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Selective versus routine use of episiotomy for vaginal birth (Review)

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[Intervention Review]

Selective versus routine use of episiotomy for vaginal birth

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ABSTRACT

Background

Some clinicians believe that routine episiotomy, a surgical cut of the vagina and perineum, will prevent serious tears during childbirth. On the other hand, an episiotomy guarantees perineal trauma and sutures.

Objectives

To assess the effects on mother and baby of a policy of selective episiotomy ('only if needed') compared with a policy of routine episiotomy ('part of routine management') for vaginal births.

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register (14 September 2016) and reference lists of retrieved studies.

Selection criteria

Randomised controlled trials (RCTs) comparing selective versus routine use of episiotomy, irrespective of parity, setting or surgical type of episiotomy. We included trials where either unassisted or assisted vaginal births were intended. Quasi-RCTs, trials using a cross-over design or those published in abstract form only were not eligible for inclusion in this review.

Data collection and analysis

Two authors independently screened studies, extracted data, and assessed risk of bias. A third author mediated where there was no clear consensus. We observed good practice for data analysis and interpretation where trialists were review authors. We used fixed-effect models unless heterogeneity precluded this, expressed results as risk ratios (RR) and 95% confidence intervals (CI), and assessed the certainty of the evidence using GRADE.

Selective versus routine use of episiotomy for vaginal birth (Review)

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Main results

This updated review includes 12 studies (6177 women), 11 in women in labour for whom a vaginal birth was intended, and one in women where an assisted birth was anticipated. Two were trials each with more than 1000 women (Argentina and the UK), and the rest were smaller (from Canada, Germany, Spain, Ireland, Malaysia, Pakistan, Columbia and Saudi Arabia). Eight trials included primiparous women only, and four trials were in both primiparous and multiparous women. For risk of bias, allocation was adequately concealed and reported in nine trials; sequence generation random and adequately reported in three trials; blinding of outcomes adequate and reported in one trial, blinding of participants and personnel reported in one trial.

For women where an unassisted vaginal birth was anticipated, a policy of selective episiotomy may result in 30% fewer women experiencing **severe perineal/vaginal trauma** (RR 0.70, 95% CI 0.52 to 0.94; 5375 women; eight RCTs; low-certainty evidence). We do not know if there is a difference for **blood loss at delivery** (an average of 27 mL less with selective episiotomy, 95% CI from 75 mL less to 20 mL more; two trials, 336 women, very low-certainty evidence). Both selective and routine episiotomy have little or no effect on infants with **Apgar score less than seven at five minutes** (four trials, no events; 3908 women, moderate-certainty evidence); and there may be little or no difference in **perineal infection** (RR 0.90, 95% CI 0.45 to 1.82, three trials, 1467 participants, low-certainty evidence).

For pain, we do not know if selective episiotomy compared with routine results in fewer women with **moderate or severe perineal pain** (measured on a visual analogue scale) at three days postpartum (RR 0.71, 95% CI 0.48 to 1.05, one trial, 165 participants, very low-certainty evidence). There is probably little or no difference for **long-term (six months or more) dyspareunia** (RR 1.14, 95% CI 0.84 to 1.53, three trials, 1107 participants, moderate-certainty evidence); and there may be little or no difference for **long-term (six months or more) urinary incontinence** (average RR 0.98, 95% CI 0.67 to 1.44, three trials, 1107 participants, low-certainty evidence). One trial reported **genital prolapse** at three years postpartum. There was no clear difference between the two groups (RR 0.30, 95% CI 0.06 to 1.41; 365 women; one trial, low certainty evidence). Other outcomes relating to **long-term effects** were not reported (urinary fistula, rectal fistula, and faecal incontinence). Subgroup analyses by parity (primiparae versus multiparae) and by surgical method (midline versus mediolateral episiotomy) did not identify any modifying effects. Pain was not well assessed, and women's preferences were not reported.

One trial examined selective episiotomy compared with routine episiotomy in women where an operative vaginal delivery was intended in 175 women, and did not show clear difference on severe perineal trauma between the restrictive and routine use of episiotomy, but the analysis was underpowered.

Authors' conclusions

In women where no instrumental delivery is intended, selective episiotomy policies result in fewer women with severe perineal/vaginal trauma. Other findings, both in the short or long term, provide no clear evidence that selective episiotomy policies results in harm to mother or baby.

The review thus demonstrates that believing that routine episiotomy reduces perineal/vaginal trauma is not justified by current evidence. Further research in women where instrumental delivery is intended may help clarify if routine episiotomy is useful in this particular group. These trials should use better, standardised outcome assessment methods.

PLAIN LANGUAGE SUMMARY

Selective versus routine use of episiotomy for vaginal birth

What is the issue?

Normal birth can cause tears to the vagina and the surrounding tissue, usually as the baby's head is born, and sometimes these tears extend to the rectum. These are repaired surgically, but take time to heal. To avoid these severe tears, doctors have recommended making a surgical cut to the perineum with scissors or scalpel to prevent severe tearing and facilitate the birth. This intervention, known as an episiotomy, is used as a routine care policy during births in some countries. Both a tear and an episiotomy need sutures, and can result in severe pain, bleeding, infection, pain with sex, and can contribute to long term urinary incontinence.

Why is this important?

An episiotomy requires suturing and benefits and harms as part of routine management of normal births remains unclear. In particular, we need to know if it does indeed prevent large tears, because women otherwise may be subjected to an unnecessary operation, pain and

in some cases long-term problems. The question of whether to apply a policy of routine episiotomy is important for clinical practice and for the health and well-being of women and babies.

What evidence did we find?

We prepared this edition of this review by updating the methods and searching for evidence from the medical literature on 14 September 2016. The review now includes 11 randomised controlled trials (with 5977 women) that compared episiotomy as needed (selective episiotomy) with routine episiotomy in terms of benefits and harms for mother and baby in women at low risk of instrumental delivery.

The trials were from ten different countries. In women where health staff were only conducting selective episiotomy, there may be 30% fewer with severe perineal trauma at birth compared with women where a policy of routine episiotomy was applied (eight trials, 5375 women, low-certainty evidence). We do not know if there is a difference in average blood loss between the groups (two trials, very low-certainty evidence). There is probably no difference in Apgar less than seven at five minutes, with no events in either groups (moderate-certainty evidence). We do not know if there is a difference in the number of women with moderate or severe perineal pain three days after giving birth (one trial, 165 women, very low-certainty evidence) but careful assessment of women's pain was not well carried out in the included trials. There may be little or no difference in the number of women developing perineal infection (two trials, low-certainty evidence); and there is probably little or no difference in women reporting painful sexual intercourse six months or more after delivery (three trials, 1107 women, moderate-certainty evidence); for urinary incontinence six months or more after delivery, there may be little or no difference between the groups. One study reported genital prolapse three years after the birth and there was no clear difference between groups (low-certainty evidence). Other important outcomes relating to long-term effects were not reported in these trials (urinary fistula, rectal fistula, and faecal incontinence).

One trial examined selective episiotomy compared with routine episiotomy in women for whom an operative vaginal birth was intended. The results showed no clear difference in severe perineal trauma between the restrictive and routine use of episiotomy.

Women's views on the different policies were not reported.

What does this mean?

Overall, the findings show that selective use of episiotomy in women (where a normal delivery without forceps is anticipated) means that fewer women have severe perineal trauma. Thus the rationale for conducting routine episiotomies to prevent severe perineal trauma is not justified by current evidence, and we could not identify any benefits of routine episiotomy for the baby or the mother.

More research is needed in order to inform policy in women where an instrumental birth is planned and episiotomy is often advocated. Outcomes could be better standardised and measured.

SUMMARY OF FINDINGS FOR THE MAIN COMPARISON *[Explanation]*

Selective versus routine episiotomy: all vaginal births where operative vaginal delivery was not anticipated

Patient or population: Women in labour where operative delivery was not anticipated. (Women were above 16 years old and between 28 gestational weeks and full term, with a live singleton fetus, without severe medical or psychiatric conditions, and had vaginal birth.)

Setting: Hospitals in high-, middle- and low-income countries. (Studies were carried out between July 1982 and October 2009, in Argentina, Canada, Columbia, Germany, Ireland, Malaysia, Pakistan, Saudi Arabia, Spain, and the UK. Five studies were carried out in university teaching hospitals, and one of these five studies recruited some participants from a mid-complexity level hospital. The other six studies were conducted in maternity units with inadequate information to judge the institution's level.)

Intervention: Selective episiotomy (episiotomy rates in the selective group ranged from 8% to 59%)

Comparison: Routine episiotomy (episiotomy rates in the routine group ranged from 61% to 100%; episiotomy rate differences between the groups within trials varied from 21% to 91%)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	No. of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with routine episiotomy	Risk with selective episiotomy				
Severe perineal/vaginal trauma	3.6 per 100	2.5 per 100 (1.9 to 3.4)	RR 0.70 (0.52 to 0.94)	5375 (8 RCTs)	⊕⊕○○ low ^{1,2,3} due to imprecision and inconsistency	Selective episiotomy compared to routine may reduce severe perineal/vaginal trauma
Blood loss at delivery	The mean blood loss at delivery was 278 mL	27 mL less (95%CI from 75 mL less to 20 mL more)		336 (2 RCTs)	⊕○○○ very low ^{4,5,6} due to risk of bias, imprecision and inconsistency	We do not know if selective episiotomy compared to routine affects blood loss at delivery
Babies with newborn Apgar score < 7 at 5 minutes	0 per 100	0 per 100	no events	501 (2 RCTs)	⊕⊕⊕○ moderate ^{7,8} Due to imprecision	Both selective episiotomy and routine probably has little or no effect on Apgar < 7 at 5 minutes

Perineal infection	2 per 100	2 per 100 (0.9 to 3.6)	RR 0.90 (0.45 to 1.82)	1467 (3 RCTs)	⊕⊕○○ low ⁹ Due to imprecision	Selective episiotomy compared to routine may result in little or no difference in perineal infection
Women with moderate or severe pain (measured by visual analogue scale)	45.1 per 100	32 per 100 (21.6 to 47.3)	RR 0.71 (0.48 to 1.05)	165 (1 RCT)	⊕○○○ very low ^{10,11,12} Due to imprecision and indirectness	We do not know if selective episiotomy compared to routine results in fewer women with moderate or severe perineal pain
Women with long-term dyspareunia (≥ 6 months)	12.9 per 100	14.8 per 100 (10.9 to 19.8)	RR 1.14 (0.84 to 1.53)	1107 (3 RCTs)	⊕⊕⊕○ moderate ¹³ Due to imprecision	Selective episiotomy compared to routine probably results in little or no difference in women with dyspareunia at > 6 months
Women with long-term urinary incontinence (≥ 6 months)	32.2 per 100	31 per 100 (21.5 to 46.3)	RR 0.98 (0.67 to 1.44)	1107 (3 RCTs)	⊕⊕○○ low ^{13,14} Due to risk of bias and imprecision	Selective episiotomy compared to routine results may have little or no difference in the number of women with urinary incontinence > 6 months

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

CI: Confidence interval; **RR:** Risk ratio

GRADE Working Group grades of evidence

High quality: We are very confident that the true effect lies close to that of the estimate of the effect

Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different

Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect

Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

¹Downgraded by 1 for imprecision: confidence intervals range from no important difference to large difference.

²Downgraded by 1 for heterogeneity: there is moderate heterogeneity. Random-effects model gives confidence intervals that cross 1 (RR 0.67, 95% CI 0.41 to 1.09). However, a subgroup analysis shows that the selective episiotomy has been well implemented (episiotomy rate difference between intervention and control > 30%) there was a more substantial effect (RR 0.55, 95% CI 0.38 to 0.81; 8 trials; n = 4877).

³Funnel plot suggests publication bias with small studies showing that routine episiotomy results in higher perineal trauma.

⁴Downgraded by 1 for risk of bias: both studies used visual inspection with no specific training, but visual EBL consistently results in underestimation of large volumes and over estimation of large volumes.

⁵Downgraded by 1 for imprecision: confidence intervals range from no important average loss to an important average loss

⁶Downgraded by 1 for inconsistency: large, probably clinically important effect in 1 trial and no effect evident in the other trial

⁷Downgraded by 1 for imprecision as there were no events. Risk difference 0.0 (-0.01 to 0.01). The risk difference provides confidence intervals indicating we are confident in there being little or no difference, although for rare but important events a larger sample size is required.

⁸Apgar < 7 at 1 minute was measured in 4 trials, with RR 1.04 (95% CI 0.76 to 1.43), with no detectable heterogeneity.

⁹Downgraded by 2 for imprecision: few events, and CI included appreciable benefit and harm. (The analysis is under-powered to detect a difference between groups; the sample size required to half 2% infection rate in the control group to 1% in the intervention group with 90% power at 5% significance would be 6202)

¹⁰Downgraded by 2 for imprecision: sample size to lower the 30% pain in the selective episiotomy compared to routine would need a total size of 586 with 90% power at 5% significance level, and wide confidence intervals from substantively fewer to no fewer

¹¹Downgraded by 1 for indirectness: only one trial conducted 32 years ago. Conditions, expectations, and pain relief strategies have changed, and we don't know how representative this trial is.

¹²Additional trials report on average pain scores in the first 5 days, in a total of 355 women. Pain scores in all 3 trials were similar between the 2 groups (additional table 5).

¹³Downgraded by 1 for imprecision: confidence intervals have a wide range.

¹⁴Downgraded by 1 for risk of bias: 3 trials included, 2 trials, 1 with small sample size and 1 with large sample size had high rate of loss to follow-up, around 35%, 1 trial with large sample size had low loss to follow-up, less than 10%.

BACKGROUND

Vaginal birth can cause tears to the vagina and perineum. Estimates of the frequency vary, with some estimates (that include episiotomy) indicating this occurs in 85% of births (Kettle 2008), compared with a more recent retrospective cohort reporting that 4% of 1785 Australian women sustained a perineal scrape and 34% sustained a first- or second-degree perineal tear (Catling-Paull 2013). While minor tears may heal quickly without intervention, some are more severe, damaging tissue, muscle and sometimes extending to the anal sphincter. These more severe tears need surgical repair, and depending on the extent, may cause a number of problems in the early postnatal period. Women may experience pain, bleeding, infection, dyspareunia (pain during sexual intercourse), and have a prolonged hospital stay. In a small percentage of women, the damage to the vaginal and perineal tissues can result in some long-term problems such as pain, urinary fistula (an abnormal connection between vagina and bladder), urinary incontinence (the inability of control causing urinary 'accidents'), rectal fistula (an abnormal connection between the vagina and rectum), faecal incontinence (the inability of control causing faecal 'accidents'), dyspareunia and genital-urinary prolapse (the pelvic organs descending from their normal position) (Kettle 2008).

Tears of the perineum and vagina are classified as follows (Fernando 2006):

- first degree: involving the fourchette, perineal skin and vaginal mucous membrane, but not the underlying fascia and muscle;
- second degree: involving the perineal muscles and skin;
- third degree: injury to the anal sphincter complex;
 - 3a: less than 50% of the external anal sphincter torn;
 - 3b: 50% of the external anal sphincter torn; and
 - 3c: injury to the external and internal anal sphincter;
- fourth degree: injury extends through the anal sphincter complex to anal epithelium.

Severe perineal trauma usually refers to a third-degree or fourth-degree tear (Priddis 2013; RCOG 2007).

Episiotomy, a surgical cut of the vagina and perineum, is sometimes used in an attempt to prevent serious perineal damage caused by tearing and to facilitate the birth of the baby.

Description of the intervention

Episiotomy is a surgical incision of the vagina and perineum carried out by a skilled birth attendant to enlarge the vaginal opening (FIGO 2012). The first documented episiotomy dates back

to over 270 years ago (Ould 1741). Rates of episiotomy increased substantially during the first half of the 20th century. At that time, there was an increasing move for women to give birth in a hospital and for physicians to manage normal uncomplicated childbirths. Since then, episiotomy has become one of the most commonly performed surgical procedures in the world (Graham 1997). Reported rates of episiotomies vary from as low as 9.7% (Sweden) to as high as 100% (Taiwan) (Graham 2005). The large differences in episiotomy rates closely relate to the differences in policies regarding the use of episiotomy. Episiotomy rates are high in some countries, such as Argentina and China, with a policy of routine use of episiotomy for nearly all first births (Lede 1991; Qian 2001). Other places adopt a policy of 'selective' use of episiotomy where the use of episiotomy is restricted rather than universally performed - clinicians use their clinical judgement to determine the need for episiotomy where the benefits likely outweigh the harms in situations such as impending severe perineal tear, prolonged second stage of labour, shoulder dystocia, instrumental delivery, and non-reassuring fetal heart rate (ACOG 2006; Melo 2014). In the USA, the episiotomy rate decreased from 60.9% in 1979 to 24.5% in 2004 (Frankman 2009). In Finland, the episiotomy rate decreased from 71.5% to 54.9% between 1997 to 1999 and 2006 to 2007 among primiparous women, and from 21.5% to 9.2% between 1997 to 2001 and 2006 to 2007 among multiparous women (Räisänen 2011).

Episiotomy is made with scissors or scalpel and requires repair by suturing (Thacker 1983). There are seven ways of performing an episiotomy, with 'midline' and 'mediolateral' being the two main types of episiotomy in the literature and medical practice (Kalis 2012). A midline (sometimes called 'median') episiotomy is "a vertical incision from the posterior fourchette and runs along the midline through the central tendon of the perineal body" (Kalis 2012). Critics point out that if a midline episiotomy extends, it is likely to extend into the anal sphincter causing a third- or fourth-degree tear. A mediolateral episiotomy is "an incision beginning in the midline and directed laterally and downwards away from the rectum" (Kalis 2012). In theory, if a mediolateral tear extends, it will extend away from the anal sphincter. An episiotomy is generally done late in second stage when the perineum is stretched thin. Prior to the incision, local anaesthesia is injected to numb the perineum, if a mother does not have regional anaesthesia (ACOG 2006).

How the intervention might work

It is thought that enlarging the vaginal outlet by episiotomy would reduce vaginal soft tissue stretching and tension during childbirth, thereby preventing higher degrees of perineal traumas and their subsequent complications (Cunningham 1993; Ould 1741; Thacker 1983). More space also allows for instrumentation of assisted deliveries by forceps or vacuums (Cargill 2004; Murphy 2008a). At other times, episiotomy is performed to shorten sec-

ond stage of labour for various maternal and fetal indications (Hamilton 1861; Hartmann 2005) such as maternal exhaustion and fetal bradycardia.

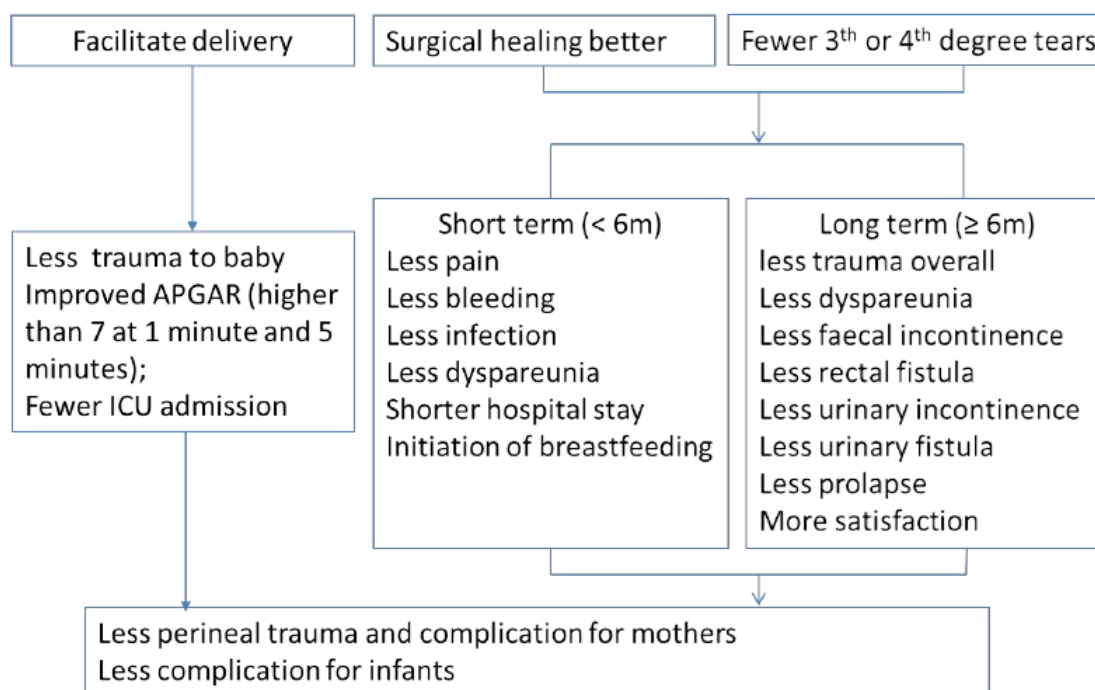
Clinicians who advocate routine episiotomies reason that perineal tears, including severe tears, can occur in women who are not thought likely to have serious tears and who have not had an episiotomy under a selective regimen. However, the effectiveness of routine episiotomy preventing severe perineal trauma has been questioned and the procedure has its own associated complications. Since not all vaginal births result in perineal trauma, some women are subjected to unnecessary incisions and their associated complications and morbidity as a result of a 'routine' episiotomy policy. Even in obstetrical emergencies such as shoulder dystocia, and in instrumental-assisted deliveries, episiotomy may not reduce severe perineal tears (Steiner 2012). Complications associated with episiotomy include bleeding, pain and discomfort of the wound and sutures (which may cause pain while sitting, and in turn affect breastfeeding), wound scarring, dyspareunia, or complications in subsequent vaginal births. Other adverse effects of episiotomy include: (a) extension of episiotomy through the anal sphincter and rectum by the clinician making the incision, or by spontaneous extension of the incision; (b) unsatisfactory anatomic

healing resulting in skin tags, asymmetry or excessive narrowing of the introitus, vaginal prolapse, recto-vaginal fistula and fistula-in-ano (Homsy 1994); (c) increased blood loss and hematoma; (d) pain and oedema around the episiotomy wound; (e) infection and dehiscence (Homsy 1994); (f) dyspareunia, which may be a short-term consequence, or may become more established and cause persistent dyspareunia (Garner 1982); and finally, (h) at least one woman has died as a result of infection complicating an episiotomy wound (Lynch 1997).

Why it is important to do this review

Given the wide use of episiotomy globally and questions on its benefits and harms, it is important to provide solid evidence to inform the appropriate clinical practice and to ensure the well-being of women and their infants. This review aims to evaluate the evidence of selective versus routine use of episiotomy. To help our thinking on this, we developed a diagram to summarise the rationale commonly used to justify routine episiotomy (Figure 1). We used the outcomes identified in this diagram to evaluate research evidence of whether this rationale is justified.

Figure 1. The rationale commonly used to justify routine episiotomy



OBJECTIVES

To assess the effects on mother and baby of a policy of selective episiotomy ('only if needed') compared with a policy of routine episiotomy ('part of routine management') for vaginal births.

METHODS

Criteria for considering studies for this review

Types of studies

Randomised controlled trials (RCT). Cluster-RCTs would have been eligible for inclusion in this review but none were identified. Quasi-RCTs, trials using a cross-over design or those published in abstract form only were not eligible for inclusion in this review. We included trials where spontaneous or instrumental vaginal births were intended.

Types of participants

Pregnant women having normal or assisted vaginal births.

Types of interventions

We compared a policy of performing episiotomy only if needed ('selective', intervention group) with routine episiotomy (control group).

Types of outcome measures

Main outcomes

- Severe perineal/vaginal trauma. This was perineal trauma, with or without severe vaginal trauma, and included third- or fourth-degree trauma
 - Blood loss at delivery
 - Newborn Apgar score less than seven at five minutes
 - Perineal infection
 - Moderate or severe pain (assessed using a standardised quantitative scale, such as 'visual analogue scale')
 - Long-term dyspareunia (defined as dyspareunia at least six months after delivery)
 - Long-term effects (defined as trauma at least six months after delivery, including urinary fistula, urinary incontinence, genital prolapse, rectal fistula, faecal incontinence and genital prolapse)

Other outcomes

- Need for perineal suturing (excluding episiotomy repair)
- Admission to special care baby unit
- Days in hospital after birth
- Breastfeeding (initiation of breastfeeding, exclusive breastfeeding on discharge from hospital)
- Satisfaction (assessed using a standardised scale)

Search methods for identification of studies

The following methods section of this review was based on a standard template used by Cochrane Pregnancy and Childbirth.

Electronic searches

We searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (14 September 2016). The Register is a database containing over 22,000 reports of controlled trials in the field of pregnancy and childbirth. For full search methods used to populate Pregnancy and Childbirth's Trials Register, including the detailed search strategies for CENTRAL, MEDLINE, Embase and CINAHL; the list of handsearched journals and conference proceedings, and the list of journals reviewed via the current awareness service, please follow this link to the editorial information about the [Cochrane Pregnancy and Childbirth](#) in the Cochrane Library and select the 'Specialized Register' section from the options on the left side of the screen.

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

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

Search results are screened by two people and the full text of all relevant trial reports identified through the searching activities described above is reviewed. Based on the intervention described, each trial report is assigned a number that corresponds to a specific Pregnancy and Childbirth review topic (or topics), and is then added to the Register. The Information Specialist searches the Register for each review using this topic number rather than keywords. This results in a more specific search set which has been fully accounted for in the relevant review sections ([Included studies](#); [Excluded studies](#); [Ongoing studies](#)).

Searching other resources

We searched the reference lists of retrieved studies. We did not apply any language or date restrictions.

Data collection and analysis

This extensively updated version of the review is based on an updated protocol, revised outcomes and use of new Cochrane methods, including risk of bias assessment and GRADE. All previously included trials had the inclusion criteria, assessment of risk of bias, and data re-extracted.

Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. The inclusion criteria for studies in the final analysis included: the study was an RCT; it compared selective with routine episiotomy; and was full text. We resolved any disagreement through discussion or, if required, we consulted with the other experienced review authors in the team.

We created a study flow diagram to map out the number of records identified, included and excluded (Liberati 2009).

Data extraction and management

We designed a form to extract data. For eligible studies, (Hong Jiang, Xu Qian) review authors extracted the data using the agreed form. We resolved discrepancies through discussion or, in some conditions, we consulted Paul Garner (PG) and Guillermo Carroli (GC). We entered data into Review Manager 5 (RevMan 5) software (RevMan 2014) and checked them for accuracy.

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

In the description of studies we were aware that the degree of trauma was classified differently between studies, and in some might not be well defined. We reassessed the appropriateness of the categories based on the standard 'degree scale' and mapped the trial outcomes on to these categories.

We described length of follow-up for all our pre-specified outcomes. These data are presented in the [Characteristics of included studies](#) tables. However, in our results we only reported on longer-term outcomes as specified in the protocol.

For patient-reported outcomes, we recorded the method used, whether the questionnaire was by interview or self-completed. For pain we sought for exact words used by the researchers to evaluate the degree of pain by functional impairment wherever possible.

GC was the principal investigator on a large trial included in this review. Risk of bias assessment and data extraction were carried out by authors independent of GC. PG provided oversight on data

extraction from this trial and on interpretation of its findings on account of this potential conflict of interest.

Assessment of risk of bias in included studies

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

(1) Random sequence generation

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

- low risk of bias (any truly random process, for example, random number table; computer random number generator);
- high risk of bias (any non-random process, for example, odd or even date of birth; hospital or clinic record number);
- unclear risk of bias.

(2) Allocation concealment

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

- low risk of bias (for example, telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes. We assessed the methods as:

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

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

We described for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed methods used to blind outcome assessment as:

- low, high or unclear risk of bias.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data)

We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes.

We assessed methods as:

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

(5) Selective reporting (checking for reporting bias)

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

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

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

We described for each included study any important concerns we have about other possible sources of bias. We assessed whether each study was free of other problems that could put it at risk of bias:

- low risk of other bias;
- high risk of other bias;
- unclear whether there was risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). With reference to the above points, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Assessment of the certainty of the evidence using the GRADE approach

We used GRADE to assess the evidence for our main comparison of selective versus routine episiotomy. We assessed the following outcomes for the certainty of the evidence using the GRADE approach (Guyatt 2008; GRADE Working Group 2009).

- Severe perineal/vaginal trauma. This was perineal trauma, with or without severe vaginal trauma, and included third- or fourth-degree trauma
 - Blood loss at delivery
 - Newborn Apgar score less than seven at five minutes
 - Perineal infection
 - Moderate or severe pain (assessed using a standardised quantitative scale, such as a 'visual analogue scale')
 - Long-term dyspareunia (defined as dyspareunia at least six months after delivery)
 - Long-term effects (defined as of trauma at least six months after delivery, including: urinary fistula, urinary incontinence, genital prolapse, rectal fistula, and faecal incontinence)*

(*In order to confine the number of outcomes in [Summary of findings for the main comparison](#) to seven (the maximum recommended) we asked midwives to prioritise long-term effects outcomes. In the table we have set out findings for urinary incontinence; where reported, for other long-term effects we graded the certainty of the evidence and have presented findings in the text.) We used the [GRADEpro](#) Guideline Development Tool to import data from RevMan 5 (RevMan 2014) in order to create 'Summary of findings' tables. We produced a summary of the intervention effect and a measure of the certainty of the evidence for each of the above outcomes using the GRADE approach (Guyatt 2008; GRADE Working Group 2009). The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the quality of the body of evidence for each outcome. The evidence was downgraded from 'high' by one level for serious (or by two levels for very serious) limitations, depending on assessments for risk of bias, indirectness of evidence, serious inconsistency, imprecision of effect estimates or potential publication bias.

Measures of treatment effect

Dichotomous data

For dichotomous data, we presented results as summary risk ratio (RR) with 95% confidence intervals (CI).

Continuous data

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

Unit of analysis issues

Cluster-randomised trials

We did not identify any cluster-randomised trials for inclusion in this review. In future updates, if we identify any such trials for inclusion we will utilise appropriate methods as per the *Cochrane Handbook for Systematic Reviews of Interventions*.

Studies with more than two treatment arms

None of the included studies had more than two treatment arms. In future updates, if we identify any studies for inclusion with more than two treatment arms we will utilise appropriate methods as per the *Cochrane Handbook for Systematic Reviews of Interventions*.

Dealing with missing data

For included studies, we documented levels of attrition. We explored the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis. For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, that is, we attempted to include all participants randomised to each group in the analyses, and all participants were analysed in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial was the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the T^2 , I^2 (Higgins 2003) and Chi^2 statistics. We regarded heterogeneity as moderate if I^2 was greater than 30% and either T^2 was greater than zero, or there was a low P value (less than 0.05) in the Chi^2 test for heterogeneity; and substantial if I^2 was greater than 50%.

Assessment of reporting biases

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

Data synthesis

We reported adherence to the allocated groups and recorded episiotomy rates in both groups. We conducted analysis by intention to treat. We carried out statistical analysis using the RevMan 5 software (RevMan 2014). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying intervention effect: that is, where trials were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected (greater than 50%), we used both fixed-effect and random-effects meta-analysis to produce an overall summary of an average treatment effect. The random-effects summary was treated as the average of the range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful we did not combine trials. If we used random-effects analyses, the result was presented as the average treatment effect with 95% confidence intervals, and the estimates of T^2 and I^2 .

We used GRADE to assess the certainty of the evidence for all the main outcomes.

Subgroup analysis and investigation of heterogeneity

Where we identified substantial heterogeneity, we used subgroup analyses and sensitivity analyses. We also considered whether an overall summary was meaningful, and if it was, we used random-effects analysis to produce it.

We conducted the main analysis around studies where instrumental birth was not anticipated. There was one trial where instrumental birth was anticipated, and this was included as a separate comparison, as it is a different clinical group, and the outcomes may be different; furthermore there are additional trials being carried out in this area suggesting some degree of clinical equipoise and a clearly defined separate clinical question.

Irrespective of the absence or presence of heterogeneity, we carried out a subgroup analysis by parity (primiparous and multiparous) and type of episiotomy (midline and mediolateral).

We assessed subgroup differences by interaction tests available within RevMan 5 (RevMan 2014). We reported the results of subgroup analyses quoting the Chi^2 statistic and P value, and the interaction test I^2 value, if there were sufficient data to make these analyses valid.

Sensitivity analysis

We conducted sensitivity analyses based on the risk of bias in studies for the primary outcomes (third and fourth degree trauma) in relation to two criteria; allocation concealment and completeness of outcome data.

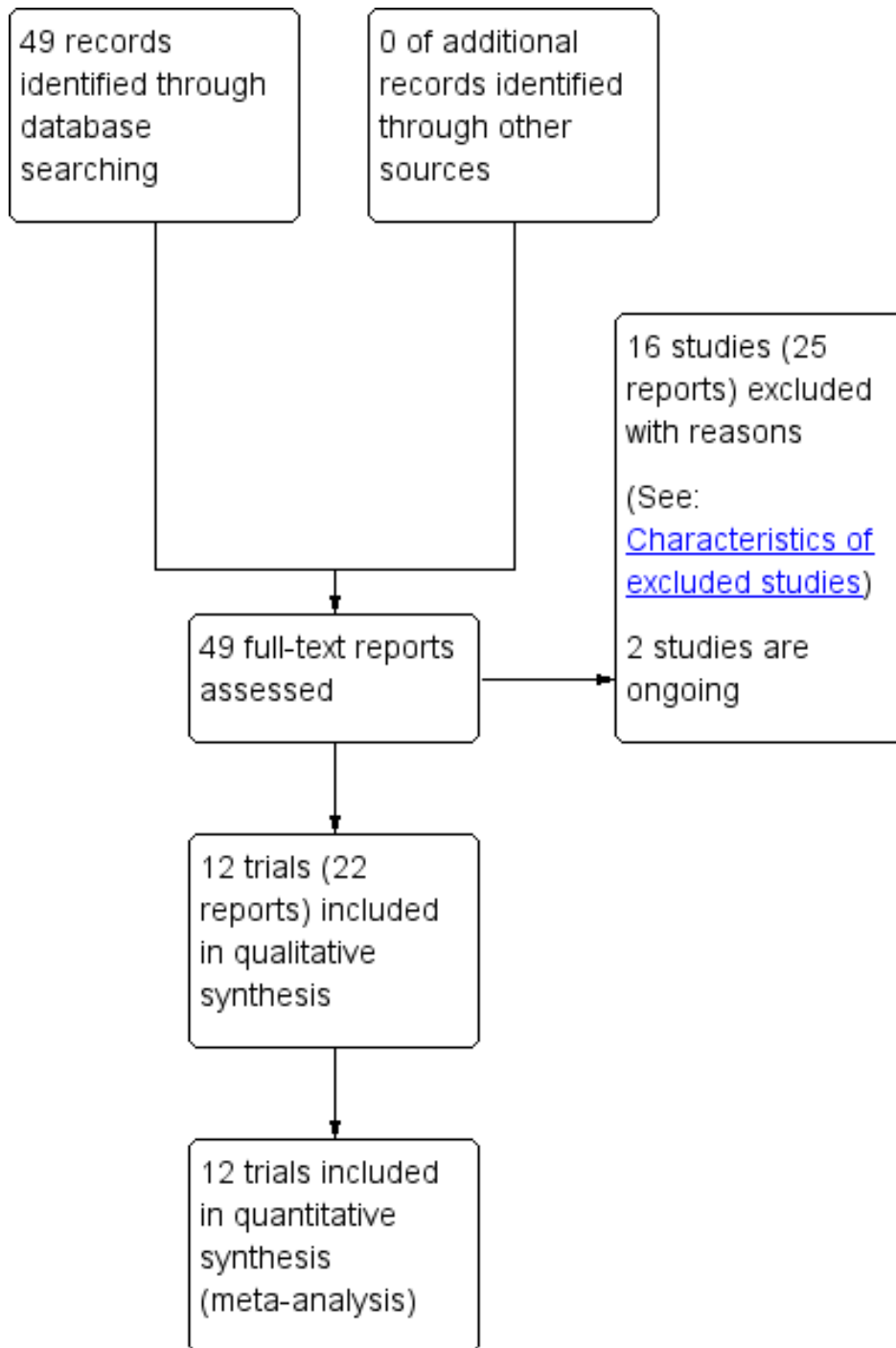
RESULTS

Description of studies

Results of the search

The search of Cochrane Pregnancy and Childbirth's Trials Register retrieved 49 reports among which 12 RCTs (22 reports) were included (see [Characteristics of included studies](#)). We excluded 16 studies (25 reports) (see [Characteristics of excluded studies](#)). Two studies are ongoing (see [Characteristics of ongoing studies](#)) ([Figure 2](#)).

Figure 2. Study flow diagram



Included studies

The search identified 29 studies, of which 12 were included (Ali 2004; Belizan 1993; Dannecker 2004; Eltorkey 1994; Harrison 1984; House 1986; Juste-Pina 2007; Klein 1992; Murphy 2008b; Rodriguez 2008; Sleep 1984; Sulaiman 2013).

Design

All 12 trials were individually randomised.

Setting

Ten of the included 12 studies were carried out between July 1982 and October 2009 (Ali 2004; Belizan 1993; Dannecker 2004; Eltorkey 1994; Harrison 1984; Juste-Pina 2007; Klein 1992; Murphy 2008b; Rodriguez 2008; Sulaiman 2013). Two studies did not describe when the studies took place (House 1986; Sleep 1984). Seven of the 11 studies were carried out in high-income countries, including Canada (Klein 1992), Germany (Dannecker 2004), Ireland (Harrison 1984), Spain (Juste-Pina 2007), and the UK (House 1986; Murphy 2008b; Sleep 1984). Five of the studies were conducted in middle- and low-income countries, and these included Argentina (Belizan 1993), Columbia (Rodriguez 2008), Malaysia (Sulaiman 2013), Pakistan (Ali 2004), and Saudi Arabia (Eltorkey 1994).

Five studies were carried out in university teaching hospitals, relatively high complexity care institutions (Dannecker 2004; Juste-Pina 2007; Klein 1992; Rodriguez 2008; Sulaiman 2013). One of these five studies also recruited some of participants from a mid-complexity level hospital (Rodriguez 2008). The remaining seven studies were conducted in maternity units with inadequate information to judge the institution's level of care (Ali 2004; Belizan 1993; Eltorkey 1994; Harrison 1984; House 1986; Murphy 2008b; Sleep 1984).

One trial (Ali 2004) stated that there was no severe perineal trauma in either selective or routine episiotomy group. However, the main table reported 100% severe perineal trauma in both groups. We have assumed the results are as stated in the abstract but have written to the study authors for clarification.

Sample sizes

Overall, the sample sizes in the included studies ranged from 109 (Dannecker 2004; 146 randomised but data for only 109 reported) to 2606 (Belizan 1993). Two trials (Belizan 1993; Sleep 1984) had a sample size of 1000 or above; one trial (Klein 1992) involved more than 500 women and the remaining eight studies involved between 100 and 500 women.

Participants

The participants in the included studies were pregnant women (above 16 years old), between 28 gestational weeks and full term, with a live singleton fetus, and had vaginal birth. The women did not have severe medical or psychiatric conditions.

The gravidity of the trial participants is summarised in Table 1. Eight trials included primiparous women only (Ali 2004; Dannecker 2004; Eltorkey 1994; Harrison 1984; Juste-Pina 2007; Murphy 2008b; Rodriguez 2008; Sulaiman 2013), and the other four included both primiparous and multiparous women (Belizan 1993; House 1986; Klein 1992; Sleep 1984).

In 11 studies randomisation was done during labour, and in one study (Dannecker 2004) there was no description.

Interventions and comparisons

In all but one of the trials vaginal births without complications were anticipated; the Murphy 2008b study, which only recruited women where operative vaginal delivery was anticipated at the start of labour. The Murphy 2008b study was included, but data are reported separately.

Location

The indication for selective episiotomy was specified differently in the various studies, although overall related to both fetal or maternal indications. Seven trials performed selective episiotomy to avoid either severe perineal tear or fetal distress (Ali 2004; Belizan 1993; Eltorkey 1994; Juste-Pina 2007; Klein 1992; Rodriguez 2008; Sulaiman 2013). Two studies only conducted the selective episiotomy for fetal reasons (Dannecker 2004; Sleep 1984). Two studies carried out selective episiotomy mainly to prevent laceration (Harrison 1984; House 1986). One study provided the selective episiotomy to avoid severe perineal tear at operative vaginal delivery (Murphy 2008b).

Ten trials utilised mediolateral episiotomies (Ali 2004; Belizan 1993; Dannecker 2004; Eltorkey 1994; Harrison 1984; House 1986; Juste-Pina 2007; Murphy 2008b; Sleep 1984; Sulaiman 2013) and two trials used midline episiotomies (Klein 1992; Rodriguez 2008).

Episiotomy rates

The actual episiotomy rates are described in Table 2. Rates in the selective arm ranged from 8% to 59% with a median of 32%, in the routine arm rates ranged from 100% in four studies through to 51%, with a median of 83%.

The difference within trials between the selective and the routine episiotomy groups ranged from 21% to 92% more episiotomies in the control arm.

Operative delivery rates

The operative delivery rate in the selective arm ranged from 1% (Rodriguez 2008) to 8% (Dannecker 2004), median of 4% (Eltorkey 1994) (Table 3). In the comparator, routine arm rates ranged from 2% in two studies (Belizan 1993; Rodriguez 2008), through to 15% (Dannecker 2004), with a median of 5%. All trials included these operative deliveries in their reporting of outcomes.

Outcomes

Length of follow up is described in Table 1. Three trials only reported on outcomes in the immediate postnatal period (under one month); a further three trials reported outcomes in the short term (up to six months); four studies reported on long-term follow-up (beyond six months). An additional study included follow-up beyond six months, but only reported the mean time of follow-up which would include women followed-up for a shorter period (Dannecker 2004).

At discharge (immediately postpartum up to discharge from the hospital)

Severe perineal/vaginal trauma (review primary outcome) was reported in all studies. We compared our definition and the trial definitions (Table 4). All the trials described third and fourth degree tears as in the standard definition, and one trial (Sleep 1984) specifically mentioned upper vaginal tear in the definition.

The need for perineal suturing was reported in six trials (Ali 2004; Belizan 1993; Eltorkey 1994; Harrison 1984; House 1986; Sleep 1984).

Blood loss at delivery was reported in two trials (House 1986; Sulaiman 2013).

Newborn Apgar scores at five minutes were reported in two trials (Dannecker 2004; Juste-Pina 2007).

Admission to special care baby unit was reported in five trials (Eltorkey 1994; Juste-Pina 2007; Klein 1992; Sleep 1984; Sulaiman 2013).

Perineal infection was reported in two trials at three days postpartum (House 1986) and seven days postpartum (Belizan 1993).

Pain assessed using a visual analogue scale was reported by three trials (Dannecker 2004; House 1986; Klein 1992). Moderate or severe pain by visual analogue scale was only reported in one trial at three days postpartum (House 1986). Another two trials presented pain using scores, analysed as a continuous variable (Dannecker 2004; Klein 1992) (Table 5). A number of trials reported pain at different time points (any measure), for example, at hospital puerperium (Juste-Pina 2007), at days one, two and 10 postpartum (Klein 1992), seven days postpartum (Belizan 1993), or at 10 days postpartum (Sleep 1984).

For the outcomes of days in hospital, initiation and exclusive breastfeeding, and satisfaction with the experience of childbirth, results were not reported in any of the included studies.

Short term (at least one month and less than six months)

Three trials reported dyspareunia (Dannecker 2004; Juste-Pina 2007; Sleep 1984). Two of them collected the data through questionnaire survey (Dannecker 2004; Sleep 1984) and one through telephone interview (Juste-Pina 2007). The parameters measured relating to dyspareunia included “pain during sex in the last four weeks” (Dannecker 2004), “dyspareunia” (Juste-Pina 2007; Sleep 1984), “pain with coitus” (Juste-Pina 2007), “ever suffering painful sexual intercourse” (Sleep 1984). Two trials reported short-term dyspareunia at three months postpartum (Juste-Pina 2007; Sleep 1984) (Table 6).

Four trials reported urinary incontinence (Dannecker 2004; Juste-Pina 2007; Klein 1992; Sleep 1984). Three of them collected the data through questionnaire survey (Dannecker 2004; Klein 1992; Sleep 1984) and one through telephone interview (Juste-Pina 2007). The parameters measured included “reported urinary incontinence” and agreement/disagreement with the statement “leak urine involuntarily” (Table 7). Short-term urinary incontinence was reported by two studies at three months postpartum (Klein 1992; Sleep 1984).

Long term (six months or more)

Long-term dyspareunia and urinary incontinence was reported in three trials at two time points, at the mean time of 7.3 months postpartum (Dannecker 2004), and three years after childbirth (Juste-Pina 2007; Sleep 1984) (Table 6, Table 7). Genital prolapse was reported by one trial at three years postpartum (Juste-Pina 2007).

Murphy 2008b, who evaluated women with anticipated operative vaginal delivery, also reported incontinence of urine and faeces at one year.

There were a number of outcomes in the trial reports that were not listed in our protocol. Anterior trauma was reported by eight trials (Belizan 1993; Dannecker 2004; Eltorkey 1994; Juste-Pina 2007; Klein 1992; Rodriguez 2008; Sleep 1984; Sulaiman 2013). One study reported haematoma and wound dehiscence (Belizan 1993), and another one reported bulging (Klein 1992).

Excluded studies

We excluded a total of 16 studies (Amorim 2015; Coats 1980; Detlefsen 1980; Dong 2004; El-Din 2014; Golmakani 2011; Henriksen 1992; Islam 2013; Javed 2007; Karbanova 2013; Moini 2009; Roy 2015; Sawant 2015; Shembekar 2009; Swift 2014; Werner 1991).

For details of excluded studies, see table of Characteristics of excluded studies. The main reason for exclusion (12 studies) was that studies did not compare selective versus routine use of episiotomy; rather they compared policies of no episiotomy versus selective episiotomy or different techniques for carrying out episiotomy (Amorim 2015; Detlefsen 1980; Dong 2004; El-Din

2014; Islam 2013; Javed 2007; Karbanova 2013; Moini 2009; Roy 2015; Sawant 2015; Swift 2014; Werner 1991). Two studies were quasi-randomised trials (Coats 1980; Henriksen 1992). Finally, two studies published as abstracts included too little information on methods and results to allow assessment of risk of bias or to interpret results (Golmakani 2011; Shembekar 2009).

Risk of bias in included studies

Risk of bias in included studies is summarised in Figure 3 and Figure 4.

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

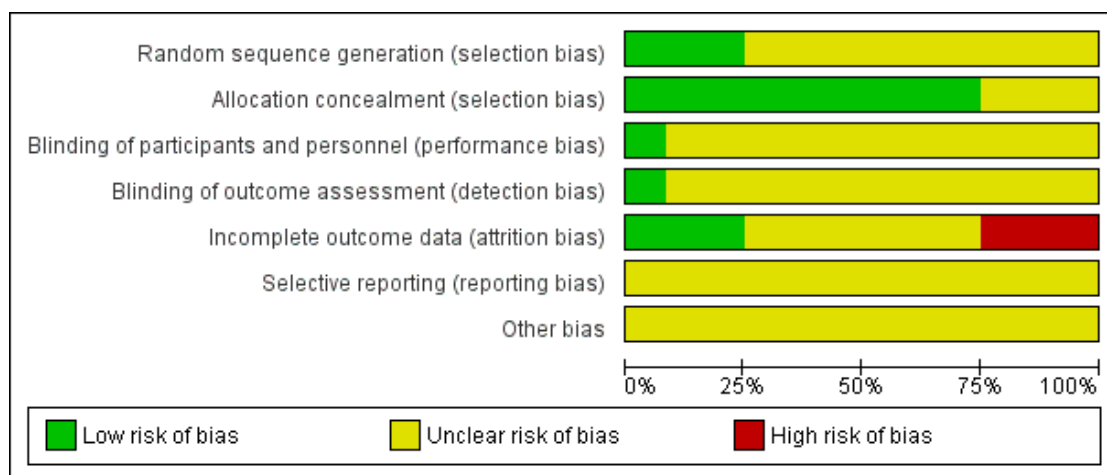


Figure 4. Risk of bias summary: review authors' judgements about each risk of bias item for each included study

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Ali 2004	?	+	?	?	-	?	?
Belizan 1993	+	+	?	+	-	?	?
Dannecker 2004	?	+	?	?	?	?	?
Eltorkey 1994	?	+	?	?	?	?	?
Harrison 1984	?	?	?	?	-	?	?
House 1986	?	+	+	?	?	?	?
Juste-Pina 2007	?	?	?	?	+	?	?
Klein 1992	?	+	?	?	+	?	?
Murphy 2008b	+	+	?	?	?	?	?
Rodriguez 2008	+	?	?	?	?	?	?
Sleep 1984	?	+	?	?	?	?	?
Sulaiman 2013	?	+	?	?	+	?	?

Allocation

Two of the studies reported an adequate method of producing randomisation (Belizan 1993; Murphy 2008b) including both random sequence generation and allocation concealment - we assessed these studies as low risk of bias for selection bias.

Eight studies only reported adequate random sequence generation (Rodriguez 2008) or allocation concealment (Ali 2004; Dannecker 2004; Eltorkey 1994; House 1986; Klein 1992; Sleep 1984; Sulaiman 2013). Consequently, Rodriguez 2008 was assessed as low risk of bias for sequence generation and unclear risk of bias for allocation concealment and Ali 2004; Dannecker 2004; Eltorkey 1994; House 1986; Klein 1992; Sleep 1984; and Sulaiman 2013 were assessed as unclear risk of bias for random sequence generation and low risk of bias for allocation concealment. Two studies reported neither the procedure of randomisation nor allocation concealment (Harrison 1984; Juste-Pina 2007) and these were assessed as having an unclear risk of selection bias.

Blinding

Blinding of participants or observer was only mentioned in three studies (Belizan 1993; House 1986; Sleep 1984). In the remaining studies blinding of participants and personnel was judged as unclear (Ali 2004; Dannecker 2004; Eltorkey 1994; Harrison 1984; Juste-Pina 2007; Klein 1992; Murphy 2008b; Rodriguez 2008; Sulaiman 2013).

In the House 1986 trial, participants were blinded to the group assignments, judged as low risk of performance bias and unclear risk of detection bias. In the Sleep 1984 trial, the observer was reported to be blind to treatment assignments when measuring the outcomes at 10 days after the birth and maternal reports of perineal discomfort three months after the birth. However, there was not enough information to judge how blinding was carried out or whether blinding was used in other outcome assessment. So the study was judged as unclear for risk of performance and detection bias. In the Belizan 1993 trial the assessment of the healing and morbidity outcomes were blinded to the observer, judged as low risk of detection bias and unclear bias of performance bias.

None of the other studies (Ali 2004; Dannecker 2004; Eltorkey 1994; Harrison 1984; Juste-Pina 2007; Klein 1992; Murphy 2008b; Rodriguez 2008; Sulaiman 2013) clearly reported blinding, and were judged as unclear risk of performance and detection biases.

Incomplete outcome data

Sleep 1984 and Dannecker 2004 included long-term follow-up, with a loss to follow-up of about 33% and 40% of the participants respectively. Klein 1992 showed a loss to follow-up rate around

1% at birth and three months postpartum. In the Belizan 1993 trial the total number of women randomised was included in the analysis of the primary outcome with a 5% loss to follow-up at the time of the birth, 7% at postnatal discharge and 57% at seven months postpartum. In the study by Juste-Pina 2007, the loss to follow-up was around 4% during hospital puerperium, 5% at three months postpartum, and 9% three years after childbirth. In the study by Murphy 2008b, the rate of follow-up was 92% at first/second day after childbirth, and 83% six weeks postnatal. Intention-to-treat analysis was performed in all of the studies.

In one study, data were not reported by randomisation group and we judged it as high risk of bias due to incomplete outcome data (Harrison 1984). One trial was assessed as high risk because of the high rate of loss of follow-up for long-term outcomes (Belizan 1993). Another study was also assessed as high risk as there was no description of loss to follow-up, and there appeared to be a differential loss to follow-up (at 7th day postpartum, 19 women were lost from the selective group, and 12 from the routine group (Ali 2004)). Two trials were judged to be low risk due to the low rate of loss to follow-up (Klein 1992; Juste-Pina 2007). One study did not have any missing data and was judged to be at low risk of attrition bias (Sulaiman 2013). For the remaining six trials attrition bias was judged as unclear (Dannecker 2004; Eltorkey 1994; House 1986; Murphy 2008b; Rodriguez 2008; Sleep 1984).

Selective reporting

The included studies appeared to report all outcomes as intended. However, there was not enough information to fully assess the potential for reporting bias so we have judged all included studies as being at an unclear risk of bias for this domain.

Other potential sources of bias

Since there was no fully reported information, this was judged as unclear risk of bias for all included studies.

Effects of interventions

See: [Summary of findings for the main comparison](#) Selective versus routine episiotomy: all vaginal births where operative vaginal delivery was not anticipated

A total of 6352 participants in 12 trials were included in this review. Eleven trials with a total of 6177 participants examined selective versus routine use of episiotomy in births where a non-operative vaginal delivery was anticipated. One trial with 175 participants (Murphy 2008b) was conducted in women where an operative vaginal delivery was anticipated and performed. This study was analysed independently (comparison B, analysis 4) and presented at the end of the main results.

Comparison A. Selective versus routine use of episiotomy (analysis I)

See [Summary of findings for the main comparison](#). All data are included in this analysis, including all women irrespective of parity. All eleven trials included in this comparison reported episiotomy rates. Event rates in both selective and routine episiotomy groups varied considerably between trials ([Table 2](#)).

Main outcomes

Severe perineal/vaginal trauma

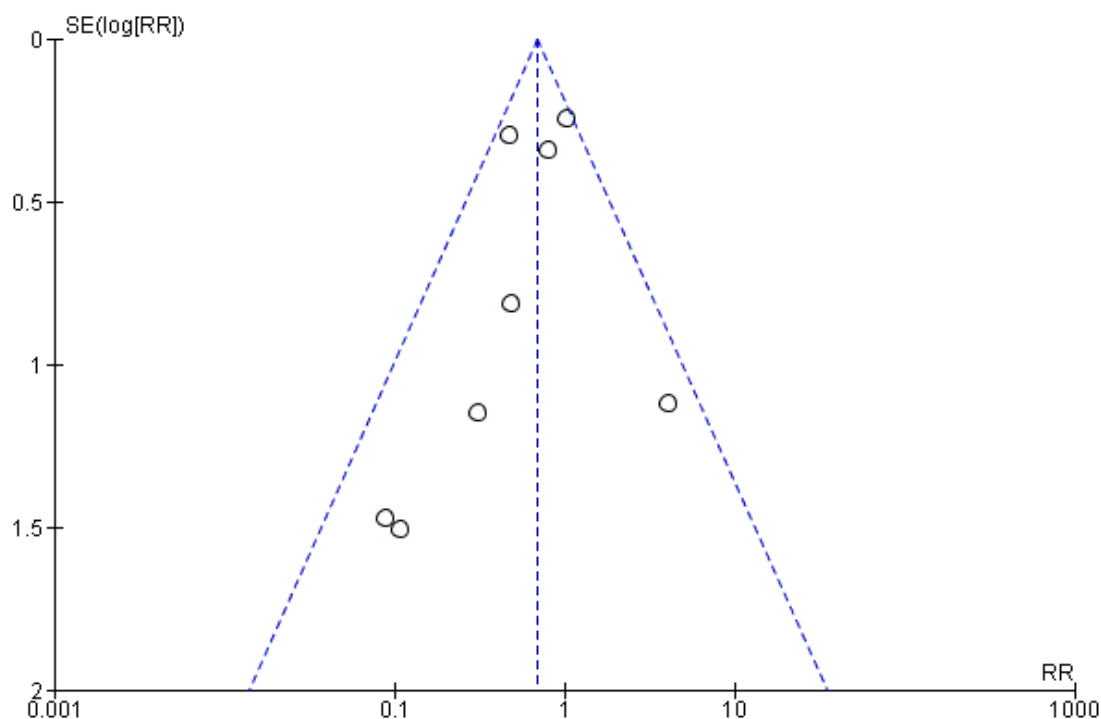
While all 11 trials reported this outcome, only eight of the trials contributed estimable data to the meta-analysis; overall, there was a 30% reduction in severe perineal/vaginal trauma (risk ratio (RR) 0.70, 95% confidence interval (CI) 0.52 to 0.94; 5375 women; 8 trials; $I^2 = 37%$; low-certainty evidence ([Analysis 1.1](#)). There was moderate quantitative heterogeneity in the analysis.

To explore possible explanations for heterogeneity, we conducted a single subgroup analysis, by the degree of success of implementing the policies. In trials where the difference in episiotomy rates between selective and routine groups was less than 30%, there was no obvious difference in outcome. In trials where the difference in the rate was greater than 30%, there was a clear effect on severe vaginal/perineal trauma (RR 0.55, 95% CI 0.38 to 0.81; 4877 women, 7 contributing trials; $I^2 = 21%$).

We carried out a sensitivity analysis only including trials with adequate allocation concealment. The estimate was similar, although the point estimate of the difference was less marked (RR 0.87, 95% CI 0.61 to 1.25; 4949 participants, 7 trials). When we only included studies with low risk of bias for follow-up, only two trials contributed and the analysis was not informative.

Visual assessment of the funnel plot suggests possible publication bias, with small studies showing that routine episiotomy resulted in higher rates of perineal trauma ([Figure 5](#)). This is noted in the GRADE assessment.

Figure 5. Funnel plot of comparison: I Restrictive versus routine episiotomy (planned non-instrumental), outcome: I.1 Severe perineal/vaginal trauma



Blood loss at delivery

Two trials reported estimated blood loss at delivery (House 1986, Sulaiman 2013). One showed a marked average difference, and the other study showed no important difference, which was apparent in the statistical test for heterogeneity ($T^2 = 902.46$; $I^2 = 72\%$). The average effect from meta-analysis was little different (mean difference 27 mL less with selective, 95% CI 74.80 less to 20.49 more; 336 women; 2 trials; Analysis 1.3; very low-certainty evidence).

Newborn Apgar score less than seven at five minutes

Two trials reported Apgar score less than seven at five minutes, but there were no events in either arm in both trials (Dannecker 2004; Juste-Pina 2007) (Analysis 1.4). With no events, it seems that neither selective nor routine episiotomy impacts on this outcome, and the risk difference shows narrow confidence intervals (-0.01 to +0.01%; 511 women; 2 trials; moderate-certainty evidence).

Perineal infection

Three trials reported perineal infection. Event rates were low, and the results indicated that there may be little or no difference between the two groups in relation to this outcome (RR 0.90, 95% CI 0.45 to 1.82; 1467 women; 3 trials; $I^2 = 0\%$; low-certainty evidence due to imprecision) (Analysis 1.5)).

Moderate or severe perineal pain (measured using visual analogue scale)

Three trials assessed pain using a visual analogue scale. Two reported average scores, with very similar values in selective and routine groups in both trials reporting this outcome (Table 5) (Dannecker 2004; Klein 1992). One trial (House 1986) used the individual women's score to categorise by severity, and provided an analysis on women with moderate to severe pain at day three, not detecting a difference between the two groups (RR 0.71, 95% CI 0.48 to 1.05, 165 women; 1 trial; low-certainty evidence due to imprecision) (Analysis 1.6).

Other trials reported on self-reported pain in different ways, not using an analogue scale, and thus not corresponding with our protocol, but we have summarised these data here briefly. Two trials reported on 'any pain at discharge from hospital', with fewer women reporting pain in the selective group in one trial, and with the other trial reporting all women, in both groups, having pain (Analysis 1.12). One trial reported 'any pain at 10 days', with no clear difference detected (Analysis 1.12); three trials reported 'moderate-severe pain in first 10 days' with no clear difference between the two groups (RR 1.14, 95% CI 0.61 to 2.12; 1127 women; Analysis 1.12). One trial reported on 'severe and moderate pain at three months' but was underpowered and no clear difference was evident (Analysis 1.12).

Dyspareunia, long term (at least six months)

Three trials reported dyspareunia at six months or more. Two trials did not exclude the subsequent pregnancy when assessing

at three years after (Juste-Pina 2007; Sleep 1984). There was no clear difference between groups for this outcome (RR 1.14, 95% CI 0.84 to 1.53; 1107 women; 3 trials; $I^2 = 12\%$; low-certainty evidence due to inconsistency and imprecision) (Analysis 1.7).

Genital prolapse, long term (at least six months)

Only one trial reported genital prolapse at least six months or more (three years postpartum). There was no clear difference between the two groups (RR 0.30, 95% CI 0.06 to 1.41; 365 women; 1 trial, low-certainty evidence due to serious imprecision Analysis 1.8).

Urinary incontinence, long term (at least six months)

Three trials reported urinary incontinence at six months or more (Dannecker 2004; Juste-Pina 2007; Sleep 1984). There was heterogeneity between trials ($T^2 = 0.07$; $I^2 = 66\%$). The pooled analysis did not demonstrate a clear difference between the two groups at six months or more postpartum (average RR 0.98, 95% CI 0.67 to 1.44; 1107 women; 3 trials; low-certainty evidence due to inconsistency and imprecision) (Analysis 1.9).

Other important outcomes relating to long-term effects were not reported (urinary fistula, rectal fistula, and faecal incontinence).

Other outcomes

Need for perineal suturing

Six trials reported need for perineal suturing (Ali 2004; Belizan 1993; Eltorkey 1994; Harrison 1984; House 1986; Sleep 1984). However, the reasons for suturing were not set out in trial reports, and repair of episiotomy incisions were not clearly differentiated from other perineal suturing. Clearly, any woman that had an episiotomy - either routinely or selectively - would require suturing. Some women that had episiotomy may have required further sutures if the incision was extended by tearing during the birth. Two trials reported the outcome "perineal surgical repair" (Ali 2004; Belizan 1993); in the Ali 2004 trial all women in the routine episiotomy group had "surgical repair" while in the Belizan 1993 trial most women in this group had repair. It was not clear whether women required any sutures over and above those needed to repair the surgical incision. In the selective episiotomy groups fewer women had surgical repair, but in this group it was not clear what proportion of the women required repair of an episiotomy, repair beyond that needed to suture any episiotomy incision, or had non-episiotomy tears requiring sutures. Two trials reported the outcome "required suturing" (Eltorkey 1994; Sleep 1984) and similar issues arise regarding lack of clarity. Results do not reveal any possible differences in the proportions of episiotomy and non-episiotomy perineal repair in the two study groups. In the other two trials, we have presented the number of women undergoing perineal suturing by adding the numbers for episiotomy, second degree tear and above (Harrison 1984; House 1986). Although for completeness we have presented these data in Analysis 1.10, we

have not pooled data as studies may have been examining different outcomes, and within studies what was reported for the routine and selective groups may also have differed. Overall, compared with the routine episiotomy group, fewer women in the selective episiotomy group required perineal suturing. However, without clear outcome definition, findings from studies are not simple to interpret and may be meaningless from a clinical point of view. (The number of women undergoing episiotomy are set out in [Table 2](#).)

Admission to neonatal special care baby unit

Five trials reported admission to neonatal special care baby unit. Two trials had no events, whilst the highest rate was 15% overall [Juste-Pina 2007](#). The pooled analysis did not demonstrate a clear difference (RR 0.77, 95% CI 0.56 to 1.07; 2471 babies; 5 trials; $I^2 = 11\%$; [Analysis 1.11](#)).

No data were available for the outcomes 'days in hospital after birth', 'breastfeeding (initiation of breastfeeding, exclusive breastfeeding on discharge from hospital)', and 'women's satisfaction'.

Subgroup analysis by parity (analysis 2)

The subgroup analysis by parity included studies that randomised only primigravida ([Ali 2004](#); [Dannecker 2004](#); [Eltorkey 1994](#); [Harrison 1984](#); [Juste-Pina 2007](#); [Rodriguez 2008](#); [Sulaiman 2013](#)) and those that recruited all parities and report the results stratified by parity ([Belizan 1993](#); [House 1986](#); [Klein 1992](#); [Sleep 1984](#)). The analysis was only possible for one of our main outcomes: severe perineal/vaginal trauma.

Severe perineal/vaginal trauma*

There was no evidence of subgroup differences between primigravida and multi-gravida for this outcome (test for subgroup differences: $\text{Chi}^2 = 0.18$, $\text{df} = 1$ ($P = 0.67$), $I^2 = 0\%$) ([Analysis 2.1](#)). Data for pain assessed by visual analogue scale were not available by parity.

Subgroup analysis by type of episiotomy (analysis 3)

The subgroup analysis by type of episiotomy included studies that used midline episiotomy ([Klein 1992](#); [Rodriguez 2008](#)) and mediolateral episiotomy ([Ali 2004](#); [Belizan 1993](#); [Dannecker 2004](#); [Eltorkey 1994](#); [Harrison 1984](#); [House 1986](#); [Juste-Pina 2007](#); [Sleep 1984](#); [Sulaiman 2013](#)). The analysis was only possible for one of our main outcomes: severe perineal/vaginal trauma.

Severe perineal/vaginal trauma

There was no evidence of subgroup differences between midline and mediolateral episiotomy on severe perineal/vaginal trauma (test for subgroup differences: $\text{Chi}^2 = 0.28$, $\text{df} = 1$ ($P = 0.60$), $I^2 = 0\%$) ([Analysis 3.1](#)).

Comparison B. Selective versus routine episiotomy: women with anticipated operative vaginal delivery (analysis 4)

One trial was conducted among women with anticipated operative vaginal delivery ([Murphy 2008b](#)).

Severe perineal/vaginal trauma

No clear difference was shown on the main outcome 'severe perineal/vaginal trauma' between the two groups (RR 1.30, 95% CI 0.55 to 3.07, 175 women) ([Analysis 4.1](#)).

Apgar less than seven at five minutes

The trial reported two events in each arm for Apgar less than seven at five minutes (RR 0.94, 95% CI 0.14 to 6.56, 175 women) ([Analysis 4.2](#)).

Perineal infection

There was no clear difference on perineal infection (RR 0.47, 95% CI 0.04 to 5.11; 175 women) ([Analysis 4.3](#)) between the two groups.

Moderate/severe dyspareunia, long term (at least six months)

No difference was demonstrated for the outcome of moderate/severe dyspareunia in the long term (at least six months) (RR 3.71, 95% CI 0.43 to 32.16, 108 women) ([Analysis 4.4](#)) between the two groups.

Urinary incontinence, long term (at least six months)

No difference was shown for urinary incontinence in the long term (at least six months) (RR 0.46, 95% CI 0.09 to 2.43, 108 women) ([Analysis 4.5](#)) between the two groups.

There was no available data for the other main outcomes including blood loss at delivery, moderate or severe pain (assessed using a standardised quantitative scale, such as 'visual analogue scale').

Other outcomes

There were no clear differences between the selective and routine episiotomy groups on admission to special care baby unit ([Analysis 4.6](#)). Data for other outcomes including need for suturing, days in hospital after birth, breastfeeding (initiation of breastfeeding, exclusive breastfeeding on discharge from hospital) and satisfaction (assessed using a standardised scale) were not provided.

DISCUSSION

Summary of main results

We included 12 trials (6177 women), 11 in women in labour for whom a vaginal birth was intended, and one in women where an assisted birth was anticipated. Two were large trials (more than 1000 women, from Argentina and the UK), and the rest smaller, from Canada, Columbia, Germany, Ireland, Malaysia, Pakistan, Saudi Arabia and Spain. Eight were only in primiparous women, and four both primiparous and multiparous women.

For women in whom an unassisted vaginal birth was intended, selective episiotomy resulted in less severe perineal/vaginal trauma. Both selective and routine episiotomy seemed to have little or no effect on Apgar less than seven at five minutes or on blood loss at delivery.

Pain was measured with an objective scale at three days in one study, and we do not know if selective episiotomy compared to routine results in fewer women with moderate or severe pain; there is probably little or no difference for long-term (at least six months) dyspareunia and there may be little or no difference in the number suffering from urinary incontinence from six months onwards or other long-term effects, such as genital prolapse.

Subgroup analyses by parity showed no clear evidence of a difference between primi- and multi-gravid women. The subgroup analysis by surgical method (midline and mediolateral) did not detect any modifying effects.

One trial examined selective episiotomy compared to routine episiotomy in women where an operative vaginal delivery was intended. The results of this study with 175 women did not show clear differences on main and other outcomes between the restrictive and routine use of episiotomy, but the analysis was underpowered.

Overall, careful assessment of women's pain was not well performed in any of the studies. The included studies did not provide any data relating to breastfeeding, the number of days in hospital after birth, or women's satisfaction.

Thus the rationale commonly used to justify routine episiotomy (Figure 1) is not supported by any evidence from randomised trials.

Overall completeness and applicability of evidence

The outcomes of the review included both potential benefits and harms. Overall, there were clear differences between groups for severe perineal trauma but for low Apgar score at 5 minutes and other important outcomes, with no clear differences were shown. Long-term outcomes were considered as important, but measuring long-term outcomes is not easy and even when it is attempted there is often high loss at follow up. Subsequent pregnancy was not excluded from the long-term outcomes in a few studies, which might not truly reflect the effect of selective episiotomy. Very few good estimates of pain were available to us and none of the studies reported women's preferences. The studies included in the review were carried out over a wide range of locations, including Europe,

North America, South America, and Asian countries. We have restricted the main analysis to births where "vaginal delivery is anticipated" rather than "operative vaginal delivery is anticipated". This was because we were not sure whether these results would apply to operative vaginal delivery.

Based on the logic framework, routine episiotomy appears to offer no advantages or benefits. Evidence in the short term is clear, and some evidence in the long term. No data were available on short-term indicators of hospital stay, initiation of breastfeeding, and long-term indicators such as urinary fistula, rectal fistula and women's satisfaction.

Quality of the evidence

The quality of evidence for the main outcome "severe perineal/vaginal trauma" was low. The downgrading on imprecision was because of no or few events, The downgrading on inconsistency was due to the heterogeneity in study population for long-term outcomes -the mix of women with or without subsequent delivery after selective episiotomy (Summary of findings for the main comparison). The heterogeneity appeared to be explained by dividing trials into those where there was a clear difference in the proportion of women receiving episiotomies between intervention and control.

Overall, there was moderate bias in the included studies although several studies had high risk of bias relating to incomplete outcome data. Long-term follow up can be challenging. Some trials did carry this out, and this is important since these long term outcomes related to the presumed benefit of selective episiotomy (Figure 1). There was considerable loss to follow-up in some trials and it was not easy to determine whether this might have caused bias differentially, but the results certainly did not demonstrate any harms of a policy of selective episiotomy.

Potential biases in the review process

We were careful to adhere to our main outcomes. We managed conflicts of interest in relation to trialists as authors (Kliner 2014).

Agreements and disagreements with other studies or reviews

In early 1980s, the routine use of episiotomy was questioned since there were no supporting data to show more benefits than risks (Banta 1982). This review has provided the evidence that routine use of episiotomy could do harm. The main findings of this review are consistent with the previous version of this review that also compared selective episiotomy with routine episiotomy (Carroli 2009). Both this and the previous version of our review found that selective episiotomy compared with routine episiotomy resulted in less severe perineal/vaginal trauma, and less need for perineal suture. Evidence synthesis by another review also reported that maternal outcomes of routine episiotomy including severe perineal

laceration, pain and pain medication use were no better than in women with selective use of episiotomy (Hartmann 2005). However, our review presents the main evidence alongside the use of GRADE - the other reviews have not done so.

AUTHORS' CONCLUSIONS

Implications for practice

Proponents of episiotomy argue that routine episiotomy facilitates delivery, that surgical healing results in better outcomes, and that the procedure reduces third- and fourth-degree tears, as outlined in our logic framework (Figure 1). In terms of the outcomes reflecting these arguments, the evidence does not support a policy of routine episiotomy: we identified increased risk of severe perineal/vaginal trauma; and no clear difference on blood loss at delivery, babies with newborn Apgar score less than seven at five minutes, perineal infection, women with moderate or severe pain (measured by visual analogue scale), long-term dyspareunia (at least six months) and long-term urinary incontinence (at least six months) when compared with the policy of selective episiotomy.

Practically speaking, it is probable that an episiotomy means that women require a longer postnatal stay in hospital while their episiotomy heals. Women with an intact perineum usually leave much more quickly. This is more convenient, and reduces hospital costs. Further cost-effectiveness analysis (Borghi 2002) may help elucidate the extent of cost savings with selective episiotomy.

Implications for research

The data on pain were mostly not well collected or standardised, which may reflect the age of the studies. Activities of daily living measured by a validated scale might have helped when comparing two different policies of episiotomy. Blood loss estimates were not

measured using a standard approach, and future studies in instrumental delivery would benefit from clear and standardised outcome definition. Few trials reported some of our key outcomes: low Apgar score at five minutes was reported in only two trials, perineal infection in two, perineal pain in one, long term dyspareunia in three, and urinary incontinence in three trials, as well as any possible effect on breastfeeding. The trials included in this review did not appear to consider women's preferences and views on these procedures and the outcomes important to them.

Other remaining questions relate to relative effects with the type of episiotomy (midline or mediolateral, or different angles of episiotomy).

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Ali 2004

Methods	RCT
Participants	Women after admission to the labour ward, 100 primigravidae in each group Inclusion criteria: primigravidae in labour at term with a singleton fetus in cephalic presentation Exclusion criteria: participants with gross fetal malformations
Interventions	Intervention group: episiotomy was avoided and was only given for fetal distress or when severe perineal trauma was judged to be imminent Control group: right mediolateral episiotomy was made in all primigravidae according to hospital policy
Outcomes	Severe perineal trauma, rate of episiotomy
Notes	Right mediolateral episiotomies. Episiotomy rates were 32% for the selective group and 100% for the routine group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Low risk	Woman was asked to open one of the two envelopes each envelope containing intervention for the either group as mentioned above (routine and selective use of episiotomy groups) for randomised selection
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	High risk	No description of loss to follow-up. Exactly 100 in each group. Table of patient variables does not give numbers of women on which these data are based. There appears to be a differential loss to follow-up (at 7th day postpartum), 19 women were lost from the selective group, and 12 from the routine group
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge

Ali 2004 (Continued)

Other bias	Unclear risk	The authors claim no “severe perineal trauma” but table 2 indicates there is 100% in both groups, leading to questions about the integrity of the data
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Belizan 1993

Methods	Generation of randomisation by computer from a random sample generator programme, organised in balanced blocks of 100, with stratification by centre and by parity (nulliparous and primiparous) Allocation concealment by sequentially-numbered, sealed, opaque envelopes, divided according to parity	
Participants	N: 2606 women; 1298 women in the intervention group and 1308 women in the control group. 1555 were nulliparous (778 in the selective group and 777 in the routine group) and 1051 primiparous (520 in the selective and 531 in the routine group). Inclusion criteria: uncomplicated labour; 37 to 42 weeks’ gestation; nulliparous or primiparous. Single fetus Cephalic presentation; no previous caesarean section or severe perineal tears	
Interventions	Intervention: selective - try to avoid an episiotomy if possible and only do it for fetal indications or if severe perineal trauma was judged to be imminent Control: routine - do an episiotomy according to the hospital’s policy prior to the trial	
Outcomes	Severe perineal trauma (primary outcome); middle/upper vaginal tears; anterior trauma; any posterior surgical repair; posterior perineal surgical repair; perineal pain at discharge; haematoma at discharge; healing complications, infection and dehiscence at 7 days Apgar score less than 7 at 1 st minute.	
Notes	Mediolateral episiotomies. Episiotomy rates were 30% for the restricted group and 80.6% for the routine group	

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The description “Random treatment assignments were derived from a random sample generator programme and was organized in balanced blocks of 100, with stratification by centre and parity”
Allocation concealment (selection bias)	Low risk	The description “Each centre was supplied with a set of sequentially- numbered, sealed, opaque envelopes, which contained the trial instructions”

Belizan 1993 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	The description “Healing and morbidity were assessed at the time of discharge from hospital and on the seventh postpartum day by an independent physician who did not know the trial allocation”. However, it was not clear whether the primary outcome “perineal trauma” “assessed by the attending physician at the time of delivery” was done with blinding. It was not clear whether participants were blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	The description “Healing and morbidity were assessed at the time of discharge from hospital and on the seventh postpartum day by an independent physician who did not know the trial allocation”. The assessment was blinded, but no details reported for other outcomes, e.g. severe perineal trauma at delivery
Incomplete outcome data (attrition bias) All outcomes	High risk	The primary outcome was with a 5% loss to follow-up at delivery. 93.0% of women in the selective group and 92.9% in the routine were assessed when discharged from hospital. This is high. However, 42.7% and 43.1% followed up for the selective and routine group respectively on the seventh day postpartum. More than half of women in both groups were not assessed, but no detailed information about this
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge as no trial protocol
Other bias	Unclear risk	Not enough information to judge

Dannecker 2004

Methods	Random generation: not stated Allocation concealment: sealed opaque envelopes
Participants	Number randomised: 146 (selective 70, routine 76) Inclusion criteria: primiparous, > 34 weeks of gestation, with an uncomplicated pregnancy and with a live singleton fetus. Women were intending to have a vaginal delivery Exclusion criteria: previous surgery at the pelvic floor, or neurologic disorder

Interventions	<p>Intervention: restrictive - try to avoid an episiotomy even if severe perineal trauma was judged to be imminent and only do it for fetal indications</p> <p>Control: liberal - in addition to fetal indications use of episiotomy when a tear is judged to be imminent</p>
Outcomes	Reduction of episiotomies, increase of intact perinea and only minor perineal trauma, perineal pain (displayed in score) in the postpartum period, percentage change in overall anterior perineal trauma, difference of the PH of the umbilical artery, percentage of umbilical artery PH less than 7.15, percentage of Apgar scores less than 7 at 1 and 5 minutes, maternal blood loss at delivery (measured by mean difference pre/post haemoglobin), percentage of severe perineal trauma, dyspareunia, urinary incontinence
Notes	Mediolateral episiotomies. Episiotomy rates were 70% for restricted group and 79% for the routine group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Not stated
Allocation concealment (selection bias)	Low risk	The description "Random treatment assignments were carried out using two opaque envelopes with the different policies enclosed for every particular participant"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up reported with reason, but unable to fully judge. For follow-up approximately 6 months or more later, the overall dropout was around 40%, 45% in selective, and 32% in routine
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge
Other bias	Unclear risk	No enough information to judge

Eltorkey 1994

Methods	Random generation: not stated Allocation concealment: sealed opaque envelopes
Participants	N: 200 women (100 in each) Inclusion criteria: primigravid women with live, singleton fetus, cephalic presentation of at least 37 weeks of gestational age, having a spontaneous vaginal delivery. Women were not suffering from any important medical or psychiatric disorder
Interventions	Intervention: selective - the intention was not to perform an episiotomy unless it was absolutely necessary for maternal or fetal reasons Control: elective - the intention was to perform an episiotomy unless it was considered absolutely unnecessary
Outcomes	First-, second-, third- and fourth-degree tears, anterior trauma, need for suturing, and neonatal outcomes: Apgar score at 1 and 5 minutes, and stay in NICU
Notes	Mediolateral episiotomies. Episiotomy rates were 53% for the restricted group and 83% for the routine group

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Low risk	The description "Entry to the trial, which was signalled by opening a sealed opaque envelope, was postponed until the attending midwife had decided to 'scrub up' in expectation of a spontaneous vaginal delivery"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No detailed reported
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge
Other bias	Unclear risk	No enough information to judge

Harrison 1984

Methods	Generation method of randomisation not established Concealment allocation method not established “Allocated randomly”
Participants	N: 181 (intervention, N = 92; control, N = 89). Inclusion criteria: women primigravid, vaginal delivery, at least 16 years old, no less than 38 weeks’ gestational age, not suffering from any important medical or psychiatric conditions or eclampsia
Interventions	Intervention: not to undergo episiotomy unless it was considered to be medically essential by the person in charge, that is the accoucheur could see that a woman was going to sustain a greater damage or if the intact perineum was thought to be hindering the achievement of a safe normal or operative delivery Control: to undergo mediolateral episiotomy
Outcomes	Severe maternal trauma. Any posterior perineal trauma. Need for suturing perineal trauma
Notes	Mediolateral episiotomies. Episiotomy rates were 7.6% for restricted group and 100% for the routine group

Risk of bias

Bias	Authors’ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Unclear risk	No details reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details reported
Incomplete outcome data (attrition bias) All outcomes	High risk	Data were not reported by randomisation group
Selective reporting (reporting bias)	Unclear risk	No enough information to judge
Other bias	Unclear risk	No enough information to judge

House 1986

Methods	Generation method of randomisation not established Concealment method of allocation by envelopes
Participants	Number of participants not established. There is only information for 165 women available to follow-up but information about women lost to follow-up is lacking, either because 1 of the study authors was not available, or because of the early discharge scheme. 98 primigravidae and 67 multigravidae. 94 in the intervention and 71 in the control group Inclusion criteria: women were at least 37 weeks' gestational age, cephalic presentation and vaginal delivery Exclusion criteria: lack of consent, labour at less than 37 weeks pregnant, presentation other than vertex, caesarean section and the unavailability of an accoucheur willing to abide by the research protocol. Women who subsequently had a forceps delivery were not excluded
Interventions	Intervention: restrict - not to perform specifically to prevent laceration Control: liberal - to receive standard current management whereby perineal damage was avoided by control of the descent of the head and supporting the perineum at crowning. An episiotomy was made if there was fetal distress, or for maternal reasons to shorten the 2nd stage such as severe exhaustion, inability to complete expulsion or unwillingness to continue pushing. Episiotomy was performed if the perineum appeared to be too tight or rigid to permit delivery without laceration, or if a laceration appeared imminent
Outcomes	Second-degree tear. Third-degree tear. Need for perineal suturing. Any perineal pain at 3 days. Healing at 3 days. Tenderness at 3 days. Perineal infection at 3 days. Blood loss during delivery
Notes	Mediolateral episiotomies. Episiotomy rate for restricted group were 18% and for the routine group were 69%

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Low risk	Judge from the description "This involved the selection of envelopes containing a questionnaire and management group"
Blinding of participants and personnel (performance bias) All outcomes	Low risk	The description "Women were not informed of the management group allocated"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details reported

House 1986 (Continued)

Incomplete outcome data (attrition bias) All outcomes	Unclear risk	The study involved above 165 women over a 12-month period. Authors did not provide how many participants were recruited at the recruitment
Selective reporting (reporting bias)	Unclear risk	No enough information to judge
Other bias	Unclear risk	Unclear risk of bias of measuring blood loss at delivery since the study used visual inspection for blood loss estimation without specific training. Not enough information to judge for other bias

Juste-Pina 2007

Methods	Generation method of randomisation not established Concealment method of randomisation not stated. Experimental study, controlled, with random allocation of women to the control group who were given routine episiotomy or to the experimental group who were given a selective episiotomy
Participants	N: 402 (intervention, N = 200; control, N = 202) Inclusion criteria: nulliparous women who fulfilled the inclusion criteria (nulliparous, to full term, single live fetus, cephalic presentation, gestational age to term and of Spanish nationality)
Interventions	Intervention: selective episiotomy (by fetal or maternal indication) Control: routine episiotomy (with the aim of trying to prevent tears)
Outcomes	Weight gain during gestation, maternal weight at the time of delivery Gestation control, maternal education and the gestational age Delivery: beginning of delivery (spontaneous or induced), use of oxytocin, epidural analgesia, duration of the dilation and expulsive stages Motives for carrying out the episiotomy or not Subsequent first-, second-, third- and fourth-degree perineum tears Previous perineum tears (lip tears) The newborn: Apgar test, weight, need for admittance to neonatology and the reasons Immediate puerperium: fever, use of antibiotics, use of analgesia, perineal oedema, perineal hematoma and application of ice, local infection, dehiscence, urinary incontinence and lactation Immediate puerperium pain, in the hospital and after 3 months: pain in general, pain with urination, bowel movement, walking and sedestation Time of commencement of sexual relations, dyspareunia
Notes	Medio-lateral; 118 of 200 women had episiotomy in the selective group; 169 of 202 women had episiotomy in the control group

Risk of bias

Juste-Pina 2007 (Continued)

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Unclear risk	No details reported
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	There was the description "On the third day after puerperium, a different midwife carried out a personalised survey and assessed the perineum". However, it was not clear whether the midwife was blinded for the group allocation
Incomplete outcome data (attrition bias) All outcomes	Low risk	402 women began the study. 14 women who received an early discharge which impeded them from being interviewed during hospital puerperium; at 3 months postpartum, 21 participants were excluded due to not being able to be contacted; at 3 years after childbirth, 37 participants from the initial sample were excluded due to the fact that it was impossible to contact women
Selective reporting (reporting bias)	Unclear risk	No details reported
Other bias	Unclear risk	No details reported

Klein 1992

Methods	Generation method of randomisation not established Concealment of allocation by opaque, sequentially-numbered envelopes
Participants	N: 703 randomised (N = 353; control, N = 350). Inclusion criteria: women had a parity of 0, 1, or 2, between the ages of 18 and 40 years, carried a single fetus, spoke English or French, and were of medical and obstetrical low risk as determined by their physician Exclusion criteria: prematurity, that is gestation less than 37 weeks, medical conditions developing late in pregnancy, fetal distress, caesarean deliveries and planned forceps
Interventions	Intervention: restricted - "Try to avoid an episiotomy". The physician should only use episiotomy for fetal indications (late fetal distress: fetal bradycardia, tachycardia, or meconium-stained amniotic fluid) or rarely for maternal perineal indications (severe tear anticipated)

	Control: liberal - "Try to avoid a tear". The physician was expected to use episiotomy liberally as the usual or routine method for preventing tears	
Outcomes	Perineal trauma including first, second, third and fourth degree and sulcus tears. Perineal pain at 1, 2, 10 days. Dyspareunia. Urinary incontinence and perineal bulging. Time on resumption and pain of sexual activity. Pelvic floor function. Admission to special care baby unit	
Notes	Midline episiotomies. Episiotomy rates were 43.8% for restricted group and 65% for the routine group	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Low risk	The description "Usage of opaque envelopes that were sequentially numbered, and contained instructions printed on opaque cards"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not blinded. As stated in the text "Blinding of the staff to subject group membership was not possible. The subjects, while they usually knew if they had received an episiotomy, were generally naive as to their study group membership (base on intention to treat)"
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	A loss to follow-up rate around 1% at delivery and 3 months postpartum
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge
Other bias	Unclear risk	No details reported

Murphy 2008b

Methods	RCT. Random allocation to: A. restrictive use of episiotomy for instrumental vaginal delivery B. routine use of episiotomy for instrumental vaginal delivery
Participants	N: 200 women (intervention, N = 101; control, N = 99) Inclusion criteria: primigravid women in the third trimester of pregnancy (> 36 weeks) with a singleton cephalic pregnancy who were English speakers and had no contra-indication to vaginal birth Exclusion criteria: women who were: non-English speakers; who had contra-indication to vaginal birth; multiple pregnancy; malpresentation; multiparous women as the rate of instrumental delivery is significantly lower in these women making the effort of recruitment unjustified; women who had not given written informed consent prior to the onset of labour
Interventions	Intervention: restrictive use of episiotomy for instrumental vaginal delivery (only if tearing becomes apparent) Control: routine use of episiotomy for instrumental vaginal delivery (in all cases)
Outcomes	Extensive perineal tearing involving the anal sphincter (third- or fourth-degree tears) Postpartum haemorrhage, shoulder dystocia, the mother's perception of pain, the length of postnatal hospital stay, urinary or bowel symptoms and the rate of healing complications, low Apgar scores, low arterial blood gases, admission to the neonatal intensive care unit and trauma, estimated blood loss
Notes	Unclear for the mediolateral or midline episiotomies

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The description "The randomisation was performed by computer program using a randomisation sequence generated by a statistician unconnected with the study. Allocation was stratified by maternity unit using randomly permuted blocks of 10"
Allocation concealment (selection bias)	Low risk	The description "The allocation was revealed immediately prior to commencing the OVD. Some randomisation were allocated using opaque envelopes due to technical difficulties with the programme. Adherence to the allocation was confirmed by the research midwife each day"
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not stated

Murphy 2008b (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Loss to follow-up reported without reasons (described as unobtained), unable to fully judge
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge
Other bias	Unclear risk	No details reported

Rodriguez 2008

Methods	Ralloc software (Boston College Department of Economics, Boston, MA) was used to create a random sequence of numbers in blocks with 2, 4, and 6 size permutations. Participants were assigned either to the routine episiotomy or the selective episiotomy group, depending of the basis of the randomisation sequence kept at the institution	
Participants	<p>N: 446 randomised, 223 in each group (intervention, N = 222 analysed; control, N = 223)</p> <p>Inclusion criteria: nulliparous women with pregnancies more than 28 weeks of gestation who had vaginal deliveries</p> <p>Exclusion criteria: women with multiple pregnancies, and with breech presentations and those who did not sign the informed consent or refused to participate in the study</p>	
Interventions	<p>Intervention: selective - to undergo the procedure only in cases of forceps delivery, fetal distress, or shoulder dystocia or when the operator considered that a severe laceration was impending and could only be avoided by performing an episiotomy.</p> <p>Control: routine - to undergo the procedure at the time the fetal head was distending the introitus</p>	
Outcomes	The primary outcome of severe laceration to perineal tissues was defined as a third-degree laceration when the extent of the lesion included the external anal sphincter totally or partially, and fourth-degree laceration when the rectal mucosa was involved	
Notes	Midline episiotomies. Episiotomy rates were 24.3% for restricted group and 100% for the routine group	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random sequence of numbers was established, and block size reported

Rodriguez 2008 (Continued)

Allocation concealment (selection bias)	Unclear risk	Inadequate information to judge as it was described “randomisation sequence was kept at the institution”
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details reported
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Reported numbers of loss with reason, but unable to fully judge
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge
Other bias	Unclear risk	No enough information to judge

Sleep 1984

Methods	Generation method of randomisation not established Concealment of allocation by opaque sealed envelopes
Participants	N: 1000 (intervention, N = 498; control, N = 502) Inclusion criteria: women randomised with spontaneous vaginal deliveries, live singleton fetus, at least 37 completed weeks of gestational age, cephalic presentation From the 1000 original women randomised in the original trial, 922 were available for follow-up and 674 of them responded to a postal questionnaire which are the women included in the analysis
Interventions	Intervention: restrict policy - “Try to avoid episiotomy”: the intention should be to avoid an episiotomy and performing it only for fetal indications (fetal bradycardia, tachycardia, or meconium-stained liquor) Control: liberal policy - “Try to prevent a tear”: the intention being that episiotomy should be used more liberally to prevent tears
Outcomes	Severe maternal trauma: extension through the anal sphincter or to the rectal mucosa or to the upper 3rd of the vagina Apgar score less than 7 at 1 minute Severe or moderate perineal pain 10 days after delivery Admission to special care baby unit in first 10 days of life. Perineal discomfort 3 months after delivery Number of resumption of sexual intercourse within a month and 3 months after delivery Any dyspareunia in 2 years. Any incontinence of urine at 3 years. Urinary incontinence severe to wear a pad at 3 years

Notes	Mediolateral episiotomies. Episiotomy rates were 10.2% for restricted group and 51.4% for the routine group	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Low risk	Sealed opaque envelope was used for group allocation
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Although 1 of the outcomes was described as "Perineal discomfort three months after delivery reported by mothers who in most cases blind to the allocation", but not enough information to judge how they were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Perineal pain 10 days after delivery, admission to special care baby unit in first 10 days of life, were assessed by community midwife blind to the allocation; not enough information to judge
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	<p>"One thousand women (93% of those who met the criteria for entry) were allocated at random to one of two management policies. But 885 were assessed on 10 days postpartum, and 895 assessed on three months postpartum." The follow-up rate at both 10 days and 3 months after delivery was 89%</p> <p>For 3-years' follow-up, the loss to follow-up was about 33%. There was the description "no attempt was made to contact 15 women: eight were known to speak little English; two had refused to adoption; open baby had been taken into care; and one baby had died in the neonatal period. 481 (49%) of the remaining 985 participants had changed their address in the three years since the original study, of whom 303 (31%) were still living within West Berkshire Health Authority. The new address of 100 of the remaining 178 women was not known". Another 63 women were unable</p>

Sleep 1984 (Continued)

		to trace because they had “registered in different name (one woman had changed her name six times during the three days), or failed to reregister for medical care in a different area, or because their husbands had been transferred to military posts overseas; one mother had died”
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge
Other bias	Unclear risk	Not enough information to judge

Sulaiman 2013

Methods	Generation method of randomisation not established Concealment method of allocation by opening a sealed opaque envelope
Participants	N: 209 randomised , 171 analysed (intervention, N = 89; control, N = 82). Inclusion criteria: Women live singleton pregnancy with cephalic presentation, gestation beyond 37 weeks, primigravida, women with no history of severe perineal injuries, no life-threatening medical or psychiatric conditions
Interventions	Intervention: selective - women in the selective group were not to undergo episiotomy unless considered essential for various reasons such as fetal distress or imminent extended perineal injury Control: routine- all women in the routine group were to undergo the usual hospital protocol
Outcomes	Prevalence of obstetrical anal sphincter injuries, incidence of first-, second-, third- and fourth-degree perineal tears, blood loss, mean birthweight, and newborns with pH less than 7.2 and admission to the NICU, blood loss, intact perineum
Notes	Mediolateral. Half in the selective group had episiotomy and all (100%) women in the routine group were subjected to an episiotomy

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	No details reported
Allocation concealment (selection bias)	Low risk	The description “Randomization into selective and routine episiotomy group was performed by opening a sealed opaque envelope”

Sulaiman 2013 (Continued)

Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	No details reported
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details reported
Incomplete outcome data (attrition bias) All outcomes	Low risk	No loss to follow-up
Selective reporting (reporting bias)	Unclear risk	All outcomes stated were reported but unable to fully judge
Other bias	Unclear risk	Unclear risk of bias of measuring blood loss at delivery since the study used visual inspection for blood loss estimation without specific training. Not enough information to judge for other bias

NICU: neonatal intensive care unit

RCT: randomised controlled trial

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Amorim 2015	This study examined a policy of no episiotomy versus selective episiotomy; this comparison was not covered in this review which focused on selective versus routine episiotomy
Coats 1980	Quasi-randomised controlled trial, participants were allocated by the last digit of their hospital numbers and the appropriate episiotomy was performed if needed
Detlefsen 1980	This study did not compare the restrictive use of episiotomy versus the routine use of episiotomy. It compared median and medio-lateral episiotomy
Dong 2004	This study focused on 2 approaches of mediolateral episiotomy (with different angles), rather than the comparison between restrictive and routine episiotomy. There was no description on the process of randomisation and how pain was scored
El-Din 2014	This paper compared 2 incision angles of mediolateral episiotomy, not the restrictive use of episiotomy and routine use of episiotomy

(Continued)

Golmakani 2011	Only translated abstract was available. Degrees of perineal trauma not clear from the abstract. The abstract only included the overall proportion of perineal trauma
Henriksen 1992	As described in the Summary, it was a quasi-randomised study. (Design: The study was a population-based observational study. 2 approaches were used in the analyses: At first we considered the women giving birth as quasi randomised to 1 of 3 equally sized groups of midwives, where episiotomy was used to different extents. Next, we studied the effect of episiotomy on the state of the anal sphincter as well as birthweight, parity and the duration of the second stage of labour.)
Islam 2013	The study compared the use of episiotomy or not, rather than the restrictive use and routine use of episiotomy
Javed 2007	The comparison was not conducted between the restrictive use of episiotomy and routine use of episiotomy, but to compare the use of episiotomy or not. Furthermore, participants were not randomly allocated to the 2 groups. (Page 107, 300 primigravida were selected randomly by lottery system but when a patient included in group B, who was not to undergo episiotomy, needed that due to fetal indication, she was shifted to the other group A who were to undergo episiotomy, medio-lateral in every case.)
Karbanova 2013	The studies aimed to compare mediolateral versus lateral episiotomy, and to compare the effect of episiotomy performed before and at time of crowning in primiparous women, not for restrictive use of episiotomy and routine use of episiotomy
Moini 2009	To compare the use of episiotomy and non-use of episiotomy
Roy 2015	The study compared the use of episiotomy or not, not comparing the selective use and routine use of episiotomy
Sawant 2015	To compare episiotomy suture angles with Braun-Stadler episiotomy scissors with the new fixed angle EPISCIS-SORS-60
Shembekar 2009	Only abstract is available, excluded
Swift 2014	This study did not compare restrictive use of episiotomy and routine use of episiotomy. It compared curved versus straight scissors to avoid 3 rd and 4 th degree tears.
Werner 1991	The study compared midline versus mediolateral episiotomy rather than selective versus routine episiotomy. There is no reference about the method of randomisation used. The effects are not shown in a quantitative format making the data uninterpretable

Characteristics of ongoing studies [ordered by study ID]

[NCT02356237](#)

Trial name or title	The effect of episiotomy on maternal and fetal outcomes (EPITRIAL)
Methods	RCT

NCT02356237 (Continued)

Participants	<p>14,842 women in 7 northern public Israeli hospitals from February 2015-February 2019</p> <p>Inclusion criteria</p> <p>18-50 years old; women in labour, or women scheduled for induction of labour, or women attending for a routine follow-up examination during third trimester of pregnancy</p> <p>First vaginal delivery</p> <p>Singleton pregnancy above 34 gestational weeks</p> <p>Vertex presentation</p> <p>Women who are able to understand and sign the informed consent forms</p> <p>Exclusion criteria</p> <p>Absolute contraindications for vaginal delivery (e.g. placenta previa, fetal macrosomia above 4.5 kg, genital herpes)</p>
Interventions	<p>Intervention: avoidance of episiotomy</p> <p>Episiotomy will not be performed in this group. Deviation from protocol (i.e. episiotomy performance) will be allowed only according to the discretion of obstetrician in charge of the delivery, in cases of unequivocal benefit to the fetus</p> <p>Control: no episiotomy</p> <p>The decision to perform episiotomy in this group will be based on routine delivery care, i.e. indistinguishable from any other delivery not participating in the trial</p>
Outcomes	<p>Obstetric anal sphincter injury (time frame: from the delivery to 1 h after delivery) (Designated as safety issue: no</p> <p>Advanced (3rd and 4th degree) perineal tears, i.e. perineal lacerations involving the anal sphincter, diagnosed by a senior obstetrician</p>
Starting date	February 2015
Contact information	Lena Sagi-Dain, email: lena2303@gmail.com
Notes	

TCTR20150212001

Trial name or title	Restrictive versus routine episiotomy: a randomised controlled trial
Methods	RCT
Participants	<p>3 study hospitals will be included, Srinagarind Hospital, a super tertiary care university hospital; Khon Kaen Hospital, a regional tertiary care hospital; Kalasin Hospital. Women who agree to participate in the trial after having signed the consent form will be randomly allocated to be delivered with either restrictive or routine episiotomy. A total of 3006 women will be recruited - for primi-parity group 1100 women (550 per arm); for multi-parity group 1906 women (953 per arm)</p> <p>Inclusion criteria</p> <p>Age > 18 years old and able to read and write</p> <p>Singleton pregnancy</p> <p>Gestational age at least 37 weeks</p> <p>Cephalic presentation</p> <p>Planned vaginal delivery</p>

	Exclusion criteria Women planned for cesarean delivery
Interventions	Intervention: restrictive episiotomy - to avoid episiotomy unless indicated for fetal indications and/or to avoid severe laceration Control: routine episiotomy - all women receive episiotomy, either medio-lateral or midline according to attending personnel
Outcomes	Primary outcome: severe perineal trauma (third-degree and fourth-degree laceration) Secondary outcomes <ul style="list-style-type: none"> ● Maternal outcomes <ul style="list-style-type: none"> ○ Duration of second stage of labour ○ Posterior perineal trauma ○ Anterior perineal trauma ○ Blood loss ○ Need for suturing ○ Duration of suturing ○ Medication for perineal pain relief ○ Perineal wound haematoma (at time of discharge) ○ Perineal wound dehiscence (at time of discharge) ○ Perineal wound infection (at time of discharge) ● (2) Fetal outcomes <ul style="list-style-type: none"> ○ Birth asphyxia (Apgar score 4-6 at 5 min after birth) ○ Severe birth asphyxia (Apgar score < 4 at 5 min after birth) ○ Need for admission to special care baby unit
Starting date	Pending (not yet recruiting as of August 2016)
Contact information	Jadsada Thinkhamrop; email: jadsada@kku.ac.th
Notes	

RCT: randomised controlled trial

DATA AND ANALYSES

Comparison 1. Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Severe perineal/vaginal trauma	11	6177	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.52, 0.94]
2 Severe perineal/vaginal trauma (grouped by trial implementation success)	11	6177	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.52, 0.94]
2.1 Difference in episiotomy rate < 30%	3	1300	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.63, 1.69]
2.2 Difference in episiotomy rate 30% +	8	4877	Risk Ratio (M-H, Fixed, 95% CI)	0.55 [0.38, 0.81]
3 Blood loss at delivery (mL)	2	336	Mean Difference (IV, Random, 95% CI)	-27.16 [-74.80, 20.49]
4 Newborn Apgar score < 7 at 5 minutes	2	511	Risk Difference (M-H, Fixed, 95% CI)	0.0 [-0.01, 0.01]
5 Perineal infection	3	1467	Risk Ratio (M-H, Fixed, 95% CI)	0.90 [0.45, 1.82]
6 Moderate or severe pain (visual analogue scale)	1	165	Risk Ratio (M-H, Fixed, 95% CI)	0.71 [0.48, 1.05]
7 Dyspareunia long term (≥ 6 m)	3	1107	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.84, 1.53]
8 Genital prolapse long term (≥ 6 m)	1	365	Risk Ratio (M-H, Fixed, 95% CI)	0.30 [0.06, 1.41]
9 Urinary incontinence long term (≥ 6 m)	3	1107	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.67, 1.44]
10 Need for perineal suturing	6		Risk Ratio (M-H, Random, 95% CI)	Totals not selected
11 Admission to special care baby unit	5	2471	Risk Ratio (M-H, Fixed, 95% CI)	0.77 [0.56, 1.07]
12 Pain at different time points (any measure)	4		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
12.1 Any perineal pain at discharge	2	2587	Risk Ratio (M-H, Random, 95% CI)	0.85 [0.25, 2.86]
12.2 Any pain at 10 days	1	885	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.78, 1.27]
12.3 Moderate-severe pain in first 10 days	3	1127	Risk Ratio (M-H, Random, 95% CI)	1.14 [0.61, 2.12]
12.4 Severe or moderate pain at 3 months postpartum	1	895	Risk Ratio (M-H, Random, 95% CI)	1.51 [0.65, 3.49]

Comparison 2. Restrictive versus routine episiotomy (non-instrumental, subgroup by parity)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Severe perineal/vaginal trauma	11	6177	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.52, 0.94]
1.1 Primiparae	11	4137	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.50, 0.93]
1.2 Multiparae	4	2040	Risk Ratio (M-H, Fixed, 95% CI)	0.83 [0.35, 2.01]

Comparison 3. Restrictive versus routine episiotomy (non-instrumental, subgroup midline-midlateral)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Severe vaginal/perineal trauma	10	5977	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.52, 0.94]
1.1 Midline	2	1143	Risk Ratio (M-H, Fixed, 95% CI)	0.74 [0.51, 1.07]
1.2 Mediolateral	8	4834	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.37, 1.04]

Comparison 4. Restrictive versus routine episiotomy (operative vaginal birth was intended)

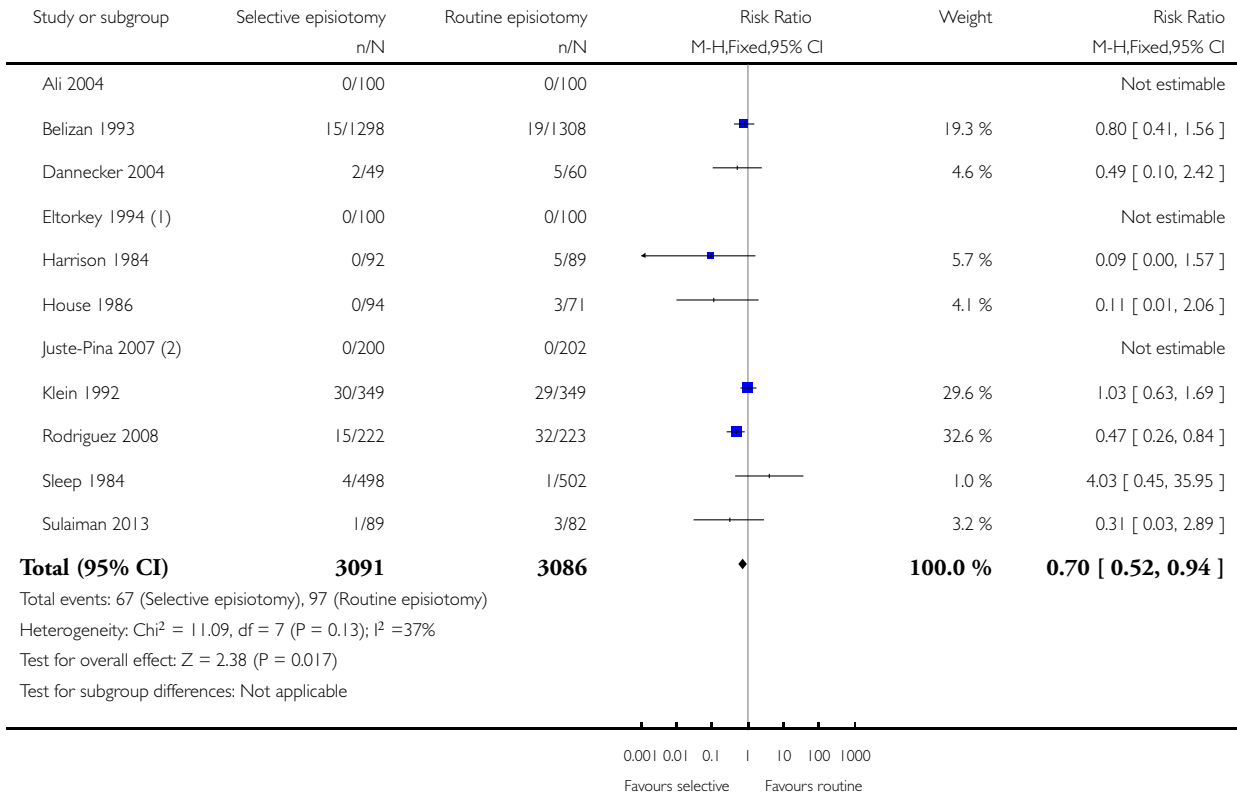
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Severe perineal/vaginal trauma	1	175	Risk Ratio (M-H, Fixed, 95% CI)	1.30 [0.55, 3.07]
2 Apgar < 7 at 5 minutes	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3 Perineal infection	1	175	Risk Ratio (M-H, Fixed, 95% CI)	0.47 [0.04, 5.11]
4 Moderate/severe dyspareunia long term (≥ 6 m)	1	108	Risk Ratio (M-H, Fixed, 95% CI)	3.71 [0.43, 32.16]
5 Urinary incontinence long term (≥ 6 m)	1	108	Risk Ratio (M-H, Fixed, 95% CI)	0.46 [0.09, 2.43]
6 Admission to special care baby unit	1	175	Risk Ratio (M-H, Fixed, 95% CI)	2.13 [0.68, 6.64]

Analysis 1.1. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 1 Severe perineal/vaginal trauma.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 1 Severe perineal/vaginal trauma



(1) No third degree lacerations in either group

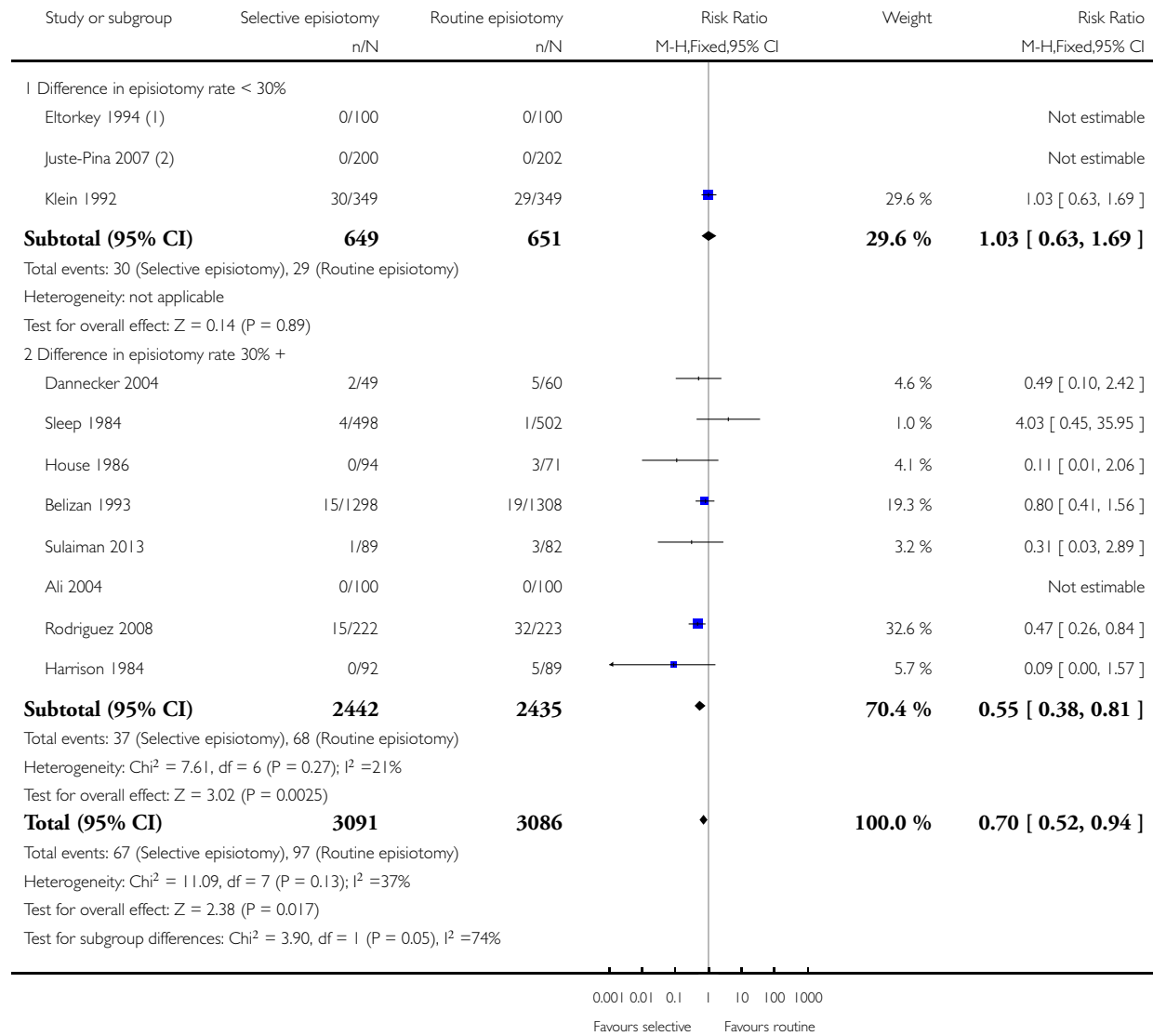
(2) No serious case of perineal trauma (3rd or 4th degree) in either group

Analysis 1.2. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 2 Severe perineal/vaginal trauma (grouped by trial implementation success).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 2 Severe perineal/vaginal trauma (grouped by trial implementation success)



(1) No third degree lacerations in either group

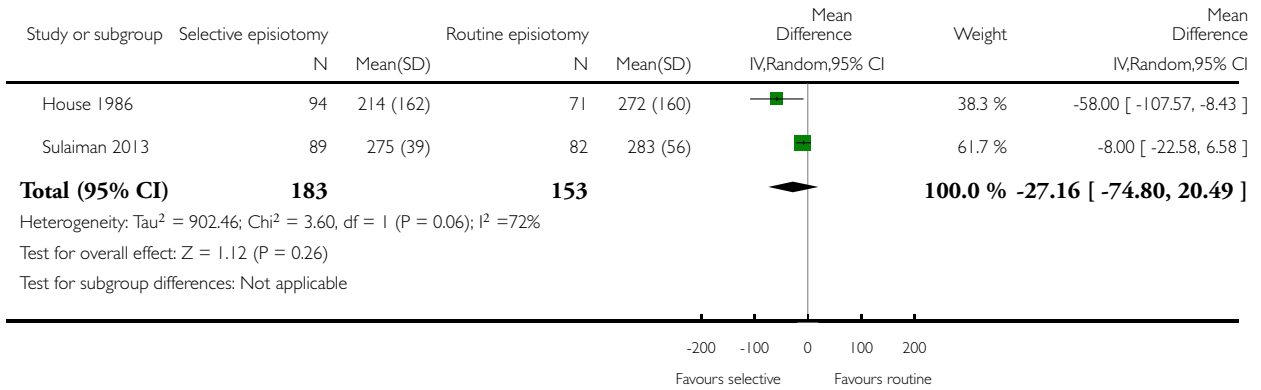
(2) No serious case of perineal trauma (3rd or 4th degree) in either group

Analysis I.3. Comparison I Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 3 Blood loss at delivery (mL).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: I Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 3 Blood loss at delivery (mL)

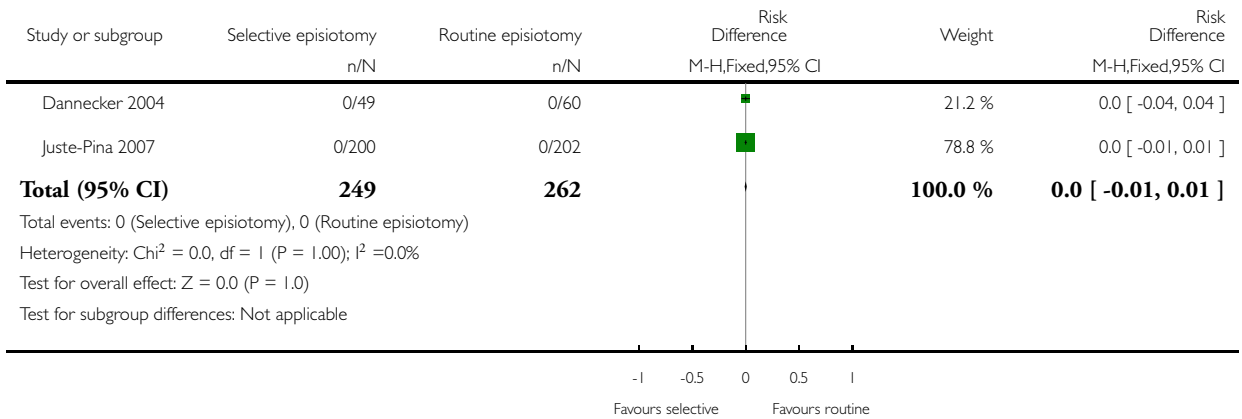


Analysis I.4. Comparison I Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 4 Newborn Apgar score < 7 at 5 minutes.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: I Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 4 Newborn Apgar score < 7 at 5 minutes

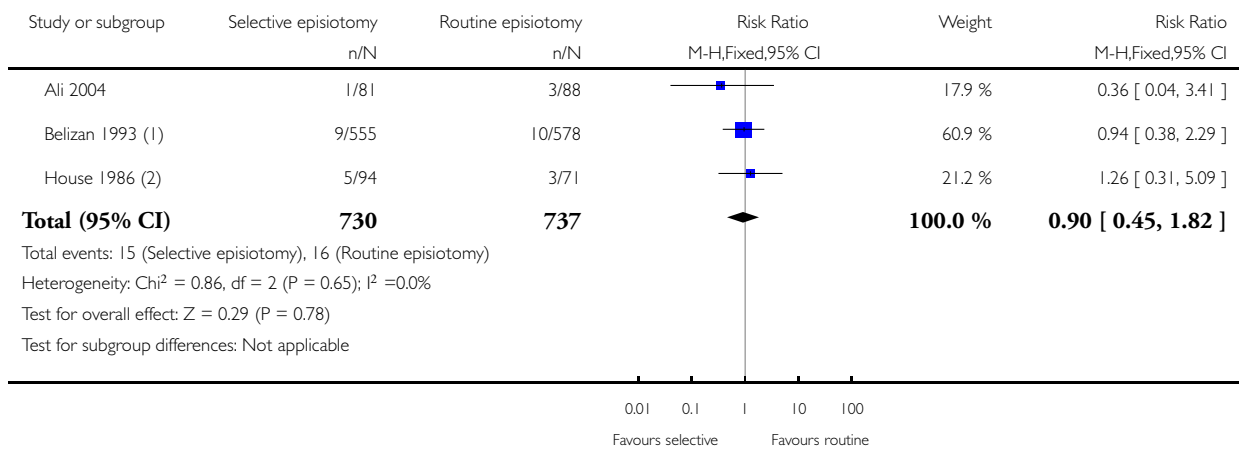


Analysis 1.5. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 5 Perineal infection.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 5 Perineal infection



(1) observed at seventh day post-partum

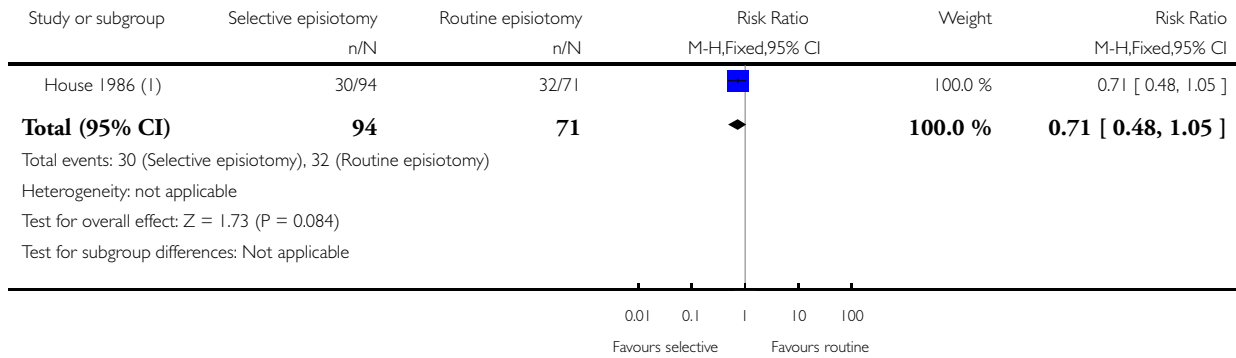
(2) From examination on day 3

Analysis 1.6. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 6 Moderate or severe pain (visual analogue scale).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 6 Moderate or severe pain (visual analogue scale)



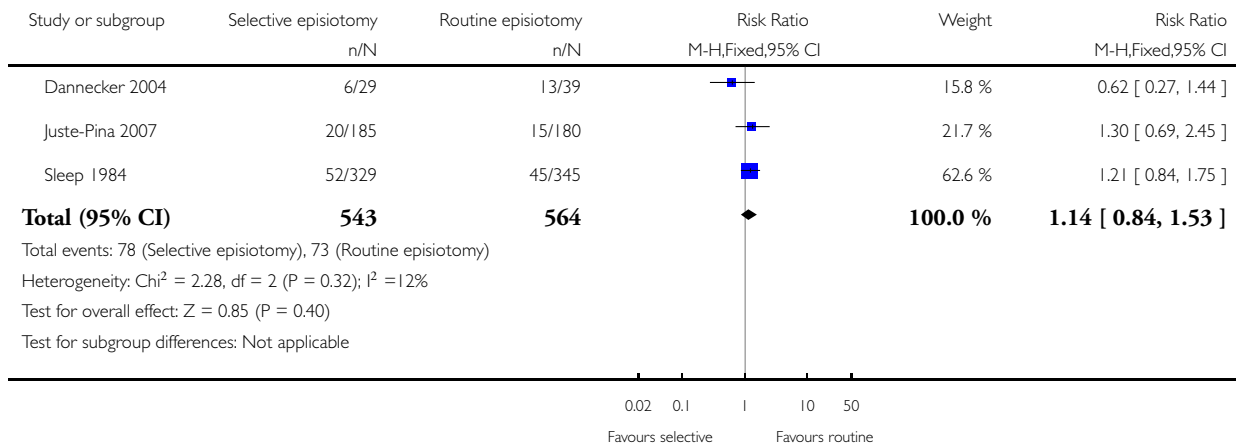
(I) measured at 3 days post-partum

Analysis 1.7. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 7 Dyspareunia long term (≥ 6 m).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 7 Dyspareunia long term (≥ 6 m)

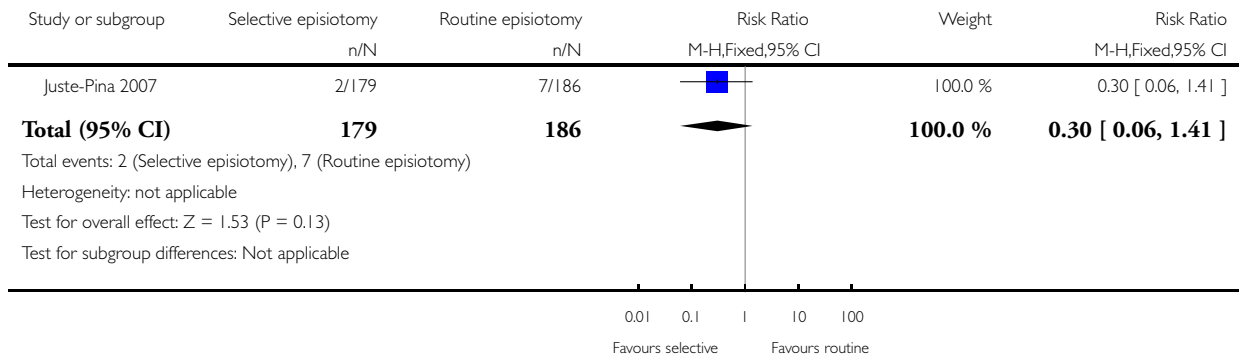


Analysis 1.8. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 8 Genital prolapse long term (≥ 6 m).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 8 Genital prolapse long term (≥ 6 m)

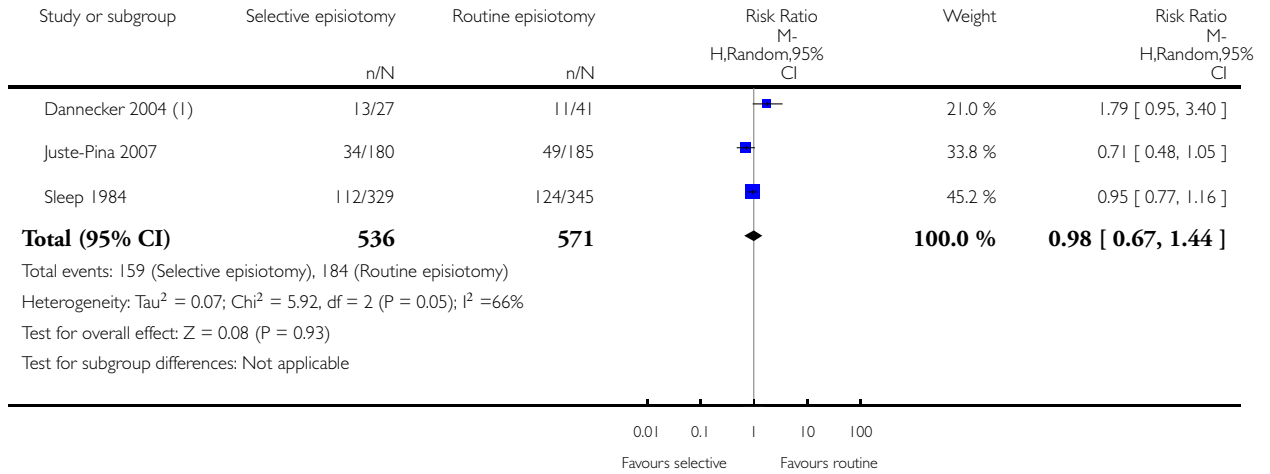


Analysis 1.9. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 9 Urinary incontinence long term (≥ 6 m).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 9 Urinary incontinence long term (≥ 6 m)



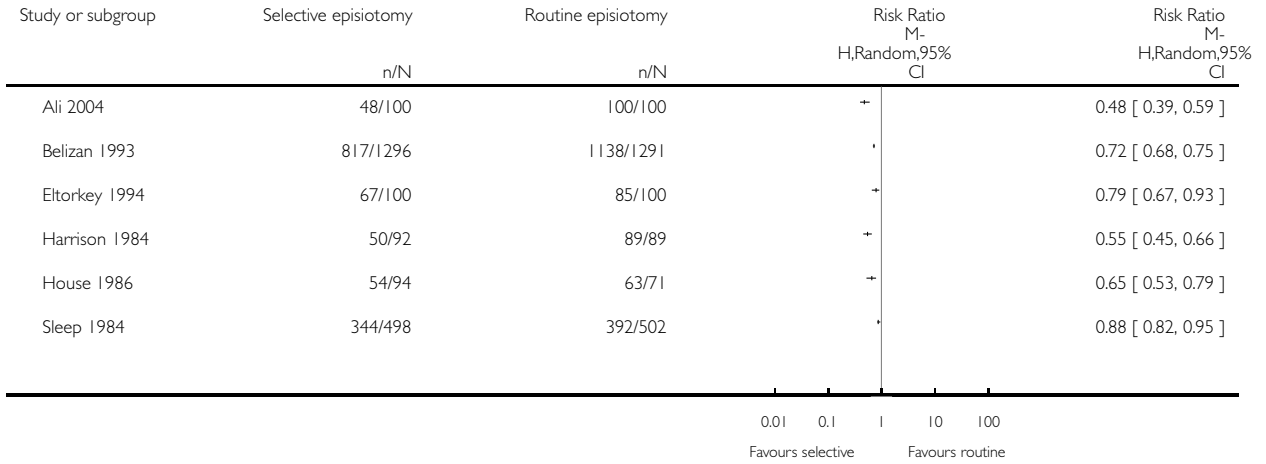
(1) Conducted at 7.3 months of follow up, on average

Analysis 1.10. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 10 Need for perineal suturing.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 10 Need for perineal suturing

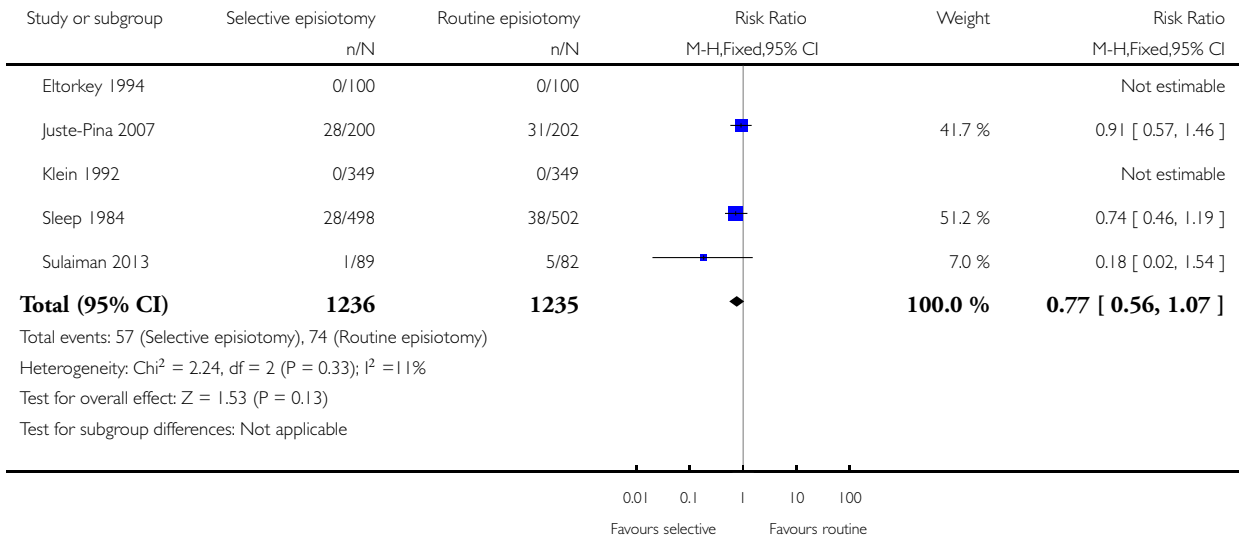


Analysis 1.11. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 11 Admission to special care baby unit.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 11 Admission to special care baby unit

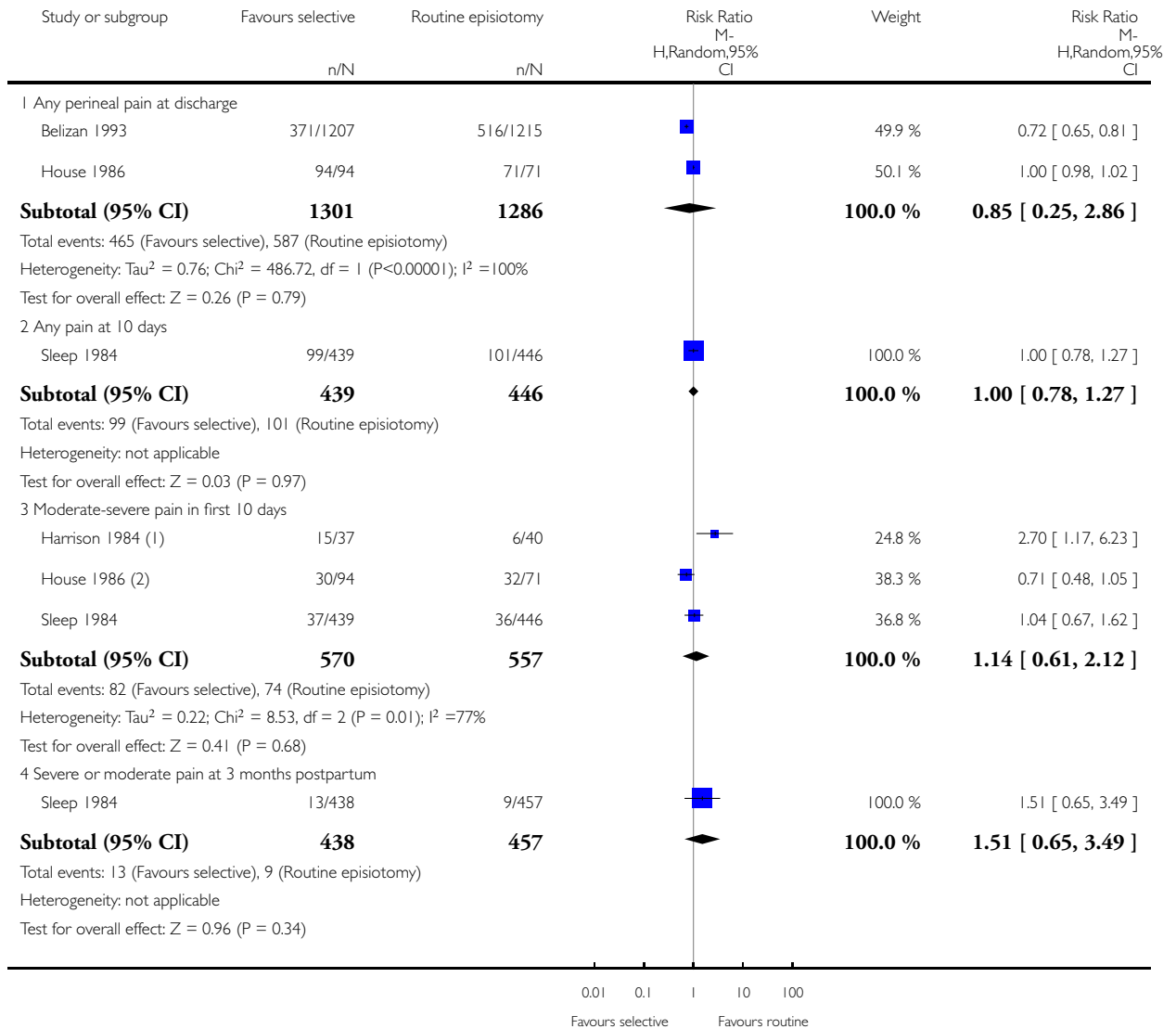


Analysis 1.12. Comparison 1 Restrictive versus routine episiotomy (where non-instrumental was intended), Outcome 12 Pain at different time points (any measure).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 1 Restrictive versus routine episiotomy (where non-instrumental was intended)

Outcome: 12 Pain at different time points (any measure)



(1) assessed at 4 days postpartum

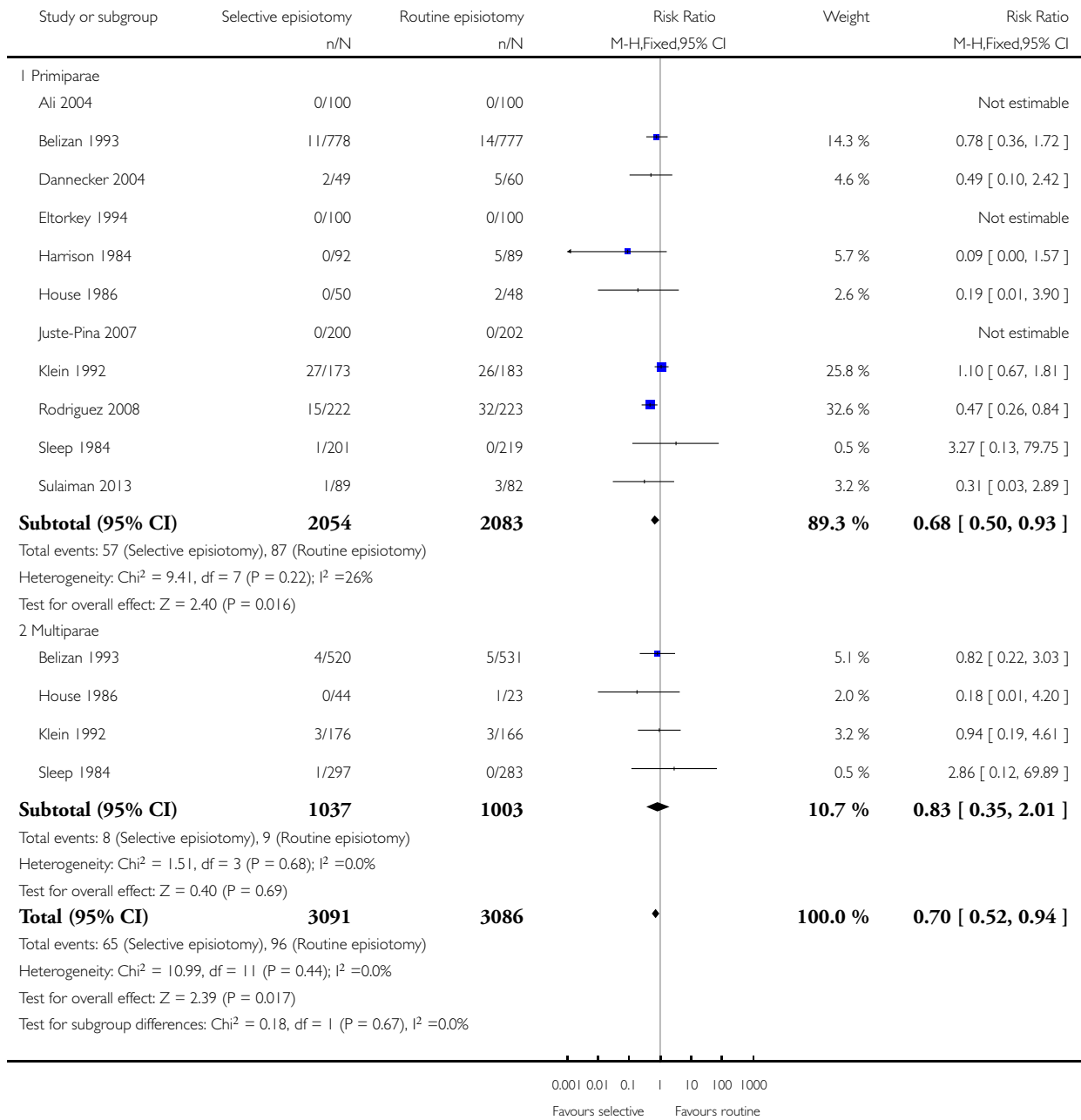
(2) assessed at 3 days postpartum

Analysis 2.1. Comparison 2 Restrictive versus routine episiotomy (non-instrumental, subgroup by parity), Outcome 1 Severe perineal/vaginal trauma.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 2 Restrictive versus routine episiotomy (non-instrumental, subgroup by parity)

Outcome: 1 Severe perineal/vaginal trauma

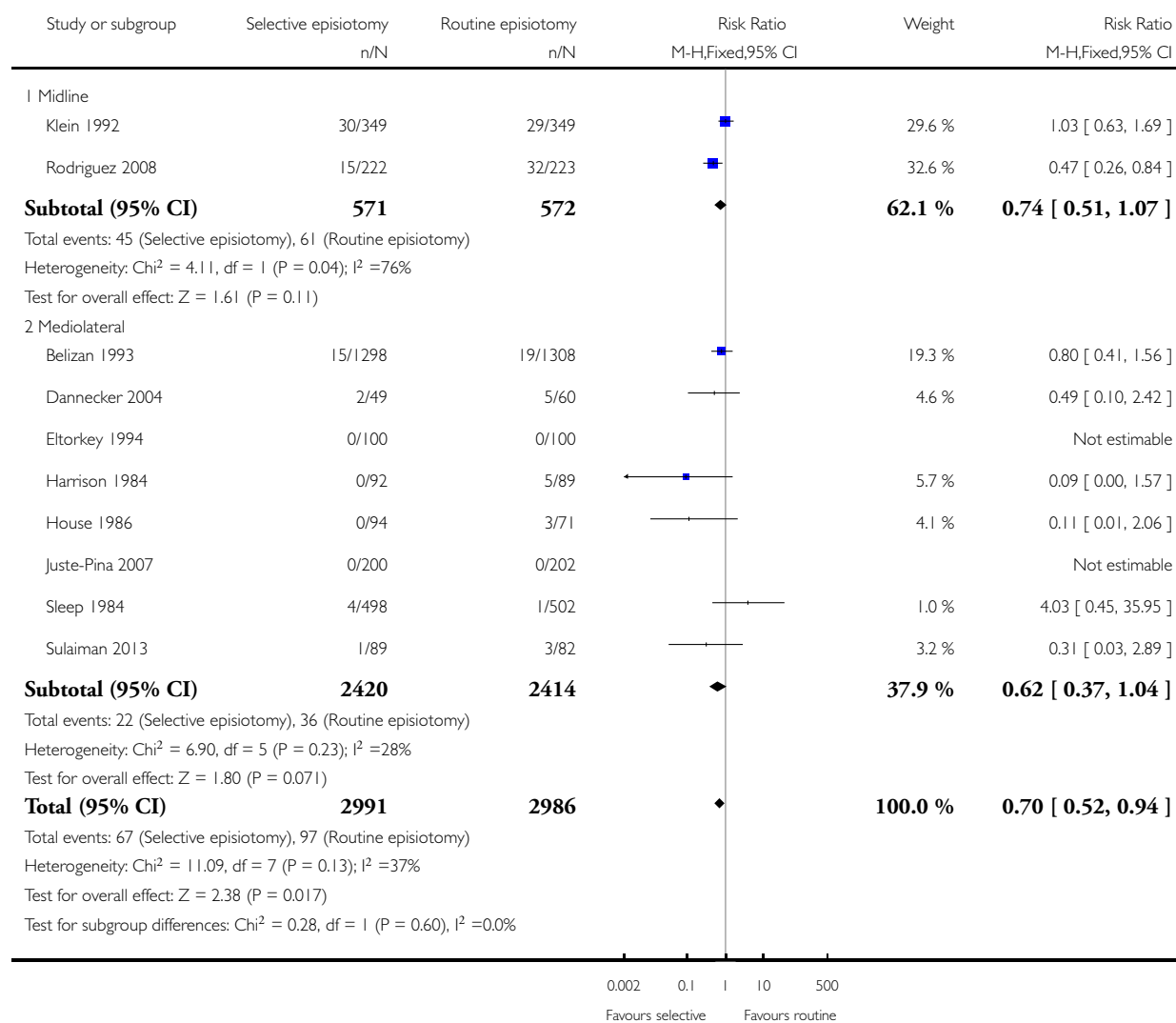


Analysis 3.1. Comparison 3 Restrictive versus routine episiotomy (non-instrumental, subgroup midline-midlateral), Outcome 1 Severe vaginal/perineal trauma.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 3 Restrictive versus routine episiotomy (non-instrumental, subgroup midline-midlateral)

Outcome: 1 Severe vaginal/perineal trauma

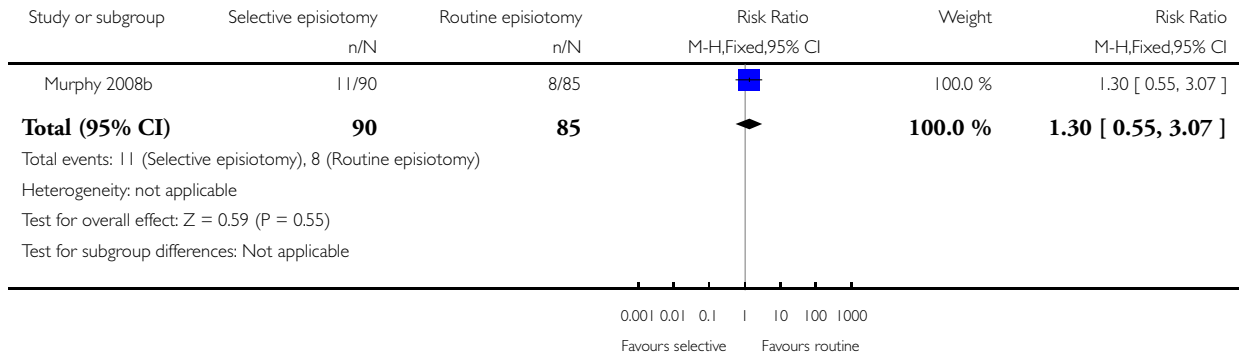


Analysis 4.1. Comparison 4 Restrictive versus routine episiotomy (operative vaginal birth was intended), Outcome 1 Severe perineal/vaginal trauma.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 4 Restrictive versus routine episiotomy (operative vaginal birth was intended)

Outcome: 1 Severe perineal/vaginal trauma

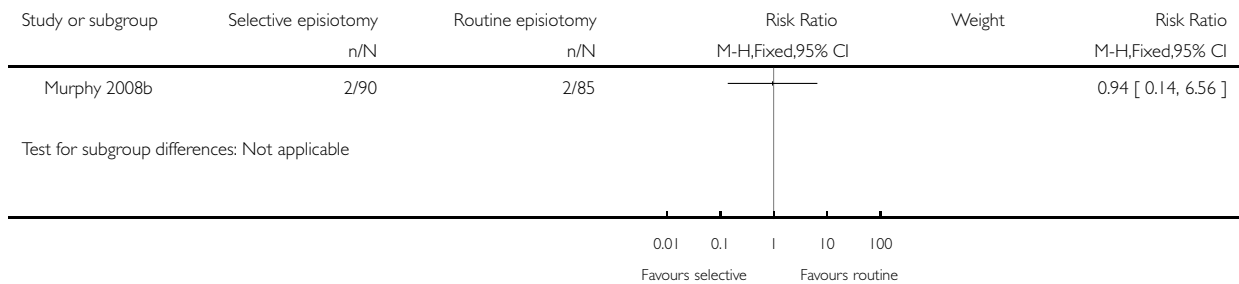


Analysis 4.2. Comparison 4 Restrictive versus routine episiotomy (operative vaginal birth was intended), Outcome 2 Apgar < 7 at 5 minutes.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 4 Restrictive versus routine episiotomy (operative vaginal birth was intended)

Outcome: 2 Apgar < 7 at 5 minutes

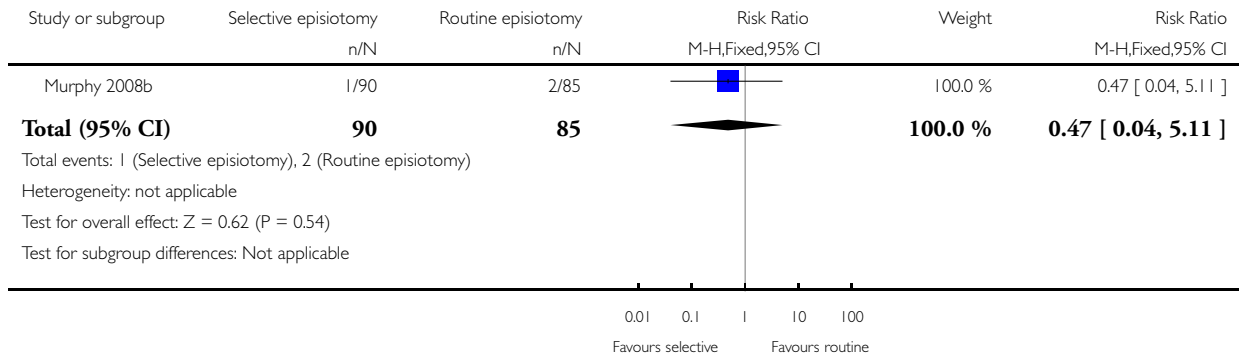


Analysis 4.3. Comparison 4 Restrictive versus routine episiotomy (operative vaginal birth was intended), Outcome 3 Perineal infection.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 4 Restrictive versus routine episiotomy (operative vaginal birth was intended)

Outcome: 3 Perineal infection

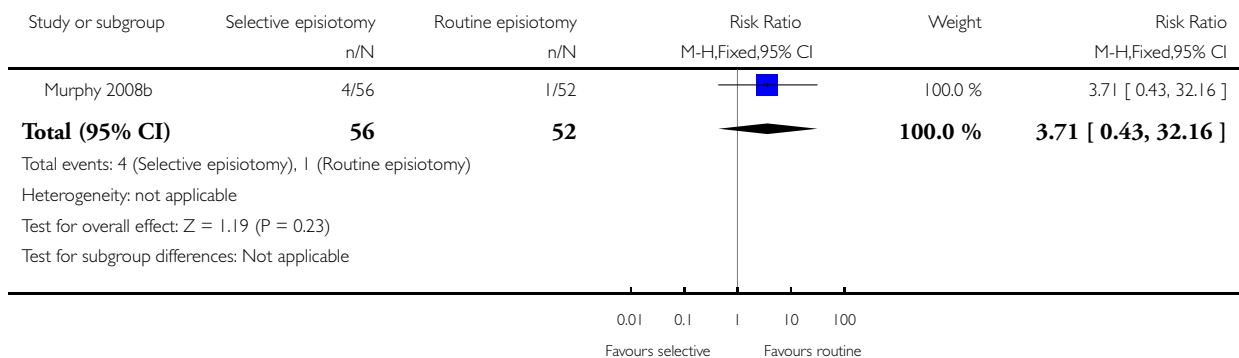


Analysis 4.4. Comparison 4 Restrictive versus routine episiotomy (operative vaginal birth was intended), Outcome 4 Moderate/severe dyspareunia long term (≥ 6 m).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 4 Restrictive versus routine episiotomy (operative vaginal birth was intended)

Outcome: 4 Moderate/severe dyspareunia long term (≥ 6 m)

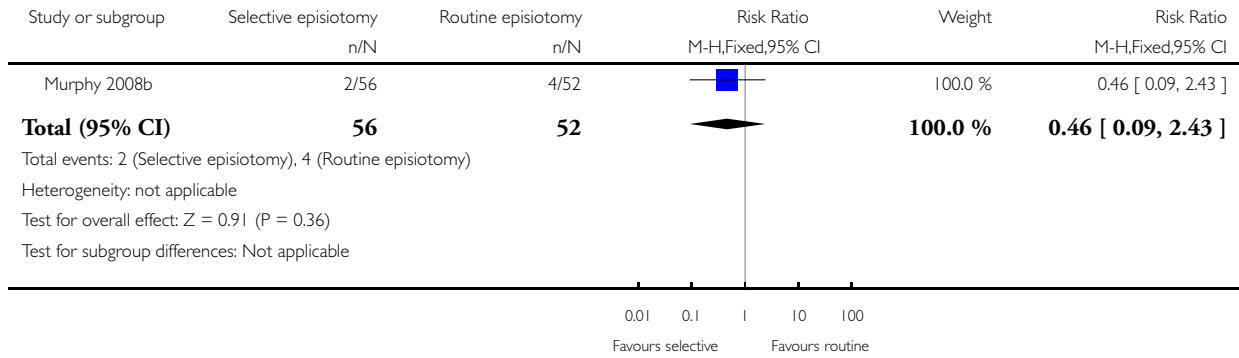


Analysis 4.5. Comparison 4 Restrictive versus routine episiotomy (operative vaginal birth was intended), Outcome 5 Urinary incontinence long term (≥ 6 m).

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 4 Restrictive versus routine episiotomy (operative vaginal birth was intended)

Outcome: 5 Urinary incontinence long term (≥ 6 m)

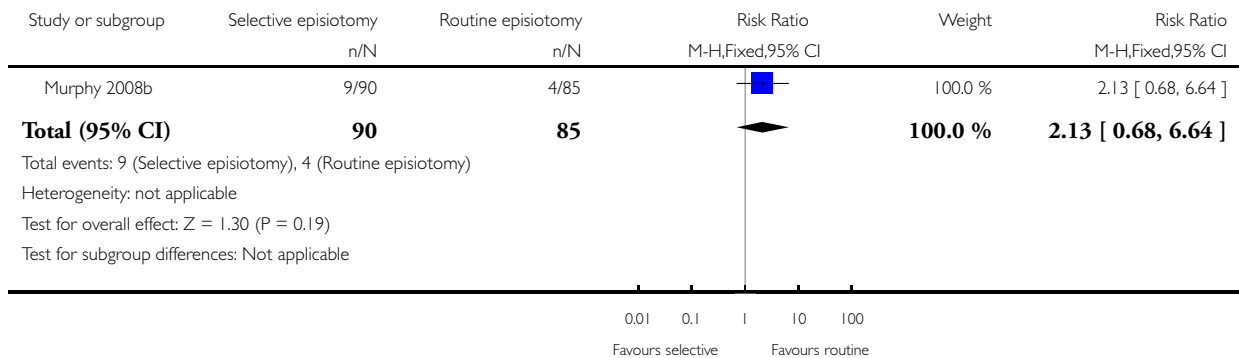


Analysis 4.6. Comparison 4 Restrictive versus routine episiotomy (operative vaginal birth was intended), Outcome 6 Admission to special care baby unit.

Review: Selective versus routine use of episiotomy for vaginal birth

Comparison: 4 Restrictive versus routine episiotomy (operative vaginal birth was intended)

Outcome: 6 Admission to special care baby unit



ADDITIONAL TABLES

Table 1. Included studies: parity, operative vaginal delivery and period of follow-up

Trial	Primigravidae		Follow-up		
	N	per cent (%)	Immediate (< 1 month)	Short-term (1-6 months)	Long-term (\geq 6 months)
Ali 2004	200	100	Discharge & day 7	No data	No data
Belizan 1993	1555/2606	60 ^a	Discharge & day 7	No data	No data
Dannecker 2004	146	100	Discharge	Several months	A mean follow-up time of 7.3 months (SD 3.4)
Eltorkey 1994	200	100	Delivery only	No data	No data
Harrison 1984	181	100	4 days	6 weeks	No data
House 1986	98/165	59	3 days	3 months	No data
Juste-Pina 2007	402	100	No data	3 months	3 years 365/402 (91%)
Klein 1992	356/703	51	Discharge	3 months	No data
Murphy 2008b	200	100	Discharge	6 weeks	1 year
Rodriguez 2008	446	100	Delivery only	N	No data
Sleep 1984	420/1000	42	2 & 10 days	3 months	3 years
Sulaiman 2013	209	100	Delivery only	No data	No data

^aStratified analysis (primary outcome only)

Table 2. Episiotomy rates for included studies (non-operative vaginal delivery anticipated)

Trial	Selective		Routine		Difference (%)
	n/N	%	n/N	%	
Klein 1992	124/349	36	198/349	57	21
Juste-Pina 2007	118/200	59	169/202	84	25
Eltorkey 1994	53/100	53	83/100	83	30
Dannecker 2004	20/49	41	46/60	77	36

Selective versus routine use of episiotomy for vaginal birth (Review)

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Table 2. Episiotomy rates for included studies (non-operative vaginal delivery anticipated) (Continued)

Sleep 1984	51/498	10	258/502	51	41
House 1986	17/94	18	49/71	69	51
Belizan 1993	391/1298	30	1080/1308	83	53
Sulaiman 2013	39/89	44	82/82	100	56
Ali 2004	32/100	32	100/100	100	68
Rodriguez 2008	54/222	24	223/223	100	76
Harrison 1984	7/92	8	89/89	100	92

Table 3. Operative vaginal delivery rates (OVD) in included studies

Trial	OVD Included In trial	Total	Included in analysis	Intervention	Control
Belizan 1993	Y	56/2599	Y	24/1302	32/1297
Dannecker 2004	Y	13/109	Y	4/49	9/60
Eltorkey 1994	Y	9/200	Y	4/100	5/100
Harrison 1984	Y	Unknown	Y	4/92	Unknown
House 1986	Y	20/165	Y	10/94	10/71
Juste-Pina 2007	Unclear	/	/	/	/
Klein 1992	Y	20/703	Y	Unknown	Unknown
Murphy 2008b	ALL	200/200		101/101	99/99
Rodriguez 2008	Y	7/445	Y	3/222	4/223
Sleep 1984	Unknown	/	/	/	/
Ali 2004	Unknown	/	/	/	/
Sulaiman 2013	Unclear	/	/	/	/

Table 4. Trial primary outcomes, and outcomes closest to review primary outcome

Trial	Primary outcome	Outcome related to review primary outcome	Description	Match?
Belizan 1993	Severe perineal trauma	Same	“Extension through the anal sphincter and/or the anal or rectal mucosa (3 rd or 4 th degree lacerations)”	Matches
Ali 2004	Severe perineal trauma	Same	Severe perineal trauma (3 rd and 4 th degree tear)	Matches
Dannecker 2004	Not specified	Severe perineal trauma	“extension through the anal sphincter or rectal mucosa”	Matches
Eltorkey 1994	Not specified	Third-degree tear	“complete tear including the anal sphincter”	Matches
Harrison 1984	Not specified	Third-degree tear	“a complete tear including the anal sphincter, usually extending 2 cm or more up the anal canal”	Matches
House 1986	Not specified	Third-degree tear	“one in which the anal sphincter was involved”	Matches
Juste-Pina 2007	Not specified	Serious case of perineal trauma	“third or fourth degree tear”	Matches
Klein 1992	Not specified	Third- or fourth-degree tear	As stated	Matches
Murphy 2008b^a	Third-/fourth-degree tear	Same	Extensive perineal tearing involving the anal sphincter	Matches
Rodriguez 2008	Severe laceration to perineal tissues	Same	Third-degree laceration when the extent of the lesion including the external anal sphincter totally or partially and 4 th degree laceration when the rectal mucosa was involved	Matches
Sleep 1984	Not known	Severe maternal trauma	Extension through the anal sphincter or to the rectal mucosa or to the upper 3rd of the vagina	Matches

Table 4. Trial primary outcomes, and outcomes closest to review primary outcome (Continued)

Sulaiman 2013	Obstetrical anal sphincter injuries	3 rd /4 th degree	No further details given	Matches
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^aMurphy included only women where operative delivery was anticipated and this is described and analysed separately.

Table 5. Pain assessed using visual analogue scale (3 trials)

Trial	Parity	Time assessed	Outcome	Selective n/N (%)	Routine n/N (%)
House 1986	All parities	day 3	Moderate and severe pain (defined by score categories)	30/94 (32%)	32/71 (45%)
Klein 1992	Primigravida	day 2	Average score	Score 1.4, SD 0.8 (N 150)	Score 1.3, SD 0.7 (N 156)
Klein 1992	Multigravida	day 2	Average score	Score 0.9, SD 0.8 (N 156)	Score 0.9, SD 0.7 (N 145)
Dannecker 2004	Primigravida	1-5 days	Average score	Score 51, SD 25, 22 (N 49)	Score 69, SD 23, 31 (N 60)

Table 6. Dyspareunia in included studies (4 trials)

Trial	Parameter measured	Collection	Selective n/N (%)	Routine n/N (%)
Dannecker 2004	Pain during sex in the last 4 weeks	Questionnaire. Follow up average time of 7.3 months in about 65% of those randomised	6/29 (21%)	13/39 (33%)
Juste-Pina 2007	Dyspareunia at 3 months; and pain with coitus at 3 years postpartum	Telephone survey 3 months postpartum and interview by telephone at 3 years postpartum. Loss to follow up was 6% in the selective, 5% in the routine group at 3 months; and 8% in the selective, 11% in the routine group at 3 years postpartum	3 months postpartum: 42/189 (22%) 3 years postpartum: 20/185 (11%)	3 months postpartum: 67/192 (35%) 3 years postpartum: 15/180 (8%)
Klein 1992	Not reported	Collected but not reported	NA	NA

Table 6. Dyspareunia in included studies (4 trials) (Continued)

Sleep 1984	Reported dyspareunia at 3 months postpartum	Self administered postal questionnaire. Follow up rate 66% in selective, and 69% in routine at 3 years postpartum	3 months postpartum: 87/394 (22%) 3 years postpartum: 52/329 (16%)	3 months postpartum: 74/411 (18%) 3 years postpartum: 45/345 (13%)
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Table 7. Urinary incontinence in included studies (4 trials)

Trial	Parameter measured	Collection	Selective n/N (%)	Routine n/N (%)
Dannecker 2004	Urinary incontinence was considered as present whenever a participant gave an answer other than 'never' when replying to "How often do you leak urine involuntarily?"	Questionnaire. Follow-up average time of 7.3 months in about 65% of those randomised	13/27 (48%)	11/41 (27%)
Juste-Pina 2007	Urinary incontinence at 3 years postpartum	Telephone survey 3 years postpartum. Loss to follow-up was 8% in the selective, 11% in the routine group at 3 years postpartum	34/180 (19%)	49/185 (26%)
Klein 1992	Urinary incontinence at 3 months	Questions employing a 4-point scale	57/337 (17%)	60/337 (18%)
Sleep 1984	Reported urinary incontinence at 3 months after delivery; Reported incontinence of urine at 3 years postpartum	Standardised postal questionnaire administered by mothers at 3 months and 3 years postpartum. Follow-up rate 62% in selective, and 67% in routine at 3 months postpartum; follow-up rate 66% in selective, and 69% in routine at 3 years postpartum	3 months postpartum: 83/438 (19%) 3 years postpartum: 112/329 (34%)	3 months postpartum: 87/457 (19%) 3 years postpartum: 124/345 (36%)

F E E D B A C K

Preston, September 2001

Summary

Results

The relative risks reported in the results section have been calculated using a fixed effects analysis. There is significant heterogeneity in the outcomes for suturing and perineal trauma. Use of the fixed effects approach ignores this variability between studies, producing artificially narrow confidence intervals. For example, the relative risk for 'need for suturing perineal trauma' changes from 0.74 (0.71,0.77) to 0.71(0.61,0.81) with a random effects model, and that for 'any anterior trauma' changes from 1.79 (1.55,2.07) to 1.48 (0.99,2.21). [Summary of comment from Carol Preston, September 2001.]

Reply

In cases of heterogeneity among the results of the studies, it is clearly of interest to determine the causes by conducting subgroup analyses or meta-regression on the basis of biological characteristics of the population, use of different interventions, methodological quality of the studies, etc, to find the source of heterogeneity. Trying to find the source of heterogeneity, we performed beforehand a sensitivity analysis stratifying by parity. When the heterogeneity were not readily explained by this sensitivity analysis, we used a random-effects model. A random-effects meta-analysis model involves an assumption that the effects being estimated in the different studies are not identical, but follow similar distribution. However, one needs to be careful in interpreting these results as, the relative risk summary for the random-effects model tend to show a larger treatment effect than the fixed-effect model while not eliminating the heterogeneity itself (Villar 2001).

Contributors

Guillermo Carroli, Luciano Mignini.

Verdurmen, 1 October 2012

Summary

This important and well-performed review assesses the effects of selective use of episiotomy compared with routine episiotomy during vaginal birth. We would like to have more information on several important definitions, used in this review. It is known that there are several strong indications for the use of an episiotomy, such as fetal distress, breech delivery and assisted delivery. We can presume that with "restricted use of episiotomy" the review authors mean that there was no episiotomy used, unless there was such a strong indication for an episiotomy in that specific case. We wonder what the exact indications were in this specific review. To prevent confusion, we think it is necessary to have a clear description of what is meant by a "restrictive use of episiotomy" policy in this Cochrane review.

The exact definitions of "anterior perineal trauma" and "posterior perineal trauma" are described properly under the subheading "description of the condition". In addition, the various degrees of spontaneous ruptures are well-defined. However, the terms "severe vaginal/perineal trauma" (outcome 5) and "severe perineal trauma" (outcome 8) are not well described. We can assume involvement of the anal sphincter complex (third and fourth degree ruptures) is defined as severe trauma. Unfortunately, this is not described in the background text, although it is of great importance to interpret the outcomes of the review correctly.

Similarly, the exact definitions of Outcomes 21, 24 and 27 (Moderate/severe perineal pain in 3 days; - 10 days; -3 months) are not clear. The methods used in the individual trials to assess the degree of experienced pain, for example the standardized visual analogue score, are not described. In Outcome 33 (Healing complications at 7 days), there is no specification of these complications and/or symptoms involved with healing complications. Therefore, it is not possible for the reader to determine how serious these complications were.

In conclusion, we think that this review would gain strength if the above mentioned definitions are added to the description of the data.

[Comments submitted by KMJ Verdurmen and PJ van Runnard Heimel, September 2012.]

Reply

In this newly updated review, the detailed definitions of severe perineal/vaginal trauma have been listed in the Background. For perineal pain, we have set 'moderate and severe pain measured by the standardized visual analogue score' in the main outcome and included it in the GRADE. We also reported other self-reported pains at different time points of interest. Please refer to Data and Analysis 1.5 and 1.11. We hope the analysis is clear to understand. Thank you for your helpful comments.

Contributors

Hong Jiang, 2016

WHAT'S NEW

Last assessed as up-to-date: 14 September 2016.

Date	Event	Description
13 December 2016	New search has been performed	Search updated. New authors have joined the team for this update We updated the protocol sections to inform this update. Outcomes have been refined and now include neonatal outcomes Four new studies included studies have been added. All data has been re-extracted. Methods have been updated (and now includes the use of GRADE and inclusion of Summary of findings tables). Women where operative delivery was anticipated have been analysed separately. We have also made improvements and changes to the results and conclusions
13 December 2016	Feedback has been incorporated	The authors have responded to Feedback 2 .
1 December 2016	New citation required and conclusions have changed	In women where no instrumental delivery is intended, selective episiotomy policies result in fewer women with severe perineal/vaginal trauma. This suggests that the rationale used to justify routine episiotomy - that it reduces perineal/vaginal trauma - is unfounded. Other findings, both in the short or long term, provide no clear indication of harm of restrictive policies The review thus demonstrates that believing that routine episiotomy reduces perineal/vaginal trauma is not justified by current evidence. Further research in women where instrumental delivery is intended may help clarify if routine episiotomy is useful in this par-

(Continued)

ticular group. These trials should use better, standardised outcome assessment methods

HISTORY

Protocol first published: Issue 2, 1997

Review first published: Issue 2, 1997

Date	Event	Description
20 September 2016	New search has been performed	Updated search
20 April 2016	New search has been performed	Updated search
1 October 2012	Feedback has been incorporated	Feedback 2 added
18 January 2012	Amended	Contact details updated
28 July 2008	New citation required but conclusions have not changed	New author
31 March 2008	New search has been performed	New search conducted; two new studies included (Dannecker 2004; Rodriguez 2008), two excluded (Detlefsen 1980; Dong 2004) and one new ongoing study identified (Murphy 2006)
31 January 2008	Feedback has been incorporated	Response to feedback from Carol Preston added
3 October 2001	Feedback has been incorporated	Received from Carol Preston, September 2001

CONTRIBUTIONS OF AUTHORS

Hong Jiang and Xu Qian screened all the searches, assessed risk of bias, and extracted data from included studies. Hong Jiang and Xu Qian drafted the review. Paul Garner provided critical comments on the revised protocol sections, helped structure the review, assess, summarise and synthesise the data, helped write the review, conducted the GRADE assessment. Guillermo Carroli provided critical comments on the review. All authors reviewed and agreed the final version of the review.

DECLARATIONS OF INTEREST

Hong Jiang received support from the Effective Health care Research Consortium, funded by UK aid from the UK government for the benefit of developing countries (Grant: 5242) - this award was paid to Hong Jiang's institution and was used to support the preparation of this review.

Xu Qian received support from the Effective Health care Research Consortium, funded by UK aid from the UK government for the benefit of developing countries (Grant: 5242) - this award was paid to Xu Qian's institution and was used to support the preparation of this review.

Guillermo Carroli is the principal investigator on a large trial included in this review. Risk of bias assessment, data extraction were carried out by authors independent of GC. PG provided oversight on expression of data from this trial and interpretation of its findings with regard to this potential conflict of interest.

Paul Garner is the Director of the Effective Health Care Research Programme Consortium, a DFID funded research programme that aims to increase the number of decisions in low and middle income countries based on reliable evidence.

SOURCES OF SUPPORT

Internal sources

- Centro Rosarino de Estudios Perinatales, Rosario, Argentina.
- Liverpool School of Tropical Medicine, UK.
- School of Public Health, Fudan University, China.

External sources

- UK Aid (grant 5242), UK.
- UNDP-UNFPA-UNICEF-WHO-World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Reproductive Health and Research (RHR), World Health Organization, Switzerland.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We removed Objective 2 of the protocol, “to compare midline and mediolateral episiotomy” since we found it inappropriate to include this objective in the course of writing the review, as the topic ‘selective versus routine episiotomy for vaginal birth’ and which procedure is used are two different topics. We did look in a subgroup analysis for evidence of a difference in effects depending on the procedure, but there was no obvious pattern. We think it better to carry out another independent review to make this comparison, although we did not find eligible studies comparing these two surgical procedures.

In the protocol, the primary outcome was described as “Severe perineal trauma including, severe vaginal trauma, or severe perineal and vaginal trauma (third- or fourth-degree trauma, irrespective of allocated group, as defined in the background)”. We noted during the review that it was a little ambiguous as to where this actually included vaginal trauma, so we altered the descriptor slightly to make this explicit.

In the protocol we included “first or second degree perineal trauma”. This outcome is uninformative as it excludes women with severe trauma. The outcome, “any trauma” is also uninformative as the control group expects women to receive an episiotomy, which is in effect “second degree trauma” but would not be reported as such. We therefore dropped this outcome.

Since the previous version of this review, we have changed the title from ‘Episiotomy for vaginal birth’ to ‘Selective versus routine use of episiotomy for vaginal birth’ for clarity about the scope of the review.

Since only one trial reported perineal pain measured by visual analogue scale, we also reported pain at different time points by any measure of interest. We think this would be informative for clinical practice.

INDEX TERMS

Medical Subject Headings (MeSH)

*Episiotomy [adverse effects; methods; standards]; *Parturition; Apgar Score; Blood Loss, Surgical; Dyspareunia [epidemiology]; Pain Measurement; Parity; Perineum [*injuries; surgery]; Randomized Controlled Trials as Topic; Surgical Wound Infection [epidemiology]; Urinary Incontinence [epidemiology]

MeSH check words

Female; Humans; Pregnancy