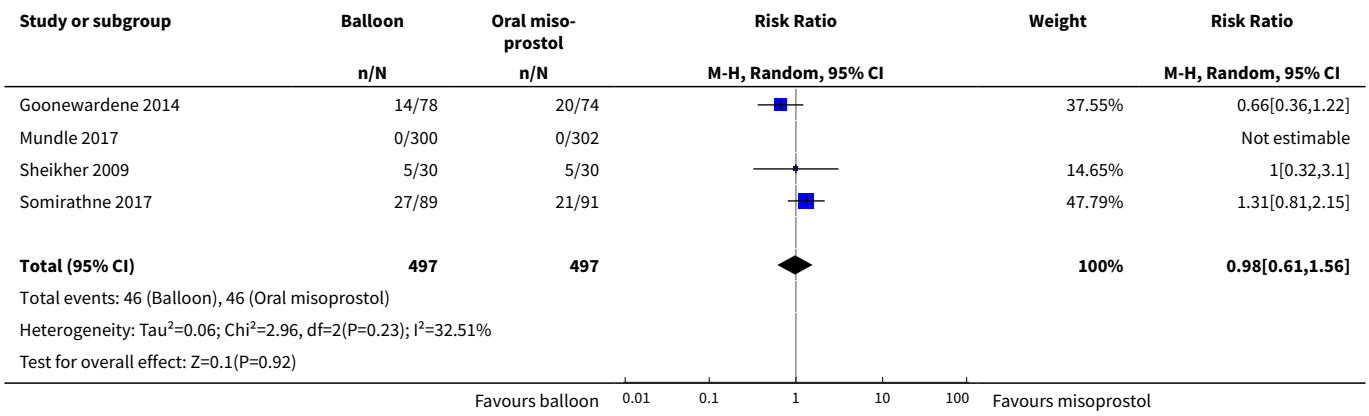
Favours balloon — Favours misoprostol

Analysis 9.5. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 5 Serious maternal morbidity or death.

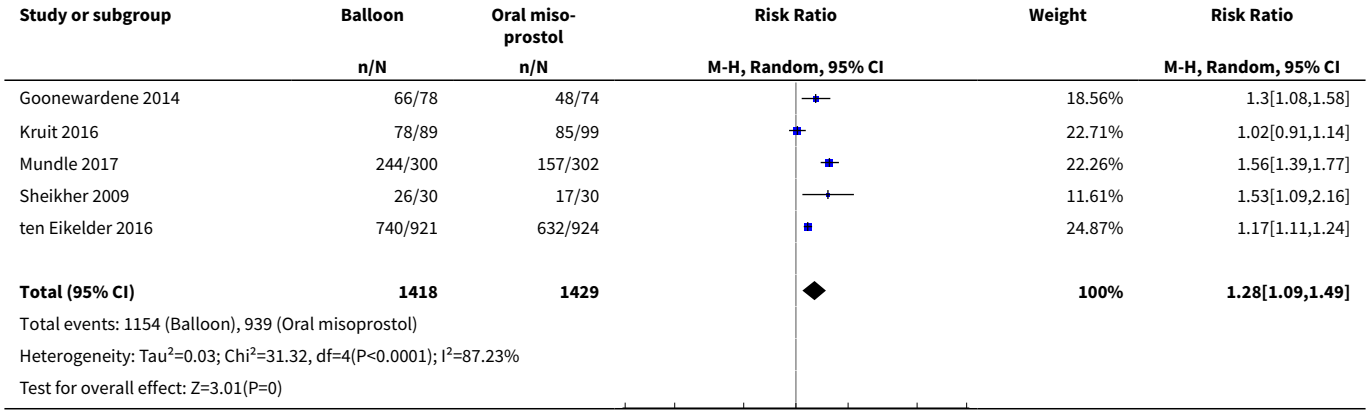
Study or subgroup	Balloon n/N	Oral misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Mundle 2017	0/300	0/302			Not estimable
Somirathne 2017	0/89	0/91			Not estimable
ten Eikelder 2016	1/921	2/924		100%	0.5[0.05,5.52]
Total (95% CI)	**1310**	**1317**		**100%**	**0.5[0.05,5.52]**
Total events: 1 (Balloon), 2 (Oral misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.56(P=0.57)					

Favours balloon — Favours misoprostol

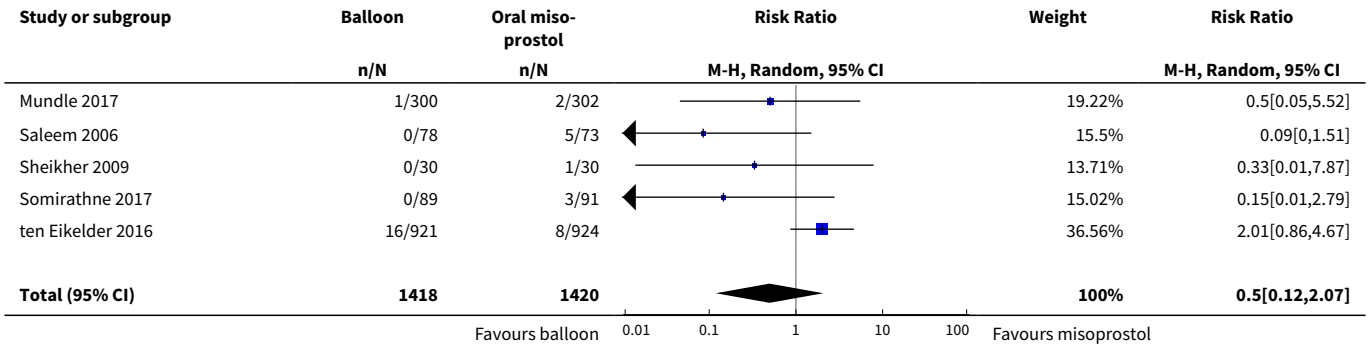
Analysis 9.6. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 6 Cervix unfavourable after 24 hours.



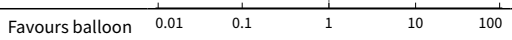
Analysis 9.7. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 7 Oxytocin augmentation.



Analysis 9.8. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 8 Uterine hyperstimulation without FHR changes.

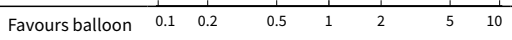


Study or subgroup	Balloon	Oral misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Total events: 17 (Balloon), 19 (Oral misoprostol)					
Heterogeneity: Tau²=1.26; Chi²=8.12, df=4(P=0.09); I²=50.75%					
Test for overall effect: Z=0.96(P=0.34)					



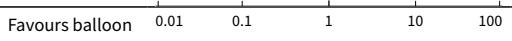
Analysis 9.9. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 9 Uterine rupture.

Study or subgroup	Balloon	Oral misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Mundle 2017	0/300	0/302			Not estimable
Somirathne 2017	0/89	0/91			Not estimable
ten Eikelder 2016	0/921	0/924			Not estimable
Total (95% CI)	**1310**	**1317**			**Not estimable**
Total events: 0 (Balloon), 0 (Oral misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



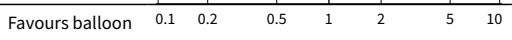
Analysis 9.10. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 10 Epidural.

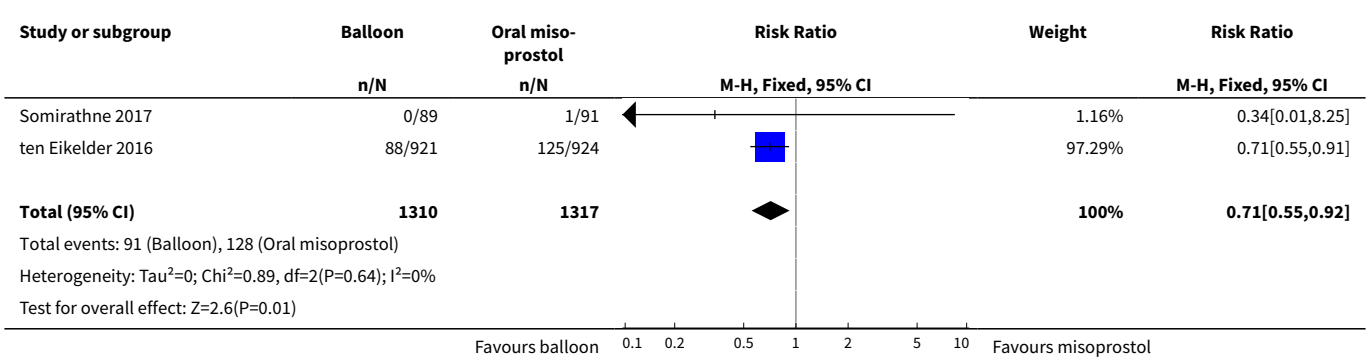
Study or subgroup	Balloon	Oral misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Random, 95% CI		M-H, Random, 95% CI
Kruit 2016	74/89	84/99		34.94%	0.98[0.86,1.11]
Mundle 2017	150/300	124/302		25.08%	1.22[1.02,1.45]
ten Eikelder 2016	421/921	386/924		39.98%	1.09[0.99,1.21]
Total (95% CI)	**1310**	**1325**		**100%**	**1.08[0.96,1.22]**
Total events: 645 (Balloon), 594 (Oral misoprostol)					
Heterogeneity: Tau²=0.01; Chi²=4.73, df=2(P=0.09); I²=57.68%					
Test for overall effect: Z=1.31(P=0.19)					



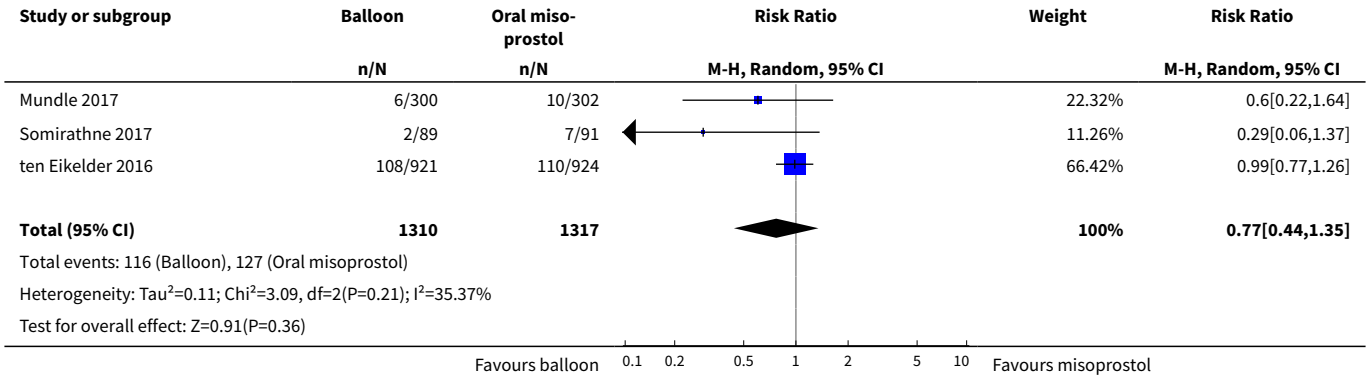
Analysis 9.11. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 11 Instrumental vaginal delivery.

Study or subgroup	Balloon	Oral misoprostol	Risk Ratio	Weight	Risk Ratio
	n/N	n/N	M-H, Fixed, 95% CI		M-H, Fixed, 95% CI
Mundle 2017	3/300	2/302		1.55%	1.51[0.25,8.97]

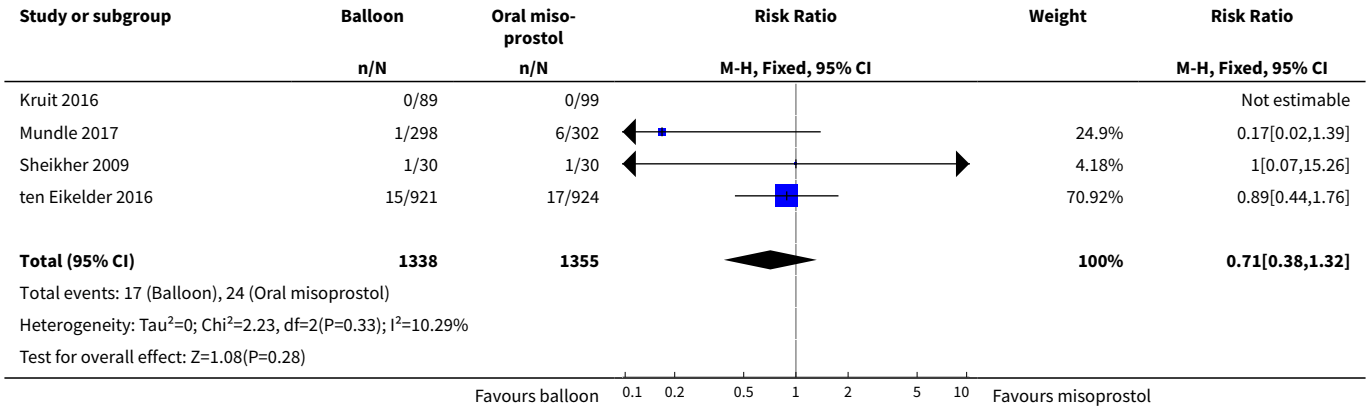




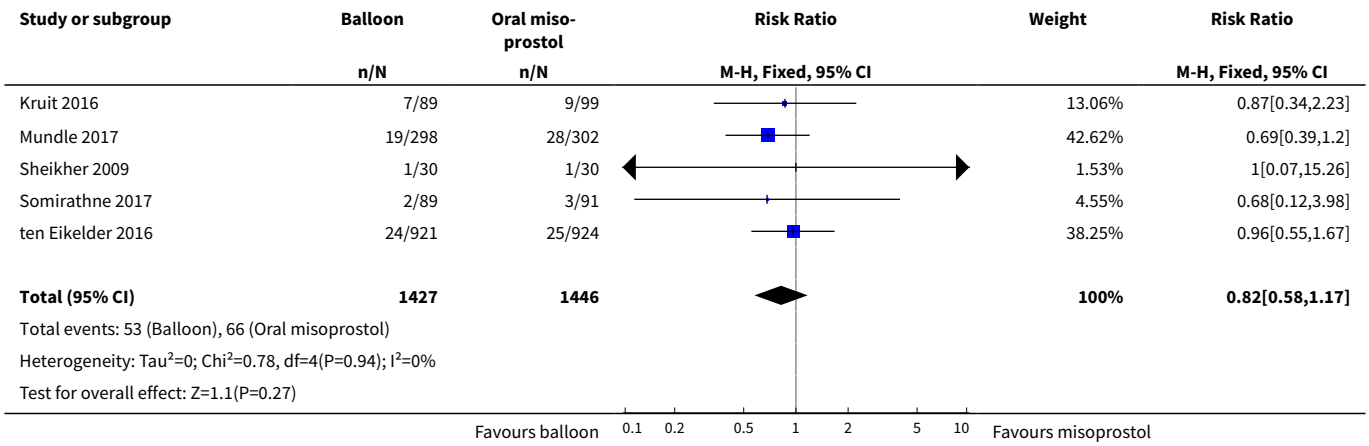
Analysis 9.12. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 12 Meconium-stained liquor.



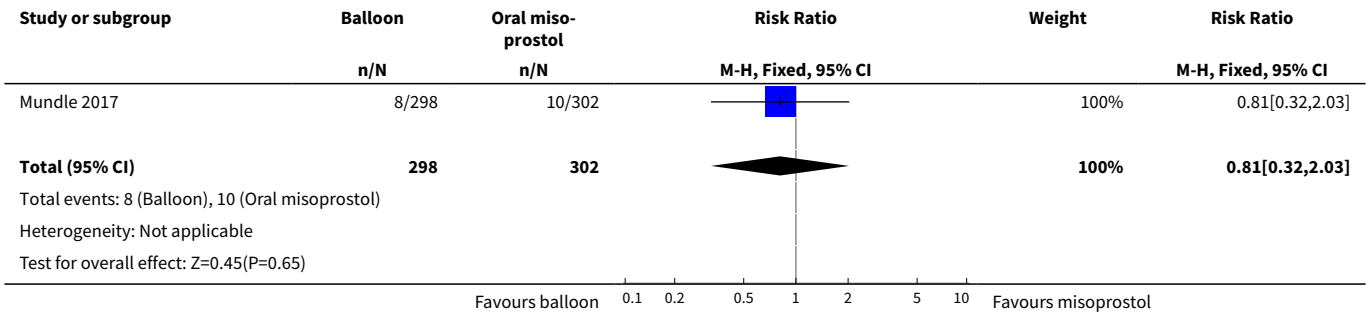
Analysis 9.13. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 13 Apgar score < 7 after 5 minutes.



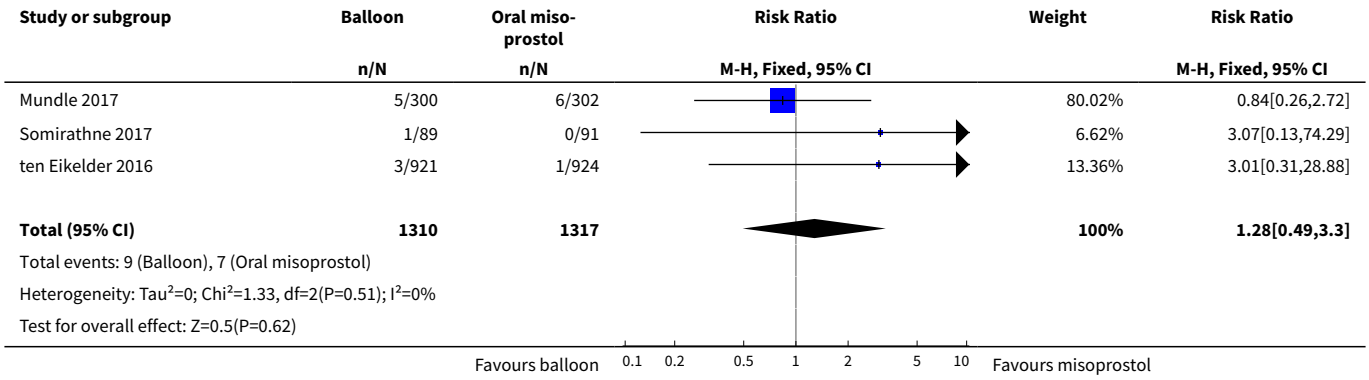
Analysis 9.14. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 14 Neonatal intensive care unit admission.



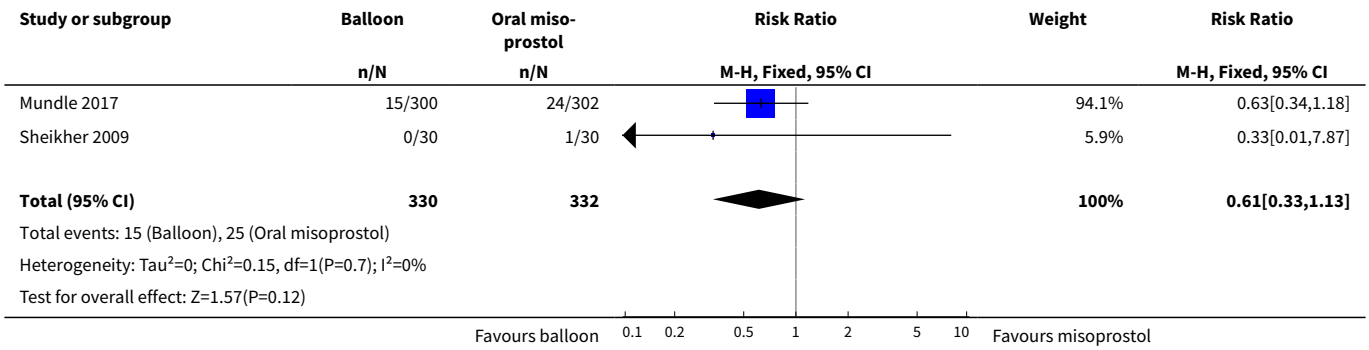
Analysis 9.15. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 15 Neonatal encephalopathy.



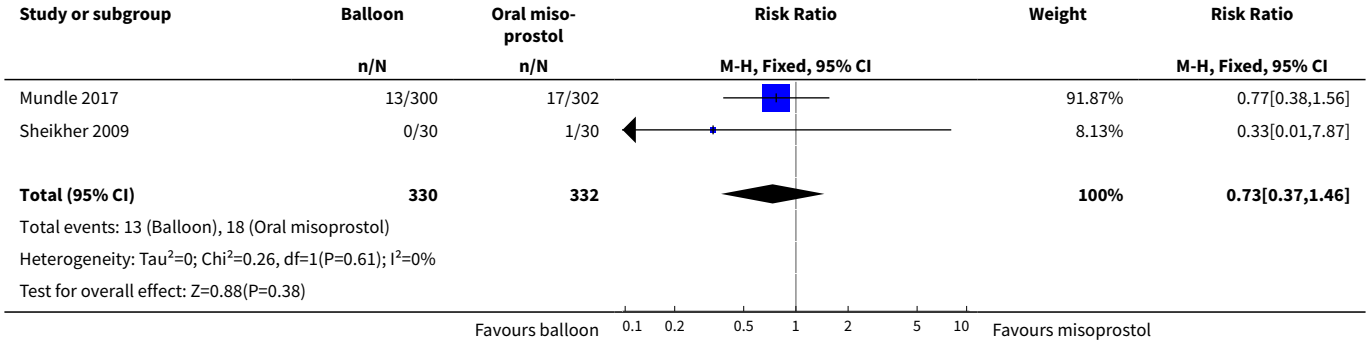
Analysis 9.16. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 16 Perinatal death.



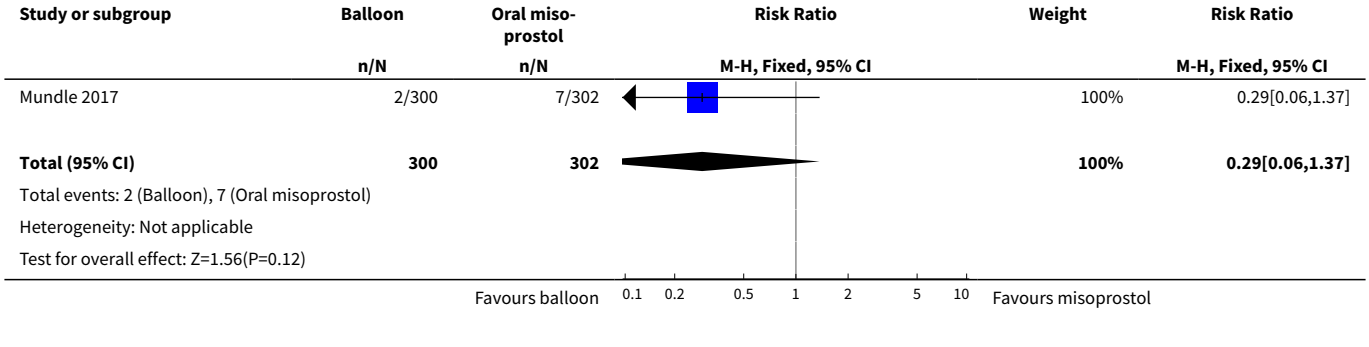
Analysis 9.17. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 17 Maternal side effects (all).



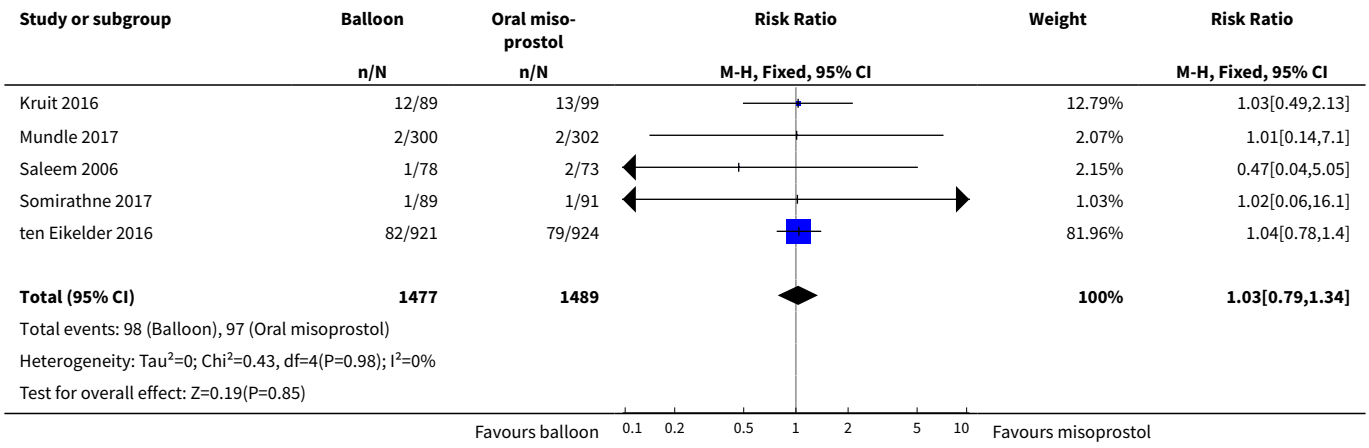
Analysis 9.18. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 18 Maternal vomiting.



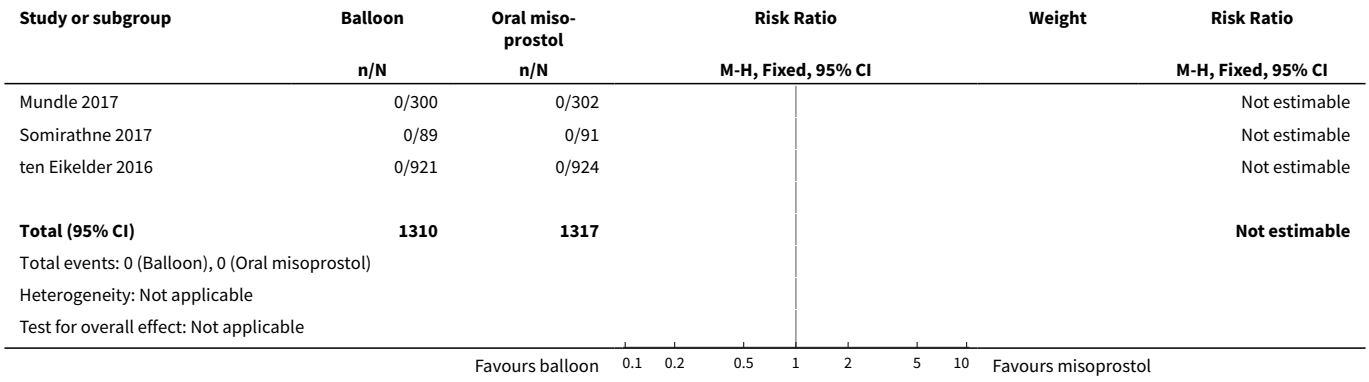
Analysis 9.19. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 19 Maternal diarrhoea.



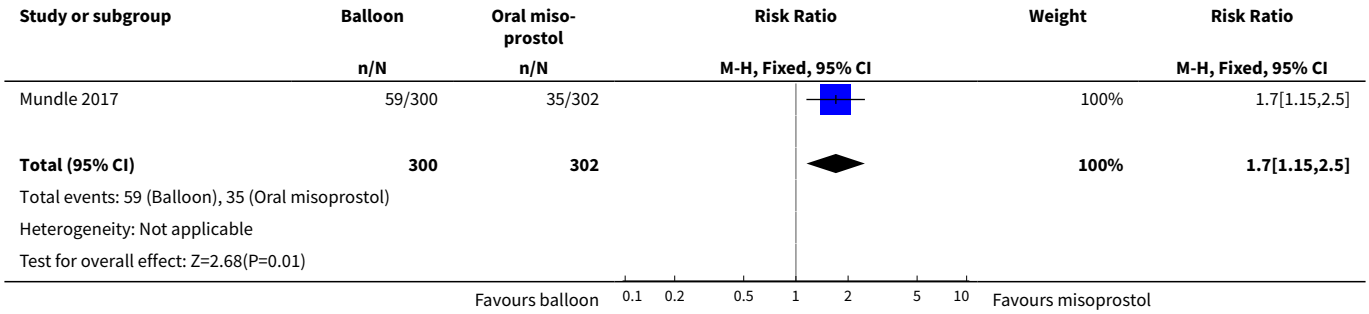
Analysis 9.20. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 20 Postpartum haemorrhage.



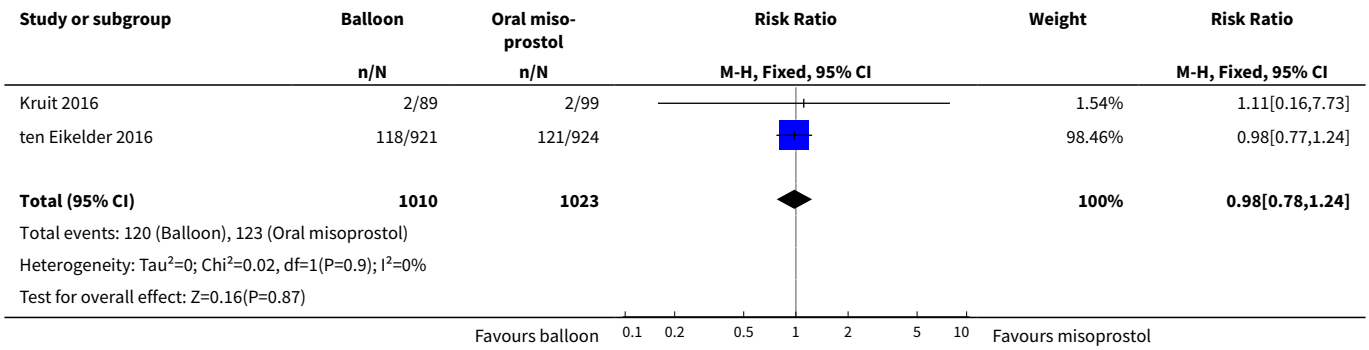
Analysis 9.21. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 21 Maternal death.



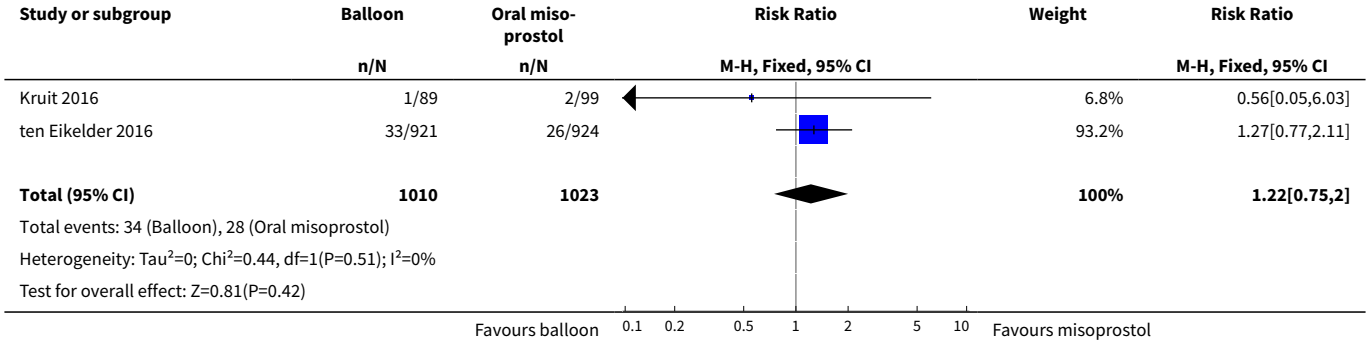
Analysis 9.22. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 22 Women not satisfied.



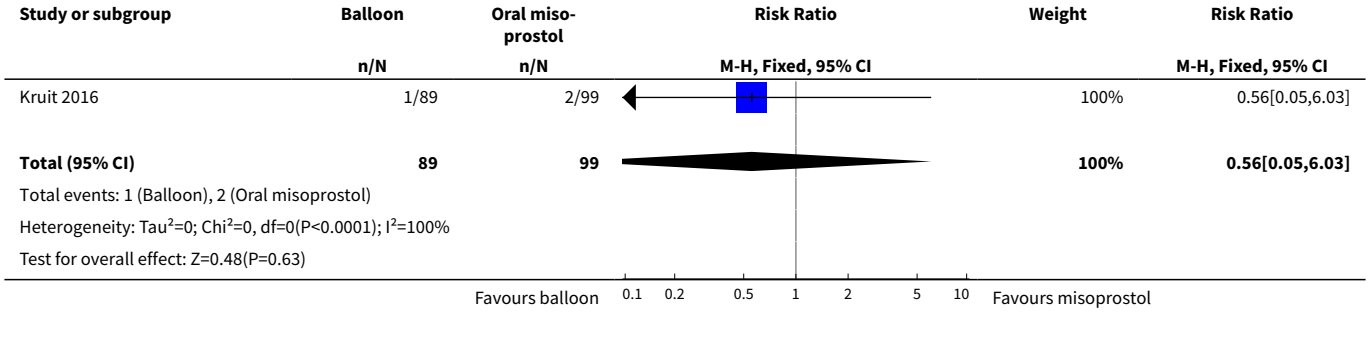
Analysis 9.23. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 23 Maternal fever during labour.



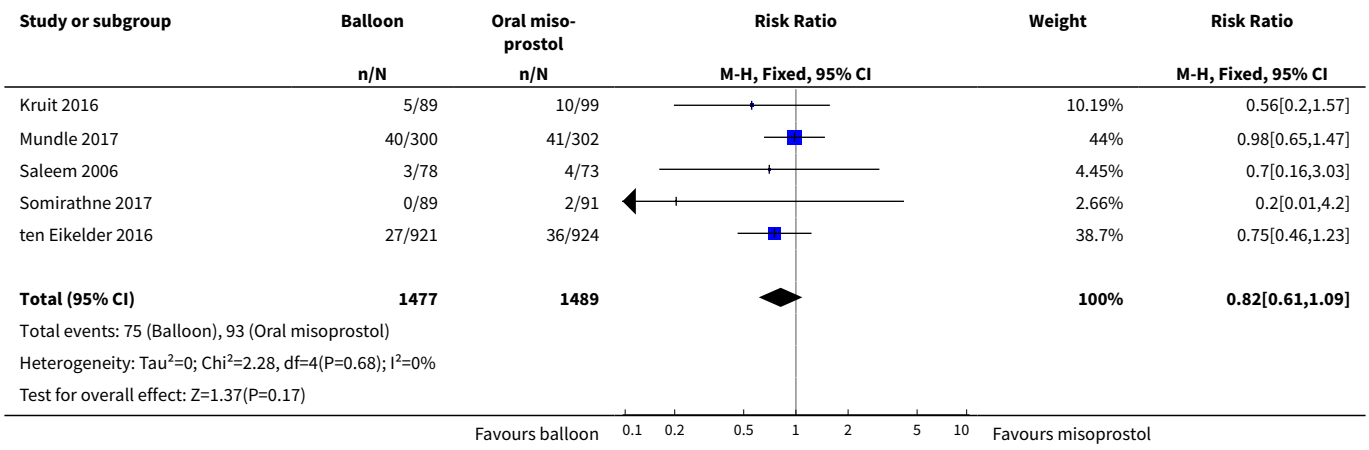
Analysis 9.24. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 24 Antibiotics during labour.



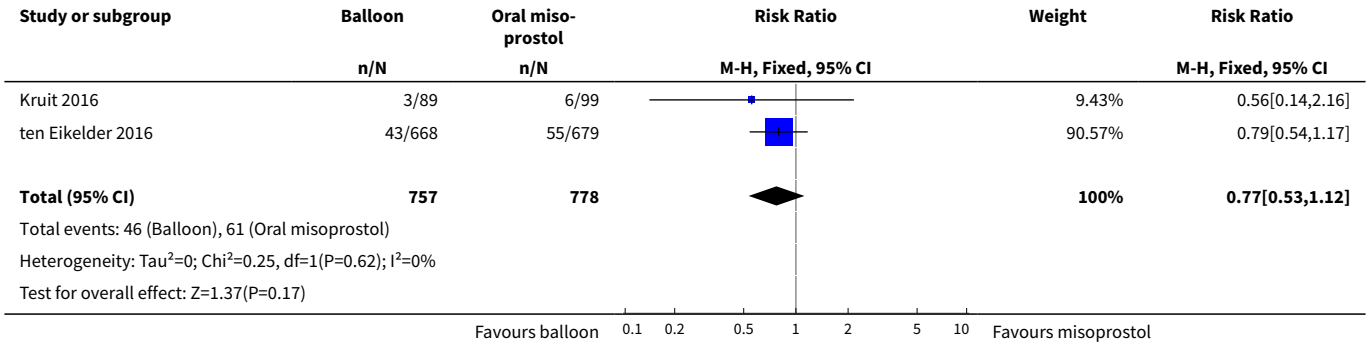
Analysis 9.25. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 25 Endometritis.



Analysis 9.26. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 26 Fetal distress.



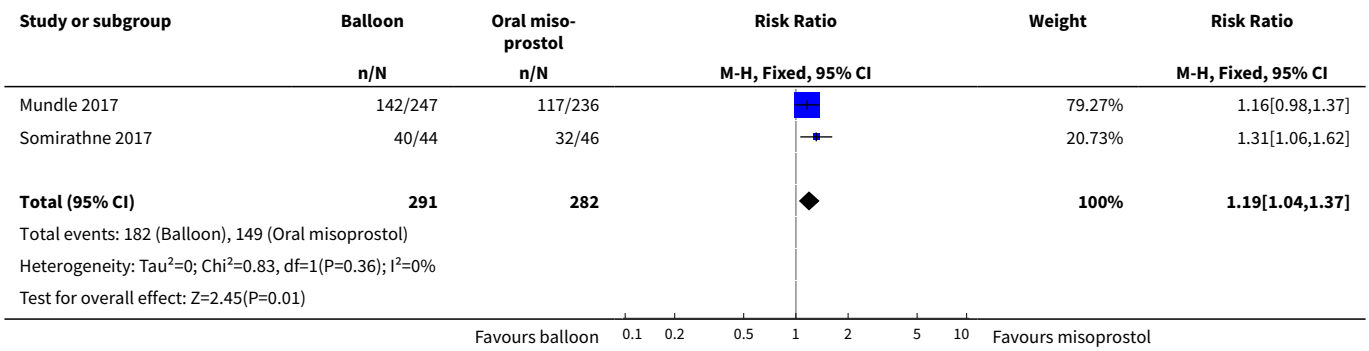
Analysis 9.27. Comparison 9 Balloon (Foley or ATAD) versus low dose oral misoprostol: all women, Outcome 27 Umbilical artery pH < 7.10.



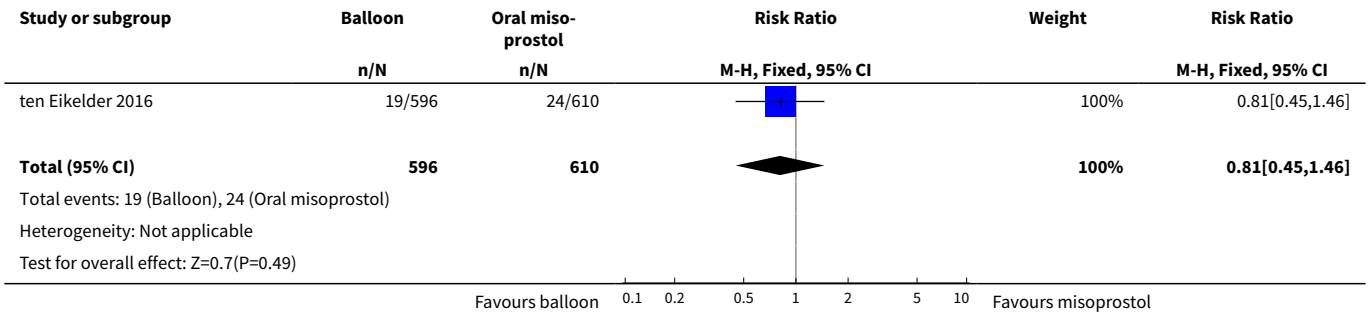
Comparison 10. Balloon (Foley or ATAD) versus low dose oral misoprostol: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	2	573	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [1.04, 1.37]
2 Uterine hyperstimulation with FHR changes	1	1206	Risk Ratio (M-H, Fixed, 95% CI)	0.81 [0.45, 1.46]
3 Caesarean section	3	1778	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [1.06, 1.38]
4 Serious neonatal morbidity/perinatal death	2	1296	Risk Ratio (M-H, Fixed, 95% CI)	4.49 [0.77, 26.14]
5 Serious maternal morbidity or death	2	1296	Risk Ratio (M-H, Fixed, 95% CI)	0.51 [0.05, 5.63]

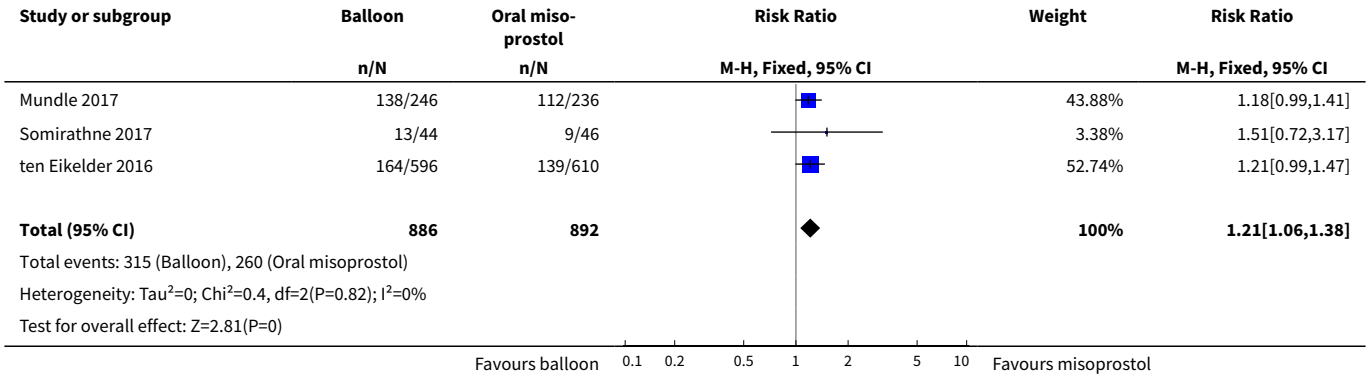
Analysis 10.1. Comparison 10 Balloon (Foley or ATAD) versus low dose oral misoprostol: all primiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



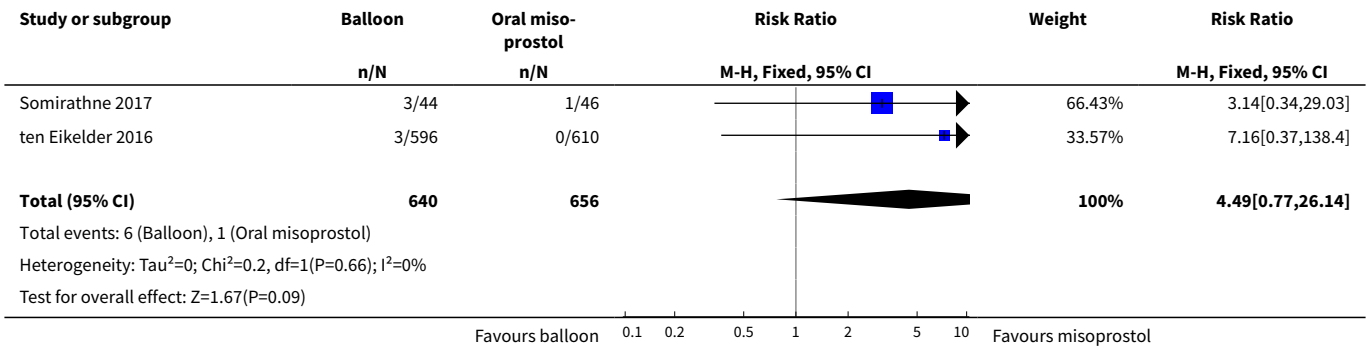
Analysis 10.2. Comparison 10 Balloon (Foley or ATAD) versus low dose oral misoprostol: all primiparae, Outcome 2 Uterine hyperstimulation with FHR changes.



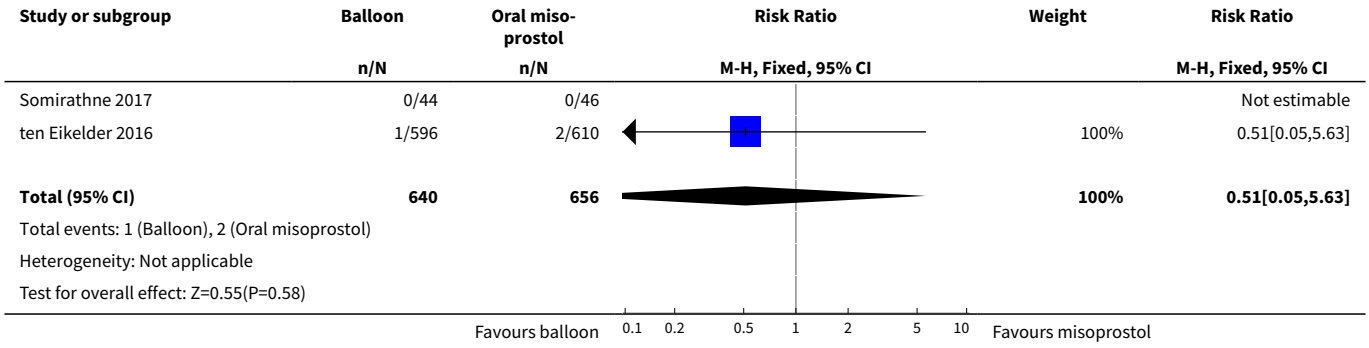
Analysis 10.3. Comparison 10 Balloon (Foley or ATAD) versus low dose oral misoprostol: all primiparae, Outcome 3 Caesarean section.



Analysis 10.4. Comparison 10 Balloon (Foley or ATAD) versus low dose oral misoprostol: all primiparae, Outcome 4 Serious neonatal morbidity/perinatal death.



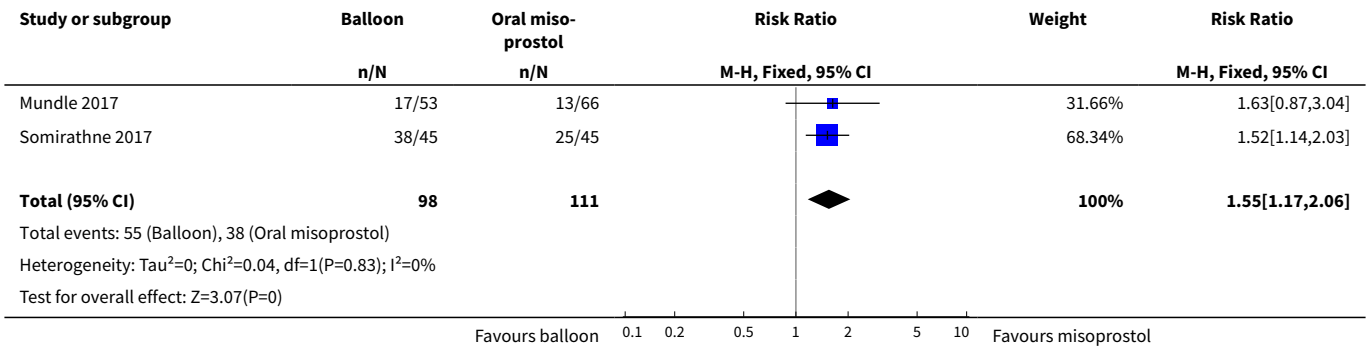
Analysis 10.5. Comparison 10 Balloon (Foley or ATAD) versus low dose oral misoprostol: all primiparae, Outcome 5 Serious maternal morbidity or death.



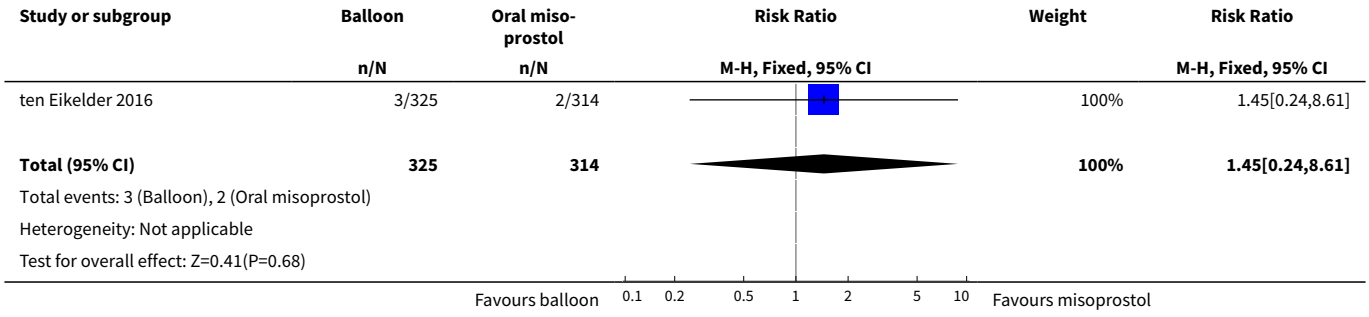
Comparison 11. Balloon (Foley or ATAD) versus low dose oral misoprostol: all multiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	2	209	Risk Ratio (M-H, Fixed, 95% CI)	1.55 [1.17, 2.06]
2 Uterine hyperstimulation with FHR changes	1	639	Risk Ratio (M-H, Fixed, 95% CI)	1.45 [0.24, 8.61]
3 Caesarean section	3	848	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.79, 1.87]
4 Serious neonatal morbidity/perinatal death	2	729	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.14, 6.86]
5 Serious maternal morbidity or death	2	729	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

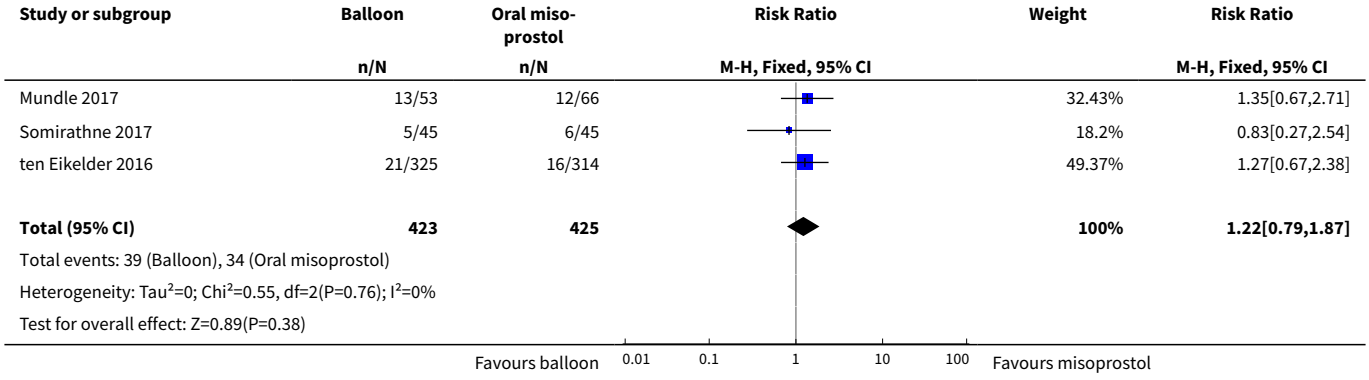
Analysis 11.1. Comparison 11 Balloon (Foley or ATAD) versus low dose oral misoprostol: all multiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



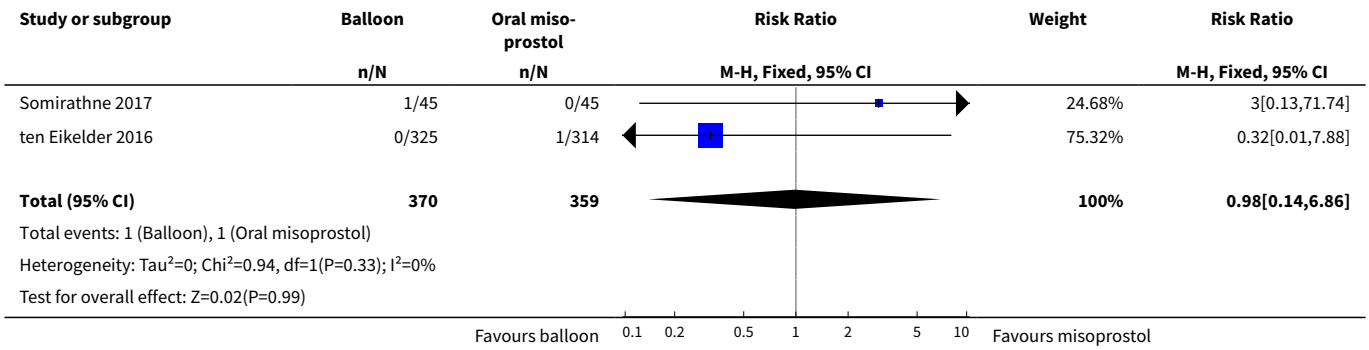
Analysis 11.2. Comparison 11 Balloon (Foley or ATAD) versus low dose oral misoprostol: all multiparae, Outcome 2 Uterine hyperstimulation with FHR changes.



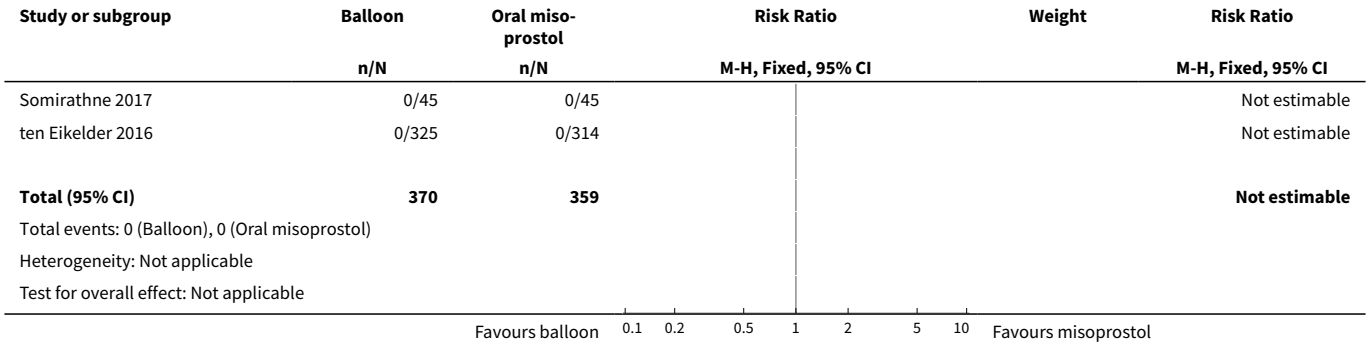
Analysis 11.3. Comparison 11 Balloon (Foley or ATAD) versus low dose oral misoprostol: all multiparae, Outcome 3 Caesarean section.



Analysis 11.4. Comparison 11 Balloon (Foley or ATAD) versus low dose oral misoprostol: all multiparae, Outcome 4 Serious neonatal morbidity/perinatal death.



Analysis 11.5. Comparison 11 Balloon (Foley or ATAD) versus low dose oral misoprostol: all multiparae, Outcome 5 Serious maternal morbidity or death.



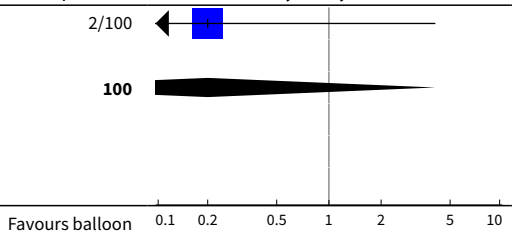
Comparison 12. Balloon (Foley or ATAD) versus oxytocin: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Uterine hyperstimulation with FHR changes	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.2 [0.01, 4.11]
2 Caesarean section	8	781	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.56, 0.83]
3 Serious neonatal morbidity/perinatal death	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Serious maternal morbidity or death	2	160	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Cervix unfavourable after 24 hours	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.20, 1.54]
6 Uterine hyperstimulation without FHR changes	3	192	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.23, 4.29]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7 Uterine rupture	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Instrumental vaginal delivery	3	220	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.55, 2.57]
9 Meconium-stained liquor	2	272	Risk Ratio (M-H, Fixed, 95% CI)	0.53 [0.23, 1.21]
10 Apgar score < 7 at 5 minutes	2	300	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.14, 3.53]
11 Neonatal intensive care unit admission	3	372	Risk Ratio (M-H, Fixed, 95% CI)	0.8 [0.32, 1.98]
12 Perinatal death	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Hemorrhagia postpartum	4	396	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [0.51, 3.11]
14 Maternal fever during labour	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.2 [0.01, 4.00]
15 Fetal distress	3	332	Risk Ratio (M-H, Fixed, 95% CI)	0.43 [0.19, 0.98]

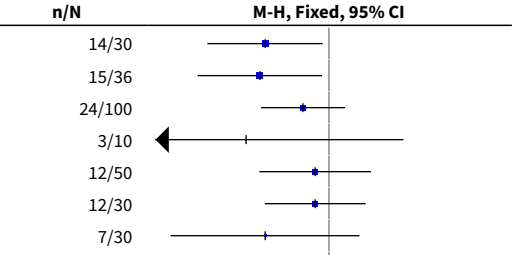
Analysis 12.1. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 1 Uterine hyperstimulation with FHR changes.

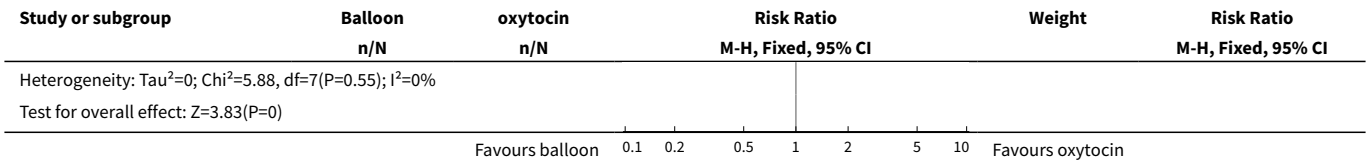
Study or subgroup	Balloon n/N	oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Gelisen 2005	0/100	2/100		100%	0.2[0.01,4.11]
Total (95% CI)	**100**	**100**		**100%**	**0.2[0.01,4.11]**
Total events: 0 (Balloon), 2 (oxytocin)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.04(P=0.3)					



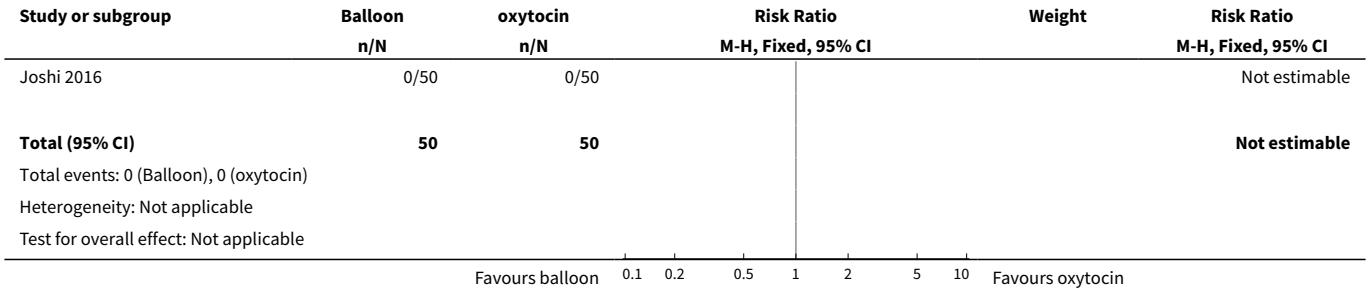
Analysis 12.2. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 2 Caesarean section.

Study or subgroup	Balloon n/N	oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Atad 1996	7/35	14/30		9.89%	0.43[0.2,0.92]
El Khouly 2017	6/36	15/36		9.84%	0.4[0.18,0.91]
Gelisen 2005	17/100	24/100		15.74%	0.71[0.41,1.24]
Jagani 1982	1/10	3/10		1.97%	0.33[0.04,2.69]
Joshi 2016	10/50	12/50		7.87%	0.83[0.4,1.75]
Meetei 2015	10/30	12/30		7.87%	0.83[0.43,1.63]
Orhue 1995	3/30	7/30		4.59%	0.43[0.12,1.5]
Sarreau 2016	50/101	65/103		42.22%	0.78[0.61,1]
Total (95% CI)	**392**	**389**		**100%**	**0.68[0.56,0.83]**
Total events: 104 (Balloon), 152 (oxytocin)					

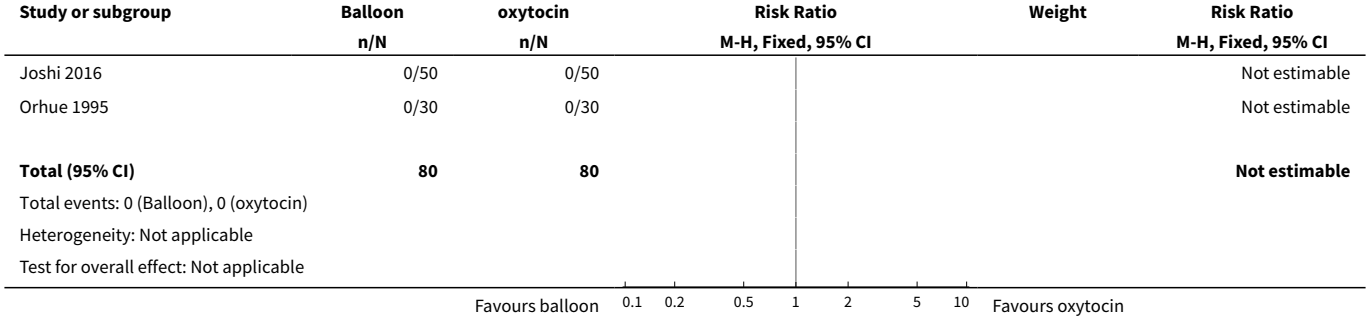




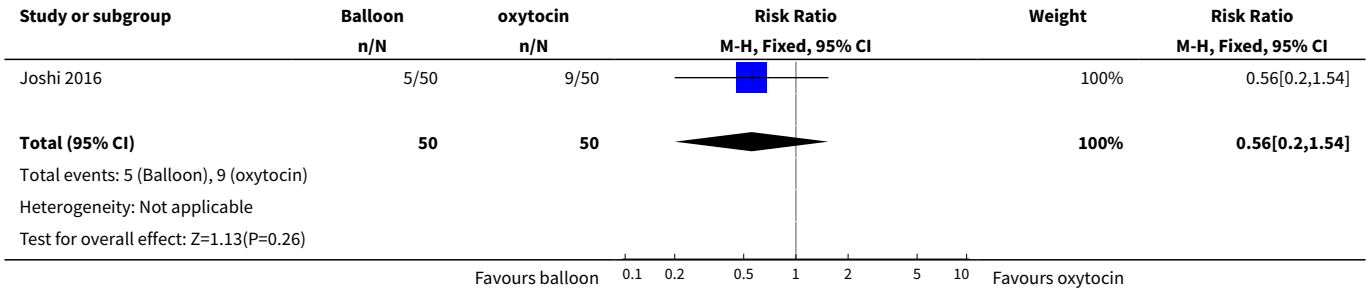
Analysis 12.3. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 3 Serious neonatal morbidity/perinatal death.



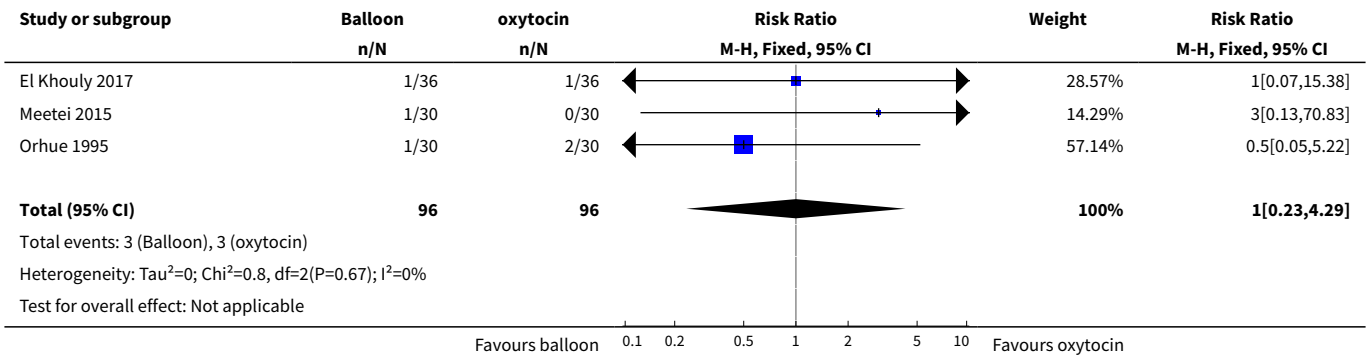
Analysis 12.4. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 4 Serious maternal morbidity or death.



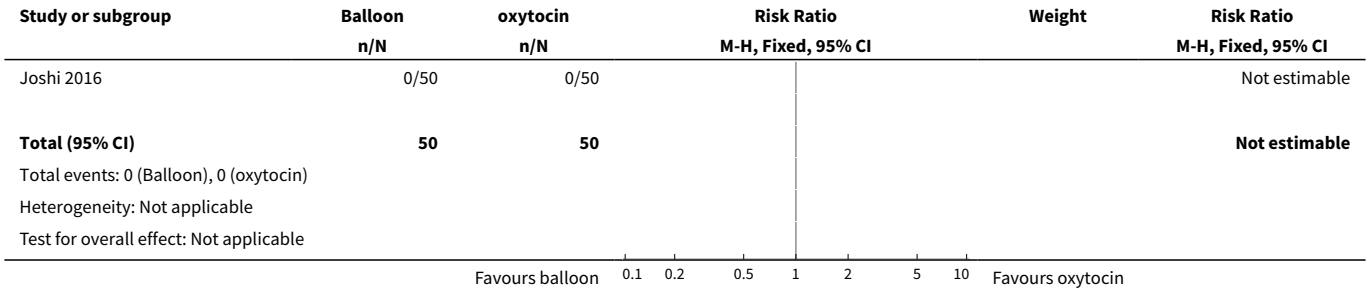
Analysis 12.5. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 5 Cervix unfavourable after 24 hours.



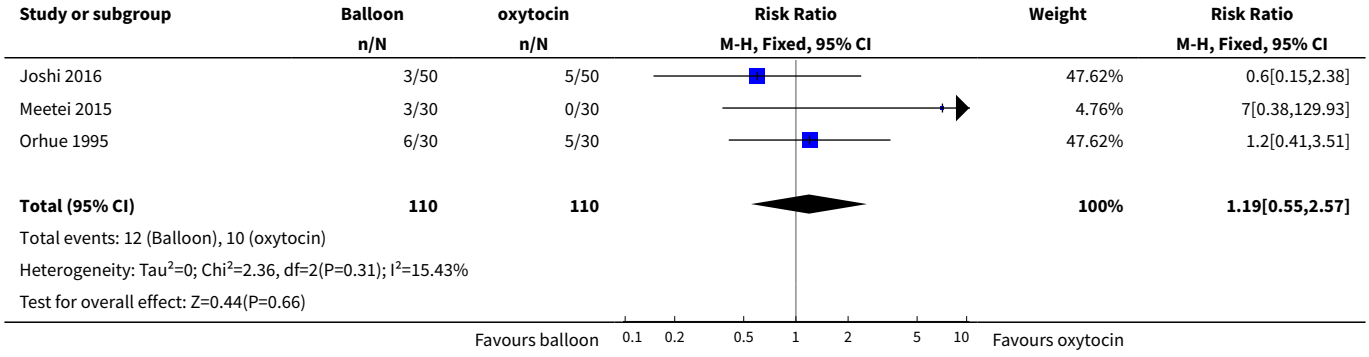
Analysis 12.6. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 6 Uterine hyperstimulation without FHR changes.



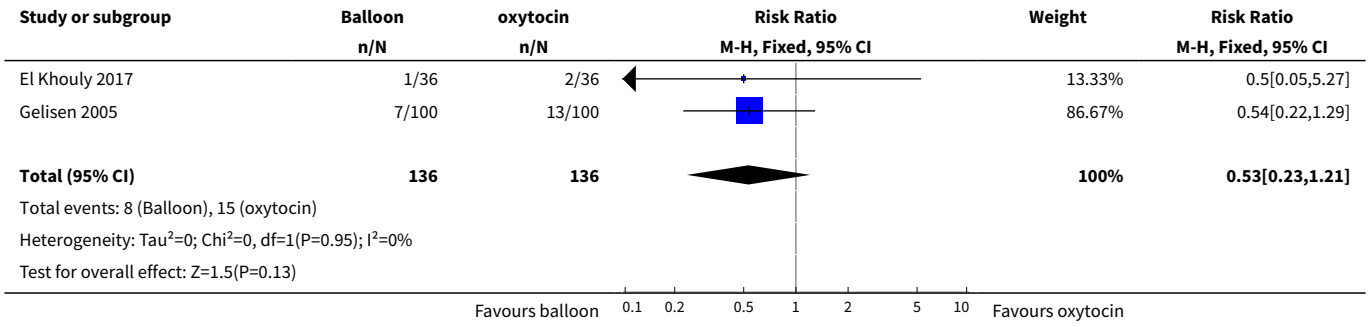
Analysis 12.7. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 7 Uterine rupture.



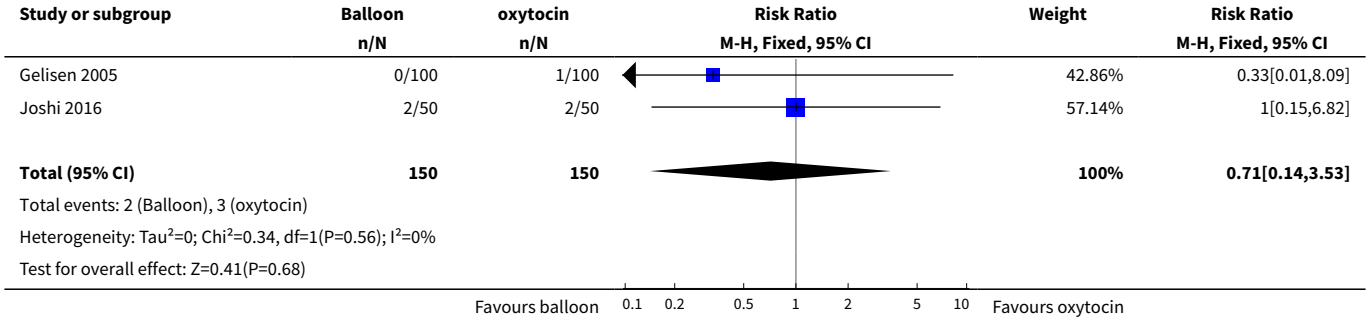
Analysis 12.8. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 8 Instrumental vaginal delivery.



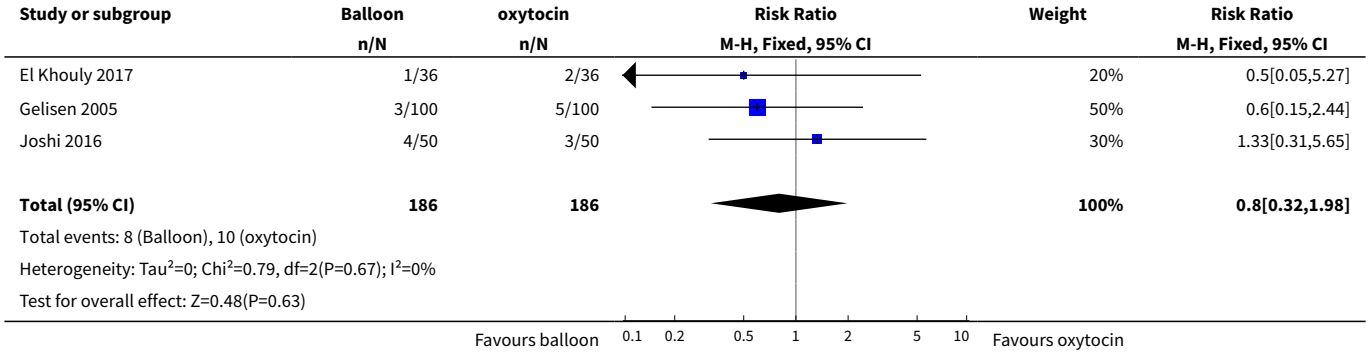
Analysis 12.9. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 9 Meconium-stained liquor.



Analysis 12.10. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 10 Apgar score < 7 at 5 minutes.



Analysis 12.11. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 11 Neonatal intensive care unit admission.

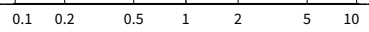


Analysis 12.12. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 12 Perinatal death.

Study or subgroup	Balloon n/N	oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Joshi 2016	0/50	0/50			Not estimable
Total (95% CI)	**50**	**50**			**Not estimable**
Total events: 0 (Balloon), 0 (oxytocin)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

Analysis 12.13. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 13 Hemorrhagia postpartum.

Study or subgroup	Balloon n/N	oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
El Khouly 2017	0/36	2/36		31.33%	0.2[0.01,4.03]
Meetei 2015	1/30	0/30		6.27%	3[0.13,70.83]
Orhue 1995	3/30	3/30		37.59%	1[0.22,4.56]
Sarreau 2016	5/101	2/103		24.82%	2.55[0.51,12.84]
Total (95% CI)	**197**	**199**		**100%**	**1.26[0.51,3.11]**
Total events: 9 (Balloon), 7 (oxytocin)					
Heterogeneity: Tau^2=0; Chi^2=2.55, df=3(P=0.47); I^2=0%					
Test for overall effect: Z=0.5(P=0.62)					

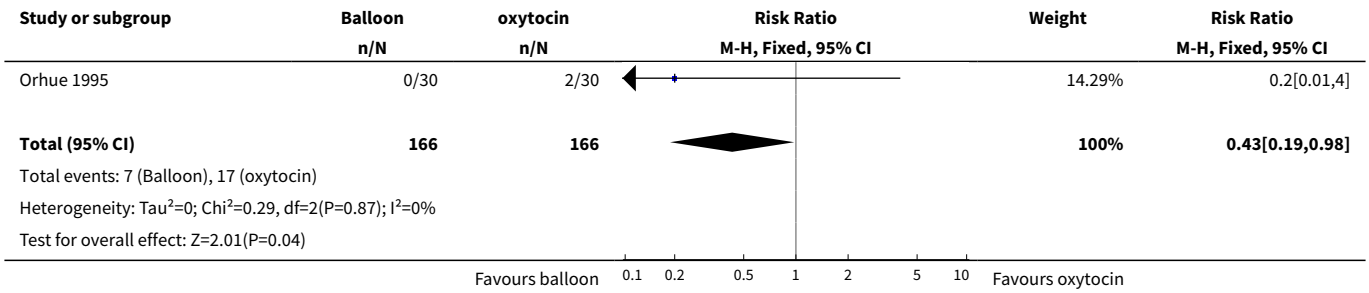


Analysis 12.14. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 14 Maternal fever during labour.

Study or subgroup	Balloon n/N	oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Meetei 2015	0/30	2/30		100%	0.2[0.01,4]
Total (95% CI)	**30**	**30**		**100%**	**0.2[0.01,4]**
Total events: 0 (Balloon), 2 (oxytocin)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.05(P=0.29)					

Analysis 12.15. Comparison 12 Balloon (Foley or ATAD) versus oxytocin: all women, Outcome 15 Fetal distress.

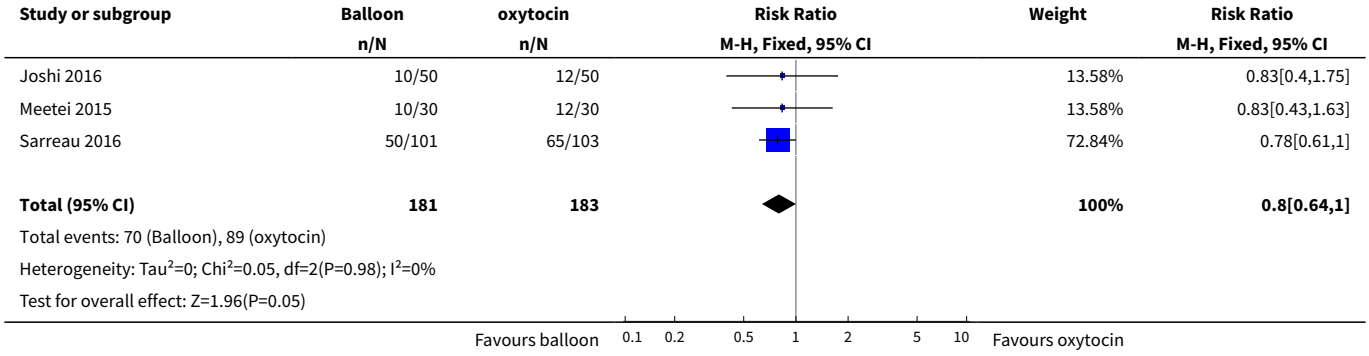
Study or subgroup	Balloon n/N	oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
El Khouly 2017	1/36	2/36		11.43%	0.5[0.05,5.27]
Gelisen 2005	6/100	13/100		74.29%	0.46[0.18,1.17]



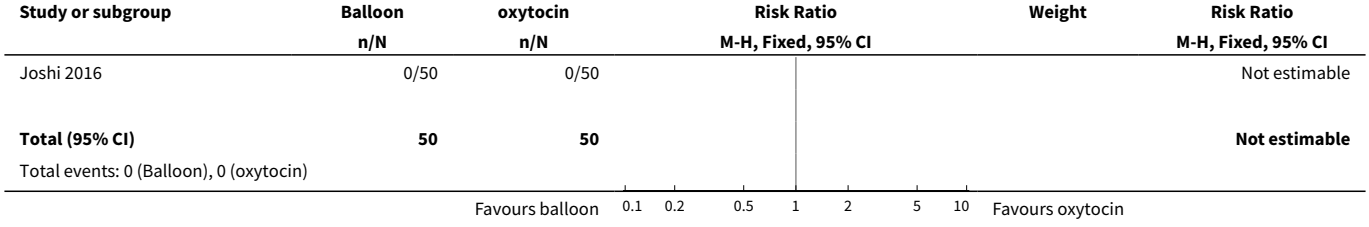
Comparison 13. Balloon (Foley or ATAD) versus oxytocin: previous caesarean section

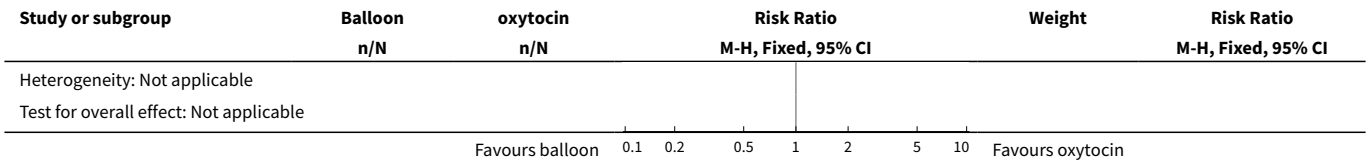
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	3	364	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.64, 1.00]
2 Serious neonatal morbidity/perinatal death	1	100	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Serious maternal morbidity or death	1	100	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Analysis 13.1. Comparison 13 Balloon (Foley or ATAD) versus oxytocin: previous caesarean section, Outcome 1 Caesarean section.

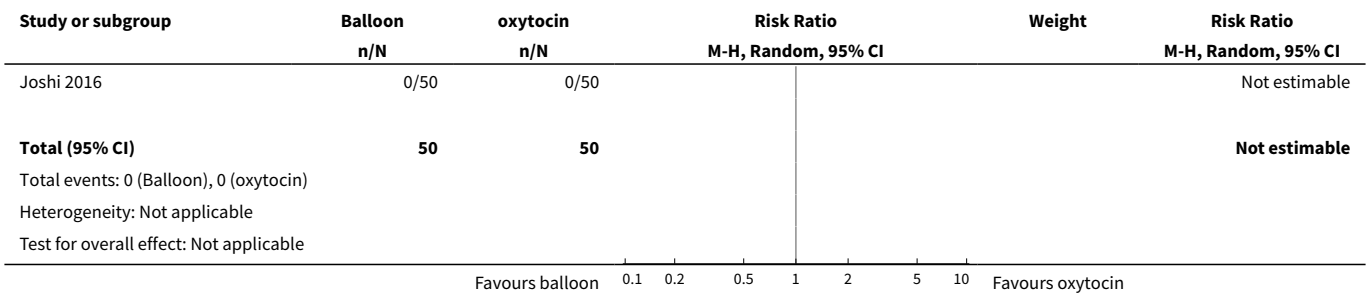


Analysis 13.2. Comparison 13 Balloon (Foley or ATAD) versus oxytocin: previous caesarean section, Outcome 2 Serious neonatal morbidity/perinatal death.





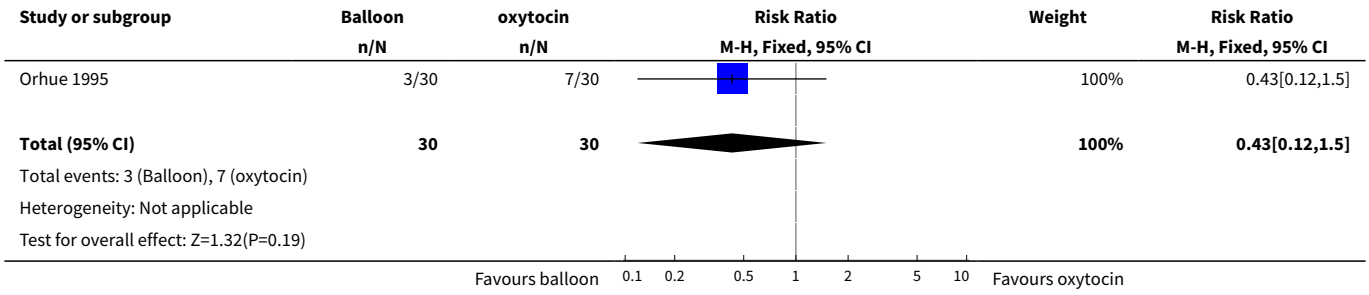
Analysis 13.3. Comparison 13 Balloon (Foley or ATAD) versus oxytocin: previous caesarean section, Outcome 3 Serious maternal morbidity or death.



Comparison 14. Balloon (Foley or ATAD) versus oxytocin: all primiparae

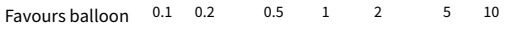
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.43 [0.12, 1.50]
2 Serious maternal morbidity or death	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 14.1. Comparison 14 Balloon (Foley or ATAD) versus oxytocin: all primiparae, Outcome 1 Caesarean section.



Analysis 14.2. Comparison 14 Balloon (Foley or ATAD) versus oxytocin: all primiparae, Outcome 2 Serious maternal morbidity or death.

Study or subgroup	Balloon n/N	oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Orhue 1995	0/30	0/30			Not estimable
Total (95% CI)	**30**	**30**			**Not estimable**
Total events: 0 (Balloon), 0 (oxytocin)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



Comparison 15. Balloon (foley or ATAD) versus amniotomy: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	20	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.03, 1.86]

Analysis 15.1. Comparison 15 Balloon (foley or ATAD) versus amniotomy: all women, Outcome 1 Caesarean section.

Study or subgroup	Balloon n/N	Amniotomy n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Jagani 1982	1/10	4/10		100%	0.25[0.03,1.86]
Total (95% CI)	**10**	**10**		**100%**	**0.25[0.03,1.86]**
Total events: 1 (Balloon), 4 (Amniotomy)					
Heterogeneity: Not applicable					
Test for overall effect: Z=1.35(P=0.18)					

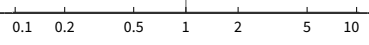
Comparison 16. Single balloon (Foley) versus double balloon (ATAD/Cook): all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	3	608	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.75, 1.25]
2 Uterine hyperstimulation with FHR changes	1	217	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Caesarean section	5	862	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.71, 1.33]
4 Serious maternal morbidity or death	1	217	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Oxytcocin augmentation	2	278	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.82, 1.08]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Uterine hyperstimulation without FHR changes	1	217	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Uterine rupture	1	217	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Epidural analgesia	3	608	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.83, 1.03]
9 Instrumental vaginal delivery	3	690	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.61, 1.20]
10 Meconium-stained liquor	1	98	Risk Ratio (M-H, Fixed, 95% CI)	0.40 [0.15, 1.04]
11 Apgar score < 7 at 5 minutes	3	608	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.25, 2.79]
12 Neonatal intensive care unit admission	2	391	Risk Ratio (M-H, Fixed, 95% CI)	1.67 [0.71, 3.93]
13 Other maternal side-effects: pain after insertion	1	74	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.20, 2.17]
14 Postpartum haemorrhage	2	291	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.27, 2.52]
15 Maternal fever during labour	3	584	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.16, 2.34]
16 Antibiotics during labour	1	217	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.61, 1.56]
17 Chorioamnionitis	1	98	Risk Ratio (M-H, Fixed, 95% CI)	1.56 [0.47, 5.20]
18 Endometritis	1	217	Risk Ratio (M-H, Fixed, 95% CI)	1.95 [0.18, 21.14]
19 Fetal distress	4	682	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.70, 1.36]
20 Umbilical artery pH < 7.10	1	217	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.11, 1.57]

Analysis 16.1. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 1 Vaginal delivery not achieved in 24 hours.

Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Hoppe 2016	40/48	35/50		37.64%	1.19[0.95,1.49]
Pennell 2009	57/110	67/107		36.59%	0.83[0.66,1.04]
Salim 2011	40/145	45/148		25.77%	0.91[0.63,1.3]
Total (95% CI)	**303**	**305**		**100%**	**0.97[0.75,1.25]**
Total events: 137 (Single balloon), 147 (Double balloon)					
Heterogeneity: Tau^2=0.03; Chi^2=5.64, df=2(P=0.06); I^2=64.54%					
Test for overall effect: Z=0.22(P=0.83)					



Analysis 16.2. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 2 Uterine hyperstimulation with FHR changes.

Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Pennell 2009	0/110	0/107			Not estimable
Total (95% CI)	**110**	**107**			**Not estimable**
Total events: 0 (Single balloon), 0 (Double balloon)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

Favours single balloon — Favours double balloon

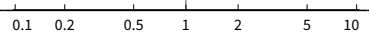
Analysis 16.3. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 3 Caesarean section.

Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Ahmed 2016	11/37	8/37		12.11%	1.38[0.62,3.03]
Haugland 2012	18/90	19/90		18.64%	0.95[0.53,1.68]
Hoppe 2016	21/48	14/50		19.73%	1.56[0.9,2.7]
Pennell 2009	40/110	46/107		31.58%	0.85[0.61,1.18]
Salim 2011	15/145	26/148		17.94%	0.59[0.33,1.07]
Total (95% CI)	**430**	**432**		**100%**	**0.97[0.71,1.33]**
Total events: 105 (Single balloon), 113 (Double balloon)					
Heterogeneity: Tau^2=0.05; Chi^2=6.99, df=4(P=0.14); I^2=42.81%					
Test for overall effect: Z=0.19(P=0.85)					

Favours single balloon — Favours double balloon

Analysis 16.4. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 4 Serious maternal morbidity or death.

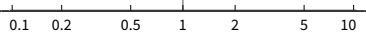
Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Pennell 2009	0/110	0/107			Not estimable
Total (95% CI)	**110**	**107**			**Not estimable**
Total events: 0 (Single balloon), 0 (Double balloon)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



Favours single balloon — Favours double balloon

Analysis 16.5. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 5 Oxytcocin augmentation.

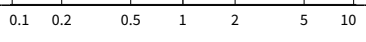
Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Haugland 2012	52/90	58/90		56.28%	0.9[0.71,1.13]
Hoppe 2016	44/48	46/50		43.72%	1[0.89,1.12]
Total (95% CI)	**138**	**140**		**100%**	**0.94[0.82,1.08]**
Total events: 96 (Single balloon), 104 (Double balloon)					
Heterogeneity: Tau^2=0; Chi^2=1.09, df=1(P=0.3); I^2=7.89%					
Test for overall effect: Z=0.87(P=0.39)					



Favours single balloon — Favours double balloon

Analysis 16.6. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 6 Uterine hyperstimulation without FHR changes.

Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Pennell 2009	0/110	0/107			Not estimable
Total (95% CI)	**110**	**107**			**Not estimable**
Total events: 0 (Single balloon), 0 (Double balloon)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



Favours single balloon — Favours double balloon

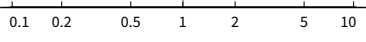
Analysis 16.7. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 7 Uterine rupture.

Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Pennell 2009	0/110	0/107			Not estimable
Total (95% CI)	**110**	**107**			**Not estimable**
Total events: 0 (Single balloon), 0 (Double balloon)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

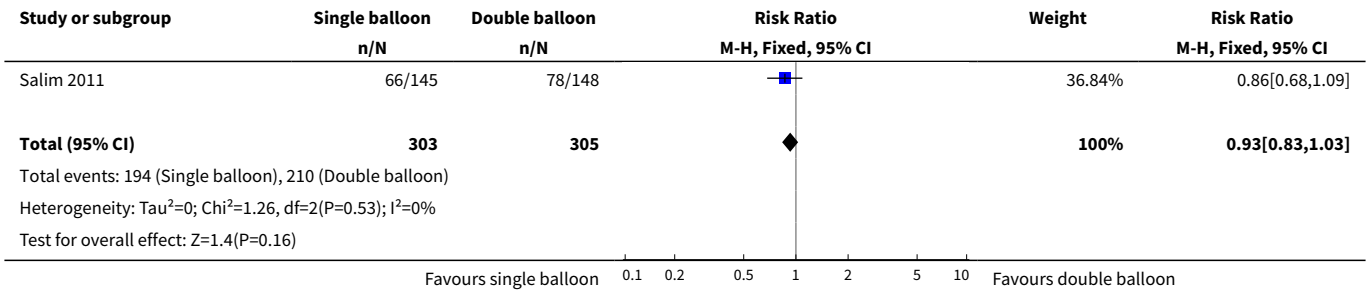
Favours single balloon — Favours double balloon

Analysis 16.8. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 8 Epidural analgesia.

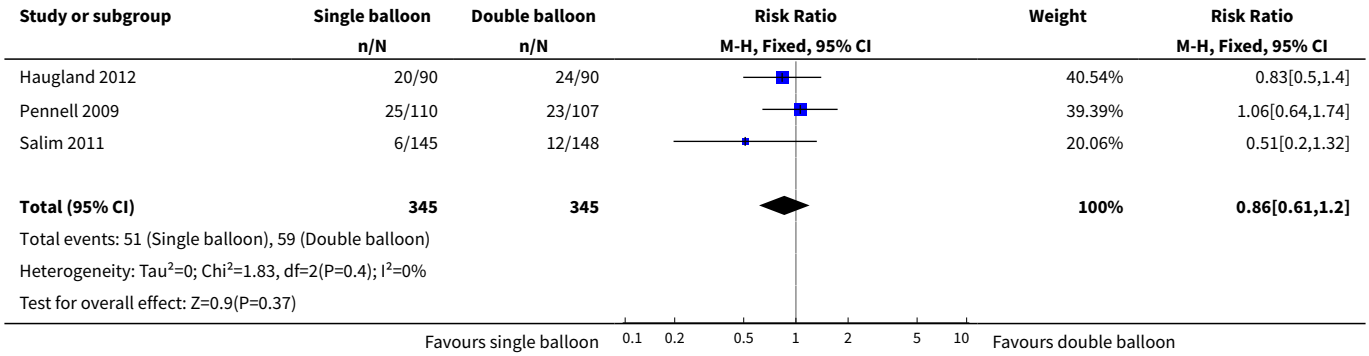
Study or subgroup	Single balloon n/N	Double balloon n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Hoppe 2016	38/48	43/50		20.1%	0.92[0.77,1.11]
Pennell 2009	90/110	89/107		43.06%	0.98[0.87,1.11]



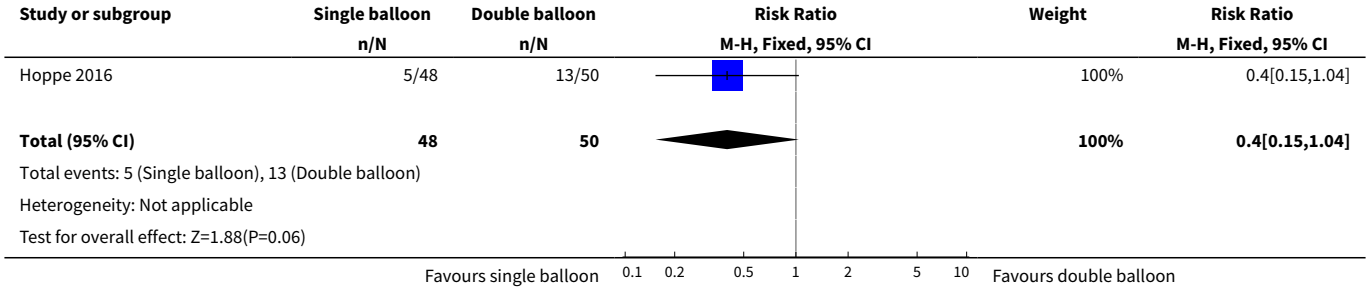
Favours single balloon — Favours double balloon



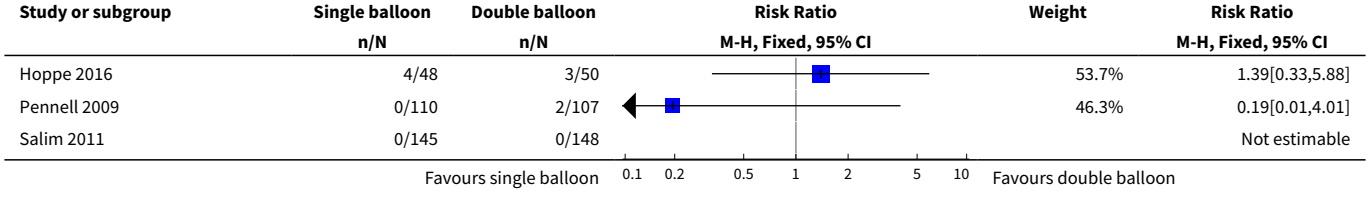
Analysis 16.9. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 9 Instrumental vaginal delivery.

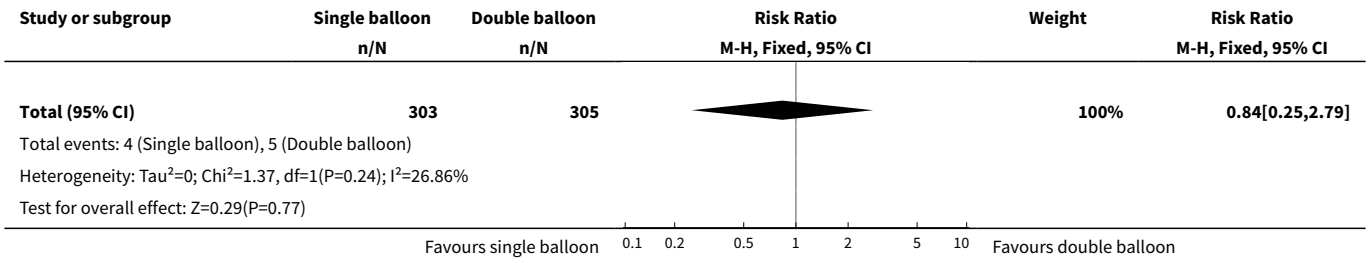


Analysis 16.10. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 10 Meconium-stained liquor.

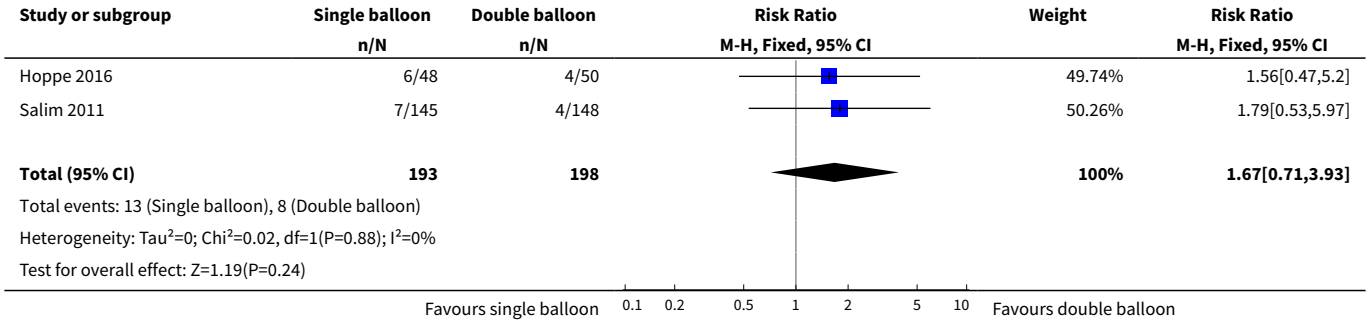


Analysis 16.11. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 11 Apgar score < 7 at 5 minutes.

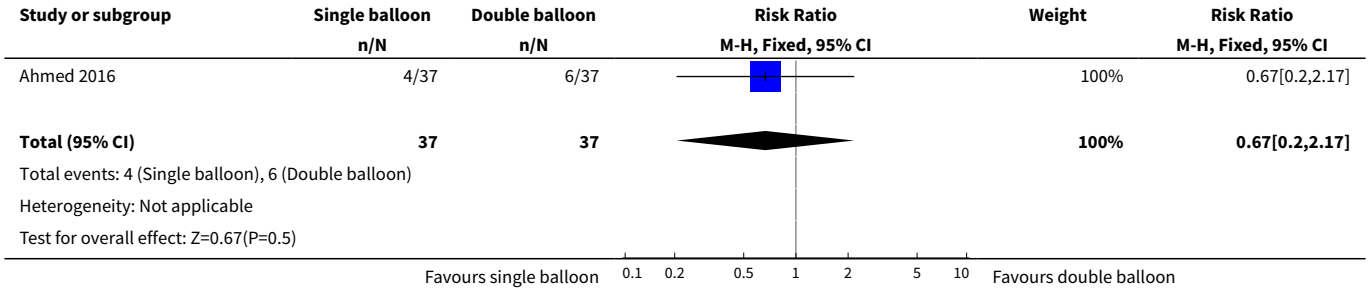




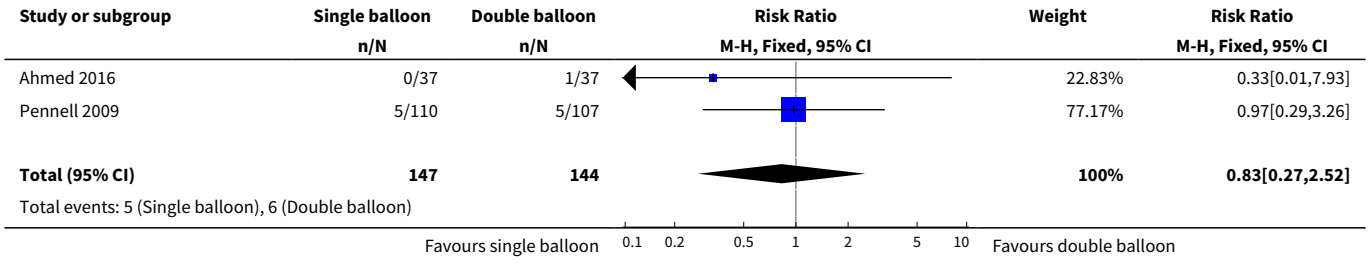
Analysis 16.12. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 12 Neonatal intensive care unit admission.

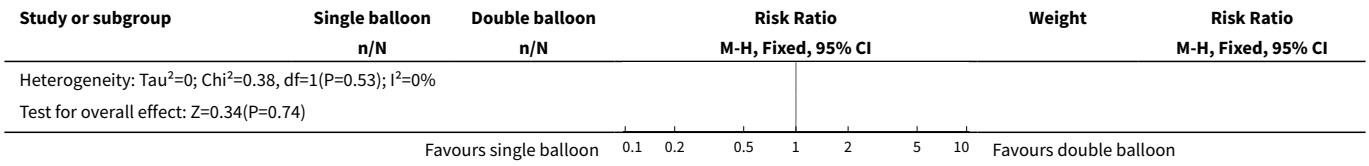


Analysis 16.13. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 13 Other maternal side-effects: pain after insertion.

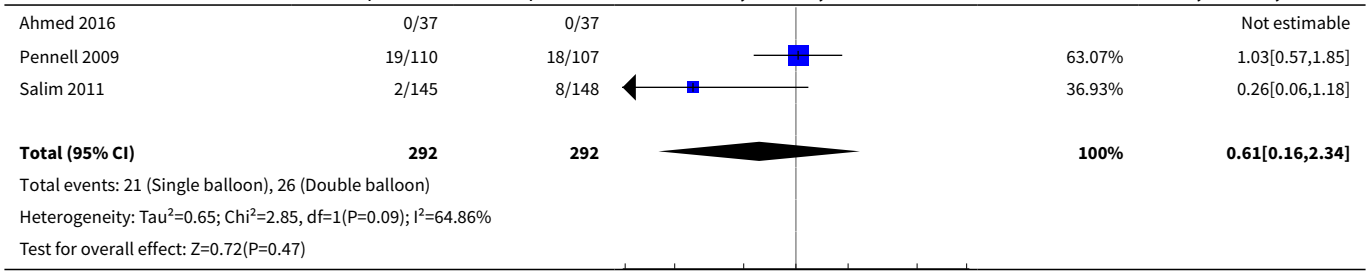


Analysis 16.14. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 14 Postpartum haemorrhage.

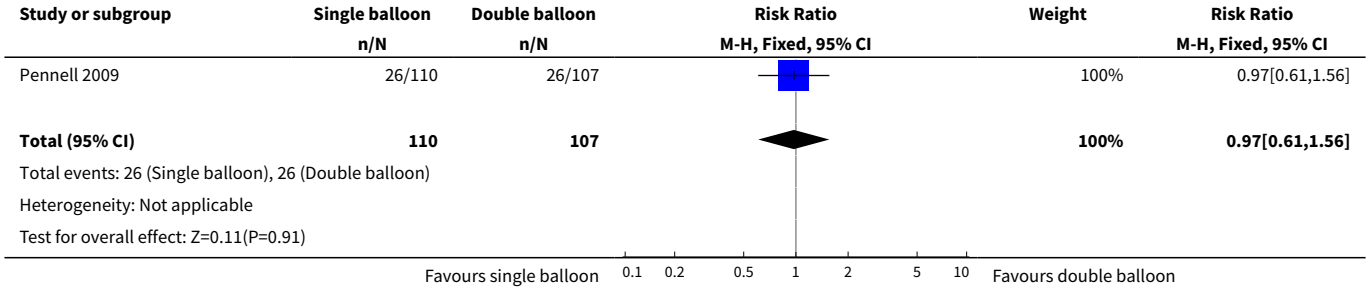




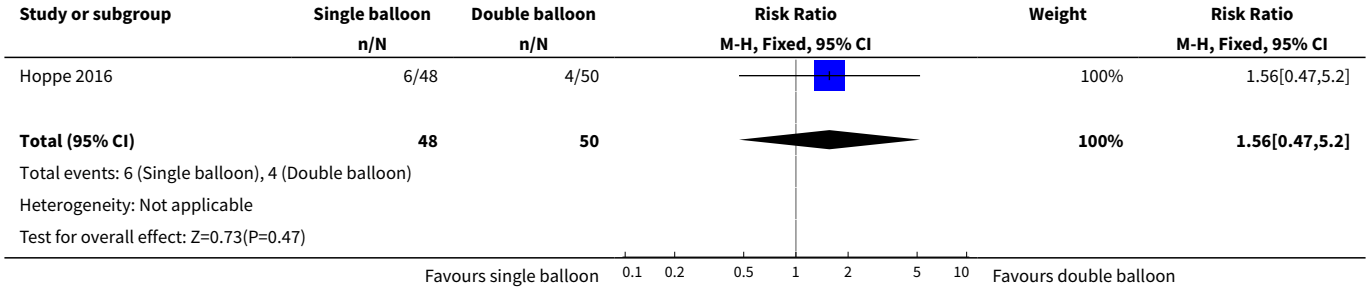
Analysis 16.15. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 15 Maternal fever during labour.



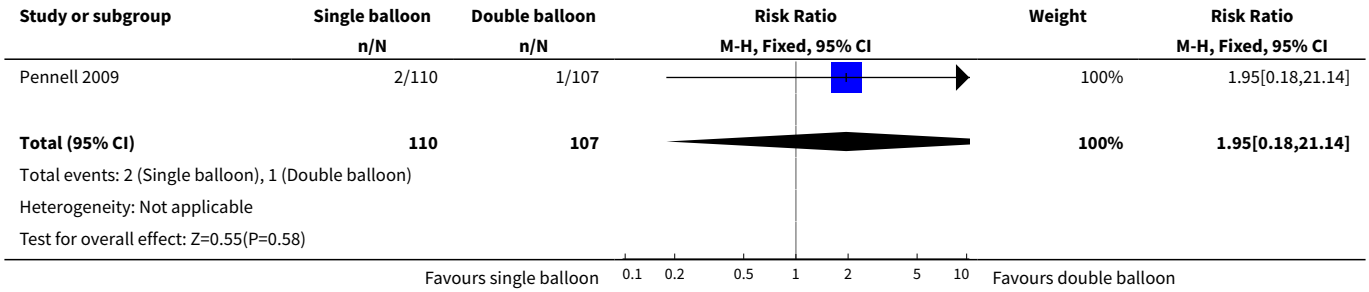
Analysis 16.16. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 16 Antibiotics during labour.



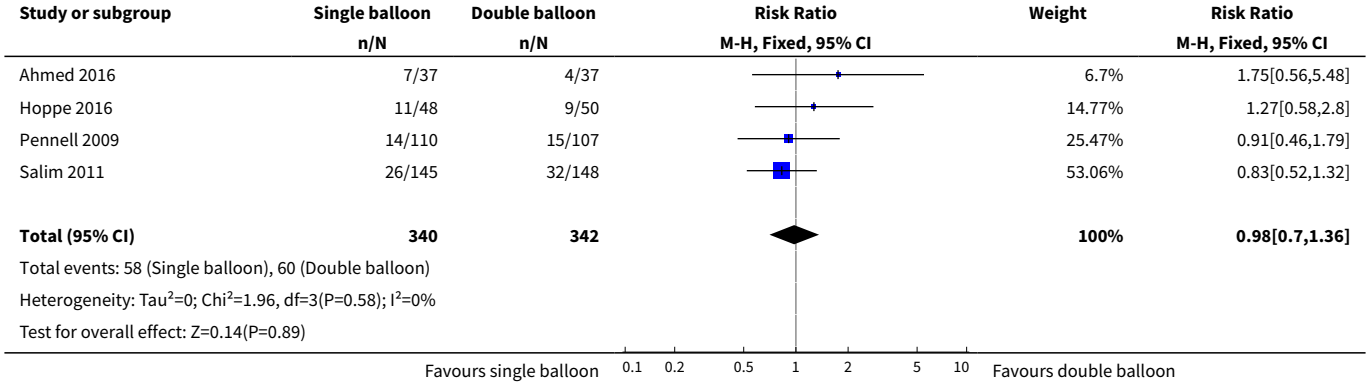
Analysis 16.17. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 17 Chorioamnionitis.



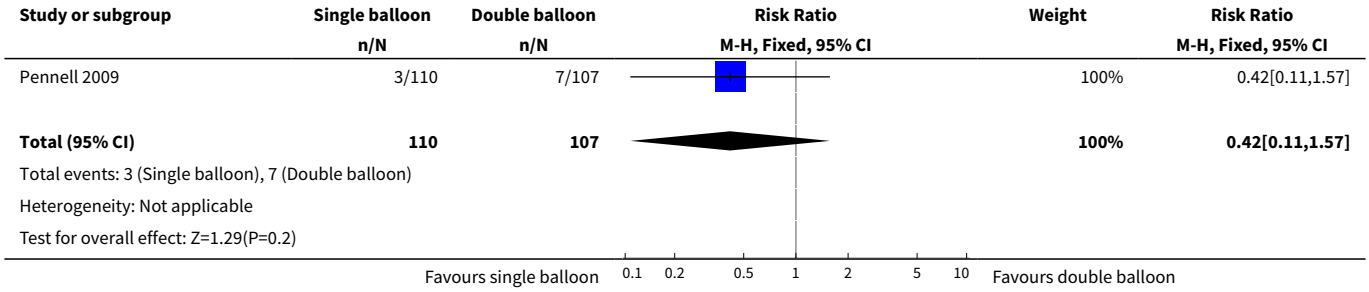
Analysis 16.18. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 18 Endometritis.



Analysis 16.19. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 19 Fetal distress.



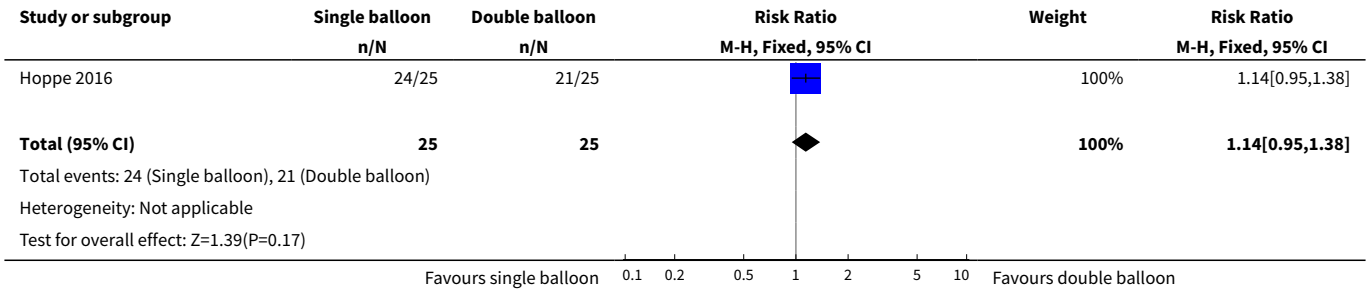
Analysis 16.20. Comparison 16 Single balloon (Foley) versus double balloon (ATAD/Cook): all women, Outcome 20 Umbilical artery pH < 7.10.



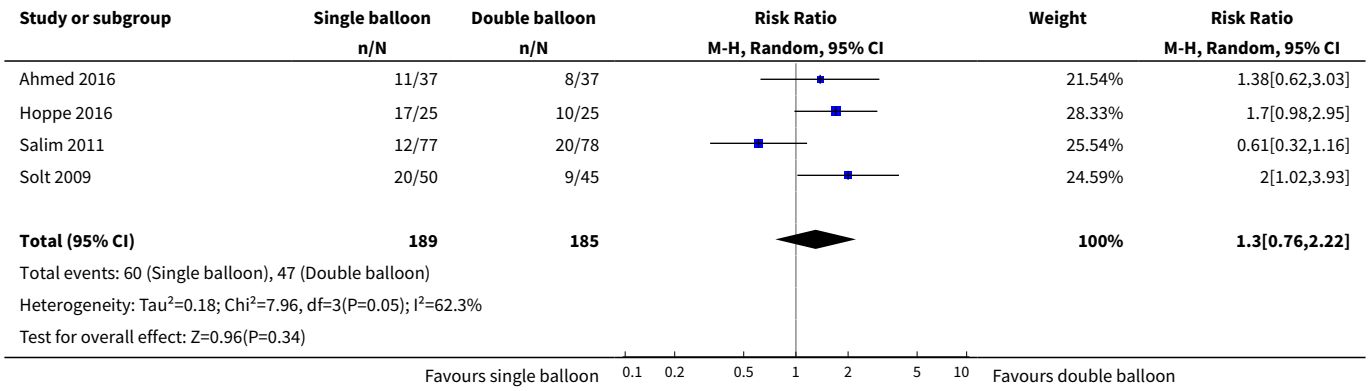
Comparison 17. Single balloon (Foley) versus double balloon (ATAD): all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	50	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.95, 1.38]
2 Caesarean section	4	374	Risk Ratio (M-H, Random, 95% CI)	1.30 [0.76, 2.22]

Analysis 17.1. Comparison 17 Single balloon (Foley) versus double balloon (ATAD): all primiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



Analysis 17.2. Comparison 17 Single balloon (Foley) versus double balloon (ATAD): all primiparae, Outcome 2 Caesarean section.

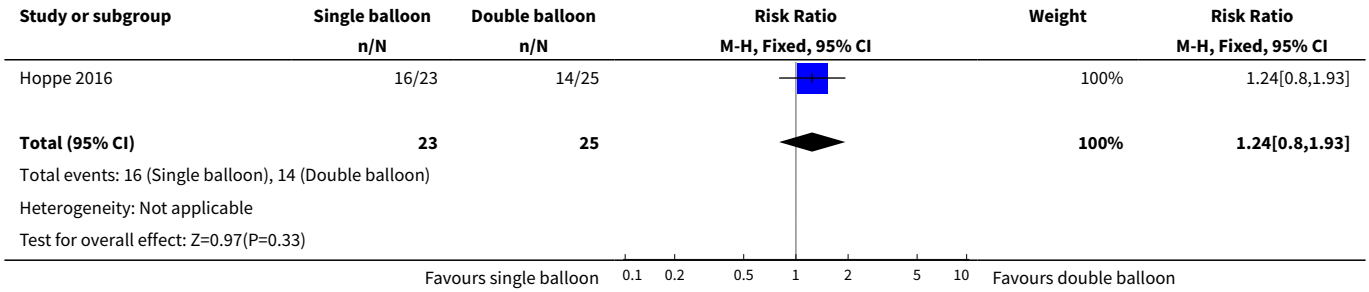


Comparison 18. Single balloon (Foley) versus double balloon (ATAD): all multiparae

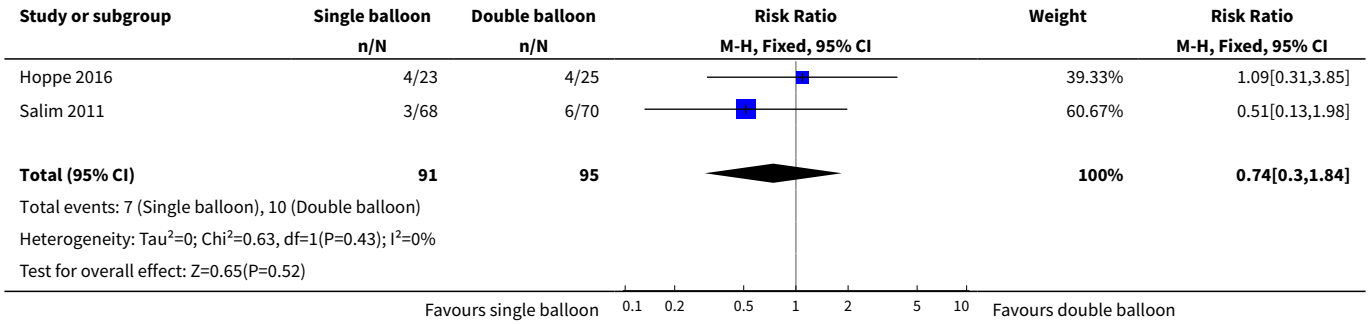
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	48	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.80, 1.93]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Caesarean section	2	186	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.30, 1.84]

Analysis 18.1. Comparison 18 Single balloon (Foley) versus double balloon (ATAD): all multiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



Analysis 18.2. Comparison 18 Single balloon (Foley) versus double balloon (ATAD): all multiparae, Outcome 2 Caesarean section.



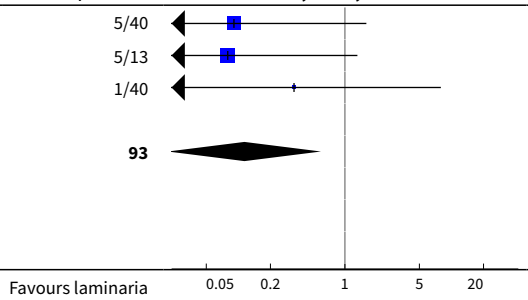
Comparison 19. Laminaria tent versus vaginal prostaglandin E2: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Uterine hyperstimulation with FHR changes	3	188	Risk Ratio (M-H, Fixed, 95% CI)	0.11 [0.02, 0.60]
2 Caesarean section	5	263	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.56, 1.48]
3 Serious perinatal morbidity/perinatal death	1	80	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Serious maternal morbidity or death	1	28	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Uterine hyperstimulation without fetal heart rate changes	3	180	Risk Ratio (M-H, Fixed, 95% CI)	0.22 [0.09, 0.49]
6 Epidural analgesia	1	80	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.74, 1.13]
7 Instrumental vaginal delivery	1	80	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.43, 1.17]
8 Meconium-stained liquor	1	80	Risk Ratio (M-H, Fixed, 95% CI)	0.14 [0.01, 2.68]
9 Apgar score < 7 at 5 minutes	2	160	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Perinatal death	1	80	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Maternal side effects: all	1	28	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.01, 6.60]
12 Maternal nausea	1	28	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.01, 6.60]
13 Fetal distress	3	188	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.34, 1.15]

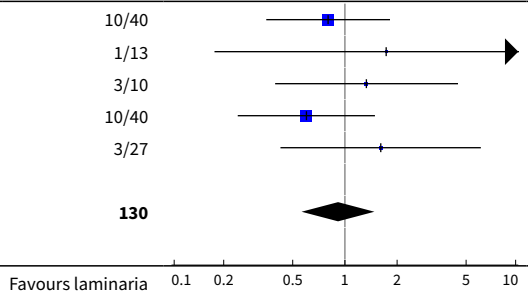
Analysis 19.1. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 1 Uterine hyperstimulation with FHR changes.

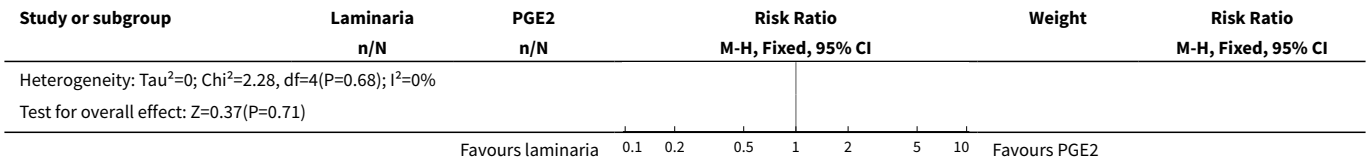
Study or subgroup	Laminaria n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Bagratee 1990	0/40	5/40		42.75%	0.09[0.01,1.59]
Hay 1995	0/15	5/13		45.6%	0.08[0,1.31]
Johnson 1985	0/40	1/40		11.66%	0.33[0.01,7.95]
Total (95% CI)	**95**	**93**		**100%**	**0.11[0.02,0.6]**
Total events: 0 (Laminaria), 11 (PGE2)					
Heterogeneity: Tau^2=0; Chi^2=0.53, df=2(P=0.77); I^2=0%					
Test for overall effect: Z=2.57(P=0.01)					



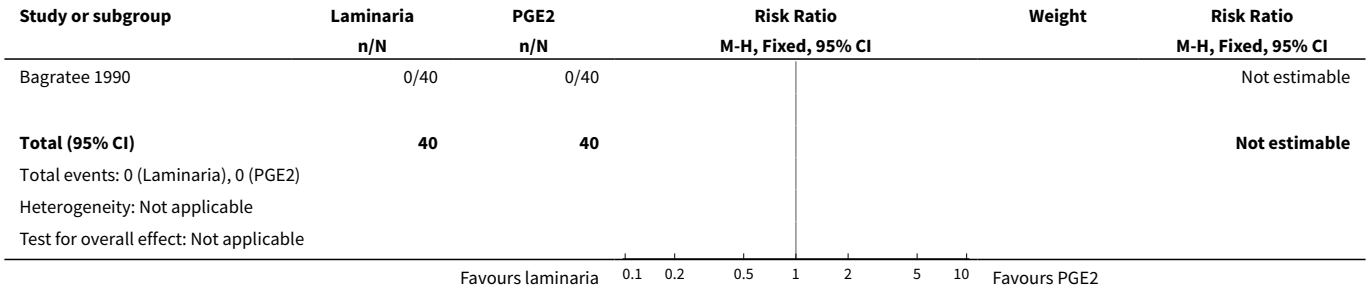
Analysis 19.2. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 2 Caesarean section.

Study or subgroup	Laminaria n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Bagratee 1990	8/40	10/40		36.87%	0.8[0.35,1.82]
Hay 1995	2/15	1/13		3.95%	1.73[0.18,16.99]
Jeeva 1982	4/10	3/10		11.06%	1.33[0.4,4.49]
Johnson 1985	6/40	10/40		36.87%	0.6[0.24,1.49]
Roberts 1986	5/28	3/27		11.26%	1.61[0.42,6.08]
Total (95% CI)	**133**	**130**		**100%**	**0.91[0.56,1.48]**
Total events: 25 (Laminaria), 27 (PGE2)					

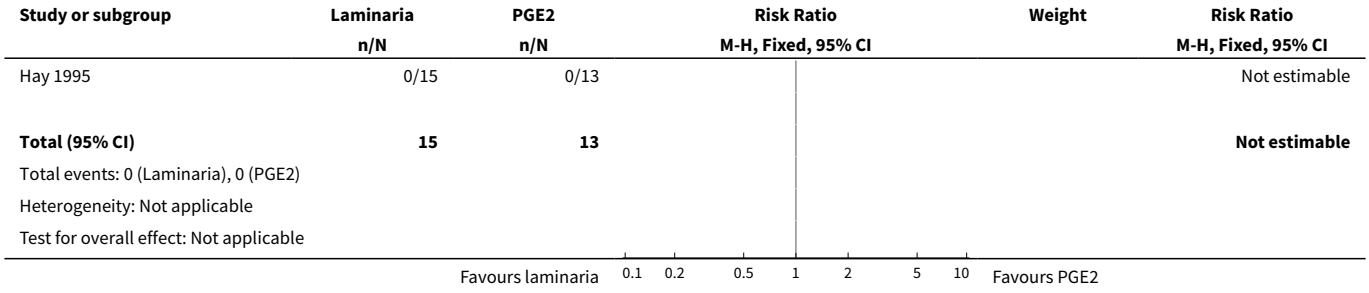




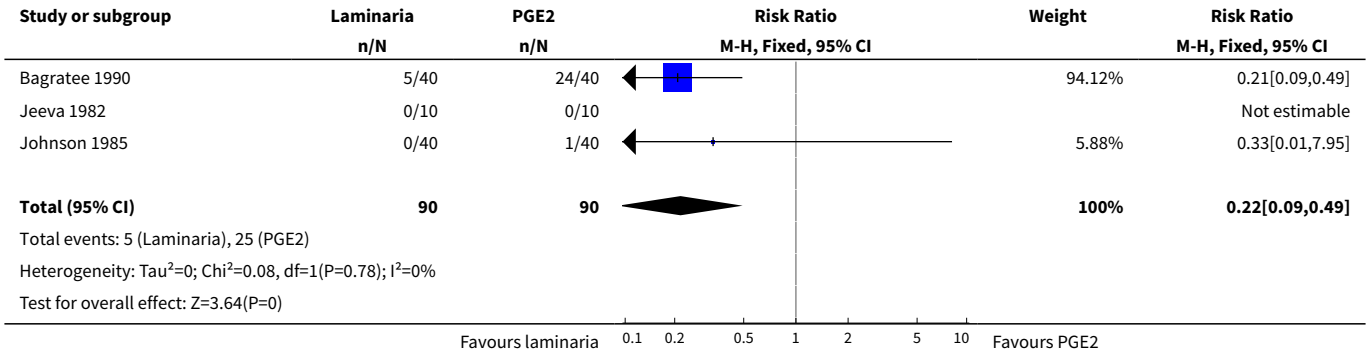
Analysis 19.3. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 3 Serious perinatal morbidity/perinatal death.



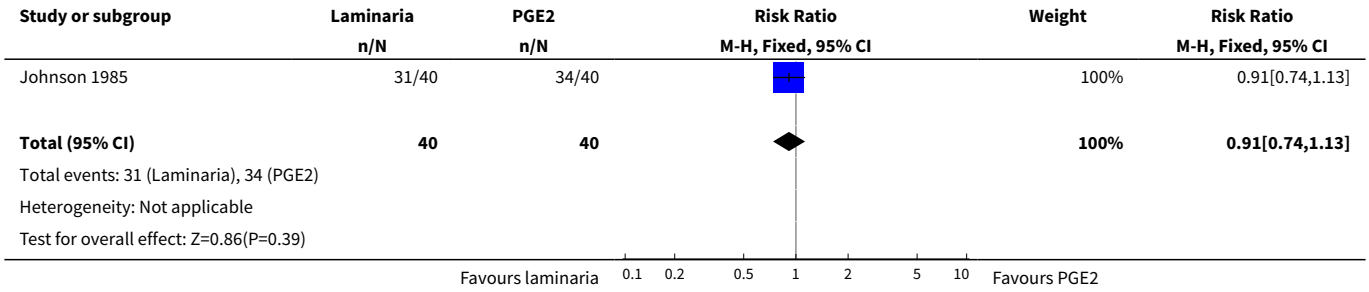
Analysis 19.4. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 4 Serious maternal morbidity or death.



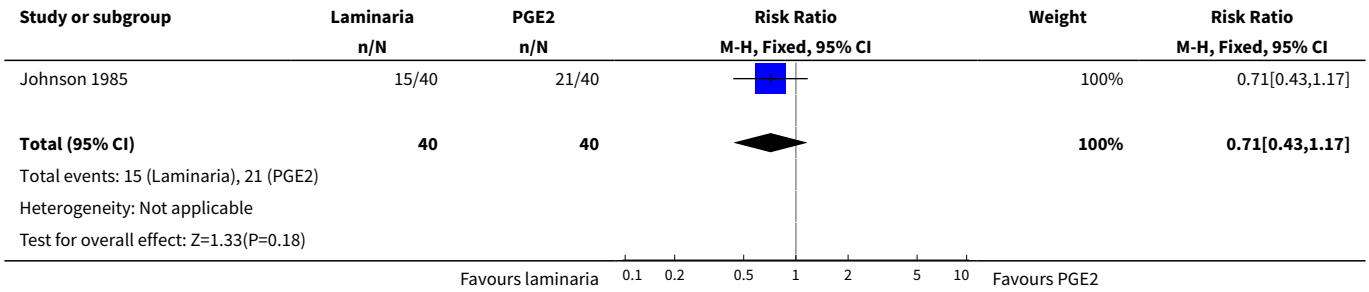
Analysis 19.5. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 5 Uterine hyperstimulation without fetal heart rate changes.



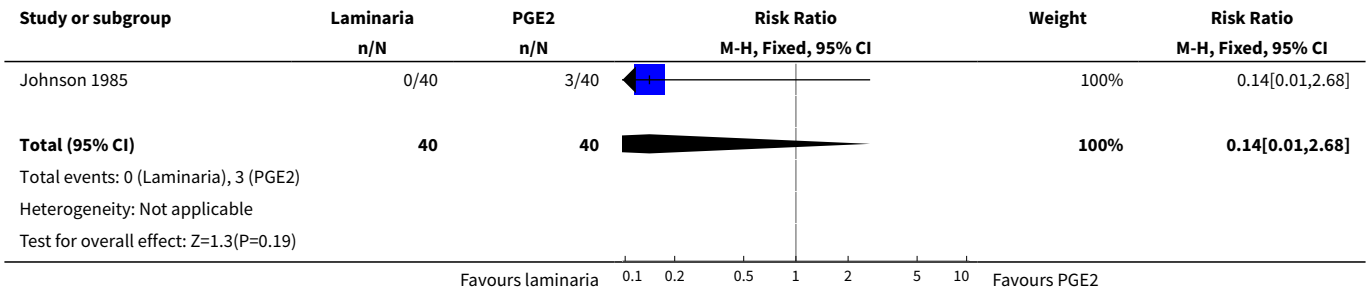
Analysis 19.6. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 6 Epidural analgesia.



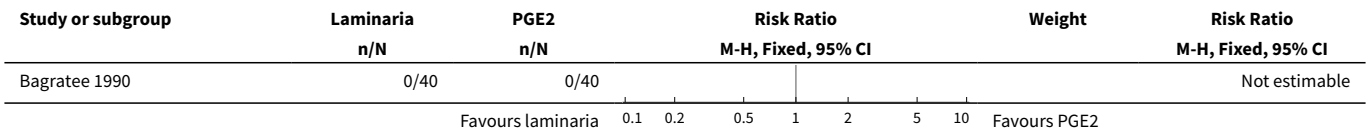
Analysis 19.7. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 7 Instrumental vaginal delivery.

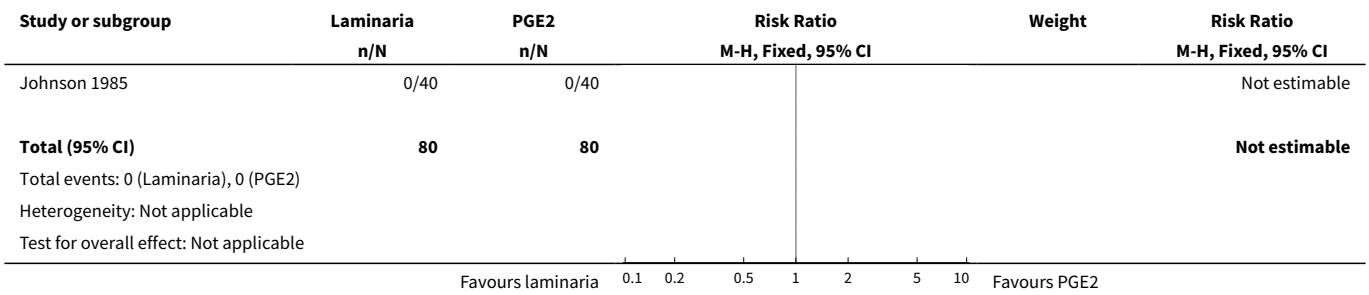


Analysis 19.8. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 8 Meconium-stained liquor.

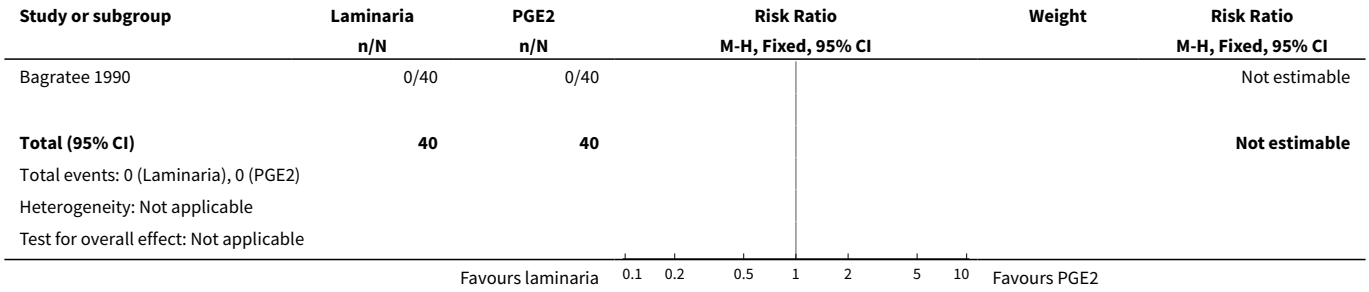


Analysis 19.9. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 9 Apgar score < 7 at 5 minutes.

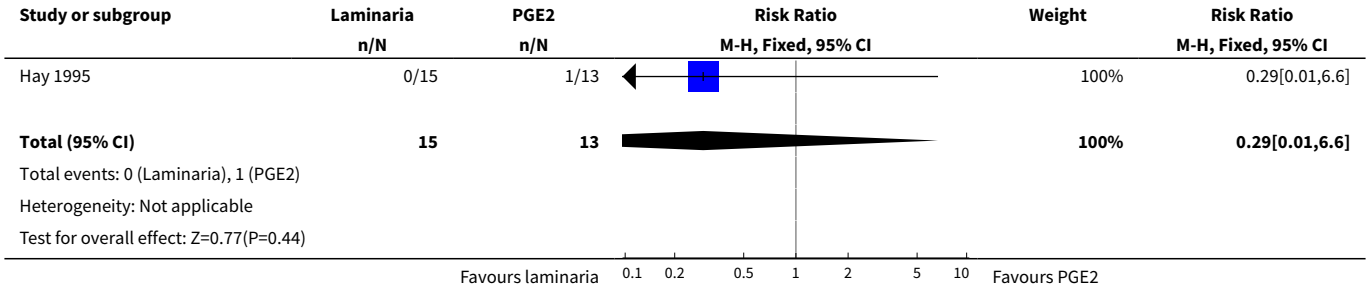




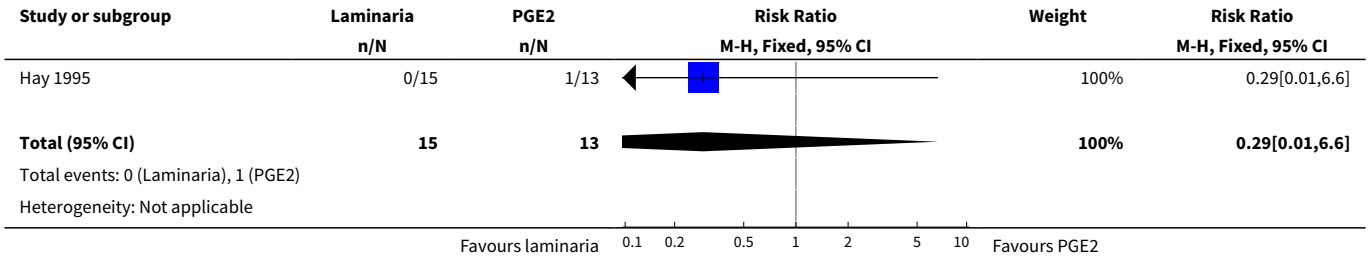
Analysis 19.10. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 10 Perinatal death.

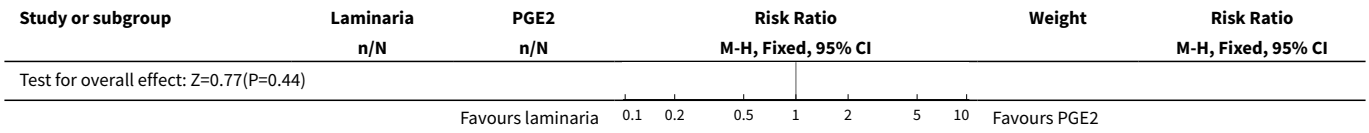


Analysis 19.11. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 11 Maternal side effects: all.

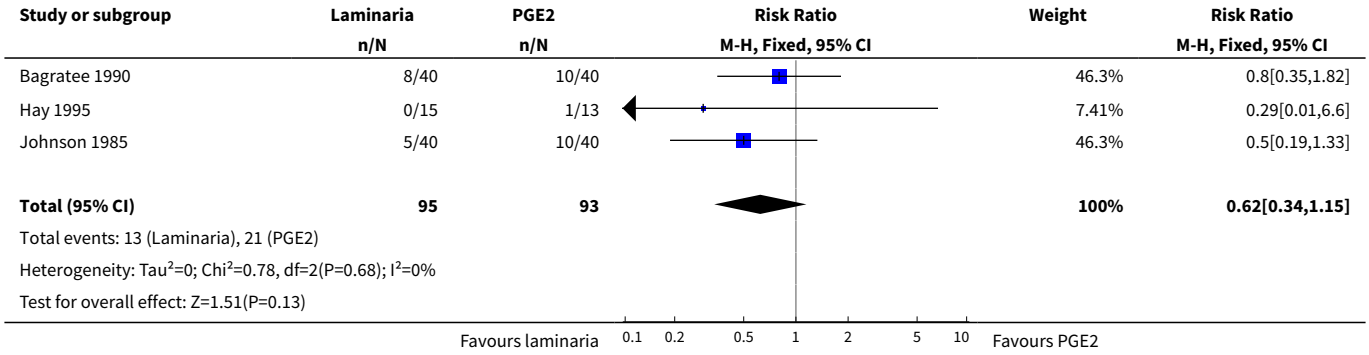


Analysis 19.12. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 12 Maternal nausea.





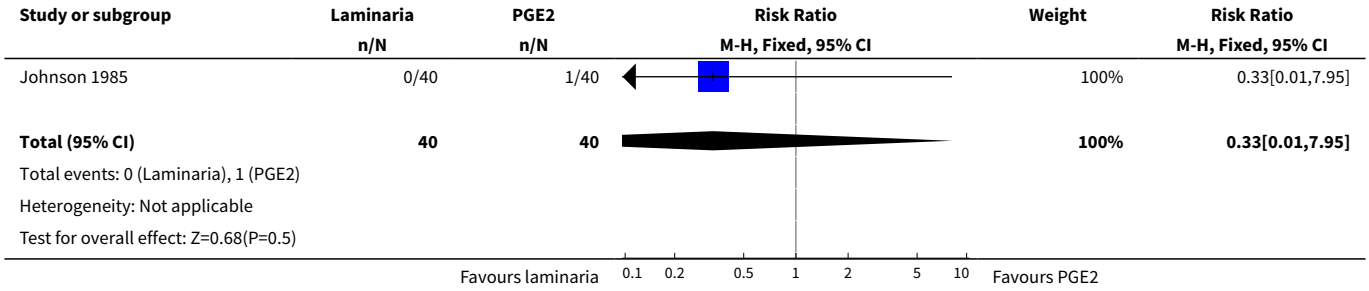
Analysis 19.13. Comparison 19 Laminaria tent versus vaginal prostaglandin E2: all women, Outcome 13 Fetal distress.



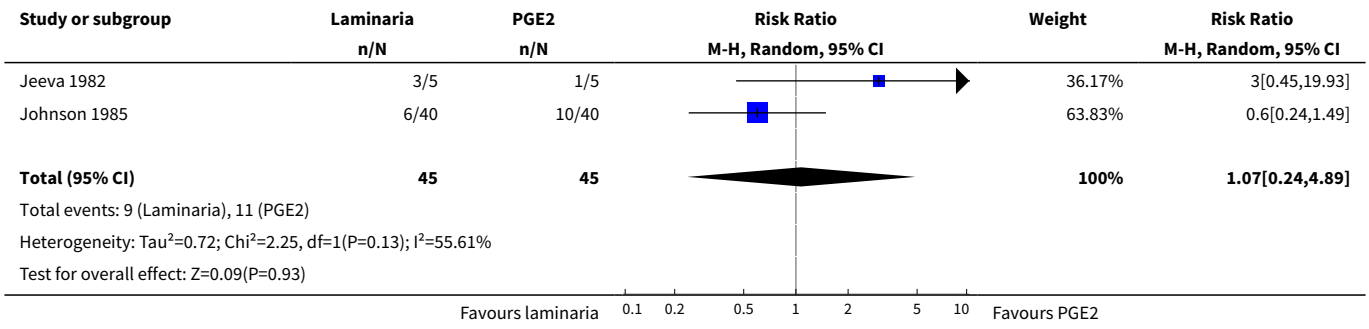
Comparison 20. Laminaria tent versus vaginal prostaglandin E2: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Uterine hyperstimulation with FHR changes	1	80	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.95]
2 Caesarean section	2	90	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.24, 4.89]

Analysis 20.1. Comparison 20 Laminaria tent versus vaginal prostaglandin E2: all primiparae, Outcome 1 Uterine hyperstimulation with FHR changes.



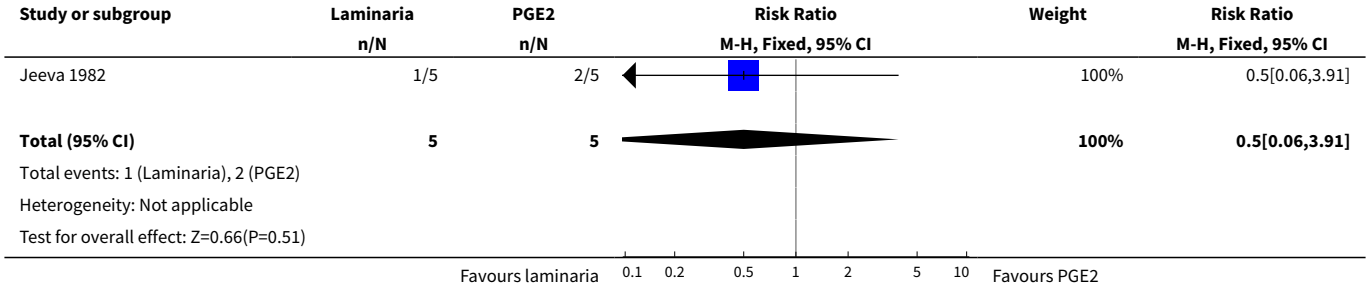
Analysis 20.2. Comparison 20 Laminaria tent versus vaginal prostaglandin E2: all primiparae, Outcome 2 Caesarean section.



Comparison 21. Laminaria tent versus vaginal prostaglandin E2: all multiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	10	Risk Ratio (M-H, Fixed, 95% CI)	0.5 [0.06, 3.91]

Analysis 21.1. Comparison 21 Laminaria tent versus vaginal prostaglandin E2: all multiparae, Outcome 1 Caesarean section.

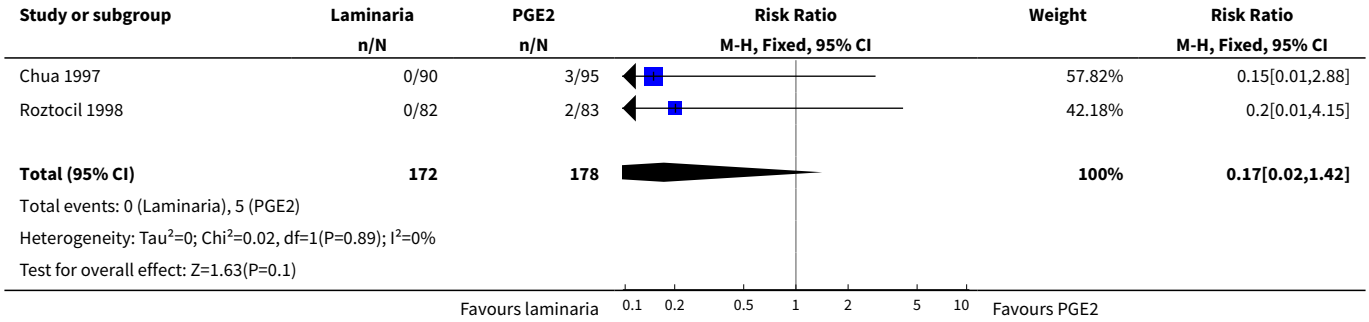


Comparison 22. Laminaria tent versus intracervical prostaglandin E2: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Uterine hyperstimulation with FHR changes	2	350	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.02, 1.42]
2 Caesarean section	5	920	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.93, 1.45]
3 Serious neonatal morbidity/perinatal death	1	185	Risk Ratio (M-H, Fixed, 95% CI)	3.16 [0.13, 76.70]
4 Serious maternal morbidity or death	1	185	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.01, 8.52]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Cervix unfavourable/unchanged after 12-24 hours	2	218	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.11, 1.96]
6 Oxytocin augmentation	1	185	Risk Ratio (M-H, Fixed, 95% CI)	1.41 [1.21, 1.64]
7 Uterine hyperstimulation without FHR changes	2	601	Risk Ratio (M-H, Fixed, 95% CI)	0.17 [0.02, 1.36]
8 Uterine rupture	1	185	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.01, 8.52]
9 Instrumental vaginal delivery	3	424	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.65, 1.69]
10 Apgar score < 7 at 5 minutes	1	185	Risk Ratio (M-H, Fixed, 95% CI)	5.28 [0.63, 44.30]
11 Neonatal intensive care unit admission	2	259	Risk Ratio (M-H, Fixed, 95% CI)	1.58 [0.58, 4.33]
12 Perinatal death	1	185	Risk Ratio (M-H, Fixed, 95% CI)	3.16 [0.13, 76.70]
13 Maternal side effects	1	165	Risk Ratio (M-H, Fixed, 95% CI)	0.20 [0.01, 4.15]
14 Postpartum haemorrhage	2	239	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.46, 2.81]
15 Chorioamnionitis	1	74	Risk Ratio (M-H, Fixed, 95% CI)	3.17 [0.35, 29.06]
16 Endometritis	2	490	Risk Ratio (M-H, Random, 95% CI)	0.30 [0.08, 1.09]
17 Fetal distress	2	128	Risk Ratio (M-H, Fixed, 95% CI)	0.44 [0.07, 2.90]

Analysis 22.1. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 1 Uterine hyperstimulation with FHR changes.



Analysis 22.2. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 2 Caesarean section.

Study or subgroup	Laminaria n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Chua 1997	22/90	20/95		18.22%	1.16[0.68,1.98]
Glagoleva 1999	7/27	5/26		4.77%	1.35[0.49,3.71]
Krammer 1995a	72/224	53/219		50.18%	1.33[0.98,1.8]
Roztocil 1998	16/82	21/83		19.54%	0.77[0.43,1.37]
Sanchez-Ramos 1992	7/36	8/38		7.29%	0.92[0.37,2.29]
Total (95% CI)	**459**	**461**		**100%**	**1.16[0.93,1.45]**
Total events: 124 (Laminaria), 107 (PGE2)					
Heterogeneity: Tau^2=0; Chi^2=3.04, df=4(P=0.55); I^2=0%					
Test for overall effect: Z=1.3(P=0.19)					

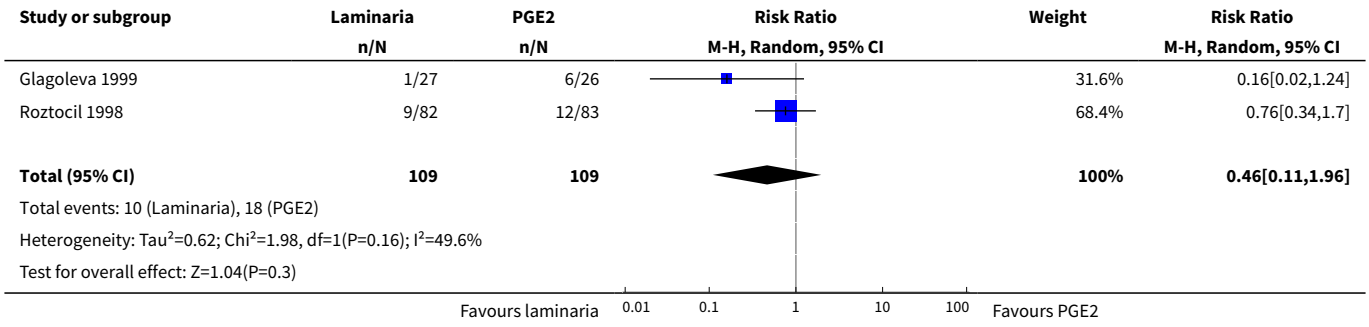
Analysis 22.3. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 3 Serious neonatal morbidity/perinatal death.

Study or subgroup	Laminaria n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Chua 1997	1/90	0/95		100%	3.16[0.13,76.7]
Total (95% CI)	**90**	**95**		**100%**	**3.16[0.13,76.7]**
Total events: 1 (Laminaria), 0 (PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.71(P=0.48)					

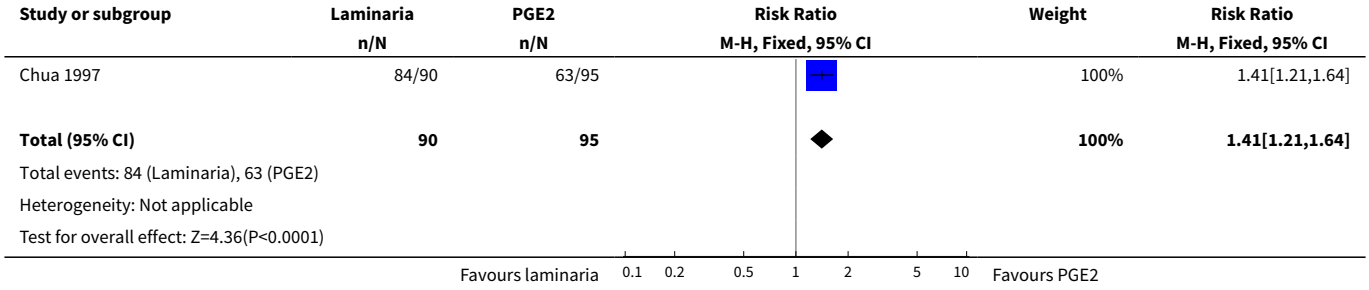
Analysis 22.4. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 4 Serious maternal morbidity or death.

Study or subgroup	Laminaria n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Chua 1997	0/90	1/95		100%	0.35[0.01,8.52]
Total (95% CI)	**90**	**95**		**100%**	**0.35[0.01,8.52]**
Total events: 0 (Laminaria), 1 (PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.64(P=0.52)					

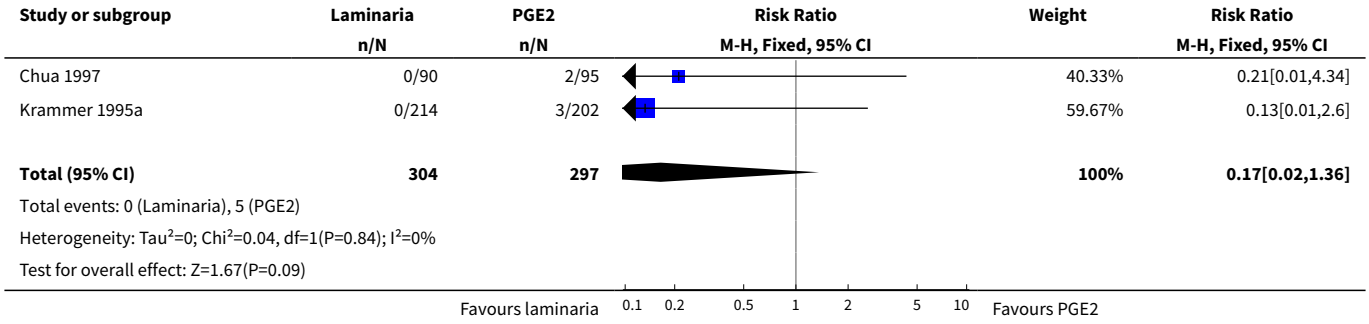
Analysis 22.5. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 5 Cervix unfavourable/unchanged after 12-24 hours.



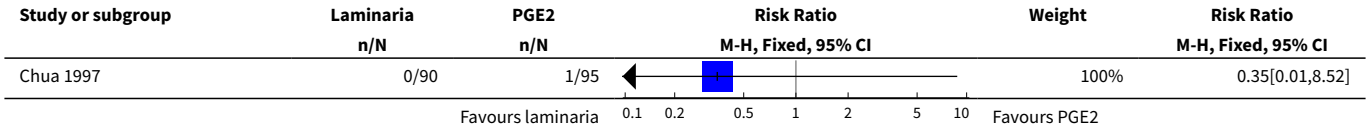
Analysis 22.6. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 6 Oxytocin augmentation.

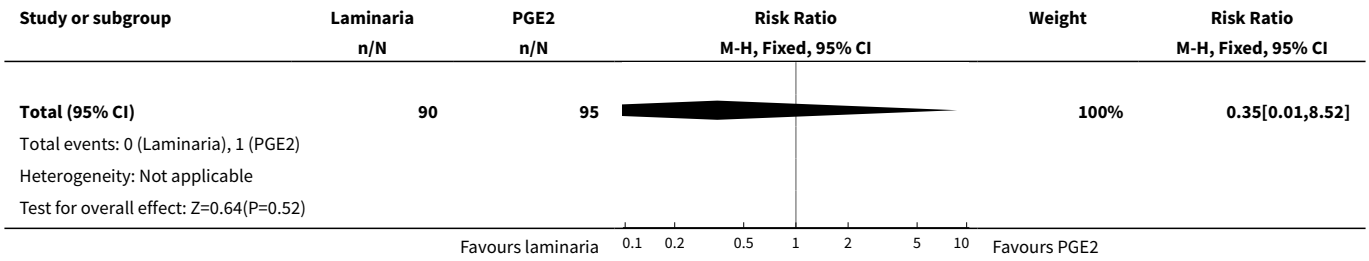


Analysis 22.7. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 7 Uterine hyperstimulation without FHR changes.

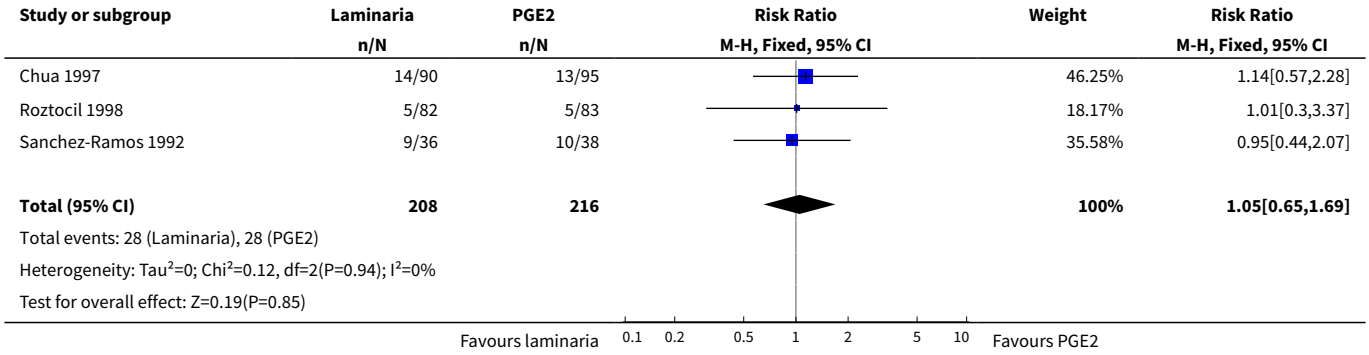


Analysis 22.8. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 8 Uterine rupture.

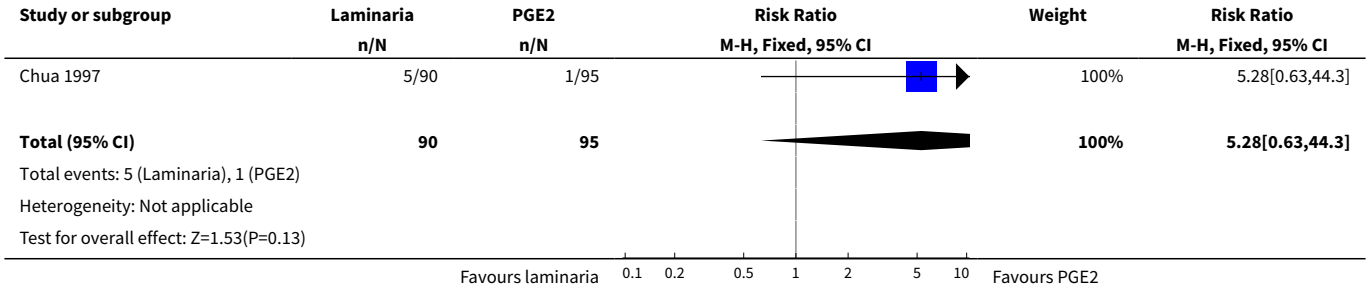




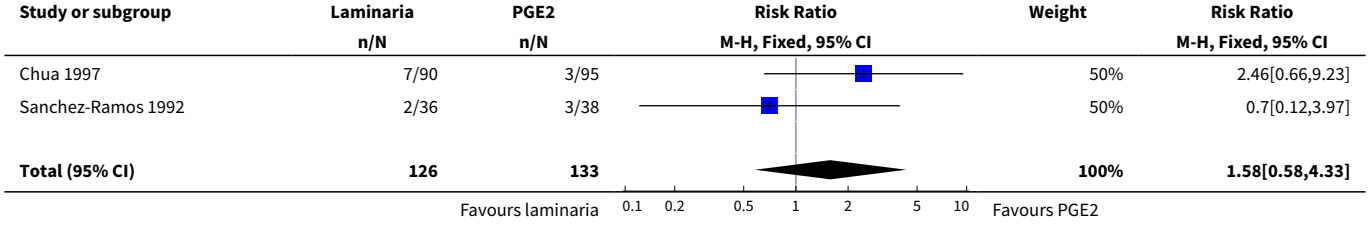
Analysis 22.9. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 9 Instrumental vaginal delivery.

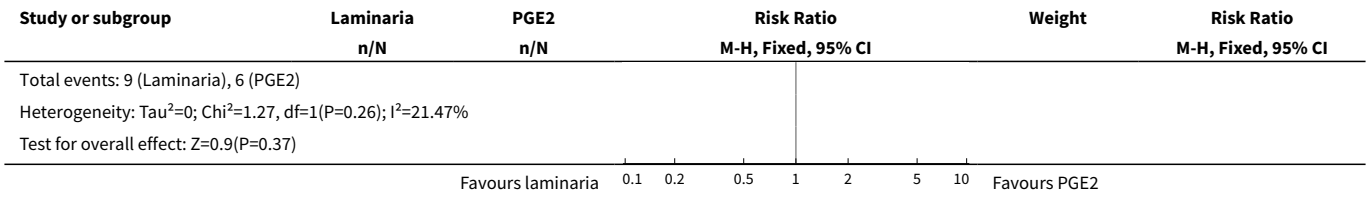


Analysis 22.10. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 10 Apgar score < 7 at 5 minutes.

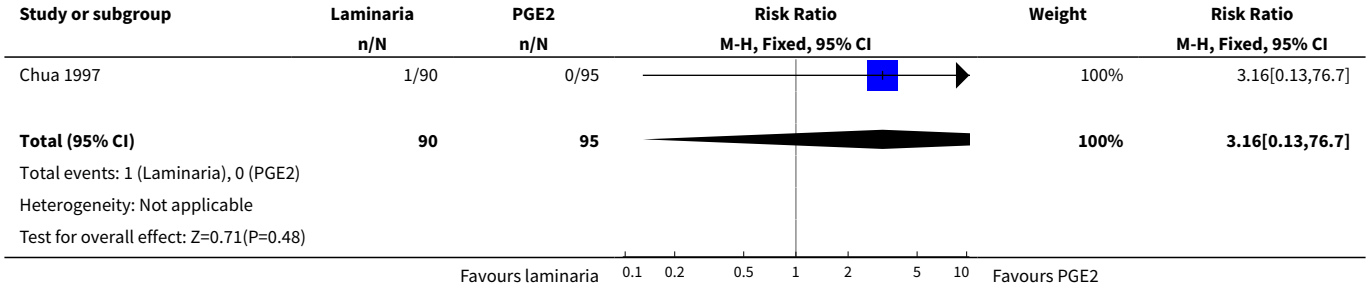


Analysis 22.11. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 11 Neonatal intensive care unit admission.

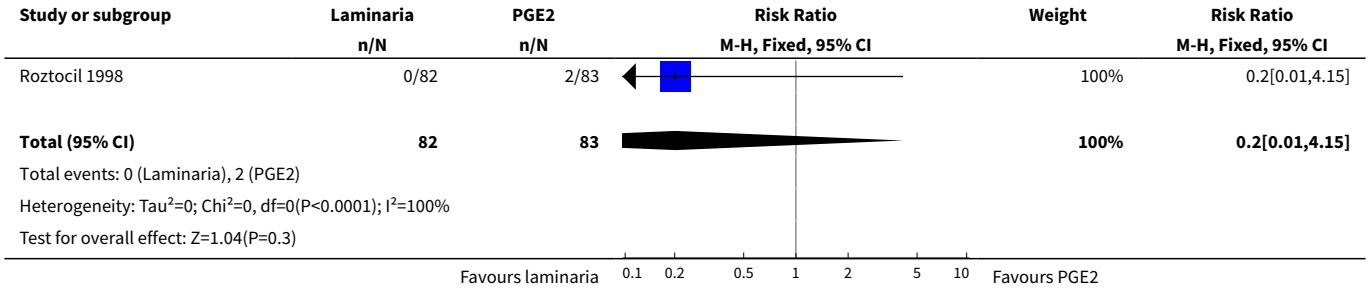




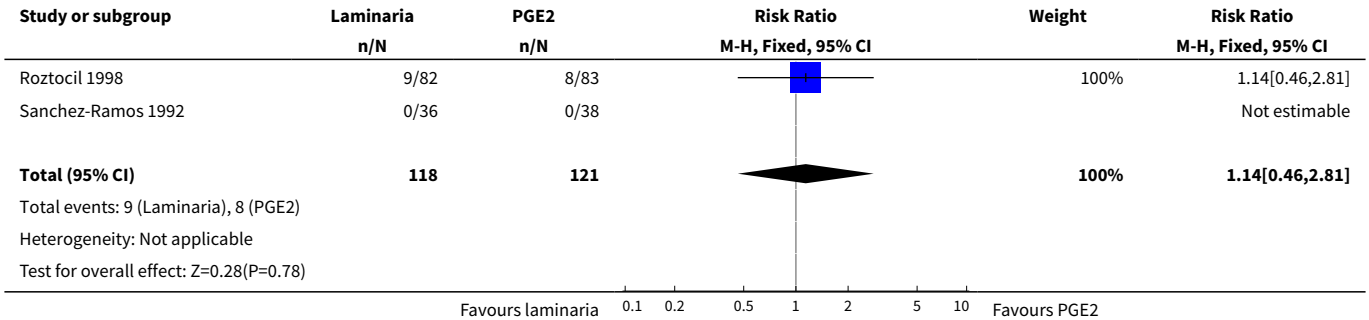
Analysis 22.12. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 12 Perinatal death.



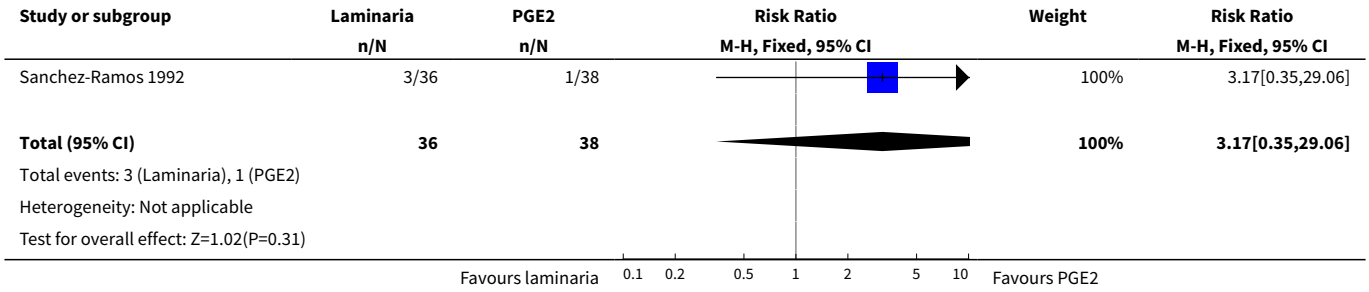
Analysis 22.13. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 13 Maternal side effects.



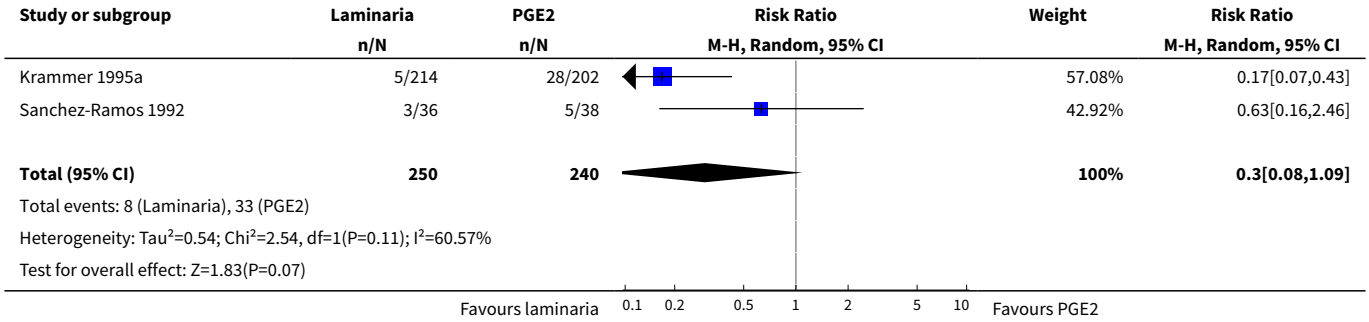
Analysis 22.14. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 14 Postpartum haemorrhage.



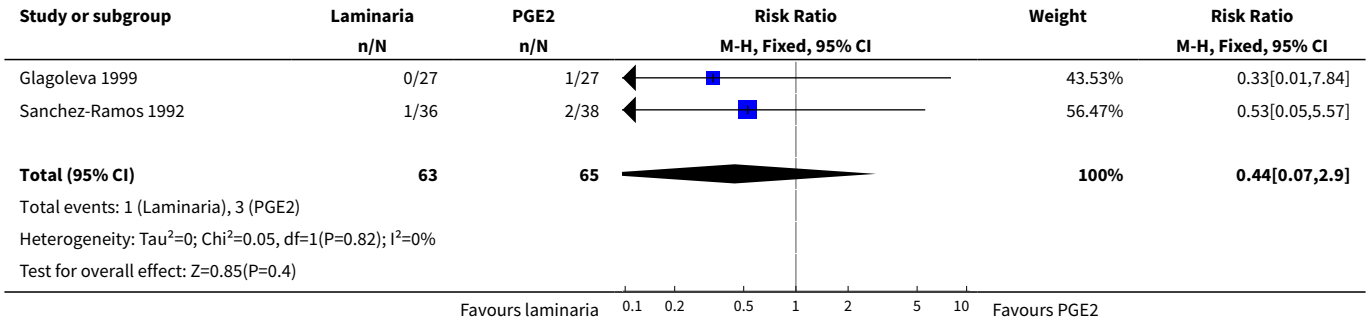
Analysis 22.15. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 15 Chorioamnionitis.



Analysis 22.16. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 16 Endometritis.



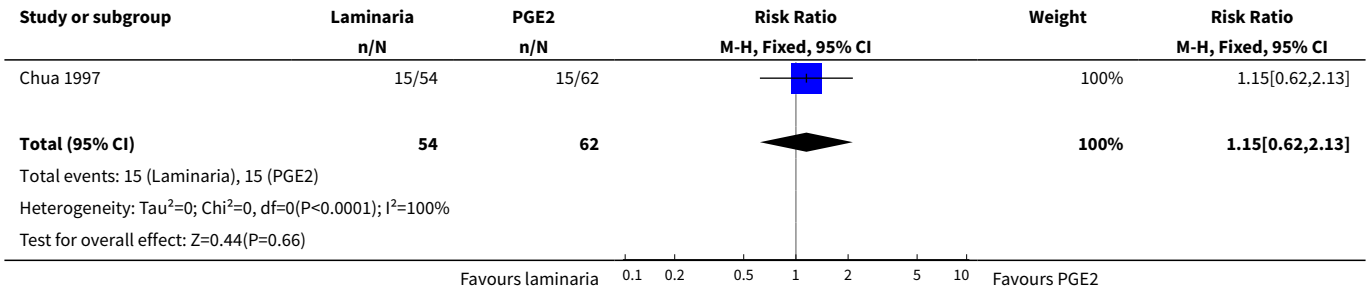
Analysis 22.17. Comparison 22 Laminaria tent versus intracervical prostaglandin E2: all women, Outcome 17 Fetal distress.



Comparison 23. Laminaria tent versus intracervical prostaglandin E2: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	116	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.62, 2.13]

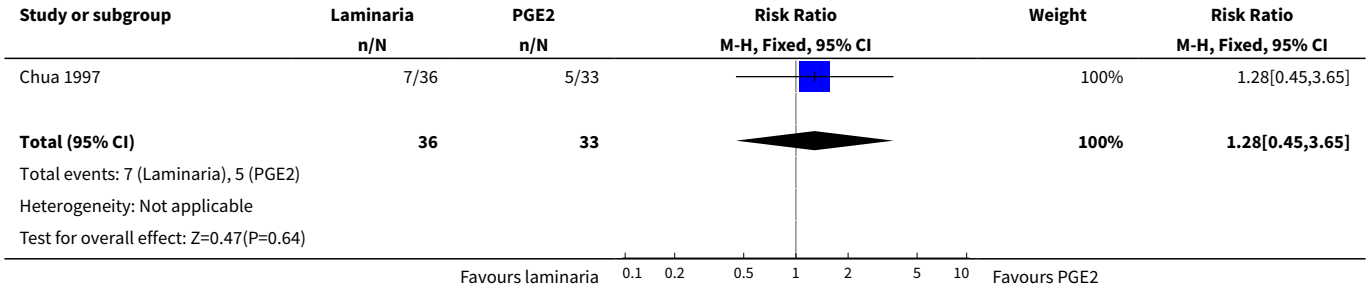
Analysis 23.1. Comparison 23 Laminaria tent versus intracervical prostaglandin E2: all primiparae, Outcome 1 Caesarean section.



Comparison 24. Laminaria tent versus intracervical: prostaglandin E2 all multiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	69	Risk Ratio (M-H, Fixed, 95% CI)	1.28 [0.45, 3.65]

Analysis 24.1. Comparison 24 Laminaria tent versus intracervical: prostaglandin E2 all multiparae, Outcome 1 Caesarean section.

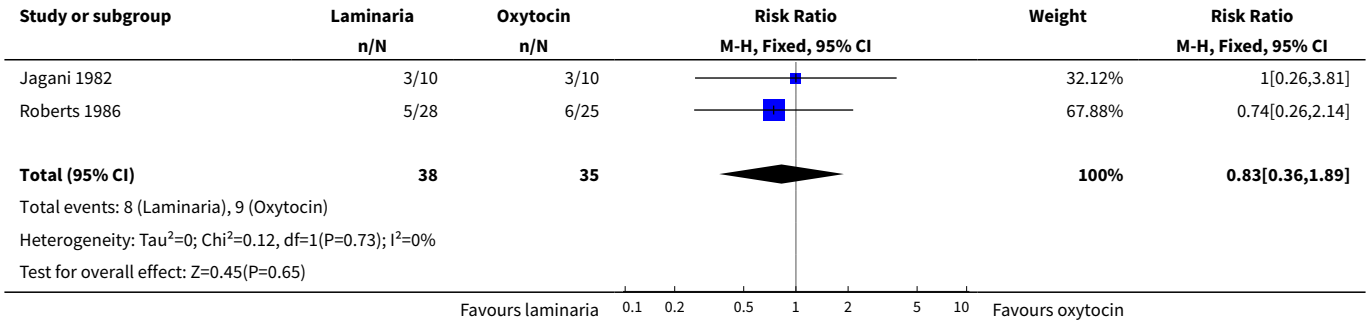


Comparison 25. Laminaria tent versus oxytocin: all women

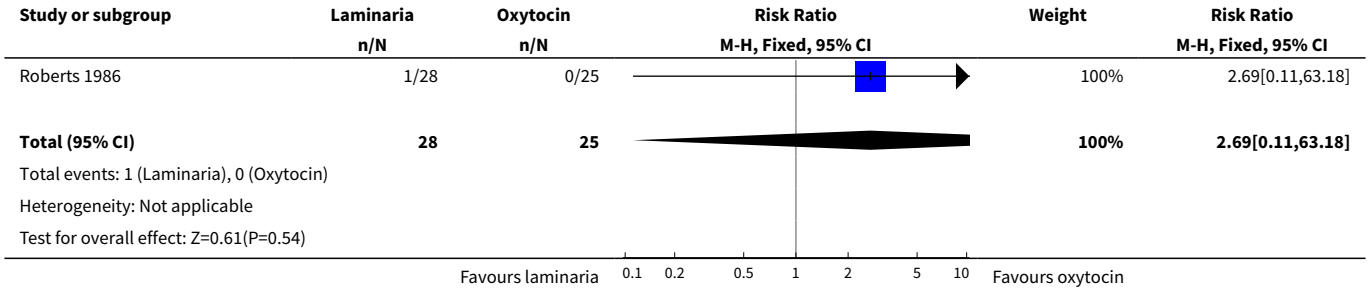
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	2	73	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.36, 1.89]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Fetal distress	1	53	Risk Ratio (M-H, Fixed, 95% CI)	2.69 [0.11, 63.18]

Analysis 25.1. Comparison 25 Laminaria tent versus oxytocin: all women, Outcome 1 Caesarean section.



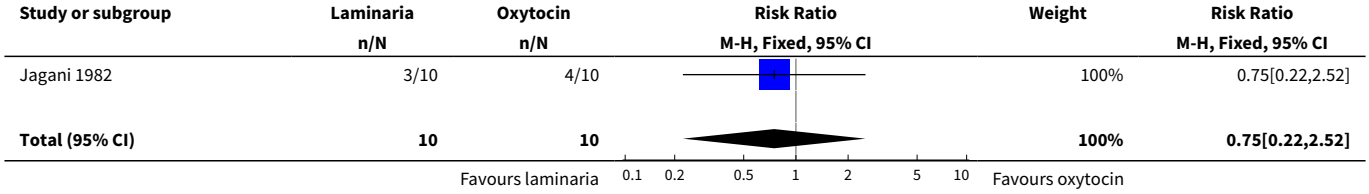
Analysis 25.2. Comparison 25 Laminaria tent versus oxytocin: all women, Outcome 2 Fetal distress.

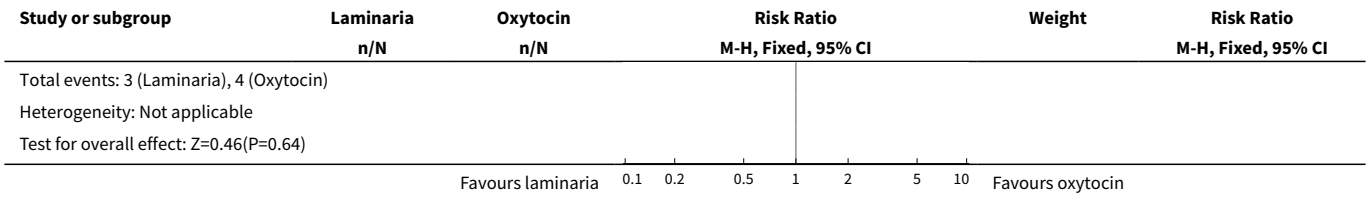


Comparison 26. Laminaria tent versus amniotomy: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	20	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.22, 2.52]

Analysis 26.1. Comparison 26 Laminaria tent versus amniotomy: all women, Outcome 1 Caesarean section.

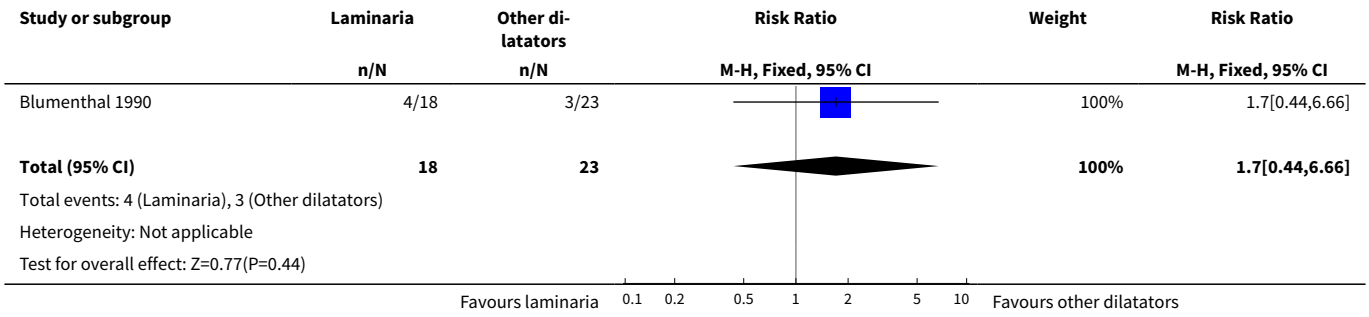




Comparison 27. Laminaria tent versus other hygroscopic dilator: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	41	Risk Ratio (M-H, Fixed, 95% CI)	1.70 [0.44, 6.66]

Analysis 27.1. Comparison 27 Laminaria tent versus other hygroscopic dilator: all women, Outcome 1 Caesarean section.

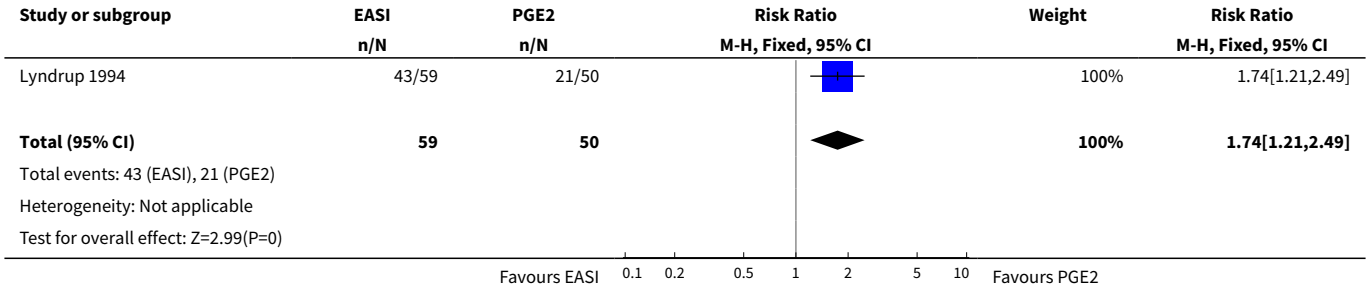


Comparison 28. EASI versus vaginal prostaglandin E2: all women

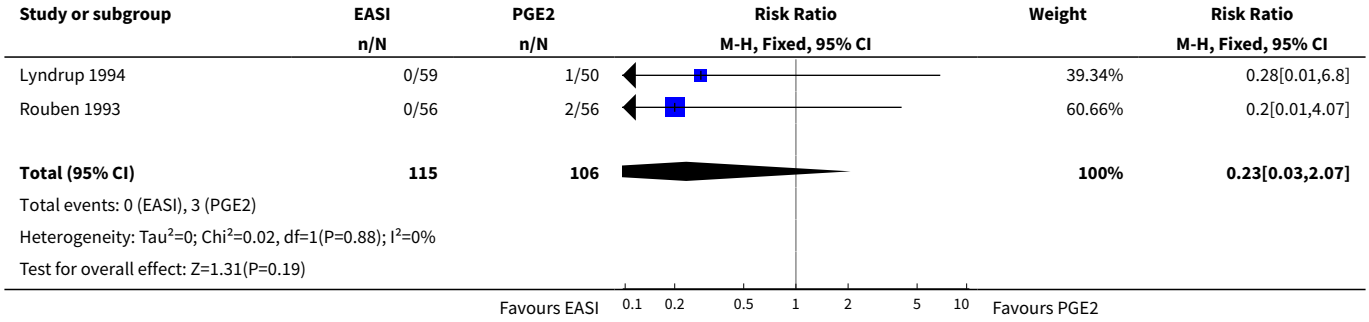
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	109	Risk Ratio (M-H, Fixed, 95% CI)	1.74 [1.21, 2.49]
2 Uterine hyperstimulation with FHR changes	2	221	Risk Ratio (M-H, Fixed, 95% CI)	0.23 [0.03, 2.07]
3 Caesarean section	2	221	Risk Ratio (M-H, Fixed, 95% CI)	1.35 [0.94, 1.96]
4 Oxytocin augmentation	1	109	Risk Ratio (M-H, Fixed, 95% CI)	12.71 [3.20, 50.57]
5 Uterine hyperstimulation without fetal heart rate changes	2	221	Risk Ratio (M-H, Fixed, 95% CI)	0.23 [0.03, 2.07]
6 Epidural analgesia	1	112	Risk Ratio (M-H, Fixed, 95% CI)	1.0 [0.97, 1.04]
7 Instrumental vaginal delivery	1	109	Risk Ratio (M-H, Fixed, 95% CI)	0.58 [0.30, 1.14]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8 Meconium-stained liquor	1	112	Risk Ratio (M-H, Fixed, 95% CI)	3.0 [0.12, 72.10]
9 Apgar score < 7 at 5 minutes	1	109	Risk Ratio (M-H, Fixed, 95% CI)	4.25 [0.21, 86.51]
10 Neonatal intensive care unit admission	1	112	Risk Ratio (M-H, Fixed, 95% CI)	1.5 [0.45, 5.03]
11 Woman not satisfied	1	109	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.10, 3.25]
12 Fetal distress	1	112	Risk Ratio (M-H, Fixed, 95% CI)	1.2 [0.39, 3.71]

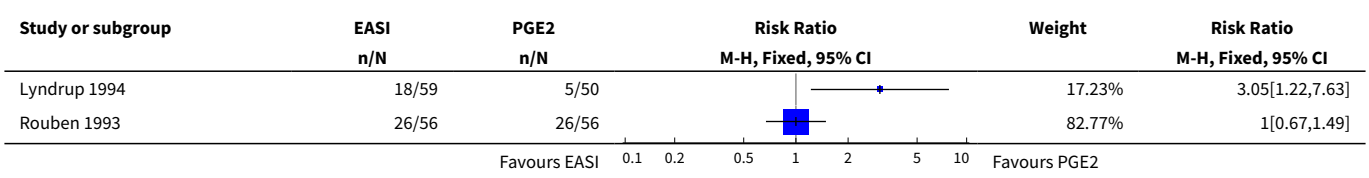
Analysis 28.1. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.

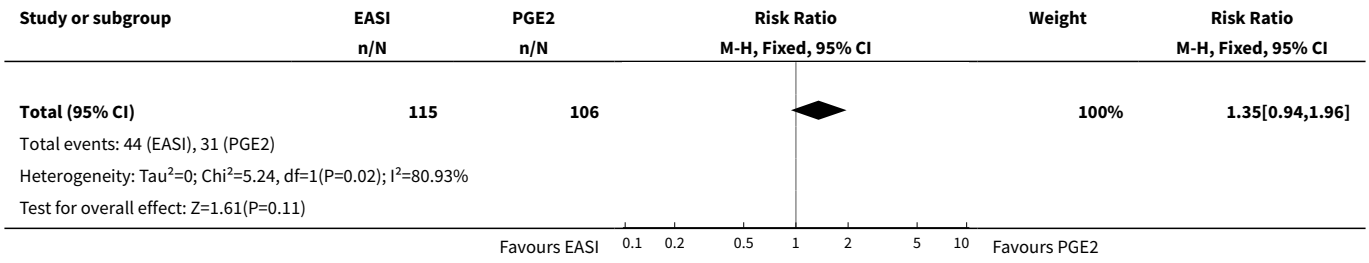


Analysis 28.2. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 2 Uterine hyperstimulation with FHR changes.

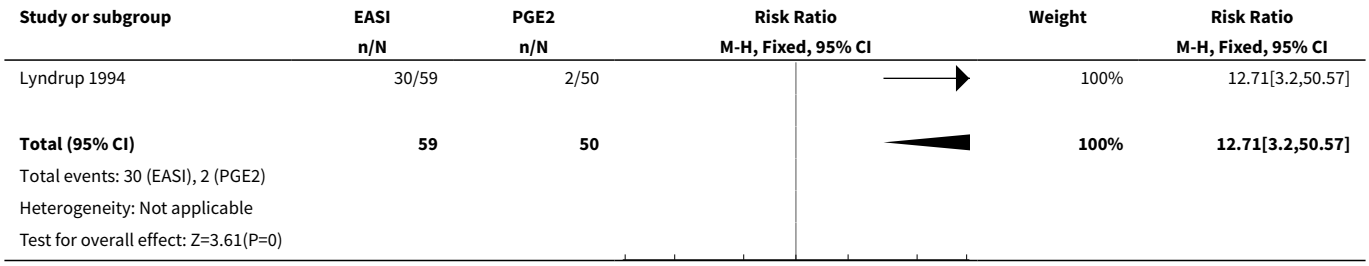


Analysis 28.3. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 3 Caesarean section.

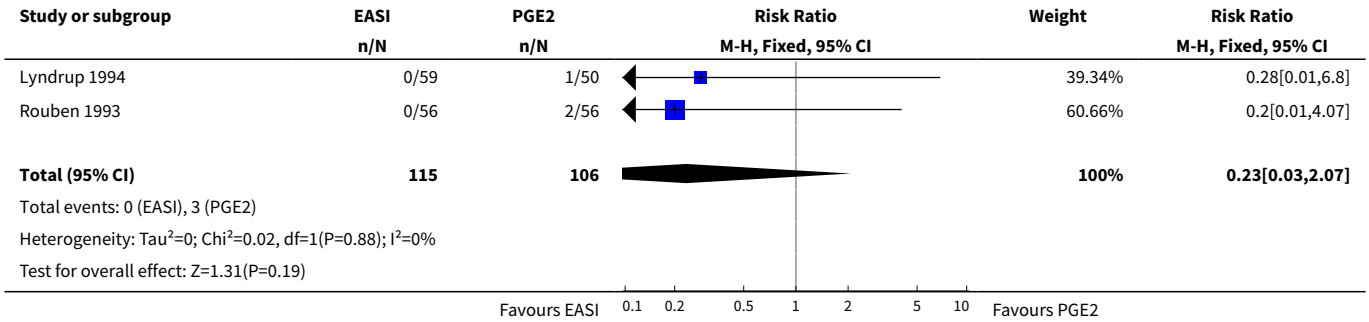




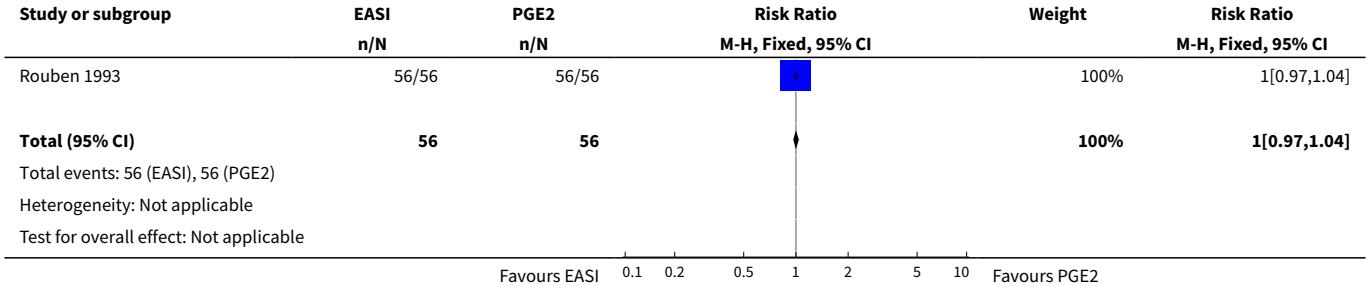
Analysis 28.4. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 4 Oxytocin augmentation.



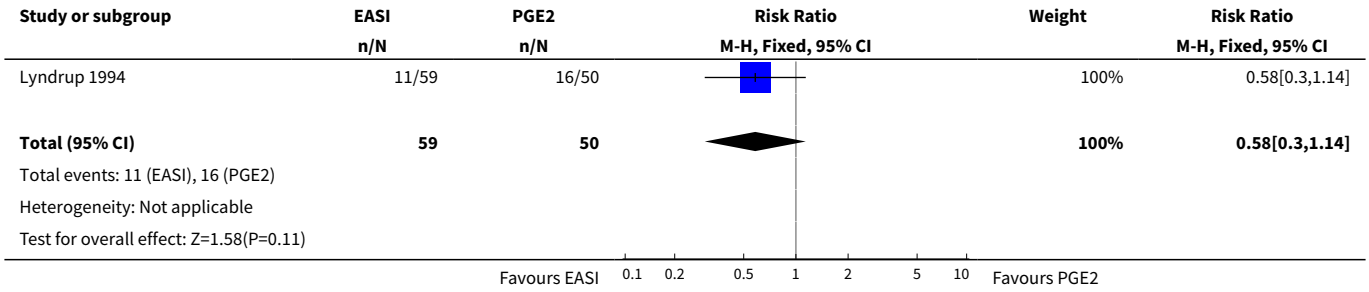
Analysis 28.5. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 5 Uterine hyperstimulation without fetal heart rate changes.



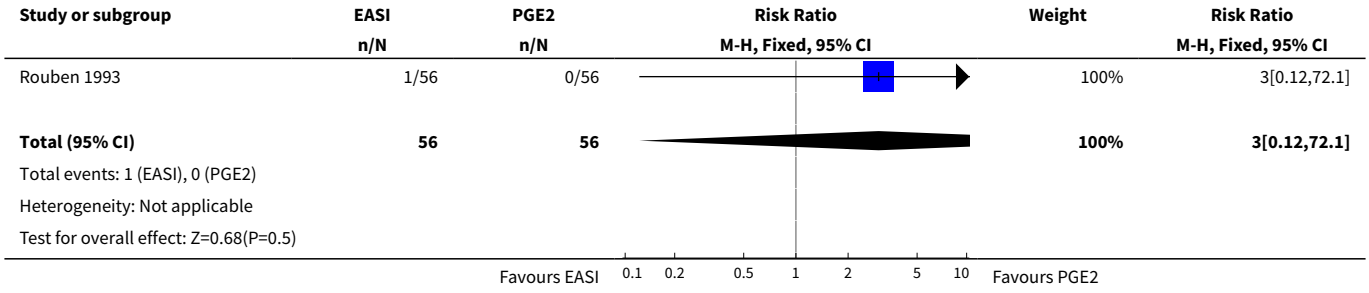
Analysis 28.6. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 6 Epidural analgesia.



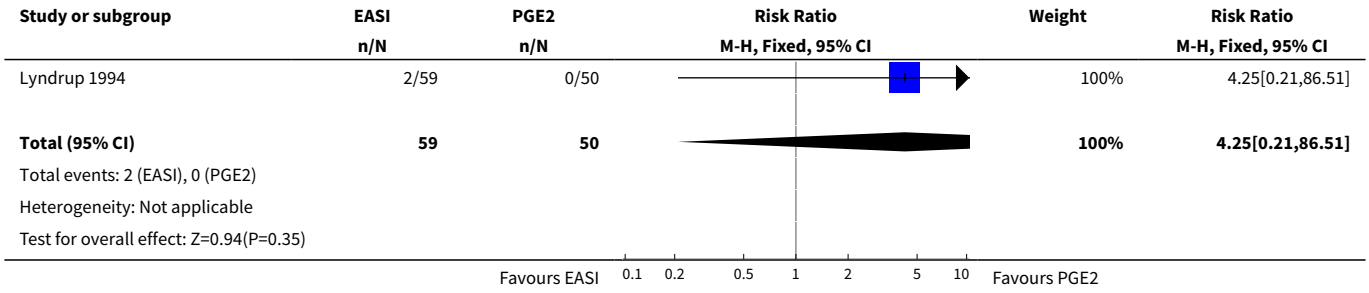
Analysis 28.7. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 7 Instrumental vaginal delivery.



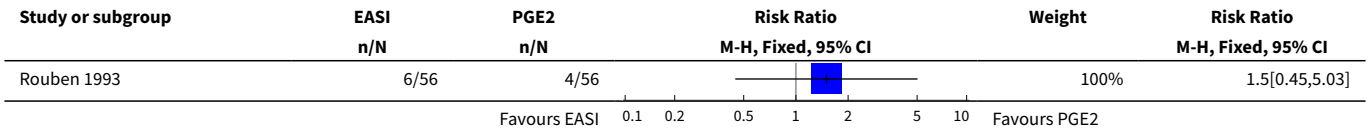
Analysis 28.8. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 8 Meconium-stained liquor.

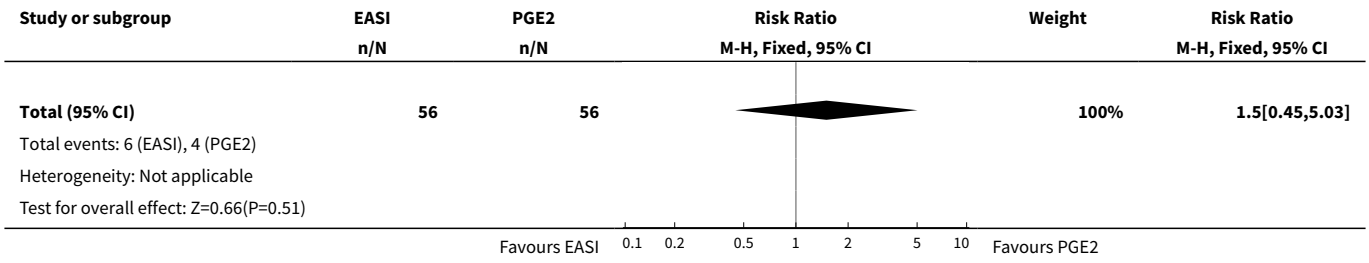


Analysis 28.9. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 9 Apgar score < 7 at 5 minutes.

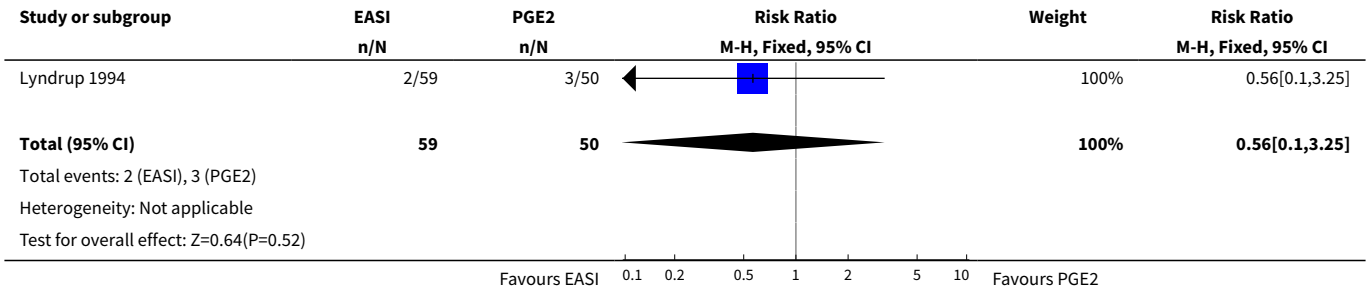


Analysis 28.10. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 10 Neonatal intensive care unit admission.

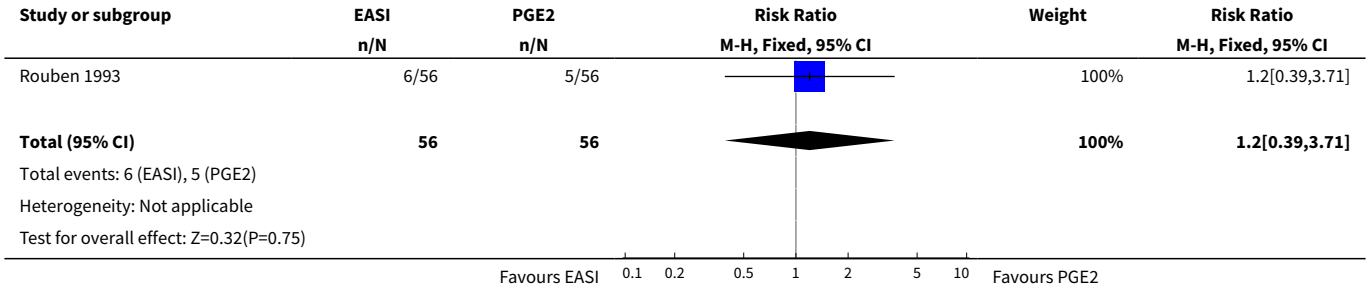




Analysis 28.11. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 11 Woman not satisfied.



Analysis 28.12. Comparison 28 EASI versus vaginal prostaglandin E2: all women, Outcome 12 Fetal distress.

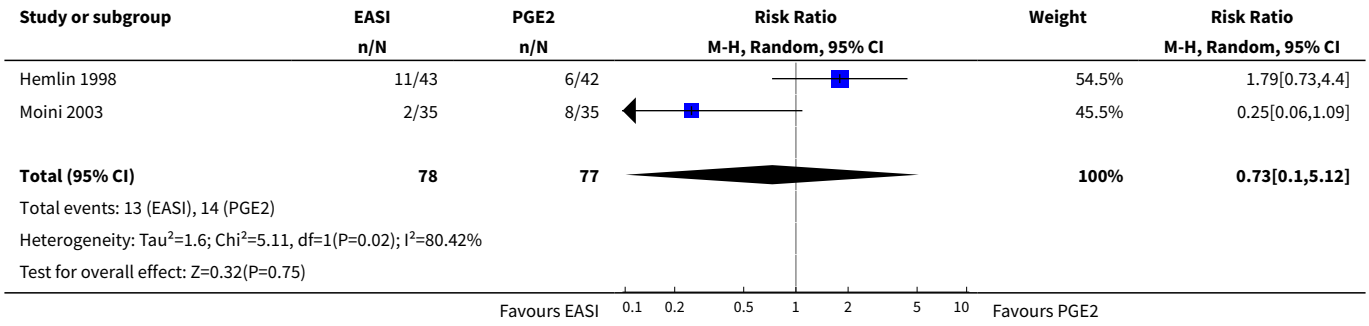


Comparison 29. EASI versus intracervical prostaglandin E2: all women

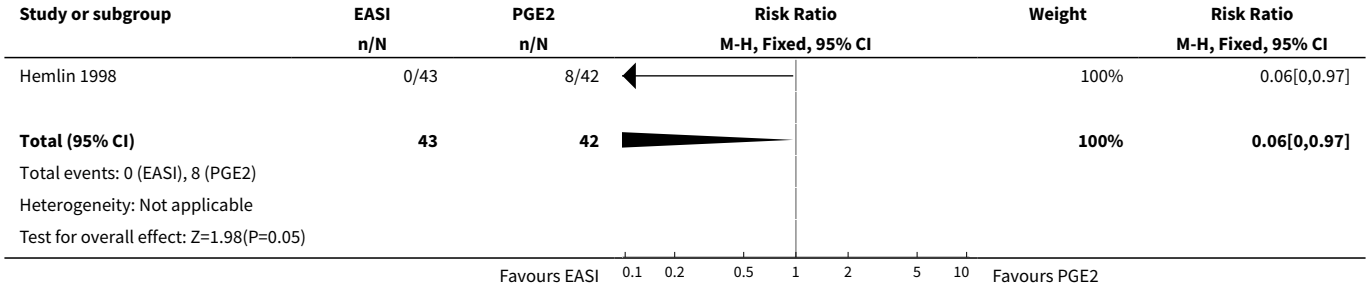
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	2	155	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.10, 5.12]
2 Cervix unfavourable/unchanged after 12-24 hours	1	85	Risk Ratio (M-H, Fixed, 95% CI)	0.06 [0.00, 0.97]
3 Oxytocin augmentation	1	70	Risk Ratio (M-H, Fixed, 95% CI)	1.1 [0.54, 2.25]
4 Instrumental vaginal delivery	1	85	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.04, 3.01]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Apgar score < 7 at 5 minutes	1	85	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Endometritis	1	85	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Fetal distress	1	70	Risk Ratio (M-H, Fixed, 95% CI)	0.29 [0.06, 1.28]

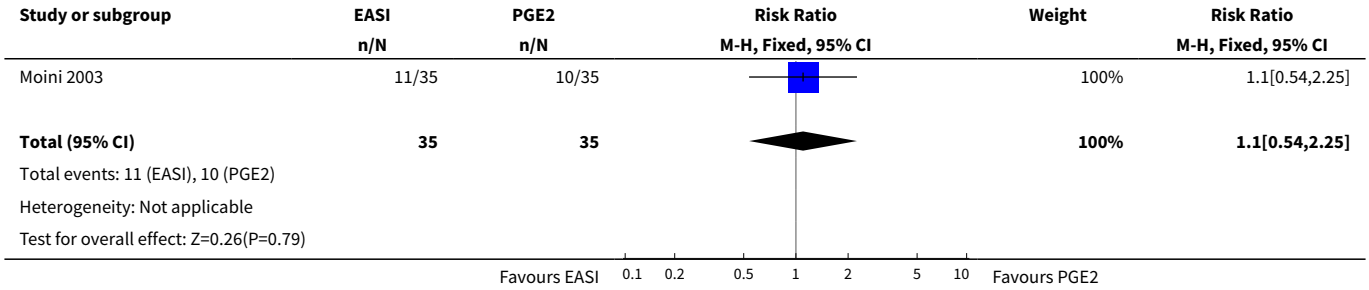
Analysis 29.1. Comparison 29 EASI versus intracervical prostaglandin E2: all women, Outcome 1 Caesarean section.



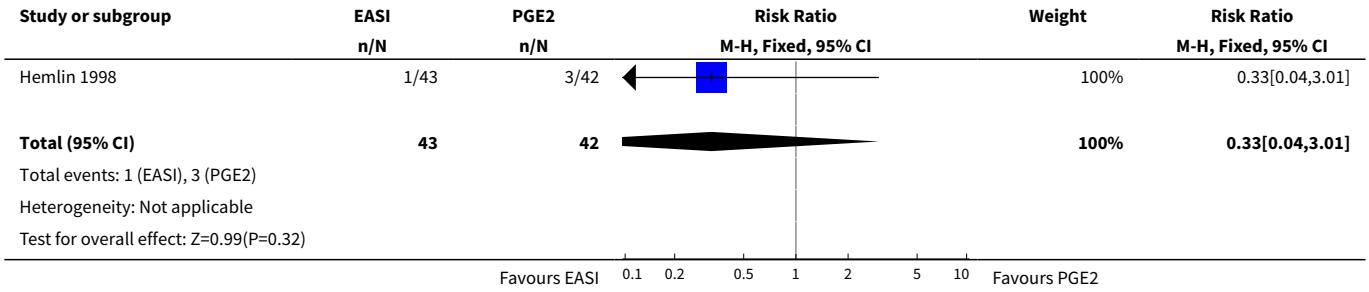
Analysis 29.2. Comparison 29 EASI versus intracervical prostaglandin E2: all women, Outcome 2 Cervix unfavourable/unchanged after 12-24 hours.



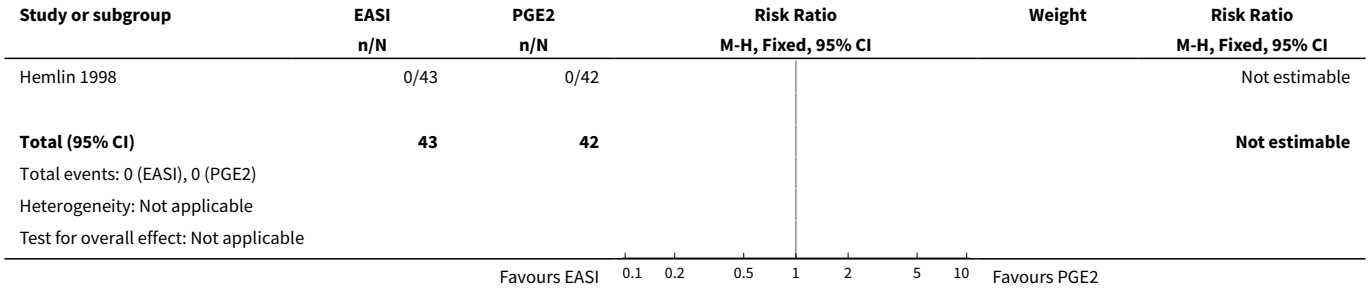
Analysis 29.3. Comparison 29 EASI versus intracervical prostaglandin E2: all women, Outcome 3 Oxytocin augmentation.



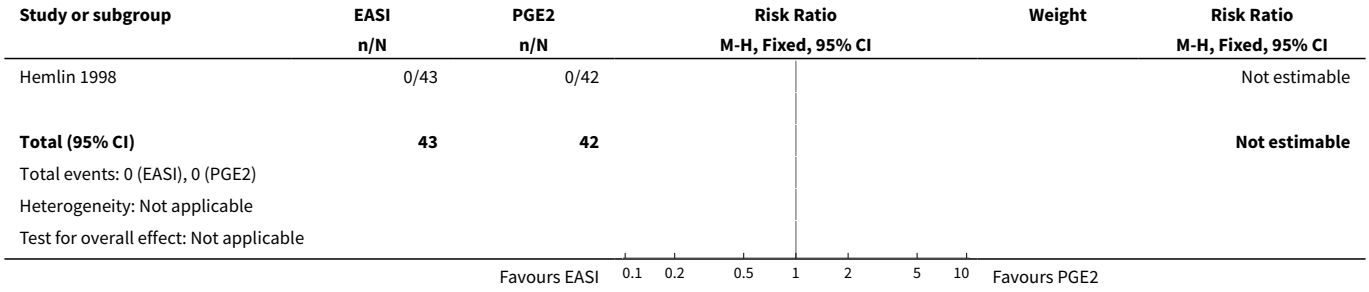
Analysis 29.4. Comparison 29 EASI versus intracervical prostaglandin E2: all women, Outcome 4 Instrumental vaginal delivery.



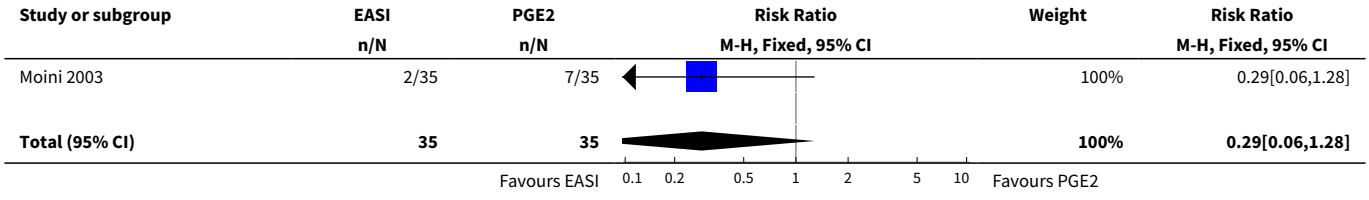
Analysis 29.5. Comparison 29 EASI versus intracervical prostaglandin E2: all women, Outcome 5 Apgar score < 7 at 5 minutes.

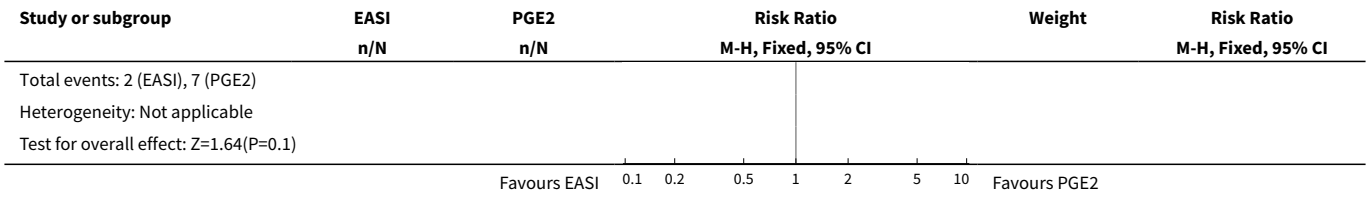


Analysis 29.6. Comparison 29 EASI versus intracervical prostaglandin E2: all women, Outcome 6 Endometritis.



Analysis 29.7. Comparison 29 EASI versus intracervical prostaglandin E2: all women, Outcome 7 Fetal distress.

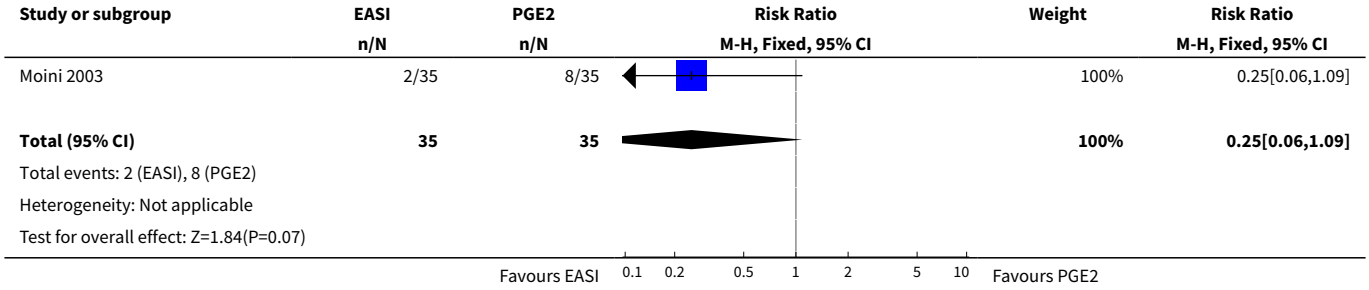




Comparison 30. EASI versus intracervical prostaglandin E2: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	70	Risk Ratio (M-H, Fixed, 95% CI)	0.25 [0.06, 1.09]

Analysis 30.1. Comparison 30 EASI versus intracervical prostaglandin E2: all primiparae, Outcome 1 Caesarean section.



Comparison 31. Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.84 [0.53, 1.33]
2 Uterine hyperstimulation with FHR changes	2	122	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.01, 5.12]
3 Caesarean section	7	517	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.66, 1.40]
4 Cervix unfavourable/unchanged after 24 hours	1	122	Risk Ratio (M-H, Fixed, 95% CI)	0.52 [0.31, 0.85]
5 Oxytocin augmentation	1	44	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.64, 1.41]
6 Uterine hyperstimulation without FHR changes	3	239	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
7 Epidural analgesia	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.77, 1.24]
8 Instrumental vaginal delivery	2	78	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.22, 1.45]
9 Meconium-stained liquor	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.33, 2.83]
10 Neonatal intensive care unit admission	1	44	Risk Ratio (M-H, Fixed, 95% CI)	0.26 [0.01, 5.12]
11 Postpartum haemorrhage	1	39	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Chorioamnionitis	2	122	Risk Ratio (M-H, Fixed, 95% CI)	1.56 [0.45, 5.45]
13 Endometritis	3	237	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.41, 2.78]
14 Fetal distress	2	140	Risk Ratio (M-H, Fixed, 95% CI)	2.28 [0.54, 9.69]

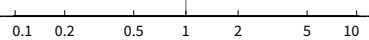
Analysis 31.1. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.

Study or subgroup	Mechanical method n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Hibbard 1998	13/22	12/17		100%	0.84[0.53,1.33]
Total (95% CI)	**22**	**17**		**100%**	**0.84[0.53,1.33]**
Total events: 13 (Mechanical method), 12 (PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.75(P=0.45)					

Favours mechanical method PGE2

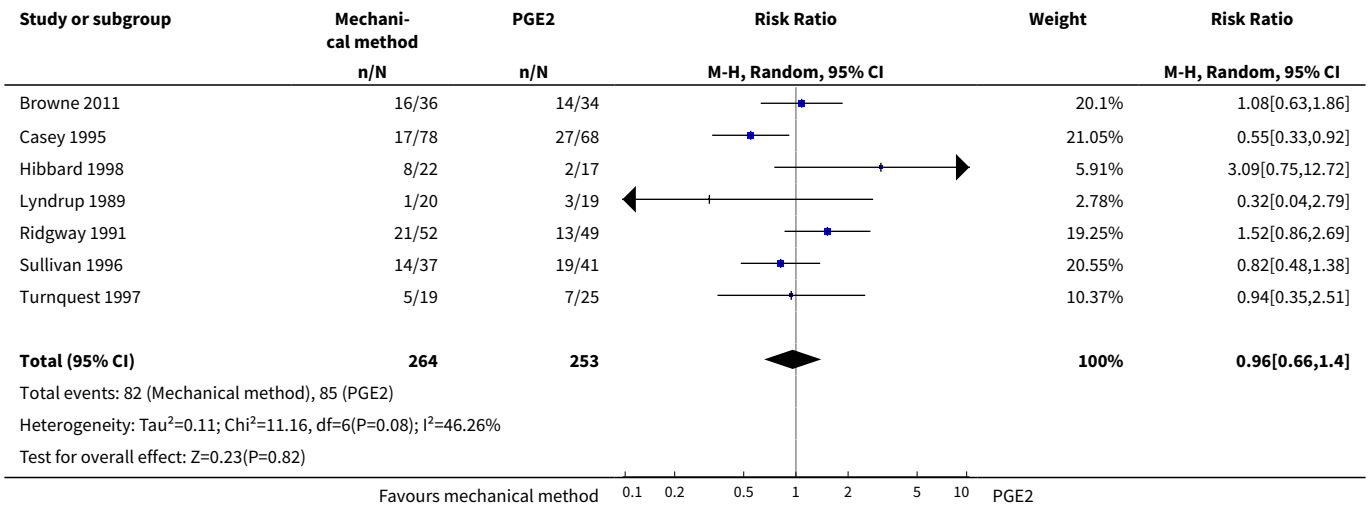
Analysis 31.2. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 2 Uterine hyperstimulation with FHR changes.

Study or subgroup	Mechanical method n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Sullivan 1996	0/37	0/41			Not estimable
Turnquest 1997	0/19	2/25		100%	0.26[0.01,5.12]
Total (95% CI)	**56**	**66**		**100%**	**0.26[0.01,5.12]**
Total events: 0 (Mechanical method), 2 (PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.89(P=0.38)					

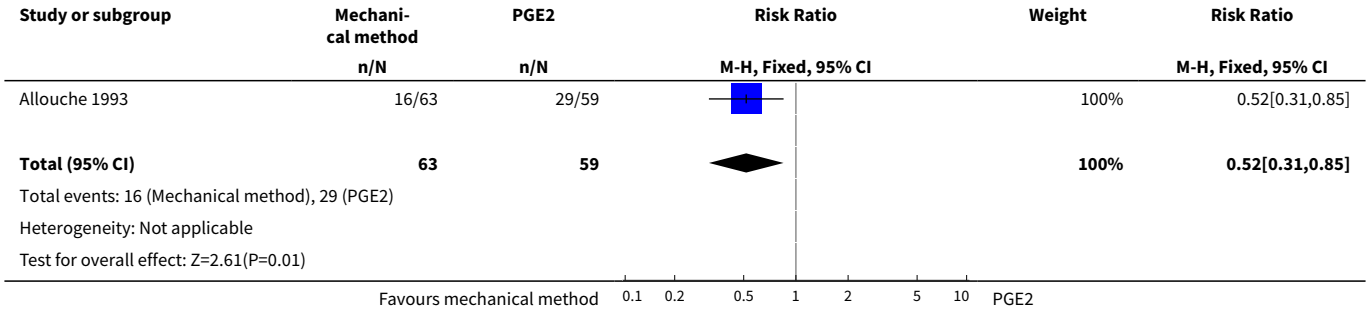


Favours mechanical method PGE2

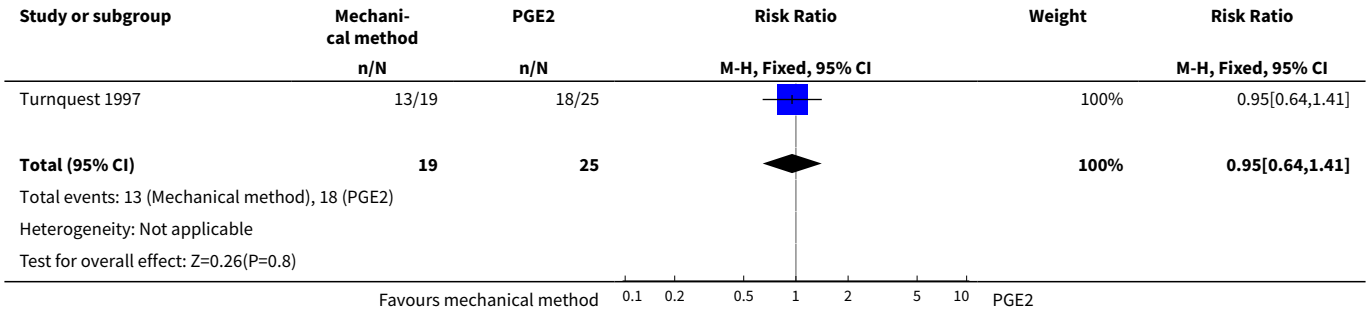
Analysis 31.3. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 3 Caesarean section.



Analysis 31.4. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 4 Cervix unfavourable/unchanged after 24 hours.

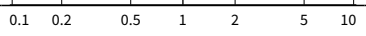


Analysis 31.5. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 5 Oxytocin augmentation.



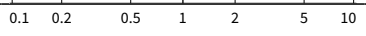
Analysis 31.6. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 6 Uterine hyperstimulation without FHR changes.

Study or subgroup	Mechanical method n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Allouche 1993	0/63	0/59			Not estimable
Hibbard 1998	0/22	0/17			Not estimable
Sullivan 1996	0/37	0/41			Not estimable
Total (95% CI)	**122**	**117**			**Not estimable**
Total events: 0 (Mechanical method), 0 (PGE2)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



Analysis 31.7. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 7 Epidural analgesia.

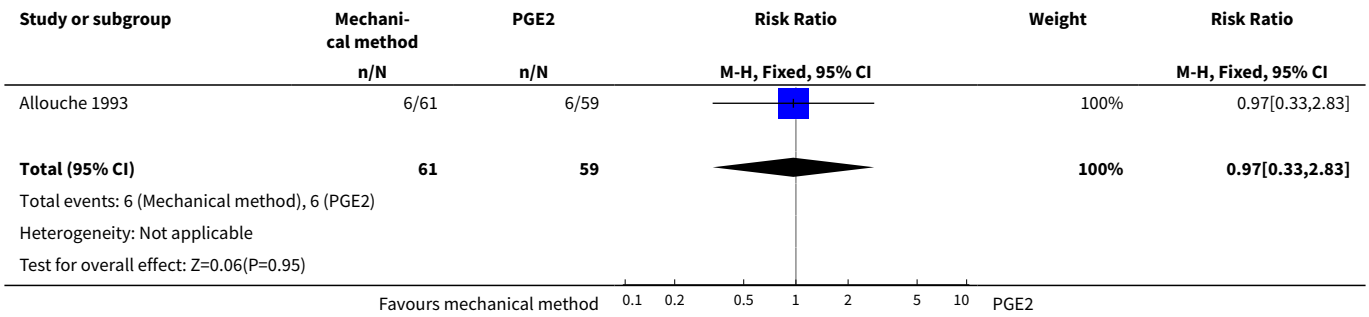
Study or subgroup	Mechanical method n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Hibbard 1998	19/22	15/17		100%	0.98[0.77,1.24]
Total (95% CI)	**22**	**17**		**100%**	**0.98[0.77,1.24]**
Total events: 19 (Mechanical method), 15 (PGE2)					
Heterogeneity: $Tau^2=0$; $Chi^2=0$, df=0(P<0.0001); $I^2=100\%$					
Test for overall effect: Z=0.17(P=0.86)					



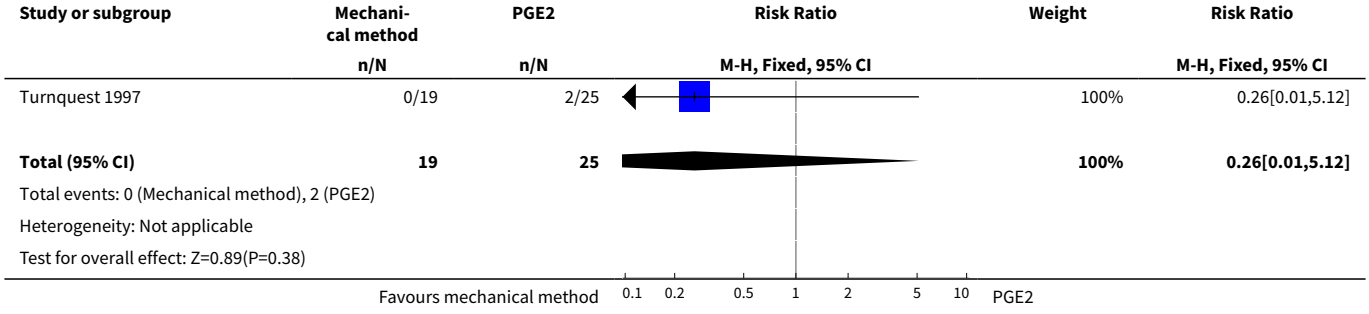
Analysis 31.8. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 8 Instrumental vaginal delivery.

Study or subgroup	Mechanical method n/N	PGE2 n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Hibbard 1998	4/22	4/17		46.81%	0.77[0.23,2.65]
Lyndrup 1989	2/20	5/19		53.19%	0.38[0.08,1.73]
Total (95% CI)	**42**	**36**		**100%**	**0.56[0.22,1.45]**
Total events: 6 (Mechanical method), 9 (PGE2)					
Heterogeneity: $Tau^2=0$; $Chi^2=0.51$, df=1(P=0.47); $I^2=0\%$					
Test for overall effect: Z=1.19(P=0.23)					

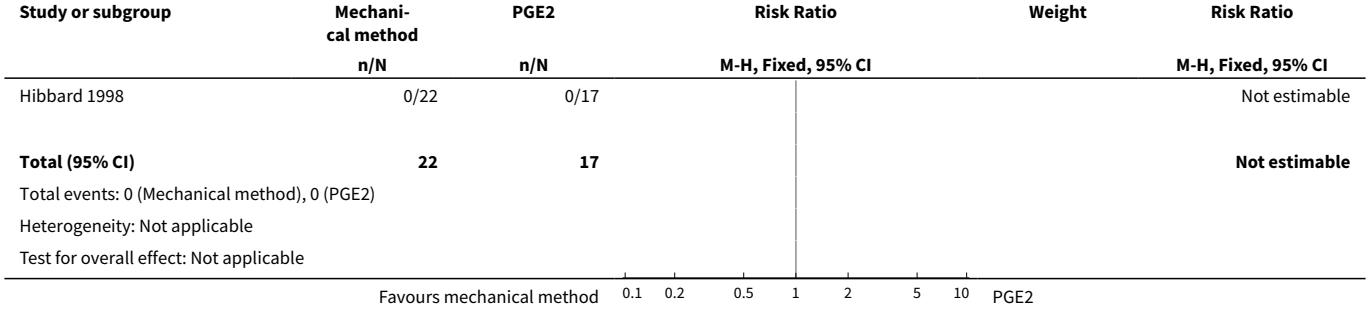
Analysis 31.9. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 9 Meconium-stained liquor.



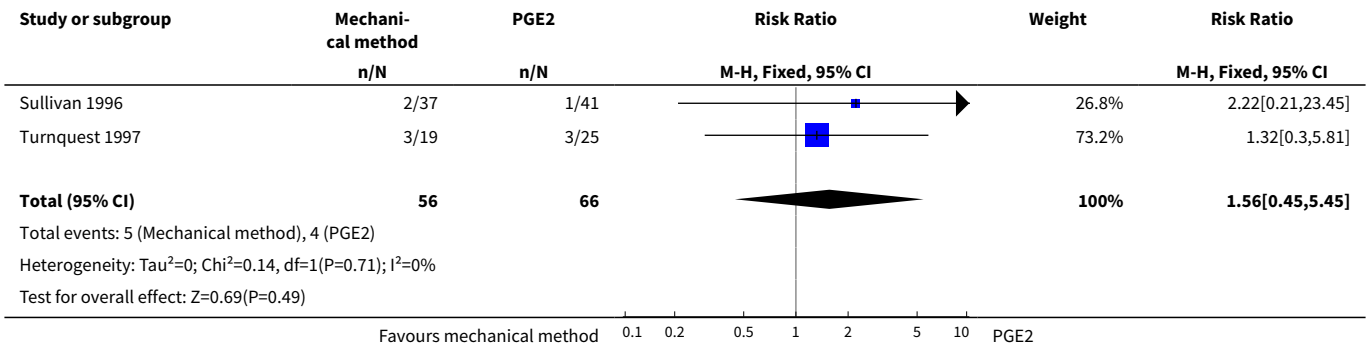
Analysis 31.10. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 10 Neonatal intensive care unit admission.



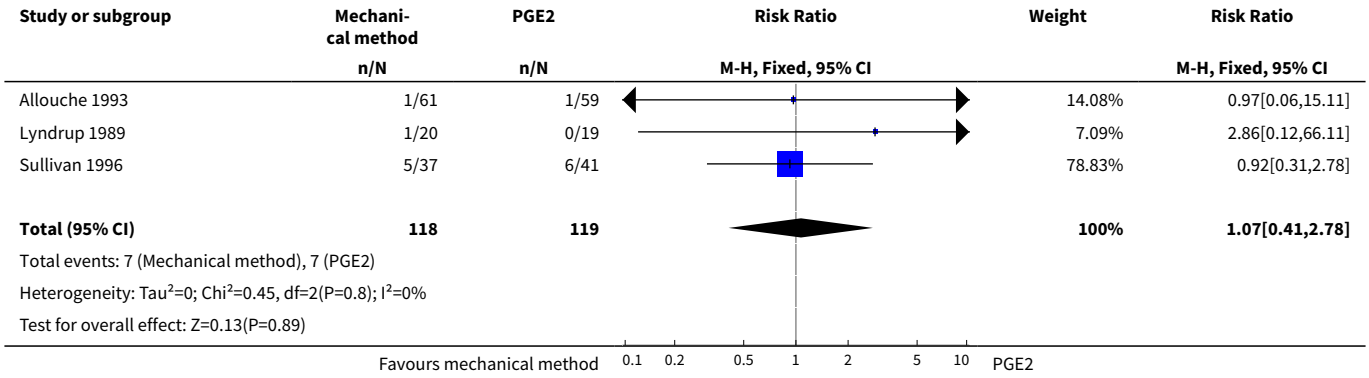
Analysis 31.11. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 11 Postpartum haemorrhage.



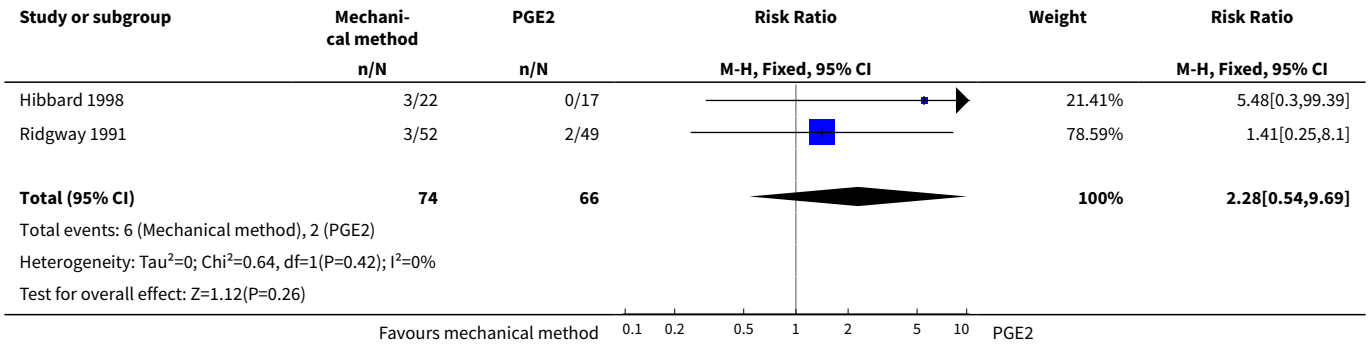
Analysis 31.12. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 12 Chorioamnionitis.



Analysis 31.13. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 13 Endometritis.



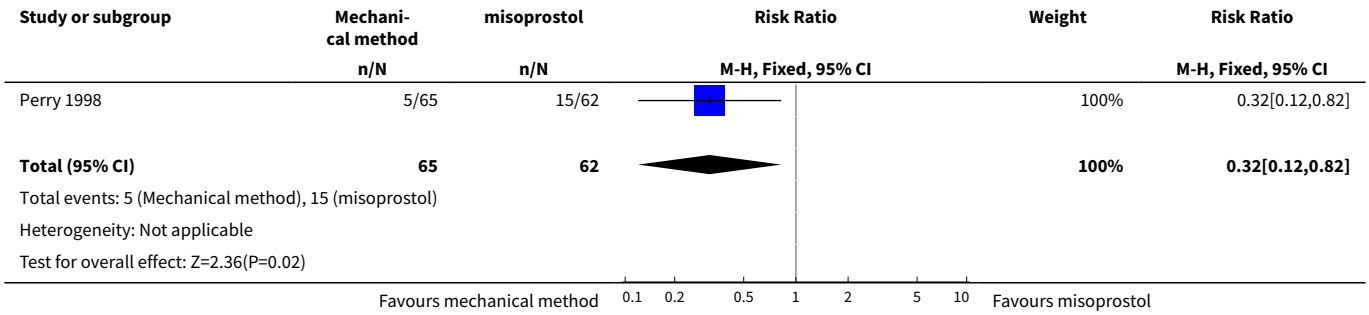
Analysis 31.14. Comparison 31 Any mechanical method and prostaglandin E2 versus prostaglandin E2 alone: all women, Outcome 14 Fetal distress.



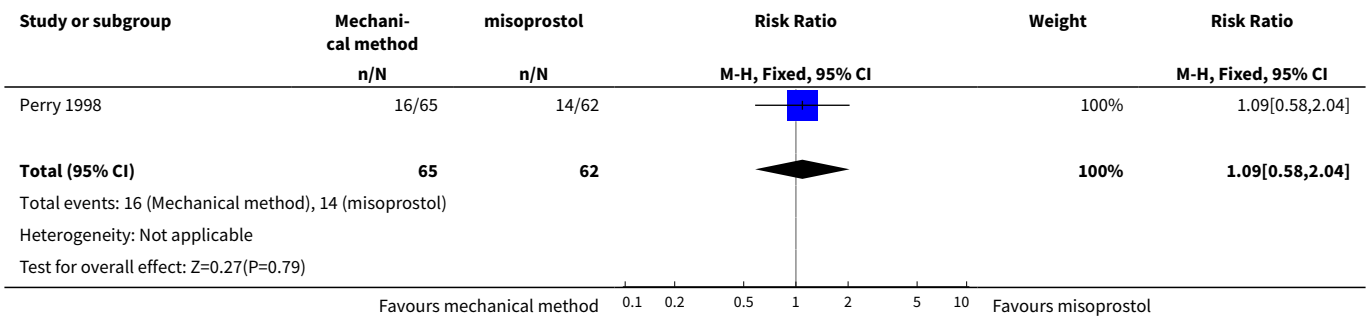
Comparison 32. Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	127	Risk Ratio (M-H, Fixed, 95% CI)	0.32 [0.12, 0.82]
2 Caesarean section	1	127	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.58, 2.04]
3 Serious neonatal morbidity/perinatal death	1	127	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.01, 3.90]
4 Cervix unfavourable/unchanged after 12-24 hours	1	127	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.25, 0.67]
5 Oxytocin augmentation	1	127	Risk Ratio (M-H, Fixed, 95% CI)	1.21 [1.01, 1.46]
6 Uterine hyperstimulation without FHR changes	1	127	Risk Ratio (M-H, Fixed, 95% CI)	4.05 [1.44, 11.38]
7 Instrumental vaginal delivery	1	127	Risk Ratio (M-H, Fixed, 95% CI)	1.26 [0.77, 2.04]
8 Meconium-stained liquor	1	127	Risk Ratio (M-H, Fixed, 95% CI)	0.56 [0.23, 1.32]
9 Apgar score < 7 at 5 minutes	1	127	Risk Ratio (M-H, Fixed, 95% CI)	1.91 [0.18, 20.51]
10 Neonatal intensive care unit admission	1	127	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.31, 1.31]
11 Perinatal death	1	127	Risk Ratio (M-H, Fixed, 95% CI)	0.19 [0.01, 3.90]
12 Chorioamnionitis	1	127	Risk Ratio (M-H, Fixed, 95% CI)	1.91 [0.18, 20.51]
13 Endometritis	1	127	Risk Ratio (M-H, Fixed, 95% CI)	1.91 [0.36, 10.05]

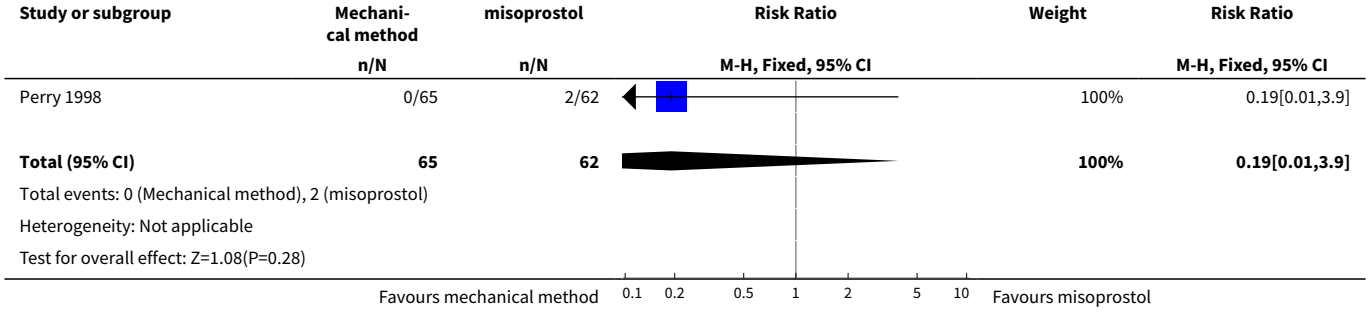
Analysis 32.1. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.



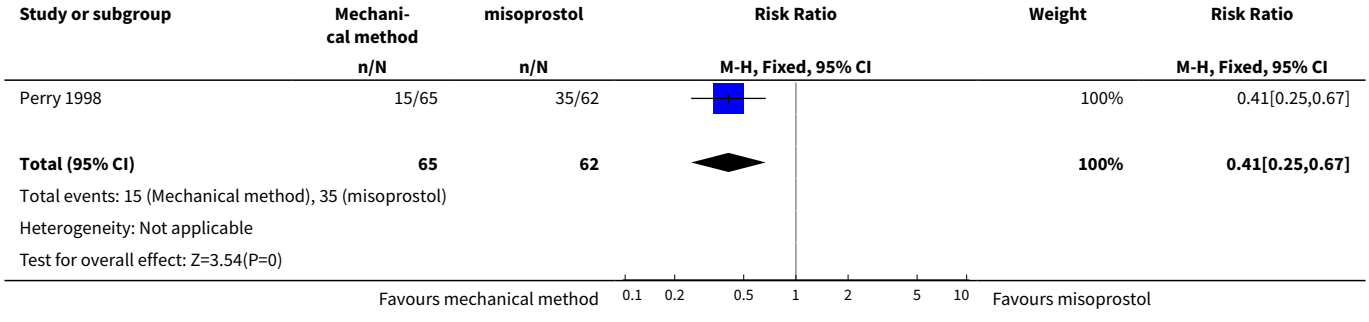
Analysis 32.2. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 2 Caesarean section.



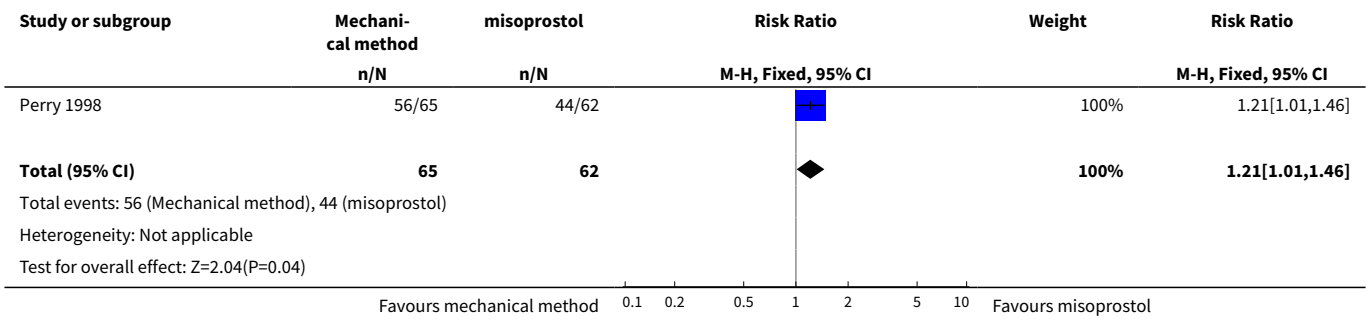
Analysis 32.3. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 3 Serious neonatal morbidity/perinatal death.



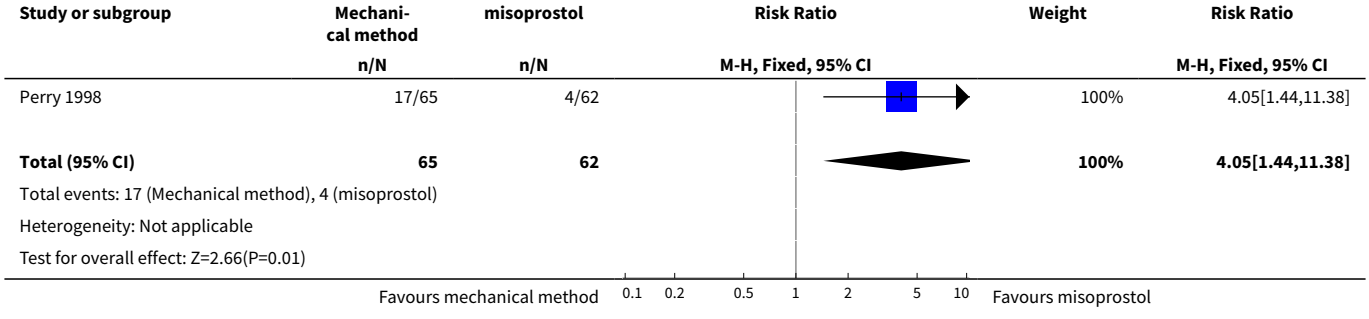
Analysis 32.4. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 4 Cervix unfavourable/unchanged after 12-24 hours.



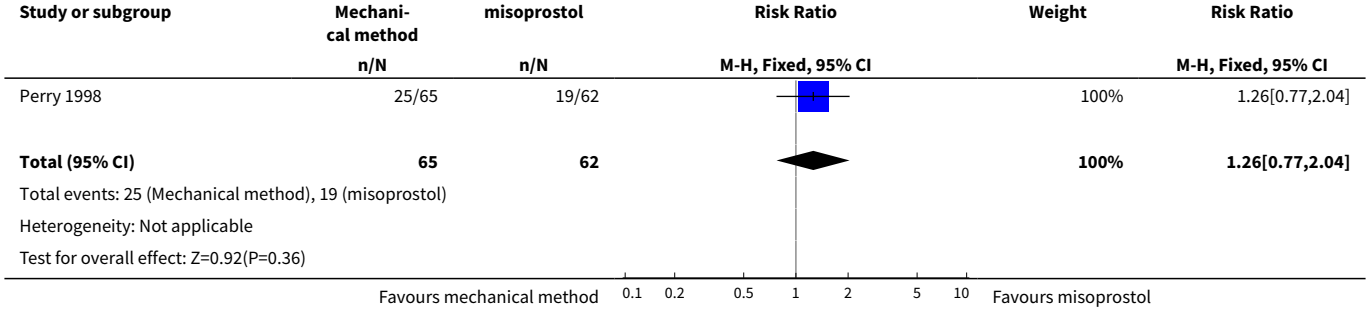
Analysis 32.5. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 5 Oxytocin augmentation.



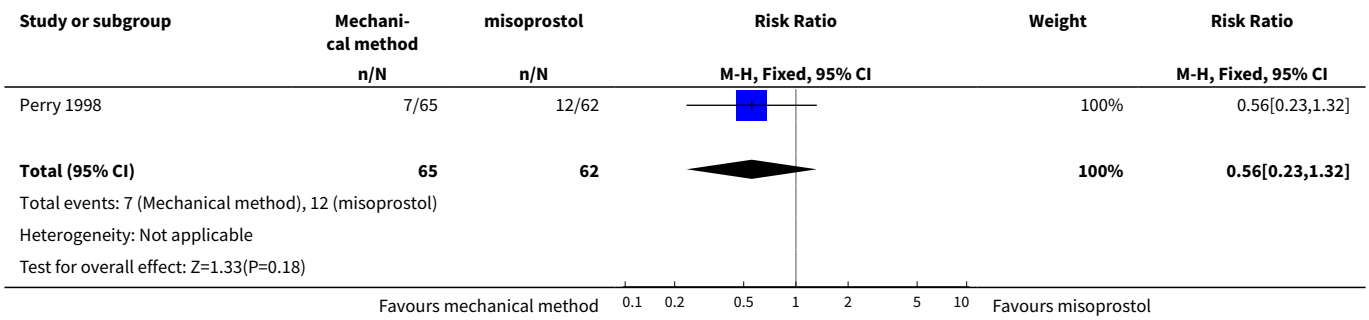
Analysis 32.6. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 6 Uterine hyperstimulation without FHR changes.



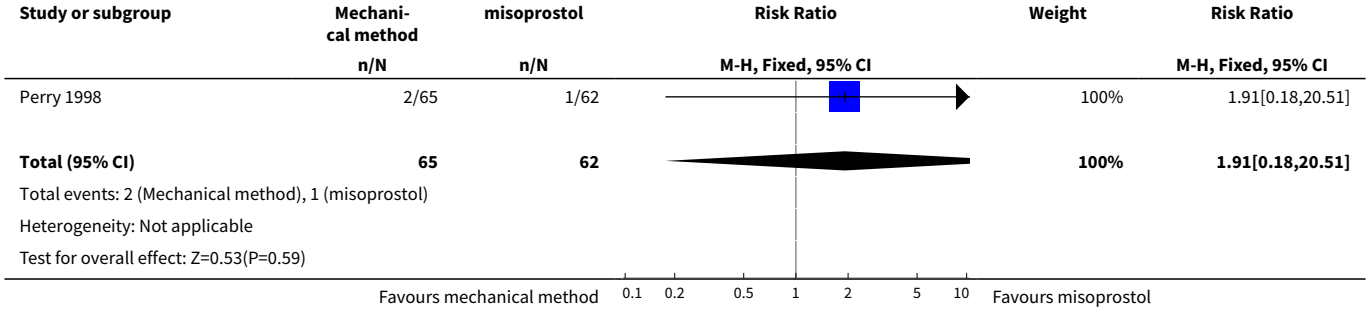
Analysis 32.7. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 7 Instrumental vaginal delivery.



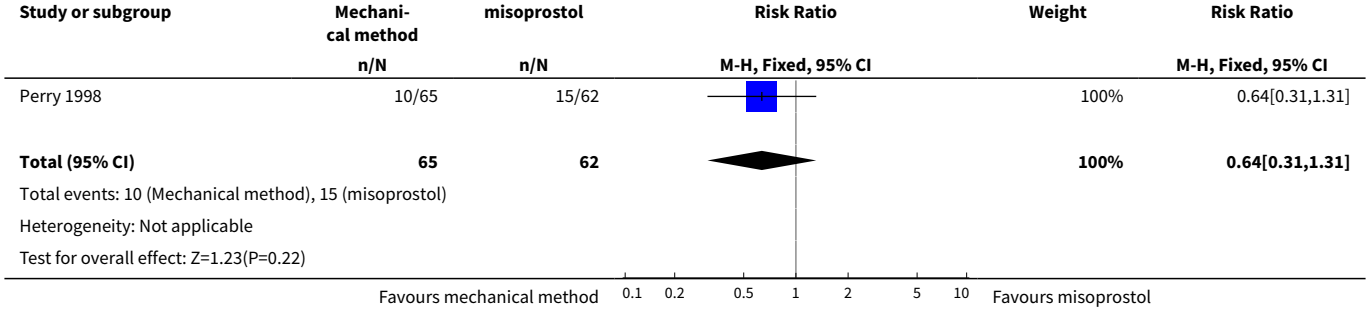
Analysis 32.8. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 8 Meconium-stained liquor.



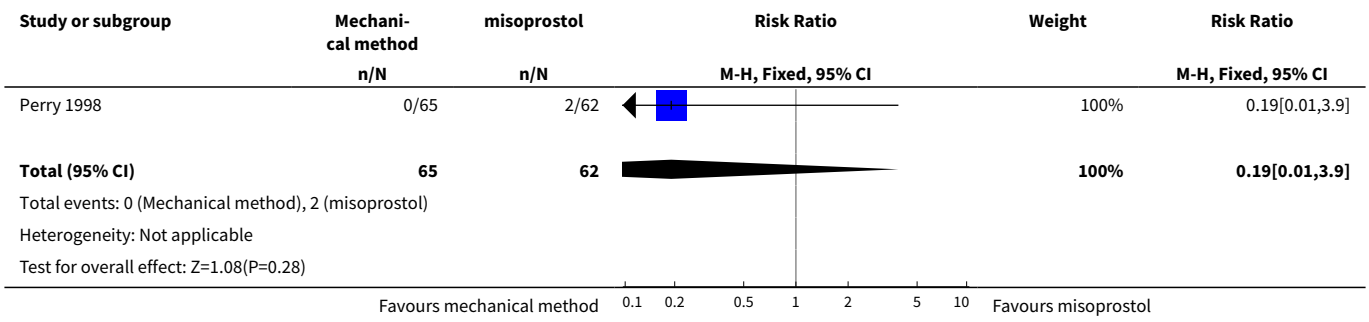
Analysis 32.9. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 9 Apgar score < 7 at 5 minutes.



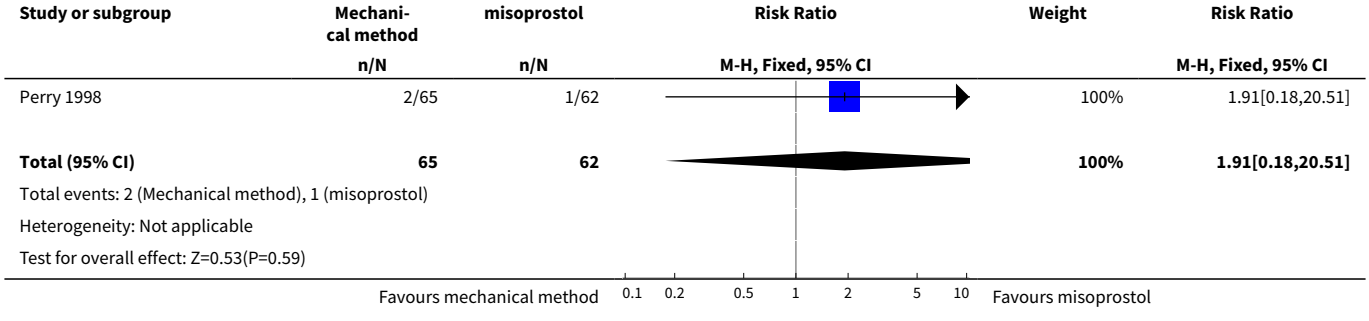
Analysis 32.10. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 10 Neonatal intensive care unit admission.



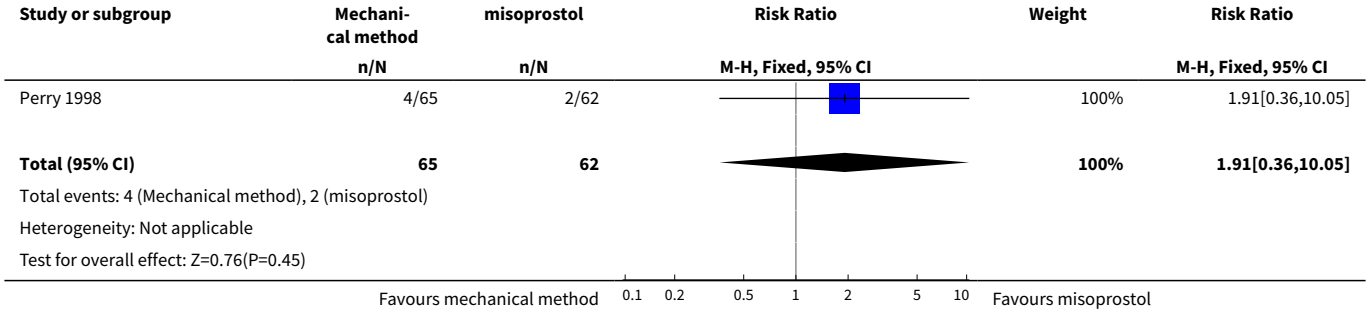
Analysis 32.11. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 11 Perinatal death.



Analysis 32.12. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 12 Chorioamnionitis.



Analysis 32.13. Comparison 32 Any mechanical method and prostaglandin E2 versus low dose misoprostol alone: all women, Outcome 13 Endometritis.

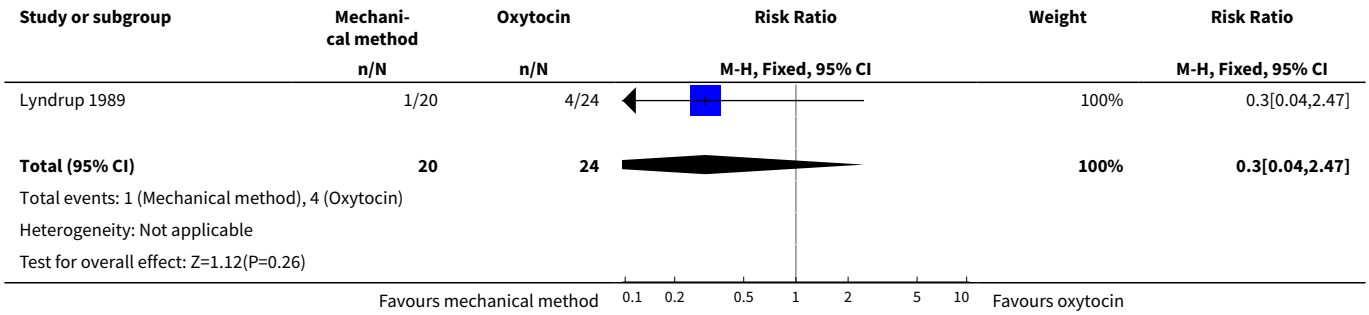


Comparison 33. Any mechanical method and prostaglandin E2 versus oxytocin alone: all women

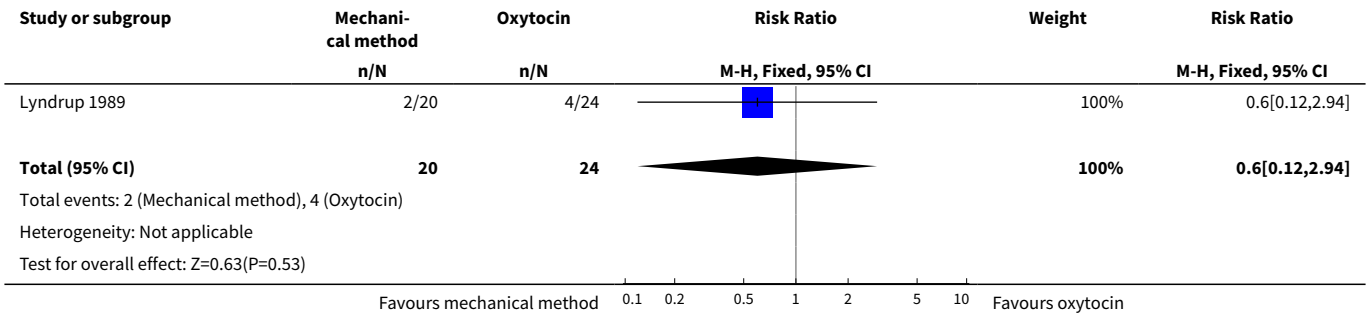
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	44	Risk Ratio (M-H, Fixed, 95% CI)	0.3 [0.04, 2.47]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2 Instrumental vaginal delivery	1	44	Risk Ratio (M-H, Fixed, 95% CI)	0.6 [0.12, 2.94]
3 Endometritis	1	44	Risk Ratio (M-H, Fixed, 95% CI)	3.57 [0.15, 83.14]

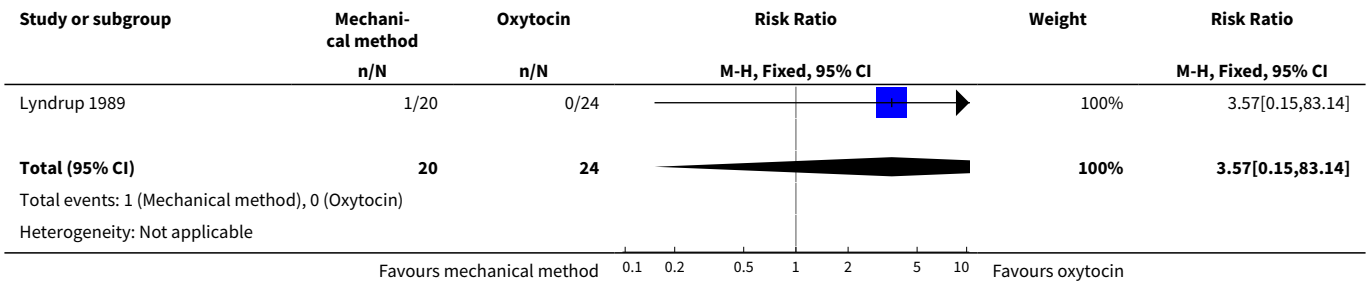
Analysis 33.1. Comparison 33 Any mechanical method and prostaglandin E2 versus oxytocin alone: all women, Outcome 1 Caesarean section.

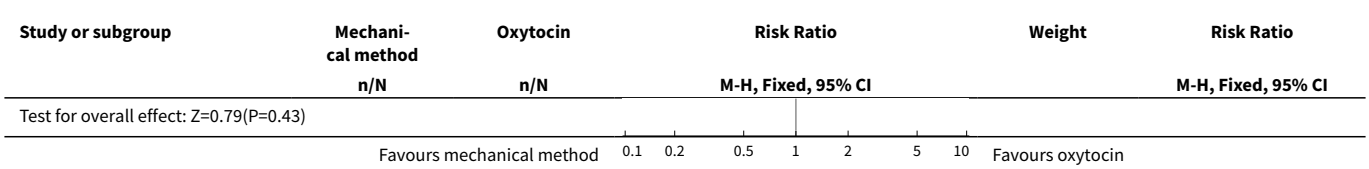


Analysis 33.2. Comparison 33 Any mechanical method and prostaglandin E2 versus oxytocin alone: all women, Outcome 2 Instrumental vaginal delivery.



Analysis 33.3. Comparison 33 Any mechanical method and prostaglandin E2 versus oxytocin alone: all women, Outcome 3 Endometritis.

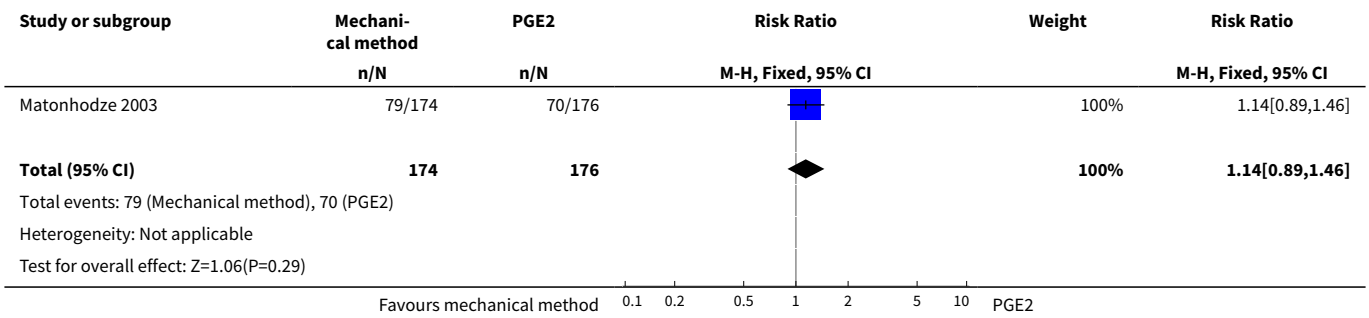




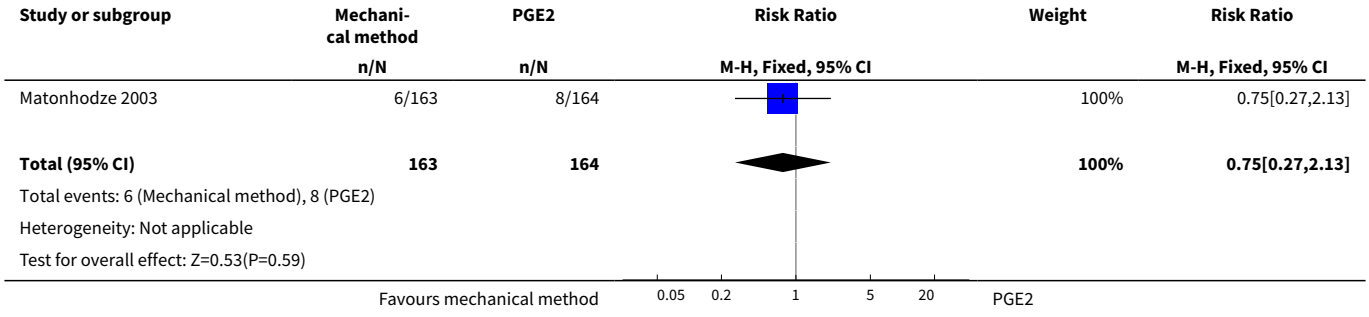
Comparison 34. Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	350	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.89, 1.46]
2 Uterine hyperstimulation with FHR changes	1	327	Risk Ratio (M-H, Fixed, 95% CI)	0.75 [0.27, 2.13]
3 Caesarean section	1	350	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.57, 1.25]
4 Serious neonatal morbidity/perinatal death	1	345	Risk Ratio (M-H, Fixed, 95% CI)	2.04 [0.19, 22.24]
5 Serious maternal morbidity or death	1	350	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Oxytocin augmentation	1	350	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.34, 0.86]
7 Uterine hyperstimulation without fetal heart rate changes	1	327	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.22, 1.32]
8 Uterine rupture	1	350	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Instrumental vaginal delivery	1	350	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.26, 3.98]
10 Meconium-stained liquor	1	339	Risk Ratio (M-H, Fixed, 95% CI)	1.15 [0.60, 2.23]
11 Apgar score < 7 at 5 minutes	1	346	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.25, 1.88]
12 Neonatal intensive care unit admission	1	346	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.12, 4.03]
13 Perinatal death	1	345	Risk Ratio (M-H, Fixed, 95% CI)	1.02 [0.06, 16.14]
14 Maternal side effects	1	314	Risk Ratio (M-H, Fixed, 95% CI)	1.16 [0.95, 1.43]
15 Maternal nausea	1	300	Risk Ratio (M-H, Fixed, 95% CI)	1.65 [0.98, 2.79]
16 Maternal diarrhoea	1	313	Risk Ratio (M-H, Fixed, 95% CI)	3.72 [1.53, 9.00]
17 Postpartum haemorrhage	1	348	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.67, 1.41]
18 Serious maternal complications	1	350	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
19 Maternal fever during labour	1	347	Risk Ratio (M-H, Fixed, 95% CI)	1.53 [0.26, 9.02]

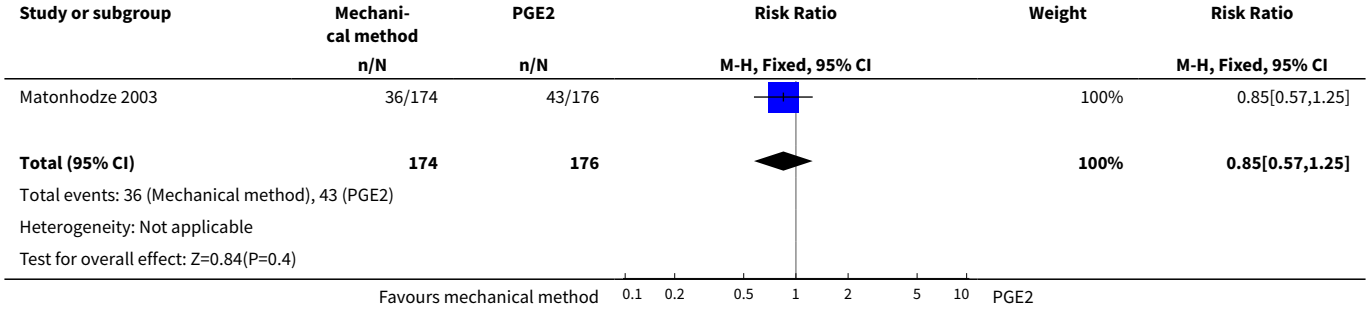
Analysis 34.1. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.



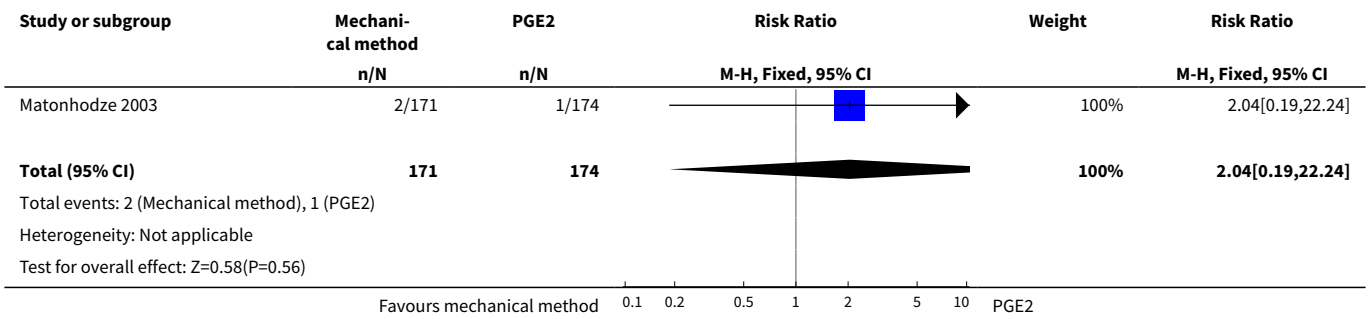
Analysis 34.2. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 2 Uterine hyperstimulation with FHR changes.



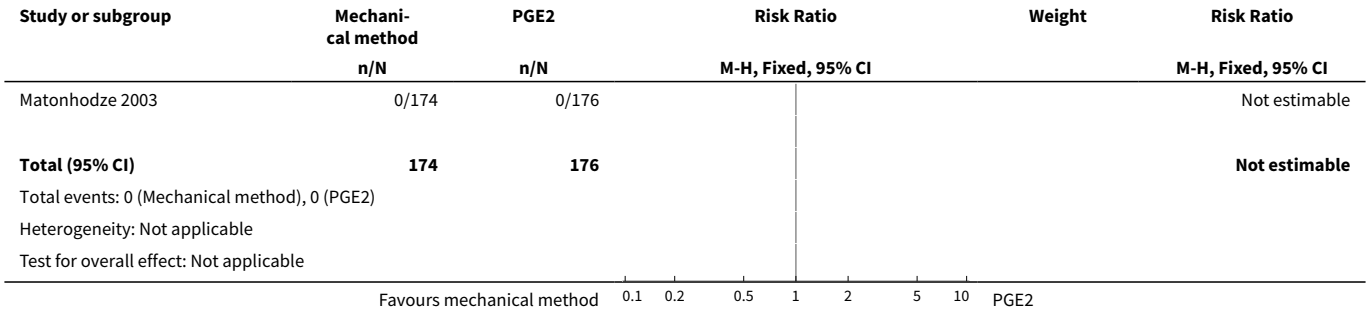
Analysis 34.3. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 3 Caesarean section.



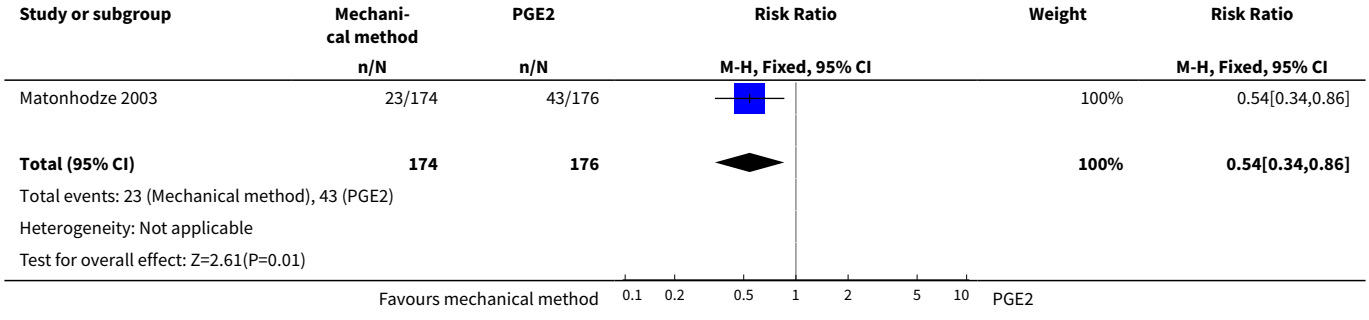
Analysis 34.4. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 4 Serious neonatal morbidity/perinatal death.



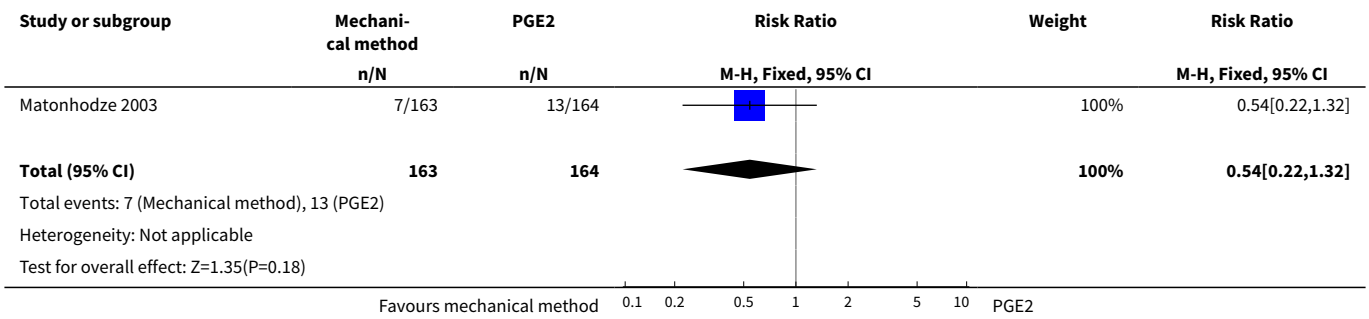
Analysis 34.5. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 5 Serious maternal morbidity or death.



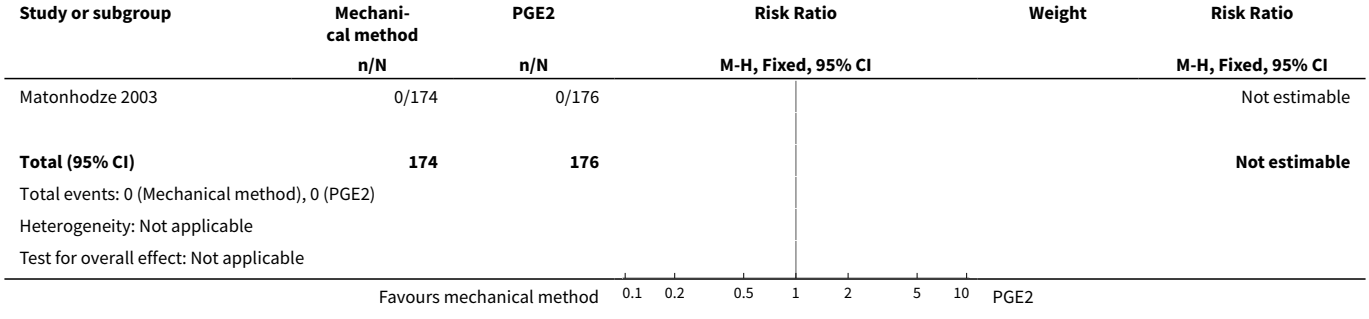
Analysis 34.6. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 6 Oxytocin augmentation.



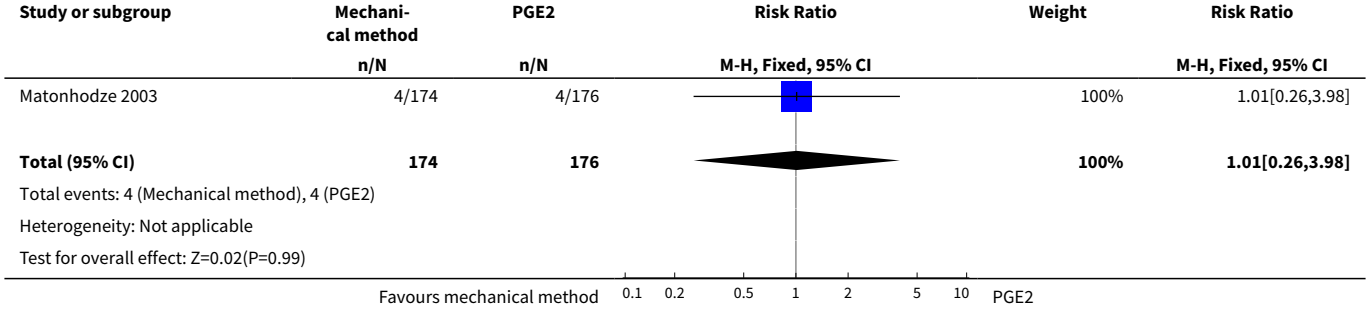
Analysis 34.7. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 7 Uterine hyperstimulation without fetal heart rate changes.



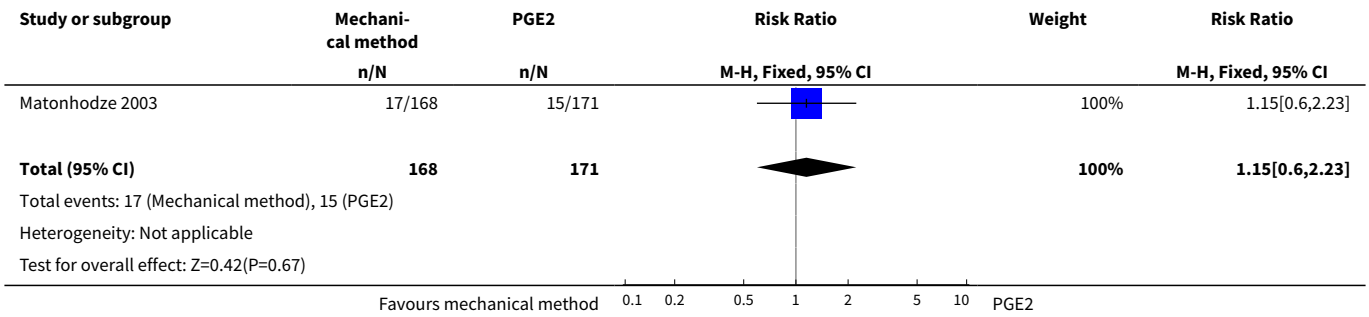
Analysis 34.8. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 8 Uterine rupture.



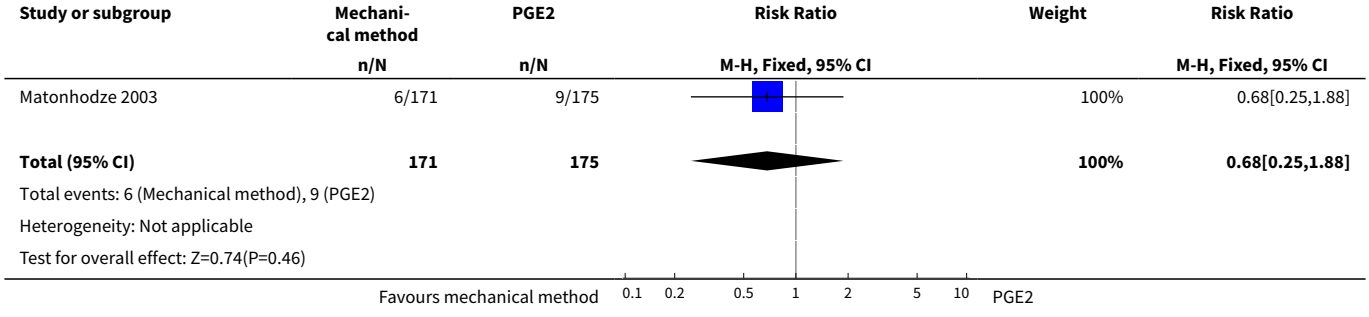
Analysis 34.9. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 9 Instrumental vaginal delivery.



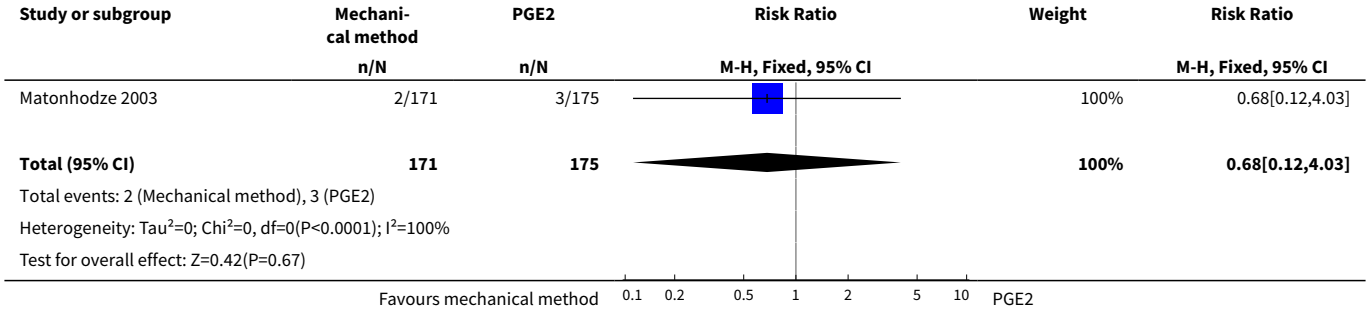
Analysis 34.10. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 10 Meconium-stained liquor.



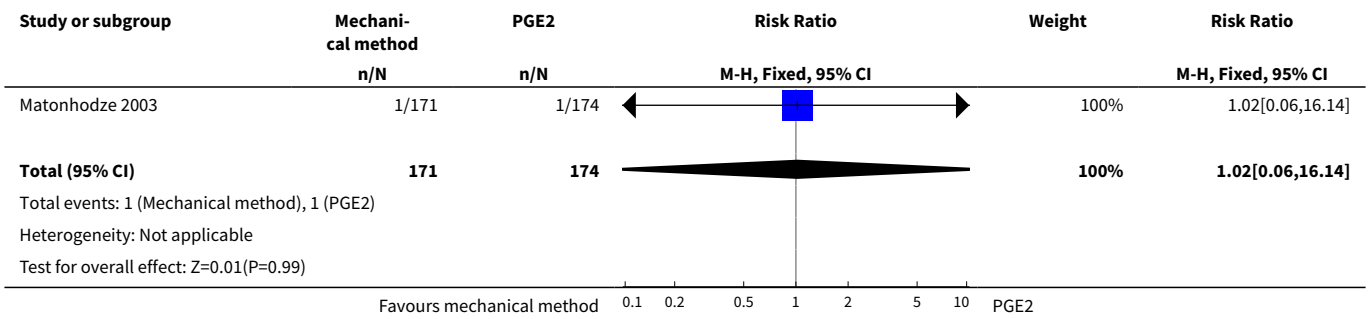
Analysis 34.11. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 11 Apgar score < 7 at 5 minutes.



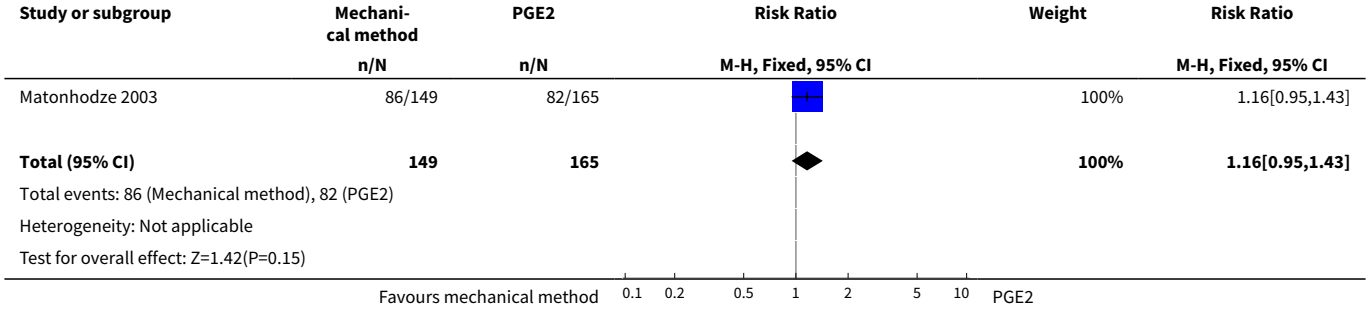
Analysis 34.12. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 12 Neonatal intensive care unit admission.



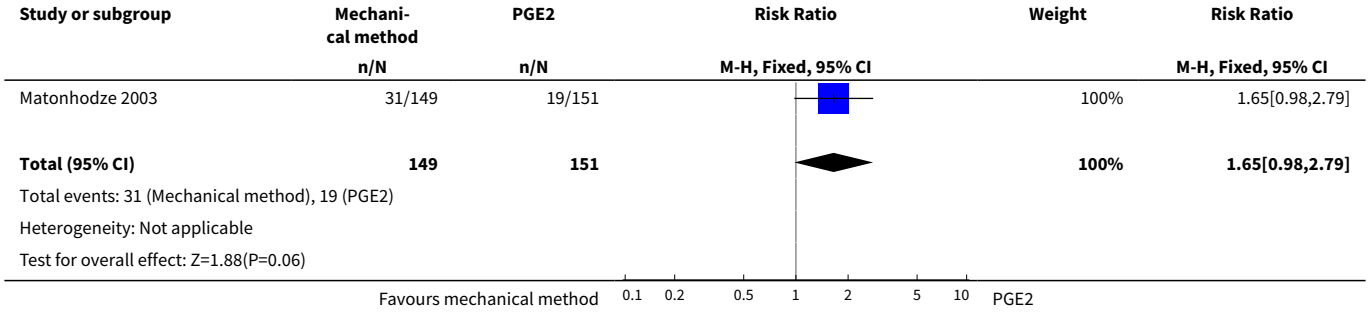
Analysis 34.13. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 13 Perinatal death.



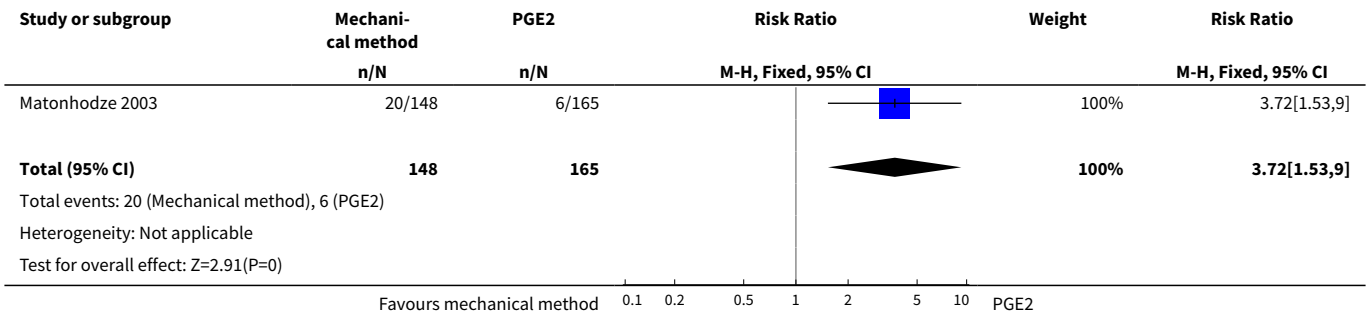
Analysis 34.14. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 14 Maternal side effects.



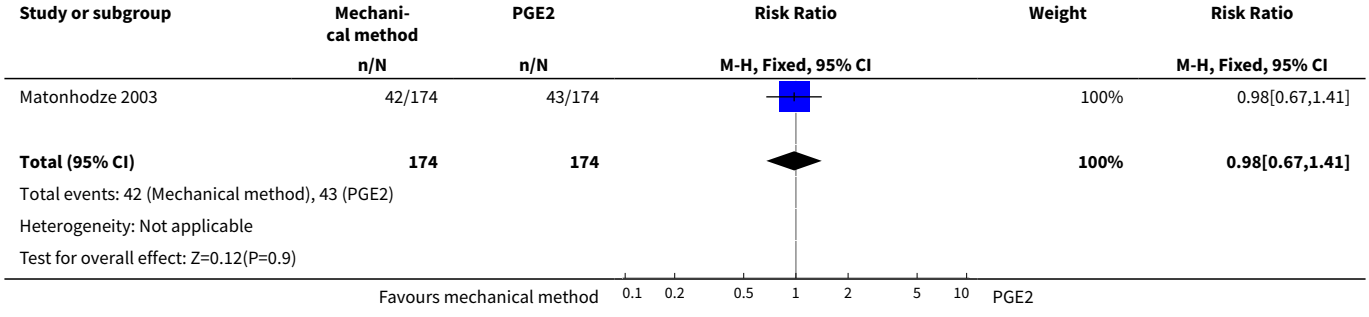
Analysis 34.15. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 15 Maternal nausea.



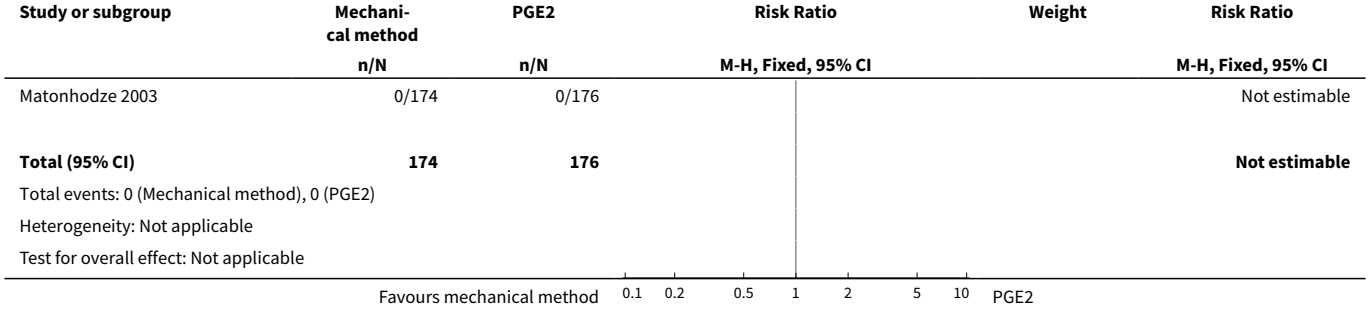
Analysis 34.16. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 16 Maternal diarrhoea.



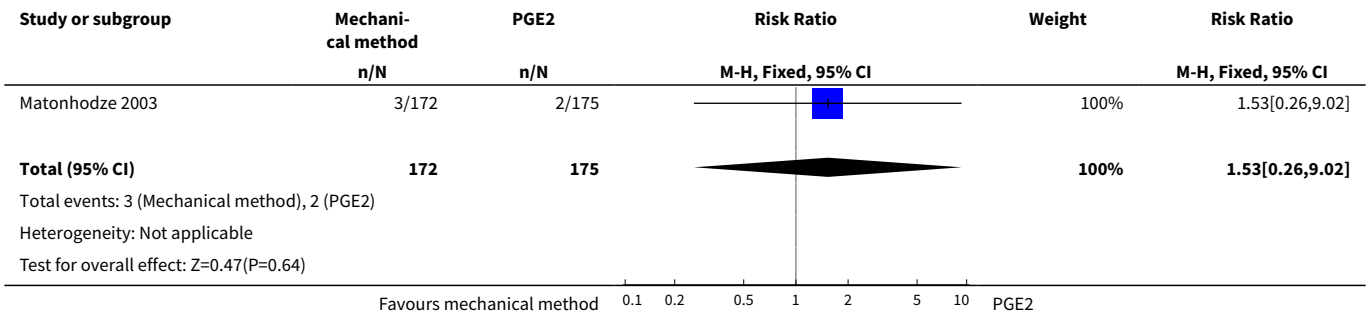
Analysis 34.17. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 17 Postpartum haemorrhage.



Analysis 34.18. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 18 Serious maternal complications.



Analysis 34.19. Comparison 34 Any mechanical method and low dose misoprostol versus prostaglandin E2 alone: all women, Outcome 19 Maternal fever during labour.



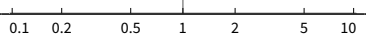
Comparison 35. Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	2	668	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.25, 1.95]
2 Uterine hyperstimulation with FHR changes	4	707	Risk Ratio (M-H, Random, 95% CI)	0.54 [0.20, 1.45]
3 Caesarean section	7	1422	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.66, 1.15]
4 Serious neonatal morbidity/perinatal death	2	487	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.34, 4.55]
5 Serious maternal morbidity or death	2	490	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Cervix unfavourable/unchanged after 12 hours	1	140	Risk Ratio (M-H, Fixed, 95% CI)	0.27 [0.08, 0.94]
7 Oxytocin augmentation	5	1051	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.70, 1.25]
8 Uterine hyperstimulation without FHR changes	4	982	Risk Ratio (M-H, Fixed, 95% CI)	0.53 [0.32, 0.90]
9 Uterine rupture	2	490	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Epidural analgesia	3	443	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.91, 1.10]
11 Instrumental vaginal delivery	3	676	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.58, 1.51]
12 Meconium-stained liquor	6	1243	Risk Ratio (M-H, Random, 95% CI)	0.61 [0.35, 1.04]
13 Apgar score < 7 at 5 minutes	3	802	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.37, 1.36]
14 Neonatal intensive care unit admission	6	1246	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.36, 0.91]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
15 Perinatal death	1	347	Risk Ratio (M-H, Fixed, 95% CI)	3.09 [0.13, 75.26]
16 Maternal side effects	1	300	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.87, 1.30]
17 Maternal nausea	1	300	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.84, 2.23]
18 Maternal diarrhoea	1	298	Risk Ratio (M-H, Fixed, 95% CI)	3.38 [1.40, 8.17]
19 Postpartum haemorrhage	2	466	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.65, 1.33]
20 Serious maternal complications	1	350	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
21 Chorioamnionitis	3	443	Risk Ratio (M-H, Fixed, 95% CI)	0.63 [0.28, 1.38]
22 Endometrits	2	435	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.08, 2.08]
23 Fetal distress	4	784	Risk Ratio (M-H, Fixed, 95% CI)	0.78 [0.53, 1.14]

Analysis 35.1. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 1 Vaginal delivery not achieved in 24 hours.

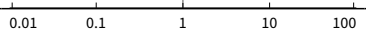
Study or subgroup	Mechanical method n/N	Misoprostol n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Husain 2017	19/161	45/157		47.85%	0.41[0.25,0.67]
Matonhodze 2003	79/174	70/176		52.15%	1.14[0.89,1.46]
Total (95% CI)	**335**	**333**		**100%**	**0.7[0.25,1.95]**
Total events: 98 (Mechanical method), 115 (Misoprostol)					
Heterogeneity: Tau^2=0.51; Chi^2=14, df=1(P=0); I^2=92.85%					
Test for overall effect: Z=0.68(P=0.5)					



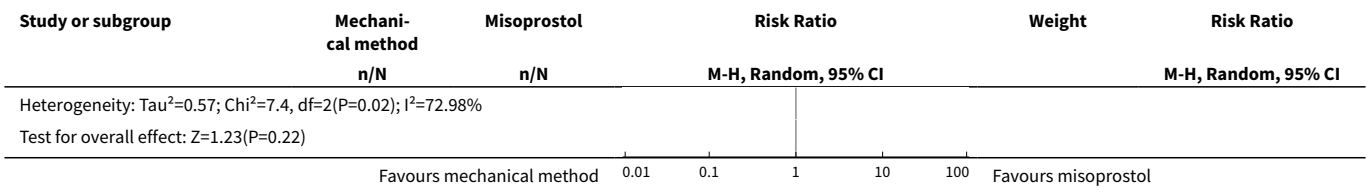
Favours mechanical method — Favours misoprostol

Analysis 35.2. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 2 Uterine hyperstimulation with FHR changes.

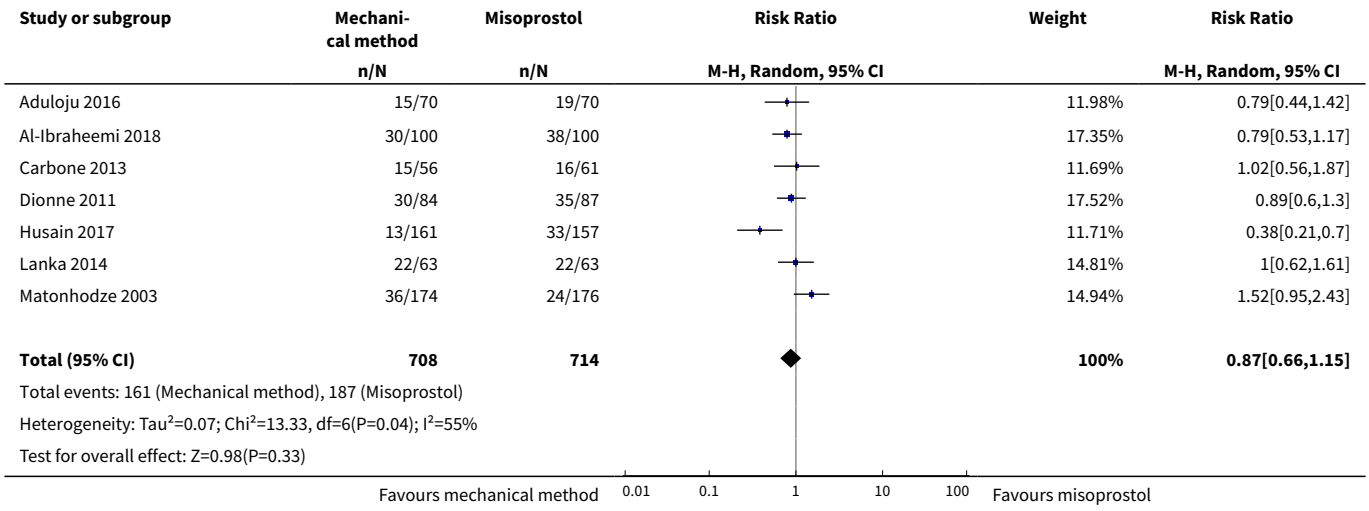
Study or subgroup	Mechanical method n/N	Misoprostol n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Aduloju 2016	0/70	0/70			Not estimable
Carbone 2013	10/56	12/61		36.34%	0.91[0.43,1.93]
Lanka 2014	5/63	25/63		33.56%	0.2[0.08,0.49]
Matonhodze 2003	6/163	7/161		30.1%	0.85[0.29,2.46]
Total (95% CI)	**352**	**355**		**100%**	**0.54[0.2,1.45]**
Total events: 21 (Mechanical method), 44 (Misoprostol)					



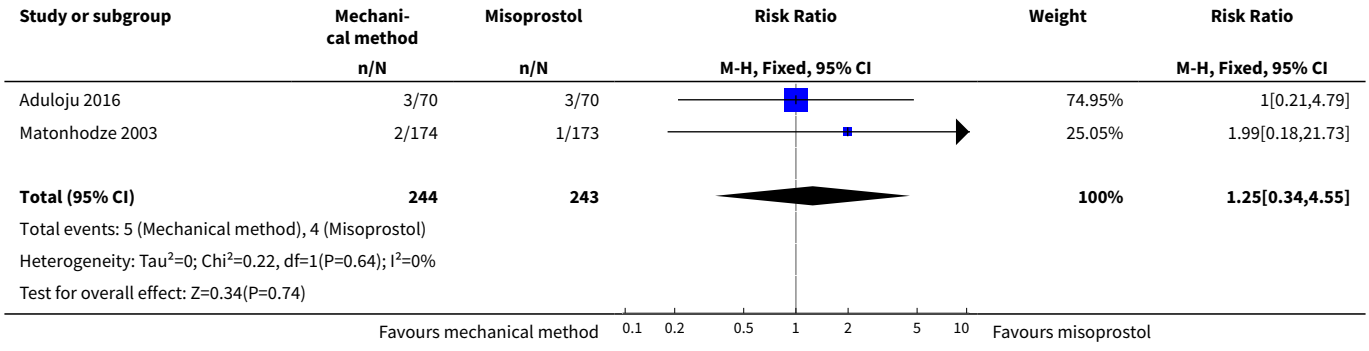
Favours mechanical method — Favours misoprostol



Analysis 35.3. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 3 Caesarean section.



Analysis 35.4. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 4 Serious neonatal morbidity/perinatal death.



Analysis 35.5. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 5 Serious maternal morbidity or death.

Study or subgroup	Mechanical method n/N	Misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	0/70	0/70			Not estimable
Matonhodze 2003	0/174	0/176			Not estimable
Total (95% CI)	**244**	**246**			**Not estimable**
Total events: 0 (Mechanical method), 0 (Misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

Favours mechanical method — Favours misoprostol

Analysis 35.6. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 6 Cervix unfavourable/unchanged after 12 hours.

Study or subgroup	Mechanical method n/N	Misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Aduloju 2016	3/70	11/70		100%	0.27[0.08,0.94]
Total (95% CI)	**70**	**70**		**100%**	**0.27[0.08,0.94]**
Total events: 3 (Mechanical method), 11 (Misoprostol)					
Heterogeneity: Not applicable					
Test for overall effect: Z=2.07(P=0.04)					

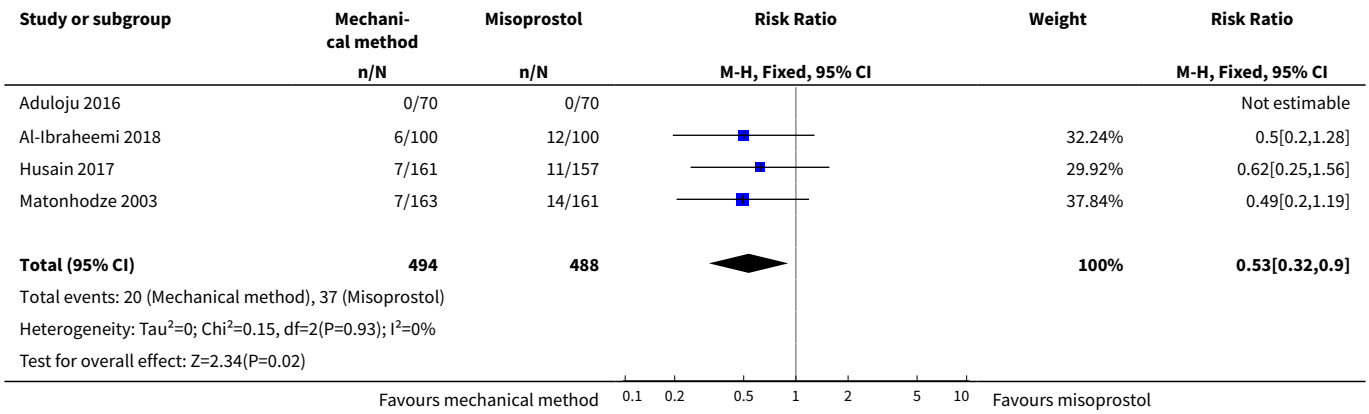
Favours mechanical method — Favours misoprostol

Analysis 35.7. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 7 Oxytocin augmentation.

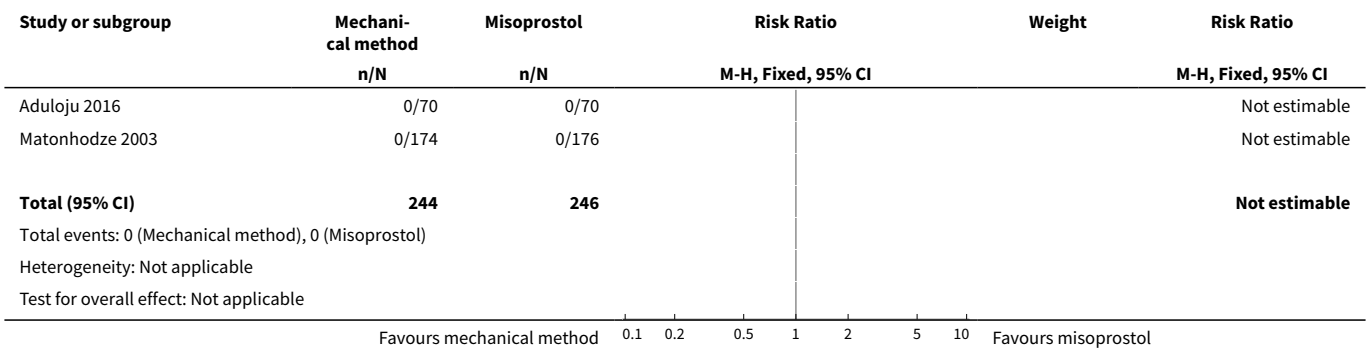
Study or subgroup	Mechanical method n/N	Misoprostol n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Aduloju 2016	22/70	43/70		18.74%	0.51[0.35,0.76]
Carbone 2013	46/56	54/61		26.75%	0.93[0.8,1.08]
Husain 2017	62/161	71/157		23.35%	0.85[0.66,1.1]
Lanka 2014	35/63	29/63		20.31%	1.21[0.85,1.71]
Matonhodze 2003	23/174	11/176		10.85%	2.11[1.06,4.21]
Total (95% CI)	**524**	**527**		**100%**	**0.94[0.7,1.25]**
Total events: 188 (Mechanical method), 208 (Misoprostol)					
Heterogeneity: Tau^2=0.07; Chi^2=16.91, df=4(P=0); I^2=76.34%					
Test for overall effect: Z=0.44(P=0.66)					

Favours mechanical method — Favours misoprostol

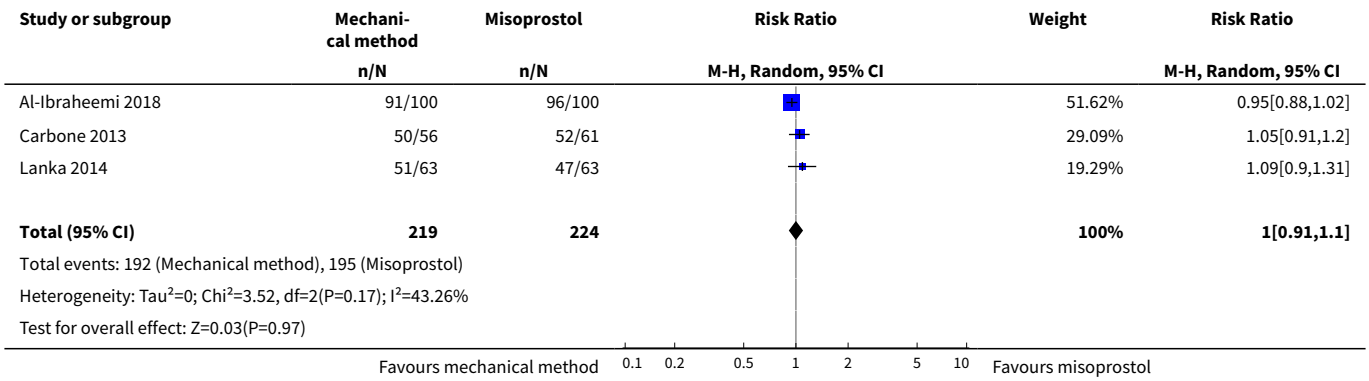
Analysis 35.8. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 8 Uterine hyperstimulation without FHR changes.



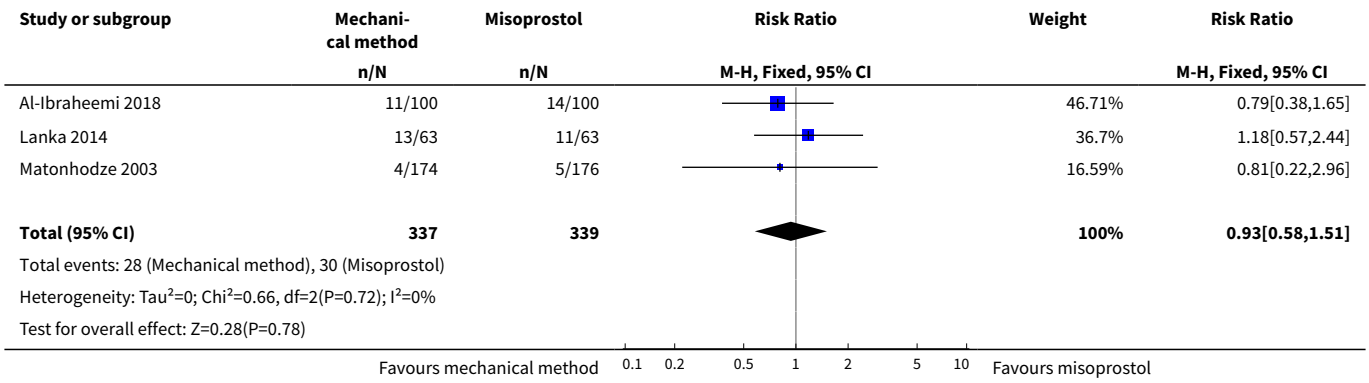
Analysis 35.9. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 9 Uterine rupture.



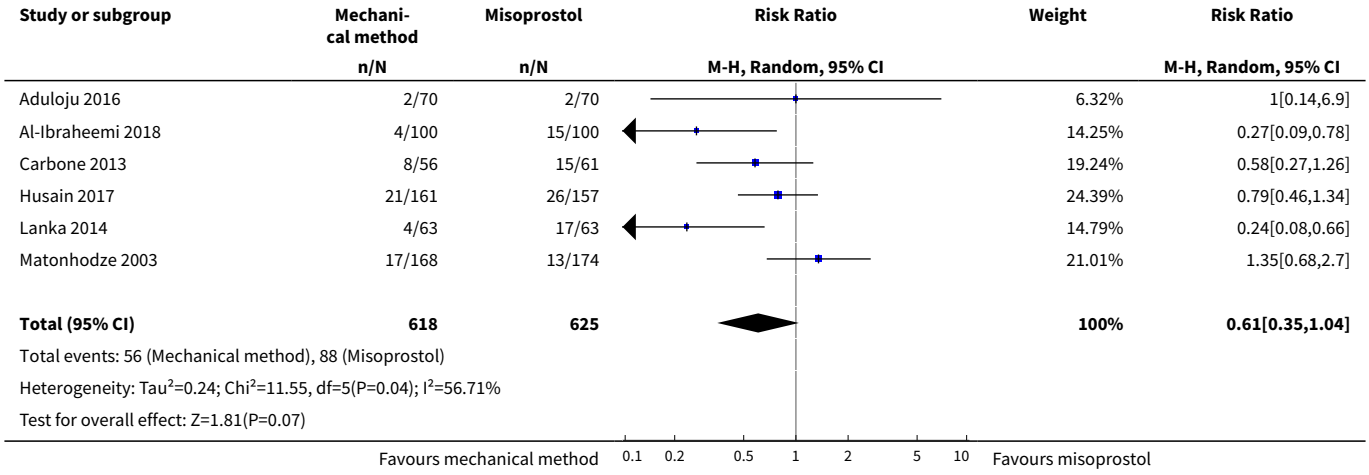
Analysis 35.10. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 10 Epidural analgesia.



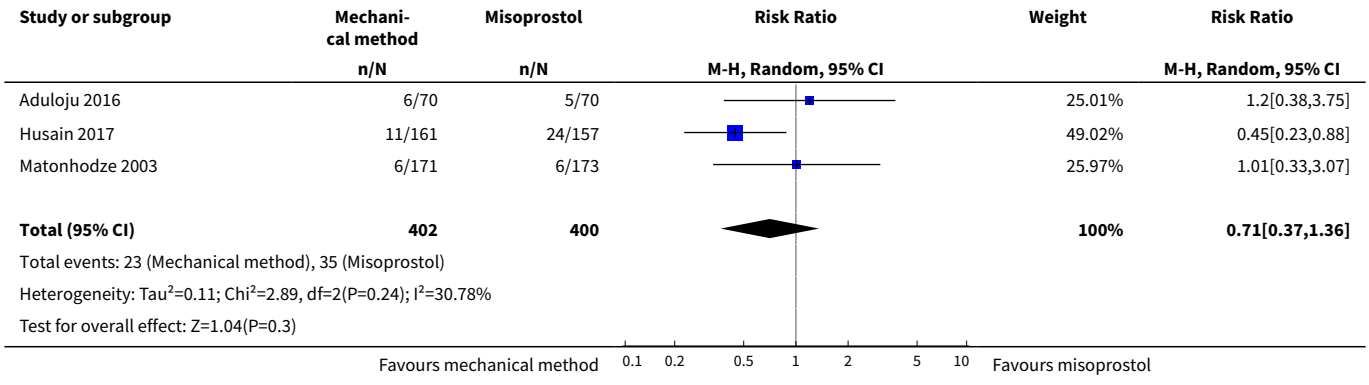
Analysis 35.11. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 11 Instrumental vaginal delivery.



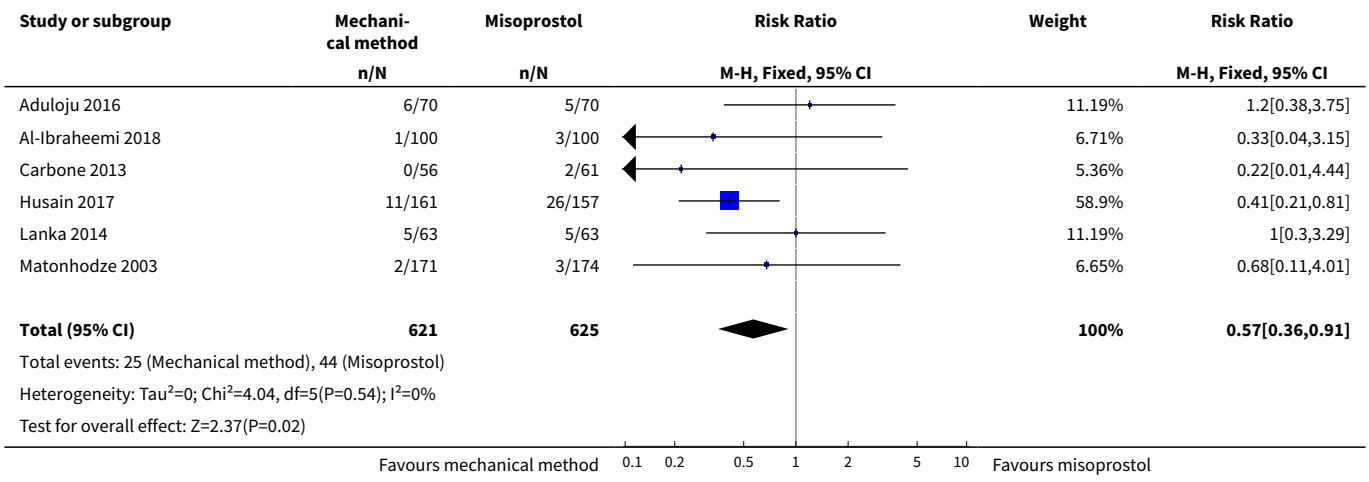
Analysis 35.12. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 12 Meconium-stained liquor.



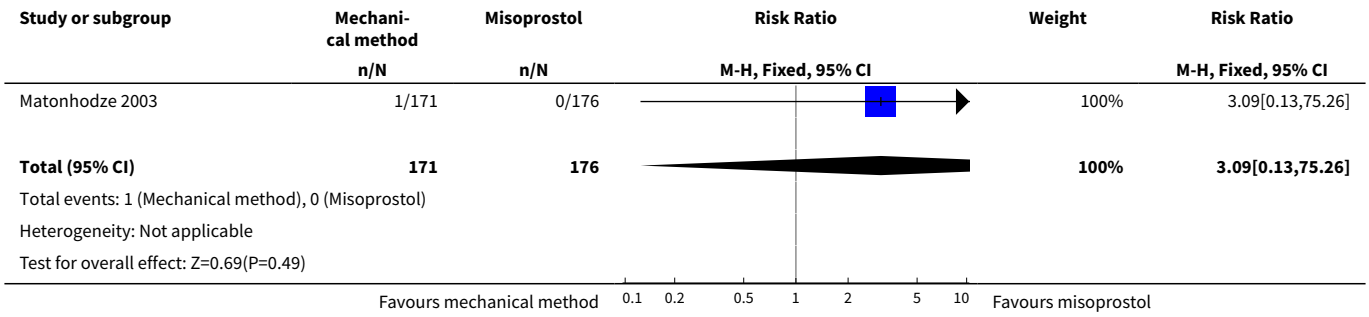
Analysis 35.13. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 13 Apgar score < 7 at 5 minutes.



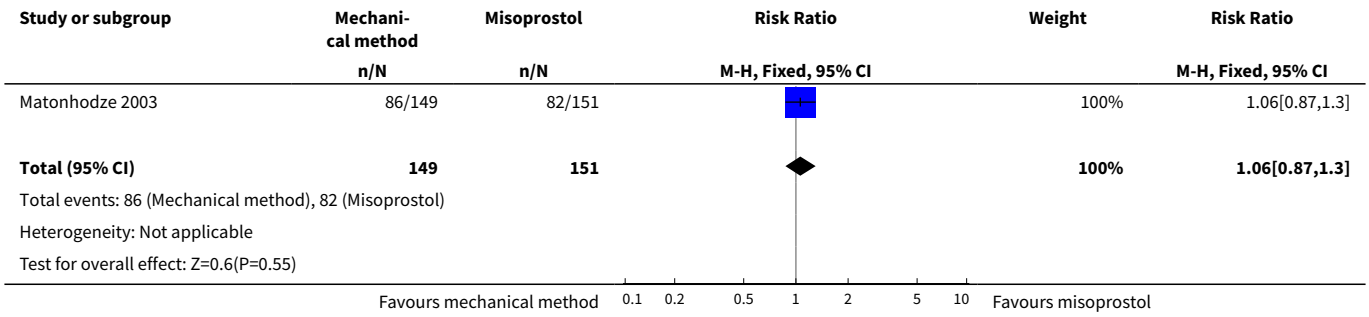
Analysis 35.14. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 14 Neonatal intensive care unit admission.



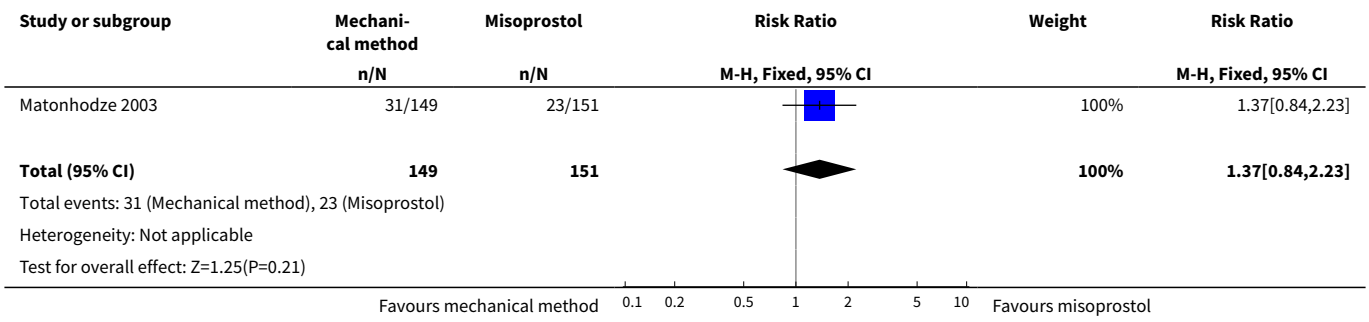
Analysis 35.15. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 15 Perinatal death.



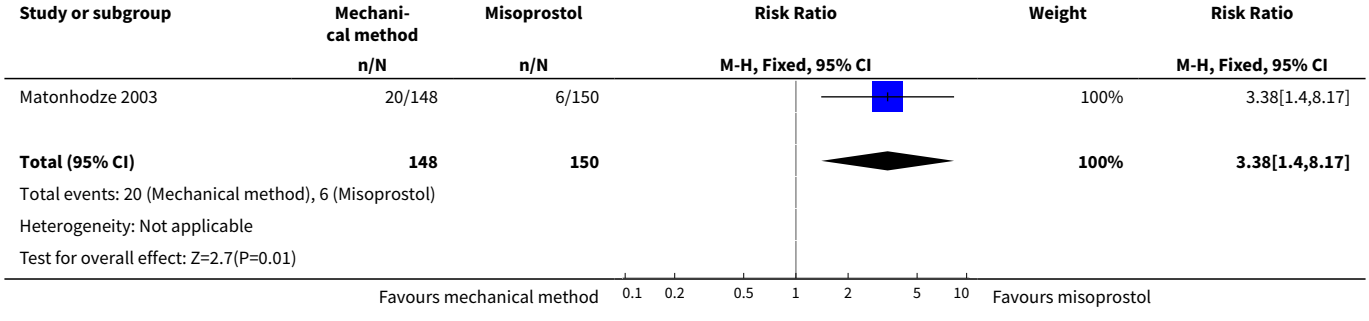
Analysis 35.16. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 16 Maternal side effects.



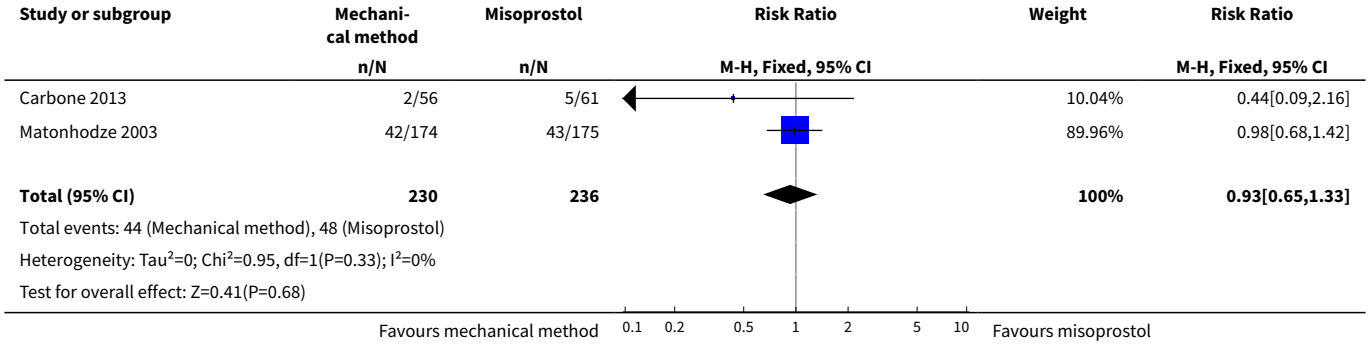
Analysis 35.17. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 17 Maternal nausea.



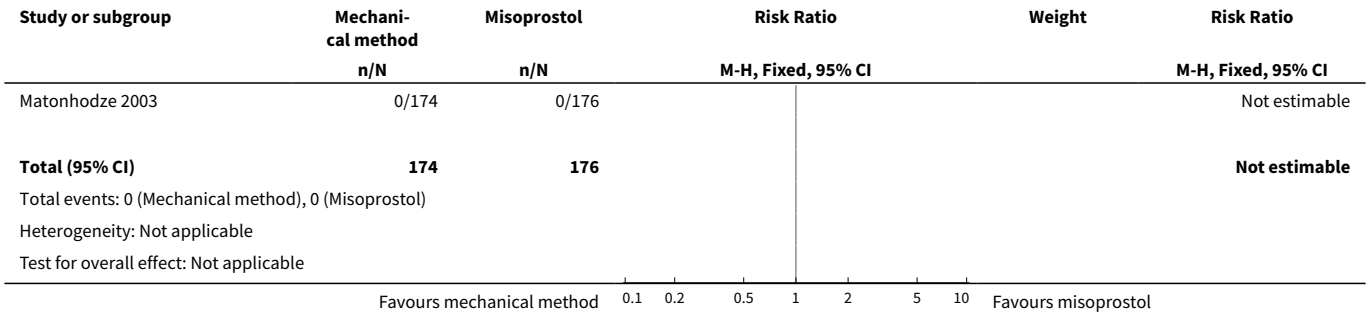
Analysis 35.18. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 18 Maternal diarrhoea.



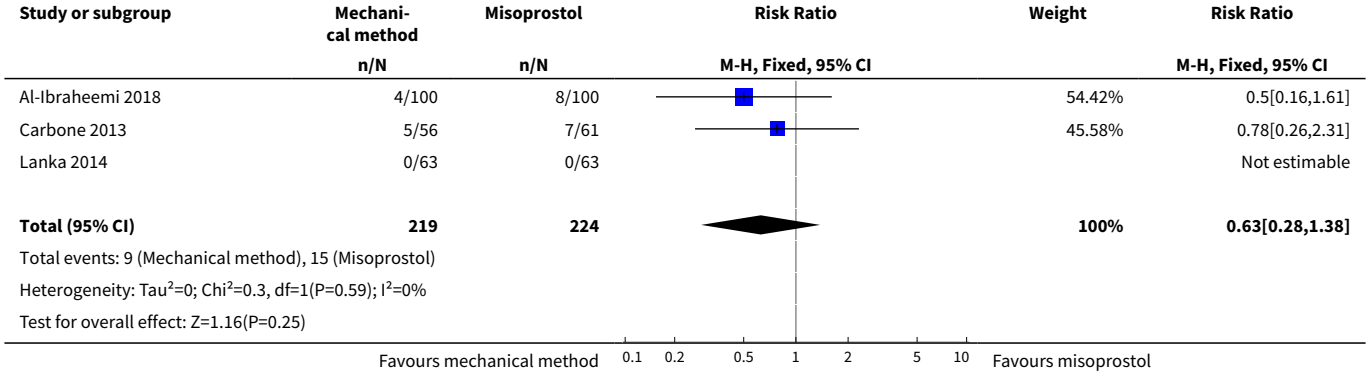
Analysis 35.19. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 19 Postpartum haemorrhage.



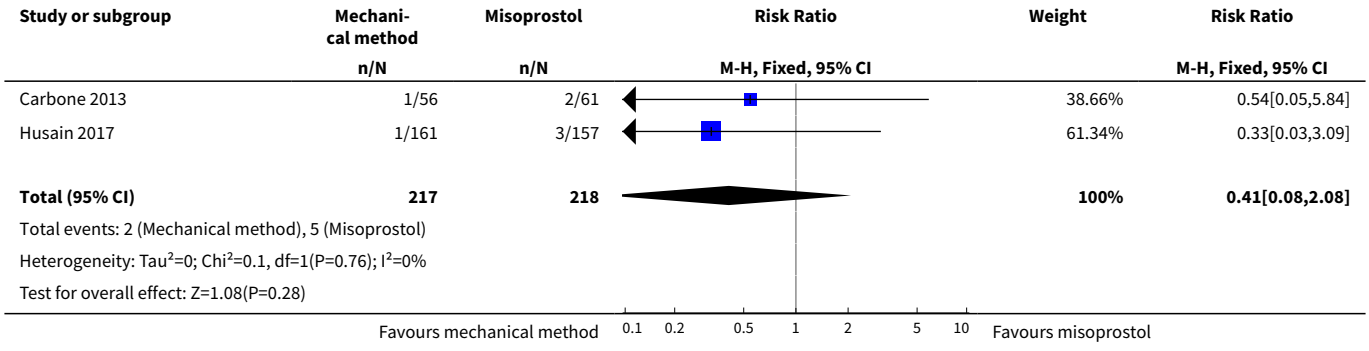
Analysis 35.20. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 20 Serious maternal complications.



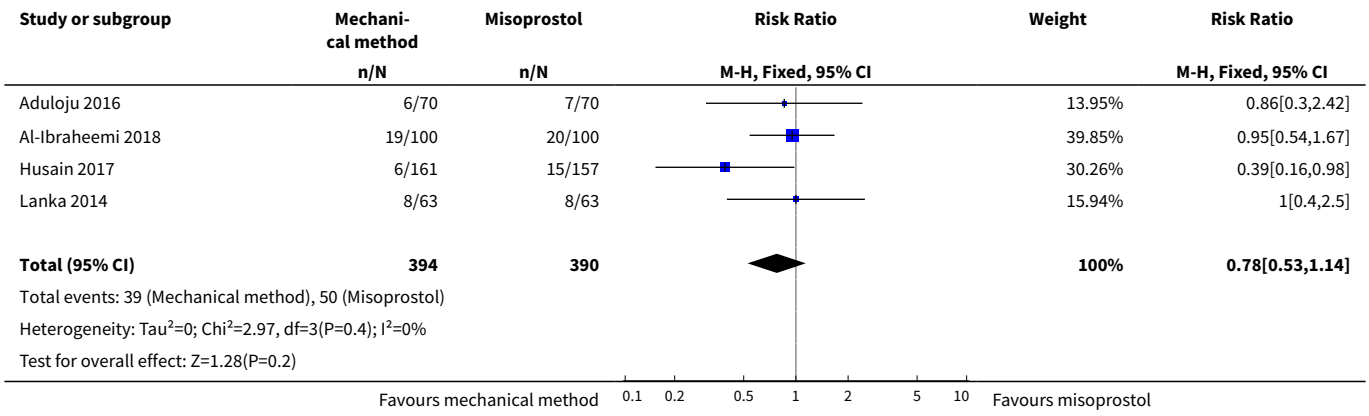
Analysis 35.21. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 21 Chorioamnionitis.



Analysis 35.22. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 22 Endometrits.



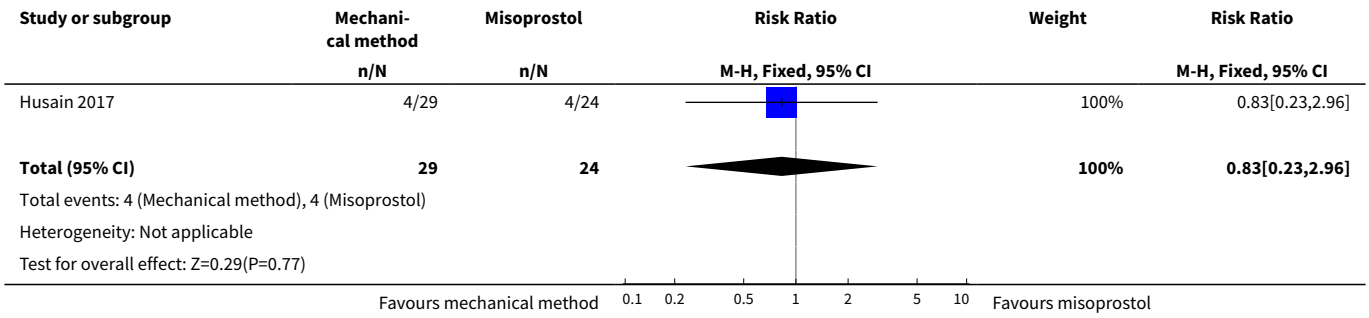
Analysis 35.23. Comparison 35 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all women, Outcome 23 Fetal distress.



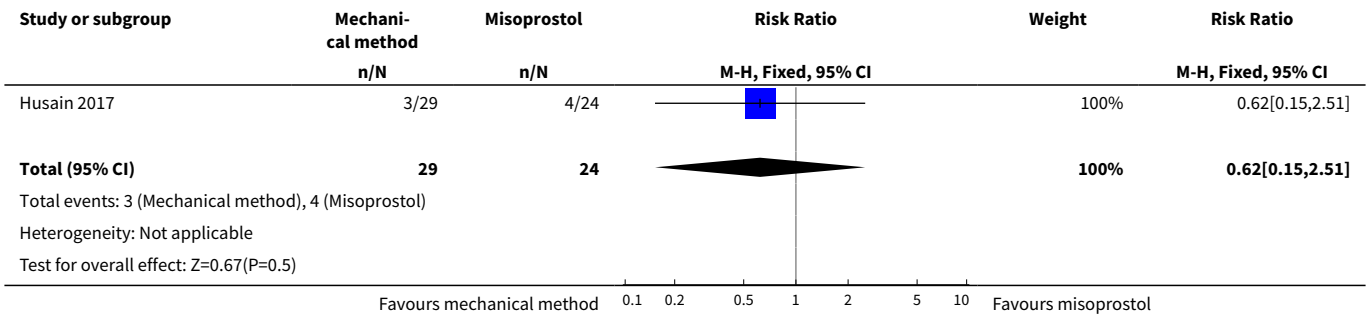
Comparison 36. Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all primiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	53	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.23, 2.96]
2 Caesarean section	1	53	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.15, 2.51]

Analysis 36.1. Comparison 36 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all primiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



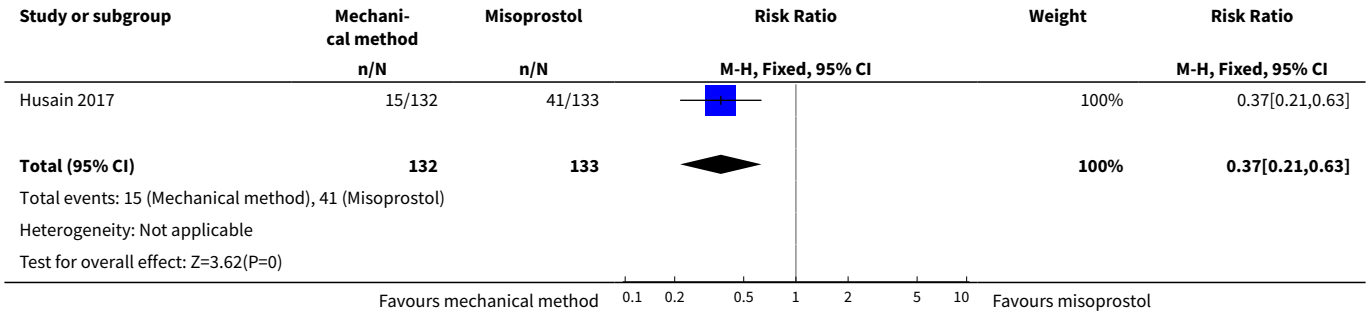
Analysis 36.2. Comparison 36 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all primiparae, Outcome 2 Caesarean section.



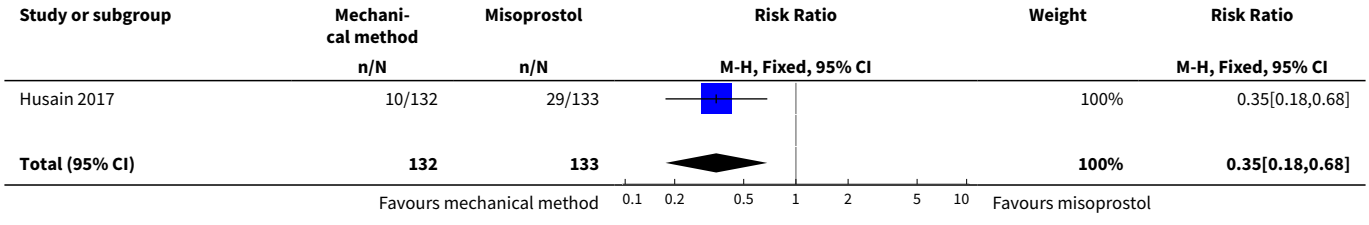
Comparison 37. Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all multiparae

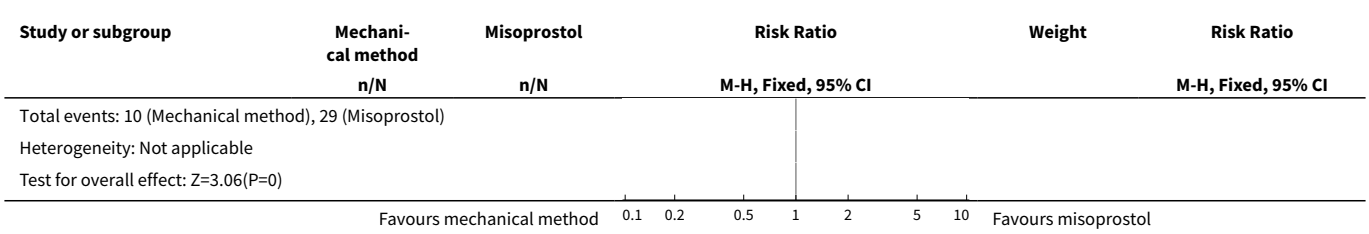
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	1	265	Risk Ratio (M-H, Fixed, 95% CI)	0.37 [0.21, 0.63]
2 Caesarean section	1	265	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.18, 0.68]

Analysis 37.1. Comparison 37 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all multiparae, Outcome 1 Vaginal delivery not achieved in 24 hours.



Analysis 37.2. Comparison 37 Any mechanical method and low dose misoprostol versus low dose misoprostol alone: all multiparae, Outcome 2 Caesarean section.

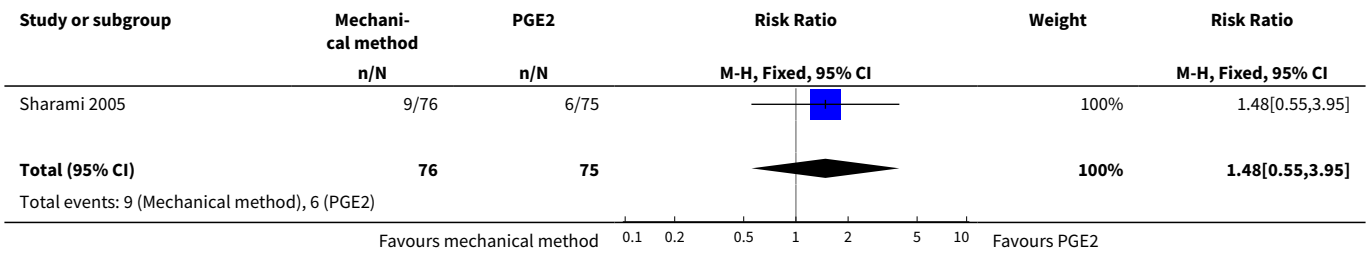


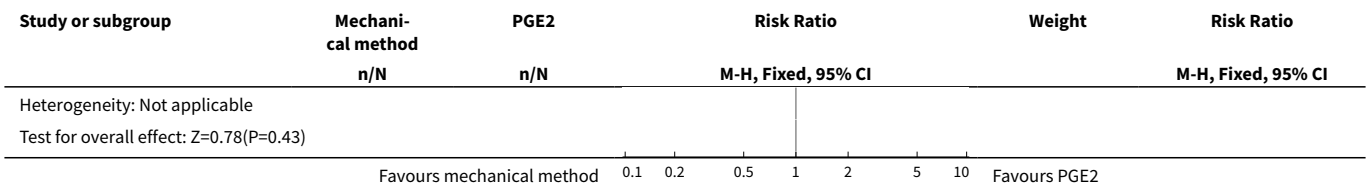


Comparison 38. Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified)

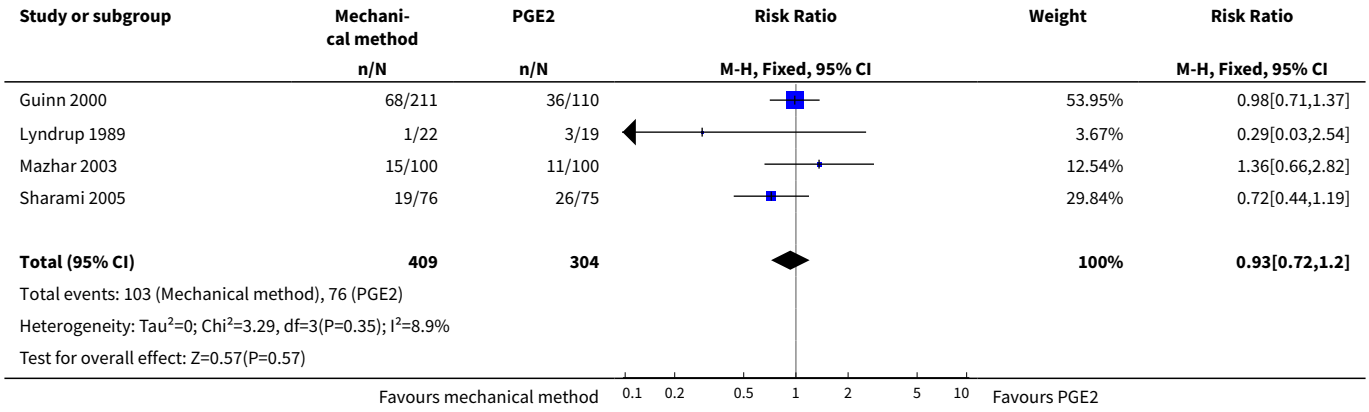
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Uterine hyperstimulation with FHR changes	1	151	Risk Ratio (M-H, Fixed, 95% CI)	1.48 [0.55, 3.95]
2 Caesarean section	4	713	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.72, 1.20]
3 Serious maternal morbidity or death	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Oxytocin augmentation	1	200	Risk Ratio (M-H, Fixed, 95% CI)	2.48 [1.95, 3.15]
5 Uterine hyperstimulation without FHR changes	1	151	Risk Ratio (M-H, Fixed, 95% CI)	2.19 [1.39, 3.46]
6 Instrumental vaginal delivery	1	41	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.08, 1.58]
7 Meconium-stained liquor	1	151	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.43, 2.95]
8 Apgar score < 7 at 5 minutes	1	151	Risk Ratio (M-H, Fixed, 95% CI)	2.96 [0.12, 71.55]
9 Neonatal intensive care unit admission	1	151	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.30, 2.40]
10 Postpartum haemorrhage	1	151	Risk Ratio (M-H, Fixed, 95% CI)	0.14 [0.01, 2.68]
11 Endometritis	1	41	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
12 Fetal distress	3	498	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.61, 1.56]

Analysis 38.1. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 1 Uterine hyperstimulation with FHR changes.

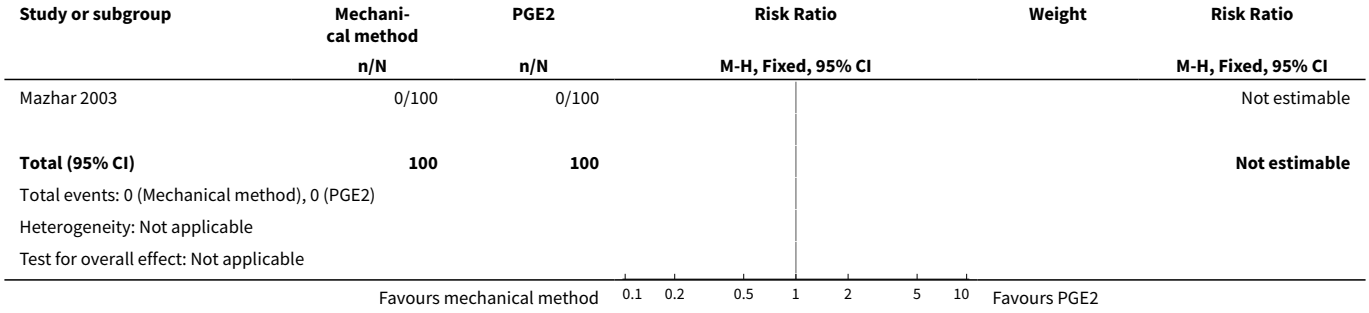




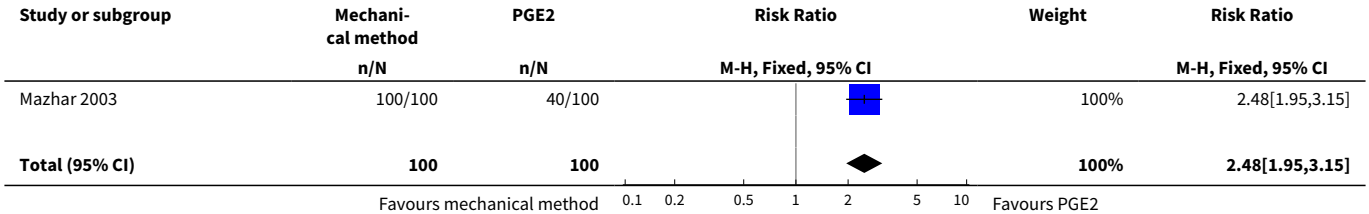
Analysis 38.2. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 2 Caesarean section.

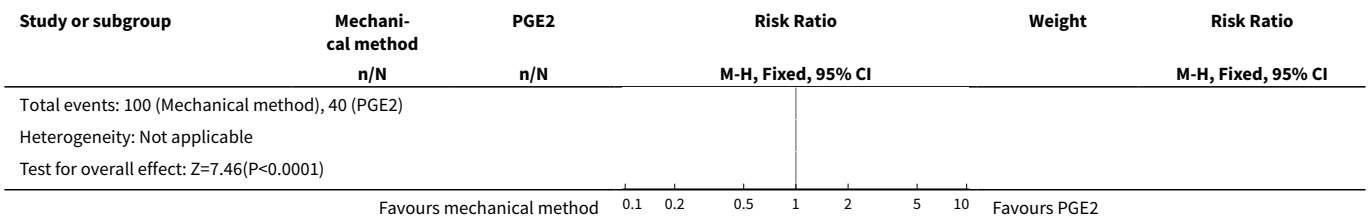


Analysis 38.3. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 3 Serious maternal morbidity or death.

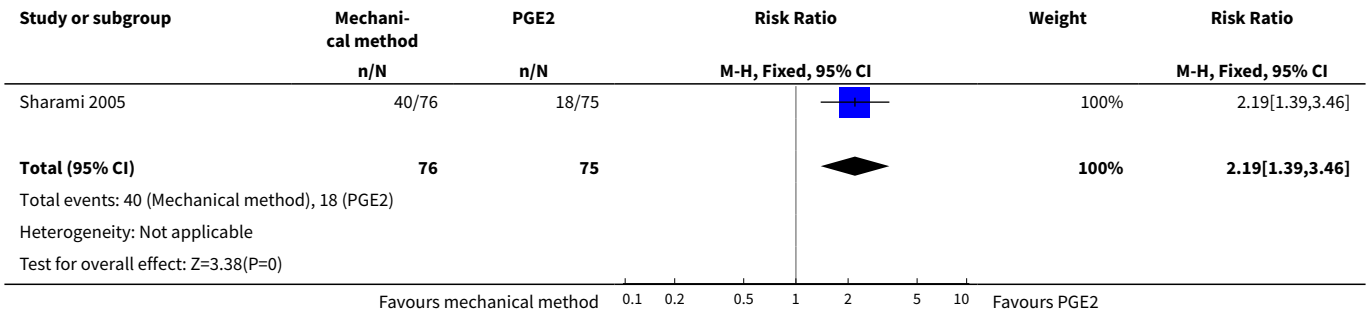


Analysis 38.4. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 4 Oxytocin augmentation.

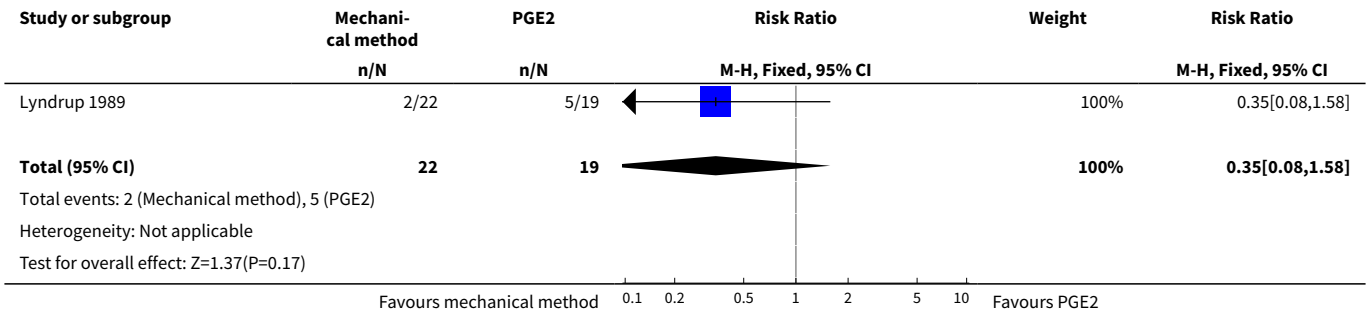




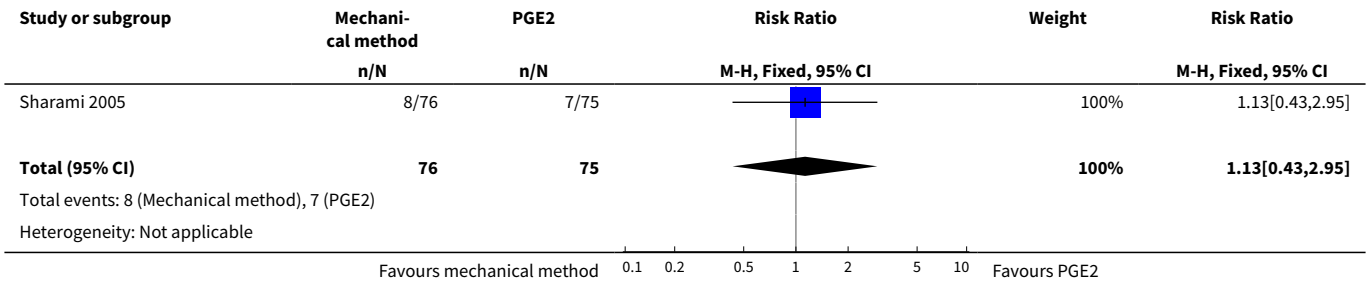
Analysis 38.5. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 5 Uterine hyperstimulation without FHR changes.

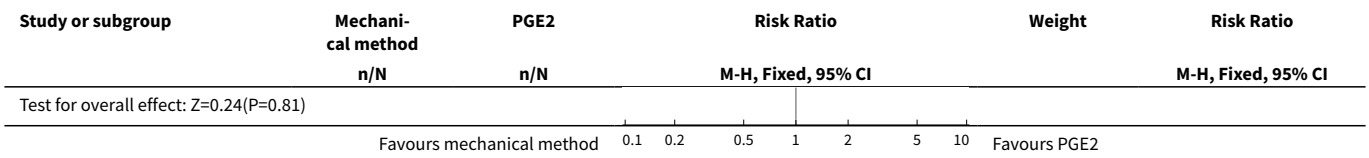


Analysis 38.6. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 6 Instrumental vaginal delivery.

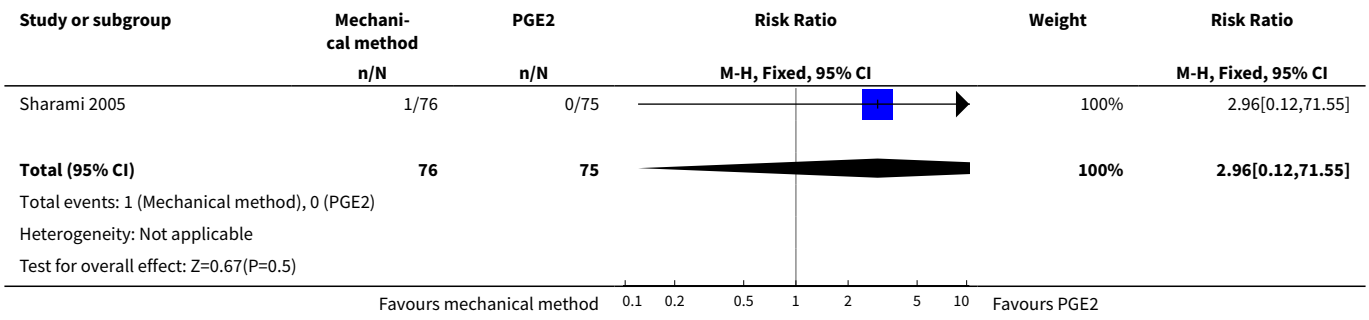


Analysis 38.7. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 7 Meconium-stained liquor.

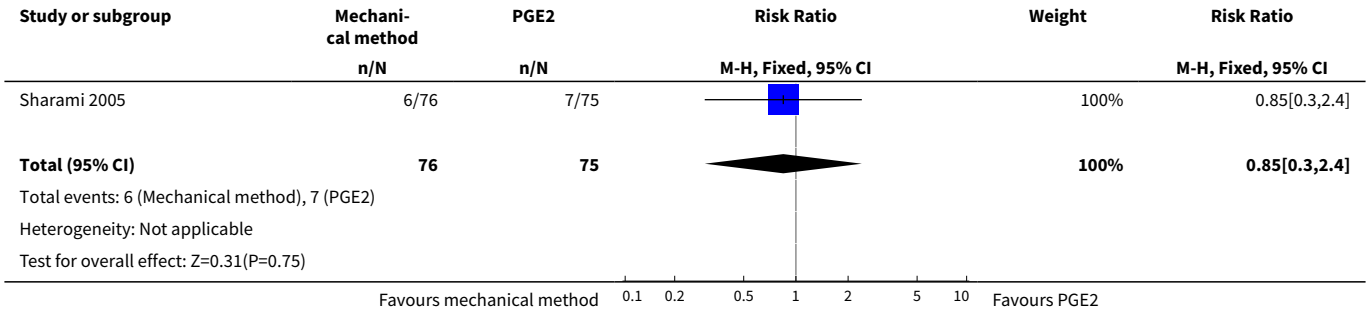




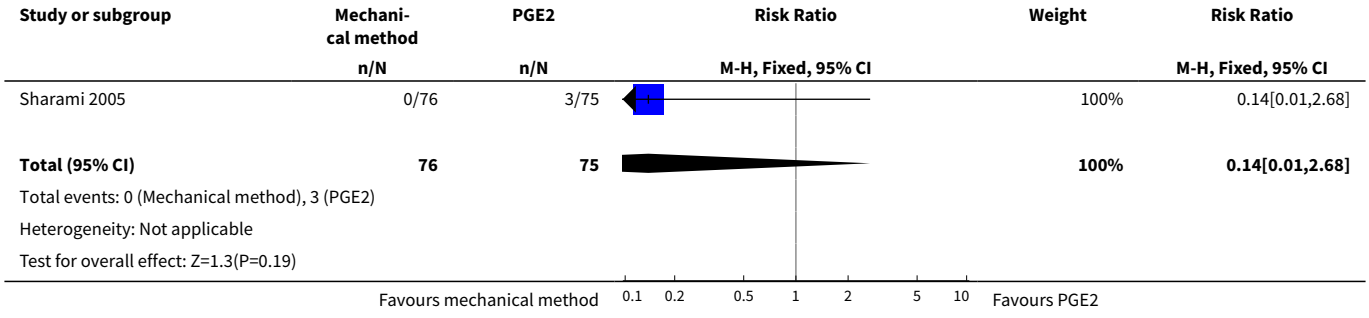
Analysis 38.8. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 8 Apgar score < 7 at 5 minutes.



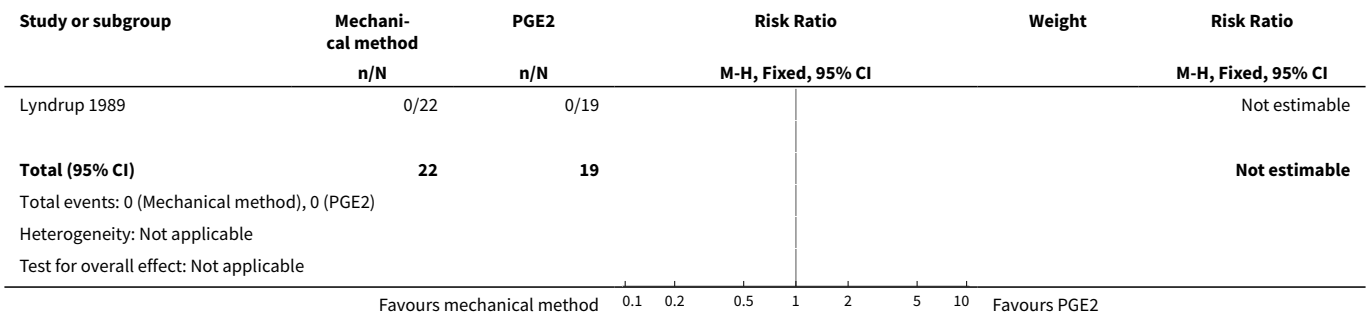
Analysis 38.9. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 9 Neonatal intensive care unit admission.



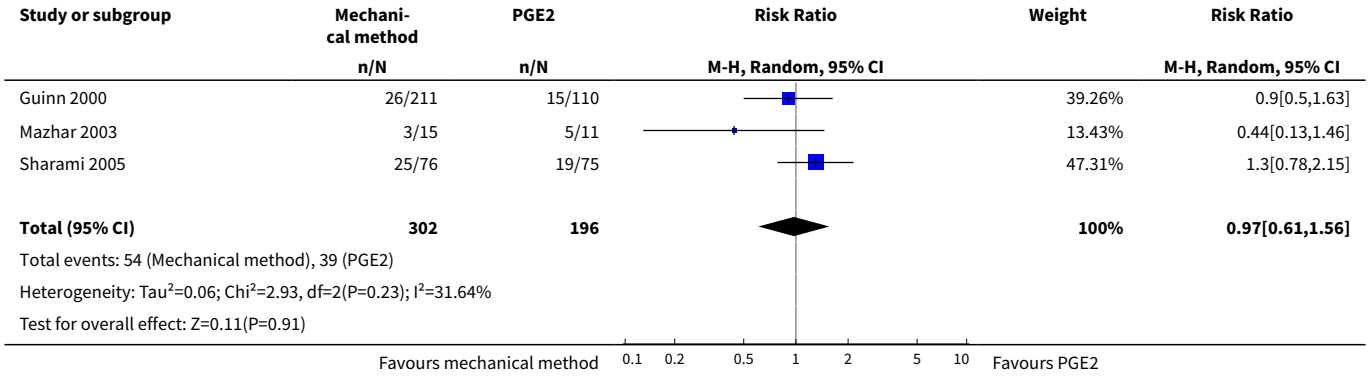
Analysis 38.10. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 10 Postpartum haemorrhage.



Analysis 38.11. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 11 Endometritis.



Analysis 38.12. Comparison 38 Any mechanical method and oxytocin versus prostaglandin E2 alone: all women (not pre-specified), Outcome 12 Fetal distress.



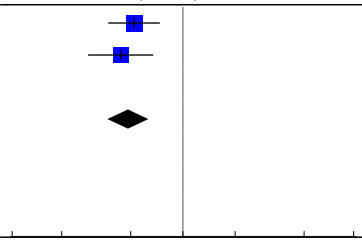
Comparison 39. Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	2	362	Risk Ratio (M-H, Fixed, 95% CI)	0.48 [0.37, 0.63]
2 Uterine hyperstimulation with FHR changes	3	1463	Risk Ratio (M-H, Fixed, 95% CI)	0.43 [0.17, 1.11]
3 Caesarean section	5	1779	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.80, 1.12]
4 Serious neonatal morbidity/perinatal death	2	1263	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.18, 3.65]
5 Oxytocin augmentation	2	336	Risk Ratio (M-H, Random, 95% CI)	3.89 [0.70, 21.72]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
6 Uterine hyperstimulation without FHR changes	3	498	Risk Ratio (M-H, Fixed, 95% CI)	0.52 [0.30, 0.92]
7 Epidural analgesia	1	162	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.90, 1.27]
8 Meconium-stained liquor	2	362	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.43, 1.19]
9 Apgar score < 7 at 5 minutes	1	162	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.20, 4.58]
10 Neonatal intensive care unit admission	4	1599	Risk Ratio (M-H, Fixed, 95% CI)	0.66 [0.49, 0.90]
11 Perinatal death	2	1263	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.18, 3.65]
12 Women not satisfied	1	866	Risk Ratio (M-H, Fixed, 95% CI)	1.68 [1.47, 1.93]
13 Maternal fever	2	298	Risk Ratio (M-H, Fixed, 95% CI)	0.13 [0.04, 0.50]
14 Chorioamnionitis	1	200	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.32, 1.31]
15 Fetal distress	2	362	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.25, 1.21]

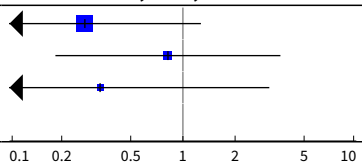
Analysis 39.1. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 1 Vaginal delivery not achieved in 24 hours.

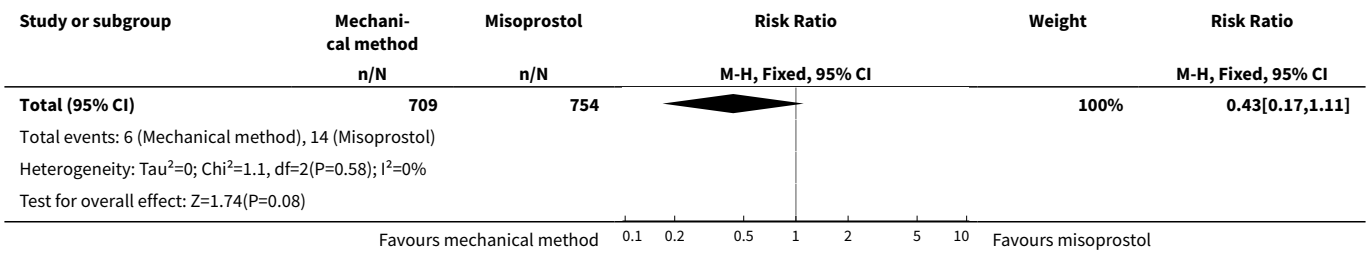
Study or subgroup	Mechanical method n/N	Misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Culver 2004	28/83	51/79		52.12%	0.52[0.37,0.74]
Mullin 2002	21/100	48/100		47.88%	0.44[0.28,0.67]
Total (95% CI)	**183**	**179**		**100%**	**0.48[0.37,0.63]**
Total events: 49 (Mechanical method), 99 (Misoprostol)					
Heterogeneity: Tau^2=0; Chi^2=0.41, df=1(P=0.52); I^2=0%					
Test for overall effect: Z=5.28(P<0.0001)					



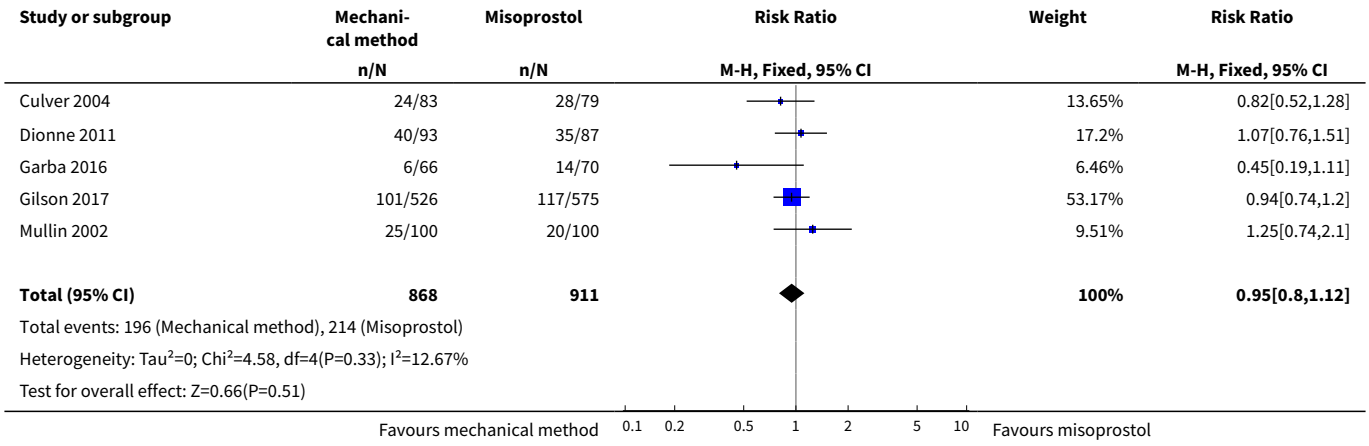
Analysis 39.2. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 2 Uterine hyperstimulation with FHR changes.

Study or subgroup	Mechanical method n/N	Misoprostol n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Culver 2004	2/83	7/79		51.25%	0.27[0.06,1.27]
Gilson 2017	3/526	4/575		27.31%	0.82[0.18,3.65]
Mullin 2002	1/100	3/100		21.44%	0.33[0.04,3.15]

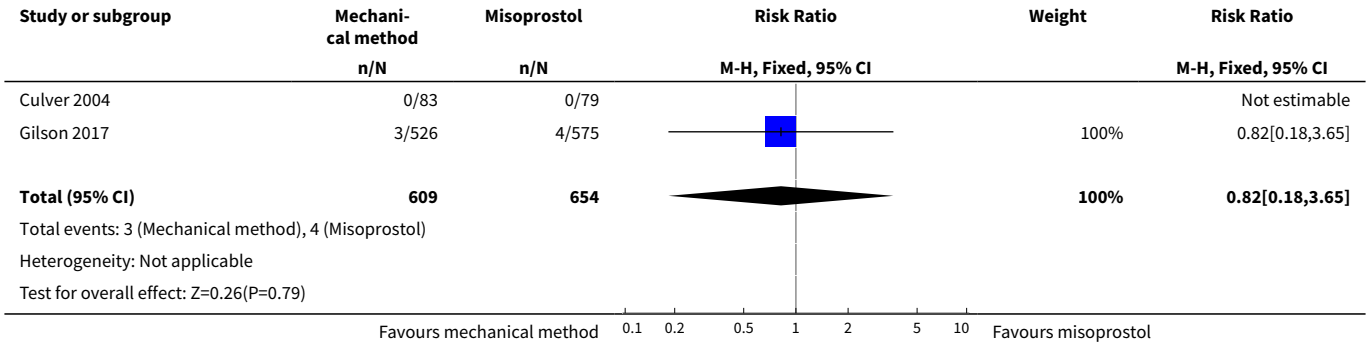




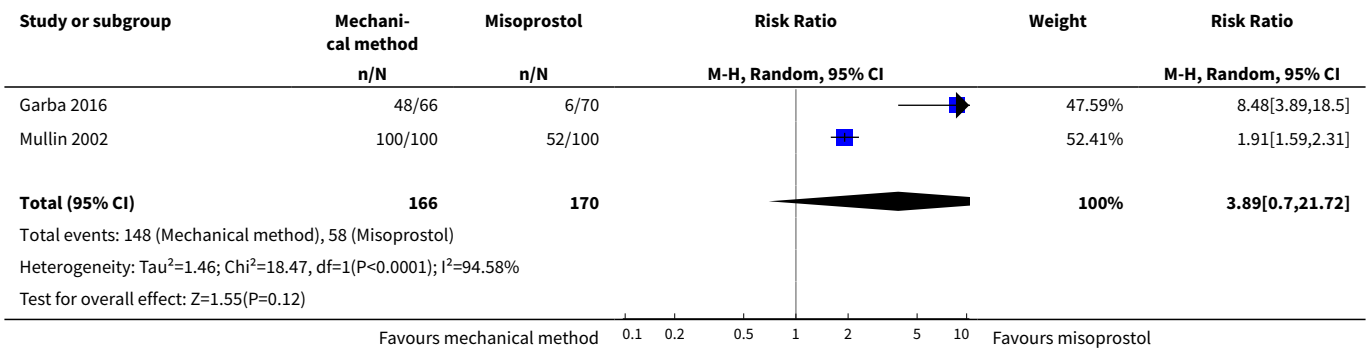
Analysis 39.3. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 3 Caesarean section.



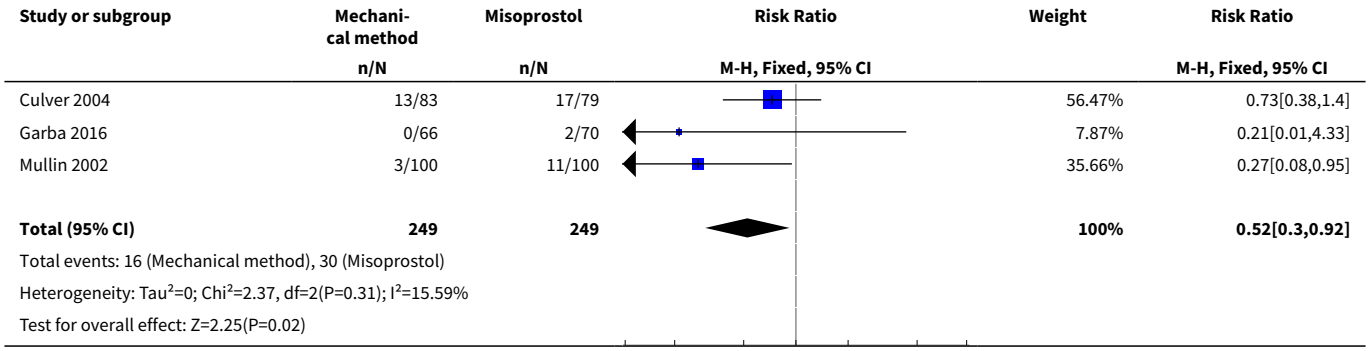
Analysis 39.4. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 4 Serious neonatal morbidity/perinatal death.



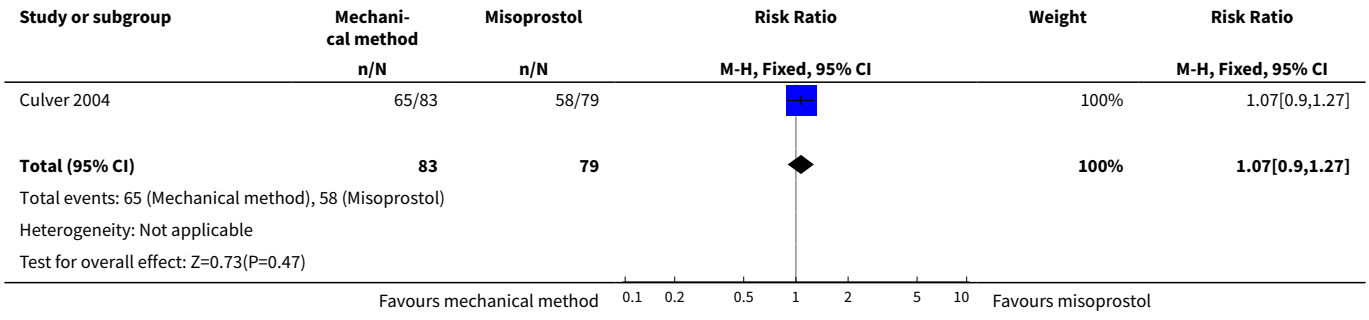
Analysis 39.5. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 5 Oxytocin augmentation.



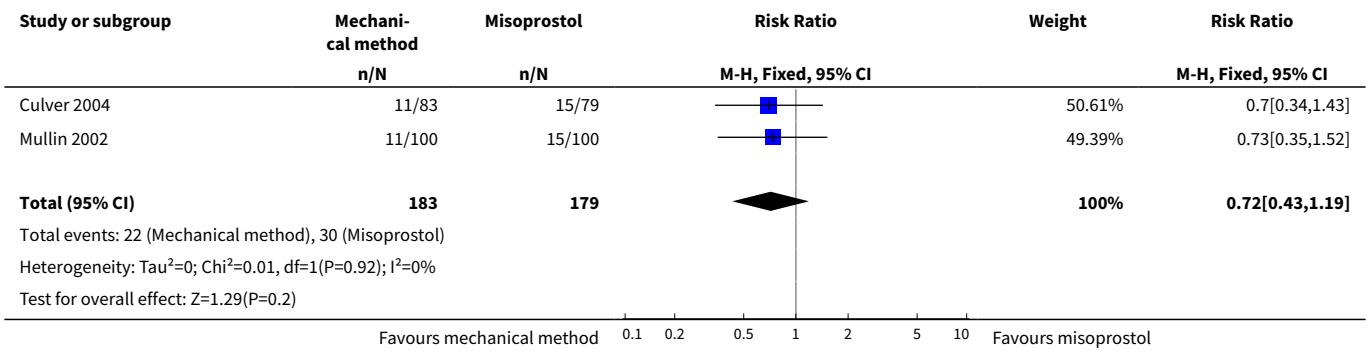
Analysis 39.6. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 6 Uterine hyperstimulation without FHR changes.



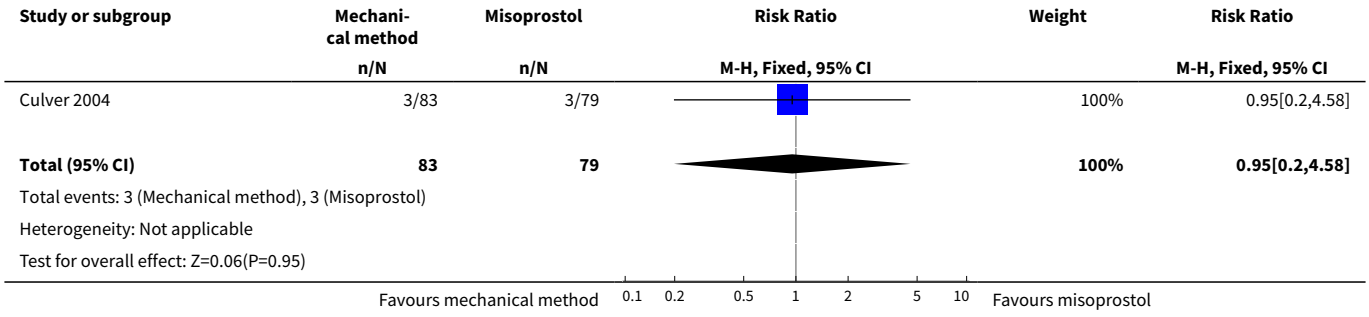
Analysis 39.7. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 7 Epidural analgesia.



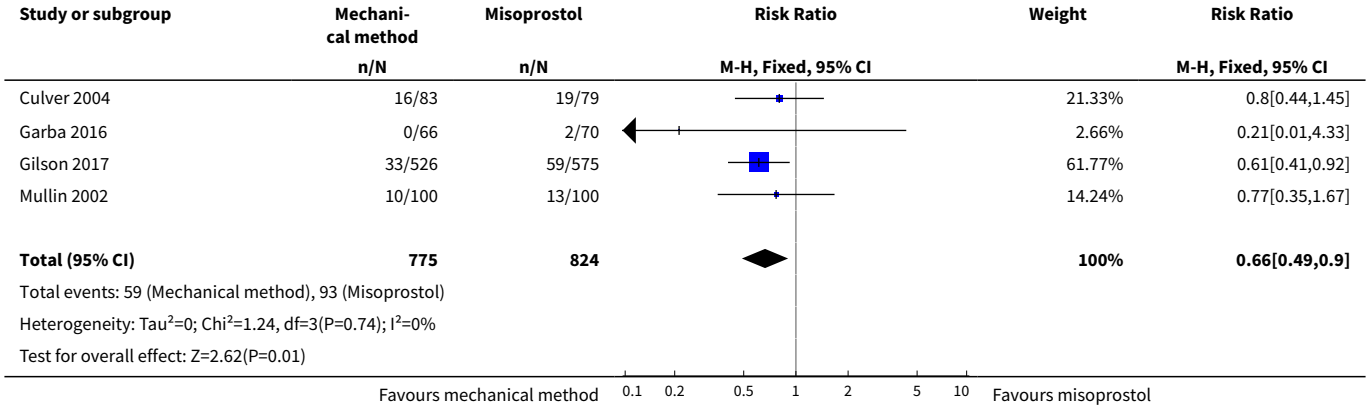
Analysis 39.8. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 8 Meconium-stained liquor.



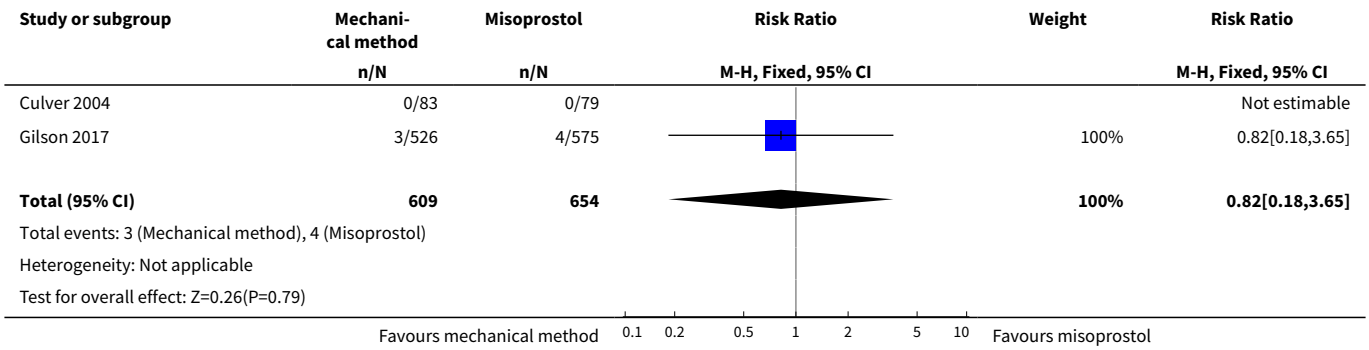
Analysis 39.9. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 9 Apgar score < 7 at 5 minutes.



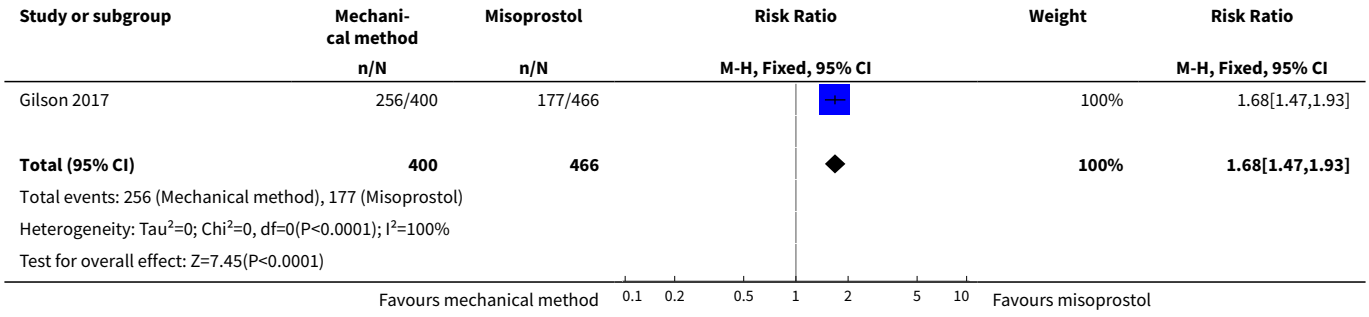
Analysis 39.10. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 10 Neonatal intensive care unit admission.



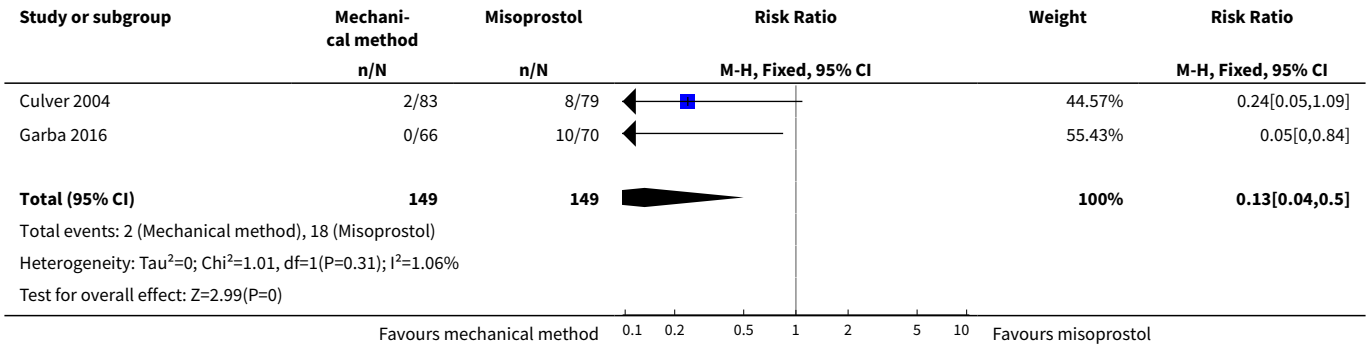
Analysis 39.11. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 11 Perinatal death.



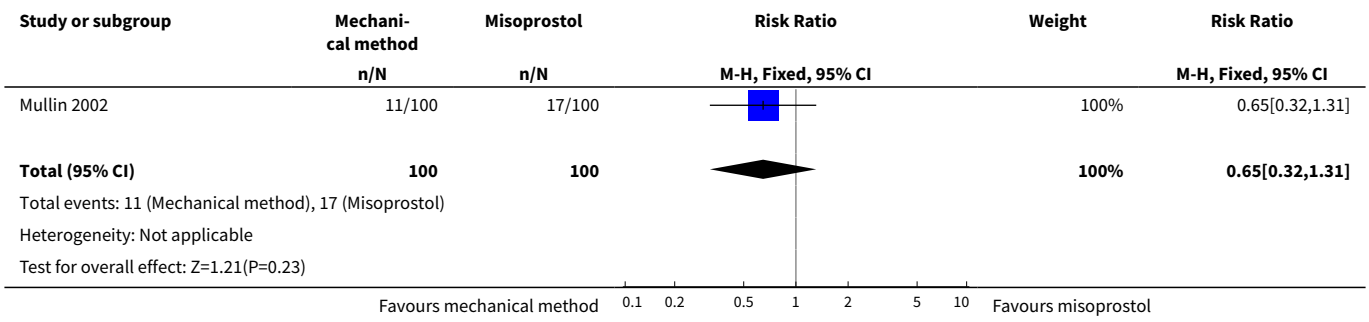
Analysis 39.12. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 12 Women not satisfied.



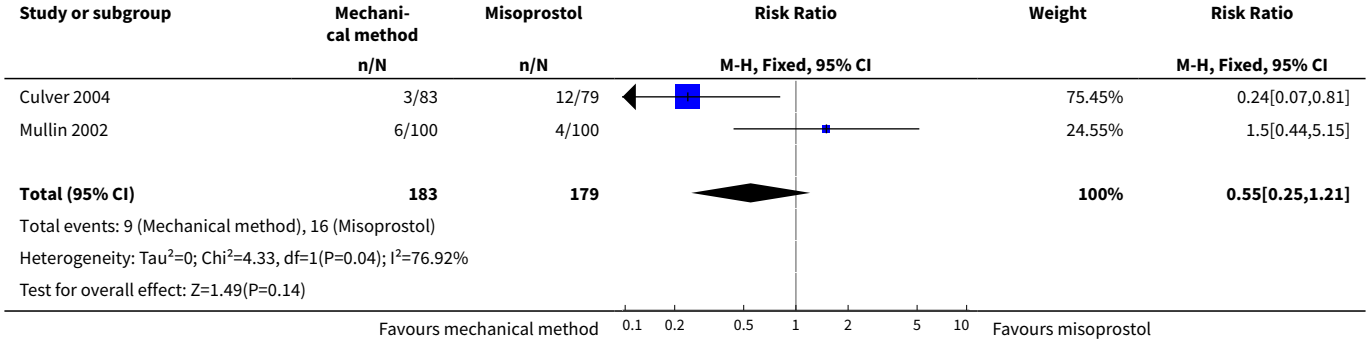
Analysis 39.13. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 13 Maternal fever.



Analysis 39.14. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 14 Chorioamnionitis.



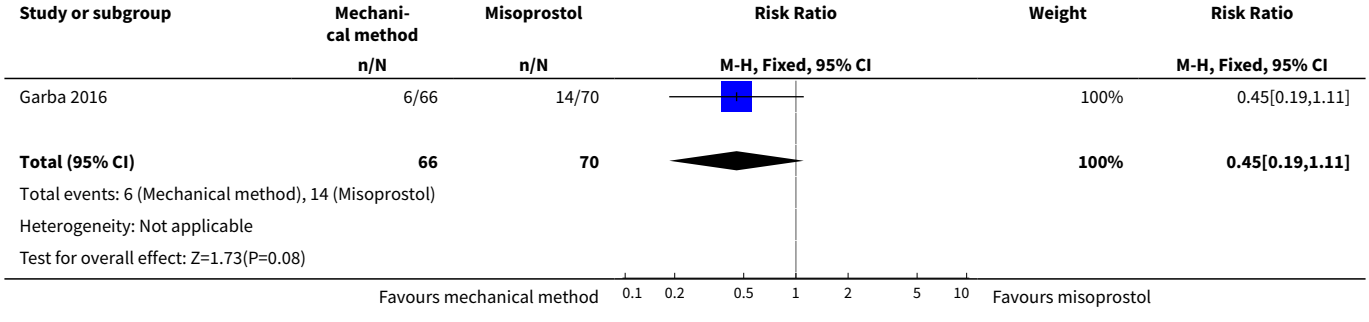
Analysis 39.15. Comparison 39 Any mechanical method and oxytocin versus low dose misoprostol alone: all women (not pre-specified), Outcome 15 Fetal distress.



Comparison 40. Any mechanical method and oxytocin versus low dose misoprostol alone: all multiparae

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	136	Risk Ratio (M-H, Fixed, 95% CI)	0.45 [0.19, 1.11]

Analysis 40.1. Comparison 40 Any mechanical method and oxytocin versus low dose misoprostol alone: all multiparae, Outcome 1 Caesarean section.

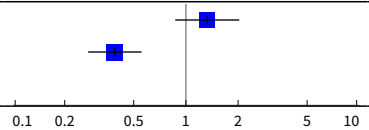


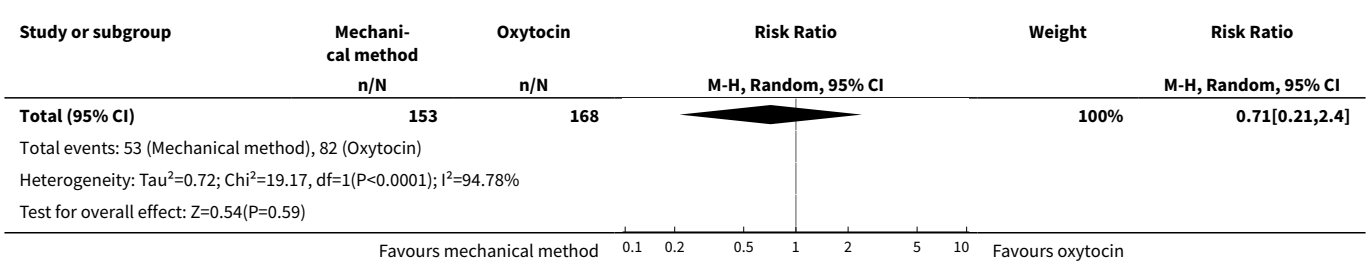
Comparison 41. Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Vaginal delivery not achieved in 24 hours	2	321	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.21, 2.40]
2 Caesarean section	6	718	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.39, 1.20]
3 Serious neonatal morbidity/perinatal death	2	321	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.12, 4.13]
4 Serious maternal morbidity or death	2	321	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Uterine hyperstimulation without FHR changes	2	199	Risk Ratio (M-H, Fixed, 95% CI)	0.85 [0.34, 2.09]
6 Uterine rupture	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Epidural analgesia	1	127	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.98, 1.09]
8 Instrumental vaginal delivery	3	293	Risk Ratio (M-H, Fixed, 95% CI)	0.99 [0.48, 2.02]
9 Meconium-stained liquor	3	319	Risk Ratio (M-H, Fixed, 95% CI)	0.72 [0.32, 1.63]
10 Neonatal intensive care unit admission	3	400	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.61, 1.58]
11 Postpartum haemorrhage	3	319	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.44, 3.18]
12 Serious maternal complications	1	201	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Antibiotics during labour	1	201	Risk Ratio (M-H, Fixed, 95% CI)	2.32 [0.82, 6.55]
14 Chorionamnionitis	2	328	Risk Ratio (M-H, Random, 95% CI)	4.34 [0.55, 34.01]
15 Endometritis	3	374	Risk Ratio (M-H, Fixed, 95% CI)	1.08 [0.16, 7.45]
16 Fetal distress	3	400	Risk Ratio (M-H, Fixed, 95% CI)	1.37 [0.68, 2.77]

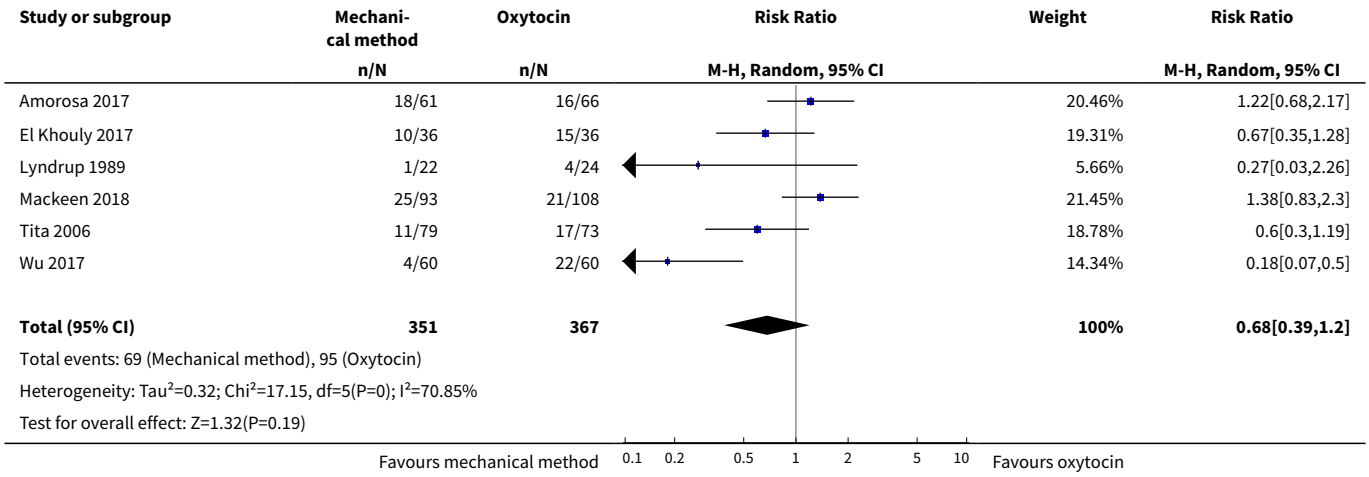
Analysis 41.1. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 1 Vaginal delivery not achieved in 24 hours.

Study or subgroup	Mechanical method n/N	Oxytocin n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Mackeen 2018	32/93	28/108		49.54%	1.33[0.87,2.03]
Wu 2017	21/60	54/60		50.46%	0.39[0.27,0.55]

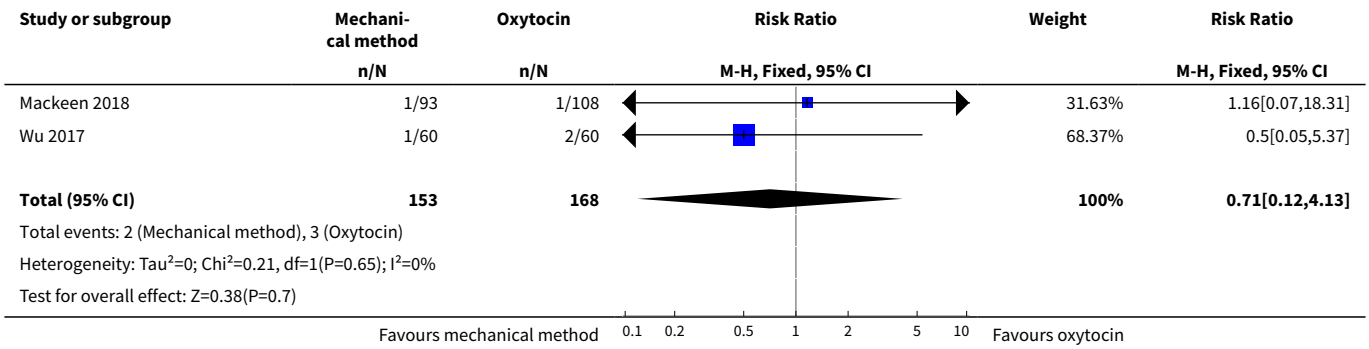




Analysis 41.2. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 2 Caesarean section.

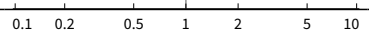


Analysis 41.3. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 3 Serious neonatal morbidity/perinatal death.



Analysis 41.4. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 4 Serious maternal morbidity or death.

Study or subgroup	Mechanical method n/N	Oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Mackeen 2018	0/93	0/108			Not estimable
Wu 2017	0/60	0/60			Not estimable
Total (95% CI)	**153**	**168**			**Not estimable**
Total events: 0 (Mechanical method), 0 (Oxytocin)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					



Favours mechanical method — Favours oxytocin

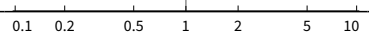
Analysis 41.5. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 5 Uterine hyperstimulation without FHR changes.

Study or subgroup	Mechanical method n/N	Oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Amorosa 2017	7/61	8/66		83.67%	0.95[0.37,2.45]
El Khouly 2017	0/36	1/36		16.33%	0.33[0.01,7.92]
Total (95% CI)	**97**	**102**		**100%**	**0.85[0.34,2.09]**
Total events: 7 (Mechanical method), 9 (Oxytocin)					
Heterogeneity: $Tau^2=0$; $Chi^2=0.39$, df=1(P=0.53); $I^2=0\%$					
Test for overall effect: Z=0.36(P=0.72)					

Favours mechanical method — Favours oxytocin

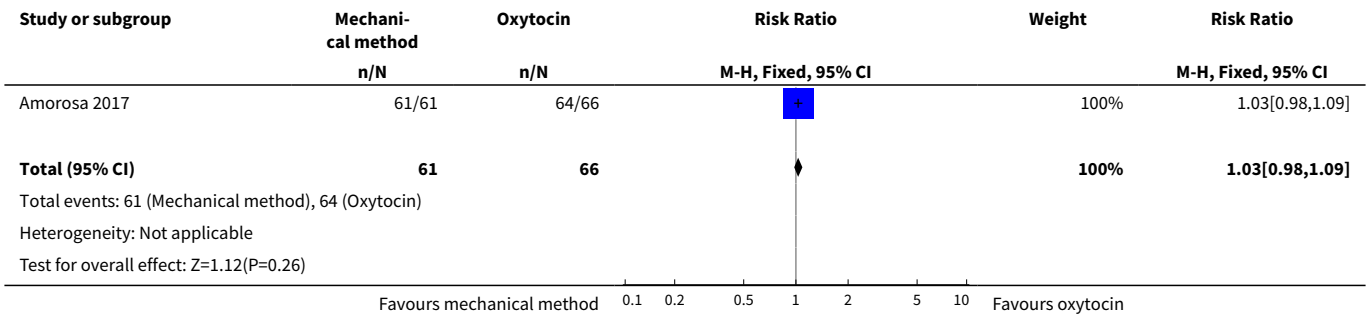
Analysis 41.6. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 6 Uterine rupture.

Study or subgroup	Mechanical method n/N	Oxytocin n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Wu 2017	0/60	0/60			Not estimable
Total (95% CI)	**60**	**60**			**Not estimable**
Total events: 0 (Mechanical method), 0 (Oxytocin)					
Heterogeneity: Not applicable					
Test for overall effect: Not applicable					

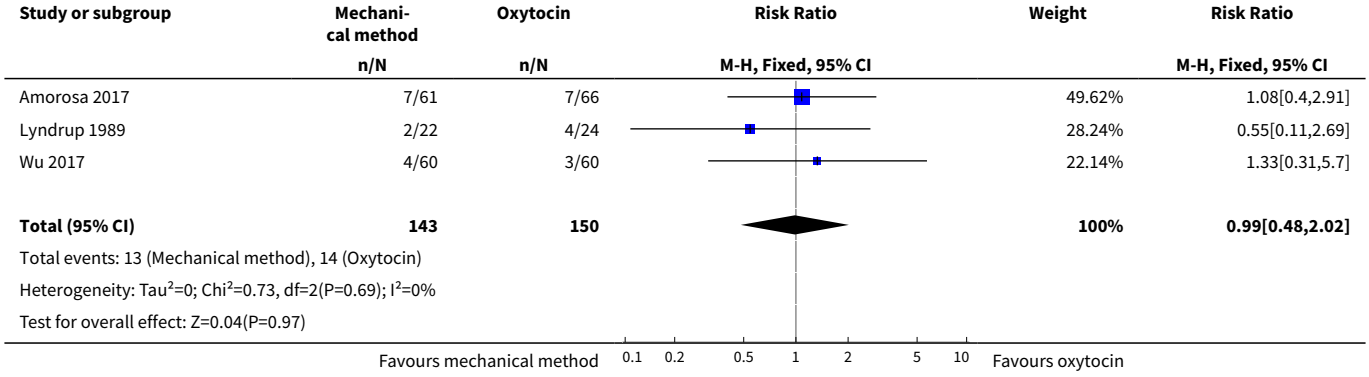


Favours mechanical method — Favours oxytocin

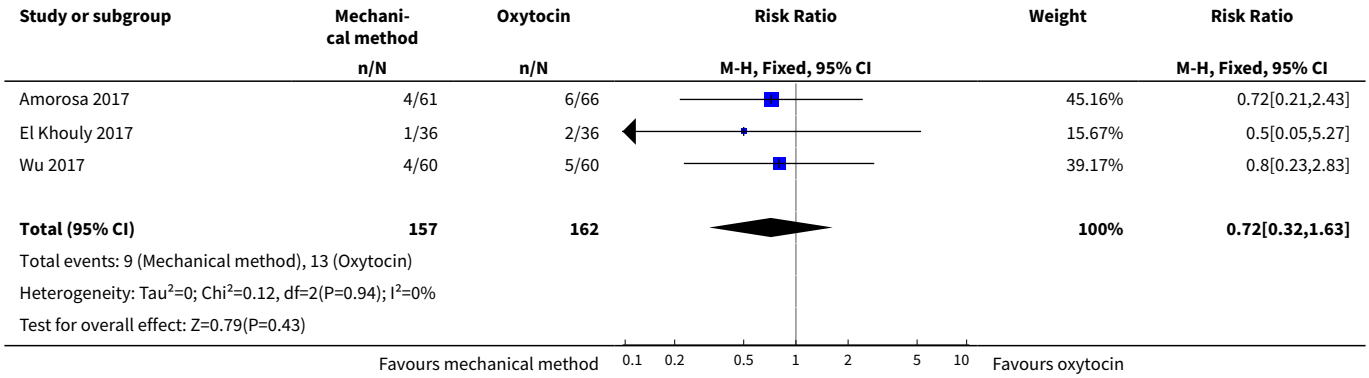
Analysis 41.7. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 7 Epidural analgesia.



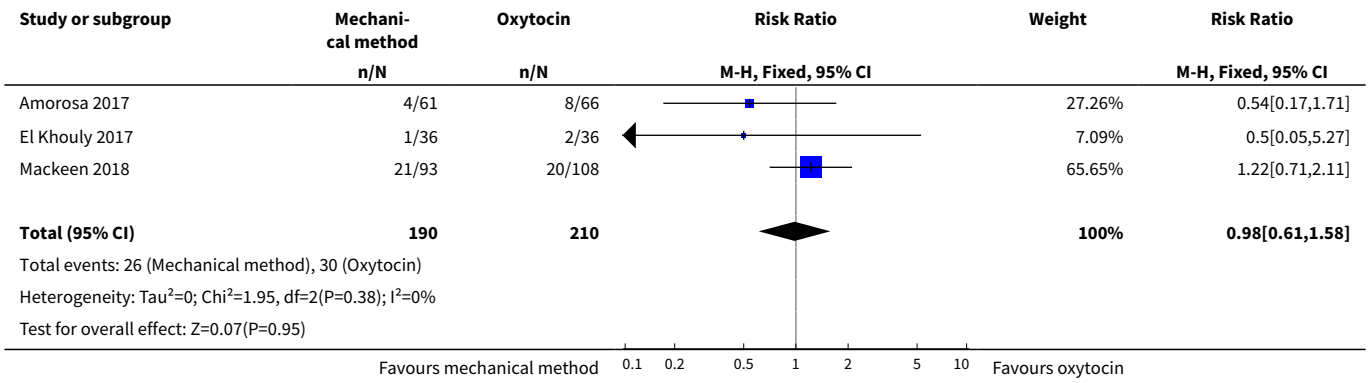
Analysis 41.8. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 8 Instrumental vaginal delivery.



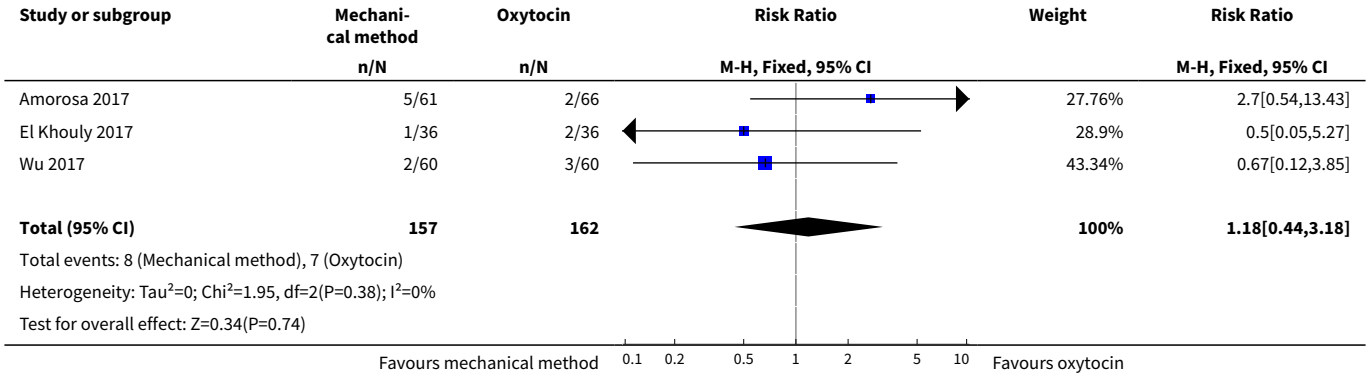
Analysis 41.9. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 9 Meconium-stained liquor.



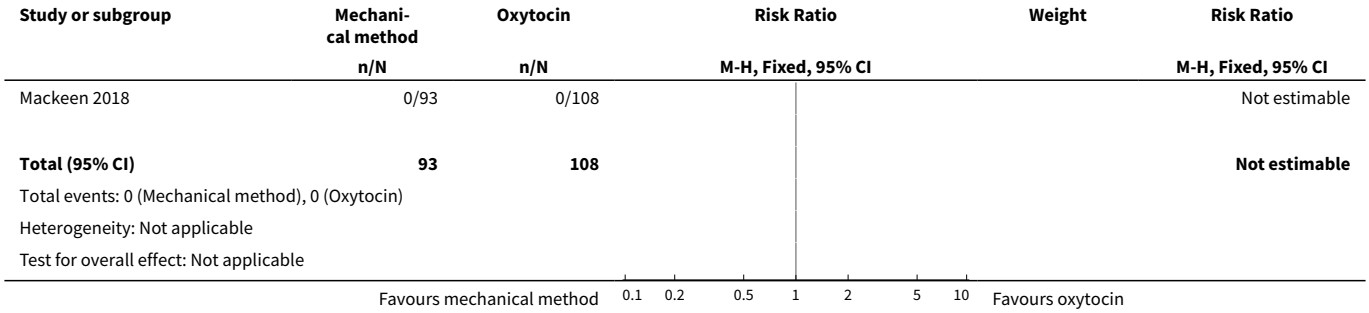
Analysis 41.10. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 10 Neonatal intensive care unit admission.



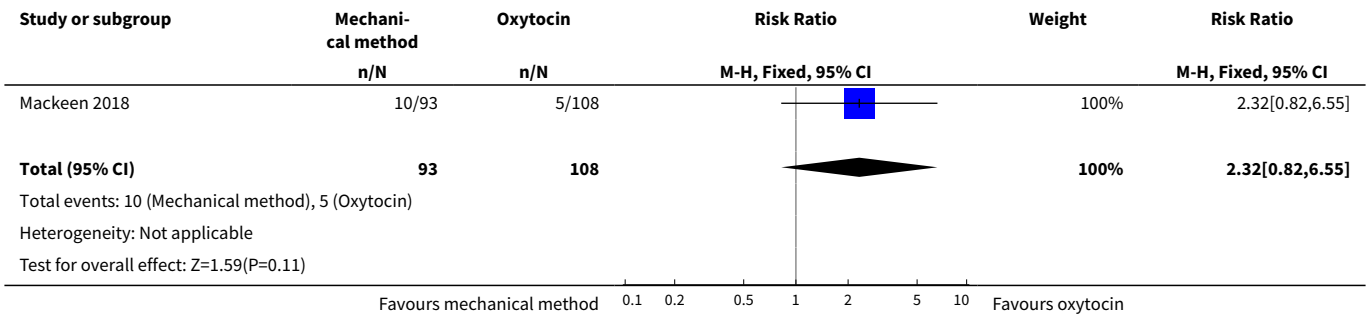
Analysis 41.11. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 11 Postpartum haemorrhage.



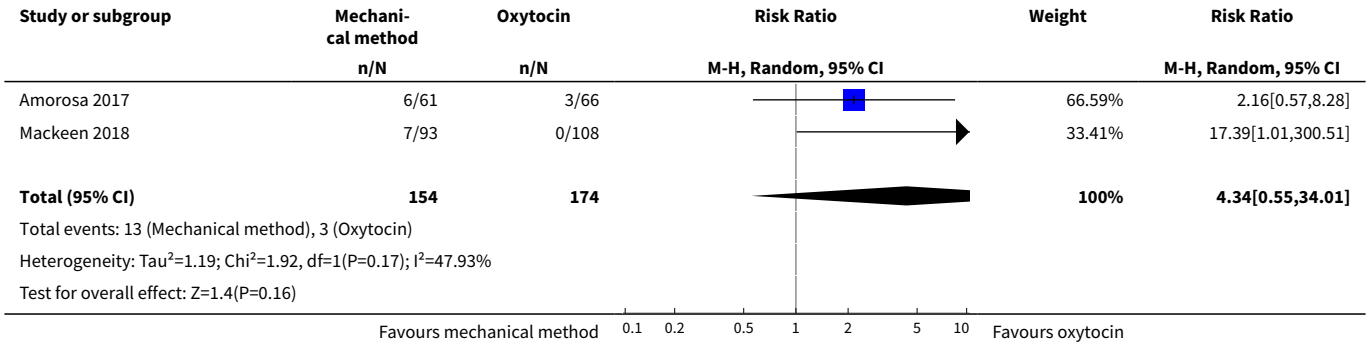
Analysis 41.12. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 12 Serious maternal complications.



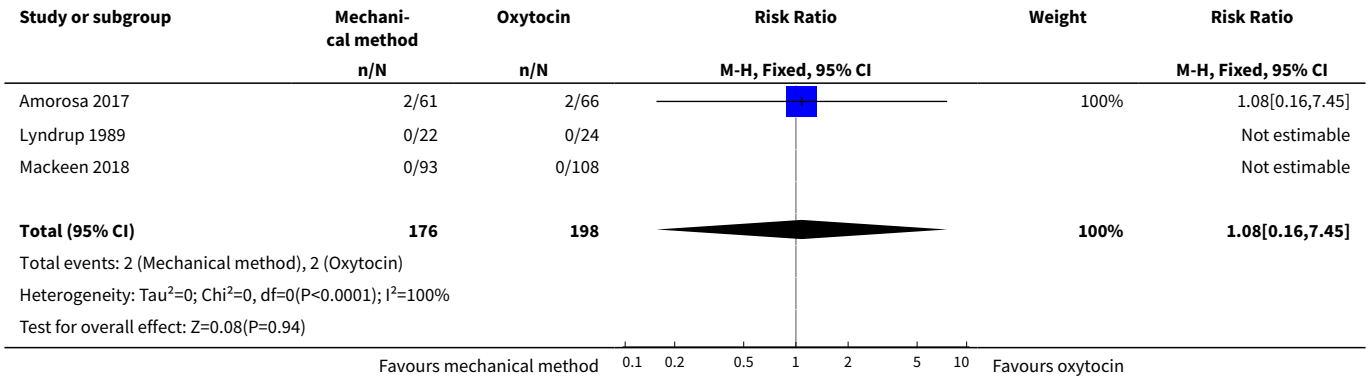
Analysis 41.13. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 13 Antibiotics during labour.



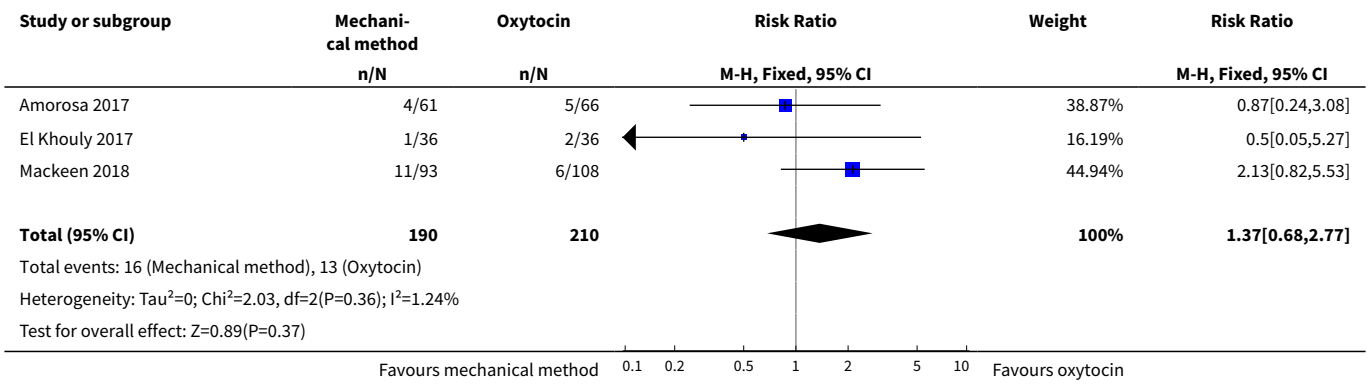
Analysis 41.14. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 14 Chorionamnionitis.



Analysis 41.15. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 15 Endometritis.



Analysis 41.16. Comparison 41 Any mechanical method and oxytocin versus oxytocin alone: all women (not pre-specified), Outcome 16 Fetal distress.



APPENDICES

Appendix 1. ICTRP and ClinicalTrials.gov - search methods

ICTRP

Each line was run separately

foley AND induction

foley AND ripening

catheter AND induction

catheter AND ripening

balloon AND induction

balloon AND ripening

laminaria AND induction

laminaria AND ripening

lamicel AND induction

lamicel AND ripening

extraamniotic AND induction

extraamniotic AND ripening

dilapan AND induction

dilapan AND ripening

ClinicalTrials.gov

Advanced search

Interventional studies | cervical ripening | catheter

Interventional studies | induction of labor | catheter

Interventional studies | cervical ripening | balloon

Interventional studies | induction of labor | balloon

Interventional studies | cervical ripening | foley

Interventional studies | induction of labor | foley

Interventional studies | cervical ripening | mechanical

Interventional studies | induction of labor | mechanical

Interventional studies | cervical ripening | laminaria

Interventional studies | induction of labor | laminaria

Interventional studies | cervical ripening | lamicel

Interventional studies | induction of labor | lamicel

Interventional studies | cervical ripening | dilapan

Interventional studies | induction of labor | dilapan

Interventional studies | cervical ripening | extraamniotic

Interventional studies | induction of labor | extraamniotic

WHAT'S NEW

Date	Event	Description
9 January 2018	New citation required and conclusions have changed	In this updated review, there is now evidence that mechanical induction of labour with a balloon probably is as effective as vaginal prostaglandin E2 (PGE2), but safer for the neonate. A balloon catheter may be slightly less effective as oral misoprostol, but It remains unclear if there is a difference in safety outcomes for the neonate. When compared to low-dose vaginal misoprostol, a balloon catheter may be less effective, but probably has a better safety profile.
9 January 2018	New search has been performed	Search updated. We included 60 new studies and excluded 74 new studies. Eighteen studies (previous included) are now excluded as they are no longer eligible. Also, 21 ongoing studies were identified (Ongoing studies) and two studies are awaiting further classification (Agboghoroma 2015; Mallah 2011). We updated the search on 19 March 2019 and added a further 38 trial reports to Studies awaiting classification for the next update. The references have been assessed but not incorporated into the review. Only seven of these trials are likely to contribute data for this review and are mainly small trials (Khatib 2019; Lim 2018; Osoti 2018; Souizi 2018; ten Eikelder 2017; Tulek 2018; Viteri 2019). We imputed the data for these trials and there is no change in results (not in direction or strength of the evidence). We will incorporate these trials fully at the next update. For this review, studies with high-dose misoprostol were excluded. Balloons, laminaria tents and extra-amniotic space infusion (EASI) were compared separately with other pharmacological methods and new comparisons were included. Comparisons with no intervention or placebo were excluded.

HISTORY

Protocol first published: Issue 2, 2000
Review first published: Issue 4, 2001

Date	Event	Description
30 September 2011	New citation required and conclusions have changed	New trials were added and the review was edited accordingly: the conclusion on primary outcome delivery before 24 hours has changed, partly due to change in statistical method (random-effects model, due to substantial heterogeneity). Also, some conclusions on secondary outcome measures have changed. We updated the search on 16 January 2012 and added the results to Studies awaiting classification for consideration in the next update.
30 April 2011	New search has been performed	Search updated. We have included 27 new studies and excluded 28 new studies. One trial (previously included) has now been reclassified as excluded (Abramovici 1999). Four new ongoing studies have also been identified (Hallak 2008a; Jozwiak 2009a; Lin 2006a; Manyonda 2007a).
18 September 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

For this update, M de Vaan, M ten Eikelder, KR Palmer and BW Mol performed data extraction. Risk of bias was assessed by M de Vaan, M ten Eikelder, KR Palmer and M Jozwiak. Marieke de Vaan and Marta Jozwiak entered the data and the review was drafted M de Vaan, which was finalised after feedback from M. ten Eikelder, M Jozwiak, KR Palmer, M Davies, K Bloemenkamp, BW Mol and M Boulvain. M. ten Eikelder, M. Jozwiak and BW Mol were not involved in data extraction nor in the 'Risk of bias' assessment of Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; ten Eikelder 2016, due to their authorship.

DECLARATIONS OF INTEREST

Marieke de Vaan received a grant from The Netherlands Organisation for Scientific Research (NWO) (023.011.051).

Mieke ten Eikelder is co-author of three included trials (Jozwiak 2013; Jozwiak 2014; ten Eikelder 2016). She has not been involved in the 'Risk of bias' assessment and data extraction of these studies.

Marta Jozwiak is co-author of four included trials (Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; ten Eikelder 2016). She has not been involved in 'Risk of bias' assessment and data extraction of these studies.

Kirsten Palmer: none known.

Miranda Davies-Tuck: none known.

Kitty Bloemenkamp is co-author of four included trials (Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; ten Eikelder 2016). She has not been involved in 'Risk of bias' assessment and data extraction of these studies.

Ben Willem Mol is co-author of four included trials (Jozwiak 2012; Jozwiak 2013; Jozwiak 2014; ten Eikelder 2016). He has not been involved in 'Risk of bias' assessment and data extraction of these studies. Ben Willem Mol also reports receiving grants from NHMRC Australia, personal fees from ObsEva, grants and personal fees from Merck and Guerbet, outside the submitted work.

Michel Boulvain: none known.

SOURCES OF SUPPORT

Internal sources

- University of Geneva, Switzerland.

External sources

- Marieke de Vaan received a grant from The Netherlands Organisation for Scientific Research (NWO), Netherlands.

  grant number: 023.011.051

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Comparisons of a balloon catheter with concurrent oxytocin or prostaglandins versus prostaglandins or oxytocin alone were added. Also, comparisons of a single versus a double balloon and different forms of laminaria tents were added. The comparisons with placebo/no treatment were excluded. Regarding studies where a comparison was made with misoprostol, we chose only to include studies in which low-dose misoprostol was used. A number of non pre-specified outcomes relevant to the comparisons made in this review were added (maternal fever, antibiotics during labour, endometritis, chorioamnionitis. fetal distress, umbilical artery pH < 7.10).

For this update, we have also searched ClinicalTrials.gov, the WHO International Clinical Trials Registry Platform (ICTRP).

INDEX TERMS

Medical Subject Headings (MeSH)

*Cervical Ripening; *Laminaria; *Oxytocics; Catheterization [*methods]; Cervix Uteri; Dinoprostone; Labor, Induced [*methods]; Misoprostol; Oxytocin; Pessaries; Polymers; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy