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Fundal pressure during the second stage of labour (Review)

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TABLE OF CONTENTS

[Intervention Review]

Fundal pressure during the second stage of labour

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ABSTRACT

Background

Fundal pressure during the second stage of labour (also known as the 'Kristeller manoeuvre') involves application of manual pressure to the uppermost part of the uterus directed towards the birth canal, in an attempt to assist spontaneous vaginal birth and avoid prolonged second stage or the need for operative birth. Fundal pressure has also been applied using an inflatable belt. Fundal pressure is widely used, however methods of its use vary widely. Despite strongly held opinions in favour of and against the use of fundal pressure, there is limited evidence regarding its maternal and neonatal benefits and harms. There is a need for objective evaluation of the effectiveness and safety of fundal pressure in the second stage of labour.

Objectives

To determine if fundal pressure is effective in achieving spontaneous vaginal birth, and preventing prolonged second stage or the need for operative birth, and to explore maternal and neonatal adverse effects related to fundal pressure.

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register (30 November 2016) and reference lists of retrieved studies.

Selection criteria

Randomised and quasi-randomised controlled trials of fundal pressure (manual or by inflatable belt) versus no fundal pressure in women in the second stage of labour with singleton cephalic presentation.

Data collection and analysis

Two or more review authors independently assessed potential studies for inclusion and quality. We extracted data using a pre-designed form. We entered data into Review Manager 5 software and checked for accuracy.

Main results

Nine trials are included in this updated review. Five trials (3057 women) compared manual fundal pressure versus no fundal pressure. Four trials (891 women) compared fundal pressure by means of an inflatable belt versus no fundal pressure. It was not possible to blind women and staff to this intervention. We assessed two trials as being at high risk of attrition bias and another at high risk of reporting bias. All other trials were low or unclear for other risk of bias domains. Most of the trials had design limitations. Heterogeneity was high for the majority of outcomes.

Manual fundal pressure versus no fundal pressure

Manual fundal pressure was not associated with changes in: **spontaneous vaginal birth within a specified time** (risk ratio (RR) 0.96, 95% confidence interval (CI) 0.71 to 1.28; 120 women; 1 trial; very low-quality evidence), **instrumental births** (RR 3.28, 95% CI 0.14 to 79.65; 197 women; 1 trial), **caesarean births** (RR 1.10, 95% CI 0.07 to 17.27; 197 women; 1 trial), **operative birth** (average RR 0.66, 95% CI 0.12 to 3.55; 317 women; 2 studies; I^2 = 43%; Tau^2 = 0.71; very low-quality evidence), **duration of second stage** (mean difference (MD) -0.80 minutes, 95% CI -3.66 to 2.06 minutes; 194 women; 1 study; very low-quality evidence), **low arterial cord pH** in newborn babies (RR 1.07, 95% CI 0.72 to 1.58; 297 women; 2 trials; very low-quality evidence), or **Apgar scores less than seven at five minutes** (average RR 4.48, 95% CI 0.28 to 71.45; 2759 infants; 4 trials; I^2 = 89%; Tau^2 = 3.55; very low-quality evidence). More women who received manual fundal pressure had **cervical tears** than in the control group (RR 4.90, 95% CI 1.09 to 21.98; 295 women; 1 trial). No **neonatal deaths** occurred in either of the two studies reporting this outcome (very low-quality evidence). No trial reported the outcome **severe maternal morbidity or death.**

Fundal pressure by inflatable belt versus no fundal pressure

Fundal pressure by inflatable belt did not reduce the number of women having**instrumental births** (average RR 0.73, 95% CI 0.52 to 1.02; 891 women; 4 trials; I^2 = 52%; Tau^2 = 0.05) or **operative births** (average RR 0.62, 95% CI 0.38 to 1.01; 891 women; 4 trials; I^2 = 78%; Tau^2 = 0.14; very low-quality evidence). Heterogeneity was high for both outcomes. **Duration of second stage** was reported in two trials, which both showed that inflatable belts shortened duration of labour in nulliparous women (average MD -50.80 minutes, 95% CI -94.85 to -6.74 minutes; 253 women; 2 trials; I^2 = 97%; Tau^2 = 975.94; very low-quality evidence). No data on this outcome were available for multiparous women. The inflatable belt did not make any difference to rates of **caesarean births** (average RR 0.56, 95% CI 0.14 to 2.26; 891 women; 4 trials; I^2 = 70%; Tau^2 = 0.98), **low arterial cord pH** in newborn babies (RR 0.47, 95% CI 0.09 to 2.55; 461 infants; 1 trial; low-quality evidence), or **Apgar scores less than seven at five minutes** (RR 4.62, 95% CI 0.22 to 95.68; 500 infants; 1 trial; very low-quality evidence). **Third degree perineal tears** were increased in the inflatable belt group (RR 15.69, 95% CI 2.10 to 117.02; 500 women; 1 trial). **Spontaneous vaginal birth within a specified time, neonatal death,** and**severe maternal morbidity or death** were not reported in any trial.

Authors' conclusions

There is insufficient evidence to draw conclusions on the beneficial or harmful effects of fundal pressure, either manually or by inflatable belt. Fundal pressure by an inflatable belt during the second stage of labour may shorten duration of second stage for nulliparous women, and lower rates of operative birth. However, existing studies are small and their generalizability is uncertain. There is insufficient evidence regarding safety for the baby. There is no evidence on the use of fundal pressure in specific clinical settings such as inability of the mother to bear down due to exhaustion or unconsciousness. There is currently insufficient evidence for the routine use of fundal pressure by any method on women in the second stage of labour. Because of current widespread use of the procedure and the potential for use in settings where other methods of assisted birth are not available, further good quality trials are needed. Further evaluation in other groups of women (such as multiparous women) will also be required. Future research should describe in detail how fundal pressure was applied and consider safety of the unborn baby, perineal outcomes, longer-term maternal and infant outcomes and maternal satisfaction.

PLAIN LANGUAGE SUMMARY

Fundal pressure during the second stage of labour for improving maternal and fetal outcomes

What is the issue?

The second stage of labour is the pushing stage, from when the cervix is fully dilated (to 10 cm) until the baby is born. Fetal distress, failure to progress, maternal exhaustion or a medical condition where prolonged pushing is dangerous, can complicate this stage. Applying fundal pressure by pushing on the mother's abdomen in the direction of the birth canal is often used to assist spontaneous vaginal birth, shorten the length of the second stage and reduce the need for instrumental birth (forceps- or vacuum-assisted) or caesarean section. It is particularly relevant in low-resource settings where options for operative birth are limited or not available. Manual pressure can be applied each time the woman has a contraction. Alternatively an inflatable belt can be worn which inflates to apply pressure during the contractions.

This review aimed to answer whether fundal pressure during contractions in the second stage of labour helps women give birth vaginally, and whether it causes any negative consequences for the woman or her unborn baby.

Why is this important?

A long labour can sometimes be dangerous for some women and their babies. Sometimes the unborn baby and woman can become exhausted during the labour and birth. In many countries, there are trained professionals who can assist with ventouse, forceps or caesarean sections. However in other countries, these resources are often lacking, and long labours can be life-threatening. Fundal pressure may help the woman to give birth. It may also possibly increase complications for the baby and mother. There is not a lot of knowledge on this topic, and it is important to know how these techniques might affect the women and their babies.

What evidence did we find?

This updated Cochrane Review found nine randomised controlled trials involving 3948 women (search date 30 November 2016). Five studies (including 3057 women) looked at manual fundal pressure versus no fundal pressure and four studies (including 891 women) looked at fundal pressure applied using an inflatable belt.

We found no evidence that manual fundal pressure made a difference to numbers of women giving birth vaginally within a given time (very low-quality evidence), or having an instrumental birth, caesarean section, or vaginal birth (very low-quality evidence). The time women took to give birth when pushing was not affected by manual fundal pressure (very low-quality evidence). The numbers of babies who did not cope well with labour and had low arterial cord pH, or low Apgar scores were the same whether their mother had fundal pressure or not (all very low-quality evidence). No babies died in either group. Studies did not report on possible severe problems or death of the women.

For women giving birth for the first time, fundal pressure by inflatable belt could possibly mean that fewer women had an instrumental or caesarean birth (very low-quality evidence), but the evidence was not clear. In these women, the inflatable belt meant they pushed for less time than women pushing without the belt (very low-quality evidence). The inflatable belt did not make any difference to numbers of women having caesarean sections, babies with low arterial cord pH (low-quality evidence), or Apgar scores five minutes after birth (very low-quality evidence). No studies reported if the women gave birth within a given time, numbers of babies that died or possible serious problems or death of the women. No studies used inflatable belts in women who had given birth before.

What does this mean?

There is not enough evidence from randomised controlled trials to show whether manual fundal pressure or fundal pressure by inflatable belt are effective ways of shortening the pushing stage of labour and avoiding operative births, and whether the techniques are safe. So currently there is insufficient evidence to support the use of fundal pressure by any method in the second stage of labour.

Future studies should be of good quality, clearly describe how fundal pressure was applied, and focus on safety of the unborn baby, perineal outcomes, longer-term maternal outcomes and the mothers' satisfaction.

Summary of findings for the main comparison. Manual fundal pressure compared to no fundal pressure for the second stage of labour

Manual fundal pressure compared to no fundal pressure for the second stage of labour

Patient or population: women with singleton pregnancy in vertex position in second stage of labour
Setting: Iran, India, South Africa and Turkey
Intervention: manual fundal pressure
Comparison: no fundal pressure

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with no fundal pressure	Risk with manual fundal pressure				
No spontaneous vaginal birth within a specified time, as defined by the trial authors	Study population 613 per 1000	588 per 1000 (435 to 785)	RR 0.96 (0.71 to 1.28)	120 (1 RCT)	⊕⊖⊖⊖ Very low[1,2]	Reported as "Time from bearing down to birth of head =/ >30 min or operative delivery". Data may contain instrumental births and should be interpreted with due caution
Operative birth - Instrumental or caesarean birth	Study population 61 per 1000	33 per 1000 (12 to 92)	Average RR 0.66 (0.12 to 3.55)	317 (2 RCTs)	⊕⊖⊖⊖ Very low[2,3,4]	
Low arterial cord pH	Study population 172 per 1000	184 per 1000 (124 to 272)	RR 1.07 (0.72 to 1.58)	297 (2 RCTs)	⊕⊖⊖⊖ Very low[1,5]	
APGAR score less than 7 at 5 minutes	Study population 5 per 1000	23 per 1000 (1 to 375)	Average RR 4.48 (0.28 to 71.45)	2759 (4 RCTs)	⊕⊖⊖⊖ Very low[6,7,8]	
Duration of active second stage	No absolute effects	No absolute effects	The mean duration of second stage was 0.8	194 (1 RCT)	⊕⊖⊖⊖ Very low[1,2]	

	Mean duration of labour 16.6 minutes	Mean duration of labour 17.4 minutes	minutes shorter in the fundal pressure group (3.66 minutes shorter to 2.06 minutes longer)			
Severe maternal morbidity or death	Study population		-	(0 study)	-	No trial reported this outcome
	See comment	See comment				
Neonatal death	Study population		-	2445 (2 RCTs)	⊕⊖⊖⊖ Very low[9,10]	Zero neonatal deaths reported in both trials
	See comment	See comment				

*__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 quality: we are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: 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 quality: our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low-quality: we have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Wide confidence interval crossing the line of no effect, few events and small sample size (-2).
[2] One study with design limitations (-1).
[3] Studies show inconsistent effects suggesting the two trials may not have measured the same outcome. Therefore not pooled (-2).
[4] Very small number of events and sample size (-2).
[5] One study with serious design limitations. Large loss to follow-up for this outcome (-2).
[6] Two studies contributing data had design limitations, with more than 40% of weight from a study with serious design limitations (-2).
[7] One study contributing data compared Gentle Assisted Pushing, the other compared manual fundal pressure (-1).
[8] Wide confidence interval crossing line of no effect (-1).
[9] One study with serious design limitations. (-2).
[10] No events and sample size below 3000 (-2).

Summary of findings 2. Fundal pressure by inflatable belt compared to no fundal pressure for second stage of labour

Fundal pressure by inflatable belt compared to no fundal pressure for second stage of labour

Patient or population: women with singleton pregnancy in vertex position in second stage of labour
Setting: Italy, South Korea and UK
Intervention: fundal pressure by inflatable belt

Comparison: no fundal pressure

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with no fundal pressure	Risk with fundal pressure by inflatable belt				
No spontaneous vaginal birth within a specified time	Study population		-	(0 study)	-	No trial reported this outcome
	See comment	See comment				
Operative birth - instrumental or caesarean section	Study population		Average RR 0.62 (0.38 to 1.01)	891 (4 RCTs)	⊕⊖⊖⊖ Very low[1,2,3]	
	516 per 1000	320 per 1000 (196 to 521)				
Low arterial cord pH	Study population		RR 0.47 (0.09 to 2.55)	461 (1 RCT)	⊕⊕⊖⊖ Low[4]	
	18 per 1000	8 per 1000 (2 to 46)				
Apgar score less than 7 after 5 minutes	Study population		RR 4.62 (0.22 to 95.68)	500 (1 RCT)	⊕⊖⊖⊖ Very low[4,5]	
	0 per 1000	0 per 1000 (0 to 0)				
Duration of second stage (minutes)	No absolute effects	No absolute effects	The average mean duration of second stage was 50.8 minutes shorter in the inflatable belt group (94.85 minutes shorter to 6.74 minutes shorter)	253 (2 RCTs)	⊕⊖⊖⊖ Very low[4,6,7]	Acanfora 2013: mean duration of second stage was 73.47 minutes shorter for women in the inflatable belt group (86.40 minutes shorter to 60.54 minutes shorter) Kim 2013: mean duration of second stage was 28.51 minutes shorter for women in the inflatable belt group (38.50 minutes shorter to 18.52 minutes shorter)
Severe maternal morbidity and death	Study population		-	(0 study)	-	No trial reported these outcomes
	See comment	See comment				
Neonatal death	Study population		-	(0 study)	-	No trial reported this outcome

	See comment	See comment

*__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 quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: 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 quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

[1] Most studies contributing data had design limitations (-1).
[2] Statistical heterogeneity ($I^2 > 60\%$). Direction of effect consistent but size of effect variable (-1).
[3] Wide confidence interval crossing the line of no effect and estimate based on small sample size (-2).
[4] Wide confidence interval crossing the line of no effect, few events and small sample size (-2).
[5] One study with design limitations (-1).
[6] Most studies contributing data had design limitations, with more than 40% of weight from a study with substantial design limitations (-2).
[7] Direction of effect consistent but considerable differences in size of effect (-2).

BACKGROUND

Description of the condition

The second stage of labour is defined as the period of time from full dilation of the cervix until complete expulsion of the baby (NICE 2016). This includes the time when the mother bears down to give birth. The duration of second stage is generally longer in nulliparous women than multiparous women, however a prolonged second stage (whether due to maternal or fetal factors) can require urgent intervention to improve perinatal outcome.

The purpose of fundal pressure is to shorten the second stage of labour. The clinical indications for this manoeuvre can be fetal distress, failure to progress in the second stage of labour and/or maternal exhaustion or medical conditions whereby (prolonged) pushing is contraindicated, for example, maternal heart disease (Cosner 1996; Simpson 2001).

Description of the intervention

Fundal pressure during the second stage of labour is a controversial manoeuvre. The obstetric technique involves application of manual pressure to the uppermost part of the uterus directed towards the birth canal in an attempt to shorten the second stage (Kline-Kaye 1990). In research settings, fundal pressure has also been applied using an inflatable belt.

The practice varies greatly between countries. Manual fundal pressure is frequently used in settings where other interventions, like instrumental deliveries, are not readily available, or cannot be performed because of professional staff shortage. While in many low- and middle-income countries the manoeuvre appears to be routine practice during vaginal births (Goldman 2003; Miller 2003), in some, mainly English-speaking, Western countries, it is seen as an obsolete procedure (Alran 2002; Buhimschi 2002). In the USA and the UK for example, this may be because of the intense medico-legal climate in those countries, and the complications supposedly arising from the manoeuvre, as described below. These factors may also contribute to under-reporting. A postpartum follow-up survey in the USA in 2005 found that 17% of the respondents had experienced fundal pressure during the second stage of their birth (Declercq 2006). In 4% of all vaginal births between 1994 and 1995 in the Netherlands, fundal pressure was recorded (De Leeuw 2001). A study in Austria found the manoeuvre being practiced in up to 23% of vaginal births in the university hospital (Schulz-Lobmeyr 1999). In a Swedish study, fundal pressure was used in 11% of vacuum-assisted births (Ahlberg 2016). In a Japanese survey, all responding institutions reported using fundal pressure in accordance with the Japan Academy of Midwifery 2012 Evidence-Based Guidelines for Midwifery Care (Baba 2016). A United Nations Population Fund study of childbirth practices and experiences in rural central Bangladesh found the use of fundal pressure and tight abdominal bands to be prevalent (Goodburn 1995). A Brazilian survey found that fundal pressure was used more frequently in labours attended by physicians than those attended by nurse-midwives (Gama 2016).

How the intervention might work

There is little evidence to demonstrate that the use of fundal pressure is effective in shortening the second stage. A study in the US examining intrauterine pressure found that fundal pressure during the contraction increased the expulsive force on average by 28%. The authors go on to suggest that fundal pressure may reduce the risks associated with either a prolonged second stage or the resulting operative procedures (Buhimschi 2002). However, an observational study found the second stage to be longer in those cases where fundal pressure was used (Cosner 1996). This may reflect selection bias rather than failure of the procedure, as fundal pressure would tend to be used in the more difficult deliveries.

More relevant than the effect of fundal pressure on length of second stage is its effect on maternal and neonatal outcomes. Several reports suggest that fundal pressure is associated with maternal and neonatal complications, for example, uterine rupture (Pan 2002; Sturzenegger 2016; Vangeenderhuysen 2002), neonatal fractures and brain damage (Amiel-Tyson 1988). An increased risk of anal sphincter damage has been reported (Cosner 1996; De Leeuw 2001; Zetterstrom 1999). Confounding factors, including birthweight, length of second stage, and malpresentation, which could have influenced the birth attendant's decision to perform fundal pressure, are not corrected for in these observational studies. On the other hand, if fundal pressure could prevent instrumental birth, the risk of a third-degree tear as a result of the instrument used would also be decreased.

Another concern is that fundal pressure might increase feto-maternal or maternal-fetal transfusion. No evidence has been found of increased transfusion of blood from mother to baby during external cephalic version, which also involves manual pressure on the uterus (Holmes 2004). Fundal pressure at the time of caesarean section does not increase the amount of transplacental micro transfusion (Owens 2003). Although this is a reassuring finding, it is still unclear whether or not fundal pressure at vaginal birth increases the risk of rhesus isoimmunisation and of vertical transmission of viruses such as HIV and hepatitis B.

Discomfort or pain from excessive pressure on the mother's abdomen is also a matter for concern.

Why it is important to do this review

The effectiveness or otherwise of fundal pressure is particularly relevant in low-resource settings where, in the presence of prolonged second stage of labour or fetal distress, the options of assisted vaginal birth or caesarean section are not available. If effective and safe, fundal pressure may be the only option, which may reduce perinatal mortality and morbidity. It is also important because the procedure is extensively used in both high- and low-income countries.

There is a need for objective evaluation of the effectiveness and safety of fundal pressure in the second stage of labour.

OBJECTIVES

To determine if fundal pressure is effective in achieving spontaneous vaginal birth, and preventing prolonged second stage or the need for operative birth, and to explore maternal and neonatal adverse effects related to fundal pressure.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCTs). Due to the expected paucity of trials, we also considered quasi-randomised controlled trials.

Trials using a crossover design are not eligible for inclusion in this review. Cluster-RCTS would be eligible for inclusion in this review but none were identified. Where abstracts were identified, we contacted the trial authors for further information. However, abstracts alone were not routinely included due to insufficient information to assess bias.

Types of participants

Women in the second stage of labour with singleton cephalic presentation. Women of all gestational ages and parity are eligible for inclusion. We excluded women who received fundal pressure at caesarean section and after delivery of the fetal head, or for shoulder dystocia.

Types of interventions

Fundal pressure versus no fundal pressure, where fundal pressure is defined as manual pressure on the fundus of the uterus towards the birth canal in the second stage of labour, with the aim of expediting the birth of the baby. This fundal pressure is also known as the 'Kristeller manoeuvre'.

We assessed fundal pressure applied by means of an inflatable belt as a separate comparison.

Types of outcome measures

Primary outcomes

Maternal

Short-term outcomes

1. No spontaneous vaginal birth within a specified time, as defined by the trial authors
2. Operative birth
   a. Instrumental birth
   b. Caesarean section

Neonatal

1. Low arterial cord pH, as defined by trial authors
2. Apgar score less than seven after five minutes

Secondary outcomes

Maternal

1. Duration of active second stage
2. Use of other interventions
   a. Episiotomy
3. Soft tissue damage
   a. Perineal/vaginal/anal sphincter
   b. Uterine
4. Postpartum haemorrhage as defined by trial authors
5. Severe maternal morbidity or death
6. Pain, after enrolment, as defined by trial authors
7. Maternal satisfaction as defined by trial authors

Long-term outcomes

1. Faecal incontinence
2. Urinary incontinence
3. Dyspareunia

Neonatal

1. Neonatal trauma
   a. Fractures
   b. Haematoma
2. Neonatal encephalopathy, as defined by trial authors
3. Admission to neonatal intensive care unit
4. HIV/hepatitis B or C infection (in populations with high prevalence)
5. Baby death
   a. Stillbirth
   b. Neonatal death

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

We searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (30 November 2016).

The Register is a database containing over 22,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate Cochrane Pregnancy and Childbirth's Trials Register, including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the Cochrane Pregnancy and Childbirth in the Cochrane Library and select the '***Specialized Register***' section from the options on the left side of the screen.

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

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

Two people screen the search results and review the full text of all relevant trial reports identified through the searching activities described above. 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 which has been fully accounted for in the relevant review sections (Included studies; Excluded studies; Studies awaiting classification; Ongoing studies).

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 Verheijen 2009.

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 (Joshua Vogel (JV) and Anna Cuthbert (AC)) independently assessed the studies for inclusion in this update. Therese Dowswell (TD) (Cochrane Pregnancy and Childbirth) and AC assessed the two studies where JV was an investigator. Any disagreements were resolved through discussion.

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors and one representative of Cochrane Pregnancy and Childbirth (JV, AC and TD), extracted the data using the agreed form. We resolved discrepancies through discussion. We entered data into Review Manager 5 (RevMan 5) software (RevMan 2014) and checked for accuracy. We contacted authors of studies as required. Peyman 2011 provided further information regarding the study. We were unable to contact Zhao 2015.

Assessment of risk of bias in included studies

Two authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). We resolved any disagreement by discussion or by involving a third assessor (TD).

(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 was unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

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

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

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

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

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

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook of Systematic Reviews of Interventions* (Higgins 2011a). With reference to (1) to (6) above, we planned to assess the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. In future updates, we will explore the impact of the level of bias through undertaking sensitivity analyses - see Sensitivity analysis.

Assessment of the quality of the evidence using the GRADE approach

For this update we assessed the quality of the evidence using the GRADE approach as outlined in the GRADE handbook in order to assess the quality of the body of evidence relating to the following outcomes for the main comparisons: manual fundal pressure versus no fundal pressure, and fundal pressure by inflatable belt versus no fundal pressure.

1. No spontaneous vaginal birth within a specified time, as defined by the trial authors
2. Operative birth - instrumental and caesarean
3. Low arterial cord pH, as defined by trial authors
4. Apgar score less than seven after five minutes
5. Duration of active second stage
6. Severe maternal morbidity or death
7. Neonatal mortality (stillbirth or neonatal death)

GRADEpro Guideline Development Tool was used to import data from RevMan 5 (RevMan 2014) in order to create 'Summary of findings' tables. We produced a summary of the intervention effect and a measure of quality for each of the above outcomes 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 (RR) with 95% confidence intervals (CI).

Continuous data

We used the mean difference (MD) if outcomes were measured in the same way between trials. In future updates, where appropriate, we will use the standardised mean difference to combine trials that measured the same outcome, but used different methods.

Unit of analysis issues

Cluster-randomised trials

In future updates, we will include cluster-randomised trials in the analyses along with individually randomised trials. We will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* Section 16.3.4 or 16.3.6 (Higgins 2011b) 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 are not appropriate for this review.

Other unit of analysis issues

Trials with more than two arms

If we had identified trials with more than two arms we would have pooled intervention group results if appropriate, or split the control group, using the methods set out in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011b) to avoid double-counting.

Multiple pregnancies

Multiple pregnancies are not included in this review.

Dealing with missing data

For included studies, we noted levels of attrition. 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, we carried out analyses, as far as possible, on an intention-to-treat basis, that is, 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 (Higgins 2003) and Chi^2 statistics (Deeks 2011). We regarded heterogeneity as moderate if I^2 was greater than 30% and either Tau^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity. If we identified substantial heterogeneity (above 30%), we planned to explore it by pre-specified subgroup analysis. When trials were reporting inconsistent results, we did not perform meta-analysis as we felt that combining the data was not meaningful.

Assessment of reporting biases

In future updates, if there are 10 or more studies in the meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots (Sterne 2011). We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We carried out statistical analysis using the RevMan 5 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: that is, where trials were examining the same intervention, and we judged the trials' populations and methods sufficiently similar.

Where we identified clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if we detected substantial statistical heterogeneity (above 50%), we used random-effects meta-analysis to produce an overall summary, if we considered an average treatment effect across trials clinically meaningful. We treated the random-effects summary as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials. Where we used random-effects analyses, we presented the results as the average treatment effect with 95% CIs, and the estimates of Tau^2 and I^2.

Subgroup analysis and investigation of heterogeneity

Where we identified substantial heterogeneity, we planned to investigate it using subgroup analyses and sensitivity analyses. We planned to consider whether an overall summary was meaningful, and if it was, we would have used random-effects analysis to produce it.

We planned to carry out the following subgroup analyses.

1. Previous caesarean section, no previous caesarean section, caesarean section status mixed/not specified.
2. Countries with low perinatal mortality rates (less than 20 per 1000), countries with high perinatal mortality rates (at least 20 per 1000), country status mixed/not specified.
3. Primiparas, multiparas, or parity mixed/not specified.
4. Fundal pressure used routinely, used for (prevention of) prolonged second stage, used for fetal distress, or indication mixed/not specified.

There was high heterogeneity for the primary outcomes of Apgar scores less than seven at five minutes in the comparison manual fundal pressure versus no fundal pressure; and instrumental birth, caesarean section, operative birth and duration of second stage in the comparison fundal pressure by inflatable belt versus no belt. We did not carry out planned subgroup analysis to explore heterogeneity due to insufficient data to make such analysis meaningful. For these outcomes we have used random-effects analysis. We presented the results as the average treatment effect with 95% CIs, and the estimates of Tau^2 and I^2. If there is sufficient data in future updates, we will carry out these subgroup analyses. In future updates, we will assess subgroup differences by interaction tests available within RevMan 5 (RevMan 2014) and report the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value. We will restrict subgroup analysis to the review's primary outcomes.

Sensitivity analysis

We planned to carry out sensitivity analyses to explore the effect of trial quality assessed by concealment of allocation, high attrition rates, or both, with studies at high risk of bias being excluded from the analyses in order to assess whether this made any difference to the overall result. We used sensitivity analysis to explore the effect of high attrition rates in Api 2009 for the outcome 'Low arterial cord pH'. We also used sensitivity analysis to explore the effect of 27 out of 40 women from the 'no fundal pressure' group receiving manual fundal pressure in Acanfora 2013. Sensitivity analysis is restricted to the review's primary outcomes.

RESULTS

Description of studies

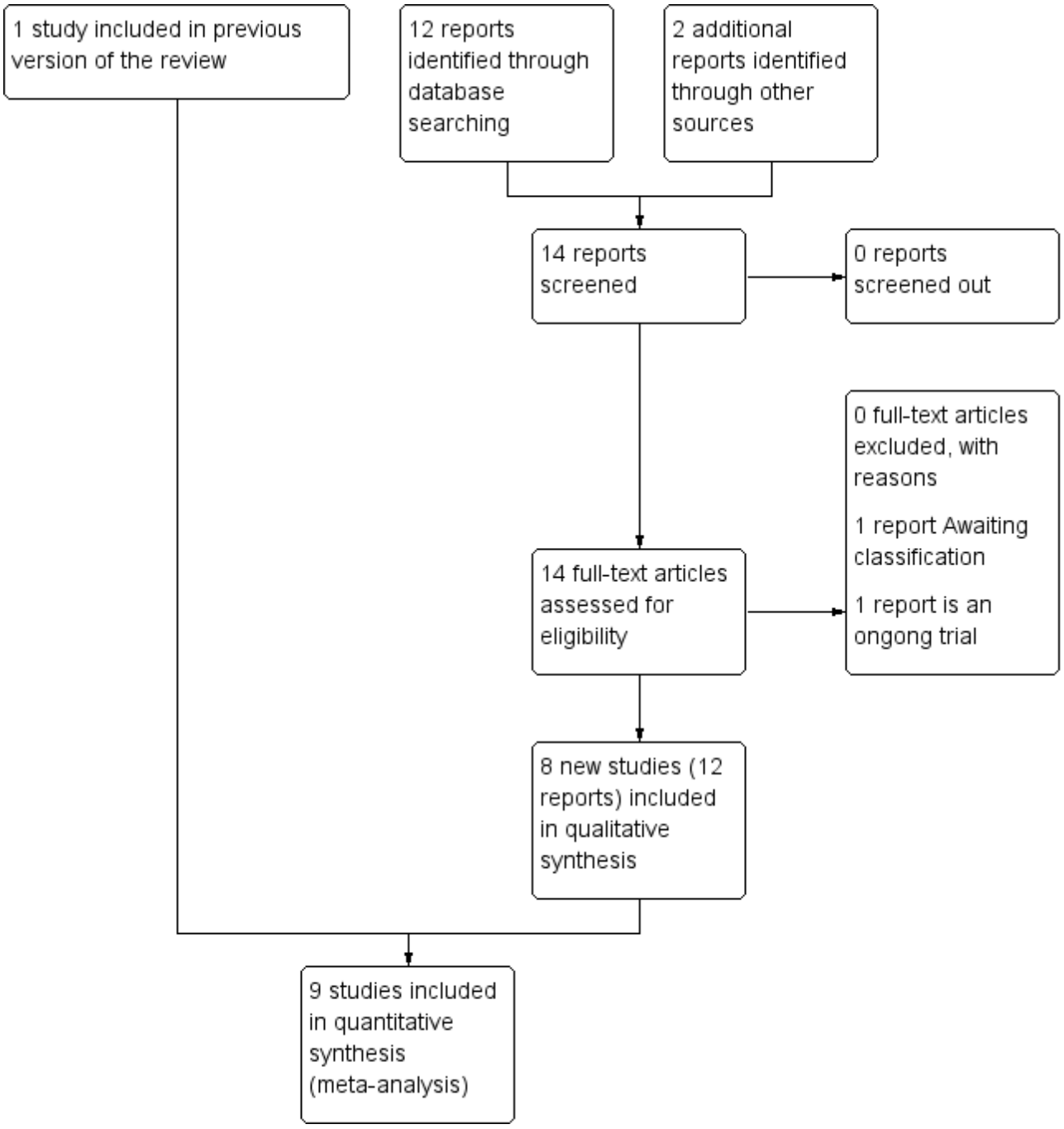
See Characteristics of included studies.

Results of the search

In the last update of this review, we identified three trials that studied fundal pressure in second stage of labour using the search criteria. One trial was excluded from the analyses as allocation to intervention group was not based on randomisation (Schulz-Lobmeyr 1999). Another (quasi-randomised) trial was excluded for reasons of poor methodological quality and high risk of bias (Zhao 1991).

In this update, we assessed 14 reports of 10 trials from an updated search in November 2016. We have included eight new trials, one trial is ongoing (Hofmeyr 2015), and one is awaiting classification (Zhao 2015). Cox 1999 was already included in the previous version of this review (See: Figure 1).

Figure 1. Study flow diagram



Included studies

Study design

This updated review is now comprised of nine randomised controlled trials (RCTs) (Acanfora 2013; Acmaz 2015; Api 2009; Cox 1999; Kang 2009; Kim 2013; Mahendru 2010; Novikova 2009; Peyman 2011) involving 3948 women.

Most women were recruited during the first stage of labour. Acanfora 2013 and Novikova 2009 randomised women when they reached second stage of labour. Novikova 2009 was the only trial that randomised women when they had not delivered after 15 minutes of active pushing. It is not clear at what stage randomisation took place in Acmaz 2015.

Setting and sample size

The largest trial in this review (Peyman 2011), involved 2236 women and took place in hospitals related to the Azad University in Iran. All other trials were single-centre RCTs with the exception of Novikova 2009 who recruited women over two hospital sites in South Africa. Remaining trials included in this review were conducted in Italy (Acanfora 2013), Republic of Korea (Kang 2009; Kim 2013) India (Mahendru 2010), Turkey (Acmaz 2015; Api 2009) and UK Cox 1999).

The studies were from 1999 to 2013. The smallest trial was Acanfora 2013 with 80 women involved.

Participants

Most trials included women with a term (37 weeks' gestation and above), singleton pregnancy who were in the first stage of labour. Novikova 2009 was the only trial to include women at 35 weeks' gestation or above.

Acmaz 2015, Api 2009 and Peyman 2011 included multiparous and nulliparous women; all other trials only included nulliparous women. Most of the trials excluded women with uterine scar or previous uterine surgery except for Api 2009 where it was not clear whether or not these women were excluded.

Women in Cox 1999, Kang 2009, Kim 2013 and Peyman 2011 received oxytocin during labour, although it was not clear in Kim 2013 or Peyman 2011 when this was given. All the women in Cox 1999 received epidural analgesia, and 44 were given oxytocin during second stage. Kang 2009 included women who received oxytocin for both induction and augmentation. Acmaz 2015 excluded women with epidural or oxytocin augmentation. Mahendru 2010 only included women in spontaneous labour, though it was not clear if women who were augmented were eligible. The remaining studies did not mention whether women received oxytocin for induction or augmentation or neither (Acanfora 2013; Api 2009; Novikova 2009).

Interventions and comparisons

All of the trials involved fundal pressure, either manual or by inflatable belt, versus no fundal pressure for women in the second stage of labour.

Comparison 1: Manual fundal pressure versus no fundal pressure (five trials, 3057 women)

Five trials (Acmaz 2015; Api 2009; Mahendru 2010; Novikova 2009; Peyman 2011) assessed manual fundal pressure versus no fundal pressure. Women participating in Api 2009 and Peyman 2011 had fundal pressure applied by a care provider pressing on the uppermost part of the uterus at a 30° to 45° angle to the maternal spine in the direction of the pelvis (Kristeller manoeuvre). Pressure was applied each time the woman had a contraction throughout second stage. Mahendru 2010 used the same technique, except that the doctor only applied pressure three times during the second stage (the women in the control groups did not receive any fundal pressure). Acmaz 2015 did not specify how manual pressure was applied in their trial.

Novikova 2009 used the Gentle Assisted Pushing technique (GAP) which seeks to avoid "forceful or rapid pressure" on the woman's abdomen. If the woman was undelivered after 15 minutes of active pushing, "the attendant knelt at the bed head with the back of the woman's head and back resting on her thighs. The attendant passed her arms under the woman's arms and placed her palms on the woman's fundus. During contractions firm and sustained fundal pressure was applied in the direction of the pelvis for the duration of the contraction." The same supportive position was used for the control group though no pressure was applied.

Comparison 2: Fundal pressure by means of an inflatable belt versus no fundal pressure (four trials, 891 women)

Four trials (Acanfora 2013; Cox 1999; Kang 2009; Kim 2013) compared fundal pressure by inflatable belt versus no fundal pressure.

All four trials used an inflatable belt that detected contractions and inflated during the contraction for 30 seconds. In all four trials, fetal heart rate was monitored continuously whilst the belts were applied, and the belt was disabled when birth seemed imminent. In all trials, except Cox 1999, women in the control group also wore the inflatable belt, but it was not activated or only inflated to minimal pressures. Cox 1999 only included nulliparous women with epidural analgesia and ruptured membranes, Kang 2009 and Kim 2013 included nulliparous women who had the choice of epidural anaesthesia, and Acanfora 2013 included nulliparous women. It is not clear if epidural anaesthesia was an option in this trial.

Acanfora 2013 also used the Kristeller manoeuvre on women in the control group (only). The indication for its use is not stated, although non-reassuring fetal heart monitoring is mentioned as a possible reason. Twenty-seven women out of 40 in the control group had fundal pressure applied during their second stage.

Excluded studies

Two studies (Schulz-Lobmeyr 1999; Zhao 1991) were excluded in the last version of this review. Schulz-Lobmeyr 1999 was judged to be at too high risk of confounding factors, as fundal pressure was performed by choice of the clinician, and not as a result of allocation. Zhao 1991 was at high risk of bias due to poor methodological quality.

Risk of bias in included studies

See Figure 2 and Figure 3 for summary of 'Risk of bias' assessment of included studies.

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

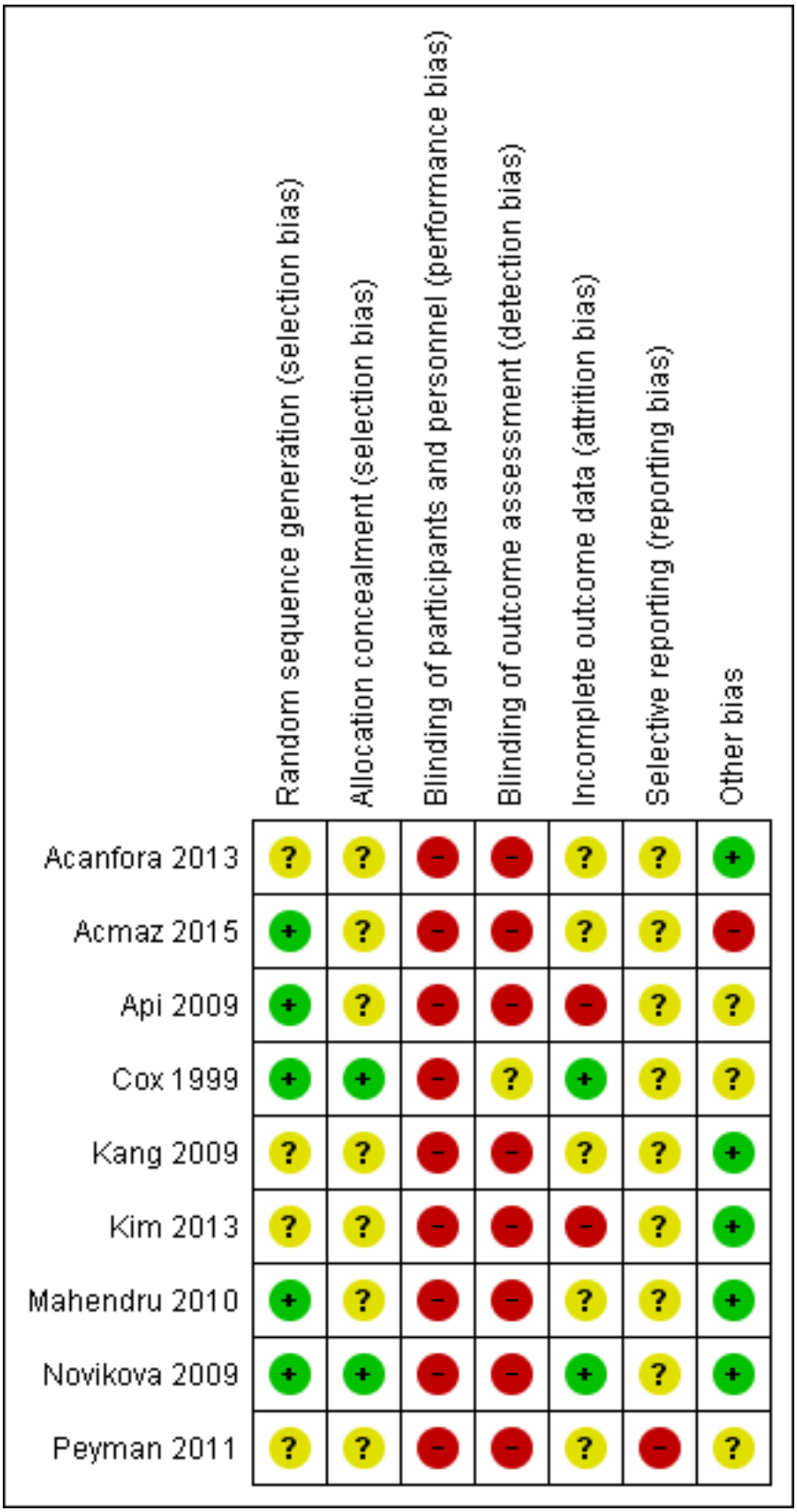
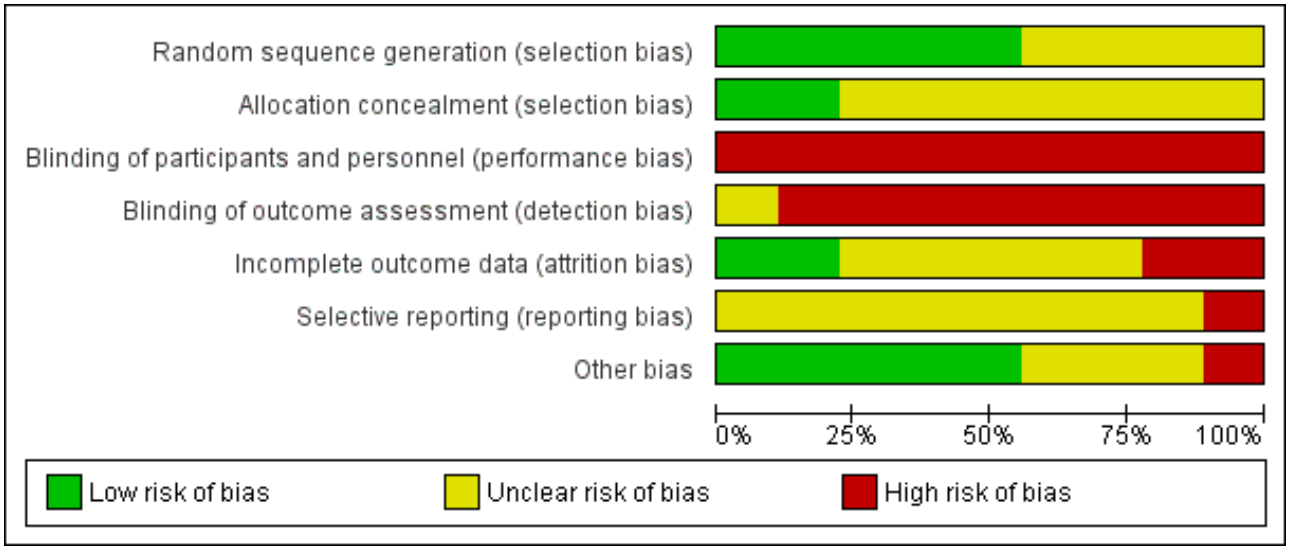


Figure 3. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies



Allocation

We observed adequate allocation concealment in Cox 1999 and Novikova 2009, where computer-generated numbers were placed in consecutively-numbered sealed opaque envelopes. In all other trials, allocation concealment was not reported (Acanfora 2013; Acmaz 2015; Api 2009; Kang 2009; Kim 2013; Mahendru 2010; Peyman 2011) or it was unclear what method was used (Acanfora 2013; Kang 2009; Kim 2013; Peyman 2011).

Blinding

All trials, except Cox 1999, either did not blind participants and outcome assessors or did not mention attempting to blind. We assumed that these trials did not blind participants or assessors (high risk of bias). Cox 1999 collected self-reported outcomes via a research doctor after birth. We judged these self-reported outcomes to be at high risk of bias because they could have been affected by a non-blinded researcher collecting the data. However, neonatal outcomes were collected by a paediatrician at 24 hours postnatal who was blinded to the study allocation. Overall, we assessed Cox 1999 as being at an unclear risk of performance and detection bias for lack of blinding.

Incomplete outcome data

Most of the trials did not give enough information to adequately assess for incomplete outcome data and were poorly reported (Acanfora 2013; Acmaz 2015; Kang 2009; Mahendru 2010; Peyman 2011). Data appeared complete in Cox 1999, and Novikova 2009 where outcomes were analysed by intention to treat. Api 2009 reported missing data in both arms of cord blood analysis, which was unexplained and disproportionately worse in the fundal pressure group (high risk of bias). Acmaz 2015 was difficult to assess, as there was no clear information about when randomisation took place and a quarter of the sample recruited were lost before second stage. Women were also lost to follow-up or excluded. Kim 2013 did not report data for a primary outcome, duration of second stage, for 15 women who had either a caesarean section or precipitous labour (high risk of bias). These women were already randomised (four women in the intervention group and 11 women in the control group).

Selective reporting

We did not see trial protocols for any of the included trials so we found it difficult to assess them for selection bias, and we assessed all except Peyman 2011 as at unclear risk. Peyman 2011 did not clearly pre-specify outcomes in the methods text and due to errors in reporting certain outcomes, such as duration of second stage (high risk of bias), we were not able to use data from this trial in the review.

Other potential sources of bias

Five trials (Acanfora 2013; Kang 2009; Kim 2013; Mahendru 2010; Novikova 2009) showed no other risk of bias and baseline data were similar across the two groups (low risk of bias). Three other trials showed differences between baseline characteristics such as parity (Acmaz 2015; Api 2009), mean age of group (Acmaz 2015; Api 2009) and epidural duration (Cox 1999). Reporting in Peyman 2011 was poor, and it was too difficult to effectively assess other sources of bias. We judged Api 2009, Cox 1999 and Peyman 2011 as being at an unclear risk of other sources of bias. Acmaz 2015 was also poorly reported but due to the imbalances in baseline characteristics and the fact that the trial was only conducted in daylight hours, we judged this trial to be at high risk of other sources of bias.

Effects of interventions

See: **Summary of findings for the main comparison** Manual fundal pressure compared to no fundal pressure for the second stage of labour; **Summary of findings 2** Fundal pressure by inflatable belt compared to no fundal pressure for second stage of labour

Comparison 1. Manual fundal pressure versus no fundal pressure

Primary outcomes

We identified five trials including 3057 women for this comparison (Acmaz 2015; Api 2009; Mahendru 2010; Novikova 2009; Peyman 2011).

Maternal outcomes

No spontaneous vaginal birth within a specified time, as defined by the trial authors

One trial (Novikova 2009) reported "time from bearing down to birth of head => 30 min or operative delivery". We saw no clear difference between the two groups (risk ratio (RR) 0.96, 95% confidence interval (CI) 0.71 to 1.28; 120 women; 1 trial; very low-quality evidence; Analysis 1.1) with similar numbers of women giving birth spontaneously or instrumentally over 30 minutes from bearing down in both the fundal pressure group and no fundal pressure group.

Instrumental birth

In Api 2009, there were similar numbers of instrumental births in the fundal pressure and no fundal pressure groups (RR 3.28, 95% CI 0.14 to 79.65; 197 women; 1 trial; Analysis 1.2).

Caesarean section

In Api 2009, there was no difference found in caesarean births between fundal pressure and no fundal pressure groups (RR 1.10, 95% CI 0.07 to 17.27; 197 women; 1 trial; Analysis 1.3).

Operative birth - instrumental or caesarean

Overall, the results were inconsistent for this outcome. Manual pressure could reduce the number of operative births and therefore increase spontaneous vaginal births but confidence intervals crossed the line of no effect (average RR 0.66, 95% CI 0.12 to 3.55; 317 women; 2 trials; I^2 = 43%; Tau^2 = 0.71 Analysis 1.4). We graded this evidence as very low quality.

Neonatal outcomes

Low arterial cord pH, as defined by trial authors

There were similar numbers of babies born with low arterial cord blood pH in fundal pressure and no fundal pressure groups (RR 1.07, 95% CI 0.72 to 1.58; 297 women; 2 trials; I^2 = 0%; very low-quality evidence; Analysis 1.5). Api 2009 had some missing data for this outcome which was unexplained and unequal between the two groups. We conducted a sensitivity analysis by excluding Api 2009 and this yielded a similar result (RR 1.07, 95% CI 0.72 to 1.58; 118 women; 1 trial).

Apgar score less than seven after five minutes

It appeared that fewer babies born to women who did not have fundal pressure had Apgar scores of less then 7 at five minutes however the wide confidence intervals crossed the line of no effect (average RR 4.48, 95% CI 0.28 to 71.45; 2759 women; 4 trials; I^2 = 89%; Tau^2 = 3.55 very low-quality evidence; Analysis 1.6). We noted that there was substantial heterogeneity for this outcome. Two trials (Api 2009; Mahendru 2010) reported Apgar scores of less than seven at five minutes, but no cases occurred in either arm. The two other trials with outcome data compared fundal pressure (Peyman 2011) or Gentle Assisted Pushing (GAP) (Novikova 2009) versus no fundal pressure. Peyman 2011 reported a particularly high rate of the outcome in the intervention arm (73/1171 vs 4/1061). A possible reason for the high heterogeneity is that Peyman 2011 used fundal pressure from full dilatation whereas Novikova 2009 only used GAP after 15 minutes of the woman bearing down. Therefore, it is likely that women in Peyman 2011, would have received fundal pressure for a longer duration than the women in Novikova 2009. These two trials were also conducted in different settings, where prevalence of low Apgar scores are likely to differ. The high risk of performance, detection and reporting bias in Peyman 2011 may also be a factor.

Acmaz 2015 reported this outcome as a median and interquartile range. We did not use this data, which reported exactly the same scores in both groups.

Secondary outcomes

Maternal secondary outcomes

Duration of active second stage

In Api 2009, there was no difference in the length of second stage between the two groups (mean difference (MD) 0.80 minutes shorter, 95% CI -3.66 minutes shorter to 2.06 minutes longer; 194 women; 1 trial; very low-quality evidence; Analysis 1.7).

Use of other interventions - episiotomy

There were similar numbers of episiotomies in fundal pressure and no fundal pressure groups (RR 1.18, 95% CI 0.92 to 1.50; 317 women; 2 trials; I^2 = 0%; Analysis 1.8). Acmaz 2015 also reported this outcome, however the trial took place in a setting where episiotomies are performed more routinely and we considered it inappropriate to include these data with those from settings where episiotomies were avoided in most women (107/149 women in the intervention group and 75/146 in the control group received episiotomy).

Soft tissue damage - perineal/vaginal/anal sphincter/uterine

Perineal damage was reported in one trial (Mahendru 2010), and occurred more in women who received manual fundal pressure, however wide confidence intervals crossed the line of no effect (RR 6.42, 95% CI 0.79 to 52.37; 209 women; 1 trial; Analysis 1.9).

Vaginal laceration was reported in one trial (Acmaz 2015). There was no clear difference in the two groups (RR 1.24, 95% CI 0.75 to 2.03; 295 women; 1 trial; Analysis 1.10).

Acmaz 2015 also reported that more women who received manual fundal pressure had cervical tears than in the control group (RR 4.90, 95% CI 1.09 to 21.98; 295 women; 1 trial; Analysis 1.11).

Other types of soft tissue damage (anal, uterine) were not reported by any trial under this comparison.

Postpartum haemorrhage as defined by trial authors

One trial (Novikova 2009) reported blood loss of over 300 ml and found no meaningful difference between the two groups (RR 1.87, 95% CI 0.58 to 6.06; 120 women; 1 trial; Analysis 1.12).

Pain, after enrolment, as defined by trial authors

One trial reported women requesting one, two or three doses of injectable diclofenac following birth. Thirty-four women requested analgesia (i.e. one, two or three doses) in the manual fundal

pressure group and eight requested analgesia in the control group (RR 4.54, 95% CI 2.21 to 9.34; 209 women; 1 trial; Analysis 1.13).

Neonatal secondary outcomes

Neonatal trauma - fractures

One trial (Mahendru 2010) reported no fractures in either group (Analysis 1.14).

Neonatal trauma - haematoma

One trial (Mahendru 2010) reported no haematomas in either group (Analysis 1.15).

Admission to neonatal intensive care unit

Similar numbers of babies were admitted to intensive care baby unit in both groups in one trial that reported this outcome (RR 1.63, 95% CI 0.40 to 6.71; 295 women; 1 trial; Analysis 1.16).

Baby death - neonatal death

Only two trials (Mahendru 2010; Peyman 2011) reported this outcome: there were no neonatal deaths in either group (2 trials, 2445 women, 0 deaths in either arm; very low-quality evidence; Analysis 1.17).

Other secondary outcomes

The following secondary outcomes were not reported for this comparison:

- Severe maternal morbidity or death
- Maternal satisfaction as defined by trial authors
- Long-term outcomes: faecal incontinence/urinary incontinence, dyspareunia
- Neonatal encephalopathy, as defined by trial authors
- Admission to neonatal intensive care unit
- HIV/hepatitis B or C infection (in populations with high prevalence)
- Baby death - stillbirth

Comparison 2. Fundal pressure by means of an inflatable belt versus no fundal pressure

Primary outcomes

We included four trials including 891 women for this comparison (Acanfora 2013; Cox 1999; Kang 2009; Kim 2013).

Maternal outcomes

No spontaneous vaginal birth within a specified time, as defined by the trial authors

This outcome was not reported in the trials under this comparison.

Instrumental birth

Fewer women in the group using the inflatable belt for fundal pressure received instrumental deliveries than those in the control group with no belt (average RR 0.73, 95% CI 0.52 to 1.02; 891 women; 4 trials; I^2 = 52%; Tau^2 = 0.05 Analysis 2.1) however, due to wide confidence intervals which just crossed the line of no effect, we could not be certain that this result was not due to chance. However, in Acanfora 2013 27 out of 40 women in the control group also received manual fundal pressure. Therefore, we performed a sensitivity analysis excluding Acanfora 2013 which showed no difference between the two groups (average RR 0.81, 95% CI 0.63 to 1.04; 811 women; 3 trials; I^2 = 34%; Tau^2 = 0.02 Analysis 2.15).

Caesarean section

There was no clear difference in use of caesarean section in women treated with the inflatable belt and those in control groups (average RR 0.56, 95% CI 0.14 to 2.26; 891 women; 4 trials; I^2 = 70%; Tau^2 = 0.98; Analysis 2.2). There were insufficient data to perform planned subgroup analysis for this outcome. A sensitivity analysis excluding Acanfora 2013 showed no difference between the groups and higher heterogeneity (average RR 0.80, 95% CI 0.20 to 3.19; 811 women; 3 trials; I^2 = 75%; Tau^2 = 0.75; Analysis 2.16).

Operative birth - instrumental or caesarean

More women in the control groups had operative birth, however, wide CIs just crossed the line of no effect (average RR 0.62, 95% CI 0.38 to 1.01; 891 women; 4 trials; I^2 = 78%; Tau^2 = 0.14; very low-quality evidence; Analysis 2.3). Due to high heterogeneity, we conducted a sensitivity analysis by excluding Acanfora 2013. This indicated that risk of operative birth was no different between the two groups (RR 0.77, 95% CI 0.52 to 1.13; 811 women; 3 trials; I^2 = 71%; Tau^2 = 0.07; Analysis 2.17). Heterogeneity remained substantial.

Neonatal outcomes

Low arterial cord pH, as defined by trial authors

Only one trial reported this outcome (Cox 1999). The risk of babies experiencing low arterial cord pH were similar in both groups (RR 0.47, 95% CI 0.09 to 2.55; 461 infants; 1 trial;*low-quality evidence;* Analysis 2.4).

Apgar score less than seven after five minutes

Only one trial reported this outcome (Cox 1999). The risk of babies experiencing Apgars of less than seven at five minutes was similar in both groups (RR 4.62, 95% CI 0.22 to 95.68; 500 infants; 1 trial; very low-quality evidence; Analysis 2.5).

Secondary outcomes

Maternal outcomes

Duration of second stage (minutes)

Duration of second stage of labour was observed to be much shorter in the inflatable belt group compared to the control group in the two trials which reported this outcome (Acanfora 2013; Kim 2013). Fundal pressure by inflatable belt appeared to have a positive effect by reducing the duration of second stage, however until there are further trials examining this outcome, it is not possible to tell how large this effect is, and whether it is also seen in other sub-populations (such as multiparous women) given the inconsistency between the trials (average MD 50.80 minutes shorter, 95% CI 94.85 minutes to 6.74 minutes shorter; 253 women; 2 trials; I^2 = 97%; Tau^2 = 975.94; very low-quality evidence; Analysis 2.6).

Episiotomy

Similar numbers of women received episiotomy in both groups (average RR 0.98, 95% CI 0.86 to 1.12; 811 women; 3 trials; I^2 = 86%; Tau^2 = 0.01; Analysis 2.7). There was high heterogeneity in the outcome data. It appears that women in Kang 2009 received routine

episiotomy, and the data from the other two trials (Cox 1999; Kim 2013) in the meta-analysis were inconsistent.

Soft tissue damage - perineal/vaginal/anal sphincter/uterine

The risk of perineal damage in the two groups was not clearly different (average RR 0.53, 95% CI 0.20 to 1.38; 897 women; 4 trials; I^2 = 87%; Tau^2 = 0.66; Analysis 2.8). Acanfora 2013 and Kang 2009 both contributed significantly to the high heterogeneity in the meta-analysis; Acanfora 2013 reported that the belt reduced the number of women with perineal damage, however the majority of women in the control group in this trial also had the Kristeller manoeuvre applied, which could have affected this result. In Kang 2009, a high proportion of women underwent episiotomies and thus very few perineal tears were reported.

Only Kang 2009 reported vaginal tears- similar numbers of women in each group experienced this outcome (RR 0.74, 95% CI 0.27 to 2.00; 123 women; 1 trial; Analysis 2.9).

Cox 1999 (the only trial reporting anal sphincter damage) reported 17 third degree tears in the inflatable belt group compared with just one in the control group (RR 15.69, 95% CI 2.10 to 117.02; 500 women; 1 trial; Analysis 2.10).

Acanfora 2013 and Kang 2009 reported cervical tears; there was no difference between the two groups (RR 0.42, 95% CI 0.06 to 2.82; 203 women; 2 trials; I^2 = 0%; Analysis 2.11).

No trial reported uterine rupture.

Postpartum haemorrhage as defined by trial authors

One trial (Cox 1999) reported "need for blood transfusion" and found no meaningful difference between the two groups (RR 0.35, 95% CI 0.09 to 1.29; 500 women; 1 trial; Analysis 1.12).

Maternal satisfaction

We did not meta-analyse the data due to different methods and questions used to rate maternal satisfaction. However, 39/40 women who wore the inflatable belt perceived it as useful in Acanfora 2013. Kang 2009 reported that "Based on a postpartum questionnaire, more women reported positively about the device in the active group in terms of confidence, comfort, and satisfaction". Cox 1999 and Kim 2013 reported visual analogue scores of outcomes related to maternal satisfaction but did not clearly explain the scoring system, so we have not reported these results in the review.

Neonatal outcomes

Neonatal trauma - haematoma

One cephalhaematoma was reported in the control group of Kang 2009 (RR 0.33, 95% CI 0.01 to 7.90; 123 infants; 1 trial; Analysis 2.13).

Admission to neonatal intensive care unit

The results for this outcome were inconsistent across the trials (Acanfora 2013; Cox 1999; Kang 2009; Kim 2013) and wide CIs crossed the line of no effect (average RR 0.64, 95% CI 0.19 to 2.14; 891 infants; 4 trials; I^2 = 59%; Tau^2 = 0.82; Analysis 2.14). The heterogeneity could be partly explained by some of the women in the control group in Acanfora 2013 receiving the Kristeller manoeuvre, as seven babies from this group were admitted to intensive care compared with no babies requiring admission in the inflatable belt group.

Other secondary outcomes

The following secondary outcomes were not reported for this comparison:

- Severe maternal morbidity or death
- Pain, after enrolment, as defined by trial authors
- Long-term outcomes: faecal incontinence/urinary incontinence/dyspareunia
- Neonatal trauma - fractures
- Neonatal encephalopathy, as defined by trial authors
- HIV/hepatitis B or C infection (in populations with high prevalence)
- Baby death - stillbirth and neonatal death

DISCUSSION

This updated review now comprises nine randomised controlled trials involving 3653 women. There are five trials of manual fundal pressure and four trials of use of inflatable belts. We found limited evidence, which does not currently support the routine use of fundal pressure in clinical settings, either manually or by inflatable belt. There is still uncertainty around the majority of outcomes due to substantial heterogeneity, inconsistent findings and insufficient data.

Summary of main results

Manual fundal pressure versus no fundal pressure

(See Summary of findings for the main comparison)

Neither mode of birth (vaginal, instrumental or caesarean birth) or time to birth was affected by applying manual fundal pressure to women in second stage of labour. Perineal damage may be more likely for women receiving fundal pressure but this result may be due to chance; other types of soft tissue damage were not reported in included trials. In the single trial that reported pain felt by the women, postnatal pain was increased in the fundal pressure group. Maternal satisfaction was not reported in included trials.

Apgar scores were higher in the babies born to women who did not receive fundal pressure - this may indicate that manual fundal pressure results in poorer outcomes for babies, but this finding is not conclusive, with wide confidence intervals that cross the line of no effect. There were no fractures, haematomas or deaths reported in this comparison. Of note, the Gentle Assisted Pushing method of applying fundal pressure was not associated with a difference in neonatal outcomes between the two groups. Further research could establish whether this technique is more effective and safer than other forms of fundal pressure.

Fundal pressure by inflatable belt versus no fundal pressure

(See Summary of findings 2)

Rates of instrumental birth and operative deliveries overall were lower in the inflatable belt group, although we cannot be certain that this result is not due to chance due to wide confidence intervals. Results were also inconsistent for caesarean section, possibly due to differences in study design. Duration of second

stage labour was substantially shorter for the women when the inflatable belt was used. Perineal, vaginal and cervical tears were not clearly different between the two groups, however one study found an increase in third degree tears in the inflatable belt group. Generally, women reported that they were satisfied with the belt.

The possible increase in intact perineum, as well as in anal sphincter tears in women wearing the belt, is somewhat contradictory. While in the belt group, 16 of 17 cases of sphincter tears were associated with an instrumental birth, in the control group an instrumental birth was only associated with one third-degree tear. The belt was switched off prior to instrumentation in the trial that collected these data. It seems therefore unlikely that there is a causative relation between the intervention and the tears. The trial authors reported their suspicion that the outcome assessors were more diligent in identifying and reporting perineal trauma in the experimental group. The lack of blinding seem to have introduced bias for assessment of this outcome. However, the possibility of a causal link should not be discounted.

Numbers of babies with low arterial cord pH, low Apgar scores, and admissions to neonatal intensive care, were similar across the groups. One baby had a cephalhaematoma in the control group. Fractures and neonatal deaths were not reported.

Overall completeness and applicability of evidence

In this update, we were able to include two separate comparisons; manual fundal pressure versus no fundal pressure; and fundal pressure by an inflatable belt versus no fundal pressure, with five trials in the first comparison and four trials in the second comparison.

Only small sample sizes were available for primary outcomes in both comparisons, and no data were available for many secondary outcomes (for example, no data on maternal morbidity, mortality and stillbirth were reported). Longer-term maternal outcomes were also not reported. Only five trials reported any type of soft tissue damage including vaginal and perineal tears of any degree of severity. Neonatal outcomes were even less well reported in the inflatable belt comparison. Only one trial reported Apgar score and low arterial cord pH. It is therefore difficult to draw conclusions on the benefits and harms on the use of fundal pressure, and whether the findings are generalisable to other settings or groups of women.

The trials took place in a range of countries, however, the majority of trials were poorly conducted or poorly reported. Heterogeneity was high in most meta-analyses - the results should be viewed with caution.

There is currently insufficient evidence available to indicate whether fundal pressure is beneficial or safe, or both, particularly in resource-limited settings where operative birth is not possible.

Quality of the evidence

The overall quality of the evidence was low to moderate. None of the included studies used blinding. While blinding of participants and personnel may not have been possible, outcome assessors could have been blinded (but generally were not). Reporting of the included trials was generally quite poor, thus assessments for random sequence generation and allocation concealment were often unclear. We assessed Api 2009 and Kim 2013 as being at high risk of attrition bias. Peyman 2011 was the largest trial with 2236 women participating, however the reporting was very poor, and we generally assessed it as being at high or unclear risk of bias. Please see 'Risk of bias' summary figures for a summary of these assessments: Figure 2 and Figure 3.

For the comparison of manual fundal pressure to no fundal pressure (Summary of findings for the main comparison), we rated evidence for no spontaneous vaginal birth within a specified time as low quality, and operative birth - instrumental or caesarean birth, low arterial cord pH, Apgar score less than 7 at five minutes and duration of active second stage were all rated as very low-quality evidence.

For the comparison of fundal pressure by inflatable belt to no fundal pressure (Summary of findings 2), we rated evidence for operative birth - instrumental or caesarean birth and duration of second stage as very low quality, and low arterial cord pH and Apgar score less than seven at five minutes were rated as low-quality evidence.

We based decisions for downgrading on risk of bias, indirectness due to differences in study design, or imprecision of effect estimates.

Potential biases in the review process

We are aware that it is possible to introduce bias at every stage in the review process so we have taken steps to minimise bias. Two review authors (JV and AC) independently assessed eligibility for each trial, conducted data extraction and assessed the quality of each trial. Any disagreements were resolved by discussion, but it is possible that another review team may have made different judgements.

Three review authors (GJH, JV and MS) are authors of two trials that we assessed for inclusion, one of which is ongoing (Hofmeyr 2015, GJH, JV and MS) and the other that was included (Novikova 2009, GJH and MS). They were not involved in assessing eligibility, conducting data extraction or assessing risk of bias for the respective trials. Therese Dowswell, from Cochrane Pregnancy and Chidbirth, and AC assessed these trials.

Agreements and disagreements with other studies or reviews

We did not identify any non-Cochrane reviews of fundal pressure. A Cochrane Review looking at positions in the second stage of labour for women without epidurals (Gupta 2012) found that upright positions resulted in fewer instrumental births and episiotomies, though increased numbers of women had second degree tears. While a woman's position at the time of application of fundal pressure was not always well described, it is possible that fundal pressure by inflatable belt and gentle assisted pushing (Novikova 2009) favour more upright positions, which could impact on outcomes (such as the possible increase in unassisted vaginal births observed in the inflatable belt group). This increase was not seen in the manual fundal pressure group which often required the women to give birth in a supine position.

Recent retrospective observational studies on use of fundal pressure largely align with the findings of the review:

Satore 2012 found that women who received manual fundal pressure were more likely to have an episiotomy and suffer with

postpartum perineal pain, whilst the women in the control group were more likely to have an intact perineum or first degree perineal lacerations.

Moiety 2014 agreed that duration of second stage of labour was shorter for women with manual fundal pressure and that severe perineal trauma was increased in this group.

Furrer 2015 also found that fundal pressure increased anal sphincter tears, fetal acidosis and babies born with low Apgar scores.

Obsevational studies are subject to confounding as the reason for use of fundal pressure may be the cause of poor outcomes.

AUTHORS' CONCLUSIONS

Implications for practice

There is insufficient evidence available to conclude whether use of fundal pressure (performed manually or by inflatable belt) is beneficial or harmful - more good-quality trials are required.

Manual fundal pressure does not appear to affect rates of spontaneous vaginal birth or operative birth. Single trials reported that manual fundal pressure resulted in an increased need for pain relief, and the number of babies with Apgar scores of less than seven at five minutes was higher when manual fundal pressure was used (although this finding is uncertain). There is insufficient evidence regarding safety for the baby.

Fundal pressure by inflatable belt during the second stage of labour reduces the duration of the second stage of labour and might increase the rate of spontaneous vaginal births in women though available evidence is not conclusive. There is also insufficient evidence regarding safety for the baby, and the effects on the maternal perineum.

Implications for research

Good quality randomised controlled trials are needed to study the effect of manual fundal pressure on maternal and fetal outcomes, including maternal satisfaction with the intervention. These trials should collect data on important maternal and neonatal outcomes that would inform assessments of their benefits or harms. Given the potential role for manual fundal pressure where operative birth is not immediately available, trials in resource-limited settings are needed. Trials should describe in detail how fundal pressure was applied. Further evaluation in other groups of women (such as multiparous women) will also be required.

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As part of the pre-publication editorial process, this updated review has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of Cochrane Pregnancy and Childbirth's international panel of consumers and the Group's Statistical Adviser.

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The World Health Organization, GJ Hofmeyr, A Cuthbert and M Singata retain copyright and all other rights in their respective contributions to the manuscript of this Review as submitted for publication.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

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

Acanfora 2013

Methods	Randomised, controlled, single-blind prospective study
Participants	Trial conducted in Obstetrics and Gynecology Unit, San Giuseppe Hospital, Empoli, Italy from January 24-March 24, 2011. 80 women randomised **Inclusion criteria:** primiparous women in active labour at term, maternal age 23–42 years, singleton pregnancy, cephalic presentation of the fetus **Exclusion criteria:** preterm delivery (gestational age < 37 weeks), breech or transverse position of the fetus, gestational diabetes mellitus, pregnancy-induced hypertension, fetal macrosomia, placental abnormalities (low-lying placenta or placental abruption), uterine anatomic abnormalities, previous uterine scar, fetal heart-rate anomalies at the time of enrolment (bradycardia, tachycardia, or prolonged variable decelerations).

Acanfora 2013 *(Continued)*

Interventions	**Intervention:** 40 women allocated to having Baby-guard Belt inflated to optimal pressures (80–150 mm Hg) during the second stage of labour. "During the second stage of labor, the operator inflated the ergonomic belt for 30 seconds at every contraction according to the pressures prescribed in the study protocol. Uterine fundal pressure through the inflatable belt was set at a 30°–40° angle to the spine toward the pelvic outlet, standardizing the force and surface area of application (980 cm2). The frequency of inflation was limited to fewer than 6 times (each time for 30 seconds) for a total period of 20 minutes, followed by a pause of 10 minutes." **Control:** 40 women allocated to having Baby-guard Belt inflated with minimal pressures (10–20 mm Hg). All participants received standard management of the second stage of labour, which included fetal heart rate monitoring and care from the attending physician or midwife.
Outcomes	• Incidences of perineal and cervical lacerations • Use of Kristeller maneuver • Incidence of vacuum extractions • Rate of caesarean delivery during labour • Duration of the second stage of labour • Degree of maternal psychologic and physical fatigue (10-point visual analogue scale) • Number of maternal requests for caesarean delivery during labour • Number of admissions to the neonatal intensive care unit • Participants' satisfaction with the Baby-guard system • Usefulness of the inflatable belt in assisting vaginal delivery • Apgar score (not pre-specified)
Notes	Baby-guard Belt: “The Baby-guard system consists of a disposable ergonomic 3-chamber inflatable belt and a detector of electro-physiologic signals of myographic uterine activity from the maternal abdomen (i.e. fetal and maternal heart signals). The 3 chambers of the belt can be inflated individually in order to reposition the fetus. These chambers are filled according to the pressures set by the operator (midwife or clinician) and allow gentle positioning of the fetus in the correct position toward the pelvis. Once the correct fetal position has been attained, all 3 chambers are inflated synchronously during uterine contraction. The maternal and fetal heart monitoring unit comprises a medical touch-screen computer that records electro-physiologic signals collected by a medical signal amplifier deriving from the mother (uterine contractions and maternal heart rate) and the fetus (fetal heart rate). There is also the possibility to record Doppler parameters of the fetal heart from the cardiotocograph.“ **27 out of 40 women in the low pressure group had Kristeller manoeuvre.**

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“Eligible participants were assigned to 1 of 2 groups and randomisation was performed using numbered envelopes during full dilatation of the cervix.” No information on generation of random sequence
Allocation concealment (selection bias)	Unclear risk	Envelopes numbered, but not discussed if opaque/sealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	"The obstetrician, midwife, and participants were blind to whether the belt was inflated with sufficient pressure or not. During the second stage of labor, the operator inflated the ergonomic belt for 30 seconds at every contraction according to the pressures prescribed in the study protocol."

Acanfora 2013 *(Continued)*

		The operator inflated the belt every 30 seconds for study group, so blinding was likely easy to ascertain.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Insufficient information provided. Unlikley to be feasible to blind this type of intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Difficult to assess, several outcomes are reported as continuous outcomes, and dichotomous outcomes do not report missing rates.
Selective reporting (reporting bias)	Unclear risk	Apgar score was not pre-specified outcome, but its inclusion is reasonable. Other pre-specified outcomes all reported
Other bias	Low risk	No evidence of other bias. Baseline demographics similar in both groups. 27/40 in the low pressure group had Kristeller manoeuvre.

Acmaz 2015

Methods	Prospective randomised controlled trial. Individual randomisation
Participants	Trial conducted at Kayseri Education and Training Hospital of Medicine, Turkey 295 women randomised **Inclusion criteria**: all participants were between 37 and 40 weeks of gestation with singleton cephalic presentation and none had any medical or obstetrical problems. Neither epidural nor combined spinal epidural analgesia was used. **Exclusion criteria:** pregnant women who required oxytocin augmentation, multiple gestations, pregnancy with medical problems (such as asthma, thyroid, cardiac, liver, kidney disease, pre-eclampsia and diabetes), pregnancy with previous caesarean and pregnancy with estimated fetal weight < 2500 g or > 4000 g were not included into the study.
Interventions	**Intervention:** fundal pressure (Kristeller manoeuvre) in second stage. No further detail given **Control:** no fundal pressure. No further detail given
Outcomes	• Patient's vaginal laceration • Cervical laceration • Length of episiotomy • Length of vagina before and after delivery • Duration of the second stage of labour in minutes • Infant birthweight • Apgar scores • Requirement for paediatric help • Admission to NICU
Notes	Not clear what outcome was used for power calculation Conducted between 25 July 2012-01 March 2013 at Kayseri Education and Training Hospital of Medicine, Turkey

Risk of bias

Bias	Authors' judgement	Support for judgement

Acmaz 2015 *(Continued)*

Random sequence generation (selection bias)	Low risk	Used a computer-generated random number chart
Allocation concealment (selection bias)	Unclear risk	Not well described. "In all consecutive patients, numbers were written on envelopes, while the allocation data were entered on separate papers that were put into the numbered envelopes which were then sealed." Envelopes not opened until women reached second stage. A quarter of the women were excluded between admission and before they reached the 2nd stage
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and caregivers aware of intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Many of the outcomes reported were subjective and may have been influenced by lack of blinding
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	"As a result of inadequate sample collection, 4 volunteers in the control group and 2 volunteers in the intervention group were excluded from the study. Because of blood clotting, 2 volunteers in the study and 2 volunteers in the control group were excluded from study." There was no clear information re when exactly randomisation took place and a quarter of the sample recruited were lost before the 2nd stage. A small number of women were lost to follow-up or excluded post randomisation 10/295).
Selective reporting (reporting bias)	Unclear risk	No protocol was available. It was not stated what outcome was used for the power calculation.
Other bias	High risk	Control group had more multiparous women 98/140. Intervention group had less 63/145. Mean age of women also differed The study was conducted only during daylight hours by the same obstetrician and fundal pressure was applied by the same obstetric staff. This may have affected which women were enrolled.

Api 2009

Methods	Randomised controlled trial. Participants individually randomised
Participants	Trial took place in Turkey - no further details given 197 women randomised **Inclusion criteria:** pregnant women between 37-42 weeks' gestation, singleton cephalic presentation, none had any medical or obstetrical problems. **Exclusion criteria:** neither epidural nor combined spinal epidural analgesia was used. “excluded before the second stage by cesarean section, three were post- term pregnancies, seven were preeclamptic and one was a diabetic mother.”
Interventions	**Intervention:** 94 women allocated to fundal pressure (Kristeller manoeuvre) Fundal pressure was applied manually with 1 of the provider’s forearms pressed on the uppermost part of the uterus at a 30°-45° angle to the maternal spine in the direction of the pelvis. Fundal pressure was

Api 2009 *(Continued)*

	applied by obstetricians concomitant with each uterine contraction when the cervix was fully dilated and the woman felt a spontaneous urge to push down, until delivery of the fetal head. **Control:** 103 women had no fundal pressure
Outcomes	Primary: duration of the second stage Secondary • Umbilical artery pH, HCO3, base excess, pO2, pCO2 values • Apgar scores after 5 min • The rate of spontaneous vaginal delivery • Instrumental delivery • Soft tissue damage (perineal, vaginal, anal sphincter) • Severe maternal morbidity/mortality • Neonatal trauma (fractures, hematoma) • Admission to NICU • Neonatal death
Notes	Vaginal examinations were done every 30 min when the cervix reached 8 cm dilatation. If the woman felt a strong urge to push down, the examination was performed earlier.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated random number chart
Allocation concealment (selection bias)	Unclear risk	Opaqueness of envelopes was not discussed. "numbers were written on envelopes, while the allocation data were entered on separate papers that were put into the numbered envelopes which were then sealed. When the woman was admitted to the delivery ward and met the inclusion criteria, she signed the informed consent form and was given her participation number. When the woman had reached the second stage, the envelope with the participation number on its cover was opened to reveal the randomization."
Blinding of participants and personnel (performance bias) All outcomes	High risk	When the woman had reached the second stage, the envelope with the participation number on its cover was opened to reveal the randomisation and the obstetrician was informed whether fundal pressure was to be applied or not.
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not specified, presumably unblinded
Incomplete outcome data (attrition bias) All outcomes	High risk	1 participant lost to follow-up Some missing data in both arms on umbilical cord blood analysis, disproportionately worse in intervention group
Selective reporting (reporting bias)	Unclear risk	Several outcomes did not have numerical data reported.

Api 2009 *(Continued)*

Other bias	Unclear risk	Control group were slightly older (26.68 ± 5.69 versus 24.41 ± 5.33, P = 0.007) and contained more nulliparous woman (54% (56/103) versus 36% (34/94) 0.009) than the study group. No other sources of bias evident

Cox 1999

Methods	Simple randomisation by computer-generated random numbers held within opaque sealed envelopes. Recruitment during first stage of labour, randomised at full dilatation. No blinding
Participants	Trial conducted in Queen Charlotte's and Chelsea Hospital, London, UK 500 women randomised **Inclusion criteria:** nulliparous women, singleton cephalic at term, functioning epidural anaesthesia, ruptured membranes, maternal weight < 100 kg, maternal age between 20 and 40
Interventions	**Intervention:** routine care plus inflatable obstetric belt, to produce fundal pressure synchronised with the contractions. Applied immediately after randomisation, at full dilatation. Switched off when head was crowning/before instrumentation **Control:** routine care: 1 h passive second stage, 1 h pushing after which instrumental delivery if delivery not imminent
Outcomes	• Mode of delivery • Duration of second stage • Malpresentations • Maternal blood loss • Intact perineum • Anal sphincter tear • Meconium • Frequency of FBS • Review of CTGs • Cord pH • Apgar scores • SCBU admissions • Maternal satisfaction on second stage of labour • Degree of fetal maternal transfusion
Notes	Non-blinding appears to have had a significant impact on the outcomes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	"Women who had given their consent to participate were randomised at full dilatation by means of computer- generated random numbers held within sealed, opaque, sequentially numbered envelopes."
Allocation concealment (selection bias)	Low risk	"Women who had given their consent to participate were randomised at full dilatation by means of computer- generated random numbers held within sealed, opaque, sequentially numbered envelopes." "No randomisation envelopes were lost during the study."

Cox 1999 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind this intervention
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"Participants were reviewed by the research registrar after delivery and asked about their second stage of labour by grading their levels of satisfaction using visual analogue scores. Women who used the belt were also asked to grade whether the belt was comfortable, restricted movement and gave them confidence." Self-reported outcomes at high risk of bias due to lack of blinding of participants and the researchers collecting the data. "Information about fetal wellbeing was obtained from the routine 24-hour paediatric check (paediatricians were blind to allocation group)." Fetal wellbeing outcomes low risk of detection bias.
Incomplete outcome data (attrition bias) All outcomes	Low risk	Difficult to assess for some outcomes, but does not appear to be a missing data problem.
Selective reporting (reporting bias)	Unclear risk	Unable to locate protocol.
Other bias	Unclear risk	"Both groups were homologous with regard to demographic and obstetric details at entry into the second stage of labour**,** except that women in the belt group had had their epidural in situ for significantly shorter than the control group **(**435 *vs* 526 min, P = 0.03)."

Kang 2009

Methods	Randomised, controlled, prospective study. Women individually randomised
Participants	123 women randomised during first stage of labour between November 2006-August 2007 Trial conducted in hospital in Seoul, Korea **Inclusion criteria:** nulliparous women, 20-35 years of age, term (37 + 0 to 41 + 6 weeks' gestation), singleton cephalic presentation, with a clinically adequate pelvis, cervical dilatation < 10 cm on admission, and the estimated fetal body weight was > 2.8 kg and < 3.8 kg **Exclusion criteria:** • Previous surgical history involving the uterine myometrium • Uterine anomaly • Uterine myoma (> 5 cm or multiple in number) • History of gestational trophoblastic disease • Known maternal medical diseases (hypertension, gestational diabetes mellitus, etc.) • Abnormal placental location • Placental abruption • Polyhydramnios • Oligohydroamnios • Suspected chorioamnionitis • Abnormalities of the abdominal wall (hematoma or erythema) • Abnormal fetal heart monitoring at the time of enrolment

Kang 2009 *(Continued)*

- Abnormal uterine activity
- Current history of drug or alcohol abuse
- Meconium-stained amniotic fluid
- Intrauterine fetal growth restriction

Interventions	**Intervention:** 62 women randomised to Labor Assister "Upon full dilation of the cervix, indicating the onset of the second stage of labor, the Labor AssisterTM was switched on in the active group. As a uterine contraction started, the inflatable obstetric belt was inflated synchronously and maintained at 200 mmHg for 30 sec. The Labor AssisterTM was not used for more than 3 hr and was discontinued when delivery was imminent, when the obstetrician decided to remove the device, or when the patient requested removal of the device." **Control:** 61 women randomised to standard care Both arms: all participants wore the belt in the first stage of labour, but were unable to see the belt due to a draped screen. In addition, all the women, whether randomised to the belt or the control group, received standard management of the second stage of labour, which included 1-to-1 support, continuous electronic fetal heart rate monitoring, and care from midwife. All of the participants had continuous external fetal heart monitoring.
Outcomes	NB: outcomes were not pre-specified. Below list is based on reported results. • Duration of second stage (min) • Operative deliveries • Caesarean delivery • Vacuum extraction • Birthweight (g) • Apgar score (1 min) • Apgar score (5 min) • Maternal hospital stay (days) • Neonatal hospital stay (days) • Episiotomy • Perineal laceration - Vaginal, cervical, perineal, other • Oxytocin use - induction, augmentation • Epidural analgesia • Meconium-stained amniotic fluid • Non-reassuring fetal surveillance • NICU admission • Special care nursery
Notes	The Labor AssisterTM consists of a toco transducer, a control unit, and an inflatable belt. The toco transducer on the inflatable belt detects uterine contractions and sends the signal to the control unit, which then injects 200 mmHg of air into the belt for 30 sec. The frequency of inflation was limited to fewer than 7 times per 15 min.

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	They were divided into 2 groups by randomly numbered envelopes.
Allocation concealment (selection bias)	Unclear risk	Not specified

Kang 2009 *(Continued)*

Blinding of participants and personnel (performance bias) All outcomes	High risk	"All patients wore the belt in the first stage of labor, but were unable to see the belt due to a draped screen." Blinding likely to be broken
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not stated; based on protocol of LA use, blinding was unlikely
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Difficult to assess, as insufficient information provided
Selective reporting (reporting bias)	Unclear risk	Difficult to assess, as outcomes were not pre-specified in methods text
Other bias	Low risk	No evidence of this - baseline data similar in both groups

Kim 2013

Methods	Randomised, controlled, and prospective study
Participants	Trial conducted in university hospital and medical centre in Korea from July 2009-December 2010 188 women randomised **Inclusion criteria:** nulliparous women, gestation between 37 + 0 and 41 + 6 weeks, singleton cephalic presentation, less than 10 cm of cervical dilatation on admission, with a clinically adequate pelvis, and between 2.8 kg and 4.0 kg of estimated fetal birthweight. **Exclusion criteria:** • Previous uterine myomectomy history • Uterine anomaly • Uterine myoma (> 5 cm or multiple in number) • History of gestational trophoblastic disease • Known maternal medical diseases (hypertension, gestational diabetes mellitus, etc.) • Abnormal placental location • Pregnancy-induced hypertension • Placental abruption • Hydramnios • Oligohydroamnios • Suspected chorioamnionitis • Abnormalities of the abdominal wall • Abnormal fetal heart rate pattern at enrolment • Abnormal uterine activity • Meconium-stained amniotic fluid • Fetal growth restriction • Major fetal anomaly
Interventions	**Intervention:** 97 women randomised to multi-function inflatable belt (The Labor Assister). "Upon full dilation of the cervix, indicating the onset of the second stage of labor, the Labor Assister was switched on in the active group. It was begun in 10 min after the start of the second stage of labor. As a uterine contraction started, the inflatable obstetric belt was inflated synchronously and main-

Kim 2013 *(Continued)*

	tained at 200 mmHg for 30s. The Labor Assister was not used for more than 3h and was discontinued when delivery was imminent, when the obstetrician decided to remove the device, or when the patient requested removal of the device." **Control:** 91 women randomised to standard care. Both arms: all patients wore the belt in the first stage of labour, but were unable to see the belt due to a draped screen. In addition, all the women, whether randomised to the belt or the control group, received standard management of the second stage of labour, which included 1-to-1 support, continuous electronic fetal heart rate monitoring and care from doctor.
Outcomes	• Duration of the second stage (not measured in 14 women who had caesarean sections and 1 woman who delivered precipitously) • Rate of caesarean delivery • Use of vacuum or forceps • Oxytocin administration • Extents of perineal laceration • Abnormal fetal heart rate patterns including tachycardia, bradycardia, late deceleration, prolonged deceleration, absent or minimal beat-to-beat variability, sinusoidal pattern, and significant variable deceleration in second stage of labour • Visual analogue scale • Neonatal complications • Umbilical arterial blood gases
Notes	"The Labor Assister (Baidy M-520/Curexo, Inc., Seoul, Korea) consists of a toco transducer, a control unit, an air hose and an inflatable belt (Figure 1). The toco transducer on the inflatable belt detects uterine contractions and sends the signal to the control unit, which then injects 200 mmHg of air into the belt for 30 sec." "The frequency of inflation was limited to fewer than 7 times per 15 min when oxytocin was administered."

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	“For all participants, numbers were written on envelopes, and the allocation data were entered on separate papers that were put into the numbered envelopes which were then sealed. When the woman was admitted to the delivery ward and met the inclusion criteria, she signed the informed consent form and was given her participation number. When the woman reached the second stage, the envelope with the participation number on its cover was opened to reveal the randomization and the obstetrician was informed whether inflatable obstetric belt was to be applied or not.” Does not specify opaque envelopes or not, or where randomisation sequence was generated from.
Allocation concealment (selection bias)	Unclear risk	See above - not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Belt was draped so that participant could not see inflation, this blinding is likely to be broken
Blinding of outcome assessment (detection bias)	High risk	Obstetrician controlled belt and given the nature of intervention, blinding is very unlikely

Kim 2013 *(Continued)*
All outcomes

Incomplete outcome data (attrition bias) All outcomes	High risk	Duration of the second stage was the primary outcome measure. It was not measured in 14 women who had caesarean sections and 1 woman who delivered precipitously.
Selective reporting (reporting bias)	Unclear risk	No protocol seen
Other bias	Low risk	No evidence of other bias – similar baseline characteristics in both groups

Mahendru 2010

Methods	Pilot randomised controlled trial
Participants	209 women individually randomised Trial took place Maharishi Markendeshwar Institute of Medical Sciences and Research, Mullana, Ambala, India Inclusion criteria: healthy primigravidae women (aged 20-27 years), singleton fetus in cephalic presentation, having spontaneous onset of labour, between 37-40 weeks, pelvis being average adequate gynaecoid with no clinical evidence of cephalo- pelvic disproportion Exclusion criteria • Women with a previously scarred uterus • Uterine anomalies • Previous instrumental abortion • Clinical or sonographic evidence of intrauterine growth restriction • Induction of labour • Inappropriate prostaglandin and oxytocin usage • Vacuum extraction/forceps delivery • Intrauterine manipulations • Caesarean sections
Interventions	**Intervention:** 101 women received manual pressure applied to the uterine fundus during the second stage of labour "Fundal pressure was applied manually at a 30-to 40-degree angle to the spine in the direction of the pelvis by the same doctor and three applications at the most in group-I patients after the clinical confirmation of full cervical dilatation with the vertex below the level of the ischial spines (plus-station) and occipito-anterior position." **Control:** 108 women received no fundal pressure Both arms: "to observe uniformity, right medio- lateral episiotomy was employed at the instance of crowning of the vertex in all the cases and the placenta was delivered by modified Brandt- Andrew's technique (controlled cord traction) at the clinical confirmation of its separation following delivery of the baby".
Outcomes	• Difference in the duration of the second stage of labour • Mother's condition and findings from postpartum examination • Complications like perineal injuries • Apgar score of the babies • Any neonatal complications

Mahendru 2010 *(Continued)*

- Any other unforeseen eventualities in either of the groups

Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomised table of numbers
Allocation concealment (selection bias)	Unclear risk	"Index cards with the random assignment were prepared and placed in sealed envelopes and a researcher who was blinded to the baseline examination findings opened the envelope, approximately at the onset of the second stage of labour, and the proceedings were done according to the group assignment." Does not specify opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not stated, but blinding unlikely given nature of intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not stated, but blinding unlikely given nature of intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Difficult to assess, insufficient information
Selective reporting (reporting bias)	Unclear risk	Difficult to assess, but all outcomes appear to be reported. Protocol not seen
Other bias	Low risk	No evidence of other bias – similar baseline characteristics in both groups

Novikova 2009

Methods	Pilot randomised control trial. Individual randomisation
Participants	Trial undertaken at Frere and Cecilia Makiwane Hospitals, East London, South Africa 120 women randomised **Inclusion criteria:** healthy nulliparous women singleton pregnancy and cephalic presentation and gestational age of 35 weeks and above, who had not given birth after 15 min of bearing down. **Exclusion criteria:** obstetric or medical complications
Interventions	**Intervention:** 58 women allocated to planned controlled fundal pressure during the second stage. Women randomised after 15 minutes of bearing down if they had not yet delivered. "During contractions steady firm fundal pressure was applied using the palms of both hands in the direction of the pelvis using only the strength of her forearms. Steady, sustained pressure was maintained for the full duration of each contraction or 30 seconds, whichever was shorter. Forceful or rapid pressure and the use of body weight to apply pressure were avoided." **Comparison:** 62 women allocated to no fundal pressure. "The attendant assumed the same supportive position, but no fundal pressure was applied."

Novikova 2009 *(Continued)*

	In both groups women were encouraged to bear down
Outcomes	**Primary outcome:** • Number of assisted/operative deliveries **Other outcomes:** • Time from enrolment to delivery of head • Operative delivery or time period between enrolment and delivery of the head of more than 15 min • Operative delivery or time from bearing down to birth of the head more than 30 min • Cord blood pH < 7.2 • 5-minute Apgar score < 7 • Episiotomy or 2nd/3rd degree tear • Blood loss more than 300 mL (measured by weighing)
Notes	Additional information was provided by the authors. Pilot study underpowered to identify any but very large differences between groups for study outcomes

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Allocation was ordered using a computer-generated random sequence in balanced blocks of variable size in a 1:1 ratio
Allocation concealment (selection bias)	Low risk	Consented women…were enrolled in the trial by research midwives, by entering the name in a recruitment register, then opening the next in a consecutively numbered series of sealed opaque envelopes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding women or staff to this intervention was not feasible
Blinding of outcome assessment (detection bias) All outcomes	High risk	Outcome assessment and recording would mainly be by staff aware of the allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data appears complete. Analysis by intention to treat
Selective reporting (reporting bias)	Unclear risk	Protocol not available
Other bias	Low risk	Other bias not apparent. Groups appeared similar at baseline

Peyman 2011

Methods	Described as double-blind clinical trial
Participants	Trial took place in hospitals related to the Azad University in Tehran 2236 women randomised

Peyman 2011 *(Continued)*

	Inclusion criteria: active labour at term with a singleton fetus in vertex presentation **Exclusion criteria:** • Caesarean section or vacuum delivery because they had medical or obstetrical problems (Such as abnormal baseline heart rate, dysfunction of uterus, and failure in progress of labour) • Preterm labour (gestational age below 37 weeks) • No vertex presentation (breech or transverse) • Neither epidural nor combined spinal epidural analgesia was used • Abnormalities of placentation (low lying placenta, abruption placenta) • Uterine and pelvic structural abnormalities • History of previous shoulder dystocia • Previous uterine scar
Interventions	**Intervention:** 1171 women randomised to receive fundal pressure "Fundal pressure often was applied manually by impatient obstetricians or midwifes on part of the uterus at a 30_45 angle to the maternal spine in the direction of the pelvis with each uterine contraction when the cervix was fully diluted." **Control:** 1065 women randomised to receive no fundal pressure
Outcomes	• Apgar scores 1 and 5 minutes following delivery • Duration of the second stage of labour
Notes	Additional information provided by trial authors

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	"Experienced group and control group were formed by randomized selection." Insufficient information provided
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	" Physicians, hospital personnel and mothers did not know that Researchers oversee the delivery process." Blinding with this intervention is unlikely
Blinding of outcome assessment (detection bias) All outcomes	High risk	Blinding with this intervention is unlikely
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	There are some errors in the totals for various tables
Selective reporting (reporting bias)	High risk	Difficult to assess, outcomes not well specified. Errors in reporting of certain outcomes such as duration of active second stage meant that data could not be used in this review. Protocol not seen
Other bias	Unclear risk	Trial reporting lacked clarity. Difficult to assess other sources of bias

CTG: cardiotocogram

FBS: fetal blood sampling
NICU: neonatal intensive care unit
SCBU: special care baby unit

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

Study	Reason for exclusion
Schulz-Lobmeyr 1999	The studied intervention of fundal pressure was performed by choice of the clinician, and not as a result of allocation. Therefore, the risk of confounding factors is too high. This study cannot be considered as (quasi-) randomised.
Zhao 1991	This is a poor methodological quality study, with a high risk of bias. The description of allocation, "these women were allocated into the groups according to the order they came to the hospital", does not give adequate confirmation that serious allocation bias was excluded. Given that several studies with well-described random allocation are available for the abdominal belt analysis, the reason for considering quasi-randomised trials (paucity of randomized data) does not apply.

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

Zhao 2015

Methods	Randomised controlled trial (more information needed to ascertain)
Participants	100 primiparous women, with normal vaginal delivery
Interventions	**Intervention group**: 50 women used multi-functional abdominal pressure belt during the second and third stages of labour **Control group**: 50 women did not use the belt in labour
Outcomes	• Duration of second stage of labour, head emergence and third stage of labour • Volume of postpartum haemorrhage • Episiotomy rate • Maternal signs after 2 h postpartum • Apgar score • Cord blood gases
Notes	Trial conducted in Guangzhou, China Unable to find contact details of trial authors

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

Hofmeyr 2015

Trial name or title	The Gentle Assisted Pushing study (GAP). A multi-centre randomised controlled trial of gentle assisted pushing in the upright posture (GAP) or upright posture alone compared with routine practice to reduce prolonged second stage of labour
Methods	Randomised, controlled, unblinded, clinical trial with 3 parallel arms across 4 hospital sites in South Africa
Participants	**Inclusion criteria**:

Hofmeyr 2015 *(Continued)*

	• ≥ 18 years old • Nulliparous women • Gestational age > 35 weeks • Singleton pregnancy • Vaginal delivery anticipated • Cephalic fetal presentation • Baby's heartbeat detected **Exclusion criteria**: • No chronic medical conditions, including heart disease, epilepsy, hypertension, diabetes mellitus and renal disease • No obstetric complications, including hypertensive disorders of pregnancy, cephalo-pelvic disproportion, antepartum haemorrhage, intra-uterine growth restriction, fetal distress, intra-amniotic infection
Interventions	**Intervention arm 1**: Gentle Assisted Pushing. The woman will be assisted to assume an upright kneeling or squatting posture on the bed. The trained birth attendant will kneel behind her on the bed or stand behind her with the woman positioned at right angles to the length of the bed and back close to the side of the bed. The trained birth attendant will wrap her arms around the woman passing below her axillae, and place both open palms, overlapping, on the fundus of her uterus. Steady pressure in the long axis of the uterus will be applied only during contractions. The duration of pressure will be limited to 30 s with a minimum of 30 s rest before the next pressure **Intervention arm 2**: upright crouching or kneeling position for second stage **Control**: recumbent/supine posture only

Outcomes	**Primary outcome**:
	
	• mean time (minutes) from randomisation to delivery
	
	Secondary outcomes:
	
	• Birth outcomes:
	  * No spontaneous delivery within 15 minutes of randomisation
	  * Operative delivery (vacuum, forceps or caesarean section)
	  * Episiotomy or 2nd/3rd degree tears
	• Neonatal outcomes:
	  * Cord blood pH < 7.2
	  * 5-minute Apgar score < 7
	  * Neonatal injury
	  * Neonatal encephalopathy
	  * Admission to neonatal high care nursery for ≥ 24 hours
	  * Neonatal death
	• Mothers will also be asked to grade their discomfort experienced during the second stage of labour
	• All adverse events

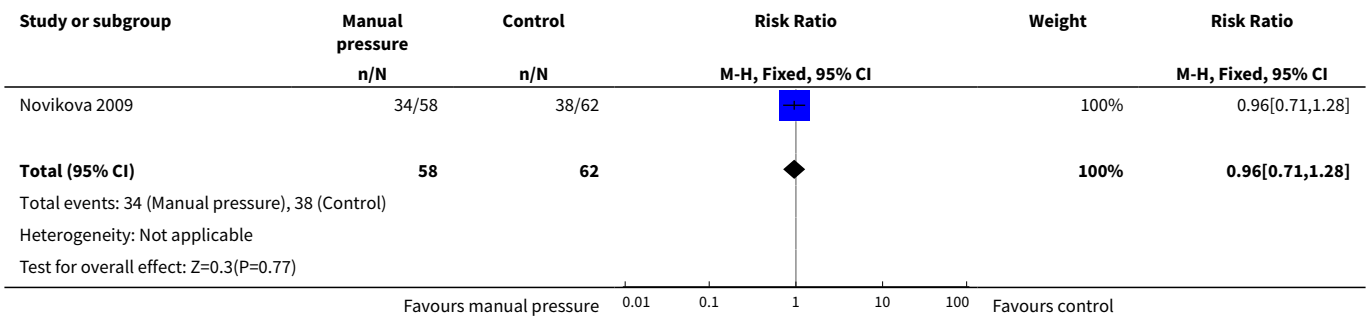
Starting date	March 2015
Contact information	Correspondence to vogeljo@who.int
Notes	Likely to finish June 2017

DATA AND ANALYSES

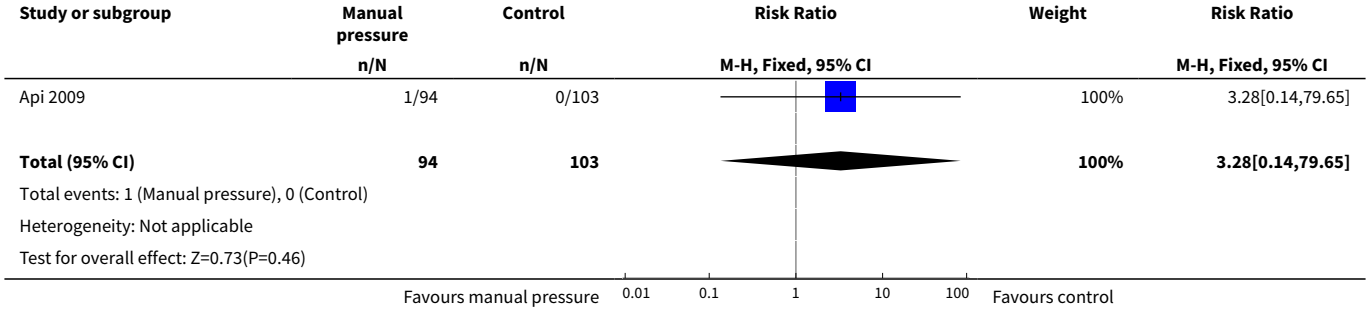
Comparison 1. Manual fundal pressure versus no fundal pressure

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 No spontaneous vaginal birth within a specified time, as defined by the trial authors	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.71, 1.28]
2 Instrumental birth	1	197	Risk Ratio (M-H, Fixed, 95% CI)	3.28 [0.14, 79.65]
3 Caesarean section	1	197	Risk Ratio (M-H, Fixed, 95% CI)	1.10 [0.07, 17.27]
4 Operative birth - instrumental or caesarean	2	317	Risk Ratio (M-H, Random, 95% CI)	0.66 [0.12, 3.55]
5 Low arterial cord pH	2	297	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.72, 1.58]
6 Apgar score less than 7 at 5 minutes	4	2759	Risk Ratio (M-H, Random, 95% CI)	4.48 [0.28, 71.45]
7 Duration of active second stage	1	194	Mean Difference (IV, Fixed, 95% CI)	-0.80 [-3.66, 2.06]
8 Episiotomy	2	317	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.92, 1.50]
9 Soft tissue damage - perineal	1	209	Risk Ratio (M-H, Fixed, 95% CI)	6.42 [0.79, 52.37]
10 Soft tissue damage - vaginal laceration	1	295	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.75, 2.03]
11 Soft tissue damage - cervical	1	295	Risk Ratio (M-H, Fixed, 95% CI)	4.90 [1.09, 21.98]
12 Postpartum haemorrhage	1	120	Risk Ratio (M-H, Fixed, 95% CI)	1.87 [0.58, 6.06]
13 Pain after enrolment as defined by trial authors	1	209	Risk Ratio (M-H, Fixed, 95% CI)	4.54 [2.21, 9.34]
14 Neonatal trauma - fractures	1	209	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
15 Neonatal trauma - haematoma	1	209	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
16 Admission to neonatal intensive care unit	1	295	Risk Ratio (M-H, Fixed, 95% CI)	1.63 [0.40, 6.71]
17 Neonatal death	2	2445	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
18 Sensitivity analysis: low arterial cord pH	1	118	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.72, 1.58]

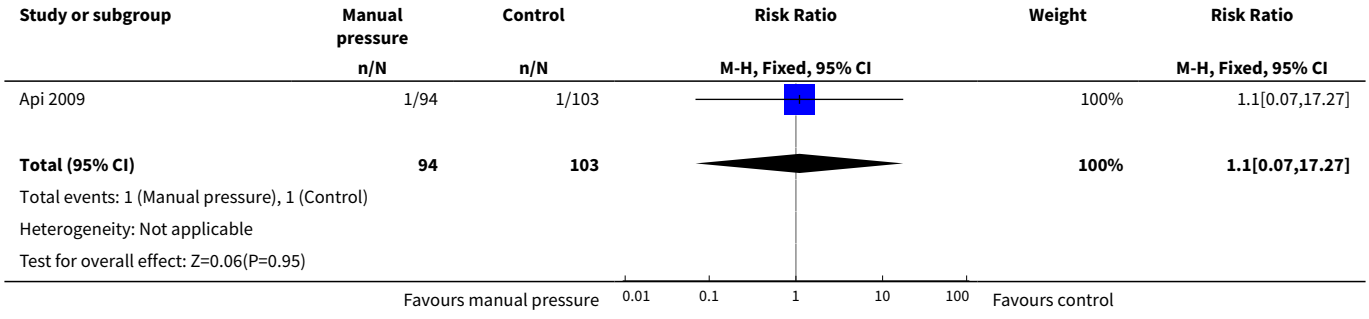
Analysis 1.1. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 1 No spontaneous vaginal birth within a specified time, as defined by the trial authors.



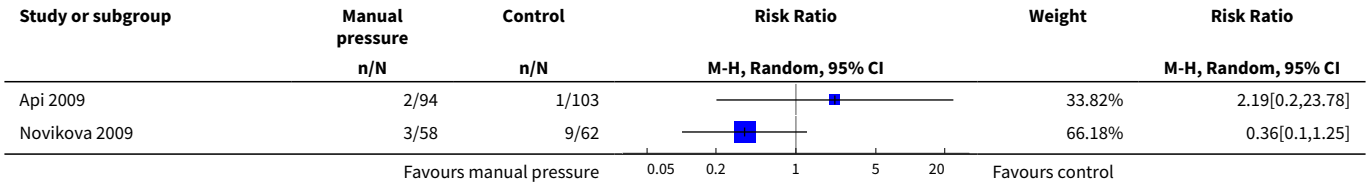
Analysis 1.2. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 2 Instrumental birth.

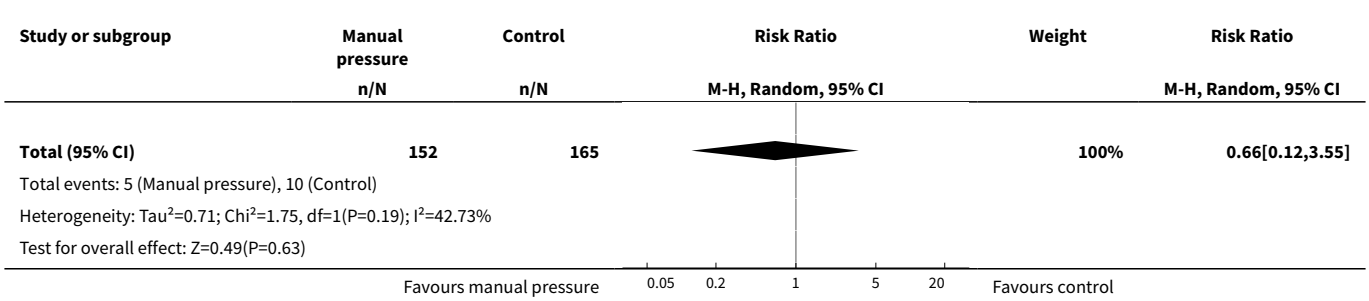


Analysis 1.3. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 3 Caesarean section.

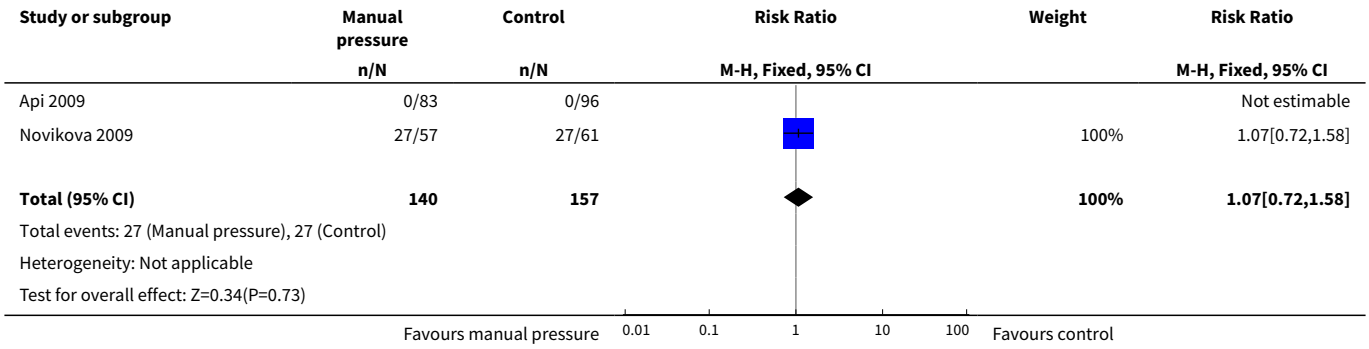


Analysis 1.4. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 4 Operative birth - instrumental or caesarean.

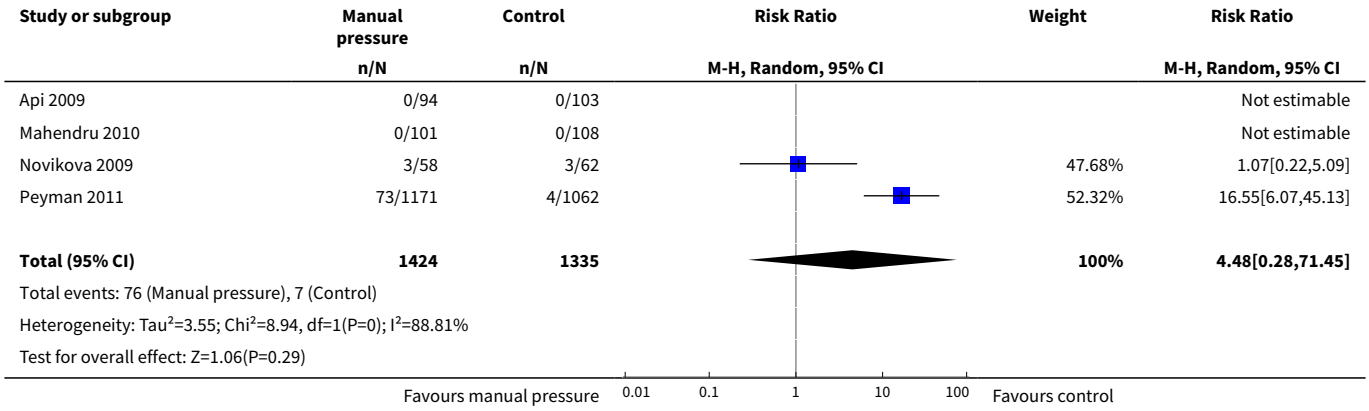




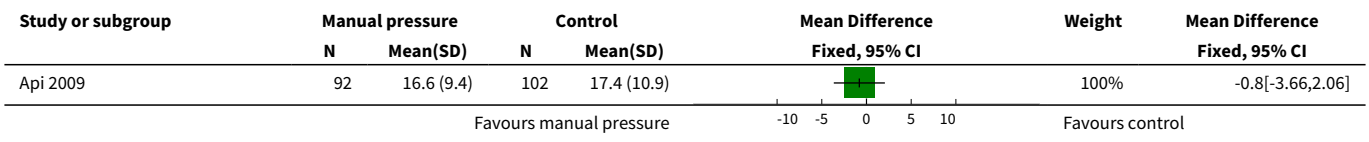
Analysis 1.5. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 5 Low arterial cord pH.

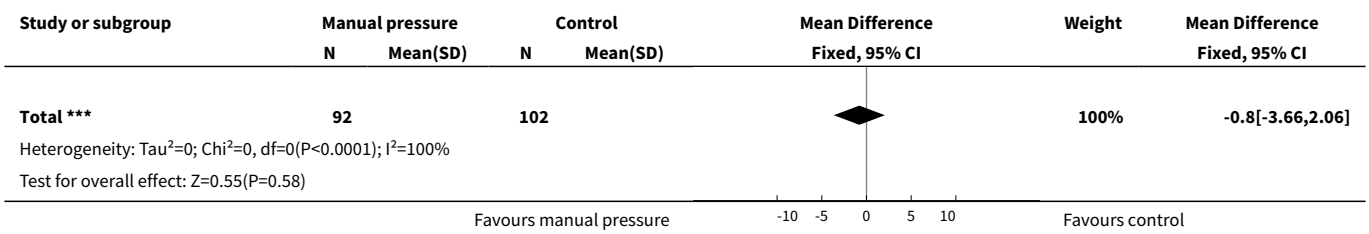


Analysis 1.6. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 6 Apgar score less than 7 at 5 minutes.

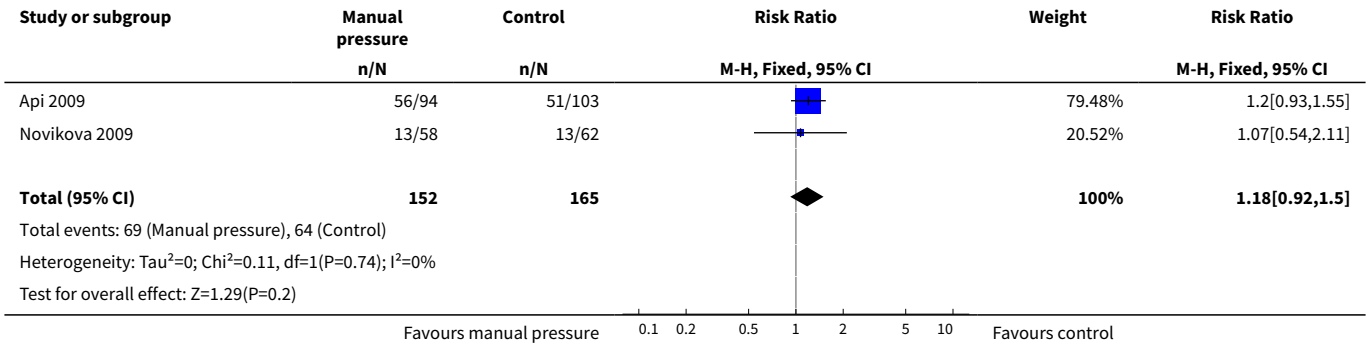


Analysis 1.7. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 7 Duration of active second stage.

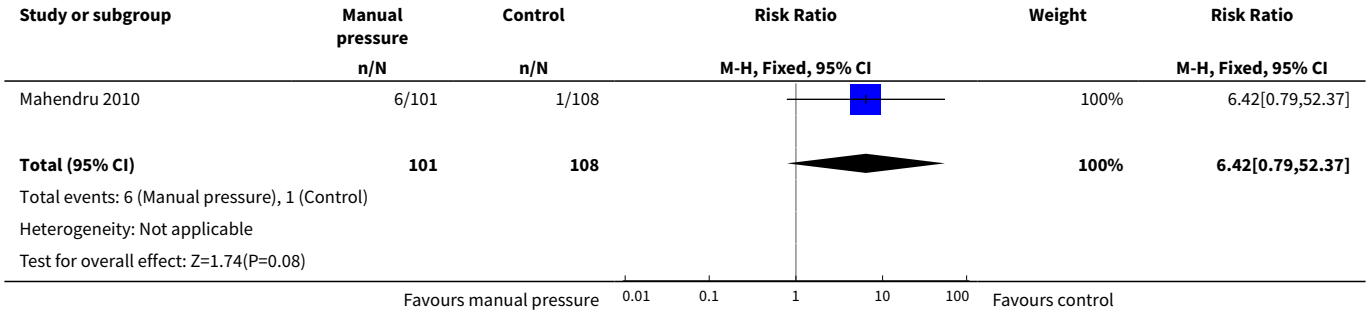




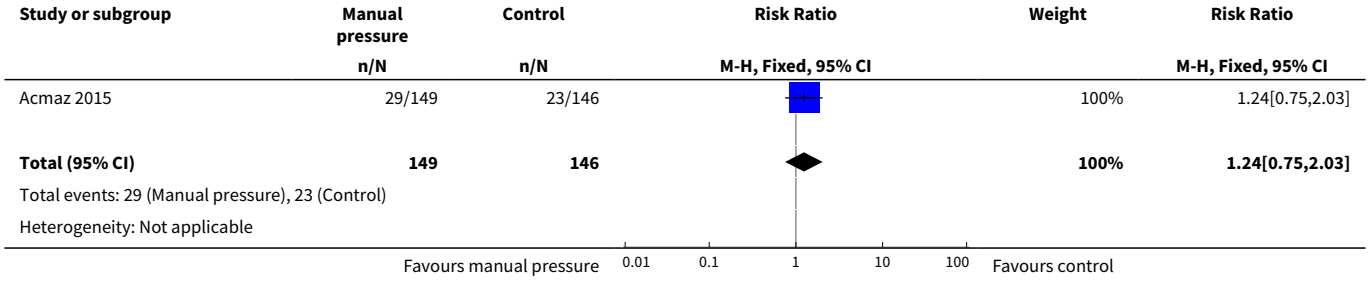
Analysis 1.8. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 8 Episiotomy.

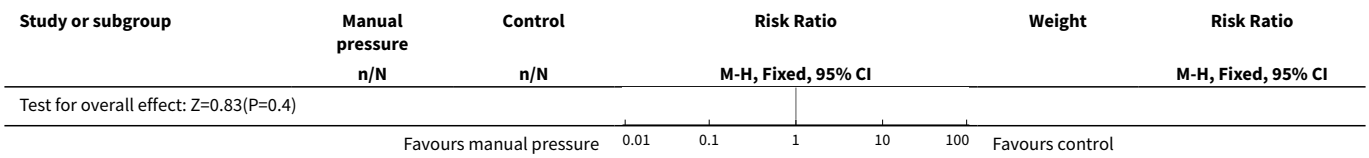


Analysis 1.9. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 9 Soft tissue damage - perineal.

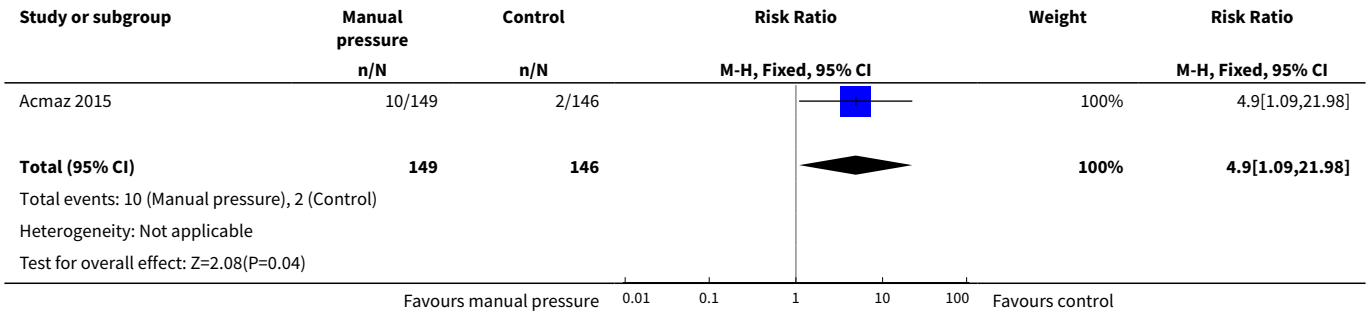


Analysis 1.10. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 10 Soft tissue damage - vaginal laceration.

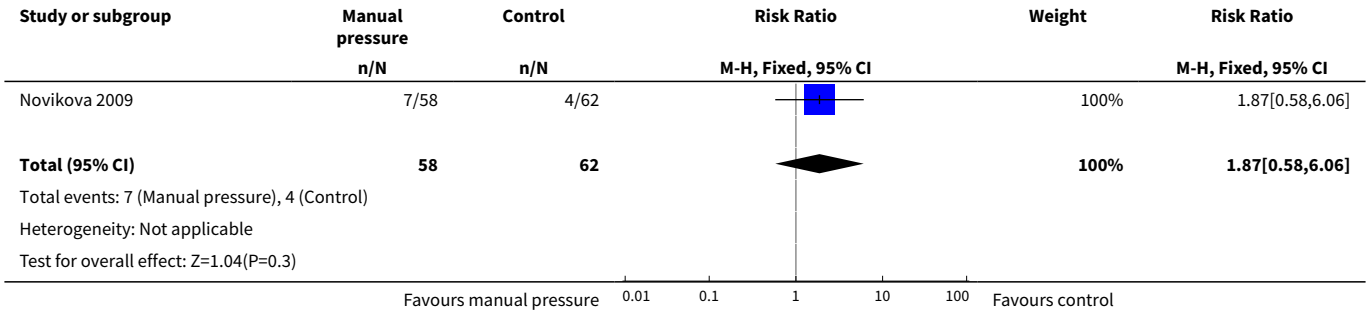




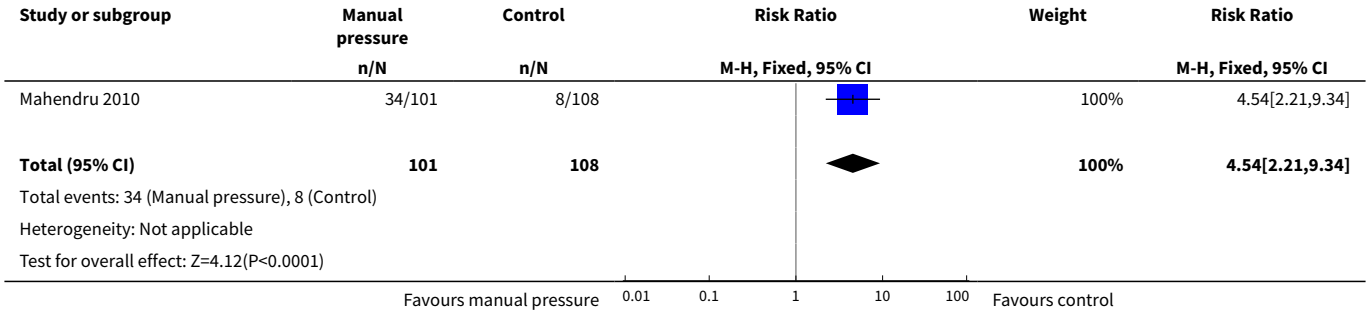
Analysis 1.11. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 11 Soft tissue damage - cervical.



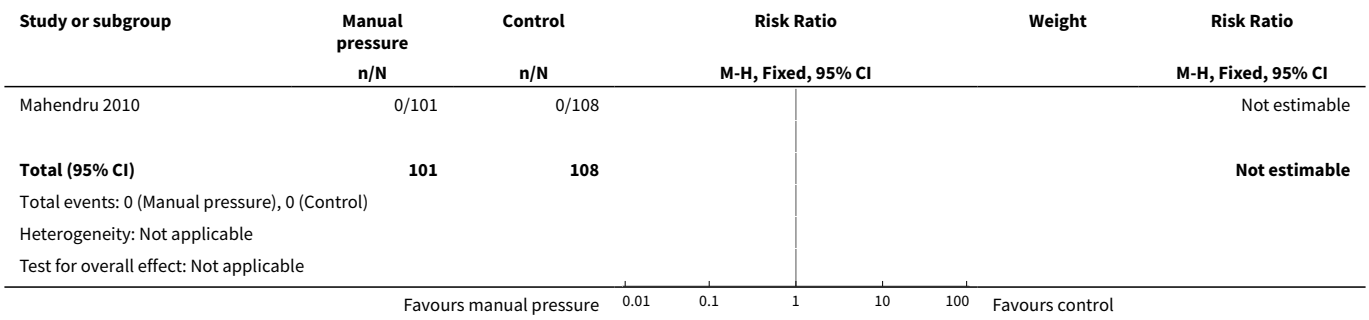
Analysis 1.12. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 12 Postpartum haemorrhage.



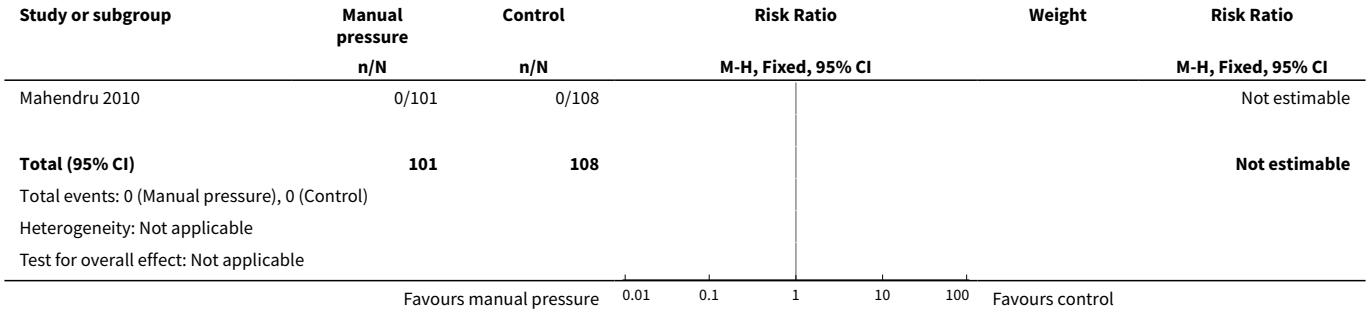
Analysis 1.13. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 13 Pain after enrolment as defined by trial authors.



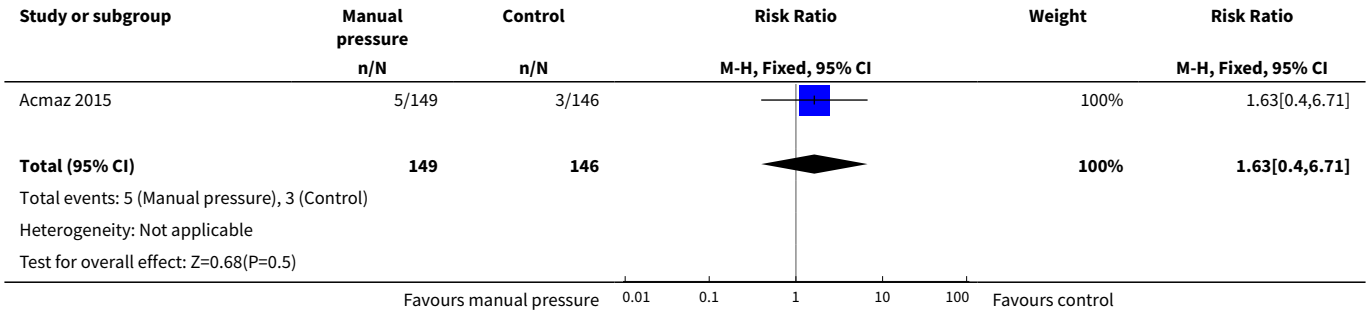
Analysis 1.14. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 14 Neonatal trauma - fractures.



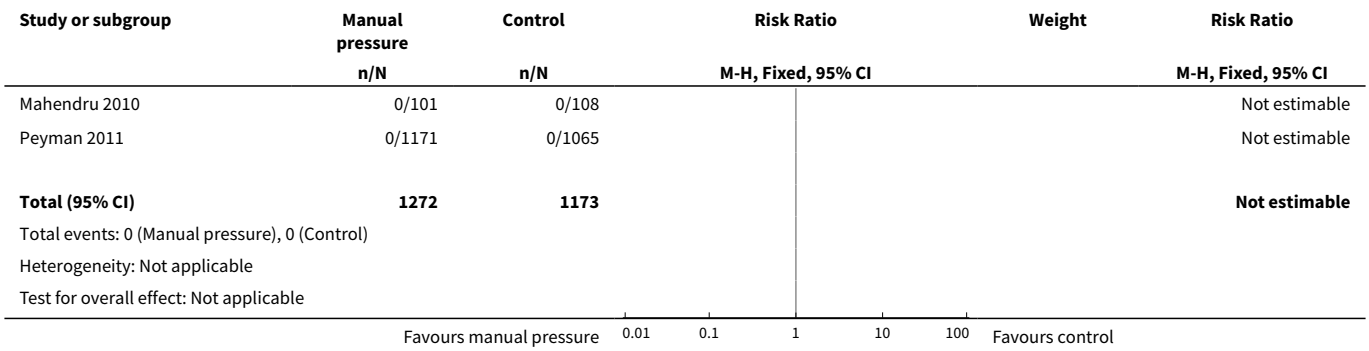
Analysis 1.15. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 15 Neonatal trauma - haematoma.



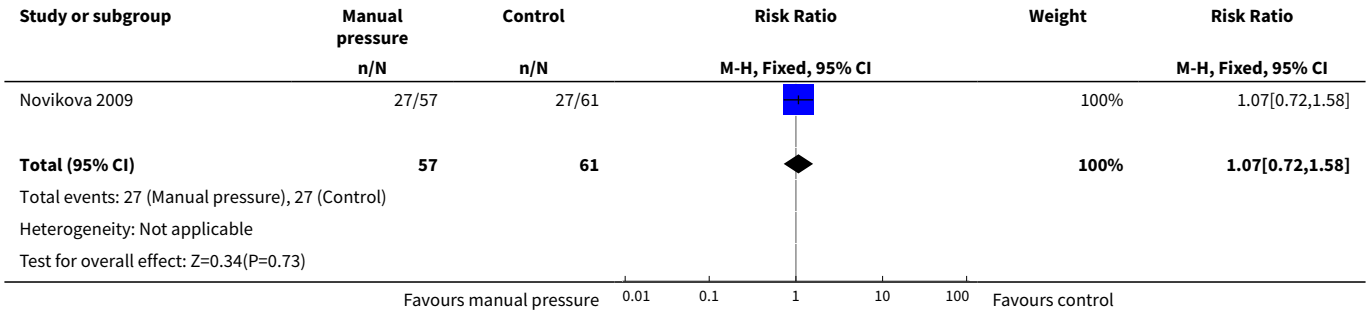
Analysis 1.16. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 16 Admission to neonatal intensive care unit.



Analysis 1.17. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 17 Neonatal death.



Analysis 1.18. Comparison 1 Manual fundal pressure versus no fundal pressure, Outcome 18 Sensitivity analysis: low arterial cord pH.



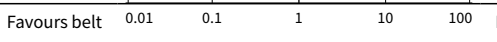
Comparison 2. Fundal pressure by inflatable belt versus no fundal pressure

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Instrumental birth	4	891	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.52, 1.02]
2 Caesarean section	4	891	Risk Ratio (M-H, Random, 95% CI)	0.56 [0.14, 2.26]
3 Operative birth - instrumental or caesarean section	4	891	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.38, 1.01]
4 Low arterial cord pH	1	461	Risk Ratio (M-H, Fixed, 95% CI)	0.47 [0.09, 2.55]
5 Apgar score less than 7 after 5 minutes	1	500	Risk Ratio (M-H, Fixed, 95% CI)	4.62 [0.22, 95.68]
6 Duration of second stage	2	253	Mean Difference (IV, Random, 95% CI)	-50.80 [-94.85, -6.74]
7 Episiotomy	3	811	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.86, 1.12]

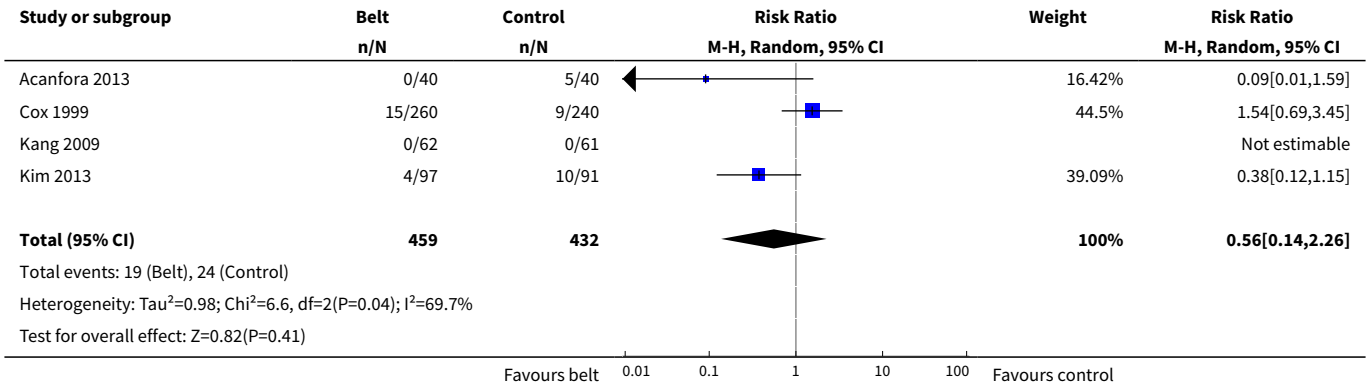
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8 Soft tissue damage - perineal	4	897	Risk Ratio (M-H, Random, 95% CI)	0.53 [0.20, 1.38]
9 Soft tissue damage - vaginal	1	123	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.27, 2.00]
10 Soft tissue damage - anal sphincter	1	500	Risk Ratio (M-H, Fixed, 95% CI)	15.69 [2.10, 117.02]
11 Soft tissue damage - cervical/uterine	2	203	Risk Ratio (M-H, Fixed, 95% CI)	0.42 [0.06, 2.82]
12 Postpartum haemorrhage	1	500	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.09, 1.29]
13 Neonatal trauma - haematoma	1	123	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.01, 7.90]
14 Admission to neonatal intensive care unit	4	891	Risk Ratio (M-H, Random, 95% CI)	0.64 [0.19, 2.14]
15 Sensitivity analysis: instrumental birth	3	811	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.63, 1.04]
16 Sensitivity analysis: caesarean section	3	811	Risk Ratio (M-H, Random, 95% CI)	0.80 [0.20, 3.19]
17 Sensitivity analysis: operative delivery - instrumental or caesarean section	3	811	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.52, 1.13]

Analysis 2.1. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 1 Instrumental birth.

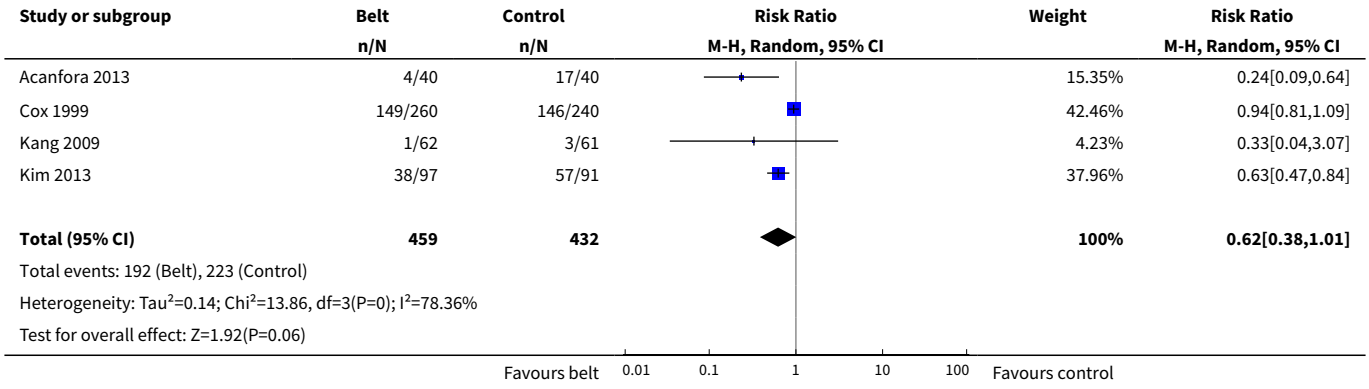
Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Acanfora 2013	4/40	12/40		9.02%	0.33[0.12,0.95]
Cox 1999	134/260	137/240		51.55%	0.9[0.77,1.06]
Kang 2009	1/62	3/61		2.24%	0.33[0.04,3.07]
Kim 2013	34/97	47/91		37.2%	0.68[0.48,0.95]
Total (95% CI)	**459**	**432**		**100%**	**0.73[0.52,1.02]**
Total events: 173 (Belt), 199 (Control)					
Heterogeneity: Tau^2=0.05; Chi^2=6.25, df=3(P=0.1); I^2=51.97%					
Test for overall effect: Z=1.85(P=0.07)					



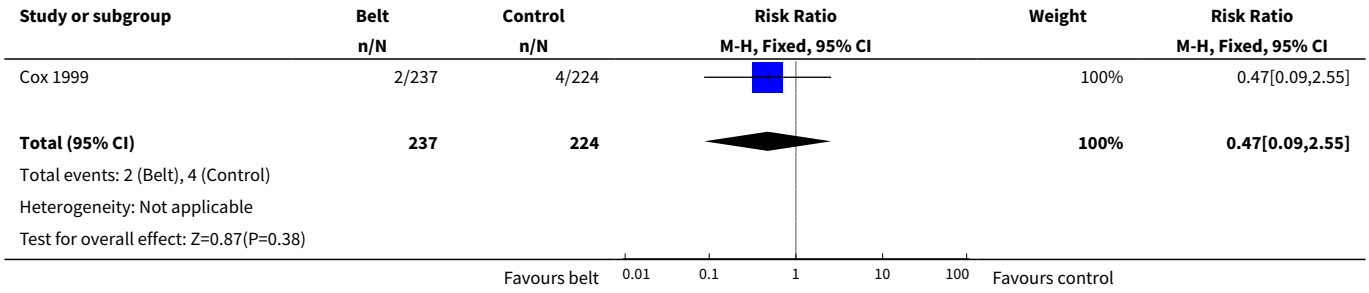
Analysis 2.2. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 2 Caesarean section.



Analysis 2.3. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 3 Operative birth - instrumental or caesarean section.



Analysis 2.4. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 4 Low arterial cord pH.



Analysis 2.5. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 5 Apgar score less than 7 after 5 minutes.

Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Fixed, 95% CI	Weight	Risk Ratio M-H, Fixed, 95% CI
Cox 1999	2/260	0/240		100%	4.62[0.22,95.68]
Total (95% CI)	**260**	**240**		**100%**	**4.62[0.22,95.68]**
Total events: 2 (Belt), 0 (Control)					
Heterogeneity: Not applicable					
Test for overall effect: Z=0.99(P=0.32)					

Favours belt — Favours control

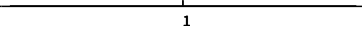
Analysis 2.6. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 6 Duration of second stage.

Study or subgroup	Favours belt N	Mean(SD)	Control N	Mean(SD)	Mean Difference Random, 95% CI	Weight	Mean Difference Random, 95% CI
Acanfora 2013	40	37.9 (22.6)	40	111.4 (35.1)		49.57%	-73.47[-86.4,-60.54]
Kim 2013	93	46.5 (28)	80	75 (37.5)		50.43%	-28.51[-38.5,-18.52]
Total ***	**133**		**120**			**100%**	**-50.8[-94.85,-6.74]**
Heterogeneity: Tau²=975.94; Chi²=29.08, df=1(P<0.0001); I²=96.56%							
Test for overall effect: Z=2.26(P=0.02)							

Favours belt — Favours control

Analysis 2.7. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 7 Episiotomy.

Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Cox 1999	132/260	139/240		25.42%	0.88[0.75,1.03]
Kang 2009	62/62	61/61		40%	1[0.97,1.03]
Kim 2013	91/97	81/91		34.58%	1.05[0.96,1.15]
Total (95% CI)	**419**	**392**		**100%**	**0.98[0.86,1.12]**
Total events: 285 (Belt), 281 (Control)					
Heterogeneity: Tau²=0.01; Chi²=14.5, df=2(P=0); I²=86.21%					
Test for overall effect: Z=0.23(P=0.82)					

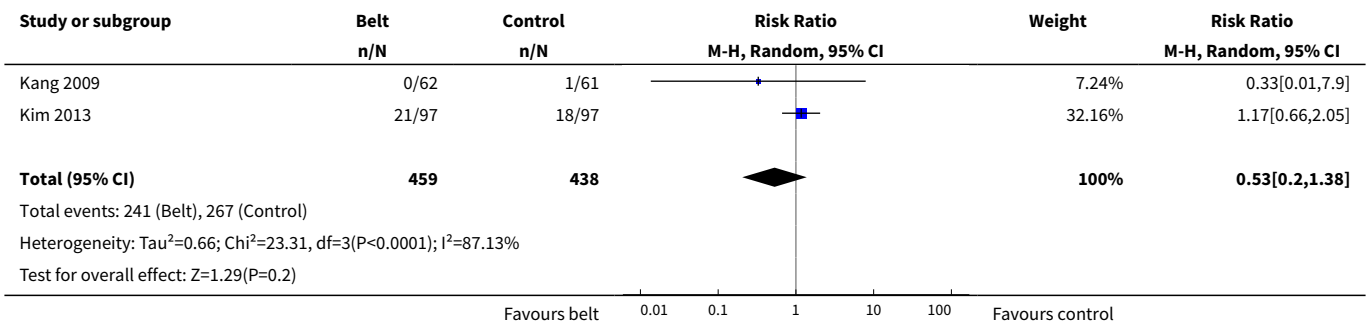


Favours belt — Favours control

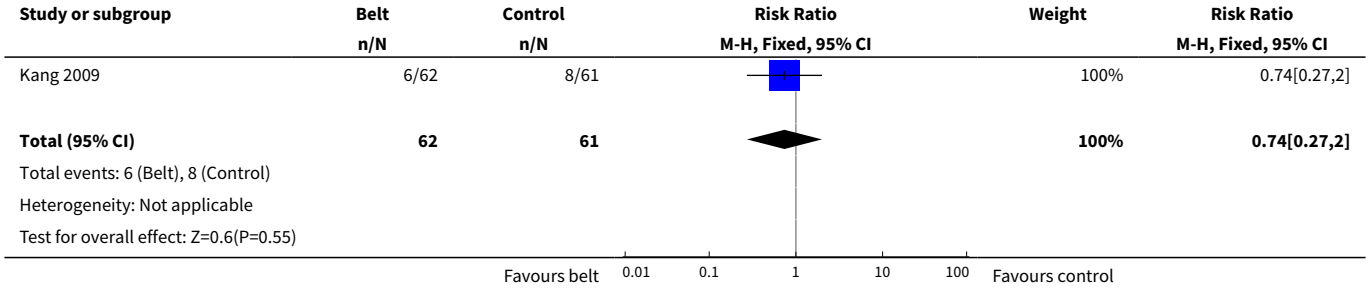
Analysis 2.8. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 8 Soft tissue damage - perineal.

Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Acanfora 2013	3/40	31/40		24.47%	0.1[0.03,0.29]
Cox 1999	217/260	217/240		36.13%	0.92[0.86,0.99]

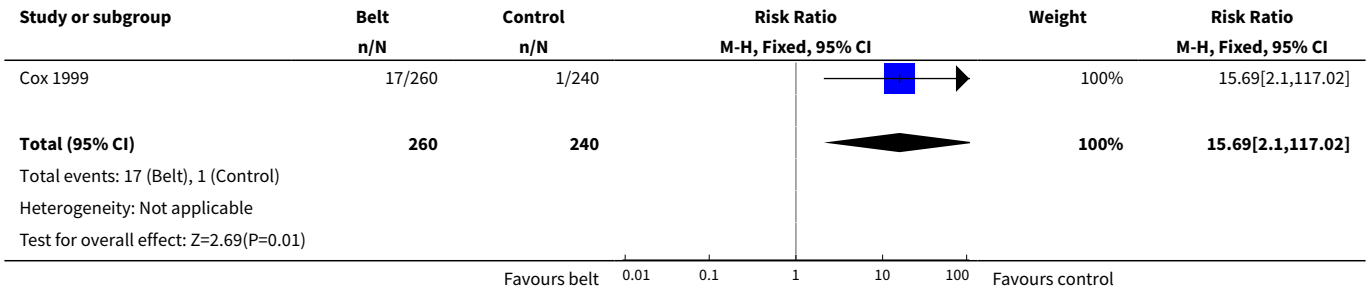
Favours belt — Favours control



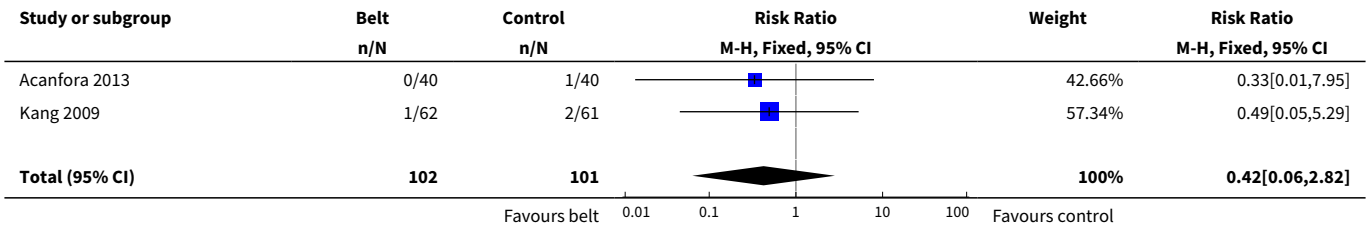
Analysis 2.9. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 9 Soft tissue damage - vaginal.

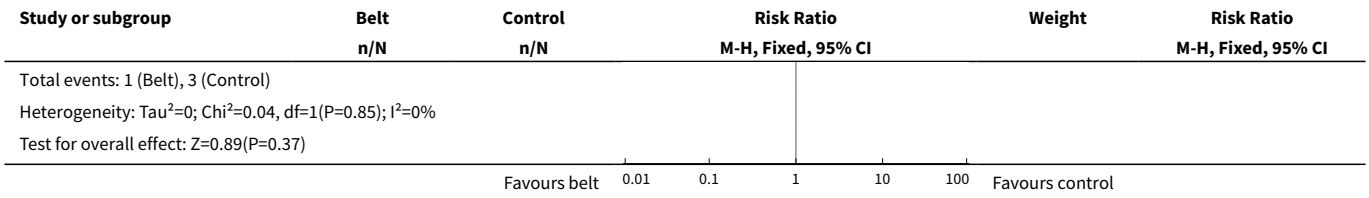


Analysis 2.10. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 10 Soft tissue damage - anal sphincter.

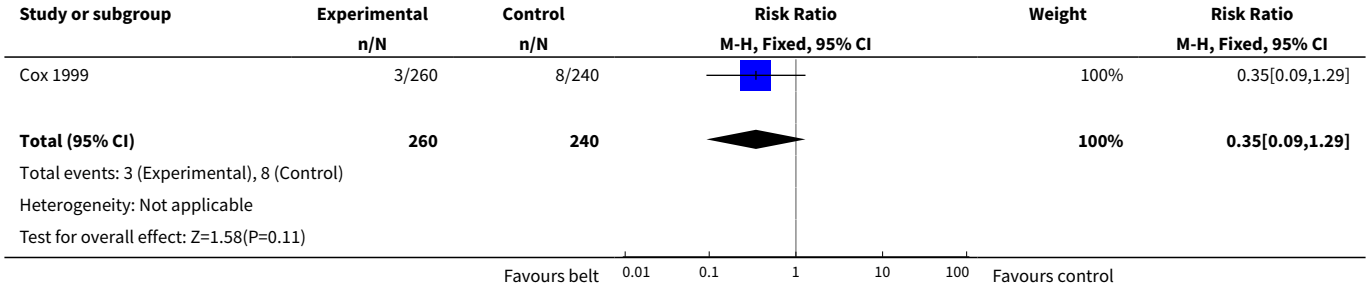


Analysis 2.11. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 11 Soft tissue damage - cervical/uterine.

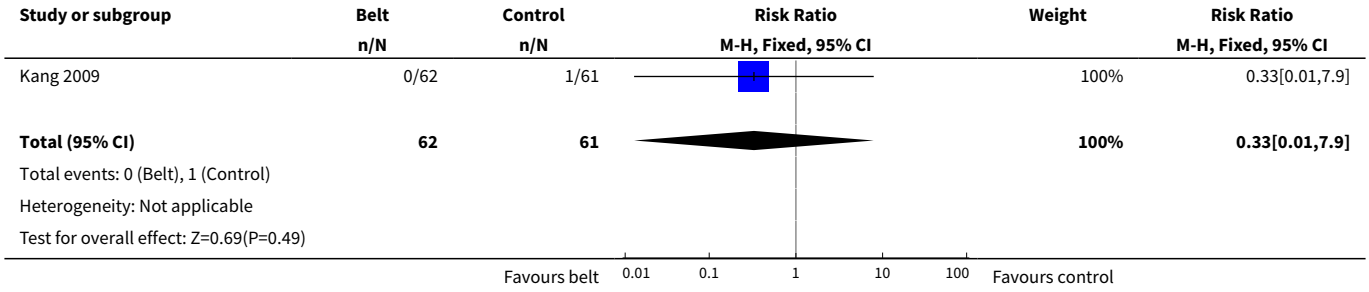




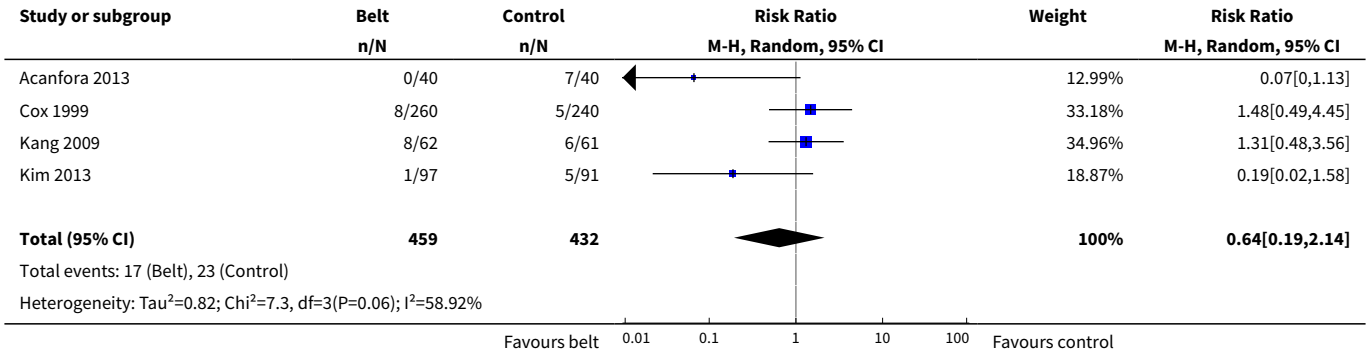
Analysis 2.12. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 12 Postpartum haemorrhage.



Analysis 2.13. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 13 Neonatal trauma - haematoma.



Analysis 2.14. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 14 Admission to neonatal intensive care unit.



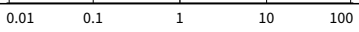
Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Test for overall effect: Z=0.72(P=0.47)					

Analysis 2.15. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 15 Sensitivity analysis: instrumental birth.

Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Cox 1999	134/260	137/240		64.93%	0.9[0.77,1.06]
Kang 2009	1/62	3/61		1.21%	0.33[0.04,3.07]
Kim 2013	34/97	47/91		33.85%	0.68[0.48,0.95]
Total (95% CI)	**419**	**392**		**100%**	**0.81[0.63,1.04]**
Total events: 169 (Belt), 187 (Control)					
Heterogeneity: Tau^2=0.02; Chi^2=3.01, df=2(P=0.22); I^2=33.66%					
Test for overall effect: Z=1.67(P=0.1)					

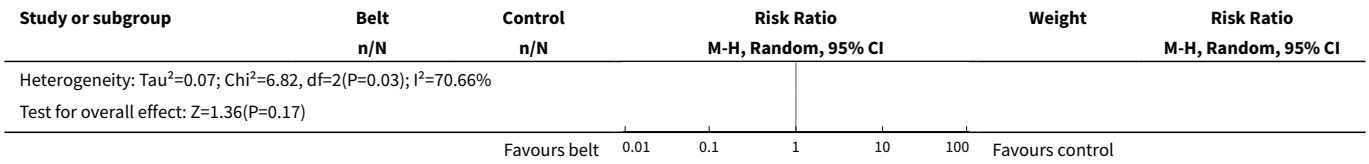
Analysis 2.16. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 16 Sensitivity analysis: caesarean section.

Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Cox 1999	15/260	9/240		53.99%	1.54[0.69,3.45]
Kang 2009	0/62	0/61			Not estimable
Kim 2013	4/97	10/91		46.01%	0.38[0.12,1.15]
Total (95% CI)	**419**	**392**		**100%**	**0.8[0.2,3.19]**
Total events: 19 (Belt), 19 (Control)					
Heterogeneity: Tau^2=0.75; Chi^2=4, df=1(P=0.05); I^2=74.99%					
Test for overall effect: Z=0.31(P=0.76)					



Analysis 2.17. Comparison 2 Fundal pressure by inflatable belt versus no fundal pressure, Outcome 17 Sensitivity analysis: operative delivery - instrumental or caesarean section.

Study or subgroup	Belt n/N	Control n/N	Risk Ratio M-H, Random, 95% CI	Weight	Risk Ratio M-H, Random, 95% CI
Cox 1999	149/260	146/240		53.72%	0.94[0.81,1.09]
Kang 2009	1/62	3/61		2.83%	0.33[0.04,3.07]
Kim 2013	38/97	57/91		43.45%	0.63[0.47,0.84]
Total (95% CI)	**419**	**392**		**100%**	**0.77[0.52,1.13]**
Total events: 188 (Belt), 206 (Control)					



FEEDBACK

Erich Cosmi, Pierfrancesco Belli and Massimo Montisci, 12 March 2018

Summary

NOTE: this comment is published 'as submitted' by Erich Cosmi, Pierfrancesco Belli and Massimo Montiscion 12 March 2018.

Comment: Kristeller Maneuver a fiction in scientific analysis and clinical application

We read with interest the review titled "Fundal pressure during the second stage of labour for improving maternal and fetal outcomes" published in Chocrane library, by Hofmeyr G, Vogel JP, Cuthbert A, Singata M, (1) and disappointment on the methodology used raised.

In this review, the authors compare the clinical results of 2 parturient groups:

Group of parturient in which the manual "Kristeller / Fundal Pressure" maneuver is performed "VS" manual control group without Kristeller / Fundal Pressure AND "Delivery" group to which the "Kristeller maneuver (KM) with AN " INFLATABLE BELT" is performed -VS control group without Kristeller maneuver.

The authors of the Cochrane Review assume that this comparison is necessary to understand if the Kristeller Maneuver /Fundal Pressure (FP), widely used in labor floor, is of some use or, as reported in the literature is not useful or even harmful.

The conclusions are still doubtful on the effect of the so-called KM / FP, which requires studies of better quality: the so-called manual KM does not affect the percentage of vaginal deliveries. In fact, only one trial reports the need for an increase in the need for relief from pain and that infants have an Apgar score <7 at 5 min; there is not enough evidence that it is safe for the newborn. The KM with AN INFLATABLE BELT reduces the second stage of labor and can increase the percentage of spontaneous deliveries, even if the available evidence is not conclusive. There is not enough evidence that it is safe for the baby and is not safe either on the perineum.

Maternal and fetal clinical effects of the so called MK / FP manual through randomized trials, are studies that might give conclusive information on the beneficial or dangerous outcomes. Given the potential role of the so-called MK / FP manual where operative deliveries are not used for lack of instruments, trials are necessary in developing countries and should be performed also in multipara.

Comments:

Kristeller maneuver in its true origin was an accompaniment from the outside to uterine contractions. In all cases Samuel Kristeller recorded the number and duration of the accompaniment of the contractions uterine with the hands, during the whole expulsion period, with the maximum technologies of the time available, that was a clock. In many cases Samuel Kristeller also measured the amount of pressure in Kg that was needed to give birth to the fetus through a forceps with dynamometer. Therefore, since the authors of the Cochrane Review cite Samuel Kristeller comparing the Fundal Pressure to the so-called Kristeller maneuver, we highlight how this is scientifically incorrect for the reasons given above. In this regard Next we will call the current way of practicing fundal pressure: "kristeller maneuver".

The authors confuse the prevention of maternal-fetal-neonatal risks and complications which are generated by the delays of assistance in childbirth often lead to use in emergency conditions and in need of caesarean section during labor, that the healthcare staff is used to dealing with the so - called KRISTELLER 'S MANEUVER /FP with the TRUE prevention of these clinical conditions through a CONTROLLED AND MEASURED accompaniment of uterine contractions performed using a device with CE certificate equipped with an ergonomic inflatable belt. (2)Therefore the effects of the INFLATABLE BELT of Baby Guard studied according to ergonomics and biomechanics and engineered principles just to redesign the times and ways of labor AND delivery and therefore avoid them clinical conditions of risk that then induce to use the Kristeller maneuver, show that the technical and scientific principles published in the Baby Guard study. Moreover this article has been selected as a publication in the analysis of meta-analysis but being the owner of the database the authors have never ever asked for the data. At this point the question is simple: how the authors may perform a meta-analysis without having our data?

The authors' statements about the application of Kristeller's maneuver/FP are questionable as the data presented as real lacks of actual verification on their demonstration since the Kristeller's maneuver /FP is practiced manually and it is NOT possible to establish to what pressure it is applied, and therefore in the various studies chosen in the review there is no control and verification of the pressure exerted. Because the INFLATABLE BELT related to the Baby Guard study is inserted into an electromechanical system [that also detects the electro-physiologic signals of myographic uterine activity from the maternal abdomen , i.e. fetal and maternal heart signals] that allows recording

of the measurement and control of the pressure administered to the parturient , to the fetus and the newborn, all of them recordings are documented and verifiable retrospectively even for medical reasons.

The study of the INFLATABLE BELT OF BABY GUARD are determined from an analysis of the ORIGINAL publication of Samuel Kristeller and analysis of the criticalities due to the lack of Ergonomic processes that allowed a correct accompanying direction contractions; the 3 chambers that have facilitated the positioning of the fetus, the INFLATABLE BELT size and biomechanical engineering improvements made by means of a correct direction of accompaniment contractions . The 3 chambers that facilitated the positioning of the fetus, the INFLATABLE BELT size and biomechanical engineering improvements, made through the TECHNICAL evaluations of the "Labor Assister" tool, that is the Korean BELT.

Therefore it is a very serious methodological error to combine the results of 2 belts/instruments used in the studies cited by the Cochrane Review designed and engineered with different technicians principles one of which (Baby Guard) is the one that thanks to the improvements obtained.

A proof of the importance of the fact that the INFLATABLE BELT relative to the study by Baby Guard is differentiates from the belts of the other studies cited by the Cochrane Review and 'why' the belt of the study on Baby Guard and equipped with CB certificate on risk analysis, and that after obtaining the CE certification the same SSR Toscana has in more studies and even in a tender contract purchased the MEDICAL DEVICE Baby Guard for the measured and controlled accompaniment of uterine contractions in order to eliminate the use of the MK / FP cd , the second methodological error is to compare 2 BELTS , although technically different, however both with the aim of eliminating the so-called MK / FP, with a practice that instead both the above mentioned BELTS had as their purpose its elimination and that is the c.d MK / FP.

Without risk analysis and consequently without the assessment of the pressure exerted on the fetus and newborn child is impossible scientifically and clinically to exclude that an adverse event and sentinel NOT was caused by the risk factor regardless of whether the customizations of the pressure exerted are called "Gentle Assisted Pushing technique (GAP)" [among the Authors DI GAP there are Hofmeyr G, Singata M : which have conflicts of interests in writing this review] or c.d. MK / FP in as both do not allow measurability and pressure control administered.

The negative or positive effects of a pressure exerted by an operator on parturient, fetus / newborn can only be determined through an analysis of the risks that can through the control and measurement of the pressure exerted establish the correct amount of pressure and consequently verify its effects preventing maternal and fetal complications.

In fact it is scientifically proven that the international literature relating to studies with the BELTS establishes up to 200 millibar of pressure the parturient the fetus and newborn NOT cause changes in maternal / fetal / neonatal health conditions whereas it is scientifically proven that if the operator diligently follows the clinical instructions of use of the BELT and MEDICAL DEVICE Baby Guard are prevented in statistically significant maternal / fetus / neonatal complications during the labor and delivery. While it is scientifically proven that to practice c.d MK/FP a pressure of 30 kg must be used.

References

1. Hofmeyr GJ, Vogel JP, Cuthbert A, Singata M. Fundal pressure during the second stage of labour. Cochrane Database of Systematic Reviews 2017, Issue 3.
2. Acanfora L, Rampon M, Filippeschi M, Marchi M, Montisci M, Viel G, Cosmi E. An inflatable ergonomic 3-chamber fundal pressure belt to assist vaginal delivery. International Journal of Gynecology and Obstetrics. 120, 2013; 78-81

Declaration: I do not have any affiliation with or involvement in any organisation with a financial interest in the subject matter of my comment.

Reply

We thank the writer for feedback on our review, and offer the following responses:

1. We recognise that techniques of ‘fundal pressure’ or the ‘Kristellar manoeuvre’ may vary, and are difficult to standardise.
2. In our meta-analysis we used the data published by the writer in: Acanfora L, Rampon M, Filippeschi M, Marchi M, Montisci M, Viel G, Cosmi E. An inflatable ergonomic 3-chamber fundal pressure belt to assist vaginal delivery. International Journal of Gynecology and Obstetrics 2013;120(1):78-81.
3. We followed a pre-specified, published protocol, which specified a planned meta-analysis of trials of manual fundal pressure, and trials of inflatable belts. We recognize that there may be differences in effectiveness of different designs of inflatable belts. Where the results of studies of different belt designs were inconsistent (heterogeneous), we used a random effects model in the meta-analysis. The data for the trials of different belt designs are available in the review so that readers can access data on specific belt designs.
4. We agree that risk factors requiring fundal pressure or belt application may be responsible for bad outcomes rather than the procedure. For this reason our review is restricted to randomized trials in which risk factors in the intervention group and the control group are balanced by the randomization process.
5. We have declared our conflicts of interest (participation of some of the review team in studies of manual fundal pressure). Authors of trials under consideration for the review do not participate in decisions regarding the inclusion or data extraction from their trials.

Contributors

Justus Hofmeyr, Joshua Vogel, Anna Cuthbert and Mandisa Singata

WHAT'S NEW

Date	Event	Description
21 May 2018	Amended	Corrected the spelling of one contributor's name in Feedback 1

HISTORY

Protocol first published: Issue 3, 2006
Review first published: Issue 4, 2009

Date	Event	Description
21 May 2018	Amended	Additional names added to authors of Feedback 1
3 May 2018	Feedback has been incorporated	Feedback and response added.
3 May 2018	Amended	Feedback added from Erich Cosmi and authors' response included See Feedback 1.
1 December 2016	New citation required but conclusions have not changed	In this update, we assessed 14 reports of 10 trials from an updated search in November 2016. Eight new trials are included, one trial is ongoing (Hofmeyr 2015), and one is awaiting classification (Zhao 2015). Cox 1999 was already included in the previous version of this review. GRADEpro Guideline Development Tool was used in order to create 'Summary of findings' tables. A summary of the intervention effect and a measure of quality for selected outcomes was produced using the GRADE approach. There is insufficient evidence to draw conclusions on the beneficial or harmful effects of fundal pressure, either manually or by inflatable belt. Fundal pressure by an inflatable belt during the second stage of labour might shorten duration of second stage for nulliparous women, and lower rates of operative birth. However, existing studies are small and their generalizability uncertain. There is insufficient evidence regarding safety for the baby.
30 November 2016	New search has been performed	Search updated and nine new trials included.
19 June 2008	Amended	Converted to new review format.

CONTRIBUTIONS OF AUTHORS

E Verheijen assessed the studies for inclusion, extracted data and wrote an earlier version of the review. J Raven assessed the studies for inclusion, extracted data and commented on drafts of the earlier version. GJ Hofmeyr initiated the protocol and review, designed the data-extraction form and contributed to the development of the review by commenting on drafts.

A Cuthbert and J Vogel assessed studies for inclusion and extracted data for the current version (except for studies in which J Vogel was involved). A Cuthbert conducted the first analysis and interpretation of data for the current version. J Vogel, GJ Hofmeyr and Mandisa Singata reviewed and contributed to the interpretation and the final manuscript.

GJ Hofmeyr is now the contact person and guarantor for this review.

DECLARATIONS OF INTEREST

GJH is an author of one included (Novikova 2009) and one ongoing study (Hofmeyr 2015), but he has not participated in assessment of or data extraction from these studies.

JV is the research project manager on the ongoing Gentle Assisted Pushing Trial (Hofmeyr 2015). No other conflicts of interest to declare.

AC is a research assistant working in the editorial base of Cochrane Pregnancy and Childbirth. She is employed by the University of Liverpool to work as a research assistant in Cochrane Pregnancy and Childbirth (who receives infrastructure funding from the NIHR, UK). She has no other conflicts of interest to declare.

MS is an author of one included (Novikova 2009) and one ongoing study (Hofmeyr 2015), but she has not participated in assessment of or data extraction from these studies.

SOURCES OF SUPPORT

Internal sources

- No sources of support supplied

External sources

- UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Reproductive Health and Research (RHR), World Health Organization, Switzerland.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The background of the protocol has been updated and the methods have been updated to incorporate the current standard methods for Cochrane Pregnancy and Childbirth. We have included the use of GRADE to assess the quality of the body of evidence and included 'Summary of findings' tables (Summary of findings for the main comparison; Summary of findings 2).

New co-authors have joined the review team for this update and Justus Hofmeyr has taken over the role of contact person and guarantor for the review.

Methods/types of interventions - we have edited 'inflatable girdle' to 'inflatable belt' to make it clearer for the reader.

INDEX TERMS

Medical Subject Headings (MeSH)

Apgar Score; Cervix Uteri [injuries]; Cesarean Section [statistics & numerical data]; Delivery, Obstetric [adverse effects] [*methods] [statistics & numerical data]; Labor Stage, Second [*physiology]; Perineum [injuries]; Pressure; Randomized Controlled Trials as Topic; Time Factors

MeSH check words

Female; Humans; Pregnancy