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Perineal techniques during the second stage of labour for reducing perineal trauma (Review)

Aasheim V, Nilsen ABV, Reinar LM, Lukasse M

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TABLE OF CONTENTS

[Intervention Review]

Perineal techniques during the second stage of labour for reducing perineal trauma

Vigdis Aasheim[1], Anne Britt Vika Nilsen[1], Liv Merete Reinar[2], Mirjam Lukasse[3,4]

[1]Faculty of Health and Social Sciences, Western Norway University of Applied Sciences, Bergen, Norway. [2]Unit for Primary Care and Clinical Procedures, Norwegian Institute of Public Health, Oslo, Norway. [3]Faculty of Health Sciences, Oslo and Akershus University College, Oslo, Norway. [4]Faculty of Health and Social Sciences, University College of Southeast Norway, Oslo, Norway

Contact address: Vigdis Aasheim, Faculty of Health and Social Sciences, Western Norway University of Applied Sciences, Bergen, Norway. vaa@hvl.no.

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ABSTRACT

Background

Most vaginal births are associated with trauma to the genital tract. The morbidity associated with perineal trauma can be significant, especially when it comes to third- and fourth-degree tears. Different interventions including perineal massage, warm or cold compresses, and perineal management techniques have been used to prevent trauma. This is an update of a Cochrane review that was first published in 2011.

Objectives

To assess the effect of perineal techniques during the second stage of labour on the incidence and morbidity associated with perineal trauma.

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register (26 September 2016) and reference lists of retrieved studies.

Selection criteria

Published and unpublished randomised and quasi-randomised controlled trials evaluating perineal techniques during the second stage of labour. Cross-over trials were not eligible for inclusion.

Data collection and analysis

Three review authors independently assessed trials for inclusion, extracted data and evaluated methodological quality. We checked data for accuracy.

Main results

Twenty-two trials were eligible for inclusion (with 20 trials involving 15,181 women providing data). Overall, trials were at moderate to high risk of bias; none had adequate blinding, and most were unclear for both allocation concealment and incomplete outcome data. Interventions compared included the use of perineal massage, warm and cold compresses, and other perineal management techniques.

Most studies did not report data on our secondary outcomes. We downgraded evidence for risk of bias, inconsistency, and imprecision for all comparisons.

Hands off (or poised) compared to hands on

Hands on or hands off the perineum made no clear difference in incidence of intact perineum (average risk ratio (RR) 1.03, 95% confidence interval (CI) 0.95 to 1.12, two studies, Tau² 0.00, I² 37%, 6547 women; moderate-quality evidence), first-degree perineal tears (average RR 1.32, 95% CI 0.99 to 1.77, two studies, 700 women; low-quality evidence), second-degree tears (average RR 0.77, 95% CI 0.47 to 1.28, two studies, 700 women; low-quality evidence), or third- or fourth-degree tears (average RR 0.68, 95% CI 0.21 to 2.26, five studies, Tau² 0.92, I² 72%, 7317 women; very low-quality evidence). Substantial heterogeneity for third- or fourth-degree tears means these data should be interpreted with caution. Episiotomy was more frequent in the hands-on group (average RR 0.58, 95% CI 0.43 to 0.79, Tau² 0.07, I² 74%, four studies, 7247 women; low-quality evidence), but there was considerable heterogeneity between the four included studies.

There were no data for perineal trauma requiring suturing.

Warm compresses versus control (hands off or no warm compress)

A warm compress did not have any clear effect on the incidence of intact perineum (average RR 1.02, 95% CI 0.85 to 1.21; 1799 women; four studies; moderate-quality evidence), perineal trauma requiring suturing (average RR 1.14, 95% CI 0.79 to 1.66; 76 women; one study; very low-quality evidence), second-degree tears (average RR 0.95, 95% CI 0.58 to 1.56; 274 women; two studies; very low-quality evidence), or episiotomy (average RR 0.86, 95% CI 0.60 to 1.23; 1799 women; four studies; low-quality evidence). It is uncertain whether warm compress increases or reduces the incidence of first-degree tears (average RR 1.19, 95% CI 0.38 to 3.79; 274 women; two studies; I² 88%; very low-quality evidence).

Fewer third- or fourth-degree perineal tears were reported in the warm-compress group (average RR 0.46, 95% CI 0.27 to 0.79; 1799 women; four studies; moderate-quality evidence).

Massage versus control (hands off or routine care)

The incidence of intact perineum was increased in the perineal-massage group (average RR 1.74, 95% CI 1.11 to 2.73, six studies, 2618 women; I² 83% low-quality evidence) but there was substantial heterogeneity between studies). This group experienced fewer third- or fourth-degree tears (average RR 0.49, 95% CI 0.25 to 0.94, five studies, 2477 women; moderate-quality evidence).

There were no clear differences between groups for perineal trauma requiring suturing (average RR 1.10, 95% CI 0.75 to 1.61, one study, 76 women; very low-quality evidence), first-degree tears (average RR 1.55, 95% CI 0.79 to 3.05, five studies, Tau² 0.47, I² 85%, 537 women; very low-quality evidence), or second-degree tears (average RR 1.08, 95% CI 0.55 to 2.12, five studies, Tau² 0.32, I² 62%, 537 women; very low-quality evidence). Perineal massage may reduce episiotomy although there was considerable uncertainty around the effect estimate (average RR 0.55, 95% CI 0.29 to 1.03, seven studies, Tau² 0.43, I² 92%, 2684 women; very low-quality evidence). Heterogeneity was high for first-degree tear, second-degree tear and for episiotomy - these data should be interpreted with caution.

Ritgen's manoeuvre versus standard care

One study (66 women) found that women receiving Ritgen's manoeuvre were less likely to have a first-degree tear (RR 0.32, 95% CI 0.14 to 0.69; very low-quality evidence), more likely to have a second-degree tear (RR 3.25, 95% CI 1.73 to 6.09; very low-quality evidence), and neither more nor less likely to have an intact perineum (RR 0.17, 95% CI 0.02 to 1.31; very low-quality evidence). One larger study reported that Ritgen's manoeuvre did not have an effect on incidence of third- or fourth-degree tears (RR 1.24, 95% CI 0.78 to 1.96,1423 women; low-quality evidence). Episiotomy was not clearly different between groups (RR 0.81, 95% CI 0.63 to 1.03, two studies, 1489 women; low-quality evidence).

Other comparisons

The delivery of posterior versus anterior shoulder first, use of a perineal protection device, different oils/wax, and cold compresses did not show any effects on perineal outcomes. Only one study contributed to each of these comparisons, so data were insufficient to draw conclusions.

Authors' conclusions

Moderate-quality evidence suggests that warm compresses, and massage, may reduce third- and fourth-degree tears but the impact of these techniques on other outcomes was unclear or inconsistent. Poor-quality evidence suggests hands-off techniques may reduce episiotomy, but this technique had no clear impact on other outcomes. There were insufficient data to show whether other perineal techniques result in improved outcomes.

Further research could be performed evaluating perineal techniques, warm compresses and massage, and how different types of oil used during massage affect women and their babies. It is important for any future research to collect information on women's views.

PLAIN LANGUAGE SUMMARY

Perineal techniques during the second stage of labour for reducing perineal trauma

What is the issue?

Vaginal births are often associated with some form of trauma to the genital tract, and tears that affect the anal sphincter or mucosa (third- and fourth-degree tears) can cause serious problems. Perineal trauma can occur spontaneously or result from a surgical incision (episiotomy). Different perineal techniques are being used to slow down the birth of the baby's head, and allow the perineum to stretch slowly to prevent injury. Massage, warm compresses and different perineal management techniques are widely used by midwives and birth attendants. The objective of this updated review was to assess the effect of perineal techniques during the second stage of labour on the incidence of perineal trauma. This is an update of a review that was published in 2011.

Why is this important?

Trauma to the perineum can cause pain and other problems for women after the birth. The damage is described as first-, second-, third- and fourth-degree tears - first-degree tears being the least damage and fourth-degree tears being the most. Third- and fourth-degree tears, affect the anal sphincter or mucosa, thus causing the most problems. Reducing the use of episiotomies will reduce trauma to the perineum. Also, different perineal techniques are being used to slow down the birth of the baby's head. Massage, warm compresses and different perineal management techniques are widely used by midwives and birth attendants. It is important to know if these do indeed reduce trauma and pain for women.

What evidence did we find?

We searched for studies in September 2016. Twenty two trials were eligible for inclusion in this updated review but only twenty studies (involving 15,181 women), contributed results to the review. The participants in the studies were women without medical complications who were expecting a vaginal birth. The studies varied in their risk of bias, and the quality of the studies was very low to moderate.

Hands off (or poised) compared to hands on

Using 'hands off' the perineum resulted in fewer women having an episiotomy (low-quality evidence), but made no difference to numbers of women with no tears (moderate-quality evidence), first-degree tears (low-quality evidence), second-degree tears (low-quality evidence), or third- or fourth-degree tears (very low-quality evidence). There were considerable unexplained differences in results between the four studies. None of the studies provided data on the number of tears requiring suturing.

Warm compresses versus control (hands off or no warm compress)

Fewer women in the warm-compress group experienced third- or fourth-degree tears (moderate-quality evidence). A warm compress did not affect numbers of women with intact perineum (moderate-quality evidence), tears requiring suturing (very low-quality evidence), second-degree tears (very low-quality evidence), or episiotomies (low-quality evidence). It is uncertain whether warm compresses increase or reduce the incidence of first-degree tears (very low-quality evidence).

Massage versus control (hands off or routine care)

There were more women with an intact perineum in the perineal massage group (low-quality evidence), and fewer women with third- or fourth-degree tears (moderate-quality evidence). Massage did not appear to make a difference to women with perineal trauma requiring suturing (very low-quality evidence), first-degree tears (very low-quality evidence), second-degree tears (very low-quality evidence), or episiotomies (very low-quality evidence).

Ritgen's manoeuvre versus standard care

One small study found that women who had Ritgen's manoeuvre had fewer first-degree tears (very low-quality evidence), but more second-degree tears (very low-quality evidence). There was no difference between groups in terms of the number of third- or fourth-degree tears, or episiotomies (both low-quality evidence).

What does this mean?

We found that massage and warm compresses may reduce serious perineal trauma (third- and fourth-degree tears). Hands-off techniques may reduce the number of episiotomies but it was not clear that these techniques had a beneficial effect on other perineal trauma. There remains uncertainty about the value of other techniques to reduce damage to the perineum during childbirth.

More research is necessary, to evaluate different perineal techniques and to answer questions about how to minimise perineal trauma. There is insufficient evidence on women's experiences and views (only one included study collected information on this). It is important for future research to ascertain whether these interventions are acceptable to women.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON [Explanation]

Hands off (or poised) compared to hands on for reducing perineal trauma

Patient or population: pregnant women expecting a vaginal birth, singleton vertex presentation at term, with no medical complications
Setting: Hospitals in Brazil, Iran, Austria and UK
Intervention: hands off (or poised)
Comparison: hands on

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with hands on	Risk with hands off (or poised)				
Intact perineum	Study population		RR 1.03 (0.95 to 1.12)	6547 (2 RCTs)	⊕⊕⊕◯ Moderate[1,2,3]	
	354 per 1000	364 per 1000 (336 to 396)				
Perineal trauma requiring suturing	Study population		-	(0 RCTs)	-	No trial reported this outcome
	See comment	See comment				
1st degree tear	Study population		RR 1.32 (0.99 to 1.77)	700 (2 RCTs)	⊕⊕◯◯ Low[4,5]	
	180 per 1000	238 per 1000 (178 to 319)				
2nd degree tear	Study population		RR 0.77 (0.47 to 1.28)	700 (2 RCTs)	⊕⊕◯◯ Low[4,5]	
	86 per 1000	66 per 1000 (40 to 110)				
3rd or 4th degree tears	Study population		RR 0.68 (0.21 to 2.26)	7317 (5 RCTs)	⊕◯◯◯ Very low[1,5,6]	

	15 per 1000	10 per 1000 (3 to 34)			
Episiotomy	Study population		RR 0.58 (0.43 to 0.79)	7247 (4 RCTs)	⊕⊕◯◯ Low[1,6]
	146 per 1000	85 per 1000 (63 to 115)			

*__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; **RCT**: randomised controlled trial; **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 had design limitations, one study had serious design limitations (downgraded 1 level).
[2]Heterogeneity < 60% (not downgraded).
[3]Sample size > 6000, events > 2000, confidence intervals cross line of no effect but are not wide (not downgraded).
[4]Both studies contributing data had design limitations (downgraded 1 level).
[5]Wide confidence interval crossing the line of no effect (downgraded 1 level).
[6]Statistical heterogeneity ($I^2 \geq 60\%$). Variation in size of effect (downgraded 1 level).

BACKGROUND

Description of the condition

Most vaginal births are associated with some form of trauma to the genital tract (Albers 2003). Anterior perineal trauma is injury to the labia, anterior vagina, urethra, or clitoris and is usually associated with little morbidity. Posterior perineal trauma is any injury to the posterior vagina wall, perineal muscles or anal sphincter (Fernando 2015; Kettle 2008). Spontaneous tears are defined as first degree when they involve the perineal skin only; second-degree tears involve the perineal muscles and skin; third-degree tears involve the anal sphincter complex (classified as 3a where less than 50% of the external anal sphincter is torn; 3b where more than 50% of the external anal sphincter is torn; 3c where the internal and external anal sphincter is torn); fourth-degree tears involve the anal sphincter complex and anal epithelium (Fernando 2015; Kettle 2008). The term obstetric anal sphincter injuries (OASIS) is used for both third- and fourth-degree perineal tears (Fernando 2015). Perineal trauma can occur spontaneously or result from a surgical incision of the perineum, called episiotomy. The incidence of some form of perineal trauma is reported to be 85% (McCandlish 1998) and the incidence of trauma that affects the anal sphincter is reported to be from 0.5% to 7.0% for all vaginal deliveries (Sultan 1999) and between 0.5% and 2.5% of spontaneous vaginal deliveries (Byrd 2005). There is considerable variation in the number of reported rates of perineal trauma between countries, partly due to differences in definitions and reporting practices (Byrd 2005), and studies also show that the extent of perineal trauma often is underestimated (Andrews 2006; Groom 2002). Studies with restrictive use of episiotomy report rates of perineal trauma that require suturing between 44% and 79% (Dahlen 2007; Soong 2005), and a recent Cochrane Review found no evidence to support the routine use of episiotomy (Jiang 2017). Higher rates of perineal injury are consistently noted in first vaginal births and with instrumental birth (Christianson 2003).

Morbidity associated with perineal trauma

Perineal trauma is associated with significant short- and long-term morbidity. Perineal pain is reported to be most severe in the immediate postnatal period (Macarthur 2004). However, discomfort continues for up to two weeks postpartum in about 30% of women and 7% report pain at three months (McCandlish 1998). Women who sustain obstetric anal sphincter injury are shown to report more pain seven weeks after birth than those with lesser degree of perineal trauma (Andrews 2007). Women giving birth with an intact perineum, however, report pain less frequently at one, seven and 45 days postpartum (Macarthur 2004). Perineal pain can be intense and often requires pain relief (Andrews 2007; Hedayati 2003). Maternal morbidity associated with perineal trauma also includes dyspareunia (Barrett 2000) and fecal incontinence (Reid 2014; Sultan 2002) and can lead to major physical problems, psychological and social problems, and affect the woman's ability to care for her new baby and cope with the daily tasks of motherhood (Sleep 1991). Urinary problems following childbirth have been reported to be more prevalent in association with perineal trauma (Boyles 2009). Anal sphincter injury can be occult or wrongly classified as a minor degree of perineal tear (Andrews 2006). Women with an intact perineum are more likely to resume intercourse earlier, report less pain with first and subsequent sexual intercourse, report greater satisfaction with sexual experience and report greater sexual sensation and likelihood of orgasm at six months postpartum (Radestad 2008; Williams 2007).

Generally, the degree of morbidity is directly related to the degree of the perineal injury sustained, that is, first- and second-degree perineal trauma causing less severe morbidity than third- and fourth-degree tears (Radestad 2008; Williams 2007). Anal sphincter or mucosal injuries are identified following 3% to 5% of all vaginal births (Ekeus 2008). Around 8% of women experience incontinence of stool and 45% suffer involuntary escape of flatus following anal sphincter injury (Eason 2002). The type of suture material used (Kettle 2002), skills of the operator and technique of suturing influence morbidity experienced by women (Fernando 2006; Sultan 2002). If immediate repair is adequate, the likelihood of better long-term outcomes are improved, both when it comes to symptoms and quality of life (QoL) (Reid 2014).

Factors associated with perineal trauma

Numerous factors have been suggested as potential determinants of perineal trauma. Some determinants of perineal trauma appear to be present before pregnancy and may be intrinsic to the pregnant woman (Klein 1997). It is uncertain which role demographic factors and nutrition in the years before and during pregnancy play in the occurrence of perineal trauma (Klein 1997). Ethnicity is a factor that may affect perineal trauma and association has been found between Asian ethnicity and severe perineal trauma (Dahlen 2007b; Goldberg 2003). A familial risk of obstetric anal sphincter injuries has also been suggested (Baghestan 2013), maybe with contribution of both maternal and paternal factors.

Nulliparity, maternal age greater than 30 years, a large baby (both weight and head circumference), a prolonged second stage and malposition increase the risk for perineal trauma (Andrews 2006; Baghestan 2010; Fitzpatrick 2001; Mayerhofer 2002; Soong 2005). Restrictive use of episiotomy is associated with less perineal trauma (Jiang 2017), as is the use of vacuum extraction for instrumental birth as opposed to forceps (Fitzpatrick 2003; O'Mahony 2010). Antenatal digital perineal massage from approximately 35 weeks' gestation reduces the incidence of perineal trauma requiring suturing (Beckmann 2006). Maternal upright position in the second stage of labour, for women without epidural anaesthesia, results in a reduction in assisted deliveries and episiotomy usage, no difference regarding severe perineal trauma and, on the other hand, an increased risk of blood loss greater than

500 mL (Gupta 2012). Physical inactivity before pregnancy may represent an independent risk factor for third- and fourth-degree tears (Voldner 2009). Giving birth in alternative birth settings and planned home birth have been shown to be associated with a reduced prevalence of episiotomy (Hodnett 2010; Radestad 2008), as has the midwifery model of care (Hatem 2008). Planned home birth has also been shown to be associated with a lower prevalence of sphincter rupture (Radestad 2008) and a low prevalence of perineal trauma has been found among women opting for home birth (Edqvist 2016).

Retrospective studies on water birth report fewer episiotomies, an overall decrease in perineal trauma and no significant difference in third- and fourth-degree tears (Bodner 2002; Otigbah 2000) and an observational study found fewer episiotomies as well as third- and fourth-degree tears in the water-birth group (Geissbuehler 2004). However, a Cochrane Review did not find any association between immersion in water during labour/water birth and perineal trauma (Cluett 2009).

Trauma to the birth genital tract does not seem affected by active directed pushing versus spontaneous pushing (Bloom 2006; Schaffer 2005). A recent Cochrane Review (Lemos 2015) concludes that due to insufficient evidence, women's preferences and clinical situations should guide decisions concerning pushing/bearing down methods, regardless of use of epidural analgesia. Retrospective studies on the occurrence of perineal trauma suggest an association between augmentation of labour and trauma (Jandér 2001). One observational study found a higher prevalence of anal sphincter injuries when oxytocin was used in the second stage of labour during spontaneous deliveries of normal-sized infants (Rygh 2014). An association has also been found between accoucheur type (Bodner-Adler 2004) and perineal trauma.

Description of the intervention

Awareness of morbidity following perineal trauma has led to the search for different interventions to be used during the second stage of labour to reduce perineal trauma. These interventions include the use of perineal massage, warm and cold compresses, and perineal-management techniques (Albers 2005; Dahlen 2007; Myrfield 1997; Pirhonen 1998; Shirvani 2014a; Stamp 2001). Different massage techniques are performed using different lubricants; different oils, jelly, Vaseline or wax (Araujo 2008; Harlev 2013; Geranmayeh 2012). Perineal management techniques, termed as guiding or support techniques, are believed to reduce perineal trauma (Myrfield 1997; Pirhonen 1998). A wide variety of techniques are practiced, among them the flexion technique and Ritgen's manoeuvre. Each technique claims to reduce perineal trauma by reducing the presenting diameter of the fetal head through the woman's vaginal opening (Myrfield 1997). The flexion technique involves the maintenance of flexion of the emerging fetal head, by exerting pressure on the emerging occiput in a downwards direction towards the perineum, preventing extension until crowning; and the guarding of the perineum by placing a hand against the perineum to support this structure (Mayerhofer 2002; Myrfield 1997). In Ritgen's manoeuvre the fetal chin is reached for between the anus and coccyx and pulled interiorly, while using the fingers of the other hand on the fetal occiput to control speed of birth and keep flexion of the fetal head (Cunningham 2005; Jönsson 2008). Ritgen's manoeuvre is called 'modified' (Jönsson 2008) when performed during a contraction, rather than between contractions as originally recommended (Cunningham 2008). A recent systematic review, including both randomised and non randomised studies (Bulchandani 2015) concludes that current evidence regarding perineal techniques are insufficient to drive change of practice.

How the intervention might work

Support techniques slow down the birth of the head, allowing the perineum to stretch slowly, thus reducing perineal trauma (Downe 2003). This is why birth attendants, together with the use of support techniques, commonly ask women to breathe instead of push as the head is delivered. The birth of the infant's shoulders is usually assisted by downward traction first, to free the anterior shoulder, and subsequently the posterior shoulder is delivered by guiding the baby in an upward curve (Downe 2003). An alternative technique to the usual practice of birth of the anterior shoulder first is a primary delivery of the posterior shoulder (Aabakke 2016).

Why it is important to do this review

It has been suggested that both the flexion technique and Ritgen's manoeuvre act against the normal mechanism of labour in which the baby naturally angles itself in the most appropriate attitude to pass through the birth canal (Myrfield 1997). This poses the question of which support and other perineal techniques are beneficial for preventing perineal trauma. In this review we update the initial version of this review (Aasheim 2011), which was the first published systematic review comparing different perineal support and other techniques used during the second stage of labour for reducing perineal trauma.

OBJECTIVES

The objective of this updated review was to assess the effect of perineal techniques during the second stage of labour on the incidence and morbidity associated with perineal trauma.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published and unpublished randomised and quasi-randomised controlled trials evaluating any described perineal techniques during the second stage of labour. Trials using a cross-over design were not eligible for inclusion in this review. We included abstracts when enough information was provided to assess eligibility. Where further information was required, we contacted trial authors.

Types of participants

Pregnant women planning to have a spontaneous vaginal birth (after 36 weeks of pregnancy, pregnant with single fetus, cephalic presentation).

Types of interventions

Any perineal techniques, for example: perineal massage, flexion technique, Ritgen's manoeuvre, warm compresses, hands-on or hands-poised, etc. all performed during the second stage of labour.

Types of outcome measures

Primary outcomes

- Intact perineum
- Perineal trauma not requiring suturing
- Perineal trauma requiring suturing
- First-degree perineal tear
- Second-degree perineal tear
- Third- and fourth-degree tears
- Incidence of episiotomy

Secondary outcomes

- Third-degree perineal tear
- Fourth-degree perineal tear
- Length of second stage
- For the newborn: Apgar less than seven at five minutes
- Admission to special care baby unit
- Perineal pain postpartum
- Perineal pain at three and at six months after birth
- Breastfeeding: initiation
- Breastfeeding: at three months and at six months after birth
- Women's satisfaction (as defined by trial authors)
- Morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia)

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 (26 September 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 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 Cochrane Pregnancy and Childbirth in the Cochrane Library and select the '***Specialized Register***' section from the options on the left side of the screen.
Briefly, Cochrane Pregnancy and Childbirth's Trials Register is maintained by their Information Specialist and contains trials identified from:

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

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set, which has been fully accounted for in the relevant review sections (Included studies; Excluded studies; Studies awaiting classification; Ongoing studies).
(See: Aasheim 2011 for additional author searches carried out in the previous version of the review. We did not carry out additional searches for this update.)

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 Aasheim 2011.

For this update, we used the following methods - these are based on a standard methods template used by Cochrane Pregnancy and Childbirth.

Selection of studies

Two review authors V Aasheim (VAA) and ABV Nilsen (ABVN), independently assessed for inclusion all the potential studies identified as a result of the search strategy. We resolved any disagreement through discussion or, if required, we consulted the third review author M Lukasse (ML).

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors (ML and Liv Merete Reinar (LMR)) extracted the data using the agreed form. Data were also extracted by research assistant Anna Cuthbert (AC) and the studies in Persian were extracted by Bita Mesgarpour (BM). We resolved discrepancies through discussion in the team. We entered data into Review Manager 5 (RevMan 5) software (RevMan 2014) and checked them 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

Review authors (ML, LMR, AC or BM) independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011a). Any disagreement was resolved by discussion or by involving all the review team (ML, LMR, ABVN and VAA).

(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 we undertook.

We assessed methods as:

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

(5) Selective reporting (checking for reporting bias)

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- low risk of bias (where it is clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review have been reported);
- high risk of bias (where not all the study's pre-specified outcomes have been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest 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 for 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 (comparisons 1 to 4).

- Intact perineum
- Perineal trauma requiring suturing
- First-degree perineal tear
- Second-degree perineal tear
- Third-degree or fourth-degree perineal tear
- Incidence of episiotomy

We used the GRADEpro Guideline Development Tool (GRADEpro GDT) to import data from RevMan 5 (RevMan 2014) in order to create Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3; and Summary of findings 4. 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 (CIs).

Continuous data

We did not identify any continuous outcome data for inclusion in this update. In future updates, we will use mean difference if outcomes were measured in the same way between trials. We will use 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 or standard errors using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Section 16.3.4 or 16.3.6 as appropriate; Higgins 2011b) using an estimate of the intra cluster 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.

Other unit of analysis issue

Trials with multiple treatment arms

We included trials with multiple treatment arms; the interventions were analysed in different comparisons (Albers 2005; Fahami 2012; Sohrabi 2012), or were combined to create one comparison group (Terre-Rull 2014). In future updates, if we identify more trials with multiple arms, which require inclusion in the same comparison, we will split the control group to form independent comparisons and avoid double counting as described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Section 16.5.4; Higgins 2011b).

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 using sensitivity analysis.
For all outcomes, analyses were carried out, 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 Tau², I² (Higgins 2003) and Chi² (Deeks 2011) statistics. We regarded heterogeneity as substantial if I² was greater than 50% and either Tau² was greater than zero, or there was a low P value (less than 0.10) in the Chi² test for heterogeneity. If we identified substantial heterogeneity (above 50%), we planned to explore it by pre-specified subgroup analysis.

Assessment of reporting biases

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

Data synthesis

We carried out statistical analysis using the RevMan 5 software (RevMan 2014). Because there was clinical heterogeneity sufficient to expect that the underlying treatment effect differed between trials, and substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary where an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. When the average treatment effect was not clinically meaningful, we did not combine trials. The results were presented as the average treatment effect (RR) with 95% CI, and the estimates of Tau² and I².

Subgroup analysis and investigation of heterogeneity

If we, in future reviews, identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.
There were insufficient data in each analysis to carry out our pre-specified subgroup analyses. However, in future updates of this review, as more data become available, we will carry out the following subgroup analyses.

- Nulliparous women versus multiparous women
- Birthweight: less than 4000 g versus 4000 g or more
- Maternal age: less than 35 years versus 35 years or more
- Ethnicity: women from one ethnic group versus women from another ethnic group

We will use the following outcomes in subgroup analysis.

- Intact perineum
- Perineal trauma requiring suturing
- Third- or fourth-degree perineal tear

For random-effects meta-analyses using methods other than inverse variance, we will assess differences between subgroups by inspection of the subgroups' CIs; non-overlapping CIs indicate a statistically significant difference in treatment effect between the subgroups.

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 poor-quality studies being excluded from the analyses in order to assess whether this makes any difference to the overall result. We also planned to carry out sensitivity analysis to examine the effect of the randomisation unit where we include cluster-RCTs along with individually-randomised trials. It was not possible to carry out our planned sensitivity analysis because mostly the included trials were at moderate to high risk of bias, and we did not identify any cluster-RCTs for inclusion in this update. In future updates, we will carry out planned sensitivity analyses, where appropriate.

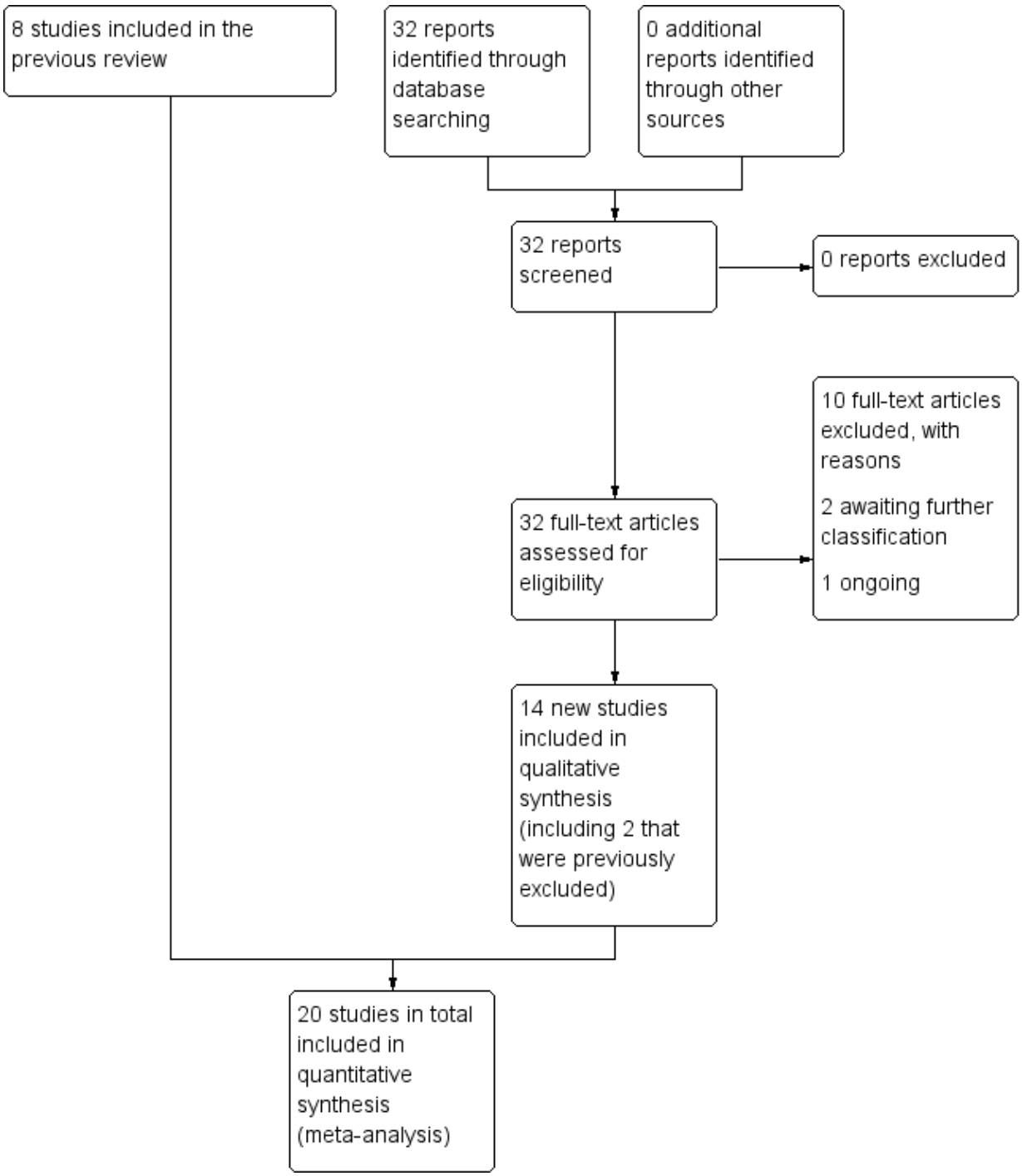
RESULTS

Description of studies

Results of the search

See: Figure 1

Figure 1. Study flow diagram



Our 2011 search identified 17 citations related to 12 trials. They were identified by the Information Specialist and we found no additional trials by the MEDLINE and CINAHL search. We found one additional unpublished study from a reference list (Musgrove 1997). Of the identified studies, we included data from eight trials involving 11,651 randomised women; two further trials (Most 2008; Musgrove 1997) were otherwise eligible for inclusion but did not contribute any data to the review as either relevant outcomes were not reported or were reported in a way that did not allow us to include them in the review. As they do not contribute to the results of the review, these two studies are not discussed in the effects of interventions sections below.

The updated search in September 2016 identified a further 32 citations relating to 23 trials. We included 12 new trials, and two previously excluded trials, so this review now involves 15,181 randomised women in 22 studies. (See Characteristics of included studies.) Overall, we excluded 10 trials.

Two trials are awaiting further assessment pending further information from trial authors (Taavoni 2015; Velev 2013) (see Characteristics of studies awaiting classification). One study is ongoing (NCT02588508).

Included studies

Two trials did not contribute data to the review; Most 2008 examined a gel lubricant and Musgrove 1997 warm packs applied to the perineum in the second stage of labour. Neither study reported outcome data that we were able to include in this review update.

We included data from 20 trials with data involving 15,181 randomised women (Aabakke 2016; Albers 2005; Araujo 2008; Attarha 2009; Dahlen 2007; De Costa 2006; Fahami 2012; Foroughipour 2011; Galledar 2010; Geranmayeh 2012; Harlev 2013; Jönsson 2008; Lavesson 2014; Mayerhofer 2002; McCandlish 1998; Rezaei 2014; Shirvani 2014a; Sohrabi 2012; Stamp 2001; Terre-Rull 2014). For more details *see* Characteristics of included studies.

The studies varied in size. Aabakke 2016 included 650 women, Albers 2005 1211 women, Araujo 2008 106 women, Attarha 2009 204 women, Dahlen 2007 717 women, De Costa 2006 70 women, Fahami 2012 99 women, Foroughipour 2011 100 women, Galledar 2010 141 women, Geranmayeh 2012 82 women, Harlev 2013 164 women, Jönsson 2008 1575 women, Lavesson 2014 1148 women, Mayerhofer 2002 1161 women, McCandlish 1998 5471 women, Rezaei 2014 600 women, Shirvani 2014a 64 women, Sohrabi 2012 120 women, Stamp 2001 1340 women and Terre-Rull 2014 198 women.

Four studies included three treatment arms (Albers 2005; Fahami 2012; Sohrabi 2012; Terre-Rull 2014); three of these studies (Albers 2005; Fahami 2012; Sohrabi 2012) were analysed in different comparisons, and one was combined to create one comparison group (Terre-Rull 2014).

Settings

The studies contributing data were conducted in hospital settings in the following countries: Denmark (Aabakke 2016); Iran (Attarha 2009; Fahami 2012; Foroughipour 2011; Galledar 2010; Geranmayeh 2012; Rezaei 2014; Shirvani 2014a; Sohrabi 2012); USA (Albers 2005); Australia (Dahlen 2007; Stamp 2001); Brazil (Araujo 2008; De Costa 2006); Sweden (Jönsson 2008; Lavesson 2014); Austria (Mayerhofer 2002); Spain (Terre-Rull 2014); Israel (Harlev 2013) and UK (McCandlish 1998).

Participants

The participants in the studies contributing data to the review were nulliparous and multiparous women expecting a vaginal birth, singleton vertex presentation at term, with no medical complications. Thirteen studies had nulliparous as an inclusion criteria (Aabakke 2016; Araujo 2008; Attarha 2009; Dahlen 2007; De Costa 2006; Fahami 2012; Foroughipour 2011; Galledar 2010; Geranmayeh 2012; Jönsson 2008; Rezaei 2014; Shirvani 2014a; Sohrabi 2012).

Interventions

Various interventions/perineal management techniques are described in the included studies. One study compared birth of the anterior versus the posterior shoulder first (Aabakke 2016). One study compared warm compresses held to the mother's perineum and external genitalia versus hands-off, and perineal massage inside the woman's vagina versus hands-off (Albers 2005). One study compared warm compresses versus Ritgen's manoeuvre and standard care, and perineal massage versus Ritgen's manoeuvre and standard care (Sohrabi 2012). One study compared warm packs on the perineum versus not having warm packs (Dahlen 2007). One study compared the use of moist and dry heat to the perineum versus control (Terre-Rull 2014). Five studies compared hands off versus hands on the perineum (De Costa 2006; Foroughipour 2011; Mayerhofer 2002; McCandlish 1998; Rezaei 2014). Seven studies compared massage of the perineum with no massage or routine care (Albers 2005; Attarha 2009; Fahami 2012; Galledar 2010; Geranmayeh 2012; Sohrabi 2012; Stamp 2001). Ritgen's manoeuvre was included as part of routine care in Sohrabi 2012. One study compared a modified Ritgen's manoeuvre with standard practice (with one hand to apply pressure on the perineum, and the other hand on the fetal occiput) (Jönsson 2008) and one study compared Ritgen's manoeuvre with no touch of the perineum (Fahami 2012). One study compared the use of a perineal protection device versus perineal support (Lavesson 2014), one study compared the use of enriched oil versus liquid wax (Harlev 2013), one study compared cold compresses towards the perineum versus no cold compresses (Shirvani 2014a) and one study compared application of petroleum jelly to the perineum with no application of jelly (Araujo 2008). See Characteristics of included studies for a more detailed description of the experimental and comparison interventions.

Outcomes

The included trials had various primary outcomes. Aabakke 2016 had any perineal trauma requiring suturing as a primary outcome. In Albers 2005 the primary outcome was an intact perineum (defined as no tissue separation). In Araujo 2008 the primary outcome was frequency of perineal trauma, intact perineum or trauma, degree of trauma (first or second) and location (posterior or anterior or both). Attarha 2009 had incidence of episiotomy, intact perineum, perineal tear as primary outcomes. Dahlen 2007 had suturing after birth as the primary outcome (defined as perineal trauma greater than first-degree tear, any tear that was bleeding and any tear that did not fall into anatomical apposition). In De Costa 2006 the primary outcome was the degree of perineal trauma and in Fahami 2012 the primary outcome was perineal laceration and perineal pain. In Foroughipour 2011 the outcomes were perineal traumas, need for episiotomy, severity of perineal tears, haemorrhage, perineal pain and haematoma, and birth outcome including the duration of each labour stage, amount of haemorrhage in first, second, third and fourth stage of labour, and neonatal Apgar score. Galledar 2010 had duration of the second stage of labour, intact perineum, perineal tear, episiotomy, degree of perineal tear and intensity of perineal pain as outcomes. Geranmayeh 2012 had oxytocin consumption during labour, the length of the second stage of labour, nuchal cord, neonate's weight, perineal tears and episiotomy, Apgar scores and neonatal complications as primary outcomes. Harlev 2013 had birthweight, perineal tears and episiotomy. In Jönsson 2008 outcomes were the rate of third- to fourth-degree perineal ruptures, including external anal sphincter. In Lavesson 2014 perineal tears and incidence of episiotomy were primary outcomes. In the Mayerhofer 2002 study the primary outcome was perineal trauma (degree and episiotomy) and in the McCandlish 1998 study it was perineal pain 10 days postpartum. In Rezaei 2014 the outcomes were perineal trauma, in Shirvani 2014a the duration of second and fourth stage, fetal heart rate, Apgar score, episiotomy and laceration; Sohrabi 2012 had severity and degree of perineal ruptures, the rate of lacerations in the anterior perineal region and the amount of stitches required for repair as outcomes. In Stamp 2001, the primary outcomes were: rates of intact perineum; episiotomy; and first-, second-, third- and fourth-degree tear and finally Terre-Rull 2014 had perineal trauma and Apgar score as outcomes.

One study (Shirvani 2014a) described perineal tears as degree one. Three studies (Araujo 2008; Galledar 2010; Geranmayeh 2012) described perineal tears (non sphincter) as degrees one and two; one study (Aabakke 2016) described perineal tears as any perineal trauma, any anterior or posterior trauma. Four studies described perineal tears as degrees one, two and three (Foroughipour 2011; Harlev 2013; Mayerhofer 2002; Terre-Rull 2014); one study (Jönsson 2008) described perineal tears as degrees three and four, one study (Lavesson 2014) described degrees one and two, and anal sphincter rupture; and the other studies described perineal tears as degrees one, two, three and four (Albers 2005; Attarha 2009; Dahlen 2007; De Costa 2006; Fahami 2012; McCandlish 1998; Rezaei 2014; Sohrabi 2012; Stamp 2001).

Excluded studies

We excluded 10 trials (Ashwal 2016; Barbieri 2013; Behmanesh 2009; Corton 2012; Demirel 2015; Hassaballa 2015; Karacam 2012; Low 2013; Schaub 2008; Taavoni 2013).

Eight trials were excluded because they examined interventions that took place in the first stage of labour (Ashwal 2016; Barbieri 2013; Behmanesh 2009; Demirel 2015; Hassaballa 2015; Karacam 2012; Schaub 2008; Taavoni 2013). One trial (Low 2013) looked at an intervention in pregnancy and one trial (Corton 2012) looked at the use of stirrups, which is not a relevant intervention for this review of perineal techniques. (For further information see Characteristics of excluded studies.)

Risk of bias in included studies

We have provided details for each trial in Characteristics of included studies. We have presented a summary of the methodological quality for each individual study in Figure 2 and a summary of methodological quality across all studies in Figure 3.

Figure 2. Methodological quality summary: review authors' judgements about each methodological quality item for each included study

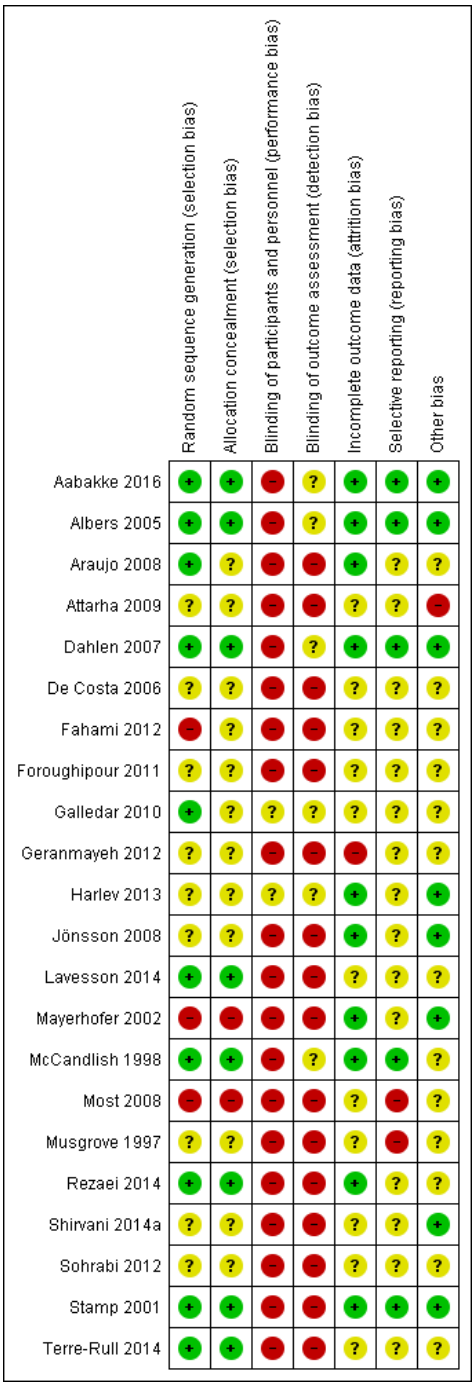
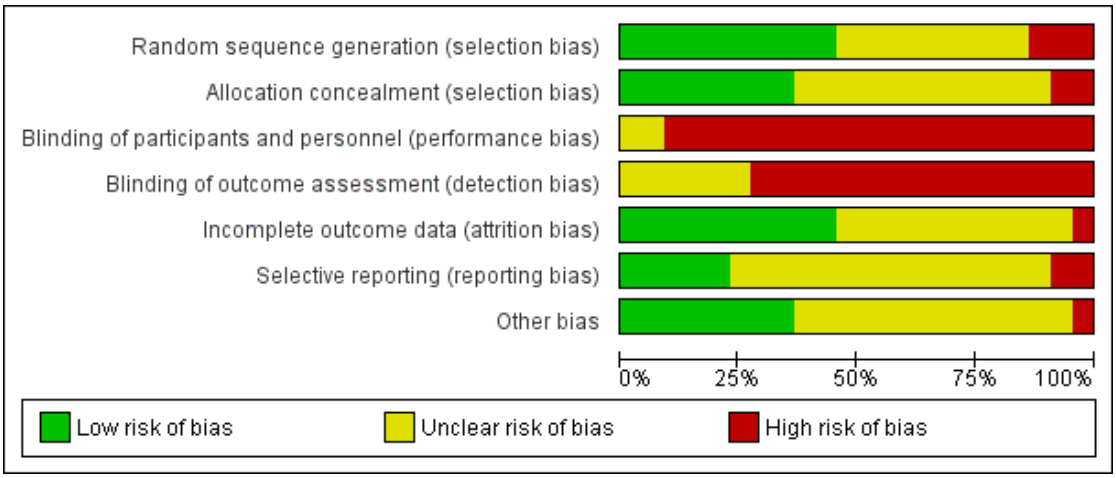


Figure 3. Methodological quality graph: review authors' judgements about each methodological quality item presented as percentages across all included studies



Allocation

We assessed random sequence generation as 'low risk of bias' in 10 included studies (Aabakke 2016; Albers 2005; Araujo 2008; Dahlen 2007; Galledar 2010; Lavesson 2014; McCandlish 1998; Rezaei 2014; Stamp 2001; Terre-Rull 2014). Two studies contributing data were assessed as high risk of bias for sequence generation: Fahami 2012 used a randomly-generated number table but the selection was performed by a researcher pointing at the table of numbers with their eyes closed, and Mayerhofer 2002 randomised according to date of birth. All the remaining studies were assessed as unclear risk of bias in this domain.

We assessed allocation concealment as 'low risk of bias' in eight of 20 included studies contributing data (Aabakke 2016; Albers 2005; Dahlen 2007; Lavesson 2014; McCandlish 1998; Rezaei 2014; Stamp 2001; Terre-Rull 2014). The only study that was assessed as having high risk of bias on this criteria was Mayerhofer 2002, where women were randomised according to date of birth (even or odd days). The others were assessed as having an unclear risk of bias (Araujo 2008; Attarha 2009; De Costa 2006; Fahami 2012; Foroughipour 2011; Galledar 2010; Geranmayeh 2012; Harlev 2013; Jönsson 2008; Shirvani 2014a; Sohrabi 2012).

For the two included studies that did not contribute data, Most 2008 was a quasi-randomised trial with allocation by hospital number and we assessed this as high risk of bias for sequence generation and allocation concealment, while the other (Musgrove 1997) was assessed as unclear for both of these domains.

Blinding

Performance bias

Given the nature of the intervention, it was not possible to blind the intervention for the clinician/the midwife performing the technique. It was also impossible to blind women to the allocated group therefore we assessed most studies to be at high risk of performance bias. In Aabakke 2016 the randomisation envelope was opened by the midwife when the women entered the second stage of labour and was destroyed thereafter. The allocation was only shown to the midwife and the assistant, and if necessary the obstetrician, and the participants might have been blinded. Some women may have been disappointed with the allocation group, thus affecting the results. Also, some women may have been convinced that the technique they received was best, thus causing a 'placebo' effect. In McCandlish 1998, women were not told which group they ended up in, unless the women asked for that information. When a women was informed, it was noted in the data form. About a third of the women in each group were informed of their allocation.

We assessed two studies to be at unclear risk of performance bias. In Harlev 2013 both the oils for the intervention were contained in similar bottles differentiated only by a number on the bottle and the midwives and the physicians who delivered the woman were

blinded to the oil type. It is possible that this blinding was broken. It was unclear Galledar 2010's report if blinding was attempted.

Detection bias

The outcome assessors could have been blinded to the perineal technique. In Dahlen 2007, the outcome assessor was blinded and the midwives were asked not to discuss allocation. As this method of blinding could be easily broken, this study was assessed to be at unclear risk of detection bias. In most of the included studies there was some degree of blinding. Five other studies were at unclear risk of detection bias; Aabakke 2016 used a blinded midwife to assess the perineum but other outcomes were recorded by unblinded midwives; Albers 2005 used the midwife caring for the woman as outcome assessor but 25% of births were attended by an independent observing midwife; another study attempted to blind staff to allocation but is not explicit in whether women were blinded which could have broken blinding of staff (McCandlish 1998); it was unclear in two studies whether assessors were blinded (Galledar 2010; Harlev 2013). The remaining studies were at high risk of detection bias; Araujo 2008, Fahami 2012, Jönsson 2008; Lavesson 2014; Mayerhofer 2002; Rezaei 2014; Shirvani 2014a; Terre-Rull 2014 did not blind outcome assessors; Attarha 2009, De Costa 2006, Foroughipour 2011, Geranmayeh 2012; Sohrabi 2012 did not give enough information to allow assessment of this domain and it was assumed blinding was not attempted; and Stamp 2001 used an independent assessor when available though it is not clear how often this occurred.

For the two included studies that did not contribute data, we assessed both as high risk of performance and detection bias due to lack of blinding (Most 2008; Musgrove 1997).

Incomplete outcome data

We assessed incomplete outcome data as unclear in nine of 20 studies contributing data; Attarha 2009; De Costa 2006; Fahami 2012; Foroughipour 2011; Galledar 2010; Lavesson 2014; Shirvani 2014a; Sohrabi 2012; Terre-Rull 2014. We assessed 10 studies as low risk of attrition bias (Aabakke 2016; Albers 2005; Araujo 2008; Dahlen 2007; Harlev 2013; Jönsson 2008; Mayerhofer 2002; McCandlish 1998; Rezaei 2014; Stamp 2001). The only study that we assessed as having high risk of attrition bias was Geranmayeh 2012.

For the two included studies that did not contribute data, we assessed attrition bias as unclear in both cases (Most 2008; Musgrove 1997).

Selective reporting

From the 20 studies contributing data to this review, we assessed five studies (Aabakke 2016; Albers 2005; Dahlen 2007; McCandlish 1998; Stamp 2001) as being free of selective reporting bias (low risk of bias). The others we assessed as having an unclear risk of bias on this domain (Araujo 2008; Attarha 2009; De Costa 2006; Fahami 2012; Foroughipour 2011; Galledar 2010; Geranmayeh 2012; Harlev 2013; Jönsson 2008; Lavesson 2014; Mayerhofer 2002; Rezaei 2014; Shirvani 2014a; Sohrabi 2012; Terre-Rull 2014).

For the two included studies that did not contribute data, due to inconsistencies in data and selective reporting, we assessed both Most 2008 and Musgrove 1997 as high risk of bias for this domain.

Other potential sources of bias

From the 20 studies contributing data to this review, we considered eight studies to be free of problems that could put them at risk of bias (Aabakke 2016; Albers 2005; Dahlen 2007; Harlev 2013; Jönsson 2008; Mayerhofer 2002; Shirvani 2014a; Stamp 2001). We considered the risk of other bias to be 'unclear' for 11 studies (Araujo 2008; De Costa 2006; Fahami 2012; Foroughipour 2011; Galledar 2010; Geranmayeh 2012; Lavesson 2014; McCandlish 1998; Rezaei 2014; Sohrabi 2012; Terre-Rull 2014) and one study (Attarha 2009) to be at high risk of bias. We have described the sources of other bias under Characteristics of included studies.

For the two included studies that did not contribute data, we assessed other sources of bias for Most 2008 and Musgrove 1997 as unclear. In both cases results were published in brief abstracts.

Effects of interventions

See: **Summary of findings for the main comparison** Hands off (or poised) compared to hands on for reducing perineal trauma; **Summary of findings 2** Warm compresses compared to control (hands off or no warm compress) for reducing perineal trauma; **Summary of findings 3** Massage compared to control (hands off or care as usual) for reducing perineal trauma; **Summary of findings 4** Ritgen's manoeuvre compared to standard care for reducing perineal trauma

We included data for the following comparisons:

- hands off (or poised) versus hands on (five studies);
- warm compresses versus control (hands off or no warm compress) (four studies);
- massage versus control (hands off/care as usual) (seven studies);
- Ritgen's manoeuvre versus standard care (two studies);
- primary delivery of posterior versus anterior shoulder (one study);
- perineal protection device versus perineal support (one study);
- enriched oil versus liquid wax (one study);
- cold compresses versus control (one study).

As many of the studies reported third- and fourth-degree tears together, we chose to combine third- and fourth-degree tears as one outcome for the meta-analyses, except for Analysis 7.4.

1. Hands off (or poised) versus hands on

Five studies compared hands off versus hands on the perineum (De Costa 2006; Foroughipour 2011; Mayerhofer 2002; McCandlish 1998; Rezaei 2014). One of the studies was small and did not give any estimable effect (De Costa 2006).

Primary outcomes

Intact perineum

When measuring the incidence of intact perineum, an outcome reported in two studies (Mayerhofer 2002; McCandlish 1998), the incidence was similar in each group (average risk ratio (RR) 1.03, 95% confidence interval (CI) 0.95 to 1.12, $Tau^2 = 0.00$, $I^2 = 37\%$, two studies, 6547 women); see Analysis 1.1. We graded this evidence as moderate quality.

Perineal trauma not requiring suturing

The included studies under this comparison did not report on this outcome.

Perineal trauma requiring suturing

The included studies under this comparison did not report on this outcome.

First-degree perineal tear

When measuring the incidence of first-degree perineal tear, an outcome reported in two studies (Foroughipour 2011; Rezaei 2014), the treatment effect was not clear though it appeared to favour 'hands on' (average RR 1.32, 95% CI 0.99 to 1.77, two studies, 700 women); see Analysis 1.2. We graded this evidence as low quality.

Second-degree perineal tear

When measuring the incidence of second-degree perineal tear, an outcome reported in two studies (Foroughipour 2011; Rezaei 2014), the treatment effect was not clear (average RR 0.77, 95% CI 0.47 to 1.28, two studies, 700 women); see analyses Analysis 1.3. We graded this evidence as low quality.

Third-degree or fourth-degree perineal tear

Five studies reported the incidence of third-degree and fourth-degree perineal tear (De Costa 2006; Foroughipour 2011; Mayerhofer 2002; McCandlish 1998; Rezaei 2014). One study reported only on third-degree tears (Mayerhofer 2002), and one study (McCandlish 1998) reported third- and fourth-degree tears together. The average treatment effect was not clear (average RR 0.68, 95% CI 0.21 to 2.26, $Tau^2 = 0.92$, $I^2 = 72\%$, five studies, 7317 women); however, the substantial heterogeneity means that the treatment effects in any individual study could be in either direction; see Analysis 1.4. We graded this evidence as very low quality.

Incidence of episiotomy

Four studies (Foroughipour 2011; Mayerhofer 2002; McCandlish 1998; Rezaei 2014) measured the incidence of episiotomy. The average the treatment effect was not clear (RR 0.58, 95% CI 0.43 to 0.79, $Tau^2 = 0.07$, $I^2 = 74\%$, four studies, 7247 women), but there was considerable unexplained heterogeneity between the four included studies (Foroughipour 2011; Mayerhofer 2002, McCandlish 1998; Rezaei 2014); see Analysis 1.5. We graded this evidence as low quality. Women receiving hands off (or poised) as opposed to hands on treatment were, on average, less likely to experience episiotomy; see Analysis 1.5, though the magnitude of the effect is not clear.

Secondary outcomes

Third-degree tear

Four studies reported third-degree tears alone (De Costa 2006; Foroughipour 2011; Mayerhofer 2002; Rezaei 2014) but found no clear difference between the two groups (average RR 0.49, 95% CI 0.09 to 2.73, $Tau^2 = 1.37$, $I^2 = 59\%$, four studies, 1846 women); see Analysis 1.6. Heterogeneity is high for this outcome.

Fourth-degree tear

Only one small study (De Costa 2006) reported fourth-degree tears separately and reported zero in both groups (Analysis 1.7).
The included studies under this comparison did not report data on any of the review's secondary outcomes, these are: length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

2. Warm compresses versus control (hands off or no warm compress)

Four studies (Albers 2005; Dahlen 2007; Sohrabi 2012; Terre-Rull 2014) compared warm compresses versus hands off or no warm compress.

Primary outcomes

Intact perineum

All four studies reported on intact perineum but there was no clear difference between the groups. Warm compresses did not result in a treatment effect when the presence of intact perineum was used as an outcome (average RR 1.02, 95% CI 0.85 to 1.21, four studies, 1799 women); see Analysis 2.1. We graded this evidence as moderate quality.

Perineal trauma not requiring suturing

One study (Sohrabi 2012) reported similar rates of perineal trauma not requiring suturing in the two groups (RR 0.82, 95% CI 0.48 to 1.42, one study, 76 women); see Analysis 2.2.

Perineal trauma requiring suturing

One study (Sohrabi 2012) reported similar rates of perineal trauma requiring suturing in the two groups (RR 1.14, 95% CI 0.79 to 1.66, one study, 76 women); see Analysis 2.3. We graded this evidence as very low quality.

First-degree perineal tear

Two studies (Sohrabi 2012; Terre-Rull 2014) reported this outcome. The evidence was graded as very low quality and it is uncertain whether warm compress is likely to increase or reduce the likelihood of having a first-degree tear (average RR 1.19, 95% CI 0.38 to 3.79, $Tau^2 = 1.37$, $I^2 = 88\%$, two studies, 274 women); see Analysis 2.4. We observed substantial heterogeneity in this analysis so these results should be interpreted with caution.

Second-degree perineal tear

When measuring the incidence of second-degree perineal tear, an outcome reported in two studies (Sohrabi 2012; Terre-Rull 2014), there was no clear difference between the groups (average RR 0.95, 95% CI 0.58 to 1.56, two studies, 274 women); see Analysis 2.5. We graded this evidence as very low quality.

Third-degree or fourth-degree perineal tear

Four studies reported on third-or fourth-degree perineal tear (Albers 2005; Dahlen 2007; Sohrabi 2012; Terre-Rull 2014). Women receiving warm compresses as opposed to hands off or no warm compresses were, on average, less likely to experience third- or fourth-degree perineal tear. The use of warm compresses led to a reduction in the average number of third- and fourth-degree tears (average RR 0.46, 95% CI 0.27 to 0.79, four studies, 1799 women); see Analysis 2.6. We graded this evidence as moderate quality.

Incidence of episiotomy

Four studies reported on episiotomy (Albers 2005; Dahlen 2007; Sohrabi 2012; Terre-Rull 2014) and there were similar rates of episiotomies (55/54) in each group (RR 0.86, 95% CI 0.60 to 1.23, four studies, 1799 women); see Analysis 2.7. No episiotomies were reported in either group in Sohrabi 2012. We graded this evidence as low quality.

Secondary outcomes

Third-degree tear

Three studies reported on third-degree tears (Albers 2005; Sohrabi 2012; Terre-Rull 2014) and found no clear difference between the treatment and control groups (average RR 0.51, 95% CI 0.04 to 7.05, $Tau^2 = 2.12$, $I^2 = 57\%$; 1082 women; three studies); see Analysis 2.8. Heterogeneity is high for this outcome and the results should be viewed with caution. Sohrabi 2012 did not report any third-degree tears. Terre-Rull 2014 used both damp and dry compresses which may have affected results.

Fourth-degree tear

Two studies (Albers 2005; Sohrabi 2012) reported fourth-degree tears but there were zero events in the Sohrabi 2012 study. The meta-analysis suggests that warm compress favours fewer fourth-degree tears but the wide confidence intervals cross the line of no effect, so this result may be due to chance (average RR 0.11, 95% CI 0.01 to 2.06, two studies, 884 women); see Analysis 2.9.

None of the included studies under this comparison reported data on any other of this review's secondary outcomes, these are: length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

3. Massage versus control (hands off or care as usual)

Seven studies (Albers 2005; Attarha 2009; Fahami 2012; Galledar 2010; Geranmayeh 2012; Sohrabi 2012; Stamp 2001) compared massage versus hands off or care as usual.

Primary outcomes

Intact perineum

This outcome was reported in six studies (Albers 2005; Attarha 2009; Galledar 2010; Geranmayeh 2012; Sohrabi 2012; Stamp

2001). Massage was associated with a higher incidence in the average number of women with intact perineum (average RR 1.74, 95% CI 1.11 to 2.73, Tau² = 0.20, I² = 83%, six studies, 2618 women); see Analysis 3.1. We graded this evidence as low quality. However, the substantial heterogeneity means that the treatment effects in any individual study could be in either direction. Two studies (Attarha 2009; Geranmayeh 2012) seem to contribute substantially to the heterogeneity by their implausibly large treatment effects. This could be caused by a number of factors, both studies were assessed as having a high risk of bias.

Perineal trauma not requiring suturing

The included studies under this comparison did not report on this outcome.

Perineal trauma requiring suturing

One study (Sohrabi 2012) reported this outcome and there were similar rates in both groups (23/21) (RR 1.10, 95% CI 0.75 to 1.61, one study, 76 women); see Analysis 3.2. We graded this evidence as very low quality.

First-degree perineal tear

When measuring the incidence of first-degree perineal tear, an outcome reported in five studies (Attarha 2009; Fahami 2012; Galledar 2010; Geranmayeh 2012; Sohrabi 2012), there was no clear difference between the groups (average RR 1.55, 95% CI 0.79 to 3.05, Tau² = 0.47, I² = 85%, five studies, 537 women); see Analysis 3.3. We graded this evidence as very low quality. However, the substantial heterogeneity means that the treatment effects in any individual study could be in either direction, and this result should be interpreted with caution.

Second-degree perineal tear

When measuring the incidence of second-degree perineal tear, an outcome reported in five studies (Attarha 2009; Fahami 2012; Galledar 2010; Geranmayeh 2012; Sohrabi 2012), there was no clear difference between the groups (average RR 1.08, 95% CI 0.55 to 2.12, Tau² = 0.32, I² = 62%, five studies, 537 women); see Analysis 3.4. We graded this evidence as very low quality. However, the substantial heterogeneity means that the treatment effects in any individual study could be in either direction.

Third-degree or fourth-degree perineal tear

The incidence of third-degree and fourth-degree perineal tear was reported in five studies (Albers 2005; Attarha 2009; Geranmayeh 2012; Sohrabi 2012; Stamp 2001). However two of the studies (Geranmayeh 2012; Sohrabi 2012) did not contribute in the analyses (zero events, effect not estimable). Women receiving warm massage as opposed to control (hands off or care as usual) were, on average, less likely to experience third- or fourth-degree perineal tears (average RR 0.49, 95% CI 0.25 to 0.94, five studies, 2477 women); see Analysis 3.5. We graded this evidence as moderate quality.

Incidence of episiotomy

When measuring the incidence of episiotomy, an outcome reported by seven studies (Albers 2005; Attarha 2009; Fahami 2012; Galledar 2010; Geranmayeh 2012; Sohrabi 2012; Stamp 2001), there was no clear difference between the groups (average RR 0.55, 95% CI 0.29 to 1.03, Tau² = 0.43, I² = 92%, seven studies, 2684 women); see Analysis 3.6. We graded this evidence as very low quality. However, the substantial heterogeneity means that the treatment effects in any individual study could be in either direction, and these results should be viewed with caution.

Secondary outcomes

Third-degree perineal tear

Five studies reported the outcome third-degree tears (Albers 2005; Attarha 2009; Geranmayeh 2012; Sohrabi 2012; Stamp 2001), and found no clear difference between the groups (RR 0.57, 95% CI 0.16 to 2.02; Tau² = 0.64, I² = 50%, five studies, 2477 women); see Analysis 3.7. However, the heterogeneity means that the treatment effects in any individual study could be in either direction. Geranmayeh 2012 and Sohrabi 2012 did not report any third-degree tears.

Fourth-degree perineal tear

The same five studies reported this outcome (Albers 2005; Attarha 2009; Geranmayeh 2012; Sohrabi 2012; Stamp 2001) but we observed three zero events in three studies (Attarha 2009; Geranmayeh 2012; Sohrabi 2012). No clear difference was found although the results appear to favour massage (RR 0.26, 95% CI 0.04 to 1.61; five studies, 2477 women); see Analysis 3.8.

None of the included studies under this comparison reported data on any other of this review's secondary outcomes, these are: length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

4 Ritgen's manoeuvre versus standard care

Two studies (involving 1489 women) evaluating Ritgen's manoeuvre met the inclusion criteria for this review (Fahami 2012; Jönsson 2008).

Primary outcomes

Intact perineum

This outcome was only reported in one small study (Fahami 2012), the treatment effect was not clearly different between the two groups (RR 0.17, 95% CI 0.02 to 1.31, one study, 66 women) and we graded this evidence as very low quality. See Analysis 4.1.

Perineal trauma not requiring suturing

Neither of the included studies under this comparison reported on this outcome.

Perineal trauma requiring suturing

Neither of the included studies under this comparison reported on this outcome.

First-degree perineal tear

When measuring the incidence of first-degree perineal tear, an outcome reported in one small study (Fahami 2012), women receiving Ritgen's manoeuvre versus standard care were less likely to experience first-degree perineal tears (RR 0.32, 95% CI 0.14 to 0.69, one study, 66 women); see Analysis 4.2. Women receiving Ritgen's manoeuvre versus standard care were, on average, less likely to experience first-degree perineal tears. We graded this evidence as very low quality.

Second-degree perineal tear

The incidence of second-degree perineal tear was reported in one small study (Fahami 2012). Women receiving Ritgen's manoeuvre versus standard care were more likely to experience second-degree perineal tears (RR 3.25, 95% CI 1.73 to 6.09, one study, 66 women); see Analysis 4.3. We graded this evidence as very low quality. It seems improbable that women receiving Ritgens' manoeuvre should be less likely to have a first-degree tear but more likely to have a second-degree tear; this could be due to lack of blinding, or chance.

Third-degree or fourth-degree perineal tear

One study (Jönsson 2008) reported this outcome. For third- and fourth-degree tears together, there was no clear difference between the groups (RR 1.24, 95% CI 0.78 to 1.96, one study, 1423 women); see Analysis 4.4. We graded this evidence as low quality.

Incidence of episiotomy

The incidence of episiotomy was reported in two studies (Fahami 2012; Jönsson 2008), although there were no events observed in Fahami 2012. There was no clear difference between the groups (RR 0.81, 95% CI 0.63 to 1.03, two studies, 1489 women); see Analysis 4.5. We graded this evidence as low quality.

Secondary outcomes

Third-degree perineal tear

When measuring the incidence of third-degree perineal tear, an outcome reported in one study (Jönsson 2008), there was no clear difference between the groups (RR 1.42, 95% CI 0.86 to 2.36, one study, 1423 women); see Analysis 4.6.

Fourth-degree perineal tear

When measuring the incidence of fourth-degree perineal tear, an outcome reported in one study (Jönsson 2008), there were similar rates (4/7) between the two groups (RR 0.60, 95% CI 0.18 to 2.03, one study, 1423 women); see Analysis 4.7.

None of the included studies under this comparison reported data on any of the other secondary outcomes, these are: length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

5 Primary delivery of posterior versus anterior shoulder

One study (involving 543 women) evaluating primary delivery of posterior versus anterior shoulder met the inclusion criteria for this review (Aabakke 2016).

Primary outcomes

Intact perineum

The included study under this comparison did not report on this outcome.

Perineal trauma requiring suturing

The included study under this comparison did not report on this outcome.

Perineal trauma requiring suturing

When measuring the incidence of perineal trauma requiring suturing, an outcome reported in one study (Aabakke 2016), there was no clear difference between the groups (RR 1.01, 95% CI 0.96 to 1.07, one study, 543 women); see Analysis 5.1.

First-degree perineal tear

The included study under this comparison did not report on this outcome.

Second-degree perineal tear

The included study under this comparison did not report on this outcome.

Third-degree or fourth-degree perineal tear

When measuring the incidence of third-degree or fourth-degree perineal tear, an outcome reported in one study (Aabakke 2016), there was no clear difference between the groups (RR 0.81, 95% CI 0.39 to 1.67, one study, 543 women); see Analysis 5.2.

Incidence of episiotomy

The included study under this comparison did not report on this outcome.

Secondary outcomes

The included study under this comparison did not report data on any other of this review's secondary outcomes, these are: third-degree tear; fourth-degree tear; length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

6 Perineal protection device versus perineal support

One study (involving 1098 women) evaluating the use of a perineal protection device versus perineal support met the inclusion criteria for this review (Lavesson 2014).

Primary outcomes

Intact perineum

The included study under this comparison did not report on this outcome.

Perineal trauma not requiring suturing

The included study under this comparison did not report on this outcome.

Perineal trauma requiring suturing

The included study under this comparison did not report on this outcome.

First- and second-degree perineal tear

When measuring the incidence of first- and second-degree perineal tears, there was no clear difference between the groups (RR 1.00, 95% CI 0.98 to 1.02, one study, 1098 women); see Analysis 6.1.

Third- and fourth-degree perineal tear

When measuring the incidence of third- and fourth-degree perineal tears, there was no clear difference between the groups (RR 1.01, 95% CI 0.54 to 1.89; one study, 1098 women); see Analysis 6.2.

Incidence of episiotomy

When measuring the incidence of episiotomy, there was no clear difference between the groups (RR 0.90, 95% CI 0.53 to 1.53, one study, 1098 women); see Analysis 6.3.

Secondary outcomes

Third-degree perineal tear

When measuring the incidence of third-degree perineal tears, an outcome reported in one study (Lavesson 2014), there was no clear difference between the groups (RR 1.01, 95% CI 0.54 to 1.89, one study, 1098 women); see Analysis 6.4.

Fourth-degree perineal tear

When measuring the incidence of fourth-degree perineal tears, an outcome reported in one study (Lavesson 2014), there was no clear difference between the groups (RR 0.67, 95% CI 0.11 to 4.02, one study, 1098 women).

The included study under this comparison did not report data on any other of this review's secondary outcomes, these are: length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

7 Enriched oil versus liquid wax

One study (involving 164 women) evaluating the use of an enriched oil versus liquid wax met the inclusion criteria for this review (Harlev 2013).

Primary outcomes

Intact perineum

The included study under this comparison did not report on this outcome.

Perineal trauma not requiring suturing

The included study under this comparison did not report on this outcome.

Perineal trauma requiring suturing

The included study under this comparison did not report on this outcome.

First-degree perineal tear

When measuring the incidence of first-degree perineal tear, an outcome reported in one study (Harlev 2013), there was no clear difference between the groups (RR 1.09, 95% CI 0.84 to 1.40, one study, 164 women); see Analysis 7.1.

Second-degree perineal tear

When measuring the incidence of second-degree perineal tear, an outcome reported in one study (Harlev 2013), there was no clear difference between the groups (RR 0.88, 95% CI 0.58 to 1.31, one study, 164 women); see Analysis 7.2.

Third- and fourth-degree perineal tears

The included study under this comparison did not report on this outcome.

Incidence of episiotomy

When measuring the incidence of episiotomy, an outcome reported in one study (Harlev 2013), there was no clear difference between the groups (RR 1.33, 95% CI 0.48 to 3.67, one study, 164 women); see Analysis 7.3.

Secondary outcomes

Third-degree perineal tear

When measuring the incidence of third-degree perineal tear, an outcome reported in one study (Harlev 2013), there was no clear difference between the groups (RR 1.00, 95% CI 0.14 to 6.93, one study, 164 women); see Analysis 7.4.

The included study under this comparison did not report data on any other of this review's secondary outcomes, these are: fourth-degree tear; length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

8 Cold compresses versus control

One study (involving 64 women) evaluating the use of cold compresses versus control met the inclusion criteria for this review (Shirvani 2014a).

Intact perineum

The included study under this comparison did not report on this outcome.

Perineal trauma not requiring suturing

The included study under this comparison did not report on this outcome.

Perineal trauma requiring suturing

The included study under this comparison did not report on this outcome.

First-degree perineal tear

When measuring the incidence of first-degree perineal tear, an outcome reported in one study (Shirvani 2014a), there was no clear difference between the groups (RR 2.50, 95% CI 0.52 to 11.96, one study, 64 women); see Analysis 8.1.

Second-degree perineal tear

The included study under this comparison did not report on this outcome.

Third- and fourth-perineal tears

The included study under this comparison did not report on this outcome.

Incidence of episiotomy

When measuring the incidence of episiotomy, an outcome reported in one study (Shirvani 2014a), there was no clear difference between the groups (RR 0.90, 95% CI 0.76 to 1.07, one study, 64 women); see Analysis 8.2.

Secondary outcomes

The included study under this comparison did not report data on any of this review's secondary outcomes, these are: third-degree tear; fourth-degree tear; length of second stage; Apgar less than seven at five minutes; admission to special care baby unit; perineal pain postpartum; perineal pain at three and at six months after birth; breastfeeding initiation; breastfeeding at three months and at six months after birth; women's satisfaction; maternal morbidity after birth related to sexual health (i.e. stress incontinence and dyspareunia).

ADDITIONAL SUMMARY OF FINDINGS [Explanation]

Warm compresses compared to control (hands off or no warm compress) for reducing perineal trauma

Patient or population: pregnant women expecting a vaginal birth, singleton vertex presentation at term, with no medical complications
Setting: Hospitals in Australia, Iran, Spain and USA
Intervention: warm compresses
Comparison: control (hands off or no warm compress)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with control (hands off or no warm compress)	Risk with warm compresses				
Intact perineum	Study population		RR 1.02 (0.85 to 1.21)	1799 (4 RCTs)	⊕⊕⊕◯ Moderate[1]	
	236 per 1000	241 per 1000 (200 to 285)				
Perineal trauma requiring suturing	Study population		RR 1.14 (0.79 to 1.66)	76 (1 RCT)	⊕◯◯◯ Very low[2,3]	
	553 per 1000	630 per 1000 (437 to 917)				
1st degree tear	Study population		RR 1.19 (0.38 to 3.79)	274 (2 RCTs)	⊕◯◯◯ Very low[3,4,5]	
	288 per 1000	343 per 1000 (110 to 1000)				
2nd degree tear	Study population		RR 0.95 (0.58 to 1.56)	274 (2 RCTs)	⊕◯◯◯ Very low[1,3]	
	192 per 1000	183 per 1000 (112 to 300)				

3rd or 4th degree tears	Study population		RR 0.46 (0.27 to 0.79)	1799 (4 RCTs)	⊕⊕⊕◯ Moderate[6]
	45 per 1000	21 per 1000 (12 to 36)			
Episiotomy	Study population		RR 0.86 (0.60 to 1.23)	1799 (4 RCTs)	⊕⊕◯◯ Low[6,7]
	62 per 1000	54 per 1000 (37 to 77)			

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence interval; **RCT**: randomised controlled trial; **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]One study with design limitations and one study with serious design limitations though contributing < 40% weight (downgraded 1 level).
[2]One study with serious design limitations contributing all data (downgraded 2 levels).
[3]Wide confidence intervals crossing the line of no effect and small sample size (downgraded 2 levels).
[4]One study with design limitations and one study with serious design limitations contributing all data (downgraded 2 levels).
[5]Statistical heterogeneity I^2 > 60% (downgraded 1 level).
[6]One study with design limitations, one study with serious design limitations though not contributing any events (downgraded 1 level).
[7]Wide confidence intervals crossing the line of no effect (downgraded 1 level).

Massage compared to control (hands off or care as usual) for reducing perineal trauma

Patient or population: pregnant women expecting a vaginal birth, singleton vertex presentation at term, with no medical complications
Setting: Hospitals in Australia, Iran and USA
Intervention: massage
Comparison: control (hands off or care as usual)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with control (hands off or care as usual)	Risk with massage				
Intact perineum	Study population		RR 1.74 (1.11 to 2.73)	2618 (6 RCTs)	⊕⊕◯◯ Low[1,2]	
	227 per 1000	396 per 1000 (252 to 621)				
Perineal trauma requiring suturing	Study population		RR 1.10 (0.75 to 1.61)	76 (1 RCT)	⊕◯◯◯ Very low[3,4]	
	553 per 1000	608 per 1000 (414 to 890)				
1st degree perineal tear	Study population		RR 1.55 (0.79 to 3.05)	537 (5 RCTs)	⊕◯◯◯ Very low[5,6,7]	
	287 per 1000	445 per 1000 (227 to 876)				
2nd degree perineal tear	Study population		RR 1.08 (0.55 to 2.12)	537 (5 RCTs)	⊕◯◯◯ Very low[5,6,7]	
	213 per 1000	230 per 1000 (117 to 451)				
3rd or 4th degree tears	Study population		RR 0.49 (0.25 to 0.94)	2477 (5 RCTs)	⊕⊕⊕◯ Moderate[8]	

	29 per 1000	14 per 1000 (7 to 27)			
Episiotomy	Study population		RR 0.55 (0.29 to 1.03)	2684 (7 RCTs)	⊕◯◯◯ Very low[5,7,9]
	249 per 1000	137 per 1000 (72 to 257)			

*__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; **RCT**: randomised controlled trial; **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 (downgraded 1 level).
[2]Statistical Heterogeneity ($I^2 \geq 60\%$). Variation in size of effect (downgraded 1 level).
[3]One study with design limitations (downgraded 1 level).
[4]Wide confidence interval crossing the line of no effect, few events and small sample size (downgraded 2 levels).
[5]Most studies contributing data had design limitations, one study has serious design limitations (downgraded 1 level).
[6]Statistical Heterogeneity ($I^2 \geq 60\%$). Variation in direction of effect (downgraded 1 level).
[7]Wide confidence interval crossing the line of no effect (downgraded 1 level).
[8]Most studies contributing data had design limitations, one study had serious design limitations but did not report any events (downgraded 1 level).
[9]Statistical heterogeneity ($I^2 \geq 60\%$). Variation in size and direction of effect (downgraded 2 levels).

Ritgen's manoeuvre compared to standard care for reducing perineal trauma

Patient or population: pregnant women expecting a vaginal birth, singleton vertex presentation at term, with no medical complications
Setting: Hospitals in Iran and Sweden
Intervention: Ritgen's manoeuvre
Comparison: standard care

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	№ of participants (studies)	Quality of the evidence (GRADE)	Comments
	Risk with standard care	Risk with Ritgen's manoeuvre				
Intact perineum	Study population		RR 0.17 (0.02 to 1.31)	66 (1 RCT)	⊕◯◯◯ Very low[1,2]	
	182 per 1000	31 per 1000 (4 to 238)				
Perineal trauma requiring suturing	Study population		-	(0 studies)	-	No trial reported this outcome
	See comment	See comment				
1st degree tear	Study population		RR 0.32 (0.14 to 0.69)	66 (1 RCT)	⊕◯◯◯ Very low[1,3]	
	576 per 1000	184 per 1000 (81 to 397)				
2nd degree tear	Study population		RR 3.25 (1.73 to 6.09)	66 (1 RCT)	⊕◯◯◯ Very low[1,3]	
	242 per 1000	788 per 1000 (419 to 1000)				
3rd or 4th degree tears	Study population		RR 1.24 (0.78 to 1.96)	1423 (1 RCT)	⊕⊕◯◯ Low[4,5]	
	44 per 1000	55 per 1000 (34 to 86)				

Episiotomy	Study population		RR 0.81 (0.63 to 1.03)	1489 (2 RCTs)	⊕⊕◯◯ Low[5,6]
	162 per 1000	131 per 1000 (102 to 167)			

*__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; **RCT**: randomised controlled trial; **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]One study with serious design limitations (downgraded 2 levels).
[2]Wide confidence interval crossing the line of no effect, few events and small sample size (downgraded 2 levels).
[3]Few events and small sample size (downgraded 1 level).
[4]One study with design limitations (downgraded 1 level).
[5]Wide confidence interval crossing the line of no effect (downgraded 1 level).
[6]One study with serious design limitations did not report any events. One study with design limitations (downgraded 1 level).

DISCUSSION

Summary of main results

This systematic review is an update of a review that was published in 2011 (Aasheim 2011). This review aimed to evaluate the research evidence of how different perineal techniques could contribute in reducing the severity and frequency of perineal trauma. While 22 trials were eligible for inclusion in this updated review, we were only able to include data from 20 trials involving 15,181 randomised women. These trials took place in 10 different countries, all in hospital settings. All the included trials explored different perineal management techniques. These techniques included: compresses held to the mother's perineum or perineal massage inside the woman's vagina versus hands off, warm compresses on the perineum versus not having warm compresses, various hands-on techniques versus hands-off techniques, massage of the perineum versus no massage, the use of different oils versus liquid wax, a modified Ritgen's manoeuvre versus standard practice, the use of a perineal protection device versus perineal support, and birth of the anterior shoulder versus the posterior shoulder first. The studies measured various outcomes, but they all reported on condition of the perineum in one way or another, for example, by presenting the number of women with an intact perineum, the frequency of the need for suturing after birth or the degree and location of perineal tear.

The results of our meta-analyses comparing hands off (or poised) versus hands on suggests that practicing the hands-off technique reduces the use of episiotomy but does not affect rates of intact perineum, perineal trauma requiring suturing, or perineal trauma rates of any degree. Even though the rate of episiotomy was reduced, there was no increase of third- and fourth-degree tears. There was a high degree of heterogeneity in this analysis and as episiotomy is heavily influenced by individual practice, this analysis should be viewed with caution. These results are based on moderate- to very low-quality evidence.

We did observe a reduction in incidence of third- and fourth-degree perineal tears when the perineal technique of holding warm compresses against the perineum was used compared to no application of warm compresses against the perineum, however the effect of warm compresses on other the incidence of perineal trauma and grades of perineal tears is uncertain. Substantial heterogeneity was observed in our analyses for first-degree tears and third-degree tears. Similar rates of episiotomy were observed. These results are based on moderate- to very low-quality evidence.

Perineal massage was associated with a reduced risk of third- and fourth-degree tears. The effect of perineal massage on perineal trauma requiring suturing or first-degree tears or second-degree tears is uncertain (with high levels of heterogeneity observed for both first- and second-degree tears). Perineal massage was also associated with an increase in the number of women with intact perineum but this outcome should be interpreted with caution due to substantial heterogeneity. There was some reduction in the rate of episiotomy but there was considerable uncertainty around the effect estimate, and again, high levels of heterogeneity were evident. These results are based on moderate- to very low-quality evidence.

Women receiving Ritgen's manoeuvre versus standard care were less likely to experience first-degree perineal tears, but more likely to experience second-degree perineal tears. We are uncertain what effect the intervention has on the incidence of intact perineum. There were no clear differences in the risk of third- and fourth-degree perineal tears, intact perineum, and episiotomy. There were no data for the outcome of perineal trauma requiring suturing. Data for these outcomes were based on one small study and the evidence ranged from low to very low quality.

The delivery of posterior versus anterior shoulder first, the use of perineal protection device, the use of different oils/wax and the use of cold compresses did not show any effects on perineal outcomes. Only one study contributed to each of these comparisons, so data were insufficient to draw conclusions.

Overall completeness and applicability of evidence

The question of how to prevent perineal trauma is an important research topic in midwifery and obstetrics. Despite a large overall sample size, within most individual comparisons sample sizes were small and did not give sufficient good-quality data to allow us to draw reliable conclusions. There is no strong evidence for perineal techniques during the second stage of labour to reduce perineal trauma. Very few secondary outcomes were reported in any of the included studies. Women's views and choice on perineal techniques should be central to which method is implemented, however the included studies did not report women's opinion of the method studied, except for the use of warm compresses which was acceptable to both women and midwives (Dahlen 2009). Further research is required to ascertain which technique prevents perineal trauma and is acceptable to women and their caregivers.

Quality of the evidence

There was great variation in methodological quality of the trials (Figure 2). Five of the studies contributing data had low risk of problems that could put them at risk of bias (Aabakke 2016; Albers 2005; Dahlen 2007; McCandlish 1998; Stamp 2001). We were uncertain about the risk of bias in seven of the studies due to methods of reporting (Araujo 2008; Harlev 2013; Jönsson 2008; Lavesson 2014; Mayerhofer 2002; Rezaei 2014; Terre-Rull 2014). The rest of the studies had a high risk of bias (Attarha 2009; De Costa 2006; Fahami 2012; Foroughipour 2011; Galledar 2010; Geranmayeh 2012; Shirvani 2014a; Sohrabi 2012).

The studies in our meta-analyses have considerable clinical heterogeneity. The perineal techniques used in the included studies varied. The terms 'hands on', 'hands off', 'standard care' and 'perineal support' meant different things across the studies and were not always defined sufficiently. In McCandlish 1998, 'hands off' not only meant no hand on the perineum and infant's head until the head was born but, also no manual assistance for the birth of the shoulders. While Mayerhofer 2002 defined 'hands off' as no hands on the perineum or fetal head until the head was born, but made no distinction between 'hands on' and 'hands off' for the assistance of the birth of the shoulders. Most extreme is the 'hands off' in Albers 2005, where 'hands off' only meant no hands on the perineum until crowning of the head. Although the standard care or 'hands on' manual support techniques are poorly described in most of the studies, it is clear that all studies aimed at a slow and controlled birth of the head.

The results of our meta-analyses comparing hands on versus hands off suggest that practicing the hands-off technique reduces the use of episiotomy, but we graded the quality of the evidence as low. The quality of the evidence from the meta analyses of warm compresses for a reduction in incidence of third- and fourth-degree perineal tears is moderate. The use of warm compresses probably prevents perineal trauma (third- and fourth-degree tears). The quality of the evidence from the meta analyses of massage for a reduction in incidence of third- and fourth-degree perineal tears is moderate. The use of massage probably prevents perineal trauma (third- and fourth-degree tears) and the practice of massage may also improve the rate of intact perineum (low quality of evidence). It is uncertain whether Ritgen's manoeuvre versus standard care decreased the rate of first-degree perineal tears and also increased the rate of second-degree tears because the quality of the evidence is very low. The delivery of posterior versus anterior shoulder first, the use of perineal protection device, the use of different oils/wax and the use of cold compresses did not show any effects on perineal outcomes. We used GRADEpro GDT software to assess the evidence for the four main comparisons. The evidence was, at best, of moderate quality. For hands off (or poised) compared to hands on for reducing perineal trauma, we graded evidence for intact perineum as moderate-quality. We graded evidence for first-degree, and second-degree tears, and episiotomy as being of low-quality, and for third- or fourth-degree tears as very low-quality. We downgraded evidence for risk of bias, inconsistency, and imprecision of effect estimates. For the comparison warm compresses compared to control (hands off or no warm compress), intact perineum and third- or fourth-degree tears, we graded evidence as moderate-quality, evidence for episiotomy was low-quality, and evidence for first- and second-degree tears was very low-quality. We downgraded evidence for risk of bias, inconsistency, and imprecision of effect estimates with small sample sizes and few events. For massage compared to control (hands off or care as usual), we graded evidence for third- or fourth-degree tears as moderate-quality, intact perineum as low-quality, and perineal trauma requiring suturing, first-degree tears, second-degree tears, and episiotomy as very low-quality evidence. We downgraded evidence for risk of bias, inconsistency, and imprecision of effect estimates with small sample sizes and few events. Only two studies contributed data to the comparison Ritgen's manoeuvre compared to standard care. We graded evidence for third- or fourth-degree tears, and episiotomy as low-quality, for intact perineum, first-degree tear, and second-degree tear as very low-quality. Again, we downgraded evidence for risk of bias, inconsistency, and imprecision of effect estimates with small sample sizes and few events. For some of the comparisons there was only one study; the delivery of posterior versus anterior shoulder (Aabakke 2016), the perineal device (Lavesson 2014), the use of oil (Harlev 2013) and the use of cold compresses (Shirvani 2014a), and we did not use the GRADE assessment tool for these studies. It was not possible to blind the intervention for the midwives or birth attendants in the involved trials. It may be difficult to blind the outcome assessor, but it is not impossible and future trials should definitely attempt to do so. Theoretically, midwives' convictions about the advantage or disadvantage of the intervention could influence their evaluation of the perineal outcome.

We were not able to perform all the analyses proposed in the protocol for all the primary and secondary outcomes recorded, as the included studies did not contribute enough data.

Potential biases in the review process

We are aware of the possibility of adding bias at any stage of the review process. We tried to minimise this possibility by two review authors independently assessing each trial for eligibility and extracting data from relevant studies. We resolved discrepancies through discussion in the team. Data were entered into RevMan 5 software (RevMan 2014) and checked for accuracy. When information regarding any of the above was unclear, we contacted authors of the original reports to provide further details.

As to the studies in Persian language, and one in Spanish, these studies were read by only one person, but we believe that both consideration of inclusion of the studies and the data extraction are of sufficient quality.

Agreements and disagreements with other studies or reviews

The conclusion in this revised form of the review is the same as in the first version of the review.

Another Cochrane Review found that selective episiotomy resulted in less severe perineal trauma than routine episiotomy (Jiang 2017). A non-Cochrane systematic review (Eason 2000) with a broader scope than this review (including antenatal techniques, mode of birth, and birth position) also found that selective use of episiotomy produced less severe trauma to the perineum. This review found that perineal massage in the weeks leading up to

labour appeared to reduce perineal trauma but also reported a lack of evidence around perineal techniques restricted to the second stage of labour.

AUTHORS' CONCLUSIONS

Implications for practice

There was moderate-quality evidence suggesting that the use of warm compresses, and the use of massage, may reduce the occurrence of third- and fourth-degree perineal tears but evidence on the benefits of these techniques on other outcomes was unclear or inconsistent. There was poor-quality evidence suggesting that hands-off techniques may reduce episiotomy, but these techniques had no clear impact on other important outcomes. There are insufficient data to show whether other perineal techniques result in improved outcomes for labouring women and their babies.

Warm compresses and massage may improve outcomes and do not seem to cause harm, although data on women's views of these techniques was not reported.

Implications for research

A limitation of this review is that it only considers perineal techniques and not all the factors of the birth process. The question of how to prevent tears is complicated and involves many other factors in addition to the perineal techniques that are evaluated here. It has to do with the birth position, the women's tissue and other ways to control the speed of the birth. To our knowledge, none of the studies included in this review have women's experience of the interventions as an outcome. This could be considered in further research. A controlled birth can be achieved in different ways; controlled by the midwife or by the woman, controlled by breathing technique or by perineal support. Further research in this field is necessary.

Further randomised controlled trials could be performed evaluating perineal techniques, warm compresses and massage.

More research is also needed to answer the questions of determinants of perineal trauma. We still do not know enough of the effect of, for example, training, demographic factors or nutrition as determinants. We also lack knowledge of how different types of oil used during massage affect women and their babies. We do not know whether these varied perineal techniques are acceptable to women, and future research should collect information on women's views.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Aabakke 2016

Methods	Single-centre, prospective, single-blinded, RCT. 650 women individually randomised Start date: June 2013; end date: March 2015
Participants	Setting: undertaken at the University of Copenhagen, Holbæk Hospital, which is a Danish community hospital with an obstetric unit with 1600 deliveries annually Inclusion criteria: • nulliparous women and women with a previous caesarean birth having their first vaginal birth • planned vaginal birth • cephalic presentation • participants had to be able to provide informed oral and written consent Exclusion criteria: • multiparity with a previous vaginal birth • multiple pregnancy • caesarean birth • birth before 35 weeks of gestation • breech presentation • participants received no financial compensation
Interventions	Experimental intervention: primary delivery of the anterior shoulder Total number randomised: n = 325 Control/comparison intervention: primary delivery of the posterior shoulder Total number randomised: n = 325
Outcomes	Primary outcome was any perineal trauma requiring suturing. Secondary outcomes were perineal injury subtypes, postpartum bleeding in mL evaluated 2 h after birth, umbilical artery pH, Apgar scores at 5 min, and neonatal birth trauma including brachial plexus injury and fractures of the clavicle and humerus
Notes	The participants could deliver in the position they preferred, and if spontaneous birth of the shoulders occurred, this was to be respected regardless of randomisation The method of perineal support during the birth of the head was not standardised Funding sources: non-profit grants from the Danish Association of Midwives, the Region Zealand Health Sciences Research Fund, Axel Muusfeldt's Fund, Torben and Alice Frimodt's Fund, and Aase and Ejnar Danielsen's Fund Conflicts of interest: none declared

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation was computer-generated, with a 1:1 allocation to primary delivery of the anterior or posterior shoulder by a third

		party not otherwise involved in the trial
Allocation concealment (selection bias)	Low risk	The allocation was concealed in 650 identical, opaque, sequentially-numbered sealed envelopes. The allocation list was stored electronically by a third party not otherwise involved in the trial
Blinding of participants and personnel (performance bias) All outcomes	High risk	"The randomisations envelope was opened by the midwife when the patient entered the second stage of labour and was destroyed thereafter. The allocation was only shown to the midwife and the assistant, and if necessary the obstetrician." Participants may have been blinded. Impossible to blind midwives but method of perineal care may have varied between midwives and affected outcomes
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	"After birth of the placenta, a blinded midwife or an obstetrician not otherwise involved in the birth assessed the perineum and graded the perineal tears. Secondary outcomes and information about which shoulder was delivered first were registered by the midwife responsible for the birth." Midwife responsible for delivery could have assessed certain outcomes differently in the knowledge of the allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Reported performing both ITT and per-protocol analysis. The primary analysis (described as ITT), did not include women who had caesarean section, and these women, excluded after randomisation varied in the 2 groups (60/325 vs 41/325). There were protocol deviations with 193/262 and 211/281 having the allocated intervention (although it was reported that the envelope was not opened until the 2nd stage, so it is not clear at what point women were actually allocated)
Selective reporting (reporting bias)	Low risk	The trial was registered and further details on methods were reported previously. All relevant outcomes appeared to be reported
Other bias	Low risk	No other bias evident. Most baseline characteristics similar except for more in the an-

		terior should having an epidural and fewer delivering lying on their side. This may have impacted on outcomes

Albers 2005

Methods	RCT. Procedure: computer-generated block randomisation (1:1:1 within balanced blocks). Unit of randomisation: women in midwifery care were recruited antenatally but randomised in active labour when vaginal birth appeared likely Start date: October 2001; end date: December 2004
Participants	Setting: teaching hospital in New Mexico 1211 women were included. Inclusion criteria: women in midwifery care, 18 years or older, healthy, expecting a vaginal birth, no medical complications, a singleton vertex presentation at term. Exclusion criteria: those who did not meet the inclusion criteria
Interventions	Experimental interventions: Compresses versus hands off and massage versus hands off • Warm compresses were held continuously to the mother's perineum and external genitalia by the midwife's gloved hand during and between pushes, regardless of mother's position • Perineal massage with lubricant was gentle, slow massage, with 2 fingers of the midwife's gloved hand moving from side to side just inside the patient's vagina. Mild, downward pressure (toward the rectum) was applied with steady, lateral strokes, which lasted 1 second in each direction. This motion precluded rapid strokes or sustained pressure. A sterile, water-soluble lubricant was used to reduce friction with massage. Massage was continued during and between pushes, regardless of maternal position and the amount of downward pressure was dictated by the woman's response Comparison: • No touch of the woman's perineum until crowning of the infant's head
Outcomes	Primary outcome was intact perineum (defined as no tissue separation at any site) Secondary outcomes: episiotomy, degree of trauma (1st, 2nd, 3rd, 4th), location of trauma (vaginal, labial, periurethral, clitoral, cervical), trauma sutured and from the postpartum visit: presence of anatomic abnormalities, faulty healing of childbirth lacerations, and continued perineal pain. Reported as postpartum perineal problems
Notes	Contact with the study author did not supply us with further information of secondary outcomes such as breastfeeding, maternal satisfaction with birth, stress incontinence or dyspareunia Funding sources: National Institute of Nursing Research/National Institutes of Health Conflicts of interest: not reported

Risk of bias

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

Albers 2005 (*Continued*)

Random sequence generation (selection bias)	Low risk	Computer-generated, ratio 1:1:1 within balanced blocks of 12
Allocation concealment (selection bias)	Low risk	Sequentially-numbered, sealed, opaque envelopes were prepared by the data manager and study administrator and stored in metal box in a restricted area at the hospital's labour unit. The clinical midwife selected the lowest numbered envelope once vaginal birth appeared likely. The envelope contained a card with the study group allocation. When the envelope was drawn, the midwife signed the study register and noted date and time.
Blinding of participants and personnel (performance bias) All outcomes	High risk	It was not possible to blind the intervention for the participant or the clinician. The outcome assessment was done by the midwife who performed the birth, and thus not blinded, but to counter this potential bias, a random 25% of the study births had a 2nd midwife observer present (additional information by contact with the study author). Women and staff not blind to allocation
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	The outcome assessment was done by the midwife who performed the birth, and thus not blinded, but to counter this potential bias, a random 25% of the study births had a 2nd midwife observer present (additional information by contact with the study author)
Incomplete outcome data (attrition bias) All outcomes	Low risk	There were no losses to follow-up for primary outcome after randomisation. Some (88 + 79 + 79) lost to follow-up for data from the postpartum visit. There was no exclusion after randomisation. The analysis was ITT
Selective reporting (reporting bias)	Low risk	Outcomes pre-specified in protocol
Other bias	Low risk	Very low episiotomy rate at baseline, under 1%. They also have a high baseline of intact perineum compared to most others Similar baseline characteristics between groups.

Araujo 2008

Methods	RCT Start date: February 2003; end date: June 2003
Participants	Setting: philanthropic hospital in Brazil 106 women were included. Inclusion criteria: no previous vaginal births; age ≥ 15 years, gestational age 37-41 6/7 weeks, live single cephalic fetus with no abnormality detected, uterine height no more than 36 cm, cervical dilatation ≤ 5 cm, no perineal preparation during pregnancy, no infection in the perineum, agree to use the lateral left size position during birth Exclusion criteria: use of oxytocin, obstetrical conditions during labour and birth that required intervention as episiotomy, forceps and caesarean Nulliparous women
Interventions	Experimental intervention: petroleum jelly was applied to the entire area of the perineum with 2 fingers, using a sweeping motion. The clitoris, labia majora, labia minora, vestibule, fourchet and perineal body were covered with 30 mL of the lubricant without any stretching or massage of the complete cervical dilatation until the beginning of the cephalic birth. It was done time after time from the complete cervical dilatation until the beginning of the cephalic birth Control/comparison intervention: routine care, did not receive the jelly
Outcomes	Perineal conditions: frequency, intact perineum or trauma, degree of trauma (1st, 2nd) and location (posterior or anterior or both) Newborn outcomes: Apgar score Expulsive period length: the time between full cervical dilatation to fetal birth
Notes	We contacted the study author and were provided with more information on why the inclusion took such a long time, on details on the application of the jelly on the perineum and of the routine care in the hospital Funding sources: not reported Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomisation was computer-generated random numbers
Allocation concealment (selection bias)	Unclear risk	It was stated that randomisation was at the moment of birth - it was not clear what this meant. Elsewhere it says the intervention was from full dilatation. It was not clear how allocation was concealed
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and staff not blinded and use of the intervention was normal practice, so midwives were being asked to withdraw care

Araujo 2008 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	The nurse-midwives were informed about which group (control or experimental) the woman was allocated to by the researcher when the woman was in the expulsive period
Incomplete outcome data (attrition bias) All outcomes	Low risk	106 women were assessed for eligibility at stage 1, 3 excluded because of exclusion criteria (2) and lack of consent (1). After randomisation: 15 excluded from the intervention and 12 from the control group because of episiotomy
Selective reporting (reporting bias)	Unclear risk	No protocol seen and outcomes not clearly pre-specified in main text. Episiotomy may have been expected to be an outcome rather than a reason for exclusion
Other bias	Unclear risk	Very few women followed the eligibility criteria: 106 of > 600 nulliparous women. No other signs of bias evident. The power calculation appears post hoc (same number as analysed rather than randomised) . Groups appeared comparable at baseline.

Attarha 2009

Methods	RCT Study dates not reported.
Participants	Setting: labour room of a university hospital in Arak (Iran) Inclusion criteria: 38-42 weeks of gestation, nulliparous women expecting normal vaginal birth of a singleton, cephalic presentation, lack of premature rupture of membranes, placental abruption, narrow pelvis, fetal distress, lack of vaginal infections and genital herpes (if there was any wound or painful lesions on the perineum and vulva, genital herpes was diagnosed), lack of Kegel exercises and professional exercises Exclusion criteria: lack of labour progress, the occurrence of fetal distress, opioids prescription (pethidine), birth with forceps and vacuum, rash, erythema and perineal edema, withdrawal of mothers from massage
Interventions	Experimental intervention: perineal massage Total number randomised: n = 102 (!) Control/comparison intervention: routine care. Total number randomised: n = 102 (!)
Outcomes	Perineal outcomes (incidence of episiotomy, intact perineum, perineal tear, length of second stage, Apgar score at minute 1 and 5)

Attarha 2009 (*Continued*)

Notes	The sample size was estimated 204 (68 + 20% in case of loss to follow-up). The total number of participants has been noted 190 only in Persian abstract but 204 in English abstract. There is no detail on this number in the full text. However, the percentages in the table of results show that number of participants in each group was 85 Assessment from translation of trial report Funding sources: not reported Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The researchers used simple random sampling
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	Insufficient information provided - assumed to be no blinding
Blinding of outcome assessment (detection bias) All outcomes	High risk	Sufficient information is not provided. Assumed to be no blinding. Outcomes susceptible to bias from assessor
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Sample size and denominators not clear
Selective reporting (reporting bias)	Unclear risk	The study protocol was not available to check this
Other bias	High risk	The sample size was estimated 204 (68 + 20% in case of loss to follow-up). The total number of participants has been noted 190 only in Persian abstract but 204 in English abstract. There is no detail on this number in the full text. However, the percentages in the table of result shows that number of participants in each group was 85

Dahlen 2007

Methods	RCT. Randomly-generated numbers with participants being stratified into 6 subgroups by age and ethnicity Unit of randomisation: nulliparous women in the late second stage of labour. Pregnant women were asked at the antenatal clinics or in the labour ward if they were not in labour Start date: November 1997; end date: June 2004

Participants	Setting: two maternity hospitals in Australia 717 women were included. Inclusion criteria: nulliparous women, at least 36 weeks pregnant, singleton pregnancy with a cephalic presentation; anticipated a normal birth, who had not performed perineal massage antenatally and were older than 16 years Exclusion criteria: women not fulfilling the inclusion criteria and those women who experienced intrauterine fetal death The 6 strata were: Asian younger than 25, non-Asian younger than 25, Asian 25-34 years old, non-Asian 24-34 years old, Asian older than 34 and non-Asian older than 34
Interventions	Experimental intervention: 1) warm packs/pads on the perineum as the baby's had began to distend the perineum and the woman was aware of a stretching sensation. A sterile pad was soaked in a metal jug with boiled tap water (between 45 and 59 degrees C) then wrung out and gently placed on the perineum during contractions. The pad was re-soaked to maintain warmth between contractions. The water in the jug was replaced every 15 min until birth Comparison: standard group, which did not have warm pack applied to their perineum in second stage
Outcomes	Primary outcome was suturing after birth (defined as perineal trauma greater than first-degree tear, any tear that was bleeding and any tear that did not fall into anatomical apposition) Secondary outcomes: degree of trauma divided into minor or no trauma (intact, 1st degree, vaginal/labial tear), major trauma (2nd, 3rd, 4th degree and episiotomy), episiotomy and severe perineal trauma including 3rd and 4th degree tears Other secondary outcome: pain when giving birth, and perineal pain on day 1 and 2, at 6 weeks and 3 months, and urinary incontinence, sexual intercourse and breastfeeding
Notes	We contacted the study author and asked for additional information according to more detailed data on the perineal trauma and for this review's secondary outcomes but such data were not available We asked the author for the pain scores 6 weeks and 3 months after birth, breastfeeding and for resuming sexual intercourse In the article from 2007, pain scores were reported when giving birth and that was not one of our outcomes. It was also reported pain scores on different occasions - but they were presented in a survival analyses comparing the 2 groups and not in a form that we could extract data from. The data on breastfeeding were not found in the articles We received another article (Dahlen 2008), 'Perineal trauma and postpartum perineal morbidity in Asian and non-Asian nulliparous women giving birth in Australia' (Hannah Dahlen and Caroline Homer), where we found more relevant data on pain and sexual intercourse, but these data were reported divided into Asian - non Asian women and not in women receiving warm packs or not, as was needed to fit our review. So the data were not available for the actual groups in our review and the study author could not help us with these additional data Funding sources: not reported Conflicts of interest: not reported
Risk of bias	

Dahlen 2007 (*Continued*)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by the National Health and Medical Research Clinical Trials Centre using randomly-generated numbers. The article does not state if this was computer-generated, but it is perfectly possible to randomly generate numbers without a computer
Allocation concealment (selection bias)	Low risk	Randomisation by the National Health and Medical Research Clinical Trials Centre using randomly generated numbers. Sealed, opaque envelopes at the National Health and Medical Research Clinical Trials Centre kept at the neonatal intensive care unit to ensure remote allocation concealment, with randomisation occurring as close as possible to second stage of labour
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and midwives not blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	An independent, senior midwife blinded to the allocated group was asked to give an independent assessment of the degree of perineal trauma after the birth and whether or not suturing was required. Midwives were instructed not to let other midwives know the allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss of outcome data for the primary outcome. However, some loss of data for pain scores No participants were excluded after randomisation, but in both groups a number of women did not receive the care they were allocated to due to surgical intervention. A couple refused the allocated treatment. 1 gave birth too fast, 1 delivered in water and 1 received the intervention treatment while allocated to standard care. The analysis was ITT
Selective reporting (reporting bias)	Low risk	Protocol not seen. All reported, pre-specified in text

Dahlen 2007 (*Continued*)

Other bias	Low risk	Took a long time to include enough participants, from 1997-2004 Recruitment stopped at 717, only 599 women actually received the allocated treatment. 95 fewer than required by the power calculation. In the flow chart it is stated that 1047 were assessed for eligibility while only 717 were randomised. The main reason for not randomising was that midwives were too busy. It is difficult to know if this introduced bias It was difficult to differentiate between intact perineum and trauma. The classification of the degree of perineal trauma makes it difficult to compare to other studies

De Costa 2006

Methods	RCT. Procedure: electronically produced randomised tables. Unit of randomisation: pregnant nulliparous women in labour Start date: June 2001; end date: October 2001
Participants	Setting: A hospital birth centre, in Etapecerica de Serra, Brazil 70 women were included. Low-risk pregnancies received antenatal care in the basic healthcare units. The birth centre has an average of 403 deliveries a month (71% vaginal birth), and nurse-midwives attend 100% of the births Inclusion criteria: primiparous expectant mothers aged 15-35, full-term pregnancies and vertex presentation. On admission: uterine height more than 36 cm, cervical dilatation 8 cm or less, intact membranes. Additional limitations were that labour did not exceed 12 h after hospitalisation, no use of oxytocin during the first or second stage of labour, no perineal preparation during pregnancy or no episiotomy Exclusion criteria: women were excluded if there was dystocia requiring any other procedure than those described in the detailed description of the 2 methods compared. Women were excluded if they chose to deliver in the lithotomy position, if they had a caesarean section, if there were any abnormalities during labour related to fetal distress
Interventions	Experimental intervention: hands off: during the expulsive period, the nurse-midwife's conduct was exclusively expectant, only observing the successive movements of restitution, external rotation, birth of the shoulders and the remainder of the body. During birth, the nurse-midwife had to support the baby's head with 1 hand and the baby's torso with the other hand. If external rotation of the head or birth of the shoulders did not occur spontaneously within 15 seconds of the birth of the head, or if the newborn appeared hypoxic, the professional had to manually rotate the head by grasping it and applying gentle downward tracking. Once the anterior shoulder was delivered, gentle upward traction was used to deliver the posterior shoulder. After the shoulders had been delivered, the newborn's neck was held with 1 hand, while the other hand followed along the infant's back, and the legs or feet were grasped as they were delivered Comparison: hands on: when the infant's head was crowning, the nurse-midwife placed

	the index, middle ring and little fingers of the left hand close together on the infant's occiput, with the palm turned toward the anterior region of the perineum. In this manner, expulsion was controlled, by maintaining the flexion of the head, protecting the anterior region of the perineum and bilaterally supporting the ischio-cavernous and bulbo- cavernous muscles, the urethral introitus, and the labia majora and minora. Simultaneously, the right hand was flattened out and placed on the posterior perineum, with the index finger and the thumb, forming a "U" shape, exerting pressure on the posterior region of the perineum during the crowning process. The nurse-midwife left no area without protection, particularly the region of the fourchette. During the birth of the shoulders and the remainder of the body, the right hand was kept in place, protecting the posterior region of the perineum, while the left hand supported the infant's head, allowing external rotation and the birth of the shoulders spontaneously. If this did not occur, the professional continued with posterior perineal pressure, and with the left hand, pulled gently downward to deliver the anterior shoulder. Once the anterior shoulder was delivered, gentle traction was applied upward to ease birth of the posterior shoulder. After both shoulders had been delivered, the practitioner removed the right hand from the posterior perineum and supported the infant's neck with 1 hand, while supporting the remainder of the body with the other hand In both techniques, the women were allowed to push spontaneously during labour, without being directed in bearing down efforts, responding to involuntary contractions of the abdominal muscles
Outcomes	Perineal conditions (frequency, degree (intact perineum, 1st, 2nd, 3rd and 4th), and location of perineal laceration) Newborn outcomes, Apgar score, length of second stage
Notes	Funding sources: not reported Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Determined by electronically-produced randomised table. After exclusion group designations were automatically adjusted by following the randomisation table
Allocation concealment (selection bias)	Unclear risk	Electronically-produced randomised table. The researchers supervised both allocation to groups and birth technique. Insufficient information about concealment It is not clear when randomisation took place. Not ITT for 16 women who were included at first
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and staff not blinded

De Costa 2006 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Not mentioned - not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	16 women were excluded after first meeting the inclusion criteria and presumably having been included first, women receiving an episiotomy, women who chose to give birth in an lithotomy position, possibly also some women receiving oxytocin after randomisation and some with fetal distress. The analysis was not ITT as women with an episiotomy were not included in the analysis. Presumably randomisation took place before that
Selective reporting (reporting bias)	Unclear risk	There is no report on the 16 women excluded after inclusion. Why were they excluded? Which group did they belong to? Are the results of this study generalisable after so many exclusion criteria? Extreme selection Outcomes pre-specified in text. No protocol seen
Other bias	Unclear risk	Baseline characteristics similar in both groups but small number given. No other bias evident

Fahami 2012

Methods	RCT. 99 women. 3 arms Start date: November 2011; end date: February 2012
Participants	Setting: Daran Martyr Rajaei Hospital, Iran From 30 November 2011-8 February 2012, 99 primiparous women admitted to Daran Martyr Rajaei Hospital, Iran, were studied Inclusion criteria: maternal age from 18-35 years, nulliparous, singleton, gestational age from 37-41 weeks, estimated fetal weight of less than 4000 g (using the Johnson's law), displays a series of abortions, 7-8 cm dilatation of the cervix, no embryo water, spontaneous rupture of the bag before the active phase of labour, the lack of perineal preparation during pregnancy (perineal massage in the last 4 weeks of pregnancy, attending classes in preparation for labour, doing regular exercise or sport as a professional), the probability of difficult birth, no indications for caesarean section, no mental disorders, no chronic disease of the mother (maternal health, with questions and case studies), the risk of pre-eclampsia, no obvious lesions such as severe varicose veins or haematoma in the vulva or perineum, symptoms of vaginal infections and genital herpes (in the case of painful sores or lesions on the vulva and perineum, genital herpes diagnosis was possible), non-

	prescribed opioids, the use of Entonox gas for no-pain birth, no need for episiotomy (rigid and resistant perineum) Exclusion criteria: lack of progress in labour, fetal distress in the second stage of labour in each of 3 groups, using vacuum or forceps in birth, perineal oedema or rash occurrence, the mothers' withdrawal from partnership in the study
Interventions	Experimental intervention 1: Ritgen's manoeuvre - if the parturient was in the Ritgen's manoeuvre group, when the baby's head was distended the vulva and perineum (vaginal opening was open with a diameter of 5 cm or more), through the perineum and just in front of sacroiliac joint (lumbar vertebrae), with a hand within the glove and a towel thrown on it, a forward direction pressure would be applied onto the fetus' chin (this manoeuvre is traditionally called the adjusted Ritgen manoeuvre). During this action the left hand controlled the speed of the crowning of the baby's head Total number randomised: n = 33 Experimental intervention 2: perineal massage with lubricant - with completion of cervical dilation (10 cm) and also during the baby's head coronary (position of fetus head ischial tuberosity 2 +), the researcher with a glove-covered hand placed the sterile water solution (lubricant gel) on the middle finger and index finger, started a slow massaging of the vagina (in a reciprocating U-shaped motion) with gentle pressure toward the rectum from 1 wall to another wall so that each part lasted about 1 minute. The massaging was done during and among the pressures of the mother and regardless of the positioning. The downward pressure was determined by the mother's response and if the mother felt pain or burning, the pressure of midwife's fingers would be reduced. The total length of massage therapy was about 5-10 min Total number randomised: n = 33 Control/comparison intervention: non-touch technique - If the person was placed in non-touching group, the midwife would not touch any part of the perineum during the crowning of the baby's head and with the left hand prevented the sudden exit of the baby's head Total number randomised: n = 33
Outcomes	Perineal laceration and its severity (degree) The perineal pain after the first day of birth (in the first 24 h after childbirth) The perineal and genital pain associated with everyday activities at 6 weeks postpartum with the visiting units, as well as the first 24 h after childbirth
Notes	It should be noted that the researcher was present in all of the deliveries and also no episiotomy was performed in any groups Funding sources: Isfahan University of Medical Sciences Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	For sampling in this study the participants who had the inclusion criteria were randomly assigned to the 3 groups with the ratio of 1:1:1, using a random numbers table.

Fahami 2012 (*Continued*)

		This table was used by the researcher closing their eyes and putting a finger on 1 of the table numbers. Therefore, with the sequence of 5 pieces, numbers were selected from a batch of 30 each
Allocation concealment (selection bias)	Unclear risk	After preparing the white envelopes of the same shape, the numbers and code groups were noted on them. The envelopes contained the questionnaires and the codes
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible to blind
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not blinded - researcher attended all deliveries
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Difficult to assess. Denominators not given for outcomes. No mention of loss to follow-up
Selective reporting (reporting bias)	Unclear risk	Difficult to assess. Not clearly prespecified in text and no protocol seen
Other bias	Unclear risk	There was no description of maternal characteristics in the 3 groups apart from level of education so it was not clear whether groups were comparable at baseline

Foroughipour 2011

Methods	RCT to compare the effect of 2 methods, hands-on and hands-poised, on perineal traumas and neonatal outcome Individual randomisation Start date: October 2008; end date: October 2009
Participants	Setting: the study was carried out in labour ward of Shariati Hospital, in Isfahan, Iran Inclusion criteria: primiparous women, term labour, cephalic presentation, and maternal age 15-35 years Exclusion criteria: women with preterm labour, special medical conditions, dystocia (prolonged or difficult labour), or those who received analgesia during labour
Interventions	Experimental intervention: fetal head birth was performed by hands-on Total number randomised: n = 50 Control/comparison intervention: by hands-off method Total number randomised: n = 50

Foroughipour 2011 (*Continued*)

Outcomes	Perineal traumas, need for episiotomy, severity of perineal tears, haemorrhage, perineal pain and haematoma, and birth outcome including the duration of each labour stage, amount of haemorrhage in 1st, 2nd, 3rd and 4th stage of labour, and neonatal Apgar score and status
Notes	Funding sources: not reported Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	100 were randomly selected and randomly assigned to 2 groups
Allocation concealment (selection bias)	Unclear risk	100 were randomly selected and randomly assigned to 2 groups
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible with this intervention. Staff aware of allocation and decided whether to do episiotomy (a main outcome)
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not feasible with this intervention. Not clear from report who collected data. Likely to be delivering midwife, therefore lack of blinding could affect results
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Difficult to assess. Appears no loss to follow-up though totals not reported in tables
Selective reporting (reporting bias)	Unclear risk	No protocol seen. All appear to be reported from methods
Other bias	Unclear risk	Baseline data similar. No evidence of other bias

Galledar 2010

Methods	Parallel study Start date: August 2008; end date: March 2009
Participants	Setting: Imam Khomeini Hospital, Koohdasht City (Lorestan Province) in Iran Inclusion criteria: healthy and full-term nulliparous women, aged 18-35 years Exclusion criteria: prolonged second stage of labour, rapid birth, caesarean birth, shoulder dystocia, posterior position of fetal head, fetal distress, failure to fit over the hips, birthweight > 4000 g or < 2500 g and the change of address or telephone of participants

Galledar 2010 (*Continued*)

Interventions	Experimental intervention: massage Total number randomised: n = 71 Control/comparison intervention: routine care Total number randomised: n = 70
Outcomes	Outcomes: duration of the second stage of labour, intact perineum, perineal tear, episiotomy, degree perineal tear and intensity of perineal pain
Notes	Funding sources: Vice Chancellor for Research, Tehran University of Medical Sciences Conflicts of interest: not mentioned

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Sampling was carried out continuously and randomly
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Insufficient information provided
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Insufficient information provided
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information provided
Selective reporting (reporting bias)	Unclear risk	Comparing to IRCT201111053034N8 (national registry), 2 outcomes (stress urinary incontinence and fecal incontinence) were not assessed
Other bias	Unclear risk	Insufficient information provided

Geranmayeh 2012

Methods	RCT. Individual randomisation Start date: 2009; end date: 2009
Participants	Setting: in 2009 at Imam Sajjad Hospital in Shahryar, Tehran Inclusion criteria: age of 18-30 years, gestational age of 38-42 weeks, primiparous women, meeting all vaginal birth requirements with anterior cephalic presentation, nonexistence of any perineal injury (scar, inflammation, injury, etc.) which might interfere with massage and no sensitivity to Vaseline

	Exclusion criteria: fetal distress during birth and instrument-assisted birth or any reason requiring caesarean section
Interventions	Experimental intervention: receiving perineal massage with Vaseline treatment In the massage group, in the second stage of birth (after crowning and transfer of mother onto birth table), the clitoris, labia major and labia minor and the vestibule were treated with Vaseline. Another midwife performed sweeping and rotating perineal massage during uterine contractions and continued until the baby's head was out. The process would be halted if the mother felt discomfort, and resumed when feeling at ease. A maximum of 40 g of sterilised Vaseline was applied Total number randomised: n = 42 (?) Control/comparison intervention: the control group only received routine labour care Total number randomised: n = 40 (?) Both arms: in case of imminent tears in either group and at the discretion of the birth agent, medio-lateral episiotomy was performed. After the birth of the head, the mucus on the head, in the mouth and nostrils were removed and after full birth, the head and face were dried by sterilised gas and followed once again by the removal of mucus from the mouth and nose
Outcomes	Oxytocin consumption during labour, the length of the second stage of labour, nuchal cord, neonate's weight, the condition of the perineum in terms of episiotomy or perineal tear grade 1 and 2, 1-5 min neonate Apgar scores and neonatal complications. In addition, postpartum conditions or any likely side effects of Vaseline were followed-up and recorded within 10 days of birth through telephone or in person
Notes	Funding sources: not reported Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The participants were randomly assigned to the intervention group (receiving perineal massage with Vaseline treatment) and the control group (receiving routine care)
Allocation concealment (selection bias)	Unclear risk	The participants were randomly assigned to the intervention group (receiving perineal massage with Vaseline treatment) and the control group (receiving routine care). Not clearly described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and staff not blinded

Geranmayeh 2012 (*Continued*)

Blinding of outcome assessment (detection bias) All outcomes	High risk	Not feasible. Some outcomes may have been affected by lack of blinding here. An important outcome was episiotomy and this was carried out at the discretion of staff providing care. There was no mention of blinding for other outcomes that may have been affected by lack of blinding
Incomplete outcome data (attrition bias) All outcomes	High risk	It does not state anywhere how big the groups were or if there were any loss of follow-up 17 women dropped out and were replaced through random assignment
Selective reporting (reporting bias)	Unclear risk	No protocol seen. All outcomes reported from text
Other bias	Unclear risk	Lack of reporting in different parts of the study. Similar demographics in both groups

Harlev 2013

Methods	Prospective, randomised, double-blind study Start date: July 2008; end date: July 2009
Participants	Setting: Soroka University Medical Center Delivery Room, Israel Consecutive women in the first stage of labour who attended the Soroka University Medical Center Delivery Room, Israel Inclusion criteria: inclusion criteria were singleton pregnancies at term Exclusion criteria: pregnancies complicated by placenta praevia, non-vertex presentations, infection, non-progressive labour first stage, multiple gestations, grand multiparous women (more than 6 deliveries), women with previous vaginal surgery or surgical intervention and women who performed an antenatal perineal massage were excluded
Interventions	Experimental intervention: liquid wax (without additional vitamins, i.e. jojoba oil) Total number randomised: n = 82 Control/comparison intervention: purified formula of almond oil with olive oil, rich with vitamin B1, B2, B6, E and fatty acid Total number randomised: n = 82
Outcomes	Perineal trauma and location of tear
Notes	Funding sources: not reported Conflicts of interest: none declared

Risk of bias

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

Harlev 2013 (*Continued*)

Random sequence generation (selection bias)	Unclear risk	Not described Described as randomised - no detail given
Allocation concealment (selection bias)	Unclear risk	Not described Not clear when randomisation took place or by whom. Methods of allocation were not clear although there was a placebo
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Both oils were contained in similar bottles differentiated only by a number on the bottle. The midwives and the physicians who delivered the parturient were blinded to the oil type. Caregivers were instructed to use the oil during the second stage of the labour (as they routinely do)
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It is not clear if the people who performed the analyses were blinded to the allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	Appears that all women are reported for all outcomes. Does not mention loss of follow-up
Selective reporting (reporting bias)	Unclear risk	There was no protocol
Other bias	Low risk	No other bias evident

Jönsson 2008

Methods	RCT Unit of randomisation: women in the beginning of the second stage of labour at full cervical dilatation Start date: December 1999; end date: July 2001
Participants	Setting: tertiary level hospital in Sweden 1575 women were included. Inclusion criteria: eligible for the study were primiparous, women with singleton pregnancy, fetus in cephalic presentation, admitted for labour, rupture of the membranes or induction after 37 weeks Women were asked for consent on admission in labour Exclusion criteria: instrumental deliveries, emergency caesarean deliveries, parous women and preterm deliveries that had been erroneously included
Interventions	Experimental intervention: modified Ritgen's manoeuvre: lifting the fetal chin interiorly, using the fingers of 1 hand placed between anus and coccyx, and thereby extending the fetal neck, whereas the other hand should be place on the fetal occiput to control the pace of expulsion of the fetal head. The manoeuvre was used during a uterine contraction Control/comparison intervention: the standard practice at birth was using 1 hand to

	apply pressure against the perineum, and the other hand on the fetal occiput to control the expulsion of the fetal head. Standard practice was also to perform a lateral episiotomy only on indication
Outcomes	The rate of 3rd- to 4th-degree perineal ruptures including external anal sphincter
Notes	We contacted the study author and asked for additional information according to more data on the perineal trauma (intact perineum, perineal trauma not requiring suturing, perineal trauma requiring suturing, 1st- and 2nd-degree tear) but these data were not registered in the study Funding sources: Region Skone and Lund University Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The allocated randomisation was registered in an existing clinical data base, containing information of all deliveries at the 2 units Not clear how random numbers were generated
Allocation concealment (selection bias)	Unclear risk	The allocated randomisation was registered in an existing clinical data base, containing information of all deliveries at the 2 units. Randomisation was done at the beginning of the second stage of labour (at full cervical dilatation) and allocation took place off site. Midwives phoned up midwives based on different ward who kept randomised number lists for allocation
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind
Blinding of outcome assessment (detection bias) All outcomes	High risk	Delivering midwife assessed tears
Incomplete outcome data (attrition bias) All outcomes	Low risk	There is a flowchart in the article that describes any loss to follow-up. The flow chart describes the excluded participants: failure in the randomisation itself is also described in detail
Selective reporting (reporting bias)	Unclear risk	Outcomes pre-specified in text. No protocol available

Jönsson 2008 (*Continued*)

Other bias	Low risk	Similar baseline characteristics. No other bias evident

Lavesson 2014

Methods	A multicenter open RCT Start date: June 2010; end date: December 2011
Participants	Setting: Hospitals in Sweden: Helsingborg, Lund and Malmo 1148 women, individually randomised. Inclusion criteria: birth with cephalic presentation, age of > 18 years and an understanding of both oral and written information in Swedish Exclusion criteria: women undergoing emergency caesarean section were excluded
Interventions	Experimental intervention: perineal protection device Instructions: when 5-6 cm of the head was visible in the introitus during crowning, the device was to be inserted. The device was held so that the tongue and wings were kept apart with a finger. The waved tongue was inserted as indicated above the posterior commissure. The device should have been inserted without resistance. Gel could be used if needed. The vaginal opening at this stage of the birth is oval, and the wings were, therefore, spread apart. Wings were fixed against the perineum with the thumb and index finger of the right hand to support the perineum and speed of crowning was controlled with the left hand and the device pushed back during contraction when it would be squeezed out. If it fell out, it was put back As the crowning progresses, the vaginal opening becomes circular. This change results in the movement of the wings together. The posterior commissure is effectively locked between the tongue and the wings, and the device prevents the initiation of tearing when the head is maximally crowned. The device should be kept in place by the assistant during birth of the shoulders. If an episiotomy is required, it can be performed laterally of the device. In the case of an instrumental birth, the device can be used as described earlier. The assistant then holds the device in place to reduce the risk of tears, while the obstetrician performs the instrumental birth by steering the head gently through the introitus. The device is preferably kept in place during the birth of the shoulders Total number randomised: n = 546 Control/comparison intervention: the women allocated to the control group delivered following the procedures of the labour ward, which included perineal support with the fingers or the palm of the hand Total number randomised: n = 552 Both groups: if an episiotomy was required, it was performed in both groups with a lateral incision. The characteristics were not described further (length, angle etc.)
Outcomes	1st and 2nd degree tears, anal sphincter ruptures
Notes	Funding sources: grants from the Thelma Zoega and the Stig and Ragna Gorton Foundations Conflicts of interest: none except for Knut Haadem who is a shareholder in Vernix Caseosa

Lavesson 2014 (*Continued*)

Risk of bias		
Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	The women were randomly allocated to an intervention or a control group, i.e. the midwife drew an opaque sealed envelope in which the randomisation was revealed. The envelopes were numbered, and the randomisation was computerised
Allocation concealment (selection bias)	Low risk	The women were randomly allocated to an intervention or a control group, i.e. the midwife drew an opaque sealed envelope in which the randomisation was revealed. The envelopes were numbered, and the randomisation was computerised
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	High risk	Not feasible to blind this intervention. Lack of blinding could impact outcome assessment as delivering midwives assess the perineal damage
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Difficult to assess some loss of follow-up. Similar number across groups excluded following randomisation. May be related to outcome. Loss to follow up not included in ITT analysis
Selective reporting (reporting bias)	Unclear risk	No protocol seen. Pre-specified outcomes from methods reported
Other bias	Unclear risk	No other bias evident. Similar baseline characteristics in both groups. 1 researcher is shareholder in the device

Mayerhofer 2002

Methods	Quasi-randomised study. Women were randomised according to date of birth (even or odd day). Unit of randomisation: pregnant women entering the second stage of birth Start date: February 1999; end date: September 1999

Mayerhofer 2002 (*Continued*)

Participants	1161 women were included. Inclusion criteria: all women with an uncomplicated pregnancy and cephalic presentation, normal first and second stages of labour, gestational age > 37 weeks. Exclusion criteria: women with multiple pregnancy, non-cephalic presentation, caesarean section, forceps, vacuum, planned birth in water, visible perineal scar, language difficulties, gestation < 37 weeks
Interventions	Experimental intervention: the midwife keeps her hands poised, ready to put light pressure on the infants head to avoid rapid expulsion. However, in contrast to the hands-on method, the midwife does not touch the perineum with her right hand at any time during birth. Delivery of the shoulders is supported with both of the midwife's hands. Control/comparison intervention: hands-on method: the left hand of the midwife puts pressure on the infants head in the belief that flexion will be increased. The right hand is placed against the perineum to support this structure and to use lateral flexion to facilitate delivery of the shoulders
Outcomes	Maternal outcomes: perineal tear,1st, 2nd, 3rd degree, vaginal, labial, episiotomy (median or lateral). Neonatal outcomes: infant birthweight, length, head diameter, infant shoulders, Apgar score (1 min < 7, 5 min < 7) and cord pH < 7.1) (All perineal trauma were confirmed by an experienced obstetrician-gynaecologist)
Notes	We tried to contact the study author for supplementary information but did not succeed. We would like to know what the authors meant by "visible perineal scar" and for information of "perineal trauma requiring suturing", whether they had calculated the mean and the standard deviation of the length of second stage and how they defined the length of the second stage. We also asked for more details on the differences between the groups for the characteristics in table 1 and how the authors defined "normal" in the first and the second stage. In addition, were the women with augmented labour, continuous fetal monitoring and prolonged labour excluded from the study Funding sources: not reported Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	High risk	Randomised according to the date of delivery. On even days and odd days. Noon as a break point of randomisation. Women entering the second stage of labour before noon and delivering after noon were treated according to the randomisation policy of the previous day. Quasi-randomisation
Allocation concealment (selection bias)	High risk	Randomised according to the date of delivery. On even days and odd days. Noon as a break point of randomisation. Women entering the second stage of labour before noon and delivering after noon were treated

Mayerhofer 2002 (*Continued*)

		according to the randomisation policy of the previous day. There was no concealment
Blinding of participants and personnel (performance bias) All outcomes	High risk	Blinding not mentioned - assumed not blinded
Blinding of outcome assessment (detection bias) All outcomes	High risk	Assessment of tears was by the midwife carrying out intervention, although this assessment was checked by an obstetrician
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data were missing from 85 women (40 + 45) = 85, 6% of the total number of deliveries. Due to incomplete study forms. The analyses were performed according to group assignment irrespective of the form of perineal care delivered, i.e. ITT
Selective reporting (reporting bias)	Unclear risk	It is not possible to extract from the article if the primiparous women were divided equally between groups It is unclear if there were significant differences between the groups for the characteristics in table 1 (characteristics of the clinical population)
Other bias	Low risk	Hands-on group had larger percentage of women in supine position No other sources of bias evident More women in the hands-on group had episiotomy; it was not clear how this affected assessment of tears

McCandlish 1998

Methods	RCT. Block randomisation, with blocks of 4-8, stratified by centre. Unit of randomisation: pregnant women at the end of the second stage when the midwife considered a vaginal birth imminent Start date: December 1994; end date: December 1996
Participants	Setting two hospitals in UK 5471 women were included. Recruitment and randomisation happened at 2 hospitals, both National Health Service hospitals in England (not private but for the general public funded by the state). Both hospitals had approximately 5500 births a year Inclusion criteria: women with a singleton pregnancy with cephalic presentation, anticipating a normal birth giving consent antenatally Exclusion criteria: women planning to have a water birth, women who had an elective episiotomy prescribed, women planning adoption. Women were excluded on admission

	if they gave birth before 37 weeks' gestation
Interventions	Experimental intervention: hands-poised method in which the midwife keeps her hands poised, prepared to put light pressure on the baby's head in case of rapid expulsion, but not to touch the head or perineum otherwise and to allow spontaneous birth of the shoulders Control/comparison intervention: hands-on method, in which the midwife's hands are used to put pressure on the baby's head in the belief that flexion will be increased, and to support (guard) the perineum, and to use lateral flexion to facilitate the delivery of the shoulders
Outcomes	Primary outcome was perineal pain in the previous 24 h reported by the mother 10 days after birth (formed the basis for the power calculation). Other outcomes recorded: perineal trauma, if trauma was sutured, perineal pain at around 2 days and 3 months after birth, dyspareunia at 3 months, urinary and bowel problems at 10 days and 3 months and breastfeeding at 10 days and 3 months. For the newborn the Apgar score, if applicable type of resuscitation given, admission with reason for the admission were recorded
Notes	Funding sources: Medical Research Council, Southmead Health Services NHS Trust, Department of Health Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Details of the allocated group were given on coloured cards contained in sequentially-numbered, opaque, sealed envelopes. Prepared at the National Perinatal Epidemiology Unit and kept in an agreed location on each labour ward. To enter a woman into the study the midwife opened the next consecutively numbered envelope. If an envelope was not opened, the reason for non-use was recorded by the midwife who had drawn it. All envelopes, whether used or not were returned to the NPEU. Unopened but not used envelopes were not returned to the unit
Allocation concealment (selection bias)	Low risk	Details of the allocated group were given on coloured cards contained in sequentially numbered, opaque, sealed envelopes, prepared at the National Perinatal Epidemiology Unit and kept in an agreed location on each labour ward. To enter a woman into the study the midwife opened the next con-

		secutively numbered envelopes. If an envelope was not opened, the reason for non-use was recorded by the midwife who had drawn it. All envelopes, whether used or not were returned to the NPEU. Unopened but not used envelopes were not returned to the unit.
Blinding of participants and personnel (performance bias) All outcomes	High risk	Staff encouraged not to tell women allocation. Likely that this was broken
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	It was stated that allocation was not recorded in notes and postnatal midwives recording outcomes would be unlikely to know which group women were in. Some data from maternal questionnaires, it was not clear how many women were aware of allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	During the study period 18,458 deliveries took place. There is a detailed flow chart that describes the excluded participants. The reasons for not being randomised were: not recruited antenatally, planned instrumental birth or caesarean section, maternal refusal, non-cephalic presentation, multiple pregnancy, planned birth in water, intrauterine death, episiotomy prescribed and other. However 5471 (29.6%) women were randomised into experimental group 2740 and controls 2731. There was no exclusion after randomisation. The analysis was ITT
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes from methods reported. No protocol seen
Other bias	Unclear risk	Approximately ¾ midwives had a practice preference at the start of the trial. Compliance with intervention was lower in the hands-poised group

Most 2008

Methods	Quasi RCT (randomisation by hospital number) Start and end date: not reported
Participants	Setting: (not clear) New York University Medical Centre, USA Inclusion criteria: 120 women in labour with singleton pregnancies, cephalic presentation between 37 and 42 weeks of gestation
Interventions	• The intervention group had 6 g of a lubricant applied to the perineum when the cervix was fully dilated • Normal saline applied to the perineum • No special intervention
Outcomes	Number and severity of perineal lacerations, episiotomy rate
Notes	We were unable to include data from this study in the review. Although the study was otherwise eligible for inclusion, group denominators were not stated and results for randomised groups were not reported in a way that allowed inclusion in the review (P values were stated but no raw data were presented) Funding sources: not reported Conflicts of interest: not reported

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	Allocation by hospital number, which could be anticipated by staff carrying out randomisation
Allocation concealment (selection bias)	High risk	Allocation by hospital number
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not mentioned but likely to be high risk as interventions would be apparent to women and staff
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not mentioned but likely to be high risk as the outcomes reported were assessed by midwives aware of allocation
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No attrition mentioned but group denominators were not clear
Selective reporting (reporting bias)	High risk	Results were not reported by randomised groups and group denominators were not stated
Other bias	Unclear risk	We were unable to include data from this study in the review. There was little information on methods and results

Musgrove 1997

Methods	RCT Start date and end date: not reported
Participants	Inclusion criteria: (not clear) women in the second stage of labour 71 women randomised
Interventions	Hot packs to the perineum during the second stage of labour
Outcomes	Pain, episiotomy, perineal tears
Notes	Results for this study were reported in a brief abstract with very limited information about study methods. Selected results were reported and there were some inconsistencies in the data. For these reasons we were unable to include data from this study in the review Funding sources: not reported Conflicts of interest: not reported

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	Not described
Allocation concealment (selection bias)	Unclear risk	Not described
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not mentioned but likely to be high risk as women and staff would be aware of the intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not mentioned but likely to be high risk as staff assessing outcomes would be aware of the intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Not discussed. Not clear if there were missing outcome data
Selective reporting (reporting bias)	High risk	Selective outcome reporting and inconsistencies in outcome data
Other bias	Unclear risk	Results for this study were reported in a brief abstract with very limited information about study methods

Rezaei 2014

Methods	RCT Start date: April 2012; end date: August 2013
Participants	Setting: this study was conducted at the Imam Ali Central Education located in Amol City and affiliated to the Mazandran University of Medical Science, Iran Inclusion criteria: the subjects of this study were 600 primiparous healthy women aged between 15-35 years with singleton pregnancy, weighing 2500-4000 g. Amniotic membranes were intact at the time of admission and the labour duration was less than 12 h after the individuals were admitted. Oxytocin was not used at the first and second stage of birth neither was the preparation of the perineal done during pregnancy Exclusion criteria: women or fetuses that needed special medical attention were excluded from the study
Interventions	Experimental intervention: hands on When crowning was done in perineal control through the 'hands-on' method, the midwife placed the index, ring, and little fingers of her left hand close together on the fetus's occiput, with the palm turned toward the anterior region of the perineum. In this manner, expulsion was controlled by maintaining the flexion of the head protecting the anterior region of the perineum, providing support to the ischio-cavernous and bulbocavernous muscles, the urethral introitus, and the labia major and minor. Simultaneously, the right hand was flattened, and placed on the posterior perineum, with the index finger, and the thumb forming a 'U' shape, exerting pressure. All regions of the perineum, particularly the fourchette, remained protected. When the shoulders and the rest of the body were coming out, the right hand was kept in place, protecting the posterior region of the perineum and the left hand supported the baby's head so that the outside and head rotation happened spontaneously. Midwife pulled out the baby's shoulder and the rest of its body when this did not happen spontaneously Total number randomised: n = 300 Control/comparison intervention: hands off During the expulsive period of the 'hands-off' method, the midwife's conduct was exclusively expectant, she only observed the successive movements of restitution, external rotation, delivery of the shoulders, and the remainder of the body. The midwife rotated the head and helped in the birth, when this did not occur spontaneously within 15 min after the birth of head or the newborn appeared hypoxic Total number randomised: n = 300
Outcomes	Perineal trauma/degrees of tear
Notes	Funding sources: Mazandaran university of medical sciences, Sari, Iran Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	Allocation of the 2 groups (300 on each arm) was randomised using numbered opaque sealed envelopes, cards containing computer-generated random allocations

Rezaei 2014 (*Continued*)

Allocation concealment (selection bias)	Low risk	Allocation of the 2 groups (300 on each arm) was randomised using numbered opaque sealed envelopes, cards containing computer-generated random allocations
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible with this intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Data collection was done by the respective midwife in charge of the birth. Midwives were trained in the perineal methods as well as on both methods of birth. Allocation of the groups and the birth were supervised by the scientists in charge of this study
Incomplete outcome data (attrition bias) All outcomes	Low risk	Data collection was done by the respective midwife in charge of the birth. Midwives were trained in the perineal methods as well as on both methods of birth. Allocation of the groups and the birth were supervised by the scientists in charge of this study
Selective reporting (reporting bias)	Unclear risk	All outcomes appear to be reported however difficult to assess due to no protocol available
Other bias	Unclear risk	No baseline data reported. No information of how many received treatment as per protocol

Shirvani 2014a

Methods	2-site parallel RCT. Stratified randomisation, matching women to balance BMI and intact or ruptured membranes Start date: September 2011; end date: March 2012
Participants	Setting: performed in 2 hospitals in northern Iran between September 2011-March 2012 Inclusion criteria: null parity, age of 18-35, gestational age of 37-41 weeks, single pregnancy, cephalic presentation and cervix dilatation of 3-4 cm Exclusion criteria: women with psychiatric disorders, contracted pelvic, chronic systemic disorders, dermatological problems in cold-therapy region and complications of pregnancy such as gestational hypertension, decrease in fetal movement, fetus growth retardation, fetal death, abnormal fetal heart rate and application of other pharmacological or non pharmacological analgesic methods were excluded

Interventions	Experimental intervention: in cold-therapy group, a trained doula, who was a midwife applied a 25 x 9 x 15 cm ice bag filled with 500 g ice covered by a towel over back, abdomen and lower parts of the abdomen for 10 min since initiation of active phase and repeated 30 min later. Additionally, she applied a 15 x 9 x 10 cm cool pack filled with 200 g ice over perineum during the second phase of birth for 5 min every 15 min. The intervals were selected based on the minimum time for initiation of cold effect, 5-10 min, and its long effect (McCaffrey, 1999). Total number randomised: n = 32 Control/comparison intervention: to control the supporter effect, the doula gave the same supportive care to mothers in the control group during the labour. The researcher advised her about importance of similarity in supportive care and checked it during the study Total number randomised: n = 32 Both groups: a bedside midwife did routine care in both groups, such as control of fetal heart rate and uterine contractions, application of oxytocin if it was necessary and performed birth and episiotomy. We did not apply additional interventions except as part of routine care for control group. Vaginal examinations were performed based on cervix situation and labour progression, almost every 1 hour
Outcomes	Women's obstetric and demographic information was collected by interview and reviewing the record files. Pain severity was assessed by visual analogue scale A trained midwife asked participants of the 2 groups to demonstrate the severity of pain on visual analogue scale at the beginning of the active phase (dilatation of 3-4 cm) , acceleration phase (dilatation of 5-6 cm), maximum of slope (dilatation of 7-8 cm), deceleration (dilatation of 9-10 cm) and the second phase of labour. She recorded the data about duration of all phases of birth, obstetric interventions and maternal, fetal and neonatal outcomes in sheets for both groups. Women's satisfaction about labour experience was evaluated at the end of birth by a 5-point Likert questionnaire
Notes	Funding sources: Research Deputy of Mazandaran University of Medical Sciences Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	64 pregnant women admitted to labour unit were randomly allocated to 2 groups as cold therapy (n = 32) and control (n = 32). The head of research generated the random allocation sequence by numbered cards. The groups were matched based on the rupture of membranes and body mass index
Allocation concealment (selection bias)	Unclear risk	Not mentioned

Shirvani 2014a (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	No blinding feasible in this intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	No blinding feasible in this intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	4 women declined to participate. Data appear to be complete, however this is difficult to assess as no totals were given in the tables
Selective reporting (reporting bias)	Unclear risk	Protocol not available. Results reported that were outlined in methods
Other bias	Low risk	Baseline data similar in both groups

Sohrabi 2012

Methods	RCT. 3 arms. 120 women Study dates not clear from translation.
Participants	Setting: teaching hospital of Emam Khomeini - Khalkhal, Iran Inclusion criteria: age 18- 35, no underlying disease, nulliparous women expecting normal birth of singleton fetus, infant's estimated weight > 4000 g, normal birth of singleton fetuses Exclusion criteria: unwillingness of women to continue to co-operate, prolonged second stage of labour, fetal distress, meconium discharge, dystocia, detachment, attempting to use vacuum, induction and accelerated birth
Interventions	Experimental intervention 1: massage perineum. Total number randomised: n = 40 Experimental intervention 2: warm compresses. Total number randomised: n = 40 Control/comparison intervention: Ritgen's manoeuvre, routine and standard care Total number randomised: n = 40
Outcomes	Severity and degree of perineal ruptures, the rate of the lacerations in the anterior perineal region and the amount of stitches required for perineal repair
Notes	Funding sources: not mentioned in translation Conflicts of interest: not mentioned in translation

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Unclear risk	The subjects were randomly and by drawing lots divided into 3 groups; warm com-

Sohrabi 2012 (*Continued*)

		presses, perineal massage, and control
Allocation concealment (selection bias)	Unclear risk	Insufficient information provided
Blinding of participants and personnel (performance bias) All outcomes	High risk	All deliveries were done by researcher and due to the nature of the study, there was no possibility of blinding of study for researchers and pregnant mother
Blinding of outcome assessment (detection bias) All outcomes	High risk	Insufficient information provided. Assume not blinded
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Insufficient information. No denominators for results. No mention of any missing data
Selective reporting (reporting bias)	Unclear risk	The protocol was not available
Other bias	Unclear risk	No other bias evident. No information on participant characteristics

Stamp 2001

Methods	RCT 1:1, prepared batches of 100. Stratification for nulliparous and multiparous women Unit of randomisation: women in uncomplicated labour having progressed to either visible vertex, full dilatation or 8 cm or more if nulliparous and 5 cm or more if multiparous Start date: March 1995; end date: January 1998
Participants	Setting: three large hospitals in Australia 1340 women were included. From 3 hospitals in Australia with 7000 births per year (presumably the 3 together and not at each hospital). It took nearly 3 years to collect the data Inclusion criteria: women who at 36 weeks of pregnancy had given written consent while expecting a normal vaginal birth of a single baby and who presented in uncomplicated labour having progressed to either visible vertex, full dilatation or 8 cm or more if nulliparous and 5 cm or more if multiparous. English speaking Exclusion criteria: not specified specifically.
Interventions	Experimental intervention: massage and stretching of the perineum with each contraction during the second stage of labour. The midwife inserted 2 fingers inside the vagina and using a sweeping motion, gently stretched the perineum with water soluble lubricating jelly, stopping if it was uncomfortable Control/comparison intervention: the midwife's usual technique but refraining from perineal massage
Outcomes	Main outcome was intact perineum. Primary outcome was perineal trauma defined in 1st, 2nd, 3rd, 4th degree tear. Secondary outcomes were pain at 3 days, 10 days and 3 months postpartum, resumption of sexual

Stamp 2001 (*Continued*)

	intercourse, dyspareunia and urinary and faecal urgency
Notes	Funding sources: Research and Development Grants Advisory Committee of the Commonwealth Department of Health Housing and Community Services (now National Health and Medical Research Council) and the Australian College of Midwives Conflicts of interest: Johnson and Johnson provided water soluble lubricant for the perineal massage

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Envelopes were sequentially numbered, prepared by a research assistant not involved in care of the women. It appears that each hospital had their own boxes for nulliparous and multiparous women
Allocation concealment (selection bias)	Low risk	Envelopes were sequentially numbered, prepared by a research assistant not involved in care of the women. It appears that each hospital had their own boxes for nulliparous and multiparous women. To find out allocation the midwife had to ring to the emergency department were the duty midwife or clerk opened the next double packed, sealed envelope
Blinding of participants and personnel (performance bias) All outcomes	High risk	Because of the nature of the intervention it was not possible to mask the treatment allocation. Educational strategies informed midwives of the aim that as many women as possible should receive the treatment to which they had been randomised
Blinding of outcome assessment (detection bias) All outcomes	High risk	When practicable the attending midwife was asked to obtain an independent perineal assessment from a caregiver not involved in the birth
Incomplete outcome data (attrition bias) All outcomes	Low risk	3050 eligible women were approached. However, in that period about 19,000 women gave birth at these 3 hospitals. It appears likely that quite a number of eligible women were not asked Of the 2291 who consented only 1340 were randomised. The reasons for not randomising women were as follows: 217 caesarean section, 105 instrumental birth, 168 no

Stamp 2001 (*Continued*)

		reason, 112 women changed their mind, 121 rapid progress, 77 midwife forgot, 80 midwife too busy, 71 other reasons. There were no exclusions after randomisation, The analyses was performed according to ITT.
Selective reporting (reporting bias)	Low risk	Pre-specified outcomes in text all reported. Some outcomes vague
Other bias	Low risk	Similar baseline characteristics. No other sources of bias.

Terre-Rull 2014

Methods	An open multicentre clinical trial directed from the School of Nursing at the University of Barcelona was carried out between 2009 and 2010 in 5 Catalan Hospitals. The pregnant women were randomised to 3 study groups Objective: evaluate the effectiveness of heat, moist or dry to the perineum during birth in order to reduce injuries requiring perineal suturing after birth, and to assess its safety in relation to the adaptation of the newborn to extrauterine life Start date: 2009; end date: 2010
Participants	Setting: five Catalan hospitals 198 pregnant women subjected to the natural protocol for normal birth assistance
Interventions	Application of moist heat (MHG), dry heat (DHG), and control (CG). Usual care of the perineum was performed during labour in all groups and MHG or GCS was also applied in the perineum in the intervention groups
Outcomes	Apgar score in the newborn and perineum postpartum was then assessed. Perinea that required no suturing. Perineal tears
Notes	Funding sources: Grant awarded by the Department of Public Health, and the University of Barcelona Conflicts of interest: none declared

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Random sequence generation (selection bias)	Low risk	This was a randomised, open multicenter study
Allocation concealment (selection bias)	Low risk	The allocation concealment was done by using closed envelopes

Terre-Rull 2014 (*Continued*)

Blinding of participants and personnel (performance bias) All outcomes	High risk	Not feasible with this intervention
Blinding of outcome assessment (detection bias) All outcomes	High risk	Not feasible with this intervention
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Unclear type of analysis or data used (completers/ITT)
Selective reporting (reporting bias)	Unclear risk	There is no protocol seen for this study (not mentioned)
Other bias	Unclear risk	No other bias evident

ITT: intention to treat; RCT: randomised controlled trial

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

Study	Reason for exclusion
Ashwal 2016	The intervention in this study happened in the first stage of labour. This is not the focus of this systematic review
Barbieri 2013	The intervention was in the first stage of labour.
Behmanesh 2009	This RCT compared heat pad on lower back in first stage and heat pad on perineum during second stage vs routine care. The interventions in this study were carried out in both the first and second stages of labour; this review deals with interventions only in the second stage of labour
Corton 2012	This intervention study investigated the use of stirrups in labour on perineal lacerations. This is excluded because it is not a perineal technique
Demirel 2015	The intervention in this study, perineal massage, takes place in both in the first and second stages of labour and not only in the second stage. This review deals with interventions only in the second stage of labour
Hassaballa 2015	This study is presented as a short abstract and investigated the use of obstetric gel in decreasing the duration of labour and the risk of perineal lacerations. It is excluded from our review because the intervention was not confined to the second stage of labour
Karacam 2012	This study intervention started in the first stage of labour and not only in the second stage as is the topic of this review
Low 2013	In this study the perineal massage takes place in pregnancy and not in the second stage of labour

(*Continued*)

Schaub 2008	This RCT was conducted to determine whether obstetric gel shortened the second stage of labour or exerted a protective effect on the perineum. It is not a perineal technique in the second stage of labour and therefore not suitable for this review
Taavoni 2013	In this study warm, moist towels were applied to perineal and sacrum areas during what was described as active labour; women were asked to hold the towels in place with their thighs. The intervention continued until 8 cm cervical dilatation. This study examined an intervention in the first stage of labour and is not eligible for inclusion in this review

RCT: randomised controlled trial

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

Taavoni 2015

Methods	Described as RCT
Participants	Inclusion criteria • 120 healthy women in the active stage of labour (cervix 4 to 8cm at randomisation) • 18-35 years old • Primiparous • At term (38-40 weeks' gestation) Exclusion criteria: not stated
Interventions	4 groups: use of birth ball, application of heat packs, both or no intervention. Intervention during the "active phase" (not clear)
Outcomes	Pain. Not clear if other outcomes were examined
Notes	There was insufficient information in the study reports on methods, intervention and outcomes. It was not clear whether the intervention was confined to the first stage of labour. We have attempted to contact the trial author to ascertain whether the trial is eligible for inclusion in the review. (Enquiry to Tehran University 5 January 2017.)

Velev 2013

Methods	RCT
Participants	120 women during the second stage of labour
Interventions	Women were divided into 4 groups. It was not clear how many women were randomised to each group. The intervention was a gel applied to the perineum and vaginal wall in the second stage of labour
Outcomes	Duration of labour

Velev 2013 (*Continued*)

Notes	The trial report was in Bulgarian and we obtained a partial translation. There was insufficient information on methods and results to allow us to ascertain whether or not this trial was eligible for inclusion. We will attempt to contact the trial authors for further information (email address and contact information were not provided in the research report)

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

NCT02588508

Trial name or title	Effectiveness of warm packs, perineal massage and hands off during labour in the perineal outcomes
Methods	RCT
Participants	Inclusion criteria • Parturient in active phase of labour • Single fetus at term (37-42 weeks) • Bent cephalic fetal presentation • Parity < 4 children Exclusion criteria • Use any perineal preparation techniques during pregnancy • Clinical indication for caesarean section
Interventions	Warm packs, perineal massage and hands off during labour
Outcomes	The perineal outcomes are perineal tears, grade of perineal tears, need of suture, perineal oedema, perineal pain, use of drugs for perineal pain, and satisfaction with the technique used
Starting date	April 2015
Contact information	Contact: Jânio N Alves, janiourofisio@gmail.com; Melania MR Amorim, melamorim@uol.com.br
Notes	This study is currently recruiting participants. We are unable to assess eligibility until more information are made available

DATA AND ANALYSES

Comparison 1. Hands off (or poised) versus hands on

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intact perineum	2	6547	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.95, 1.12]
2 1st degree tear	2	700	Risk Ratio (M-H, Random, 95% CI)	1.32 [0.99, 1.77]
3 2nd degree tear	2	700	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.47, 1.28]
4 3rd or 4th degree tears	5	7317	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.21, 2.26]
5 Episiotomy	4	7247	Risk Ratio (M-H, Random, 95% CI)	0.58 [0.43, 0.79]
6 3rd degree tear	4	1846	Risk Ratio (M-H, Random, 95% CI)	0.49 [0.09, 2.73]
7 4th degree tear	1	70	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Comparison 2. Warm compresses versus control (hands off or no warm compress)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intact perineum	4	1799	Risk Ratio (M-H, Random, 95% CI)	1.02 [0.85, 1.21]
2 Perineal trauma not requiring suturing	1	76	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.48, 1.42]
3 Perineal trauma requiring suturing	1	76	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.79, 1.66]
4 1st degree tear	2	274	Risk Ratio (M-H, Random, 95% CI)	1.19 [0.38, 3.79]
5 2nd degree tear	2	274	Risk Ratio (M-H, Random, 95% CI)	0.95 [0.58, 1.56]
6 3rd or 4th degree tears	4	1799	Risk Ratio (M-H, Random, 95% CI)	0.46 [0.27, 0.79]
7 Episiotomy	4	1799	Risk Ratio (M-H, Random, 95% CI)	0.86 [0.60, 1.23]
8 3rd degree tears	3	1082	Risk Ratio (M-H, Random, 95% CI)	0.51 [0.04, 7.05]
9 4th degree tears	2	884	Risk Ratio (M-H, Random, 95% CI)	0.11 [0.01, 2.06]

Comparison 3. Massage versus control (hands off or care as usual)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intact perineum	6	2618	Risk Ratio (M-H, Random, 95% CI)	1.74 [1.11, 2.73]
2 Perineal trauma requiring suturing	1	76	Risk Ratio (M-H, Random, 95% CI)	1.10 [0.75, 1.61]
3 1st degree perineal tear	5	537	Risk Ratio (M-H, Random, 95% CI)	1.55 [0.79, 3.05]
4 2nd degree perineal tear	5	537	Risk Ratio (M-H, Random, 95% CI)	1.08 [0.55, 2.12]
5 3rd or 4th degree tears	5	2477	Risk Ratio (M-H, Random, 95% CI)	0.49 [0.25, 0.94]
6 Episiotomy	7	2684	Risk Ratio (M-H, Random, 95% CI)	0.55 [0.29, 1.03]
7 3rd degree tear	5	2477	Risk Ratio (M-H, Random, 95% CI)	0.57 [0.16, 2.02]

8 4th degree tear	5	2477	Risk Ratio (M-H, Random, 95% CI)	0.26 [0.04, 1.61]

Comparison 4. Ritgen's manoeuvre versus standard care

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Intact perineum	1	66	Risk Ratio (M-H, Random, 95% CI)	0.17 [0.02, 1.31]
2 1st degree tear	1	66	Risk Ratio (M-H, Random, 95% CI)	0.32 [0.14, 0.69]
3 2nd degree tear	1	66	Risk Ratio (M-H, Random, 95% CI)	3.25 [1.73, 6.09]
4 3rd or 4th degree tears	1	1423	Risk Ratio (M-H, Random, 95% CI)	1.24 [0.78, 1.96]
5 Episiotomy	2	1489	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.63, 1.03]
6 3rd degree tears	1	1423	Risk Ratio (M-H, Random, 95% CI)	1.42 [0.86, 2.36]
7 4th degree tears	1	1423	Risk Ratio (M-H, Random, 95% CI)	0.60 [0.18, 2.03]

Comparison 5. Primary delivery of posterior versus anterior shoulder

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Perineal trauma requiring suturing	1	543	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.96, 1.07]
2 3rd or 4th degree tears	1	543	Risk Ratio (M-H, Random, 95% CI)	0.81 [0.39, 1.67]

Comparison 6. Perineal protection device versus perineal support

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 1st and 2nd degree tears	1	1098	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.98, 1.02]
2 3rd or 4th degree tears	1	1098	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.54, 1.89]
3 Episiotomy	1	1098	Risk Ratio (M-H, Random, 95% CI)	0.90 [0.53, 1.53]
4 3rd degree tears	1	1098	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.54, 1.89]
5 4th degree tears	1	1098	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.11, 4.02]

Comparison 7. Enriched oil versus liquid wax

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 1st degree tear	1	164	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.84, 1.40]
2 2nd degree tear	1	164	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.58, 1.31]
3 Episiotomy	1	164	Risk Ratio (M-H, Random, 95% CI)	1.33 [0.48, 3.67]
4 3rd degree tears	1	164	Risk Ratio (M-H, Random, 95% CI)	1.0 [0.14, 6.93]

Comparison 8. Cold compresses versus control

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 1st degree tear	1	64	Risk Ratio (M-H, Random, 95% CI)	2.5 [0.52, 11.96]
2 Episiotomy	1	64	Risk Ratio (M-H, Random, 95% CI)	0.9 [0.76, 1.07]

WHAT'S NEW

Last assessed as up-to-date: 26 September 2016.

Date	Event	Description
26 September 2016	New search has been performed	Search updated. The methods have been updated and now includes the use of GRADE to assess the quality of the body of evidence We included 12 new studies, and two previously excluded trials. This updated review now has a total of 22 included studies (involving 15,181 randomised women). Ten trials are excluded
21 September 2016	New citation required but conclusions have not changed	The updated review now incorporates data from 22 studies - with five new comparisons on Ritgen's manoeuvre versus standard care, primary delivery of the posterior shoulder versus anterior shoulder, perineal protection device versus perineal support, enriched oil versus liquid wax, and cold compresses versus control. The overall conclusions have not changed

HISTORY

Protocol first published: Issue 3, 2007

Review first published: Issue 12, 2011

Date	Event	Description
11 January 2012	Amended	Corrected citation.
16 December 2011	Amended	Contact details edited.
20 September 2008	Amended	Converted to new review format

CONTRIBUTIONS OF AUTHORS

For the first version of this review all three review authors (V Aasheim (VAA), ABV Nilsen (ABVN) and M Lukasse (ML)) worked collaboratively on the development of the protocol and the review. Liv Merete Reinar (LMR) guided the other three authors in the development of the protocol and review.

For this update, VAA co-ordinated the review process. VAA and ABVN revised the text of the review. The background was revised by VAA, ABNV and ML. VAA and ABVN assessed studies for inclusion, ML and LMR extracted data and assessed risk of bias in included studies. Any disagreements were resolved by discussion. LM performed with help from Anna the GRADE assessment and preparation of 'Summary of findings' tables. Overall conclusions were discussed as a group. VAA, ABVN and ML contacted trial authors for additional information.

DECLARATIONS OF INTEREST

Vigdis Aasheim: none known.

Anne Britt Vika Nilsen: none known.

Liv Merete Reinar: has received royalties from the publisher Cappelen Damm in relation to a chapter written in a published textbook for midwives.

Mirjam Lukasse: none known.

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Internal sources

- Norwegian Health Service Research Center, Norway.
- Bergen University College, Faculty of Health and Social Sciences, Department of Postgraduate Studies, Norway.
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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

There are differences between this updated version of the review and the previously published version (Aasheim 2011).

For this update, we have made the following changes to the primary and secondary outcomes listed in our methods.

Primary outcomes

We have added 'third- and fourth-degree perineal tears' as a new primary outcome in place of two outcomes (third-degree perineal tear; fourth-degree perineal tear - which are now secondary outcomes). It can be difficult to divide these perineal outcomes and studies often report these outcomes together.

Secondary outcomes

Two outcomes, 'third-degree perineal tear' and 'fourth-degree perineal tear' have now moved from primary to secondary outcomes. Women's satisfaction has been edited to include '(as defined by the trial authors)'.

Methods

We have updated our methods text in line with the latest Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2011c) and the standard methods text of Cochrane Pregnancy and Childbirth. This update now includes the use of GRADE to assess the quality of the body of evidence and includes 'Summary of findings' tables (Summary of findings for the main comparison; Summary of findings 2; Summary of findings 3; Summary of findings 4).

INDEX TERMS

Medical Subject Headings (MeSH)

*Labor Stage, Second; Anal Canal [*injuries]; Delivery, Obstetric [*methods]; Episiotomy [adverse effects; utilization]; Hot Temperature [therapeutic use]; Lacerations [*prevention & control]; Massage; Obstetric Labor Complications [*prevention & control]; Perineum [*injuries]

MeSH check words

Female; Humans; Pregnancy