National Institute for Health and Care Excellence

Final

Intrapartum care

[I] Evidence reviews for interventions to reduce perineal trauma

NICE guideline NG235

Evidence reviews underpinning recommendations 1.9.12 to 1.9.14 and a research recommendation in the NICE guideline

September 2023

Final

These evidence reviews were developed by NICE

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Interventions to reduce perineal trauma

Review question

What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

Introduction

Vaginal birth may be associated with tears to the perineum that occur as the baby is born. These can vary in severity and include those that affect only the skin and heal quickly (first-degree tears), those that affect the perineal muscle (second-degree tears), or those that extend to the anal sphincter and may have serious long-term consequences if not repaired properly (third-and fourth-degree tears). A surgical incision (episiotomy) is sometimes used to enlarge the vaginal opening and reduce the risk of tear formation, but midwives may also use less invasive perineal care techniques to protect the perineum during the second stage of labour for the same purpose.

The aim of this review is to assess the effectiveness of different perineal care techniques in the second stage of labour.

Summary of the protocol

See Table 1 for a summary of the Population, Intervention, Comparison and Outcome (PICO) characteristics of this review.

Table 1: Summary of the protocol (PICO table)

Population	• Women in the second stage of labour who are pregnant with a single baby, who go into labour at term (37 to 42 weeks of pregnancy) and who do not have any pre-existing medical conditions or antenatal conditions that predispose to a higher risk birth • Women in the second stage of labour whose baby has not been identified before labour to be at high risk of adverse outcome • Singleton babies born at term (37 to 42 weeks of pregnancy) with no previously identified problems (for example congenital malformations, genetic anomalies, intrauterine growth restriction, placental problems)
Intervention	Any perineal technique performed during the second stage of labour, for example: • cold compresses • hand position • hands-on support • perineal massage • warm compresses
Comparison	Any of the following techniques performed during the second stage of labour: • hands-off • hands poised • no perineal intervention • other perineal technique • standard care (as defined by study authors)
Outcome	**Critical** • Episiotomy • First-degree perineal tears • Second-degree perineal tears

	• Third- and fourth-degree perineal tears **Important** • Urinary incontinence in the first year after birth • Faecal incontinence in the first year after birth (post-hoc) • Perineal pain postpartum • Women's experience of labour and birth

For further details see the review protocol in appendix A.

Methods and process

This evidence review was developed using the methods and process described in Developing NICE guidelines: the manual. Methods specific to this review question are described in the review protocol in appendix A and the methods document (supplement 1).

Declarations of interest were recorded according to NICE's conflicts of interest policy.

Effectiveness evidence

Included studies

Nine randomised control trials (RCTs) were included for this review (Aabakke 2016; Albers 2005, Califano 2022, Dahlen 2007, Harlev 2013, Jonsson 2008, Mayerhofer 2002, McCandlish 1998 and Stamp 2001).

One study compared primary delivery of the anterior shoulder versus the posterior shoulder (Aabakke 2016). One study compared warm compress versus massage with lubricant, warm compress versus hands off and massage with lubricant versus hands off (Albers 2005). One study compared warm pack versus standard care (Dahlen 2007). One study compared massage with liquid wax versus massage with purified formula of oil (Harlev 2013). One study compared Ritgen's manoeuvre versus standard care (Jonsson 2008). Three studies compared hands on versus hands poised (Califano 2022, Mayerhofer 2002 and McCandlish 1998) and 1 study compared massage with lubricant versus standard care (Stamp 2001).

The included studies are summarised in Table 2.

See the literature search strategy in appendix B and study selection flow chart in appendix C.

Excluded studies

Studies not included in this review are listed, and reasons for their exclusion are provided in appendix J.

Summary of included studies

Summaries of the studies that were included in this review are presented in Table 2.

Table 2: Summary of included studies

Study	Population	Intervention	Comparison	Outcomes	Comments
Aabakke 2016 Randomised controlled trial Denmark	N= 650 nulliparous women BMI – median (IQR)	Primary delivery of anterior shoulder	Primary delivery of posterior shoulder	• Episiotomy • Third- and fourth-degree perineal tears	<1/3 of women had their labour induced

Study	Population	Intervention	Comparison	Outcomes	Comments
	Anterior shoulder: 23.6 (21.5 - 27.5) Posterior shoulder: 24.0 (21.2 - 28.1)				
Albers 2005 Randomised controlled trial 3 arm trial¥ US	N= 1211 women (mixed parity) BMI overweight range BMI - mean ± SD Warm compress: 25.6 ± 6.1 Massage with lubricant: 25.0 ± 5.3 Hands off: 25.5 ± 5.8	Warm compress: compresses were held to the perineum and external genitalia during and between pushes Massage with lubricant: massage was continued during and between pushes, regardless of maternal position	Hands off: no touching of the woman's perineum during the second stage until crowning of the infant's head	• Episiotomy • First-degree perineal tear • Second-degree perineal tear • Third- and fourth-degree perineal tear	Induction of labour not reported
Califano 2022 Randomised controlled trial Italy	N= 70 Nulliparous women BMI overweight range BMI - mean ± SD Hands poised: 29.7±3.1 Hands on: 29.5±5.5	Hands-on: One hand placed on the fetal head to control expulsion, the other hand placed on perineum.	Hands-poised: No touching of the head or the perineum and spontaneous delivery of the shoulders.	• Episiotomy • First-degree perineal tears • Second-degree perineal tears • Third-fourth-degree perineal tears	Women who were induced were excluded
Dahlen 2007 Randomised controlled trial Australia	N= 717 nulliparous women BMI not reported	Warm pack: received standard care during labour until the baby's head began to distend the	Standard care: did not have warm packs applied to the perineum in second stage	• Episiotomy • Second-degree perineal tears • Third- and fourth-	Unclear induction of labour

Study	Population	Intervention	Comparison	Outcomes	Comments
		perineum and the woman was aware of a stretching sensation. Then a sterile perineal pad was placed on the perineum during contractions		degree perineal tears • Urinary incontinence in the first year after birth • Pain postpartum at 1 day	
Harlev 2013 Randomised controlled trial Israel	N= 164 women (mixed parity) BMI not reported	Massage with liquid wax (without additional vitamins, such as jojoba oil)	Massage with purified formula of almond oil with olive oil, rich with vitamin B1, B2, B6, E and fatty acid	• Episiotomy • First-degree perineal tear • Second-degree perineal tear • Third- and fourth-degree perineal tears	Unclear induction of labour
Jonsson 2008 Randomised controlled trial Sweden	N= 1623 women (mixed parity) BMI* - median (range) Ritgen's manoeuvre: 29 (20-48) Standard care: 29 (19-46) *At admission in labour	Ritgen's manoeuvre: extraction of the fetal head, using one hand to pull the fetal chin from between the maternal anus and the coccyx, and the other on the fetal occiput to control speed of delivery. Ritgen's manoeuvre was performed during a uterine contraction	Standard care: perineal support with one hand and control of the speed of crowning with the other, and use of Ritgen's manoeuvre only on specific indications	• Episiotomy • Third- and fourth-perineal tears	<1/3 of women had their labour induced
Mayerhofer 2002 Randomised controlled trial Austria	N= 1161 women (mixed parity) BMI not reported	'Hands poised': the midwife kept her hands poised ready to put light pressure on the infant's head to avoid rapid expulsion. The	'Hands on': The left hand of the midwife put pressure on the infant's head. The right hand was placed against the perineum to support the structure and	• Episiotomy • First-degree perineal tears • Second-degree perineal tears • Third- and fourth-degree	Unclear induction of labour

Study	Population	Intervention	Comparison	Outcomes	Comments
		midwife did not touch the perineum with her right hand at any time during delivery. Delivery of the shoulder was supported with both midwife's hands	to use lateral flexion to facilitate delivery of the shoulders	perineal tears	
McCandlish 1998 Randomised controlled trial UK	N= 5471 women (mixed parity) BMI not reported	'Hands poised': the midwife kept her hands poised, prepared to put light pressure on the baby's head in case of rapid expulsion, but did not touch the head or perineum otherwise to allow spontaneous delivery of the shoulders	'Hands on': the midwife's hands put pressure on the baby's head to increase flexion to support the perineum, and to use lateral flexion to facilitate the delivery of the shoulders	• Episiotomy • First-degree perineal tear • Second-degree perineal tear • Third- and fourth degree perineal tears • Urinary incontinence • Faecal incontinence • Perineal pain postpartum at 3 months	Unclear induction of labour
Stamp 2001 Randomised controlled trial Australia	N= 1340 women (mixed parity) BMI not reported	Massage with lubricant: massage and stretching of the perineum with each contraction during the second stage of labour	Standard care: midwives were instructed to use their usual technique but to refrain from using perineal massage	• Episiotomy • First-degree perineal tears • Second-degree perineal tears • Third- and fourth-degree perineal tears • Urinary incontinence • Faecal incontinence • Vaginal pain postpartum at 3 months	Unclear induction of labour

¥This is a 3 arm trial, so intervention and comparison groups in this table may not match the intervention and comparison group in the GRADE tables (Appendix F).
BMI: body mass index; SD: standard deviation; IQR: interquartile range

See the full evidence tables in appendix D and the forest plots in appendix E.

Summary of the evidence

In total, 9 different comparisons were included in this review. Some of the comparisons identified showed no evidence of an important difference or no important difference between the interventions compared (for example warm compress versus hands off, massage with lubricant versus hands off, massage with liquid wax versus massage with purified formula of oil, Ritgen's manoeuvre versus standard care).

The comparison warm compress versus massage with lubricant showed that the use of warm compress led to a possible important reduction in episiotomy rates in women with a body mass index (BMI) in the overweight range. Massage with lubricant showed an important benefit over standard care as it led to a reduction in third-and fourth-degree perineal tears. The application of a warm pack to the woman's perineum had an important benefit in terms of the outcomes of third-and fourth-degree perineal tears, urinary incontinence and pain postpartum when compared to standard care. The comparison hands on versus hands poised showed an important harm for hands on in terms of the outcomes of episiotomy, first-degree perineal tears, second-degree perineal tears and third- degree perineal tears.

The comparison primary delivery of the anterior shoulder versus primary delivery of the posterior shoulder showed a possible important harm whereby primary delivery of the anterior shoulder led to a possible increase in episiotomy when compared to primary delivery of the posterior shoulder.

Typically, the comparisons where no difference between interventions was found included seriously imprecise findings, therefore they should not be taken as definitive evidence of no difference between the interventions.

In terms of stratified analysis, data was very limited and not enough to draw robust conclusions. In addition, no evidence was identified on women's experience of labour and birth.

The quality of the evidence across comparisons ranged from very low to low, with most concerns around imprecision and blinding.

Economic evidence

Included studies

A systematic review of the economic literature was conducted but no economic studies were identified which were applicable to this review question.

Economic model

No economic modelling was undertaken for this review because the committee agreed that other topics were higher priorities for economic evaluation.

Unit costs

The committee agreed that some of the interventions (for example hands off, or hands poised) would not have any additional costs but that the use of warm compresses or massage with lubricant would have costs. These were estimated as follows:

Table 3: Unit costs for disposable items used for perineal care

Resource	Unit costs	Source
Sterile swabs	£0.32	https://www.mistrymedical.com/item/13220/rocialle-swabs-gauze-xrd-22-5-x-22-5cm-12ply-unlooped-pk5-d-w-sterile--pack-of-50---rml122-

Resource	Unit costs	Source
		225--?gclid=EAIaIQobChMIq9zAiPm7-AIVRvhRCh1sCwfHEAQYAyABEgLIAfD_BwE (accessed 24/06/2022)
Single-use lubricating jelly sachets	£0.18	https://www.medibargains.co.uk/50-x-optilube-lubricating-jelly-5g-sachets-sterile/ (accessed 27/06/2022)

The committee's discussion and interpretation of the evidence

The outcomes that matter most

As the aim of this review was to identify which perineal care technique was most effective at reducing perineal trauma and injury, so the committee agreed that episiotomy, first-degree perineal tears, second-degree perineal tears and third- and fourth-degree perineal tears were critical outcomes for this review. They agreed that it was important to distinguish between these because there are more likely to be longer term effects such as pain and incontinence associated with episiotomy or third- and fourth-degree tears.

The committee chose urinary incontinence in the first year after birth as an important outcomes, and based on stakeholder feedback faecal incontinence in the first year after birth was added as a post-hoc important outcome, as well as postpartum perineal pain as all these outcomes can impact the woman's quality of life during the postpartum period and in the longer term. The committee also wanted to explore women's experience of labour and birth and whether a perineal intervention in the second stage had an impact. The committee were aware of the great importance of this outcome, however they agreed that data was likely to be sparse and unlikely to inform decision making so they prioritised other outcomes as critical.

The quality of the evidence

The quality of the evidence ranged from very low to low. Some of the evidence was downgraded for risk of bias due to the lack of an available prespecified protocol as well as for imprecision around the estimate of effect. In one of the studies, the water-soluble lubricant was provided by the manufacturer, however it is unlikely this could have impacted the outcomes reported because the manufacturer did not participate in the design or analysis of the data. Due to the nature of the interventions, it was not possible to blind study participants or midwives for most of the comparisons. Whilst this may have introduced some bias, most of the outcomes (except for pain) are measured with appropriate standardised methods, and the committee interpreted the evidence taking this limitation into account.

For studies reporting method of induction, the women who had been induced accounted for less than a third of the total. There were some studies that did not provide details about whether women had been induced or that reported that women had received oxytocin, however it was not clear whether this was for augmenting or inducing labour. These studies have been downgraded to account for the possible indirectness of these populations.

Benefits and harms

The committee discussed the evidence on the effectiveness of perineal care in the second stage of labour for reducing perineal trauma and tears. Based on their experience and expertise, the committee agreed that it was important to discuss options for perineal care with the woman, to understand her personal preferences and enable her to be fully informed and involved in decisions about her care. They therefore made a recommendation stating this.

The committee noted that the evidence for the comparison of delivery of the anterior shoulder versus the posterior shoulder (for women in a semi-recumbent position) was an unusual comparison as the anterior shoulder would nearly always be delivered first, and the outcome of episiotomy may be a consequential finding and not an outcome from the mode of birth. The committee did not therefore make any recommendations based on the evidence from this comparison.

For the comparison using Ritgen's manoeuvre there was no difference between the intervention and standard care so the committee agreed not to make recommendations.

The committee noted that application of a warm pack to the woman's perineum did not have a clear effect on the incidence of episiotomies or second-degree perineal tears but showed a reduction in third- and fourth-degree perineal tears, urinary incontinence and postpartum perineal pain when compared to standard care. Based on this evidence they agreed to recommend a warm wet compress be applied to the perineum to women in the second stage of labour. The committee specified in the recommendation when the compress should be used based on the procedure described by the study (Dahlen 2007). The study had also used a temperature range for the warm compress, but the committee agreed that whilst this may be helpful in the context of a clinical trial, in clinical practice it may be impractical to measure the water temperature, however they agreed that checking that the temperature was comfortable for the woman was important and so they included this in their recommendation.

The committee discussed the evidence for massage of the perineum with a water-soluble lubricant compared to standard care and noted the reduction seen in third- and fourth-degree perineal tears during birth. The committee noted that this is a simple procedure also done antenatally as a way to increase muscle and tissue elasticity, however some women may find it invasive to have it done during labour whilst experiencing contractions. The committee were unable to make recommendations for antenatal perineal massage as this intervention was not part of this evidence review, which looked only at interventions in the second stage of labour. The committee also noted that in a comparison of warm compress and massage with lubricant there was no difference between the interventions except for a possible benefit for a reduction in episiotomies with the warm compress. Based on these factors, and the more limited evidence of benefit, the committee agreed to recommend massage during the second stage as an alternative to a warm compress if women request it.

The committee discussed the evidence for 'hands poised' (also known as hands off), a method where the midwife keeps the hands poised but not touching the head or perineum and 'hands on', a method whereby the midwife's hands are used to put pressure on the baby's head (to flex the head) and support ('guard') the perineum. They discussed the definitions of the interventions provided by the trial authors and agreed that the 'hands poised' positions were sufficiently similar to allow them to be analysed together, as were the 'hands off' positions. They noted that 2 of the 3 studies included for this comparison (Mayerhofer 2002 and McCandlish 1998) were the same as those in the 2007 update of the guideline and were surprised that there had only been 1 additional study (Califano 2022) published since the last update. The evidence from the 3 studies suggested that hands poised is beneficial for reducing the incidence of episiotomies, first-degree perineal tears (in nulliparous women in the BMI overweight range), second- degree perineal tears (in nulliparous women in the BMI overweight range) and third-degree perineal tears when compared to hands on, but that hands on may be effective for reducing perineal pain 10 days after birth, although there was uncertainty about this as different measures of pain at 10 days gave differing results. The committee noted that there appeared to be no difference between these techniques for other outcomes.

The committee discussed some of the limitations for one of the studies included in this comparison (Mayerhofer 2002). They noted that the quasi-randomised technique used to allocate women to the intervention groups (which depended on the day and time of

allocation) and the fact that the study recruited from 2 hospitals but only reported data from 1 could have biased the results significantly. In addition, the committee noted that although there was an important harm for the outcome of third-degree tears, this study was underpowered to detect important differences in this outcome. The study found a higher incidence of episiotomies in the hands on group, but around two-thirds of these were midline and it was unclear whether these were associated with third degree tears. As a result, the committee agreed that these factors meant that they were not confident to use the data by Mayerhofer 2002 to make their recommendations.

The committee found the methods used by the other study (McCandlish 1998) comparing hands on to hands poised were more robust and less subject to bias. They discussed that, in contrast to the results reported by Mayerhofer 2002, this study did not find an increase in third-degree perineal tears with the hands on technique but noted that due to the way this study had reported its results, it was not possible to separate the number of episiotomies from each tear category, and the study did not give an indication of what tear category the episiotomies were either. The study found a higher incidence of episiotomies in the hands on group, but possibly less perineal pain 10 days after birth. The committee agreed not to include perineal pain at 10 days in the recommendations due to the small effect size and because, although the effect estimate showed a statistically significant difference, the minimally important difference (MID) showed no evidence of an important difference.

The committee discussed the evidence provided by Califano 2022 and agreed that it reinforced the episiotomy data from Mayerhofer 2002 and McCandlish 1998, which showed an increased rate of episiotomies in the hands on group compared to the hands poised group. The data from Califano 2022 also showed an increased rate of first- and second-degree perineal tears for the hands on group. The committee discussed that although this is reassuring, the participants in the small Califano 2022 study only represent a small subgroup of nulliparous women in the BMI overweight range, therefore they could not extrapolate this data to all women.

The committee discussed the recommendation included in the 2007 guideline, which stated that either hands on or hands off could be used to facilitate spontaneous birth. They noted that the order that the techniques appeared in the recommendation could lead to one technique being favoured over the another by health care professionals. Based on this and the lack of new evidence, the committee agreed that they could not recommend one technique in preference to another and so agreed to remove this recommendation.

Based on the lack of strong new evidence for the hands on/hands poised technique and the wide variation in practice, the committee agreed to make a research recommendation on the effectiveness of different techniques, namely hands on or hands poised. They also specified that they would like the analysis to be spilt by ethnicity and BMI if the data allows to provide greater clarity. The committee were also aware of another technique used in practice called the Finnish grip, and as no evidence had been found on this they included this in the research recommendation too.

There was no evidence identified for the intervention cold compress, and there was no evidence found for the outcome: women’s experience of labour and birth.

The outcome of faecal incontinence was added and analysed in response to stakeholder comments. The analysis showed that there was no evidence of an important difference for hands on versus hands poised nor for massage versus standard care and therefore this post-hoc addition did not lead to any changes to the recommendations.

Cost effectiveness and resource use

The committee noted that applying a warm compress to the perineum to women in the second stage of labour was a very low-cost intervention involving the use of inexpensive sterile swabs (see Table 3). They also noted the likely improvement in health-related quality

of life and “downstream” cost savings from reductions in third- and fourth-degree perineal tears. Therefore, the committee made a qualitative assessment that recommending a warm compress applied to the perineum would be a cost-effective use of NHS resources.

The committee noted that lubricating jelly was inexpensive (see Table 3), and that perineal massage is a short procedure taking just a few minutes. They also noted that there was some clinical evidence that the procedure could reduce third- and fourth-degree perineal tears which could produce savings in terms of the need for future intervention and benefits to health-related quality of life. Therefore, the committee reasoned that this could be considered as a cost-effective alternative to a warm compress if requested by the woman.

The committee did not consider that there were resource implications with respect to adopting either a hands on or hands off technique and therefore concluded either could be recommended based on the reviewed clinical effectiveness data.

Other factors the committee took into account

The committee discussed that the Royal College of Obstetricians and Gynaecologists (RCOG) currently recommend a package of perineal care techniques called the OASI care bundle which includes hands on care. The committee discussed that the hands on technique taught as part of the OASI care bundle is a technique known as manual perineal protection (which is also known as the Finnish grip, for which the committee had found no evidence). This technique involves the use of bent fingers pressing on the perineum and the committee agreed this was not the same as the hands on technique that had been described in the included studies, and so the committee still considered more research on the use of the Finnish grip as a standalone intervention would be beneficial.

Recommendations supported by this evidence review

This evidence review supports recommendations 1.9.12 to 1.9.14 and a research recommendation.

References – included studies

Effectiveness

Aabakke 2016

Aabakke AJ; Willer H; Krebs L (2016) The effect of maneuvers for shoulder delivery on perineal trauma: a randomized controlled trial. Acta obstetricia et gynecologica Scandinavica 95(9): 1070-1077

Albers 2005

Albers, Leah L., Sedler, Kay D., Bedrick, Edward J. et al. (2005) Midwifery care measures in the second stage of labor and reduction of genital tract trauma at birth: a randomized trial. Journal of midwifery & women's health 50(5): 365-72

Califano 2022

Califano, Gianluigi; Saccone, Gabriele; Diana, Bianca; Colla Ruvolo, Claudia; Ioffredo, Daniela; Nappi, Carmen; Annella, Antonella; Gragnano, Elisabetta; Guida, Maurizio; Zullo, Fulvio; Locci, Mariavittoria; Hands-on vs hands-off technique for the prevention of perineal injury: a randomized clinical trial.; American journal of obstetrics & gynecology MFM; 2022; vol. 4 (no. 5); 100675

Dahlen 2007

Dahlen, Hannah G., Homer, Caroline S. E., Cooke, Margaret et al. (2007) Perineal outcomes and maternal comfort related to the application of perineal warm packs in the second stage of labor: A randomized controlled trial. Birth 34(4): 282-290

Harlev 2013

Harlev, Avi, Pariente, Gali, Kessous, Roy et al. (2013) Can we find the perfect oil to protect the perineum? A randomized- controlled double-blind trial. Journal of Maternal-Fetal and Neonatal Medicine 26(13): 1328-1331

Jonsson 2008

Jonsson, Eva Rubin, Elfaghi, Ibtesam, Rydhstrom, Hakan et al. (2008) Modified Ritgen's maneuver for anal sphincter injury at delivery: A randomized controlled trial. Obstetrics and Gynecology 112(2part1): 212-217

Mayerhofer 2002

Mayerhofer K, Bodner-Adler B, Bodner K et al. (2002) Traditional care of the perineum during birth. A prospective, randomized, multicenter study of 1,076 women. The Journal of reproductive medicine 47(6): 477-482

McCandlish 1998

McCandlish, R., Bowler, U., van Asten, H. et al. (1998) A randomised controlled trial of care of the perineum during second stage of normal labour. British journal of obstetrics and gynaecology 105(12): 1262-72

Stamp 2001

Stamp, G.; Kruzins, G.; Crowther, C. (2001) Perineal massage in labour and prevention of perineal trauma: Randomised controlled trial. British Medical Journal 322(7297): 1277-1280

Appendices

Appendix A Review protocol

Review protocol for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

Table 4: Review protocol

Field	Content
PROSPERO registration number	CRD42021288213
Review title	Effectiveness of perineal care in the second stage of labour for reducing perineal trauma and tears
Review question	What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?
Objective	To update the recommendation in CG190 (2014) for perineal care in the second stage of labour. Surveillance has identified that perineal massage may be associated with higher rates of intact perineum and fewer incidences of third- and fourth-degree tears. However no effect was found on perineal trauma requiring suturing or second-degree tears.
Searches	The following databases will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE & MEDLINE In-Process • International Health Technology Assessment (IHTA) database Searches will be restricted by: • English language studies • Human studies

Field	Content
	Other searches: • Inclusion lists of systematic reviews The full search strategies for the MEDLINE database will be published in the final review. For each search, the principal database search strategy is quality assured by a second information scientist using an adaptation of the PRESS 2015 Guideline Evidence-Based Checklist.
Condition or domain being studied	Labour, birth and perineal care
Population	• Women in the second stage of labour who are pregnant with a single baby, who go into labour at term (37 to 42 weeks of pregnancy) and who do not have any pre-existing medical conditions or antenatal conditions that predispose to a higher risk birth • Women in the second stage of labour whose baby has not been identified before labour to be at high risk of adverse outcome • Singleton babies born at term (37 to 42 weeks of pregnancy) with no previously identified problems (for example congenital malformations, genetic anomalies, intrauterine growth restriction, placental problems)
Intervention	Any perineal technique performed during the second stage of labour, for example: • cold compresses • hand position • hands-on support • perineal massage • warm compresses
Comparator	Any of the following techniques performed during the second stage of labour: • hands-off • hands poised • no perineal intervention • other perineal technique

Field	Content
	• standard care (as defined by study authors)
Types of study to be included	Include published full-text papers: • Systematic reviews of RCTs • Parallel RCTs (individual, cluster) Conference abstracts will not be included because these do not typically have sufficient information to allow full critical appraisal.
Other exclusion criteria	Population: • Women in labour who are identified before labour to be at high risk, or whose baby is at high risk, of complications or adverse outcomes • Women with non-cephalic presentation • Women in preterm labour • Women with an intrauterine fetal death • Women pregnant with multi-fetal pregnancies • Women who are having their labour induced (until active labour is established) • Women who have had a previous caesarean birth or who are having a planned caesarean birth Setting: • Countries other than high income countries (as defined by the OECD) If any study or systematic review includes <1/3 of women with the above characteristics/ who received care in the above setting, it will be considered for inclusion but, if included, the evidence will be downgraded for indirectness.
Context	This guideline will partly update the following: Intrapartum care for healthy women and babies (CG190)
Primary outcomes (critical outcomes)	• Episiotomy • First-degree perineal tears

Field	Content
	• Second-degree perineal tears • Third- and fourth-degree perineal tears
Secondary outcomes (important outcomes)	• Urinary incontinence in the first year after birth • Faecal incontinence in the first year after birth (post-hoc) • Perineal pain postpartum • Women's experience of labour and birth
Data extraction (selection and coding)	All references identified by the searches and from other sources will be uploaded into EPPI and de-duplicated. Titles and abstracts of the retrieved citations will be screened to identify studies that potentially meet the inclusion criteria outlined in the review protocol. Dual sifting will be performed on at least 10% of records; 90% agreement is required. Disagreements will be resolved via discussion between the two reviewers, and consultation with senior staff if necessary. Full versions of the selected studies will be obtained for assessment. Studies that fail to meet the inclusion criteria once the full version has been checked will be excluded at this stage. Each study excluded after checking the full version will be listed, along with the reason for its exclusion. A standardised form will be used to extract data from studies. The following data will be extracted: study details (reference, country where study was carried out, type and dates), participant characteristics, inclusion and exclusion criteria, details of the interventions if relevant, setting and follow-up, relevant outcome data and source of funding. One reviewer will extract relevant data into a standardised form, and this will be quality assessed by a senior reviewer.
Risk of bias (quality) assessment	Quality assessment of individual studies will be performed using the following checklists: • ROBIS tool for systematic reviews • Cochrane RoB tool v.2 for RCTs • Cochrane RoB tool v.2 for cluster randomised trials The quality assessment will be performed by one reviewer and this will be quality assessed by a senior reviewer.
Strategy for data synthesis	Quantitative findings will be formally summarised in the review. Where multiple studies report on the same outcome for the same comparison, meta-analyses will be conducted using Cochrane Review Manager software.

Field	Content
	A fixed effect meta-analysis will be conducted and data will be presented as risk ratios if possible or odds ratios when required (for example, if only available in this form in included studies) for dichotomous outcomes, and mean differences or standardised mean differences for continuous outcomes. Heterogeneity in the effect estimates of the individual studies will be assessed using the I2 statistic. Alongside visual inspection of the point estimates and confidence intervals, I2 values of greater than 50% and 80% will be considered as significant and very significant heterogeneity, respectively. Heterogeneity will be explored as appropriate using sensitivity analyses and pre-specified subgroup analyses. If heterogeneity cannot be explained through subgroup analysis then a random effects model will be used for meta-analysis, or the data will not be pooled. The confidence in the findings across all available evidence will be evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group: http://www.gradeworkinggroup.org/ Minimally important differences: • Validated scales/continuous outcomes: published MIDs where available • All other outcomes & where published MIDs are not available: 0.8 and 1.25 for all relative dichotomous outcomes ; +/- 0.5x control group SD for continuous outcomes
Analysis of subgroups	Evidence will be stratified by: • Parity ○ Nulliparous ○ Multiparous • Position ○ Upright position (kneeling, walking/mobilisation, squatting, standing, sitting upright) ○ Recumbent position (lying on back, lying on side, semi-recumbent) • Previous third- and fourth- degree tears • Birth in water • BMI thresholds on booking: ○ Underweight range: <18.5 kg/m2 ○ Healthy weight range: 18.5 to 24.9 kg/m2 ○ Overweight range: 25 to 29.99 kg/m2 ○ Obesity 1: 30 to 34.99 kg/m2

Field	Content	
	○ Obesity 2: 35 to 39.99 kg/m2 Stratifications will be dealt with in a hierarchy (this is, where possible, stratify first by parity, then by position, then by previous third- and fourth-degree tears, then by birth in water, and then by BMI thresholds on booking). Evidence will be subgrouped by the following only in the event that there is significant heterogeneity in outcomes: • Age of woman (<35 vs ≥ 35) • Ethnicity ○ White ○ Asian/Asian British ○ Black/African/Caribbean/Black British ○ Mixed/Multiple ethnic groups ○ Other ethnic group • Women with disability vs not • Deprived socioeconomic group vs not Where evidence is stratified or subgrouped the committee will consider on a case by case basis if separate recommendations should be made for distinct groups. Separate recommendations may be made where there is evidence of a differential effect of interventions in distinct groups. If there is a lack of evidence in one group, the committee will consider, based on their experience, whether it is reasonable to extrapolate and assume the interventions will have similar effects in that group compared with others.	
Type and method of review	☒	Intervention
	☐	Diagnostic
	☐	Prognostic
	☐	Qualitative
	☐	Epidemiologic
	☐	Service Delivery
	☐	Other (please specify)

Field	Content
Language	English
Country	England
Anticipated or actual start date	14/10/2021
Anticipated completion date	22/03/2023
Named contact	5a. Named contact Guideline Development Team National Guideline Alliance (NGA) 5b. Named contact e-mail IPCupdate@nice.org.uk 5c. Organisational affiliation of the review Guideline Development Team NGA, Centre for Guidelines, National Institute for Health and Care Excellence (NICE)
Review team members	From the Guideline Development Team NGA: • Senior Systematic Reviewer • Systematic Reviewer
Funding sources/sponsor	This systematic review is being completed by the Guideline Development Team NGA, Centre for Guidelines, which is part of the National Institute for Health and Care Excellence (NICE).
Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.

Field	Content
Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/cg190
Other registration details	None
URL for published protocol	https://www.crd.york.ac.uk/PROSPERO/display_record.php?RecordID=288213
Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: notifying registered stakeholders of publication publicising the guideline through NICE's newsletter and alerts issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
Keywords	Perineal care; second stage of labour
Details of existing review of same topic by same authors	Not applicable
Additional information	None
Details of final publication	www.nice.org.uk

CDSR: Cochrane Database of Systematic Reviews; CENTRAL: Cochrane Central Register of Controlled Trials; DARE: Database of Abstracts of Reviews of Effects; GRADE: Grading of Recommendations Assessment, Development and Evaluation; HTA: Health Technology Assessment; MID: minimally important difference; NGA: National Guideline Alliance; NHS: National health service; NICE: National Institute for Health and Care Excellence; OECD: Organisation for Economic Co-operation and Development; PRESS: peer review of electronic search strategies; RCT: randomised controlled trial; RoB(IS): risk of bias (in systematic reviews); SD: standard deviation

Appendix B Literature search strategies

Literature search strategies for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

Database: Medline – OVID interface

Date of last search: 07/12/2022

#	Searches
1	LABOR STAGE, SECOND/
2	(second adj3 stage?).ti,ab.
3	or/1-2
4	((perineum? or perineal) adj5 (technique? or care or method?)).ti,ab.
5	((warm* or cold* or perineum? or perineal) adj5 compress*).ti,ab.
6	((hand* or perineum? or perineal) adj5 position*).ti,ab.
7	((hand* or perineum? or perineal) adj5 support*).ti,ab.
8	(hand* adj7 (perineum? or perineal)).ti,ab.
9	PERINEUM/ and MASSAGE/
10	((perineum? or perineal) adj5 massag*).ti,ab.
11	or/4-10
12	3 and 11
13	*OBSTETRIC LABOR COMPLICATIONS/pc [Prevention & Control]
14	*PERINEUM/in [Injuries]
15	3 and 13 and 14
16	12 or 15
17	limit 16 to english language
18	LETTER/
19	EDITORIAL/
20	NEWS/
21	exp HISTORICAL ARTICLE/
22	ANECDOTES AS TOPIC/
23	COMMENT/
24	CASE REPORT/
25	(letter or comment*).ti.
26	or/18-25
27	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
28	26 not 27
29	ANIMALS/ not HUMANS/
30	exp ANIMALS, LABORATORY/
31	exp ANIMAL EXPERIMENTATION/
32	exp MODELS, ANIMAL/
33	exp RODENTIA/
34	(rat or rats or mouse or mice).ti.
35	or/28-34
36	17 not 35
37	META-ANALYSIS/
38	META-ANALYSIS AS TOPIC/
39	(meta analy* or metanaly* or metaanaly*).ti,ab.
40	((systematic* or evidence*) adj2 (review* or overview*)).ti,ab.
41	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
42	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
43	(search* adj4 literature).ab.
44	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
45	cochrane.jw.
46	or/37-45
47	randomized controlled trial.pt.
48	controlled clinical trial.pt.
49	pragmatic clinical trial.pt.
50	randomi#ed.ab.

#	Searches
51	placebo.ab.
52	randomly.ab.
53	CLINICAL TRIALS AS TOPIC/
54	trial.ti.
55	or/47-54
56	36 and 46
57	36 and 55
58	or/56-57

Database: Embase – OVID interface

Date of last search: 07/12/2022

#	Searches
1	LABOR STAGE 2/
2	(second adj3 stage?).ti,ab.
3	or/1-2
4	((perineum? or perineal) adj5 (technique? or care or method?)).ti,ab.
5	((warm* or cold* or perineum? or perineal) adj5 compress*).ti,ab.
6	((hand* or perineum? or perineal) adj5 position*).ti,ab.
7	((hand* or perineum? or perineal) adj5 support*).ti,ab.
8	(hand* adj7 (perineum? or perineal)).ti,ab.
9	PERINEUM/ and MASSAGE/
10	((perineum? or perineal) adj5 massag*).ti,ab.
11	or/4-10
12	3 and 11
13	*LABOR COMPLICATION/pc [Prevention]
14	*PERINEUM INJURY/
15	3 and 13 and 14
16	12 or 15
17	limit 16 to english language
18	letter.pt. or LETTER/
19	note.pt.
20	editorial.pt.
21	CASE REPORT/ or CASE STUDY/
22	(letter or comment*).ti.
23	or/18-22
24	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
25	23 not 24
26	ANIMAL/ not HUMAN/
27	NONHUMAN/
28	exp ANIMAL EXPERIMENT/
29	exp EXPERIMENTAL ANIMAL/
30	ANIMAL MODEL/
31	exp RODENT/
32	(rat or rats or mouse or mice).ti.
33	or/25-32
34	17 not 33
35	SYSTEMATIC REVIEW/
36	META-ANALYSIS/
37	(meta analy* or metanaly* or metaanaly*).ti,ab.
38	((systematic or evidence) adj2 (review* or overview*)).ti,ab.
39	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
40	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
41	(search* adj4 literature).ab.
42	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
43	((pool* or combined) adj2 (data or trials or studies or results)).ab.
44	cochrane.jw.
45	or/35-44
46	random*.ti,ab.
47	factorial*.ti,ab.
48	(crossover* or cross over*).ti,ab.
49	((doubl* or singl*) adj blind*).ti,ab.
50	(assign* or allocat* or volunteer* or placebo*).ti,ab.

#	Searches
51	CROSSOVER PROCEDURE/
52	SINGLE BLIND PROCEDURE/
53	RANDOMIZED CONTROLLED TRIAL/
54	DOUBLE BLIND PROCEDURE/
55	or/46-54
56	34 and 45
57	34 and 55
58	or/56-57

Databases: Cochrane Central Register of Controlled Trials; Cochrane Database of Systematic Reviews – Wiley interface

Date of last search: 07/12/2022

#	Searches
#1	MeSH descriptor: [Labor Stage, Second] this term only
#2	(second near/3 stage*):ti,ab
#3	#1 or #2
#4	((perineum* or perineal) near/5 (technique* or care or method*)):ti,ab
#5	((warm* or cold* or perineum* or perineal) near/5 compress*):ti,ab
#6	((hand* or perineum* or perineal) near/5 position*):ti,ab
#7	((hand* or perineum* or perineal) near/5 support*):ti,ab
#8	(hand* near/7 (perineum* or perineal)):ti,ab
#9	MeSH descriptor: [Perineum] this term only
#10	MeSH descriptor: [Massage] this term only
#11	#9 and #10
#12	((perineum* or perineal) near/5 massag*):ti,ab
#13	#4 or #5 or #6 or #7 or #8 or #11 or #12
#14	#3 and #13
#15	MeSH descriptor: [Obstetric Labor Complications] this term only and with qualifier(s): [prevention & control - PC]
#16	MeSH descriptor: [Perineum] this term only and with qualifier(s): [injuries - IN]
#17	#3 and #15 and #16
#18	#14 or #17

Database: International Health Technology Assessment

Date of last search: 07/12/2022

#	Searches
	All: (perineum or perineal)

Health Economics

Database: Medline – OVID interface

Date of last search: 07/12/2022

#	Searches
1	LABOR STAGE, SECOND/
2	(second adj3 stage?).ti,ab.
3	or/1-2
4	((perineum? or perineal) adj5 (technique? or care or method?)).ti,ab.
5	((warm* or cold* or perineum? or perineal) adj5 compress*).ti,ab.
6	((hand* or perineum? or perineal) adj5 position*).ti,ab.
7	((hand* or perineum? or perineal) adj5 support*).ti,ab.
8	(hand* adj7 (perineum? or perineal)).ti,ab.
9	PERINEUM/ and MASSAGE/
10	((perineum? or perineal) adj5 massag*).ti,ab.

#	Searches
11	or/4-10
12	3 and 11
13	*OBSTETRIC LABOR COMPLICATIONS/pc [Prevention & Control]
14	*PERINEUM/in [Injuries]
15	3 and 13 and 14
16	12 or 15
17	limit 16 to english language
18	LETTER/
19	EDITORIAL/
20	NEWS/
21	exp HISTORICAL ARTICLE/
22	ANECDOTES AS TOPIC/
23	COMMENT/
24	CASE REPORT/
25	(letter or comment*).ti.
26	or/18-25
27	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
28	26 not 27
29	ANIMALS/ not HUMANS/
30	exp ANIMALS, LABORATORY/
31	exp ANIMAL EXPERIMENTATION/
32	exp MODELS, ANIMAL/
33	exp RODENTIA/
34	(rat or rats or mouse or mice).ti.
35	or/28-34
36	17 not 35
37	ECONOMICS/
38	VALUE OF LIFE/
39	exp "COSTS AND COST ANALYSIS"/
40	exp ECONOMICS, HOSPITAL/
41	exp ECONOMICS, MEDICAL/
42	exp RESOURCE ALLOCATION/
43	ECONOMICS, NURSING/
44	ECONOMICS, PHARMACEUTICAL/
45	exp "FEES AND CHARGES"/
46	exp BUDGETS/
47	budget*.ti,ab.
48	cost*.ti,ab.
49	(economic* or pharmaco?economic*).ti,ab.
50	(price* or pricing*).ti,ab.
51	(financ* or fee or fees or expenditure* or saving*).ti,ab.
52	(value adj2 (money or monetary)).ti,ab.
53	resourc* allocat*.ti,ab.
54	(fund or funds or funding* or funded).ti,ab.
55	(ration or rations or rationing* or rationed).ti,ab.
56	ec.fs.
57	or/37-56
58	36 and 57

Database: Embase – OVID interface

Date of last search: 07/12/2022

#	Searches
1	LABOR STAGE 2/
2	(second adj3 stage?).ti,ab.
3	or/1-2
4	((perineum? or perineal) adj5 (technique? or care or method?)).ti,ab.
5	((warm* or cold* or perineum? or perineal) adj5 compress*).ti,ab.
6	((hand* or perineum? or perineal) adj5 position*).ti,ab.
7	((hand* or perineum? or perineal) adj5 support*).ti,ab.
8	(hand* adj7 (perineum? or perineal)).ti,ab.
9	PERINEUM/ and MASSAGE/
10	((perineum? or perineal) adj5 massag*).ti,ab.
11	or/4-10

#	Searches
12	3 and 11
13	*LABOR COMPLICATION/pc [Prevention]
14	*PERINEUM INJURY/
15	3 and 13 and 14
16	12 or 15
17	limit 16 to english language
18	letter.pt. or LETTER/
19	note.pt.
20	editorial.pt.
21	CASE REPORT/ or CASE STUDY/
22	(letter or comment*).ti.
23	or/18-22
24	RANDOMIZED CONTROLLED TRIAL/ or random*.ti,ab.
25	23 not 24
26	ANIMAL/ not HUMAN/
27	NONHUMAN/
28	exp ANIMAL EXPERIMENT/
29	exp EXPERIMENTAL ANIMAL/
30	ANIMAL MODEL/
31	exp RODENT/
32	(rat or rats or mouse or mice).ti.
33	or/25-32
34	17 not 33
35	HEALTH ECONOMICS/
36	exp ECONOMIC EVALUATION/
37	exp HEALTH CARE COST/
38	exp FEE/
39	BUDGET/
40	FUNDING/
41	RESOURCE ALLOCATION/
42	budget*.ti,ab.
43	cost*.ti,ab.
44	(economic* or pharmaco?economic*).ti,ab.
45	(price* or pricing*).ti,ab.
46	(financ* or fee or fees or expenditure* or saving*).ti,ab.
47	(value adj2 (money or monetary)).ti,ab.
48	resourc* allocat*.ti,ab.
49	(fund or funds or funding* or funded).ti,ab.
50	(ration or rations or rationing* or rationed).ti,ab.
51	or/35-50
52	34 and 51

Database: Cochrane Central Register of Controlled Trials – Wiley interface

Date of last search: 07/12/2022

#	Searches
#1	MeSH descriptor: [Labor Stage, Second] this term only
#2	(second near/3 stage*):ti,ab
#3	#1 or #2
#4	((perineum* or perineal) near/5 (technique* or care or method*)):ti,ab
#5	((warm* or cold* or perineum* or perineal) near/5 compress*):ti,ab
#6	((hand* or perineum* or perineal) near/5 position*):ti,ab
#7	((hand* or perineum* or perineal) near/5 support*):ti,ab
#8	(hand* near/7 (perineum* or perineal)):ti,ab
#9	MeSH descriptor: [Perineum] this term only
#10	MeSH descriptor: [Massage] this term only
#11	#9 and #10
#12	((perineum* or perineal) near/5 massag*):ti,ab
#13	#4 or #5 or #6 or #7 or #8 or #11 or #12
#14	#3 and #13
#15	MeSH descriptor: [Obstetric Labor Complications] this term only and with qualifier(s): [prevention & control - PC]
#16	MeSH descriptor: [Perineum] this term only and with qualifier(s): [injuries - IN]
#17	#3 and #15 and #16
#18	#14 or #17

#	Searches
#19	MeSH descriptor: [Economics] this term only
#20	MeSH descriptor: [Value of Life] this term only
#21	MeSH descriptor: [Costs and Cost Analysis] explode all trees
#22	MeSH descriptor: [Economics, Hospital] explode all trees
#23	MeSH descriptor: [Economics, Medical] explode all trees
#24	MeSH descriptor: [Resource Allocation] explode all trees
#25	MeSH descriptor: [Economics, Nursing] this term only
#26	MeSH descriptor: [Economics, Pharmaceutical] this term only
#27	MeSH descriptor: [Fees and Charges] explode all trees
#28	MeSH descriptor: [Budgets] explode all trees
#29	budget*:ti,ab
#30	cost*:ti,ab
#31	(economic* or pharmaco?economic*):ti,ab
#32	(price* or pricing*):ti,ab
#33	(financ* or fee or fees or expenditure* or saving*):ti,ab
#34	(value near/2 (money or monetary)):ti,ab
#35	resourc* allocat*:ti,ab
#36	(fund or funds or funding* or funded):ti,ab
#37	(ration or rations or rationing* or rationed):ti,ab
#38	#19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37
#39	#18 and #38

Database: International Health Technology Assessment

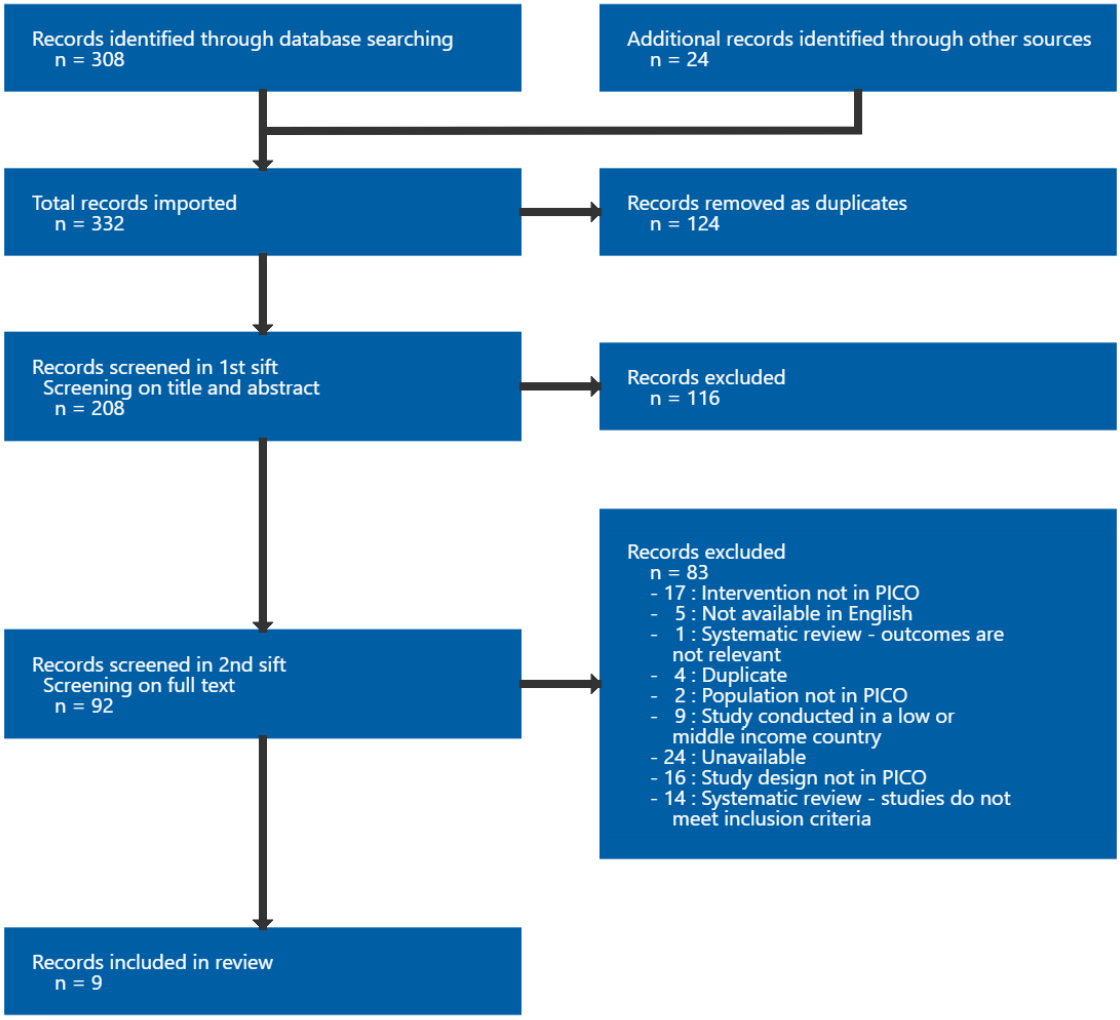
Date of last search: 07/12/2022

#	Searches
	All: (perineum or perineal)

Appendix C Effectiveness evidence study selection

Study selection for: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

Figure 1: Study selection flow chart



Appendix D Evidence tables

Evidence tables for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

Aabakke, 2016

Bibliographic Reference	Aabakke AJ; Willer H; Krebs L; The effect of maneuvers for shoulder delivery on perineal trauma: a randomized controlled trial.; Acta obstetricia et gynecologica Scandinavica; 2016; vol. 95 (no. 9)

Study details

Country/ies where study was carried out	Denmark
Study type	Randomised controlled trial (RCT)
Study dates	June 2013 - March 2015
Inclusion criteria	• Nulliparous • Previous caesarean birth having first vaginal delivery • Cephalic presentation
Exclusion criteria	Previous vaginal delivery • Multiple pregnancy • Caesarean birth • Delivery before 35 weeks gestation
Patient characteristics	Maternal age, years – median - (Inter Quartile Range) • Posterior shoulder: 26.0 (23.0 - 30.0) • Anterior shoulder: 27.0 (23.0 - 30.0)

	Gestational age, days - median - (Inter Quartile Range) • Posterior shoulder: 281 (276-287) • Anterior shoulder: 280 (273 - 287) BMI - median – (Inter Quartile Range) • Posterior shoulder: 24.0 (21.2 – 28.1) • Anterior shoulder: 23.6 (21.5 – 27.5) Parity – number - (%) **Nulliparous** • Posterior shoulder: 275 (97.9) • Anterior shoulder: 250 (95.4) **Primiparous with previous caesarean birth** • Posterior shoulder: 6 (2.1) • Anterior shoulder: 12 (4.6)
Intervention(s)/control	• Primary delivery of anterior shoulder • Primary delivery of posterior shoulder The method of perineal support during delivery of the head was not standardized
Duration of follow-up	Not reported
Sources of funding	Non industry funded
Sample size	Randomised N= 650 **Primary delivery of anterior shoulder: n= 325** Received the intervention: n= 262 Excluded: n= 63 ○ Acute caesarean birth: n= 60 ○ Breech: n= 0 ○ Twin pregnancy: n= 1

	○ Preterm delivery (GA<35): n= 2 Primary delivery of anterior shoulder: n= 262 (analysed by intention to treat) Follow up Delivered as allocated: n=193 Excluded: n= 69 ○ Primary delivery of posterior shoulder: n= 44 ○ Unknown: n= 25 Analysed per protocol: n= 193 **Primary delivery of posterior shoulder: n= 325** Received the intervention: n= 281 Excluded: n= 44 ○ Acute caesarean birth: n= 41 ○ Breech: n= 1 ○ Twin pregnancy: n= 1 ○ Preterm delivery (GA<35): n= 1 Primary delivery of posterior shoulder: n= 281 (analysed by intention to treat) Follow up Delivered as allocated: n= 211 Excluded: n= 70 ○ Primary delivery of anterior shoulder: n= 38 ○ Unknown: n= 32 Analysed per protocol: n= 211
Other information	Stimulation with oxytocin - number (%) • Posterior shoulder: 117 (41.6)

	• Anterior shoulder: 126 (48.1) Induction of labour - number (%) • Posterior shoulder: 75 (26.7) • Anterior shoulder: 66 (25.2)

Outcomes

Outcome	Posterior shoulder group, , N = 281	Anterior should group, , N = 262
Episiotomy Lower values are better No of events	n = 22	n = 33
Third- and fourth- degree perineal tears Reported as OASIS. Lower values are better No of events	n = 13	n = 15

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was computer generated by a third party and concealed. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives and women was not possible for all outcomes (episiotomy and third- and fourth- degree perineal tears), but no evidence that assignment to intervention affected implementation. No evidence that ITT protocol not followed.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for all participants for all outcomes (episiotomy and third- and fourth- degree tears)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was not inappropriate, the midwife or obstetrician (outcome assessor) was blinded and international standards were used*

Section	Question	Answer
		to classify perineal trauma. The outcomes (episiotomy and third- and fourth degree perineal tears are deemed to be low risk)
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns Protocol available but no information to indicate if the result had been selected based on multiple eligible outcome measurements or multiple eligible analyses
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable *(Stimulation with oxytocin - number (%) Posterior shoulder: 117 (41.6) Anterior shoulder: 126 (48.1) Induction of labour - number (%) Posterior shoulder: 75 (26.7) Anterior shoulder: 66 (25.2))*
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

Albers, 2005

Bibliographic Reference	Albers, Leah L.; Sedler, Kay D.; Bedrick, Edward J.; Teaf, Dusty; Peralta, Patricia; Midwifery care measures in the second stage of labor and reduction of genital tract trauma at birth: a randomized trial; Journal of midwifery & women's health; 2005; vol. 50 (no. 5); 365-72

Study details

Country/ies where study was carried out	USA
Study type	Randomised controlled trial (RCT)
Study dates	October 2001 - December 2004
Inclusion criteria	• >18 years • Expecting a vaginal birth • Previously consented

	• No medical complications • Singleton vertex presentation • Term pregnancy (>37 weeks)
Patient characteristics	Maternal age, years - mean ± standard deviation • Warm Compress: 24.9 ± 5.3 • Massage with Lubricant: 24.5 ± 5.2 • Hands Off: 24.5 ± 5.1 Body Mass Index - mean ± standard deviation • Warm Compress: 25.6 ± 6.1 • Massage with Lubricant: 25.0 ± 5.3 • Hands Off: 25.5 ± 5.8 Parity - number (%) **Nulliparous** • Warm Compress: 171 (42.3) • Massage with Lubricant: 154 (38.2) • Hands Off: 155 (38.4) **Primiparous (2nd birth)** • Warm Compress: 128 (31.7) • Massage with Lubricant: 145 (36.0) • Hands Off: 151 (37.4) **Multiparous (3rd birth or higher)** • Warm Compress: 105 (26.0) • Massage with Lubricant: 104 (25.8) • Hands Off: 98 (24.2) No differences at baseline
Intervention(s)/control	Warm compress

	• The midwife held warm compresses to the woman's perineum and external genitalia during and between pushes regardless of maternal position Massage with lubricant • The midwife performed perineal massage during and between pushes regardless of maternal position, the amount of downward pressure was dictated by woman's response Hands off • The midwife did not touch the woman's perineum until crowning of the infant's head Women in all three groups received verbal encouragement, coaching, information, and praise from their midwife. No particular verbal or social interactions were prescribed or prohibited.
Duration of follow-up	Not reported
Sources of funding	Non industry funded
Sample size	Randomised during labour N= 1211 • Warm compress: n= 404 • Massage with Lubricant: n= 403 • Hands Off: n= 404 Data available after birth • Warm compress: n= 404 • Massage with Lubricant: n= 403 • Hands Off: n= 404 Data available from postpartum office visit • Warm compress: n= 316 • Massage with Lubricant: n= 324 • Hands Off: n= 325
Other information	Oxytocin infusion - number - (%):

	• Warm compress: 147 (36.4) • Massage with Lubricant: 129 (32.0) • Hands Off: 141 (34.9)

Outcomes

Outcome	Warm Compress, , N = 404	Massage with Lubricant, , N = 403	Hands Off, , N = 404
Episiotomy Lower values are better No of events	n = 1	n = 7	n = 2
First-degree perineal tear Lower values are better No of events	n = 97	n = 91	n = 89
Second-degree perineal tear Lower values are better No of events	n = 70	n = 73	n = 74
Third- and fourth- degree perineal tears Lower values are better No of events	n = 3	n = 5	n = 6

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was computer generated and concealed. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives and women was not possible for all outcomes (episiotomy, first-degree perineal, second- degree perineal tear and third- and fourth- degree perineal tears), but no evidence that assignment to intervention affected implementation. No evidence that ITT protocol not followed.)*

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for all participants for all outcomes: (episiotomy, first- degree perineal, second- degree perineal tear and third- and fourth- degree perineal tears)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was not inappropriate, blinding of the clinical midwives (outcome assessors) was not possible for all outcomes but it is not deemed to have affected outcome measurement. The outcomes (episiotomy, first degree perineal tear, second degree perineal tear and third- and fourth degree perineal tears are deemed to be low risk)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was not available to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable *(Oxytocin infusion - number (%):Warm compress: 147 (36.4)Massage with Lubricant: 129 (32.0)Hands Off: 141 (34.9))*
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

Califano, 2022

Bibliographic Reference	Califano, Gianluigi; Saccone, Gabriele; Diana, Bianca; Colla Ruvolo, Claudia; Ioffredo, Daniela; Nappi, Carmen; Annella, Antonella; Gragnano, Elisabetta; Guida, Maurizio; Zullo, Fulvio; Locci, Mariavittoria; Hands-on vs hands-off technique for the prevention of perineal injury: a randomized clinical trial.; American journal of obstetrics & gynecology MFM; 2022; vol. 4 (no. 5); 100675

Study details

Country/ies where study was carried out	Naples, Italy
Study type	Randomised controlled trial (RCT)
Study dates	May 2021 - December 2021

Inclusion criteria	• Nulliparous • Singleton pregnancy • 37 0/7 - 42 0/7 weeks gestation • Vertex presentation
Exclusion criteria	• Multiparous • Multiple gestation • Pre-term labour • Post-term labour • Preterm premature rupture of membranes • Previous caesarean delivery • Induction of labour with either oxytocin or cervical ripening • High risk pregnancies (hypertensive disorders of pregnancies, diabetes mellitus, intrauterine growth restriction, and fetal abnormalities)
Patient characteristics	Maternal age, years - mean ± standard deviation • Hands poised: 30.3±5.6 • Hands on: 30.4±5.3 Body Mass Index - mean ± standard deviation • Hands poised: 29.7±3.1 • Hands on: 29.5±5.5 Gestational age at randomisation, weeks - mean ± standard deviation • Hands poised: 39.8±1.0 • Hands on: 39.5±1.1
Intervention(s)/control	Hands-on: • One hand placed on the fetal head to control expulsion, the other hand placed on perineum. Hands-poised:

	• No touching of the head or the perineum and spontaneous delivery of the shoulders.
Duration of follow-up	Not reported
Sources of funding	Not reported
Sample size	Enrolled N= 109 Excluded n= 39 (4 declined to participate at time of randomisation, 35 received emergent or urgent caesarean birth) Randomised N= 70
Other information	Oxytocin in the second stage - number - (%) • Hands poised: 29 (82.9%) • Hands on: 27 (77.1%)

Outcomes

Outcome	Hands poised, , N = 35	Hands on , , N = 35
Episiotomy Lower values are better No of events	n = 5	n = 14
First-degree perineal tears Lower values are better No of events	n = 7	n = 17
Second-degree perineal tears Lower values are better No of events	n = 6	n = 14
Third- and fourth-degree perineal tears Lower values are better No of events	n = 2	n = 2

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was randomly generated by a web-based system (Randomization.com). No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives and women was not possible for all outcomes: episiotomy, first degree perineal tear, second degree perineal tear and third- and fourth degree perineal tears, but no evidence that assignment to intervention affected implementation.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for all participants across all outcomes: (episiotomy, first degree perineal tear, second degree perineal tear and third- and fourth degree perineal tears).)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Blinding of the clinical midwives was not possible but it is not deemed to have affect outcome measurement.as the outcomes (episiotomy, first degree perineal tear, second degree perineal tear and third- and fourth degree perineal) are low risk)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was not available to determine bias in selected reporting)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes

Dahlen, 2007

Bibliographic Reference	Dahlen, Hannah G.; Homer, Caroline S. E.; Cooke, Margaret; Upton, Alexis M.; Nunn, Rosalie; Brodrick, Belinda; Perineal outcomes and maternal comfort related to the application of perineal warm packs in the second stage of labor: A randomized controlled trial; Birth; 2007; vol. 34 (no. 4); 282-290

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	November 1997 - July 2004
Inclusion criteria	• > 16 years • > 36 weeks gestation • Nulliparous women • Singleton pregnancy • Cephalic presentation • Perineal massage not performed • No intention to perform antenatal perineal massage
Exclusion criteria	• Intrauterine fetal death • Elective caesarean birth
Patient characteristics	Maternal age, years - mean ± standard deviation • Warm pack group: 27.0 ± 5.5 • Standard care group: 27.2 ± 4.9
Intervention(s)/control	Warm pack group: • Women received usual care until the baby's head began to distend the perineum. Then a warm pad was placed in the perineum during contractions Standard care group: • Did not have warm packs applied to their perineum in second stage.
Duration of follow-up	Not reported
Sources of funding	Johnson & Johnson Medical, Sydney, New South Wales, provided funds for translation of questionnaires and consent and information forms. The company had no input into the design or content of the study.

Sample size	Randomised: N= 717 Warm Pack group: n= 360 • Received warm pack: n= 302 • Did not receive warm pack: n= 58 Reasons: • Surgical intervention: n= 55 • Gave birth too fast: n= 1 • Refused: n= 2 Standard care: n= 357 • Received standard care: n= 297 • Did not receive standard care: n= 60 Reasons: • Surgical intervention: n= 56 • Warm pack applied: n= 3 • Water birth: n= 1
Other information	Perineal trauma was sutured with Vicryl 2/0 (Ethicon, Johnson & Johnson, Somerville, New Jersey, USA). Perineal pain post partum could not be extracted because p-values or standard deviations were not reported

Outcomes

Outcome	Warm Pack group, , N = 360	Standard Care group, , N = 357
Episiotomy Lower values are better No of events	n = 39	n = 41

Outcome	Warm Pack group, , N = 360	Standard Care group, , N = 357
Second-degree perineal tear lower values are better No of events	n = 150	n = 136
Third- and fourth- degree perineal tears Lower values are better No of events	n = 15	n = 31
Urinary Incontinence in the first year after birth Reported as urinary incontinence at 3 months. Warm pack group: n= 267; Standard care group: n= 263. Lower values are better. No of events	n = 26	n = 59
Pain postpartum at 1 day No pain. Warm pack group: n= 288 ; Standard care group: n= 293. Higher values are better No of events	n = 10	n = 1
Pain postpartum at 1 day The worst pain in my life. Warm pack group: n= 288 ; Standard care group: n= 293. Lower values are better No of events	n = 92	n = 148

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was randomly generated numbers in sealed opaque envelopes and concealed. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of the clinical midwives was not possible for all outcomes: episiotomy, second degree perineal tear, third- and fourth degree perineal tears, urinary incontinence in the first year after birth and pain postpartum at 1 day. No information on any deviations from intended intervention. Intention to treat analysis followed)*

Section	Question	Answer
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for all participants for outcomes episiotomy, second degree perineal tear, third- and fourth degree perineal tears. Data available most participants for outcomes urinary incontinence in the first year after birth.)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was not inappropriate, blinding of the clinical midwives was not possible (not outcome assessors). An independent, senior midwife blinded to the allocated group made an independent assessment of the degree of perineal trauma. The outcomes episiotomy, second degree perineal tear, third- and fourth degree perineal tears are deemed low risk. Pain postpartum at 1 day was measured by a pain analogue scale. Measurement of urinary incontinence is not specified)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was not available to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

Harlev, 2013

Bibliographic Reference	Harlev, Avi; Pariente, Gali; Kessous, Roy; Aricha-Tamir, Barak; Weintraub, Adi Y.; Eshkoli, Tamar; Dukler, Doron; Sheiner, Eyal; Ayun, Saviona Ben; Can we find the perfect oil to protect the perineum? A randomized- controlled double-blind trial; Journal of Maternal-Fetal and Neonatal Medicine; 2013; vol. 26 (no. 13); 1328-1331

Study details

Country/ies where study was carried out	Israel
Study type	Randomised controlled trial (RCT)

Study dates	July 2008 - July 2009
Inclusion criteria	• Singleton pregnancies • Term gestation
Exclusion criteria	• Placenta previa • Non-vertex presentations • Infection • Non-progressive labour first stage • Multiple gestations • Grand multiparous (>6 previous births) • Women with previous vaginal surgery or surgical intervention • Women who performed an antenatal perineal massage
Patient characteristics	Maternal age, years - mean ± standard deviation • Wax group: 26.2 ± 5.3 • Rich oil group: 26.3 ± 5.1 Gestational age, weeks - mean ± standard deviation • Wax group: 39.0 ± 1.2 • Rich oil group: 39.1 ± 1.4 No difference at baseline
Intervention(s)/control	Massage with liquid wax (without additional vitamins, for example jojoba oil) during the second stage of labour Massage with purified formula of almond oil with olive oil, rich with vitamin B1, B2, B6, E and fatty acid during the second stage of labour
Duration of follow-up	Not reported
Sources of funding	Not reported
Sample size	Randomised N= 164 • Liquid wax group: n= 82

	• Rich oil group: n= 82

Outcomes

Outcome	Liquid Wax group, , N = 82	Purified formula of oil group, , N = 82
Episiotomy Lower values are better No of events	n = 6	n = 13
First-degree perineal tear Lower values are better No of events	n = 48	n = 51
Second-degree perineal tear Lower values are better No of events	n = 32	n = 28
Third- and fourth- degree perineal tears Number of fourth degree tears not reported. Lower values are better No of events	n = 2	n = 3

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation stated as random. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Midwives, physicians and women were blind to the intervention for all outcomes (episiotomy, first-degree perineal tear, second- degree perineal tears and third- and fourth-degree perineal tears) as both oils were contained in bottles differentiated only by a number on the bottle. No evidence that ITT protocol not followed.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for all participants for all outcomes: episiotomy, first-degree*

Section	Question	Answer
		perineal tear, second- degree perineal tears and third- and fourth-degree perineal tears)
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was not inappropriate for all outcomes: episiotomy, first-degree perineal tear, second- degree perineal tears and third- and fourth-degree perineal tears. Both midwives and physicians were blinded to the intervention.)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was not available to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable *(No variation between outcomes.)*
Overall bias and Directness	Risk of bias variation across outcomes	No variation across outcomes.

Jonsson, 2008

Bibliographic Reference	Jonsson, Eva Rubin; Elfaghi, Ibtesam; Rydhstrom, Hakan; Herbst, Andreas; Modified Ritgen's maneuver for anal sphincter injury at delivery: A randomized controlled trial; Obstetrics and Gynecology; 2008; vol. 112 (no. 2part1); 212-217

Study details

Country/ies where study was carried out	Sweden
Study type	Randomised controlled trial (RCT)
Study dates	1st December 1999 - July 31st 2001
Inclusion criteria	• Singleton pregnancy • Cephalic presentation,

	• Admitted for labour • Rupture of the membranes • Induction after 37 completed gestational weeks
Exclusion criteria	• Instrumental births • Emergency caesarean births • Parous women • Preterm births
Patient characteristics	Maternal age, years - median (range) • Ritgen's manoeuvre: 28 (16-42) • Standard care: 28 (16-44) Gestational age, days - median (range) • Ritgen's manoeuvre: 280 (260-302) • Standard care: 281 (259-302) BMI* - median (range) • Ritgen's manoeuvre: 29 (20-48) • Standard care: 29 (19-46) * At admission in labour No significant differences between groups at baseline
Intervention(s)/control	Ritgen's manoeuvre: • Extraction of the fetal head, using one hand to pull the fetal chin from between the maternal anus and the coccyx, and the other on the fetal occiput to control speed of delivery. Ritgen's manoeuvre was performed during a uterine contraction. Standard care • Perineal support with one hand and control of the speed of crowning with the other, and use of Ritgen's manoeuvre only on specific indications.

Duration of follow-up	Not reported

Sample size	Randomised: N= 1623
	• Excluded for inaccurate randomisation: n= 6
	• Excluded for withdrawal of consent: n= 2
	• Excluded due to erroneous inclusion: n= 39
	  ○ Preterm birth n= 29
	  ○ Parous n= 10
	• Excluded for missing data: n= 1
	
	Correctly randomised women fulfilling the inclusion criteria: N= 1575
	• Ritgen's manoeuvre: n= 767
	• Women excluded: n= 71
	  ○ Instrumental delivery: n= 64
	  ○ Caesarean birth: n= 7
	
	• Standard care: n= 808
	• Women excluded: n= 81
	  ○ Instrumental delivery n= 78
	  ○ Caesarean birth n= 3
	
	• Women randomised to Ritgen's manoeuvre included in final analysis: n= 696
	• Women randomised to Standard care included in final analysis: n= 727

Other information	<u>Induction of labour - number (%)</u> • Ritgen's manoeuvre: 47 (6.8) • Standard care: 53 (7.3) <u>Oxytocin Infusion - number (%)</u>

	• Ritgen's manoeuvre: 360 (52.5) • Standard care: 368 (51.0)

Outcomes

Outcome	Ritgen's manoeuvre, , N = 696	Standard care, , N = 727
Episiotomy Lower values are better No of events	n = 95	n = 123
Third- and fourth- degree perineal tears Lower values are better No of events	n = 38	n = 32

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Randomisation was done via a telephone call from the delivering midwife to the other department. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives and women was not possible for all outcomes (episiotomy and third-and fourth- degree perineal tears), but no evidence that assignment to intervention affected implementation. No evidence that ITT protocol not followed.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for all participants for all outcomes episiotomy and third-and fourth- degree perineal tears)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Blinding of of the clinical midwives was not possible for all outcomes: episiotomy and third-and fourth- degree perineal tears but it is not deemed to have affected*

Section	Question	Answer
		outcome measurement as the opinion of an obstetrician was sought if the midwife was unsure.)
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was available but no information to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable *(Induction of labour - number (%) Ritgen's manoeuvre: 47 (6.8) Standard care: 53 (7.3) Oxytocin Infusion - number (%) Ritgen's manoeuvre: 360 (52.5) Standard care: 368 (51.0))*
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

Mayerhofer, 2002

Bibliographic Reference	Mayerhofer K; Bodner-Adler B; Bodner K; Rabl M; Kaider A; Wagenbichler P; Joura EA; Husslein P; Traditional care of the perineum during birth. A prospective, randomized, multicenter study of 1,076 women.; The Journal of reproductive medicine; 2002; vol. 47 (no. 6)

Study details

Country/ies where study was carried out	Austria
Study type	Randomised controlled trial (RCT)
Study dates	February 1999 - September 1999
Inclusion criteria	• Uncomplicated pregnancy • Cephalic presentation • Normal first and second stage of labour

	• Gestational age >37 weeks
Exclusion criteria	• Multiple pregnancy • Caesarean birth • Forceps • Vacuum • Planned water birth • Visible perineal scar • Language difficulties
Patient characteristics	Maternal age, years - median (Inter Quartile Range) • Hands on: 29 (25-32) • Hands poised: 29 (26-32) Gestational ages, weeks - median (Inter Quartile Range) • Hands on: 40 (39-41) • Hands poised: 40 (40-41) Parity - median (Inter Quartile Range) • Hands on: 1 (1-6) • Hands poised: 2 (1-2)
Intervention(s)/control	Hands on: • The midwife's left hand put pressure on the infant's head and the right hand is placed against the perineum for support and to use lateral flexion to facilitate delivery of the shoulders Hands poised: • The midwife's hands are kept poised ready to put light pressure on the infants head to avoid rapid expulsion. The midwife does not touch the perineum with her right hand at any time during delivery. Delivery of the shoulder is supported with both of the midwife's hands.
Duration of follow-up	Not reported

Sources of funding	Not reported
Sample size	Randomised: N= 1161 • Hands on: n= 619 • Hands poised: n= 542 • Data missing hands on: n= 45 • Data missing hands poised: n= 40 • Data available hands on: n= 574 (included in analysis) • Data available hands poised: n= 502 (included in analysis)

Outcomes

Outcome	Hands on , , N = 574	Hands poised, , N = 502
Episiotomy Lower values are better No of events	n = 103	n = 51
First-degree perineal tear Lower values are better No of events	n = 96	n = 98
Second- degree perineal tear Lower values are better No of events	n = 75	n = 77
Third- and fourth- degree perineal tears Fourth degree tears were not reported. Lower values are better No of events	n = 16	n = 5

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	High *(Allocation was quasi-random. Women were allocated according to date of birth. On even days the hands on technique was used and on odd days the hands poised technique was used. Noon was used as a break point of allocation. Women entering the second stage of labour before noon and delivering after noon were treated according to the allocation policy of the previous day. It was not clear whether there were baseline imbalances as the baseline data is provided as median (IQR) and p-values were not reported. Parity in the hands poised group seems to be higher than parity in the hands on group (median 2 [IQR 1 to 2] vs median 1 [IQR 1 to 6])*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives, physicians and women was not possible for all outcomes (episiotomy, first-degree perineal tear, second- degree perineal tears and third- and fourth-degree perineal tears), but no evidence that assignment to intervention affected implementation. No evidence that ITT protocol not followed.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for most participants. Data was missing from 85 women (40 + 45) = 5% & 6%. This was due to incomplete study forms. The missing data was balanced across groups)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was not inappropriate for all outcomes (episiotomy, first-degree perineal tear, second- degree perineal tears and third- and fourth-degree perineal tears), blinding of the obstetrician (outcome assessor) was not clear but it is not deemed to have affected outcome measurement as perineal trauma was categorised using traditional definitions and the outcomes are low risk)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was not available to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

McCandlish, 1998

Bibliographic Reference	McCandlish, R.; Bowler, U.; van Asten, H.; Berridge, G.; Winter, C.; Sames, L.; Garcia, J.; Renfrew, M.; Elbourne, D.; A randomised controlled trial of care of the perineum during second stage of normal labour; British journal of obstetrics and gynaecology; 1998; vol. 105 (no. 12); 1262-72

Study details

Country/ies where study was carried out	UK
Study type	Randomised controlled trial (RCT)
Study dates	December 1994 – December 1996
Inclusion criteria	• Singleton pregnancy • Cephalic presentation • Anticipated normal birth • Did not plan to have a water birth • Not prescribed elective episiotomy
Exclusion criteria	• In established labour at less than 37 weeks
Patient characteristics	Maternal age, years – mean ± standard deviation • Hands poised: 29.1 ± 5.1 • Hands on: 29.2 ± 4.9 Parity – number (%) **Primiparous** • Hands poised: 1051 (38.4) • Hands on: 997 (36.5)

	Gestational age, weeks – mean ± standard deviation • Hands poised: 40 ± 1.0 • Hands on: 40 ± 0.9
Intervention(s)/control	'Hands on': • The midwife's hands 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. 'Hands poised': • 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 delivery of the shoulders.
Duration of follow-up	3 months
Sources of funding	Non industry funded
Sample size	Randomised N= 5471 • Hands Poised: n= 2740 • Hands On: n= 2731
Other information	Unclear induction of labour

Outcomes

Outcome	**Hands Poised, , N = 2740**	**Hands on, , N = 2731**
Episiotomy Lower values are better No of events	n = 280	n = 351
First-degree perineal tear First degree tears included episiotomy. Lower values are better No of events	n = 802	n = 813
Second- degree perineal tear Second degree tears included episiotomy. Lower values are better	n = 1011	n = 1002

Outcome	Hands Poised, , N = 2740	Hands on, , N = 2731
No of events		
Third- and fourth- degree perineal tears Third and fourth degree tears included episiotomy. Lower values are better No of events	n = 40	n = 31
Urinary Incontinence in the first year after birth Urinary incontinence at 10 days. Hands poised n= 2669; Hands on n= 2647. Lower values are better No of events	n = 61	n = 48
Faecal Incontinence in the first year after birth Faecal incontinence at 10 days. Hands poised n= 2669; Hands on n= 2647. Lower values are better No of events	n = 14	n = 20
Perineal pain postpartum at 3 months None in the last week. Hands poised n= 2519; Hands on n= 2486. Higher values are better No of events	n = 2314	n = 2296
Perineal pain postpartum at 3 months Some mild in the last week. Hands poised n= 2519; Hands on n= 2486. Lower values are better No of events	n = 113	n = 124
Perineal pain postpartum at 3 months Some moderate in the last week. Hands poised n= 2519; Hands on n= 2486. Lower values are better No of events	n = 53	n = 46
Perineal pain postpartum at 3 months Some severe in the last week. Hands poised n= 2519; Hands on n= 2486. Lower values are better No of events	n = 5	n = 6
Perineal pain postpartum at 3 months ‘Pain all the time’. Hands poised n= 2519; Hands on n= 2486. Lower values are better No of events	n = 9	n = 11

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation random and concealed. Details of the allocated group were given on coloured cards contained in sequentially numbered, opaque, sealed envelopes. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives and women was not possible for all outcomes (episiotomy, first-degree perineal tear, second- degree perineal tears, third- and fourth-degree perineal tears, urinary incontinence the first year after birth and pain post-partum at 3 months), but no evidence that assignment to intervention affected implementation. No evidence that ITT protocol not followed.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for most participants for all outcomes (episiotomy, first-degree perineal tear, second- degree perineal tears, third- and fourth-degree perineal tears, urinary incontinence the first year after birth and pain post-partum at 3 months)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Method of outcome measurement was not inappropriate, blinding of the clinical midwives (outcome assessors) was not possible. The use of an unvalidated questionnaire to assess pain could have affected outcome measurement as it is a subjective measurement of pain related to the tolerance of each woman)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A portion of the pre-specified protocol was available within the study text but there was not any information to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable *(Unclear induction of labour)*
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

Stamp, 2001

Bibliographic Reference	Stamp, G.; Kruzins, G.; Crowther, C.; Perineal massage in labour and prevention of perineal trauma: Randomised controlled trial; British Medical Journal; 2001; vol. 322 (no. 7297); 1277-1280

Study details

Country/ies where study was carried out	Australia
Study type	Randomised controlled trial (RCT)
Study dates	March 1995 – January 1998
Inclusion criteria	• English speaking • Singleton pregnancy • Expecting a normal vaginal birth • Presenting in uncomplicated labour • Progressed to a visible vertex • Full cervical dilation (8cm+ if nulliparous or 5cm+ if multiparous)
Patient characteristics	Maternal age, years – mean Massage group: • Nulliparous: 25.5 • Multiparous: 29.0 Standard care: • Nulliparous: 26.6 • Multiparous: 29.2 Parity – number (%) **Nulliparous** • Massage group: 353 (49.9) • Standard care: 332 (52.5) **Multiparous** • Massage group: 355 (50.1)

	• Standard care: 300 (47.5)
Intervention(s)/control	Massage group: • Massage and stretching of the perineum with each contraction during the second stage of labour, stopping if it was uncomfortable for the woman. Standard care • The midwife was instructed to use her or his usual technique but to refrain from using perineal massage.
Duration of follow-up	3 months
Sources of funding	Competing interest: Johnson and Johnson provided water soluble lubricant for the perineal massage.
Sample size	Randomised N= 1340 • Massage group: n= 708 included in analysis • Standard care: n= 632 included in analysis
Other information	Use of oxytocin at birth – number • Massage group: 205 • Standard care: 157

Outcomes

Outcome	**Massage group, , N = 708**	**Standard care, , N = 632**
Episiotomy Lower values are better No of events	n = 176	n = 170
First-degree perineal tear Lower values are better No of events	n = 122	n = 106
Second- degree perineal tear Lower values are better	n = 190	n = 164

Outcome	Massage group, , N = 708	Standard care, , N = 632
No of events		
Third- and fourth- degree perineal tears Lower values are better No of events	n = 12	n = 24
Urinary incontinence Massage group n= 503; Control group n= 436. Lower values are better. (reported as loss of urinary control at 3 months) No of events	n = 123	n = 115
Faecal incontinence Massage group n= 503; Control group n= 436. Lower values are better. (reported as loss of bowel control at 3 months) No of events	n = 36	n = 35
Vaginal pain post partum at 3 months Massage group n= 503; Control group n= 436. Lower values are better No of events	n = 58	n = 54

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was random and concealed. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives and women was not possible for all outcomes episiotomy, first-degree perineal tear, second- degree perineal tears, third- and fourth-degree perineal tears, urinary incontinence and pain post-partum at 3 months, but no evidence that assignment to intervention affected implementation. No evidence that ITT protocol not followed.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for all participants for the outcomes episiotomy, first-degree perineal tear, second- degree perineal tears, third- and fourth-degree perineal tears. Data*

Section	Question	Answer
		available for most participants for the outcomes: urinary incontinence and pain post-partum at 3 months)
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Method of outcome measurement was not inappropriate for all outcomes (episiotomy, first-degree perineal tear, second- degree perineal tears, third- and fourth-degree perineal tears, urinary incontinence and pain post-partum at 3 months), blinding of the clinical midwives (outcome assessors) was not possible. The use of an unvalidated questionnaire to assess pain could have affected outcome measurement as it is a subjective measurement of pain related to the tolerance of each woman. Standard definitions of perineal trauma were used so measurement of these would have been unlikely to differ between groups)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(Study reported the outcomes as specified in the trial protocol.)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable *(Use of oxytocin at birth - number* *Massage group: n= 205* *Standard care: n= 157)*
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes

GA: Gestational age, BMI: body mass index

Appendix E Forest plots

Forest plots for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

This section includes forest plots only for outcomes that are meta-analysed. Outcomes from single studies are not presented here; the quality assessment for such outcomes is provided in the GRADE profiles in appendix F.

Comparison 8. Hands on versus hands poised

Figure 2: Episiotomy

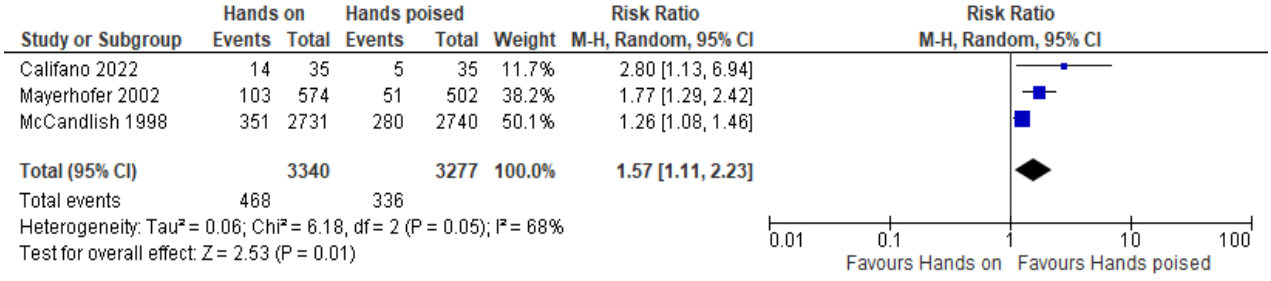


Figure 3: First-degree perineal tear

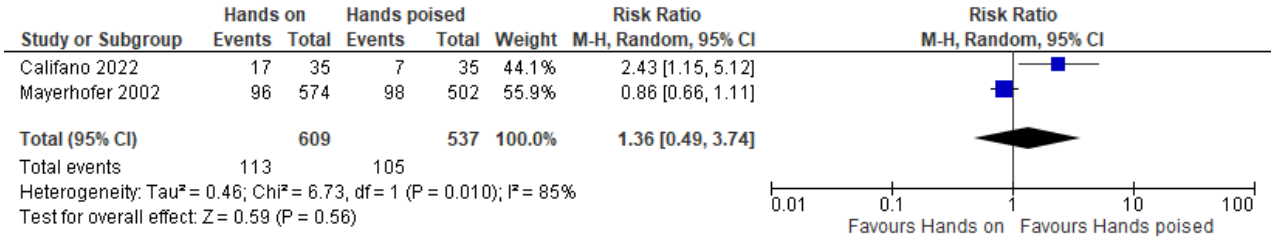
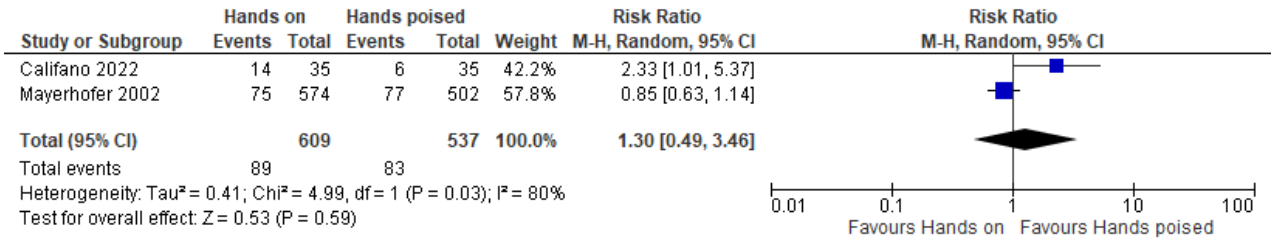


Figure 4: Second-degree perineal tear



Appendix F GRADE tables

GRADE tables for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

Table 5: Evidence profile for comparison 1. Primary delivery of anterior shoulder versus primary delivery of posterior shoulder

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Anterior shoulder	Posterior shoulder	Relative (95% CI)	Absolute		
Episiotomy - BMI healthy weight range - nulliparous												
Aabakke, 2016	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[1]	none	33/262 (12.6%)	22/281 (7.8%)	RR 1.61 (0.96 to 2.69)	48 more per 1000 (from 3 fewer to 132 more)	LOW	CRITICAL
Third- and fourth- degree perineal tears - BMI healthy weight range - nulliparous												
Aabakke, 2016	randomised trials	no serious risk of bias	no serious inconsistency	no serious indirectness	very serious[2]	none	15/262 (5.7%)	13/281 (4.6%)	RR 1.24 (0.6 to 2.55)	11 more per 1000 (from 19 fewer to 72 more)	LOW	CRITICAL

CI: confidence interval; RR: risk ratio
1 95% CI crosses 1 MID (1.25)
2 95% CI crosses 2 MIDS (0.8 and 1.25)

Table 6: Evidence profile comparison 2. Warm compress versus massage with lubricant

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Warm compress	Massage with lubricant	Relative (95% CI)	Absolute		
Episiotomy - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	1/404 (0.25%)	7/403 (1.7%)	RR 0.14 (0.02 to 1.15)	15 fewer per 1000 (from 17 fewer to 3 more)	VERY LOW	CRITICAL
First- degree perineal tear - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	very serious	serious[4]	none	97/404 (24%)	91/403 (22.6%)	RR 1.06 (0.83 to 1.37)	14 more per 1000 (from 38 fewer to 84 more)	VERY LOW	CRITICAL
Second- degree perineal tear - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[5]	none	70/404 (17.3%)	73/403 (18.1%)	RR 0.96 (0.71 to 1.29)	7 fewer per 1000 (from 53 fewer to 53 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears - BMI overweight range												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Warm compress	Massage with lubricant	Relative (95% CI)	Absolute		
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[5]	none	3/404 (0.74%)	5/403 (1.2%)	RR 0.6 (0.14 to 2.49)	5 fewer per 1000 (from 11 fewer to 18 more)	VERY LOW	CRITICAL

CI: confidence interval; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Population is indirect due to unreported induction of labour
3 95% CI crosses 1 MID (0.8)
4 95% CI crosses 1 MID (1.25)
5 95% CI crosses 2 MIDs (0.8 and 1.25)

Table 7: Evidence profile comparison 3. Warm compress versus hands off

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Warm compress	Hands off	Relative (95% CI)	Absolute		
Episiotomy - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	1/404 (0.25%)	2/404 (0.5%)	RR 0.5 (0.05 to 5.49)	2 fewer per 1000 (from 5 fewer to 22 more)	VERY LOW	CRITICAL
First- degree perineal tear - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[4]	none	97/404 (24%)	89/404 (22%)	RR 1.09 (0.85 to 1.4)	20 more per 1000 (from 33 fewer to 88 more)	VERY LOW	CRITICAL
Second- degree perineal tear - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	70/404 (17.3%)	74/404 (18.3%)	RR 0.95 (0.7 to 1.27)	9 fewer per 1000 (from 55 fewer to 49 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[4]	none	3/404 (0.7%)	6/404 (1.5%)	RR 0.5 (0.13 to 1.99)	7 fewer per 1000 (from 13 fewer to 15 more)	VERY LOW	CRITICAL

CI: confidence interval; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Population is indirect due to unreported induction of labour
3 95% CI crosses 2 MIDs (0.8 and 1.25)
4 95% CI crosses 1 MID (1.25)

Table 8: Evidence profile comparison 4. Massage with lubricant versus hands off

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Massage with lubricant	Hands of	Relative (95% CI)	Absolute		
Episiotomy - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	7/403 (1.7%)	2/404 (0.5%)	RR 3.51 (0.73 to 16.79)	12 more per 1000 (from 1 fewer to 78 more)	VERY LOW	CRITICAL
First- degree perineal tear - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	91/403 (22.6%)	89/404 (22%)	RR 1.03 (0.79 to 1.33)	7 more per 1000 (from 46 fewer to 73 more)	VERY LOW	CRITICAL
Second- degree perineal tear - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	73/403 (18.1%)	74/404 (18.3%)	RR 0.99 (0.74 to 1.32)	2 fewer per 1000 (from 48 fewer to 59 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears - BMI overweight range												
Albers, 2005	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	5/403 (1.2%)	6/404 (1.5%)	RR 0.84 (0.26 to 2.72)	2 fewer per 1000 (from 11 fewer to 26 more)	VERY LOW	CRITICAL

CI: confidence interval; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Population is indirect due to unreported induction of labour
3 95% CI crosses 2 MIDs (0.8 and 1.25)

Table 9: Evidence profile comparison 5. Warm pack versus standard care (no warm packs applied to the perineum during the second stage)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Warm pack	Standard care	Relative (95% CI)	Absolute		
Episiotomy												
Dahlen, 2007	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[3]	none	39/360 (10.8%)	41/357 (11.5%)	RR 0.94 (0.62 to 1.43)	7 fewer per 1000 (from 44 fewer to 49 more)	VERY LOW	CRITICAL
Second- degree perineal tear												
Dahlen, 2007	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[4]	none	150/360 (41.7%)	136/357 (38.1%)	RR 1.09 (0.91 to 1.31)	34 more per 1000 (from 34 fewer to 118 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears												
Dahlen, 2007	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[5]	none	15/360 (4.2%)	31/357 (8.7%)	RR 0.48 (0.26 to 0.87)	45 fewer per 1000 (from 11 fewer to 64 fewer)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Warm pack	Standard care	Relative (95% CI)	Absolute		
Urinary Incontinence at 3 months												
Dahlen, 2007	randomised trials	serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	26/267 (9.7%)	59/263 (22.4%)	RR 0.43 (0.28 to 0.67)	128 fewer per 1000 (from 74 fewer to 162 fewer)	LOW	IMPORTANT
Pain postpartum at 1 day - No pain												
Dahlen, 2007	randomised trials	serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	10/288 (3.5%)	1/293 (0.34%)	RR 10.17 (1.31 to 78.96)	31 more per 1000 (from 1 more to 266 more)	LOW	IMPORTANT
Pain postpartum at 1 day - The worst pain in my life												
Dahlen, 2007	randomised trials	serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	92/288 (31.9%)	148/293 (50.5%)	RR 0.63 (0.52 to 0.77)	187 fewer per 1000 (from 116 fewer to 242 fewer)	LOW	IMPORTANT

CI: confidence interval; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Population is indirect due to unclear induction of labour
3 95% CI crosses 2 MIDs (0.8 and 1.25)
4 95% CI crosses 1 MID (1.25)
5 95% CI crosses 1 MID (0.8)

Table 10: Evidence profile comparison 6. Massage with liquid wax versus massage with purified formula of oil

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Massage with liquid wax	Massage with purified formula of oil	Relative (95% CI)	Absolute		
Episiotomy												
Harlev, 2013	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	6/82 (7.3%)	13/82 (15.9%)	RR 0.46 (0.18 to 1.16)	86 fewer per 1000 (from 130 fewer to 25 more)	VERY LOW	CRITICAL
First- degree perineal tear												
Harlev, 2013	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	48/82 (58.5%)	51/82 (62.2%)	RR 0.94 (0.73 to 1.21)	37 fewer per 1000 (from 168 fewer to 131 more)	VERY LOW	CRITICAL
Second- degree perineal tear												
Harlev, 2013	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[4]	none	32/82 (39%)	28/82 (34.1%)	RR 1.14 (0.76 to 1.71)	48 more per 1000 (from 82 fewer to 242 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears												
Harlev, 2013	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[4]	none	2/82 (2.4%)	3/82 (3.7%)	RR 0.67 (0.11 to 3.89)	12 fewer per 1000 (from 33 fewer to 106 more)	VERY LOW	CRITICAL

CI: confidence interval; RR: risk ratio

1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Population is indirect due to unclear induction of labour
3 95% CI crosses 1 MID (0.8)
4 95% CI crosses 2 MIDs (0.8 and 1.25)

Table 11: Evidence profile comparison 7. Ritgen's manoeuvre versus standard care (perineal support with one hand and control of the speed of crowning with the other, using Ritgen's manoeuvre only on specific indications)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Ritgen's manoeuvre	Standard care	Relative (95% CI)	Absolute		
Episiotomy												
Jonsson, 2008	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	95/696 (13.6%)	123/727 (16.9%)	RR 0.81 (0.63 to 1.03)	32 fewer per 1000 (from 63 fewer to 5 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears												
Jonsson, 2008	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[4]	none	38/696 (5.5%)	32/727 (4.4%)	RR 1.24 (0.78 to 1.96)	11 more per 1000 (from 10 fewer to 42 more)	VERY LOW	CRITICAL

CI: confidence interval; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Population is indirect due to <1/3 women being induced
3 95% CI crosses 1 MID (0.8)
4 95% CI crosses 2 MIDs (0.8 and 1.25)

Table 12: Evidence profile comparison 8. Hands on versus hands poised

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hands on	Hands poised	Relative (95% CI)	Absolute		
Episiotomy - overall estimate												
Califano, 2022, Mayerhofer 2002, McCandlish 1998	randomised trials	very serious[1]	serious[2]	serious[3]	serious[4]	none	468/3340 (14%)	336/3277 (10.3%)	RR 1.57 (1.11 to 2.23)	58 more per 1000 (from 11 more to 126 more)	VERY LOW	CRITICAL
Episiotomy - BMI overweight range - nulliparous												
Califano, 2022	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[4]	none	14/35 (40%)	5/35 (14.3%)	RR 2.8 (1.13 to 6.94)	257 more per 1000 (from 19 more to 849 more)	LOW	CRITICAL
First- degree perineal tear												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hands on	Hands poised	Relative (95% CI)	Absolute		
Califano, 2022, Mayerhofer 2002	randomised trials	serious[5]	very serious[6]	serious[3]	very serious[7]	none	113/609 (18.6%)	105/537 (19.6%)	RR 1.36 (0.49 to 3.74)	70 more per 1000 (from 100 fewer to 536 more)	VERY LOW	CRITICAL
First- degree perineal tear - BMI overweight range - nulliparous												
Califano, 2022	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[4]	none	17/35 (48.6%)	7/35 (20%)	RR 2.43 (1.15 to 5.12)	286 more per 1000 (from 30 more to 824 more)	LOW	CRITICAL
First- degree perineal tear (includes episiotomy)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	813/2731 (29.8%)	802/2740 (29.3%)	RR 1.02 (0.94 to 1.1)	6 more per 1000 (from 18 fewer to 29 more)	VERY LOW	CRITICAL
Second- degree perineal tear												
Califano, 2022, Mayerhofer 2002	randomised trials	serious[5]	very serious[6]	serious[3]	very serious[7]	none	89/609 (14.6%)	83/537 (15.5%)	RR 1.30 (0.49 to 3.46)	46 more per 1000 (from 79 fewer to 380 more)	VERY LOW	CRITICAL
Second- degree perineal tear - BMI overweight range - nulliparous												
Califano, 2022	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	serious[4]	none	14/35 (40%)	6/35 (17.1%)	RR 2.33 (1.01 to 5.37)	228 more per 1000 (from 2 more to 749 more)	LOW	CRITICAL
Second- degree perineal tear (includes episiotomy)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	1002/2731 (36.7%)	1011/2740 (36.9%)	RR 0.99 (0.93 to 1.07)	4 fewer per 1000 (from 26 fewer to 26 more)	VERY LOW	CRITICAL
Third- degree perineal tears												
Mayerhofer 2002	randomised trials	serious[5]	no serious inconsistency	serious[3]	serious[4]	none	16/574 (2.8%)	5/502 (1%)	RR 2.8 (1.03 to 7.58)	18 more per 1000 (from 0 more to 66 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears - BMI overweight range - nulliparous												
Califano, 2022	randomised trials	serious[5]	no serious inconsistency	no serious indirectness	very serious[7]	none	2/35 (5.7%)	2/35 (5.7%)	RR 1 (0.15 to 6.71)	0 fewer per 1000 (from 49 fewer to 326 more)	VERY LOW	CRITICAL
Third- and fourth- degree perineal tears (includes episiotomy)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	31/2731 (1.1%)	40/2740 (1.5%)	RR 0.78 (0.49 to 1.24)	3 fewer per 1000 (from 7 fewer to 4 more)	VERY LOW	CRITICAL
Urinary Incontinence at 10 days												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hands on	Hands poised	Relative (95% CI)	Absolute		
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	serious[8]	none	48/2647 (1.8%)	61/2669 (2.3%)	RR 0.79 (0.55 to 1.15)	5 fewer per 1000 (from 10 fewer to 3 more)	VERY LOW	IMPORTANT
Faecal Incontinence at 10 days												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	Very serious[7]	none	20/2647 (0.76%)	14/2669 (0.52%)	RR 1.44 (0.73 to 2.85)	2 more per 1000 (from 1 fewer to 10 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 2 days (some in the previous 24 hours)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	1915/2686 (71.3%)	1871/2685 (69.7%)	RR 1.02 (0.99 to 1.06)	14 more per 1000 (from 7 fewer to 42 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 2 days (some currently)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	1555/2686 (57.9%)	1481/2685 (55.2%)	RR 1.05 (1 to 1.1)	28 more per 1000 (from 0 more to 55 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 10 days (some in the previous 24 hours)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	823/2647 (31.1%)	910/2669 (34.1%)	RR 0.91 (0.84 to 0.99)	31 fewer per 1000 (from 3 fewer to 55 fewer)	VERY LOW	IMPORTANT
Perineal pain postpartum at 10 days (some currently)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	524/2647 (19.8%)	568/2669 (21.3%)	RR 0.93 (0.84 to 1.03)	15 fewer per 1000 (from 34 fewer to 6 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 3 months (none in the last week)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	no serious imprecision	none	2296/2486 (92.4%)	2314/2519 (91.9%)	RR 1.01 (0.99 to 1.02)	9 more per 1000 (from 9 fewer to 18 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 3 months (some mild in the last week)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	serious[4]	none	124/2486 (5%)	113/2519 (4.5%)	RR 1.11 (0.87 to 1.43)	5 more per 1000 (from 6 fewer to 19 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 3 months (some moderate in the last week)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	very serious[7]	none	46/2486 (1.9%)	53/2519 (2.1%)	RR 0.88 (0.59 to 1.3)	3 fewer per 1000 (from 9 fewer to 6 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 3 months (some severe in the last week)												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Hands on	Hands poised	Relative (95% CI)	Absolute		
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	very serious[7]	none	6/2486 (0.24%)	5/2519 (0.2%)	RR 1.22 (0.37 to 3.98)	0 more per 1000 (from 1 fewer to 6 more)	VERY LOW	IMPORTANT
Perineal pain postpartum at 3 months (pain all the time)												
McCandlish 1998	randomised trials	very serious[1]	no serious inconsistency	serious[3]	very serious[7]	none	11/2486 (0.44%)	9/2519 (0.36%)	RR 1.24 (0.51 to 2.98)	1 more per 1000 (from 2 fewer to 7 more)	VERY LOW	IMPORTANT

CI: confidence interval; RR: risk ratio
1 Very serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Serious heterogeneity not explained by sub group analysis
3 Population is indirect due to unclear induction of labour
4 95% CI crosses 1 MID (1.25)
5 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
6 Very serious heterogeneity not explained by sub group analysis
7 95% CI crosses 2 MIDs (0.8 and 1.25)
8 95% CI crosses 1 MID (0.8)

Table 13: Evidence profile comparison 9. Massage with lubricant versus standard care (midwife's usual technique, refraining from using perineal massage)

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Massage with lubricant	Standard care	Relative (95% CI)	Absolute		
Episiotomy												
Stamp, 2001	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	176/708 (24.9%)	170/632 (26.9%)	RR 0.92 (0.77 to 1.11)	22 fewer per 1000 (from 62 fewer to 30 more)	VERY LOW	CRITICAL
First- degree perineal tear												
Stamp, 2001	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[4]	none	122/708 (17.2%)	106/632 (16.8%)	RR 1.03 (0.81 to 1.3)	5 more per 1000 (from 32 fewer to 50 more)	VERY LOW	CRITICAL
Second- degree perineal tear												
Stamp, 2001	randomised trials	serious[1]	no serious inconsistency	serious[2]	no serious imprecision	none	190/708 (26.8%)	164/632 (25.9%)	RR 1.03 (0.86 to 1.24)	8 more per 1000 (from 36 fewer to 62 more)	LOW	CRITICAL
Third- and fourth- degree perineal tears												
Stamp, 2001	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	12/708 (1.7%)	24/632 (3.8%)	RR 0.45 (0.23 to 0.89)	21 fewer per 1000 (from 4 fewer to 29 fewer)	VERY LOW	CRITICAL

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Massage with lubricant	Standard care	Relative (95% CI)	Absolute		
Urinary Incontinence at 3 months												
Stamp, 2001	randomised trials	serious[1]	no serious inconsistency	serious[2]	serious[3]	none	123/503 (24.5%)	115/436 (26.4%)	RR 0.93 (0.74 to 1.15)	18 fewer per 1000 (from 69 fewer to 40 more)	VERY LOW	IMPORTANT
Faecal Incontinence at 3 months												
Stamp 2001	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[5]	none	36/503 (7.2%)	35/436 (8%)	RR 0.89 (0.57 to 1.39)	9 fewer per 1000 (from 35 fewer to 31 more)	VERY LOW	IMPORTANT
Vaginal pain postpartum at 3 months (none in the last week)												
Stamp, 2001	randomised trials	serious[1]	no serious inconsistency	serious[2]	very serious[5]	none	58/503 (11.5%)	54/436 (12.4%)	RR 0.93 (0.66 to 1.32)	9 fewer per 1000 (from 42 fewer to 40 more)	VERY LOW	IMPORTANT

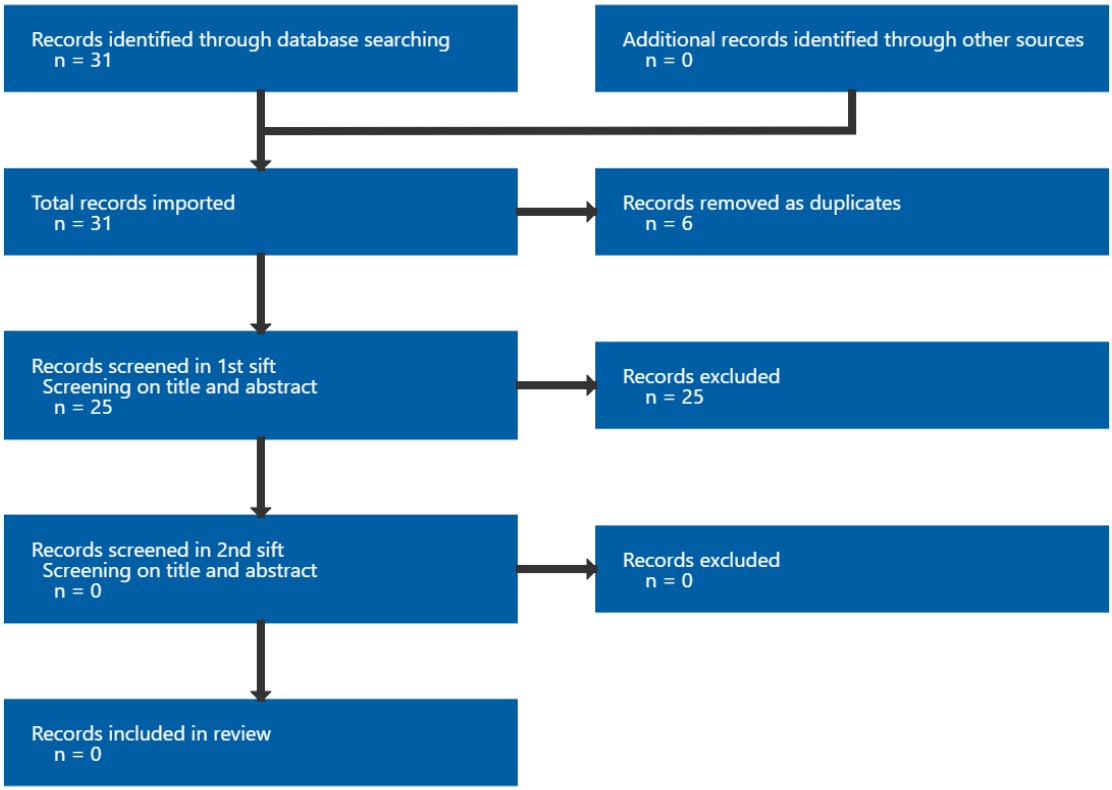
CI: confidence interval; RR: risk ratio
1 Serious risk of bias in the evidence contributing to the outcomes as per RoB 2
2 Population indirect due to unclear induction of labour
3 95% CI crosses 1 MID (0.8)
4 95% CI crosses 1 MID (1.25)
5 95% CI crosses 2 MIDs (0.8 and 1.25)

Appendix G Economic evidence study selection

Study selection for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

No economic evidence was identified which was applicable to this review question.

Figure 3: Study selection flow chart



Appendix H Economic evidence tables

Economic evidence tables for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

No evidence was identified which was applicable to this review question.

Appendix I Economic model

Economic model for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

No economic analysis was conducted for this review question.

Appendix J Excluded studies

Excluded studies for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

Excluded effectiveness studies

Table 14: Excluded studies and reasons for their exclusion

Study	Reason
Aasheim, Vigdis, Nilsen, Anne Britt Vika, Reinar, Liv Merete et al. (2017) Perineal techniques during the second stage of labour for reducing perineal trauma. Cochrane Database of Systematic Reviews 2017(6): cd006672	- Systematic review - studies do not meet inclusion criteria Eligible studies already included; 10 studies conducted in non-OECD high income country: Brazil, Iran; 1 study included women <37 weeks gestation;1 study was not available in English
Akbarzadeh, Marzieh, Vaziri, Faride, Farahmand, Mahnaz et al. (2016) The Effect of Warm Compress Bistage Intervention on the Rate of Episiotomy, Perineal Trauma, and Postpartum Pain Intensity in Primiparous Women with Delayed Valsalva Maneuver Referring to the Selected Hospitals of Shiraz University of Medical Sciences in 2012-2013. Advances in skin & wound care 29(2): 79-84	- Study conducted in a low- or middle-income country Iran is not an OECD high income country - Intervention not in PICO Intervention was conducted in both the first and second stage of labour
Akhlaghi, Farideh, Baygi, Zeynab Sabeti, Miri, Mohsen et al. (2019) Effect of perineal massage on the rate of episiotomy. Journal of Family and Reproductive Health 13(3): 160-166	- Study conducted in a low or middle income country Iran is not an OECD high income country - Intervention not in PICO Intervention was conducted in both the first and second stage of labour
Anonymous (2008) Warm packs beneficial in labor. Journal of the National Medical Association 100(3): 348	- Unavailable Unavailable from IS search
Aquino CI, Saccone G, Troisi J et al. (2020) Is Ritgen's maneuver associated with decreased perineal lacerations and pain at delivery?. The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 33(18): 3185-3192	- Systematic review - studies do not meet inclusion criteria Conducted in low/middle income country; Already included as individual study; Reference list checked for eligible studies
Aquino, Carmen Imma, Guida, Maurizio, Saccone, Gabriele et al. (2020) Perineal massage during labor: a systematic review and meta-analysis of randomized controlled trials. Journal of Maternal-Fetal and Neonatal Medicine 33(6): 1051-1063	- Systematic review - studies do not meet inclusion criteria Eligible studies already included; 7 studies conducted in non-OECD high income country - Iran, Turkey; 1 study the intervention was not in PICO - spontaneous pushing
Aquino, Carmen Imma, Guida, Maurizio, Saccone, Gabriele et al. (2019) Is Ritgen's	- Systematic review - studies do not meet inclusion criteria

Study	Reason
maneuver associated with decreased perineal lacerations and pain at delivery?. Journal of Maternal-Fetal and Neonatal Medicine: 1-8	Eligible studies already included; 2 studies were conducted in non-OECD high income countries - Iran
Ashwal, Eran, Aviram, Amir, Wertheimer, Avital et al. (2016) The impact of obstetric gel on the second stage of labor and perineal integrity: a randomized controlled trial. Journal of Maternal-Fetal and Neonatal Medicine 29(18): 3024-3029	- Intervention not in PICO The intervention was conducted in both the first and the second stage of labour
Bulchandani, S., Watts, E., Sucharitha, A. et al. (2015) Manual perineal support at the time of childbirth: a systematic review and meta-analysis. BJOG : an international journal of obstetrics and gynaecology 122(9): 1157-65	- Systematic review - studies do not meet inclusion criteria The study designs did not meet the PICO: 6 cohort study and 1 prospective study; 2 studies were conducted in non-OECD high income: Brazil and Iran
Chatfield WR and Moir DD (1966) The effect of hyaluronidase on the perineum. A controlled trial of 200 primigravid patients in labour. The Journal of obstetrics and gynaecology of the British Commonwealth 73(4): 670-671	- Intervention not in PICO Delivered as an injection, so not considered a perineal technique
Correa Junior, Mario Dias and Passini Junior, Renato (2016) Selective Episiotomy: Indications, Techinique, and Association with Severe Perineal Lacerations. Revista brasileira de ginecologia e obstetricia : revista da Federacao Brasileira das Sociedades de Ginecologia e Obstetricia 38(6): 301-7	- Intervention not in PICO Comparing routine vs selective episiotomy is not in PICO - Study design not in PICO Narrative review
Dahlen HG, Homer CS, Cooke M et al. (2007) Perineal outcomes and maternal comfort related to the application of perineal warm packs in the second stage of labor: a randomized controlled trial. Birth 34(4): 282-290	- Duplicate
de Souza Caroci da Costa, Adriana and Gonzalez Riesco, Maria Luiza (2006) A comparison of "hands off" versus "hands on" techniques for decreasing perineal lacerations during birth. Journal of midwifery & women's health 51(2): 106-11	- Study conducted in a low- or middle-income country Brazil is not an OECD high income country
Demirel, Gulbahtiyar and Golbasi, Zehra (2015) Effect of perineal massage on the rate of episiotomy and perineal tearing. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 131(2): 183-6	- Study conducted in a low- or middle-income country Turkey is not an OECD high income country
Dieb, Amira S., Shoab, Amira Y., Nabil, Hala et al. (2020) Perineal massage and training reduce perineal trauma in pregnant women older than 35 years: a randomized controlled trial. International Urogynecology Journal 31(3): 613-619	- Intervention not in PICO Intervention conducted during pregnancy - Study conducted in a low- or middle-income country Egypt is not an OECD high income country
Eason, E., Labrecque, M., Wells, G. et al. (2000) Preventing perineal trauma during childbirth: a	- Study design not in PICO Narrative review

Study	Reason
systematic review. Obstetrics and gynecology 95(3): 464-71	
Flynn, P., Franiek, J., Janssen, P. et al. (1997) How can second-stage management prevent perineal trauma? Critical review. Canadian family physician Medecin de famille canadien 43: 73-84	- Study design not in PICO Narrative review
Foroughipour, Azam, Firuzeh, Farah, Ghahiri, Ataolah et al. (2011) The effect of perineal control with hands-on and hand-poised methods on perineal trauma and delivery outcome. Journal of research in medical sciences : the official journal of Isfahan University of Medical Sciences 16(8): 1040-6	- Population not in PICO Rate of induction was 82% in both groups - Study conducted in a low- or middle-income country Iran is not an OECD high income country
Geranmayeh, Mehrnaz, Rezaei Habibabadi, Zahra, Fallahkish, Bijan et al. (2012) Reducing perineal trauma through perineal massage with vaseline in second stage of labor. Archives of gynecology and obstetrics 285(1): 77-81	- Study conducted in a low- or middle-income country Iran is not an OECD high income country
Haggsgard, C., Tern, H., Rubertsson, C. et al. (2020) One Plus One Equals Two-will that do? A trial protocol for a Swedish multicentre randomised controlled trial to evaluate a clinical practice to reduce severe perineal trauma {1}. Trials 21(1): 945	- Intervention not in PICO Intervention is one present midwife versus two present midwives which is not in PICO
Harlev, Avi, Aricha-Tamir, Barak, Kessous, Roy et al. (2009) Can we find the perfect oil to protect the perineum? A randomized-controlled double-blind trial. American Journal of Obstetrics and Gynecology 201(6suppl1): S127-S128	- Study design not in PICO Conference abstract
Healy, Maria, Spence, Dale, Nyman, Viola et al. (2020) How do midwives facilitate women to give birth during physiological second stage of labour? A systematic review. PLoS ONE 15(7july): e0226502	- Systematic review - studies do not meet inclusion criteria All studies were conducted in non-OECD high income country - Iran
Huang, Jing, Lu, Hong, Zang, Yu et al. (2020) The effects of hands on and hands off/poised techniques on maternal outcomes: A systematic review and meta-analysis. Midwifery 87: 102712	- Systematic review - studies do not meet inclusion criteria Eligible studies already included; 13 studies conducted in non-OECD high income country - China, Iran; 1 study: design not included in PICO: analytic cross section study
Irct138802031839N (2012) Effect of perineal massage in incidence of intact perineum during vaginal birth. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT138802031839N1	- Trial register/protocol
Irct201111053034N (2012) The effects of perineal massage on delivery outcome. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT201111053034N8	- Trial register/protocol
Irct2012072410327N (2012) Warm compress on the injury severity of perineal pain in labor. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT2012072410327N2	- Trial register/protocol

Study	Reason
Irct2012111211422N (2013) Warm compress on the injury severity of perinea pain in labor. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT2012111211422N1	- Trial register/protocol
Irct2013090314556N (2013) The Effect of Prineal Massage on Prineal Trauma. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT2013090314556N1	- Trial register/protocol
Irct2014051511706N (2014) The effect of warm compress bi-stage intervention on prevention of perineal trauma and second stage pain intensity and duration the first stage and second stage in primiparous with delayed valsalva maneuver. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT2014051511706N7	- Trial register/protocol
Irct20170422033583N (2020) The effect of vaginal and perineal massage with sesame oil on labor. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT20170422033583N1	- Trial register/protocol
Irct20190131042567N (2019) Evaluation of the effect of olive oil on perineal laceration. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT20190131042567N1	- Trial register/protocol
Irct20200721048154N (2020) The effect of lubricating vaginal with natural animal fat on the second stage of labor, frequency of episiotomy and preineal laceration in primiparous women. https://trialsearch.who.int/Trial2.aspx?TrialID=IRCT20200721048154N1	- Trial register/protocol
Isrctn (2018) Combined massage and warm compress to the perineum during pushing in women delivering for the first time. https://trialsearch.who.int/Trial2.aspx?TrialID=ISRCTN42773879	- Trial register/protocol
Isrctn (2019) Comparing combined perineal massage and warm compress versus perineal massage during the second stage of labour in nulliparous women. https://trialsearch.who.int/Trial2.aspx?TrialID=ISRCTN10088409	- Trial register/protocol
Kamisan Atan, I., Shek, K. L., Langer, S. et al. (2016) Does the Epi-No(R) birth trainer prevent vaginal birth-related pelvic floor trauma? A multicentre prospective randomised controlled trial. BJOG : an international journal of obstetrics and gynaecology 123(6): 995-1003	- Intervention not in PICO Intervention with Epi-No (R) was antenatal
Kapoor, Dharmesh S.; Sultan, Abdul H.; Thakar, Ranee (2015) Obstetric anal sphincter injuries: review of anatomical factors and modifiable second stage interventions. International Urogynecology Journal 26(12): 1725-1734	- Study design not in PICO Narrative review
Kavvadias, Tilemachos and Hoesli, Irene (2016) The EpiNo R Device: Efficacy, Tolerability, and Impact on Pelvic Floor-Implications for Future Research. Obstetrics and gynecology international 2016: 3818240	- Study design not in PICO Narrative review

Study	Reason
Kettle, Chris and Tohill, Susan (2011) Perineal care. BMJ clinical evidence 2011	- Systematic review - outcomes are not relevant Systematic review of multiple irrelevant interventions; 2 relevant studies are already included
Kopas, Mary Lou (2014) A review of evidence-based practices for management of the second stage of labor. Journal of midwifery & women's health 59(3): 264-76	- Study design not in PICO Narrative review
Kovacs, Gabor T.; Heath, Penny; Heather, Campbell (2004) First Australian trial of the birth-training device Epi-No: a highly significantly increased chance of an intact perineum. The Australian & New Zealand journal of obstetrics & gynaecology 44(4): 347-8	- Intervention not in PICO Intervention with Epi-No was antenatal
Lavesson T, Griph ID, Skärvad A et al. (2014) A perineal protection device designed to protect the perineum during labor: a multicenter randomized controlled trial. European journal of obstetrics, gynecology, and reproductive biology 181: 10-14	- Population not in PICO Included women at <37 weeks gestation
Lee, Lily; Dy, Jessica; Azzam, Hussam (2016) Management of Spontaneous Labour at Term in Healthy Women. Journal of obstetrics and gynaecology Canada : JOGC = Journal d'obstetrique et gynecologie du Canada : JOGC 38(9): 843-865	- Study design not in PICO SOCG clinical practice guideline
Low, L. K.; Miller, J. M.; Sampselle, C. (2010) Prevention of post partum urinary incontinence using perineal massage, spontaneous pushing and muscle training. Journal of Pelvic Medicine and Surgery 16(5suppl2): 70	- Study design not in PICO Conference abstract
Low, Lisa Kane, Miller, Janis M., Guo, Ying et al. (2013) Spontaneous pushing to prevent postpartum urinary incontinence: a randomized, controlled trial. International urogynecology journal 24(3): 453-60	- Intervention not in PICO Pushing techniques and prenatal perineal massage initiated in the third trimester are not in PICO
Magoga, Giulia, Saccone, Gabriele, Al-Kouatly, Huda B. et al. (2019) Warm perineal compresses during the second stage of labor for reducing perineal trauma: A meta-analysis. European Journal of Obstetrics and Gynecology and Reproductive Biology 240: 93-98	- Systematic review - studies do not meet inclusion criteria 7 included studies: 2 eligible studies were already included: Albers 2005 and Dahlen 2007;4 studies were conducted in non-OECD high income countries : Egypt, Turkey and Iran; 1 study was not available in English
Mei-dan, Elad, Walfisch, Asnat, Raz, Iris et al. (2008) Perineal massage during pregnancy: a prospective controlled trial. The Israel Medical Association journal : IMAJ 10(7): 499-502	- Intervention not in PICO Intervention was antenatal perineal massage
Most O; Menges DA; & Petrikovsky BM (2008) Effect of perineal lubrication on laceration severity and episiotomy rate. OBSTETRICS AND GYNECOLOGY 111(4): 35-36	- Study design not in PICO Conference abstract
Musgrove. H (1997) Perineal preservation and heat application during the second stage of labour. A randomized controlled trial. In	- Trial register/protocol

Study	Reason
Proceedings of Australian College of Midwives Inc 10th Biennial National Conference.: 381-395	
Nct (2008) Searching for the Perfect Oil to Protect the Perineum: a Randomized-Controlled, Double-Blind Trial. https://clinicaltrials.gov/show/NCT00662974	- Trial register/protocol
Nct (2008) Ritgens Maneuver for the Prevention of Anal Sphincter Tears at Delivery: a Randomized Controlled Trial. https://clinicaltrials.gov/show/NCT00652977	- Trial register/protocol
Nct (2012) Effect of Dianatal Obstetric Gel (Cross-linked Polyacrylic Acid) on Outcomes in Vaginal Delivery. https://clinicaltrials.gov/show/NCT01546129	- Trial register/protocol
Nct (2014) The Effect of Perineal Massage in Childbirth. https://clinicaltrials.gov/show/NCT02201615	- Trial register/protocol
Nct (2019) THE EFFECT OF PERİNEUM MASSAGE WİTH OLİVE OİL ON PERİNEUM INTEGRİTY AND DURATİON OF SECOND PERİOD OF DELİVERY. https://clinicaltrials.gov/show/NCT04157777	- Trial register/protocol
Nct (2021) Hands on vs Hands Off for Perineal Laceration. https://clinicaltrials.gov/show/NCT04860102	- Trial register/protocol
Nct (2021) Pushing and Manual Perineal Protection Techniques. https://clinicaltrials.gov/show/NCT04823598	- Trial register/protocol
Nct (2021) Impact of Thermotherapy During Childbirth on Postpartum Perineal Pain (PERISAFE). https://clinicaltrials.gov/show/NCT04778631	- Trial register/protocol
NCT05190913 (2022) Instrumental and Non-Instrumental Perineal Message and Childbirth. https://clinicaltrials.gov/show/NCT05190913	- Trial register/protocol Clinical trial - study completion December 2022
NCT05350670 (2022) Effect of Perineal Massage Combined With Cold Compress in the Second Stage on the Delivery Outcome of Primipara. https://clinicaltrials.gov/show/NCT05350670	- Trial register/protocol Clinical trial - study completion December 2024
Nusee, Z. and Jenal, R. (2018) The efficacy of Modified Viennese Manual Perineal Protection (VMPP) versus conventional technique in perineal protection at second stage of labour. International Urogynecology Journal 29(supplement1): S194-S195	- Study design not in PICO Conference abstract
O'LEARY JAM and EREZ SM (1965) Hyaluronidase as an Adjuvant to Episiotomy. The American College of Obstetricians and Gynecologists 26(1): 66-69	- Intervention not in PICO Delivered as an injection, so not considered a perineal technique
Petrocnik, Petra and Marshall, Jayne E. (2015) Hands-poised technique: The future technique for perineal management of second stage of labour? A modified systematic literature review. Midwifery 31(2): 274-279	- Systematic review - studies do not meet inclusion criteria Eligible studies already included; 3 studies were conducted in non OECD high income countries:

Study	Reason
	Brazil, Iran;1 study design was not included in PICO: prospective study
Pierce-Williams RAM; Saccone G; Berghella V (2021) Hands-on versus hands-off techniques for the prevention of perineal trauma during vaginal delivery: a systematic review and meta-analysis of randomized controlled trials. The journal of maternal-fetal & neonatal medicine : the official journal of the European Association of Perinatal Medicine, the Federation of Asia and Oceania Perinatal Societies, the International Society of Perinatal Obstetricians 34(6): 993-1001	- Systematic review - studies do not meet inclusion criteria Checked for eligible studies; Eligible studies have already been included; Studies conducted in a non-OECD high income country
Pizzagalli, F. (2020) Normal childbirth: physiologic labor support and medical procedures. Guidelines of the French National Authority for Health (HAS) with the collaboration of the French College of Gynaecologists and Obstetricians (CNGOF) and the French College of Midwives (CNSF) - Maternal postures during the second stage of labour, delivery techniques and perineal protection. Gynecologie Obstetrique Fertilite et Senologie 48(12): 931-943	- Not available in English
Poulsen, Mette Ostergaard, Madsen, Mia Lund, Skriver-Moller, Anne-Cathrine et al. (2015) Does the Finnish intervention prevent obstetric anal sphincter injuries? A systematic review of the literature. BMJ open 5(9): e008346	- Systematic review - studies do not meet inclusion criteria The designs of the included studies did not meet PICO: before and after studies or register studies
Rezaei Habib, Abadi Z.; Granmayeh, M.; Mazaheripour, Z. (2011) Effect of perineal massage on dimensions of episiotomy. Iranian Journal of Reproductive Medicine 9(suppl1): 28	- Not available in English
Rezaei, Habib Abadi Z.; Khakbazan, Z.; Geranmayeh, M. (2010) Outcomes of perineal massage during childbirth. Iranian Journal of Reproductive Medicine 8(suppl1): 126	- Not available in English
Rezai, R., Saatsaz, S., Sharifnia, S. H. et al. (2014) Comparison of perineal protection using "hands on" and "hands off" techniques on perineal laceration during labour. Journal of mazandaran university of medical sciences 24(114): 52-59	- Not available in English
Romano, Amy M. (2008) Research summaries for normal birth. The Journal of perinatal education 17(1): 48-52	- Study design not in PICO Conference abstract
Romina, Samira, Ramezani, Faeze, Falah, Neda et al. (2020) Effect of Perineal Massage with Ostrich Oil on the Episiotomy and Lacerations in Nulliparous Women: A Randomized Controlled Clinical Trial. Iranian journal of nursing and midwifery research 25(2): 134-138	- Study conducted in a low- or middle-income country Iran is not an OECD high income country - Intervention not in PICO The intervention was performed in both the first and second stage of labour

Study	Reason
Ruckhaberle, Eugen, Jundt, Katharina, Bauerle, Martin et al. (2009) Prospective randomised multicentre trial with the birth trainer EPI-NO for the prevention of perineal trauma. The Australian & New Zealand journal of obstetrics & gynaecology 49(5): 478-83	- Intervention not in PICO Intervention with EPI-NO was antenatal
Sagi-Dain, L., Bahous, R., Caspin, O. et al. (2017) No episiotomy versus selective lateral/mediolateral episiotomy (EPITRIAL): an interim analysis. International urogynecology journal: 1-9	- Intervention not in PICO Intervention was standard care vs. no episiotomy
Sagi-Dain, Lena, Bahous, Rabia, Caspin, Orna et al. (2018) No episiotomy versus selective lateral/mediolateral episiotomy (EPITRIAL): an interim analysis. International urogynecology journal 29(3): 415-423	- Intervention not in PICO Intervention was standard care vs. no episiotomy
Schaub, Andreas F., Litschgi, Mario, Hoesli, Irene et al. (2008) Obstetric gel shortens second stage of labor and prevents perineal trauma in nulliparous women: a randomized controlled trial on labor facilitation. Journal of perinatal medicine 36(2): 129-35	- Intervention not in PICO The intervention was performed in both the first and second stage of labour
Schreiner, Lucas, Crivelatti, Isabel, de Oliveira, Julia M. et al. (2018) Systematic review of pelvic floor interventions during pregnancy. International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics 143(1): 10-18	- Systematic review - studies do not meet inclusion criteria The interventions used in the included studies were carried out during pregnancy
Shahoei, Roonak, Zaheri, Farzaneh, Nasab, Lila Hashemi et al. (2017) The effect of perineal massage during the second stage of birth on nulliparous women perineal: A randomization clinical trial. Electronic physician 9(10): 5588-5595	- Study conducted in a low- or middle-income country Iran is not an OECD high income country
Smith LA, Price N, Simonite V et al. (2013) Incidence of and risk factors for perineal trauma: a prospective observational study. BMC pregnancy and childbirth 13: 59	- Study design not in PICO Observational study
Terre, C., Beneit, J. V., Gol, R. et al. (2014) Application of thermotherapy i. Matronas profesion 15(4): 122-129	- Not available in English
Wang, Haiying; Jayasekara, Rasika; Warland, Jane (2015) The effect of "hands on" techniques on obstetric perineal laceration: A structured review of the literature. Women and birth : journal of the Australian College of Midwives 28(3): 194-8	- Study design not in PICO Narrative review
Wickham, Sara (2007) Research unwrapped: Preventing perineal damage in childbirth. Practising Midwife 10(2): 37-39	- Trial register/protocol
Wilson AN and Homer CSE (2020) Third- and fourth-degree tears: A review of the current evidence for prevention and management. The Australian & New Zealand journal of obstetrics & gynaecology 60(2): 175-182	- Study design not in PICO Narrative review

Study	Reason
Wilson, Alyce N. and Homer, Caroline S. E. (2020) Third- and fourth-degree tears: A review of the current evidence for prevention and management. Australian and New Zealand Journal of Obstetrics and Gynaecology 60(2): 175-182	- Study design not in PICO Narrative review
Zang, Yu; Hu, Yinchu; Lu, Hong (2022) Effects of different techniques during the second stage of labour on reducing perineal laceration: An overview of systematic reviews. Journal of clinical nursing	- Systematic review - studies do not meet inclusion criteria Checked for eligible studies; Studies were from a non-OECD high income country
Zhou, Fan, Wang, Xiao Dong, Huang, Gui Qiong et al. (2014) Hyaluronidase for reducing perineal trauma. Cochrane Database of Systematic Reviews 2014(2): cd010441	- Systematic review - studies do not meet inclusion criteria 2 studies from non-OECD high income country – Brazil; 2 studies the intervention was an injection which was not considered a perineal technique

Excluded economic studies

No economic evidence was identified for this review.

Appendix K Research recommendations – full details

Research recommendations for review question: What is the effectiveness of perineal care in the second stage of labour (for example, massage, hands-on support and warm compresses) for reducing perineal trauma and tears?

K.1.1 Research recommendation

What is the effectiveness of hands on, hands poised and Finnish grip in the second stage of labour for reducing perineal trauma and postnatal pain?

K.1.2 Why this is important

There are different techniques used in clinical practice to protect the perineum during birth, however the evidence to support the use of one over another is limited. Appropriate perineal care during the second stage of labour can help prevent long term adverse outcomes, including urinary incontinence and pain, which have detrimental effects in women's quality of life and can be costly for the healthcare system. More research in the area is needed to determine if there is any difference between the techniques being used and to assess the long-term outcomes of these.

K.1.3 Rationale for research recommendation

Table 15: Research recommendation rationale

Importance to 'patients' or the population	Little is known about the long-term risks associated with hands on, hands poised and Finnish grip used to protect the perineum during the second stage of labour, and there is significant variation in practice.
Relevance to NICE guidance	Only 1 small randomised controlled trial on hands on and hands poised was published since the 2007 update of the guideline, so the committee were unable to recommend one technique over another. There is no evidence on Finnish grip, however this is being used in clinical practice as part of the OASI care bundle and there is a lack of data on long-term benefits or risks.
Relevance to the NHS	Using the most effective technique to protect the perineum during the second stage of labour can help prevent long term adverse events, including urinary incontinence and pain, which pose a significant burden to the NHS.
National priorities	High
Current evidence base	Minimal long-term data
Equality considerations	None known

K.1.4 Modified PICO table

Table 16: Research recommendation modified PICO table

Population	• Women in the second stage of labour who are pregnant with a single baby, who go into labour at term (37 to 42 weeks of pregnancy) and who do not have any pre-existing medical

	conditions or antenatal conditions that predispose to a higher risk birth • Women in the second stage of labour whose baby has not been identified before labour to be at high risk of adverse outcome • Singleton babies born at term (37 to 42 weeks of pregnancy) with no previously identified problems (for example congenital malformations, genetic anomalies, intrauterine growth restriction, placental problems)
Intervention	• Hands on • Hands poised • Finnish grip
Comparator	• One perineal technique listed in the intervention against other
Outcome	• Episiotomy • First-degree perineal tears • Second-degree perineal tears • Third- and fourth-degree perineal tears • Urinary incontinence in the first year after birth • Perineal pain postpartum • Women's experience of labour and birth
Study design	Randomised controlled trial
Timeframe	Long term (minimum 1 year follow-up)
Additional information	Consider sub-group analysis by ethnicity and BMI