

Fundal pressure during the second stage of labour (Review)

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[Intervention Review]

Fundal pressure during the second stage of labour

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Editorial group: Cochrane Pregnancy and Childbirth Group. **Publication status and date:** New, published in Issue 4, 2009. **Review content assessed as up-to-date:** 25 May 2009.

Citation: Verheijen EC, Raven JH, Hofmeyr GJ. Fundal pressure during the second stage of labour. *Cochrane Database of Systematic Reviews* 2009, Issue 4. Art. No.: CD006067. DOI: 10.1002/14651858.CD006067.pub2.

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ABSTRACT

Background

Fundal pressure during the second stage of labour involves application of manual pressure to the uppermost part of the uterus directed towards the birth canal in an attempt to assist spontaneous vaginal delivery and avoid prolonged second stage or the need for operative delivery. Fundal pressure has also been applied using an inflatable girdle. A survey in the United States found that 84% of the respondents used fundal pressure in their obstetric centres. There is little evidence to demonstrate that the use of fundal pressure is effective to improve maternal and/or neonatal outcomes. Several anecdotal reports suggest that fundal pressure is associated with maternal and neonatal complications: for example, uterine rupture, neonatal fractures and brain damage. There is a need for objective evaluation of the effectiveness and safety of fundal pressure in the second stage of labour.

Objectives

To determine the benefits and adverse effects of fundal pressure in the second stage of labour.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (November 2008).

Selection criteria

Randomised and quasi-randomised controlled trials of fundal pressure versus no fundal pressure in women in the second stage of labour with singleton cephalic presentation.

Data collection and analysis

Three review authors independently assessed for inclusion all the potential studies. We extracted the data using a pre-designed form. We entered data into Review Manager software and checked for accuracy.

Main results

We excluded two of three identified trials from the analyses for methodological reasons. This left no studies on manual fundal pressure. We included one study (500 women) of fundal pressure by means of an inflatable belt versus no fundal pressure to reduce operative delivery rates. The methodological quality of the included study was good.

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Use of the inflatable belt did not change the rate of operative deliveries (RR 0.94, 95% CI 0.80 to 1.11). Fetal outcomes in terms of five-minute Apgar scores below seven (RR 4.62, 95% CI 0.22 to 95.68), low arterial cord pH (RR 0.47, 95% CI 0.09 to 2.55) and admission to the neonatal unit (RR 1.48, 95% CI 0.49 to 4.45) were also not different between the groups. There was no severe neonatal or maternal mortality or morbidity. There was an increase in intact perineum (RR 1.73, 95% CI 1.07 to 2.77), as well as anal sphincter tears (RR 15.69, 95% CI 2.10 to 117.02) in the belt group. There were no data on long-term outcomes.

Authors' conclusions

There is no evidence available to conclude on beneficial or harmful effects of manual fundal pressure. Good quality randomised controlled trials are needed to study the effect of manual fundal pressure. Fundal pressure by an insufflatable belt during the second stage of labour does not appear to increase the rate of spontaneous vaginal births in women with epidural analgesia. There is insufficient evidence regarding safety for the baby. The effects on the maternal perineum are inconclusive.

PLAIN LANGUAGE SUMMARY

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

Fundal pressure involves using the hands (manual fundal pressure) to push on the upper part of the uterus and down toward the birth canal. It is used during the second stage of labour to shorten the labour and assist in vaginal birth, either as routine practice or because of complications such as fetal distress, failure to progress, maternal exhaustion, or medical conditions where prolonged pushing is contraindicated, for example if the mother has heart disease. Also an inflatable girdle has been used in research settings to provide fundal pressure.

Potential risks with its use include uterine rupture, anal sphincter damage, newborn fractures or brain damage, and increased blood transfusion between the mother and her unborn baby. This may be important with rhesus factor or when the mother has HIV, hepatitis B or other viral disease.

The review authors found no trials on the more widely used manual fundal pressure. There was only one controlled trial studying fundal pressure by inflatable belt. It involved 500 women who had epidural analgesia and were in the second stage of labour. The methodological quality of the trial was good. The number of women experiencing spontaneous vaginal births was similar with or without applying fundal pressure. The trial did not provide sufficient evidence to determine any safety issues of the manoeuvre for the baby, measured as low Apgar scores, low arterial fetal cord pH, or admission to the neonatal unit. Blinding was not possible with this intervention. It may have been perceived that the belt was 'doing the work' so that the women pushed less hard and the midwives encouraged them less enthusiastically. The number of women with an intact perineum increased with use of the belt but also anal sphincter tears increased, all but one associated with an instrumental delivery.

BACKGROUND

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. The clinical indications for this attempt 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). In research settings, fundal pressure has also been applied using an inflatable girdle.

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 lowand 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 US and the UK for example, this may be because of the intense medicolegal climate in those countries, and the complications supposedly arising from the manoeuvre, as described below. A postpartum follow-up survey in the United States in 2005 found that 17% of the respondents had experienced fundal pressure during the second stage of their delivery (Declerck 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). 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).

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 outcome. Several anecdotal reports suggest that fundal pressure is associated with maternal and neonatal complications, for example, uterine rupture (Pan 2002; 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 delivery, 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.

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 delivery or caesarean section are not available. If effective and safe, fundal pressure may be the only option, which may reduce perinatal mortality and morbidity.

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 delivery.

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

Types of participants

Women in second stage of labour with singleton cephalic presentation. We will include women of all gestations and parity. 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 to expedite birth of the baby. This fundal pressure is also known as the 'Kristeller manoeuvre'.

Fundal pressure applied by means of an inflatable girdle was assessed as a separate intervention.

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Types of outcome measures

Primary outcomes

Maternal

Short-term outcomes

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

2. Operative derivery

- Instrumental delivery
- 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
 - Episiotomy
- 3. Soft tissue damage
 - Perineal/vaginal/anal sphincter
 - 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
 - Fractures
 - Haematoma
- 2. Neonatal encephalopathy, as defined by trial authors
- 3. Requiring admission to neonatal intensive care unit

4. HIV/hepatitis B or C infection (in populations with high prevalence)

- 5. Baby death
 - Stillbirth
 - Neonatal death

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (November 2008).

The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-ordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);

2. weekly searches of MEDLINE;

3. handsearches of 30 journals and the proceedings of major conferences;

4. weekly current awareness alerts for a further 44 journals plus monthly BioMed Central email alerts.

Details of the search strategies for CENTRAL and MEDLINE, the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Specialized Register' section within the editorial information about the Cochrane Pregnancy and Childbirth Group.

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Three review authors (Evelyn Verheijen (EV), Joanna Raven (JR) and Princess Jafta (PJ)) independently assessed for inclusion all the

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potential studies we identified as a result of the search strategy. We resolved any disagreement through discussion.

Data extraction and management

We designed a form to extract data. For eligible studies, three review authors (EV, JR and PJ) extracted the data using the agreed form. We resolved discrepancies through discussion. We entered data into Review Manager software (RevMan 2008) and checked for accuracy.

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

Assessment of risk of bias in included studies

Three review authors independently assessed risk of bias for the included study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2008).

(1) Sequence generation (checking for possible selection bias)

We described for the included study the methods used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We assessed the methods as:

• adequate (any truly random process, e.g. random number table; computer random number generator);

- inadequate (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
 - unclear.

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

We described for the included study the method used to conceal the allocation sequence in sufficient detail and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment. We assessed the methods as:

• adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);

• inadequate (open random allocation; unsealed or nonopaque envelopes, alternation; date of birth);

• unclear.

(3) Blinding (checking for possible performance bias)

We described for the included study all the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We also provided information on whether the intended blinding was effective. Where blinding was not possible, we assessed whether the lack of blinding was likely to have introduced bias. Blinding was assessed separately for different outcomes or classes of outcomes. We assessed the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We described for the included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis.

(5) Selective reporting bias

We examined the possibility of selective outcome reporting bias.

(6) Other sources of bias

We assessed whether the study was free of other problems that could put it at risk of bias.

(7) Overall risk of bias

We made explicit judgements about whether the study was at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2008). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings.

Measures of treatment effect

Dichotomous data

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

Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We used the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2008).

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Subgroup analysis

We considered analyses of the following subgroups.

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.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

We identified three trials which studied fundal pressure in second stage of labour using the search criteria. We excluded one trial (Schulz-Lobmeyr 1999) from the analyses as allocation to intervention group was not based on randomisation. We excluded another (quasi-randomised) trial (Zhao 1991) for reasons of poor methodological quality and high risk of bias.

For details of excluded studies, see the Characteristics of excluded studies table.

I. Manual fundal pressure versus no fundal pressure

There were no studies included comparing this manoeuvre.

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

Only one study (500 participants) (Cox 1999) compared fundal pressure by inflatable belt versus no fundal pressure. Nulliparous women with epidural analgesia were randomised for the inflatable belt in the second stage or routine care to assess if it reduces operative delivery rates.

Risk of bias in included studies

The methodological quality of the included study was good. Allocation generation and concealment were adequate. Given the type of the intervention, the participants, clinicians and outcome assessors were aware of the intervention. Length of second stage and mode of delivery did not significantly change with the belt, however this may have resulted from the participants and midwives perceiving the belt as 'doing the work'. This effect of non-blinding may however be similar outside a research setting. Assessment of the outcome of perineal damage appears to have been subject to bias as a result of lack of blinding.

Effects of interventions

In the included study, use of the inflatable belt did not change the rate of operative deliveries (risk ratio (RR) 0.94, 95% confidence interval (CI) 0.80 to 1.11). Fetal outcomes in terms of five-minute Apgar scores below seven (RR 4.62, 95% CI 0.22 to 95.68), low arterial cord pH (RR 0.47, 95% CI 0.09 to 2.55) and admission to the neonatal unit (RR 1.48, 95% CI 0.49 to 4.45) were also not different between the groups. There was no severe neonatal or maternal mortality or morbidity. There was an increase in intact perineum (RR 1.73, 95% CI 2.10 to 117.02) in the belt group. The authors reported no difference in length of second stage. Maternal satisfaction about the second stage was high in both the intervention as in the control group. There were no data on long-term outcomes.

DISCUSSION

There were no trials on the effects of the more widely used manual fundal pressure.

The one included trial which studied fundal pressure by means of an inflatable belt did not find any difference in the primary outcomes (operative deliveries, and low Apgar scores or arterial fetal cord pH). Although it is possible that the lack of blinding had a significant impact on the outcomes, (the belt may have been perceived as 'doing the work' so that the patients possibly pushed less hard and the midwives encouraged less enthusiastically), this effect is also likely to occur outside a research setting, where there is no blinding either.

The increase in intact perineum, as well as in anal sphincter tears in the belt group, is somewhat contradictory. The rate of instrumental deliveries was similar in both groups. While in the belt group, 16 of 17 cases of sphincter tears were associated with an instrumental delivery, in the control group an instrumental delivery was only associated with one third-degree tear. The belt was switched off prior to instrumentation. It seems therefore unlikely that there is a causative relation between the intervention and the tears. The trial authors suspected that the outcome assessors were more diligent in searching for 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.

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AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence available to conclude on beneficial or harmful effects of manual fundal pressure.

Fundal pressure by insufflatable belt during the second stage of labour does not appear to increase the rate of spontaneous vaginal births in women with epidural analgesia.

There is insufficient evidence regarding safety for the baby. The effects on the maternal perineum are inconclusive.

The insufflatable belt should not be implemented in clinical practice before further research has provided evidence on efficacy and safety for mother and baby.

Implications for research

Good quality randomised controlled trials are needed to study the effect of manual fundal pressure on maternal and fetal outcome, including maternal satisfaction with the intervention. These studies may be best performed in settings where fundal pressure is already widely practiced.

ACKNOWLEDGEMENTS

Thanks to Caroline Summers for translating Schulz-Lobmeyr 1999.

Thanks to Huang Kun for translating Zhao 1991.

The authors would like to acknowledge the enthusiastic contribution of Princess Jafta to this review before her untimely death in February 2009, and would like to dedicate the review to her. Princess Jafta assessed the studies for inclusion and extracted data.

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

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

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		500 nulliparous women, singleton cephalic at term, functioning epidural anaesthesia, ruptured membranes, mat. weight < 100 kg, mat. age between 20 and 40.					
Interventions	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. Routine care: 1 hour passive second stage, 1 hour 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 signifi	cant impact on the outcomes.					
Risk of bias							
Item	Authors' judgement	Description					
Adequate sequence generation?	Yes	Computer-generated randomised num- bers.					
Allocation concealment?	Yes	Opaque sealed envelopes. None were lost.					
Blinding? All outcomes	No						
Incomplete outcome data addressed? All outcomes	Yes						
Incomplete outcome data addressed? maternal satisfaction	No	By questionnaire.					
Incomplete outcome data addressed? Low arterial cord pH	No						
Free of selective reporting?	Yes						

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Cox 1999 (Continued)

Free of other bias?	Yes	

CTG: cardiotocogram FBS: fetal blood sampling mat: maternal SCBU: special care baby unit.

Characteristics of excluded studies [ordered by study ID]

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. The unlikely results suggest unacceptable bias.

DATA AND ANALYSES

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Operative delivery	1	1000	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.80, 1.11]
1.1 Instrumental delivery	1	500	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.77, 1.06]
1.2 Caesarean section	1	500	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.69, 3.45]
2 Anal sphincter damage	1	500	Risk Ratio (M-H, Fixed, 95% CI)	15.69 [2.10, 117.02]
3 Intact perineum	1	500	Risk Ratio (M-H, Fixed, 95% CI)	1.73 [1.07, 2.77]
4 Episiotomy	1	500	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.75, 1.03]
5 Postpartum haemorrhage	1	500	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.09, 1.29]
5.1 Need for blood transfusion	1	500	Risk Ratio (M-H, Fixed, 95% CI)	0.35 [0.09, 1.29]
6 Apgar score less than 7 after 5 minutes	1	500	Risk Ratio (M-H, Fixed, 95% CI)	4.62 [0.22, 95.68]
7 Low arterial cord pH	1	461	Risk Ratio (M-H, Fixed, 95% CI)	0.47 [0.09, 2.55]
8 Admission to neonatal intensive care unit	1	500	Risk Ratio (M-H, Fixed, 95% CI)	1.48 [0.49, 4.45]

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

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Analysis 2.1. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome I Operative delivery.

Review: Fundal pressure during the second stage of labour

Comparison: 2 Fundal pressure by inflatable girdle versus no fundal pressure

Outcome: I Operative delivery

Study or subgroup	Belt n/N	Control n/N	١	Risk Ratio 1-H,Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% Cl
l Instrumental delivery						
Cox 1999	134/260	137/240		+	93.8 %	0.90 [0.77, 1.06]
Subtotal (95% CI)	260	240		•	93.8 %	0.90 [0.77, 1.06]
Total events: 134 (Belt), 137 (C	Control)					
Heterogeneity: not applicable						
Test for overall effect: $Z = 1.24$	P = 0.21					
2 Caesarean section						
Cox 1999	15/260	9/240		+ - -	6.2 %	1.54 [0.69, 3.45]
Subtotal (95% CI)	260	240		-	6.2 %	1.54 [0.69, 3.45]
Total events: 15 (Belt), 9 (Cont	rol)					
Heterogeneity: not applicable						
Test for overall effect: $Z = 1.05$	6 (P = 0.30)					
Total (95% CI)	520	480		•	100.0 %	0.94 [0.80, 1.11]
Total events: 149 (Belt), 146 (C	Control)					
Heterogeneity: $Chi^2 = 1.68$, df	$= (P = 0.19); ^2 =$	41%				
Test for overall effect: $Z = 0.73$	8 (P = 0.47)					
			0.01 0.	I I I0 I00		

0.01 0.1	10 100	
Favours experimental	Favours control	

Fundal pressure during the second stage of labour (Review)

Analysis 2.2. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome 2 Anal sphincter damage.

Review: Fundal pressure during the second stage of labour

Comparison: 2 Fundal pressure by inflatable girdle versus no fundal pressure

Outcome: 2 Anal sphincter damage

Study or subgroup	Belt	Control	Risk Ratio		Weight	Risk Ratio
	n/N	n/N	M-H	,Fixed,95% Cl		M-H,Fixed,95% Cl
Cox 1999	17/260	1/240		 →	100.0 %	5.69 [2.10, 7.02]
Total (95% CI)	260	240			100.0 %	15.69 [2.10, 117.02]
Total events: 17 (Belt), 1 ((Control)					
Heterogeneity: not applica	able					
Test for overall effect: Z =	= 2.69 (P = 0.0072)					
			0.01 0.1	1 10 100		
			Favours experimental	Favours control		

Analysis 2.3. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome 3 Intact perineum.

Review: Fundal pressure	e during the second s	tage of labour				
Comparison: 2 Fundal p	pressure by inflatable	girdle versus no fun	dal pressure			
Outcome: 3 Intact perir	neum					
Study or subgroup	Belt n/N	Control n/N	М-Н,	Risk Ratio Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% CI
Cox 1999	43/260	23/240			100.0 %	1.73 [1.07, 2.77]
Total (95% CI) Total events: 43 (Belt), 23	260	240		•	100.0 %	1.73 [1.07, 2.77]
Heterogeneity: not applicate Test for overall effect: $Z =$						
			0.01 0.1	1 10 100		
			Favours control	Favours experime	ental	

Fundal pressure during the second stage of labour (Review)

Analysis 2.4. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome 4 Episiotomy.

Review: Fundal pressure during the second stage of labour

Comparison: 2 Fundal pressure by inflatable girdle versus no fundal pressure

Outcome: 4 Episiotomy

Study or subgroup	Belt	Control			Risk Ra	tio		Weight	Risk Ratio
	n/N	n/N		M-H,Fi	xed,95%	% CI			M-H,Fixed,95% CI
Cox 1999	132/260	39/240			-			100.0 %	0.88 [0.75, 1.03]
Total (95% CI)	260	240			•			100.0 %	0.88 [0.75, 1.03]
Total events: 132 (Belt), 13	9 (Control)								
Heterogeneity: not applica	ble								
Test for overall effect: Z =	I.60 (P = 0.11)								
							1		
			0.01	0.1		10 10	00		
			Favours expe	erimental	Fav	ours cont	trol		

Analysis 2.5. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome 5 Postpartum haemorrhage.

Review: Fundal pressure	e during the second stage	of labour			
Comparison: 2 Fundal p	ressure by inflatable girdl	e versus no fundal pre	essure		
Outcome: 5 Postpartun	n haemorrhage				
Study or subgroup	Experimental n/N	Control n/N	Risk Ratio M-H,Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% Cl
I Need for blood transfus	ion				
Cox 1999	3/260	8/240		100.0 %	0.35 [0.09, 1.29]
Total (95% CI) Total events: 3 (Experimen Heterogeneity: not applica Test for overall effect: Z =	ble	240		100.0 %	0.35 [0.09, 1.29]
			0.01 0.1 1 10 10		
		Favo	urs experimental Favours contr	rol	

Fundal pressure during the second stage of labour (Review)

Analysis 2.6. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome 6 Apgar score less than 7 after 5 minutes.

Review: Fundal pressure during the second stage of labour

Review: Fundal pressure during the second stage of labour

Comparison: 2 Fundal pressure by inflatable girdle versus no fundal pressure

Outcome: 6 Apgar score less than 7 after 5 minutes

Study or subgroup	Belt n/N	Control n/N		Risk Ratio ked,95% Cl	Weight	Risk Ratio M-H,Fixed,95% Cl
Cox 1999	2/260	0/240			100.0 %	4.62 [0.22, 95.68]
Total (95% CI) Total events: 2 (Belt), 0 (Co Heterogeneity: not applical Test for overall effect: Z =	ble	240	_		100.0 %	4.62 [0.22, 95.68]
			0.01 0.1 Favours experimental	I IO IOO Favours control		

Analysis 2.7. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome 7 Low arterial cord pH.

Comparison: 2 Fundal pressure by inflatable girdle versus no fundal pressure Outcome: 7 Low arterial cord pH Study or subgroup Belt Control Risk Ratio Weight Risk Ratio M-H,Fixed,95% Cl n/N n/N M-H,Fixed,95% Cl 0.47 [0.09, 2.55] Cox 1999 2/237 4/224 100.0 % -----Total (95% CI) 0.47 [0.09, 2.55] 237 224 100.0 % Total events: 2 (Belt), 4 (Control) Heterogeneity: not applicable Test for overall effect: Z = 0.87 (P = 0.38) 0.01 01 10 100 Favours experimental Favours control

Fundal pressure during the second stage of labour (Review)

Analysis 2.8. Comparison 2 Fundal pressure by inflatable girdle versus no fundal pressure, Outcome 8 Admission to neonatal intensive care unit.

Review: Fundal pressure during the second stage of labour

Comparison: 2 Fundal pressure by inflatable girdle versus no fundal pressure

Outcome: 8 Admission to neonatal intensive care unit

Study or subgroup	Belt n/N	Control n/N	M-H,	Risk Ratio Fixed,95% Cl	Weight	Risk Ratio M-H,Fixed,95% Cl
Cox 1999	8/260	5/240		-	100.0 %	1.48 [0.49, 4.45]
Total (95% CI)	260	240		-	100.0 %	1.48 [0.49, 4.45]
Total events: 8 (Belt), 5 (Co	ontrol)					
Heterogeneity: not applical	ble					
Test for overall effect: Z =	0.69 (P = 0.49)					
			0.01 0.1	1 10 100		
			Favours experimental	Favours control		

HISTORY

Protocol first published: Issue 3, 2006

Review first published: Issue 4, 2009

19 June 2008 Amended Converted to new review format.

CONTRIBUTIONS OF AUTHORS

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

DECLARATIONS OF INTEREST

None known.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Since the search by the Trial Search Coordinator was very complete an additional search by the authors was not expected to reveal further trials. It was therefore, not performed.

INDEX TERMS Medical Subject Headings (MeSH)

Labor Stage, Second [*physiology]; Obstetrics [*methods]; Pressure

MeSH check words

Female; Humans; Pregnancy