

Surgical repair of spontaneous perineal tears that occur during childbirth versus no intervention

Author

Elharmeel, Suzan, Chaudhary, Yasmin, Tan, Stephanie, Scheermeyer, Elly, Hanafy, Ashraf, van Driel, Mieke

Published

2011

Journal Title

Cochrane Database of Systematic Reviews

DOI

[10.1002/14651858.CD008534.pub2](https://doi.org/10.1002/14651858.CD008534.pub2)

Rights statement

© 2011 The Cochrane Collaboration. Published by JohnWiley & Sons, Ltd. This review is published as a Cochrane Review in the Cochrane Database of Systematic Reviews 2011, Issue. 8. Cochrane Reviews are regularly updated as new evidence emerges and in response to comments and criticisms, and the Cochrane Database of Systematic Reviews should be consulted for the most recent version of the Review.

Downloaded from

<http://hdl.handle.net/10072/42893>

Griffith Research Online

<https://research-repository.griffith.edu.au>

Surgical repair of spontaneous perineal tears that occur during childbirth versus no intervention (Review)

Elharmeel SMA, Chaudhary Y, Tan S, Scheermeyer E, Hanafy A, van Driel ML



**THE COCHRANE
COLLABORATION®**

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2011, Issue 8

<http://www.thecochranelibrary.com>



Surgical repair of spontaneous perineal tears that occur during childbirth versus no intervention (Review)
Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	2
OBJECTIVES	3
METHODS	3
RESULTS	7
DISCUSSION	9
AUTHORS' CONCLUSIONS	9
ACKNOWLEDGEMENTS	10
REFERENCES	10
CHARACTERISTICS OF STUDIES	12
DATA AND ANALYSES	18
ADDITIONAL TABLES	18
APPENDICES	18
HISTORY	19
CONTRIBUTIONS OF AUTHORS	20
DECLARATIONS OF INTEREST	20
SOURCES OF SUPPORT	20
DIFFERENCES BETWEEN PROTOCOL AND REVIEW	20
NOTES	20
INDEX TERMS	20

[Intervention Review]

Surgical repair of spontaneous perineal tears that occur during childbirth versus no intervention

Suzan MA Elharmeel¹, Yasmin Chaudhary², Stephanie Tan², Elly Scheermeyer², Ashraf Hanafy¹, Mieke L van Driel²

¹Department of Obstetrics and Gynaecology, Gold Coast Hospital, Gold Coast, Australia. ²Faculty of Health Sciences and Medicine, Bond University, Gold Coast, Australia

Contact address: Suzan MA Elharmeel, Department of Obstetrics and Gynaecology, Gold Coast Hospital, 108 Nerang Street, Gold Coast, Queensland, 4215, Australia. selharmeel@yahoo.com.au.

Editorial group: Cochrane Pregnancy and Childbirth Group.

Publication status and date: New, published in Issue 8, 2011.

Review content assessed as up-to-date: 28 June 2011.

Citation: Elharmeel SMA, Chaudhary Y, Tan S, Scheermeyer E, Hanafy A, van Driel ML. Surgical repair of spontaneous perineal tears that occur during childbirth versus no intervention. *Cochrane Database of Systematic Reviews* 2011, Issue 8. Art. No.: CD008534. DOI: 10.1002/14651858.CD008534.pub2.

Copyright © 2011 The Cochrane Collaboration. Published by John Wiley & Sons, Ltd.

ABSTRACT

Background

Perineal tears commonly occur during childbirth. They are sutured most of the time. Surgical repair can be associated with adverse outcomes, such as pain, discomfort and interference with normal activities during puerperium and possibly breastfeeding. Surgical repair also has an impact on clinical workload and human and financial resources.

Objectives

To assess the evidence for surgical versus non-surgical management of first- and second-degree perineal tears sustained during childbirth.

Search strategy

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (1 May 2011), CENTRAL (*The Cochrane Library* 2011, Issue 2 of 4) and MEDLINE (Jan 1966 to 2 May 2011). We also searched the reference lists of reviews, guidelines and other publications and contacted authors of identified eligible trials.

Selection criteria

Randomised controlled trials (RCTs) investigating the effect on clinical outcomes of suturing versus non-suturing techniques to repair first- and second-degree perineal tears sustained during childbirth.

Data collection and analysis

Two review authors independently assessed trials for inclusion and assessed trial quality. Three review authors independently extracted data.

Main results

We included two RCTs (involving 154 women) with a low risk of bias. It was not possible to pool the available studies. The two studies do not consistently report outcomes defined in the review. However, no significant differences were observed between the two groups (surgical versus non-surgical repair) in incidence of pain and wound complications, self-evaluated measures of pain at hospital discharge and postpartum and re-initiation of sexual activity. Differences in the use of analgesia varied between the studies, being high in the sutured group in one study. The other trial showed differences in wound closure and poor wound approximation in the non-suturing group, but noted incidentally also that more women were breastfeeding in this group.

Authors' conclusions

There is limited evidence available from RCTs to guide the choice between surgical or non-surgical repair of first- or second-degree perineal tears sustained during childbirth. Two studies find no difference between the two types of management with regard to clinical outcomes up to eight weeks postpartum. Therefore, at present there is insufficient evidence to suggest that one method is superior to the other with regard to healing and recovery in the early or late postnatal periods. Until further evidence becomes available, clinicians' decisions whether to suture or not can be based on their clinical judgement and the women's preference after informing them about the lack of long-term outcomes and the possible chance of a slower wound healing process, but possible better overall feeling of well being if left un-sutured.

PLAIN LANGUAGE SUMMARY

Surgical repair versus non-surgical management of spontaneous perineal tears

Trauma to the perineum of varying degrees constitutes the most common form of obstetric injury. The perineum is the area between the vagina and rectum which can tear during childbirth. In clinical practice these tears are often sutured. However, small tears may also heal well without surgical interference. If pain is experienced, this can result in decreased mobility and discomfort with passing urine or faeces and may negatively impact on the woman's ability to breast feed and care for her new baby. Our review included two randomised controlled trials (involving 154 women) comparing surgical repair of first-degree (involving only the perineal or vaginal skin) or second-degree tears (also involving muscle) with leaving the wound to heal spontaneously. These trials showed no clear differences in clinical outcomes between the groups. The studies did not find any differences in pain immediately and up to eight weeks postpartum. One of the trials reported no difference in wound complications, but the other showed differences in wound closure and poor wound approximation in the non-sutured group. There was no information about the effect on long-term outcomes such as sexual discomfort or incontinence. More research is needed to provide a strong evidence-based recommendation for clinical practice.

BACKGROUND

Trauma to the perineum of varying degrees constitutes the most common form of obstetric injury. In Australia (in 2003) 43.9% of women sustain tears, predominantly first and second degree, 16% have an episiotomy and 1.4% have both an episiotomy and a tear (Laws 2005). In the UK, 15% of women undergo episiotomy and 38% sustain tears (NHS 2005). Further forms of trauma include vaginal laceration and injury to the external genitalia (labia, clitoris, periurethral) (Albers 1999). Approximately 75% of women who give birth vaginally will have tears of various levels of severity in the labia, vagina and perineum (Lundquist 2000). At present, practice regarding management of episiotomy and perineal tears is undergoing change. For example, routine episiotomy has proven to be of little benefit to women (Argentine Episiotomy Trial Group 1993; Larsson 1991; Sleep 1984). This was confirmed in a meta-analysis which provided evidence that avoiding episiotomy decreased perineal tears in subsequent pregnancies (Eason 2000).

Perineal injury is generally classified according to the degree of perineal disruption:

1. a first-degree tear involves only perineal or vaginal skin;

2. a second-degree tear occurs when the perineal skin and muscle are torn;

3. a third-degree tear occurs when in addition to the perineal skin and muscle, the anal sphincter is torn;

4. a fourth-degree tear occurs when the sphincter muscle disruption is complete with additional extension to the anal mucosa (James 2005).

Perineal trauma and its repair are strongly associated with postnatal morbidity including bleeding, infection, pain, urinary and faecal incontinence and sexual dysfunction (Albers 1999; Sleep 1991; Sultan 1994).

It is also known that episiotomies can increase the risk of more severe damage and infection in addition to pain (Isager-Sally 1986; Larsson 1991; Rockner 1991).

For example, pain can result in decreased mobility and discomfort with passing urine or faeces (Kapoor 2005; Sultan 2002) and may negatively impact on the woman's ability to care for her new baby (Sleep 1991). In addition, it may interfere with the overall experience of motherhood and contribute to depression (Hedayati 2003;

Hedayati 2005). Pain that persists beyond the immediate postpartum period may have long-term effects, such as dyspareunia (pain during intercourse) that can last up to 18 months (Buhling 2006).

Prevention or minimisation of perineal trauma can reduce pain associated with or following childbirth. Preventative measures such as perineal massage during pregnancy (Beckmann 2006), mediolateral versus midline episiotomy (Shiono 1990), birthing attendants hands on versus off the perineum during the delivery of the baby's head (McCandlish 1998) and even different methods and materials used for suturing can affect the amount of pain experienced (Kettle 2009; Kettle 2010).

Minor perineal laceration, if left un-sutured, may be associated with less discomfort, less anaesthesia at various points in time (two to three days, eight weeks and six months) and have a positive effect on breastfeeding (Lundquist 2000).

In a large study of 1780 women with first- or second-degree tears following spontaneous or simple instrumental delivery, two-stage perineal repair, leaving the skin un-sutured, appeared to reduce pain and dyspareunia at three months postpartum (Gordon 1998).

Description of the condition

Spontaneous perineal trauma of different degrees (first-, second-, third- or fourth-degree) perineal tears, of different anatomical localisation (labial, periurethral, vaginal or perineal) are associated with spontaneous vaginal delivery or assisted vaginal birth, irrespective of parity (nulliparous or multiparous) in the absence of risk factors such as diabetes mellitus, or increased risk of infection, bleeding or haematoma.

Our review focusses on minor tears, i.e. a first-degree tear involving only the perineal or vaginal skin and a second-degree tear involving perineal skin and muscle.

Description of the intervention

Surgical interventions

Different suturing techniques (continuous or interrupted suturing), as well as different suturing materials (including glue).

Non-surgical interventions

Conservative management which may include a salt bath, cold or hot packs, lotions or vaginal douches.

How the intervention might work

Suturing or using other adhesive interventions (e.g. glue) provides better wound approximation and decreases the risk of bleeding and haematoma formation, but whether it increases the pain and dyspareunia is not clear.

Conservative management may reduce the experienced pain, but whether it has an acceptable long-term outcome still needs to be determined.

Why it is important to do this review

This review provides clinicians with the evidence base for optimal management (to suture or not to suture) of women with spontaneous perineal tears of first and second degree sustained during childbirth.

OBJECTIVES

The objective of this review was to determine the evidence base for surgical versus non-surgical management of minor (first- or second-degree) perineal tears sustained during childbirth.

METHODS

Criteria for considering studies for this review

Types of studies

We included all published and unpublished randomised controlled trials (RCTs) and cluster-RCTs investigating suturing versus non-suturing techniques to repair perineal tears sustained during childbirth. We excluded non-randomised and quasi-randomised trial designs. We included studies presented as abstract if sufficient information on study design and outcome data were available.

Types of participants

Women of all ages who have sustained perineal trauma during vaginal/instrumental delivery due to spontaneous tearing of the perineum. We excluded studies including women with risk factors that may interfere with wound healing, such as increased risk of infection, bleeding or haematoma formation.

Types of interventions

Any perineal repair technique; for example, continuous or interrupted sutures and use of different suturing materials, including glue, versus natural healing without suturing performed by an obstetrician or midwifery staff after birth, with or without supportive treatment such as antibiotics, lotions or baths.

Types of outcome measures

Primary outcomes

- Pain postpartum, including perineal pain, dyspareunia (pain during intercourse), dysuria (pain when urinating), etc (measured as a pain score or analgesic requirement) in the immediate postpartum period (up to 10 days postpartum), within the first six weeks and three and six months postpartum.
- Maternal complications (including wound dehiscence, wound infection, haematoma).

Secondary outcomes

- Perineal pain up to 10 days postpartum, and within six weeks, three months and six months postpartum.
- Dysuria up to 10 days postpartum, and within six weeks, three months and six months postpartum.
- Dyspareunia (three and six months postpartum).
- Wound dehiscence.
- Wound infection.
- Wound haematoma.
- Mobilisation (ability to get out of bed and perform daily activities without assistance or as defined by the authors).
- Interference with daily activity.
- Urinary and faecal incontinence.
- Women's satisfaction regarding the birth experience.
- Psychological and emotional well-being (self-esteem, cosmetic appearance).

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (2 May 2011).

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

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

3. weekly searches of EMBASE;

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

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

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

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

In addition, we conducted an additional search of CENTRAL (2011, Issue 2 of 4) and MEDLINE (Jan 1966 to 2 May 2011) using the search strategies given in [Appendix 1](#).

Searching other resources

We searched for relevant trials in reviews, guidelines and other publications identified when preparing this review. We also contacted authors of identified eligible trials and asked if they had knowledge of other published or unpublished trials. We did not apply any language restrictions.

Data collection and analysis

Selection of studies

Two review authors (S Elharmel (SE), S Tan (ST)) independently examined the abstracts of studies identified by the search strategy. We retrieved full publications of qualifying abstracts. We resolved any discrepancies by discussion and by seeking the opinion of the third review author (Y Chaudhary (YC)). We recorded a log of excluded studies, with reasons for exclusions.

Data extraction and management

We designed a form to extract data. At least three review authors (SE, ST, YC) extracted the data using the agreed form. Two authors scrutinised each paper and resolved any discrepancies through discussion. Authors entered data independently onto a data extracting form. We discussed discrepancies with a fourth review author (E Scheermeyer (ES)) and resolved disagreement by consensus. Two review authors (M van Driel (MVD), ES) checked data and a third (SE) carried out data entry into Review Manager software ([RevMan 2011](#)). The review authors were not blinded to the names of authors, journals or institutions.

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

Assessment of risk of bias in included studies

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

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

For each included study we described the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.

We assessed the method as:

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

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

For each included study we described the method used to conceal the allocation sequence in sufficient detail and determined whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We assessed the methods as:

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

(3) Blinding (checking for possible performance bias)

For each included study we described the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We judged studies at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the 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;
- low, high or unclear risk of bias for outcome assessors.

As the intervention of interest (suturing versus non-suturing) cannot be blinded for participants and personnel, we assessed the aspect of blinding for outcome assessors only (other than the patient).

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

For each included study and outcome we described the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses. We assessed methods as:

- low risk of bias (e.g. no missing outcome data; missing outcome data balanced across groups);
- high risk of bias (less than 80% follow-up);
- unclear risk of bias.

(5) Selective reporting bias

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

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

(6) Other sources of bias

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 is risk of other bias.

(7) Overall risk of bias

We made explicit judgements about whether studies are at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely

magnitude and direction of the bias and whether we considered it likely to impact on the findings. We explored the impact of the level of bias through undertaking sensitivity analyses - see [Sensitivity analysis](#).

Measures of treatment effect

Nominal data: dichotomous data

For dichotomous data, we presented results as a summary risk ratio with 95% confidence intervals.

Nominal data: ordinal data

For nominal data reported on ordinal scales, we converted them into numerical data (e.g. pain scores reported as no pain-moderate pain, severe pain) and analysed by means of a mean difference or standardised mean difference as outlined in the *Handbook* ([Higgins 2011](#)).

Numerical data: continuous data

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

Unit of analysis issues

Cluster-randomised trials

We did not include any cluster-randomised trials for inclusion. If we identify cluster-randomised trials in future updates of this review we will include them in the analyses along with individually-randomised trials. We will adjust their standard errors using the methods described in the *Handbook* using an estimate of the intracluster correlation co-efficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we use ICCs from other sources, we will report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identify both cluster-randomised trials and individually-randomised trials, we plan to synthesise the relevant information. We will consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

We will also acknowledge heterogeneity in the randomisation unit and perform a subgroup analysis to investigate the effects of the randomisation unit.

Crossover trials

Crossover trials are not appropriate for our research question.

Multi-armed trials

If multi-armed trials are included in future updates of this review we will extract data from relevant arms.

Dealing with missing data

For included studies, we will note levels of attrition. In future updates we will explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis. We will exclude studies from meta-analyses if the proportion of missing data is greater than 20%.

For all outcomes, we carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and analysed all participants 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 are known to be missing.

Assessment of heterogeneity

In future updates of this review, as more data become available, we will assess statistical heterogeneity in each meta-analysis using the T^2 , I^2 and Chi^2 statistics. We will regard heterogeneity as substantial if I^2 is greater than 30% and either T^2 is greater than zero, or there is a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

When there are 10 or more studies in the meta-analysis we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes we will use the test proposed by [Egger 1997](#), and for dichotomous outcomes we will use the test proposed by [Harbord 2006](#). If asymmetry is detected in any of these tests or is suggested by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We will carry out statistical analysis using the Review Manager software ([RevMan 2011](#)). In future updates of this review, as more data become available, we will use fixed-effect meta-analysis for combining data where it is reasonable to assume that studies are estimating the same underlying treatment effect: i.e. where trials are examining the same intervention, and the trials' populations

and methods are judged sufficiently similar. If there is clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity is detected, we will use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials is considered clinically meaningful. We will treat the random-effects summary as the average range of possible treatment effects and we will discuss the clinical implications of treatment effects differing between trials. If the average treatment effect is not clinically meaningful we will not combine trials.

If we use random-effects analyses, we will present the results as the average treatment effect with its 95% confidence interval, and the estimates of I^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

In future updates, if we identify substantial heterogeneity, we will investigate it using subgroup analyses and sensitivity analyses. We will consider whether an overall summary is meaningful, and if it is, use random-effects analysis to produce it.

We planned to carry out the following subgroup analyses.

1. Nulliparous versus multiparous, as there may be changes in the elasticity of the perineum after the first birth.
2. Singleton versus multiple pregnancies, as multiple pregnancies may be more traumatising to the perineum.
3. Instrumental versus spontaneous vaginal deliveries.
4. Previous episiotomy versus no previous episiotomy, as a scarred perineum may impair healing of subsequent tear.
5. Comparison by degree of tear (first-, second-, third- or fourth-degree tear).
6. Trial design (cluster-randomised trials versus randomised controlled trials).

We will restrict subgroup analysis to the primary outcomes and will perform only if clinically relevant.

We will compare the results of the between-study subgroup analysis with the within-study subgroup analysis results to explore consistency.

We were not able to perform these subgroup analyses as we did not pool the available studies.

Sensitivity analysis

We planned to perform sensitivity analyses to explore the effect of missing data and heterogeneity, but were not able to pool any studies.

RESULTS

Description of studies

See: [Characteristics of included studies](#); [Characteristics of excluded studies](#).

Results of the search

The search terms identified 107 results. A preliminary screening deleted all but 15 reports (10 studies).

Of these 15 reports, we excluded 12 (eight studies) as they did not meet the inclusion criteria ([Characteristics of excluded studies](#)). This left two RCTs that provided a comparison of suturing versus non-suturing for first- and second-degree wound lacerations after vaginal delivery. The two studies included 154 women.

Included studies

We have included two studies in the review. For further details, see [Characteristics of included studies](#).

[Lundquist 2000](#) recruited 80 participants with minor perineal lacerations who were randomised by a sealed opaque envelope system into a surgical or non-surgical group. In the surgical group, women were sutured with interrupted stitches. Midwives were blinded at allocation; however, blinding was not possible at follow-up visit, as they could easily observe whether suturing had or had not been performed. Participants were assessed at two to three days, eight weeks and six months after delivery. Pain scales were not utilised; however, questionnaires were used to qualitatively determine experiences of pain or discomfort. The questionnaires were also utilised to determine secondary outcomes; including breastfeeding and sexual intercourse experiences. There was 100% follow-up for both groups in the study.

[Fleming 2003](#) recruited 74 participants with first- or second-degree perineal lacerations who were randomised by computer-generated sealed opaque envelopes into sutured or non-sutured groups. Randomisation was stratified by degree of tear. Given the nature of the intervention, it was not possible to blind participants, hospital or research staff to a woman's group allocation. The participants were assessed at days one, 10 and six weeks after vaginal delivery. Perineal pain was measured using the McGill Pain Questionnaire and visual analogue scales. Perineal healing was measured using the REEDA tool. The secondary outcome, postnatal depression, was measured using the Edinburgh Postnatal Depression Scale (EPDS). There was 100% follow-up in the suturing group; however, in the non-suturing group, one woman refused further participation at day 10 and three were unable to be contacted at six weeks.

Excluded studies

We excluded four studies because they included women with episiotomies ([Adoni 1991](#); [Bowen 2002](#); [Kindberg 2008](#); [Mota 2009](#)). The [Gordon 1998](#) study evaluated two-stage perineal repair with a traditional three-stage repair and did not include non-suturing. [Leeman 2007](#) was a prospective cohort study and not a

RCT, and [Sandland 1999](#) was a report of a proposed study (full publication of the trial results were not identified). For further details, see [Characteristics of excluded studies](#).

Risk of bias in included studies

In both studies there was adequate sequence generation and allocation concealment, but blinding was not possible due to the nature of the intervention. Incomplete outcome data were addressed and the studies seemed free of selective reporting, although in the absence of the questionnaires this is difficult to assess. There may have been some bias due to withdrawal of consent in one study ([Fleming 2003](#)). Patients consented before birth, but many with-

Primary outcomes

The primary outcomes of this review were postpartum pain, including perineal pain, dyspareunia, dysuria (measured as pain score or by analgesic requirements) in the immediate postpartum period (up to 10 days postpartum), within six weeks and three months postpartum. Maternal complications including wound dehiscence, infection and haematoma were also included in the primary outcomes.

Perineal pain was assessed using questionnaire only in the [Lundquist 2000](#) study, concluding that the type of pain was different between the two groups; however, the level in discomfort was the same: 55% of the sutured group reported pain versus 50% in the non sutured group in the first two days postpartum. In [Fleming 2003](#), pain was assessed using a questionnaire and visual analogue scale. The authors concluded no significant difference between the two groups in pain (Mann-Whitney U test $P > 0.58$ at day 1 and Day 10 for both scales). This was consistent with the observation that there was also no significant difference in the use of analgesia between the two groups.

When it comes to wound healing, the findings in the two studies are again conflicting. In the [Lundquist 2000](#) study, patients were reviewed in the early postpartum period up to day three, then at two and six months postpartum. They concluded no significant difference in the healing process, with the sutured group having more frequent visits to the midwife. It should be noted that the lack of standard measure to check for healing is an additional variable. However, healing was recorded for each type of laceration (labia, vagina, perineum) separately. In contrast, using the REEDA score, [Fleming 2003](#) reported significantly faster healing being associated with better approximation of the wound in the sutured group in the early postpartum period and up to six weeks ([Table 1](#)).

So, in summary the reported outcomes were pain and wound healing at different times. [Lundquist 2000](#) also reported on sexual intercourse at six months and found no difference in the proportion of women that had intercourse at least once, but comments on experiencing pain during sexual activity varied from 18% in

draw after birth, apparently to avoid suturing. This problem did not occur when women consented after birth.

Effects of interventions

In both studies the control group was sutured. However, the results were presented very differently. [Lundquist 2000](#) presented dichotomous data, whereas [Fleming 2003](#) presented continuous data with the median using a variety of scales as recommended in [Lundquist 2000](#). Consequently none of the data could be combined in one table and hence we have presented them in an additional table ([Table 1](#)).

the sutured group to 8% in the non-suture group. [Fleming 2003](#) reported no significant difference on depression using the EPDS score at 10 days and six weeks postpartum.

There was no significant difference for all primary outcomes in both groups, except better wound healing and approximation at six weeks follow-up in the sutured group in [Fleming 2003](#). There was a significantly higher ($P = 0.001$) proportion of women with a closed tear (REEDA approximation score of zero) in the sutured group (26/31) compared with the non-sutured group (16/36), i.e. 84% versus 44% (Analysis 1.1).

The rest of our primary outcomes were not reported in these studies, i.e. dyspareunia, dysuria, wound dehiscence and wound infection.

Secondary outcomes

The secondary outcomes in our reviews included:

- perineal pain up to 10 days postpartum, and within six weeks, three months and six months postpartum;
- dysuria up to 10 days postpartum, and within six weeks, three months and six months postpartum;
- dyspareunia (three and six months postpartum);
- wound dehiscence;
- wound infection;
- wound haematoma;
- mobilisation (ability to get out of bed and perform daily activities without assistance or as defined by the authors);
- interference with daily activity;
- urinary and faecal incontinence;
- women's satisfaction regarding the birth experience;
- psychological and emotional well-being (self-esteem, cosmetic appearance).

[Lundquist 2000](#) reported that 16% in the sutured group versus 0% in the non-sutured group considered the laceration a negative influence on their breastfeeding practices. Overall, the evidence suggested that minor perineal lacerations should be left to heal

without surgical intervention and that those who sustain more serious tears have better wound healing six weeks postpartum if sutured.

[Fleming 2003](#), on the other hand, reported a difference between the sutured versus the non-sutured groups in relation to wound healing and wound approximation at six weeks.

There was no long-term follow-up reported in either of the two studies.

The following of our secondary outcomes were not reported: interference with daily activity, urinary and faecal incontinence, women's satisfaction regarding the birth experience, and psychological and emotional well-being (self-esteem, cosmetic appearance).

DISCUSSION

Our review has found only two trials (involving 154 women) comparing suturing versus natural healing of first- to second-degree perineal tears post-vaginal delivery. Both studies report on relatively short-term outcomes only. They do not find any differences between groups with regard to pain immediately and up to six months' follow-up postpartum. However, the results of wound healing are different in the [Fleming 2003](#) study and hence the conclusions differ. [Lundquist 2000](#) concluded that it is safe to leave small perineal tears un-sutured, whereas [Fleming 2003](#) concludes that the perineum does not heal as well when left un-sutured. However, since 30 of the 33 women sutured had a second-degree tear, there is no evidence in favour of suturing first-degree tears.

[Lundquist 2000](#) indicated that, while the type of pain was different in the two groups, the sutured group had more follow-up visits with the midwife due to discomfort. In this study a validated pain scale was not used and pain was assessed using questionnaires to qualitatively determine experiences of pain and discomfort. However, in the [Fleming 2003](#) study, standardised measurement of pain did not result in differences between groups.

The outcome of the surgical group is dependent on several factors such as type of anaesthetics used, suture material, suturing technique and skill of the operator. It is not clear how the applied suturing techniques played a role in the outcome assessment. Several studies have shown the importance of different suture techniques and different materials on the clinical experience of the woman ([Fleming 1990](#); [Grant 1989](#); [Mahomed 1989](#)). Disadvantages of suturing that have been reported include interference with breastfeeding ([De Chateau 1977](#); [Salariya EM](#)), more burning sensation, longer healing process ([Lundquist 2000](#)). Leaving the perineum to heal spontaneously allows better freedom of movement so the woman can concentrate on breastfeeding. [Lundquist](#) indeed reports higher satisfaction with breastfeeding in the non-sutured group ([Lundquist 2000](#)). The [Fleming 2003](#) study shows that suturing is unlikely to have an impact on the prevalence of postnatal

depression, but the group may be too small to draw conclusions regarding this outcome.

Unfortunately, neither of the two available trials reported on longer-term follow-up of perineal functional outcomes such as obstetric future (consecutive pregnancies), urinary or faecal incontinence, psychological well being and sexual function, although [Lundquist](#) received more comments on pain with sexual intercourse at six months from the sutured group than from the non-sutured group.

A concern is the low number of women included in both studies. The sample size is too small to draw a meaningful conclusion, especially with results contradicting each other. In [Lundquist 2000](#), the number of patients was only 40 in each group. In [Fleming 2003](#), the eligible number of patients was just 74, with 41 left to heal spontaneously and 33 being allocated to the suture group (of which only three were sutured following a first-degree tear). There may have been a lack of power to detect meaningful differences between groups.

There may also be some concerns about the selection and inclusion of women into both studies. Far more women than expected were excluded immediately after birth and prior to randomisation, due to medical intervention or intact perineum. Closure of a nearby maternity hospital increased the workload in the labour ward of the main study site, causing women to be missed, and many women appeared to change their minds just to avoid suturing ([Fleming 2003](#)). Also lack of acceptance in conducting the study was reported, as the study interfered with the personal and clinical judgement of the attending midwives. Therefore the midwife's attitude is an important factor to take into account when assessing the necessity of suturing following a tear.

[Lundquist 2000](#) used a specially trained team of midwives to administer the intervention, thereby limiting generalisability of the findings.

AUTHORS' CONCLUSIONS

Implications for practice

Minor perineal tears (of first and second degree) occur frequently during vaginal childbirth (in approximately 50% of women) and it is unclear if suturing is needed. In spite of this, only two randomised controlled trials (RCTs) compare suturing versus natural healing of first- and second-degree perineal tears. These trials found no meaningful difference in pain or discomfort up to eight weeks postpartum, but one study suggests that wound healing might be faster after suturing. However, the rate of breastfeeding is lower. In the other study, the use of analgesics was still high at eight weeks (11%) in the sutured group, while no analgesics were used in the non-sutured group. Long-term follow-up including functional (perineal function) and psychological well being (quality of life, mental health, mother and child bonding etc) is not

reported. Also, long-term outcomes and complications of perineal tears and/or suturing, such as dyspareunia or incontinence are not reported.

Therefore, at present there is insufficient evidence to suggest that one method is superior to the other with regard to healing and recovery in the early or late postnatal periods in women with perineal lacerations during vaginal birth. Absence of evidence is not equal to absence of effect. Therefore this review doesn't justify a recommendation to change clinical practice at this stage. However, it points to an important clinical issue that deserves further study. Women should be offered an informed choice and information should include the lack of data on the long-term outcomes (the ones that impact on a woman's life).

Implications for research

There is a need for further research to assess the effects of suturing versus non intervention of the perineum on pain and long-term functional outcomes.

Future randomised controlled trials should address the following.

- The short-term effect related to recovery and birth experience.

- Possible risk factors affecting outcomes (e.g. active bleeding, tear size and depth and associated maternal risk factors which may affect healing, such as diabetes mellitus).

- The long-term effect on future pregnancies and labour (whether one method is more associated with recurrence/worsening tears or not).

- Effect of suturing on the woman's psychological and sexual well being.

- Effect on long-term (i.e. many years instead of only six months after the delivery) perineal function, such as urinary and faecal incontinence.

Any future RCT should be adequately powered to detect important differences in clinically relevant outcomes.

ACKNOWLEDGEMENTS

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

REFERENCES

References to studies included in this review

Fleming 2003 *{published data only}*

Fleming V. Does perineal suturing following childbirth make a difference? A randomised controlled trial. National Research Register (www.controlled-trials.com) (accessed 12 June 2002).

* Fleming VE, Hagen S, Niven C. Does perineal suturing make a difference? The suns trial. *British Journal of Obstetrics & Gynaecology* 2003;**110**(7):684-9.

Lundquist 2000 *{published data only}*

Lundquist M, Olsson A, Nissen E, Norman M. Is it necessary to suture all lacerations after a vaginal delivery?. *Birth* 2000;**27**(2):79-85.

References to studies excluded from this review

Adoni 1991 *{published data only}*

Adoni A, Anteby E. The use of Histoacryl for episiotomy repair. *British Journal of Obstetrics and Gynaecology* 1991;**98**:476-8.

Bowen 2002 *{published data only}*

Bowen ML, Selinger M. Episiotomy closure comparing enbucrilate tissue adhesive with conventional sutures. *International Journal of Gynecology & Obstetrics* 2002;**78**: 201-5.

Gordon 1998 *{published data only}*

D'Souza D. The Ipswich childbirth study: 1 A randomised evaluation of two stage postpartum perineal repair leaving the skin unsutured. *British Journal of Obstetrics and Gynaecology* 1999;**106**(1):89-90.

* Gordon B, Mackrodt C, Fern E, Truesdale A, Ayers S, Grant A. The Ipswich childbirth study: 1 A randomised evaluation of two stage postpartum perineal repair leaving the skin unsutured. *British Journal of Obstetrics & Gynaecology* 1998;**105**(4):435-40.

Grant A, Gordon B, Mackrodt C, Fern E, Truesdale A, Ayers S. The Ipswich childbirth study: one year follow up of alternative methods used in perineal repair. *BJOG: an international journal of obstetrics and gynaecology* 2001;**108**(1):34-40.

Mackrodt C, Fern E, Gordon B. Ipswich childbirth study - perineal suturing study. Proceedings of Research in Midwifery Conference; 1993 Sept 14; Birmingham, UK. 1993.

Kindberg 2008 *{published data only}*

Kindberg S, Stehouwer M, Hvidman L, Henriksen TB. Postpartum perineal repair performed by midwives: a randomised trial comparing two suture techniques leaving the skin unsutured. *BJOG: an international journal of obstetrics and gynaecology* 2008;**115**(4):472-9.

Leeman 2007 {published data only}

Leeman LM, Rogers RG, Greulich B, Albers LL. Do unsutured second degree perineal lacerations affect postpartum functional outcomes?. *Journal of the American Board of Family Medicine* 2007;**20**(5):451–7.

Mota 2009 {published data only}

Mota R, Costa F, Amaral A, Oliveira F, Santos CC, Ayres-De-Campos D. Skin adhesive versus subcuticular suture for perineal skin repair after episiotomy--a randomized controlled trial. *Acta Obstetrica et Gynecologica Scandinavica* 2009;**88**(6):660–6.

Rogers 2009 {published data only}

Rogers RG, Borders N, Leeman LM, Albers LL. Does spontaneous genital tract trauma impact postpartum sexual function?. *Journal of Midwifery & Women's Health* 2009;**54**(2):98–103. [PubMed: 19249654]
Rogers RG, Leeman LM, Migliaccio L, Albers LL. Does the severity of spontaneous genital tract trauma affect postpartum pelvic floor function?. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2008;**19**(3):429–35. [PubMed: 17896065]

Sandland 1999 {published data only}

Sandland D. Perineal tears - audit and proposed rct [letter]. *Midwifery Today* 1999;**2**(9):32.

Additional references**Albers 1999**

Albers L, Garcia J, Renfrew M, McCandlish R, Elbourne D. Distribution of genital tract trauma in childbirth and related postnatal pain. *Birth* 1999;**26**(1):11–5.

Argentine Episiotomy Trial Group 1993

Argentine Episiotomy Trial Collaborative Group. Routine vs selective episiotomy: a randomised controlled trial. *Lancet* 1993;**342**(8886-8887):1517–8.

Beckmann 2006

Beckmann MM, Garrett AJ. Antenatal perineal massage for reducing perineal trauma. *Cochrane Database of Systematic Reviews* 2006, Issue 1. [DOI: 10.1002/14651858.CD005123.pub2]

Buhling 2006

Buhling KJ, Schmidt S, Robinson JN, Klapp C, Siebert G, Dudenhausen JW. Rate of dyspareunia after delivery in primiparae according to mode of delivery. *European Journal of Obstetrics & Gynecology and Reproductive Biology* 2006;**124**(1):42–6.

De Chateau 1977

De Chateau P, Winberg B. Long term effect on mother-infant behaviour of extra contact during the first hour post partum. A follow up at 3 months. *Acta Paediatrica Scandinavica* 1977;**66**:145–51.

Eason 2000

Eason E, Labrecque M, Wells G, Feldman P. Preventing perineal trauma during childbirth: a systematic review. *Obstetrics & Gynecology* 2000;**95**(3):464–71.

Egger 1997

Egger M, Davey Smith G, Schneider M, Minder C. Bias in meta-analysis detected by a simple, graphical test. *BMJ* 1997;**315**(7109):629–34.

Fleming 1990

Fleming N. Can the suturing methods make a difference in postpartum perineal pain?. *Journal of Nurse-Midwifery* 1990;**35**:19–25.

Grant 1989

Grant A. The choice of suture materials and repair of perineal trauma. *British Journal of Obstetrics and Gynaecology* 1989;**96**:1281–9.

Harbord 2006

Harbord RM, Egger M, Sterne JA. A modified test for small-study effects in meta-analyses of controlled trials with binary endpoints. *Statistics in Medicine* 2006;**25**(20):3443–57.

Hedayati 2003

Hedayati H, Parsons J, Crowther CA. Rectal analgesia for pain from perineal trauma following childbirth. *Cochrane Database of Systematic Reviews* 2003, Issue 3. [DOI: 10.1002/14651858.CD003931]

Hedayati 2005

Hedayati H, Parsons J, Crowther CA. Topically applied anaesthetics for treating perineal pain after childbirth. *Cochrane Database of Systematic Reviews* 2005, Issue 2. [DOI: 10.1002/14651858.CD004223.pub2]

Higgins 2011

Higgins JPT, Green S, editors. *Cochrane Handbook for Systematic Reviews of Interventions* Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from www.cochrane-handbook.org.

Isager-Sally 1986

Isager-Sally I, Legarth J, Jacobsen B, Bostofte E. Episiotomy repair - immediate and long-term sequelae. A prospective randomized study of three different methods of repair. *British Journal of Obstetrics and Gynaecology* 1986;**93**:420–5.

James 2005

James DK, Steer PJ, Weiner CP, Gonik B. *High risk pregnancy: management options*. 3rd Edition. London: Saunders, 2005.

Kapoor 2005

Kapoor DS, Thakar R, Sultan AH. Combined urinary and faecal incontinence. *International Urogynecology Journal and Pelvic Floor Dysfunction* 2005;**16**(4):321–8.

Kettle 2009

Kettle C, Hills RK, Ismail KMK. Continuous versus interrupted sutures for repair of episiotomy or second degree tears. *Cochrane Database of Systematic Reviews* 2007, Issue 4. [DOI: 10.1002/14651858.CD000947.pub2]

Kettle 2010

Kettle C, Johanson RB. Absorbable suture materials for primary repair of episiotomy and second degree tears. *Cochrane Database of Systematic Reviews* 2010, Issue 6. [DOI: 10.1002/14651858.CD000006]

Larsson 1991

Larsson PG, Platz-Christensen JJ, Bergman B, Wallsterson G. Advantage or disadvantage of episiotomy compared with spontaneous perineal laceration. *Gynecologic and Obstetric Investigation* 1991;**31**(4):213–6.

Laws 2005

Laws PJ, Sullivan EA. *Australia's mothers and babies 2003. Perinatal Statistics Series. Number 16.* Sydney: AIHW National Perineal Statistics Unit, 2005.

Mahomed 1989

Mahomed K. A randomised comparison of suture materials and suturing techniques for repair of perineal trauma. *British Journal of Obstetrics and Gynaecology* 1989;**96**:1272–80.

McCandlish 1998

McCandlish R, Bowler U, van Asten H, Berridge G, Winter C, Sames L, et al. A randomised controlled trial of care of the perineum during second stage of normal labour. *British Journal of Obstetrics & Gynaecology* 1998;**105**(12):1262–72.

NHS 2005

Government Statistical Service. *NHS Maternity Statistics.* Department of Health, 2005.

RevMan 2011

The Nordic Cochrane Centre, The Cochrane Collaboration. Review Manager (RevMan). 5.1. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2011.

Rockner 1991

Rockner G. *Reconsideration of the use of episiotomy in primiparas [thesis].* Stockholm: Karolinska Institutet, 1991.

Salariya EM

Salariya EM, Easton PM, Cater JL. Infant feeding: duration of breast feeding after early initiation and frequent feeding. *Lancet* 1978;**2**:1141–3.

Shiono 1990

Shiono P, Klebanoff MA, Carey JC. Midline episiotomies: more harm than good?. *Obstetrics & Gynecology* 1990;**75**(5):765–70.

Sleep 1984

Sleep J, Grant A, Garcia J, Elbourne D, Spencer J, Chalmers I. West Berkshire perineal management trial. *BMJ* 1984;**289**(6445):587–90.

Sleep 1991

Sleep J. Perineal care: a series of five randomized controlled trials. In: Robinson S, Thomson A editor(s). *Midwives, research and childbirth.* Vol. 2, London: Chapman and Hall, 1991:199–251.

Sultan 1994

Sultan AH, Kamm MA, Bartram CI, Hudson CN. Perineal damage at delivery. *Contemporary Reviews in Obstetrics and Gynaecology* 1994;**6**:18–24.

Sultan 2002

Sultan AH, Thakar R. Lower genital tract and anal sphincter trauma. *Best Practice & Research. Clinical Obstetrics & Gynaecology* 2002;**16**(1):99–115.

* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Fleming 2003

Methods	Parallel group randomised controlled trial performed at Bellshill Maternity Hospital, Lanarkshire and St John's Hospital, Livingston	
Participants	<p>A total of 1314 women were recruited to the trial antenatally from whom 74 were randomised either to be sutured (N = 33; i.e. 3 first-degree tear and 30 second-degree tear) or not sutured (N = 41; i.e. 15 first-degree tear and 26-second degree tear) immediately after giving birth.</p> <p>Inclusion criteria: primiparous women who had given birth spontaneously to singleton, cephalic presenting babies after 37 weeks of gestation and who had sustained first- or second-degree perineal lacerations</p> <p>Excluded from the trial were women with pre-existing medical conditions that may adversely affect healing, women who required assisted births, women who developed pyrexia and women who developed primary postpartum haemorrhages</p>	
Interventions	<p>In the intervention group, suturing was carried out in accordance with hospital protocols in a standardised manner by the midwife attending the birth. Dexon was used as follows</p> <ol style="list-style-type: none"> 1. Continuous suture to the posterior vaginal wall. 2. Intermittent sutures to the muscle layer. 3. Continuous subcutaneous sutures to the perineal skin. <p>In the control group the lacerations were left to heal spontaneously</p>	
Outcomes	<p>The primary outcomes were perineal pain and perineal wound healing at 1 and 10 days and 6 weeks postpartum. Perineal pain was measured using the McGill Pain Questionnaire and visual analogue scales. Perineal healing was measured using the REEDA tool</p> <p>The secondary outcomes were postnatal depression, which was measured using the Edinburgh Postnatal Depression Scale, at 10 days and 6 weeks postpartum</p> <p>All results are presented as median and difference in medians (95% confidence interval)</p>	
Notes	<p>Source of funding: grant from the Chief Scientist's Office, Scotland</p> <p>Ethical approval was granted by the health boards concerned, and permission from the NHS Trusts to access potential participants was obtained</p>	
<i>Risk of bias</i>		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	A pool of random numbers, sufficient for the intended size of the trial, was computer-generated by SH. Even and odd numbers were assigned the instructions 'suture' and 'not suture', respectively. These instructions, in their original random order, were transferred to cards

Fleming 2003 (Continued)

		Each card was then placed in an opaque envelope and sealed. This process was used to produce separate supplies of randomisation envelopes for first- and second-degree tears, to facilitate stratification by degree of tear. However, reporting did combine degree of tear despite unequal numbers sutured
Allocation concealment (selection bias)	Low risk	Sealed, opaque envelopes were held by a neighbouring hospital switchboard where staff operated the randomisation. The labour ward midwife wishing to randomise an eligible woman telephoned this switchboard, informed them of the degree of tear and received instructions regarding whether to suture or not
Blinding (performance bias and detection bias) All outcomes	High risk	“Given the nature of the intervention, it was not possible to blind participants, hospital or research staff to a woman’s group allocation”
Incomplete outcome data (attrition bias) All outcomes	Low risk	At day 1 attrition 100%, 1 participant withdrew at day 10 from the “not suture” (ns) group (s = 33, ns = 40). At 6 weeks an additional 3 participants of the ns group were lost to follow-up (s = 33, ns = 37). In addition, 3 participants data were missing from the Reeda scale (s = 31, ns = 36). No explanation was provided for the absence of the latter data Analysis for all outcomes on remaining participants.
Selective reporting (reporting bias)	Low risk	All outcomes were reported. Shortcomings in the study were noted and additional observations in contrast to the general outcome of the study of supporting suture were provided, e.g. a positive effect on breast-feeding in the non-suture group
Other bias	High risk	Consent was sought in the antenatal period with randomisation of those assessed as eligible after birth. However, many women appeared to be ‘changing their minds’ about participating following the births of their babies. The attending midwife may have influenced this decision, particularly in cases where, having withdrawn, the women

Fleming 2003 (Continued)

		would not then be sutured. Midwives may have avoided suturing due to lack of confidence in undertaking this procedure and some midwives were hostile to the study by not being able to exercise their clinical judgement
--	--	--

Lundquist 2000

Methods	Randomised controlled trial. Participants randomly assigned at a University Hospital in Stockholm, Sweden
Participants	<p>80 healthy primiparas with a normal term pregnancy (37-42 weeks). The experimental group (n = 40) was not sutured, the control group (n = 40) was sutured.</p> <p>Study information was provided at 34-36 weeks' gestation, consent requested straight after birth when eligible</p> <p>Inclusion criteria: participants had an adequate mastery of Swedish, were non-smokers during the pregnancy, had a normal spontaneous delivery, and gave birth to a healthy child</p> <p>Participants had minor lacerations (grade I-II), i.e.:</p> <ul style="list-style-type: none"> a. labia minora: laceration should not bleed; the labia were not to be ripped apart; b. vagina: laceration should not bleed and the edges should fall well together; the mucus should not be completely separated from the bottom of the vagina; c. perineum: laceration should not bleed; lacerations should fall well together when the woman put her legs together; the depth and length of the laceration should not exceed 2 x 2 cm <p>Exclusions were women that were smokers, non-fluent in Swedish, those requiring instrumental or operative delivery, delivery of a non-healthy neonate and those that were sutured with a non-absorbable material</p> <p>No loss to follow-up noted at 6 months post-trial.</p>
Interventions	<p>Suturing was performed according to current hospital practice. The technique included 1 layer of interrupted stitches in the labia, the vagina, and the perineum and subcuticular technique in the perineum, using polyglycolic acid (Dexon)</p> <p>Xylocaine spray and/or pudendal block with mepivacaine (10 mg/mL) were used as anaesthetics when suturing</p> <p>In the experimental group the lacerations were left to heal spontaneously</p>
Outcomes	<p>The primary outcomes were perineal pain and wound healing of the labia, vagina and perineum. Pain, discomfort and wound healing were measured at three follow-up intervals: first at 2-3 days after vaginal delivery, then at 8 weeks and a final follow-up at 6 months post-delivery</p> <p>Participants were retrospectively asked about their experience of discomfort or pain in the preceding period using a questionnaire. No pain scales were utilised. The questionnaires were derived from discussions in focus groups consisting of the authors and midwives from several antenatal clinics. At the first 2 follow-up examinations the midwife assessed the laceration with respect to healing, edema, haematoma, bleeding, and infection</p> <p>Secondary outcomes were the effect on breastfeeding and subsequent intercourse, also</p>

Lundquist 2000 (Continued)

	assessed by questionnaire The results are presented as mean and standard deviation for characteristics of participants. Most results were categorical and analysed with Chi ²	
Notes	Source of funding: not reported. The study was approved by the local ethics committee.	
Risk of bias		
Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The randomisation was performed in advance. 40 opaque envelopes containing study protocols were assigned to the suturing (control) group and another 40 opaque envelopes were assigned to the non-suturing (experimental) group The 80 envelopes were sealed, thoroughly mixed, and numbered in order before placed in a box
Allocation concealment (selection bias)	Low risk	If a woman consented, the midwife picked the top envelope to allocate her to suture or no suture. The box was placed at the delivery ward in the midwife's office
Blinding (performance bias and detection bias) All outcomes	High risk	Neither the participant or midwife/personnel could be blinded Also no blinding possible at follow-up check up: because, at least at the first checkup, the midwife could easily observe whether suturing had or had not been performed
Incomplete outcome data (attrition bias) All outcomes	Low risk	2 exclusions were reported due to intervention error in the suture procedure Results for all remaining 78 participants reported. 1 participant did not answer the question on intercourse at 6-month questionnaire
Selective reporting (reporting bias)	Unclear risk	Difficult to assess. Questionnaire not included.
Other bias	Unclear risk	Pain and discomfort had to be remembered over previous time intervals in the questionnaire and women with sutures used analgesia more frequently than the non-suture group up to 8 weeks postpartum. This

Lundquist 2000 (Continued)

	would affect the pain and discomfort experience
--	---

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Adoni 1991	Included patients with episiotomies.
Bowen 2002	Included patients with episiotomies - not representative of target population
Gordon 1998	Evaluated 2-stage perineal repair compared with a traditional 3-stage repair. Did not cover non-suturing technique
Kindberg 2008	Comparison was focused on suture techniques and included patients with episiotomies. Compares a continuous suture technique with interrupted sutures using inverted knots for postpartum perineal repair of second-degree lacerations and episiotomies
Leeman 2007	Prospective cohort study, was not a randomised controlled trial
Mota 2009	The population included patients undergoing medio-lateral episiotomies at vaginal delivery (N = 100)
Rogers 2009	Cohort study. Included third- and fourth-degree tear and did not report first and second degree separately
Sandland 1999	Reference to a proposed study; full publication of the trial results not identified

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Main outcomes of included studies

Study	N	Outcome assessment	Outcome
Fleming 2003	74	Day 1 and 10; 6 weeks	<ol style="list-style-type: none"> 1. Pain < 10 days: (McGill and VAS at day 1): n = 74; difference in median = 1 and 0 respectively, (95% CI = -2, 4.99 and -8, 8 respectively). Both not SD (McGill and VAS at day 10): n = 73; difference in median = 0 and 0 respectively, (95% CI = 0, 0.001 and -2, 0.0001 respectively). Both not SD 2. Pain up to 6 weeks (McGill and VAS): n = 69; difference in median = 0 and 0 respectively, (95% CI = 0, 0 and 0, 0.0002 respectively). Both not SD 3. Complications not recorded. 4. Use of analgesia: Not significant different, result not shown 5. Wound healing (REEDA total) Day 10: n = 73; difference in median = 0, (95% CI = -1, 0). P = 0.07, not SD 6. Wound healing (REEDA approximation and total) up to 6 weeks: n = 67; difference in median = 0 and 0 respectively, (95% CI = -0.9999, 0.0001 and -0.9998, 0 respectively). P = 0.001 and P = 0.003, both SD 7. Postnatal depression (EPDS) at Day 10 and 6 weeks: sutured vs non-sutured = median 6 vs 5 and 2.5 vs 4; 95% CI = -1.999, 2.001 and -3, 0.999 not SD
Lundquist 2000	80	2-3 days; 8 weeks; 6 months	<ol style="list-style-type: none"> 1. Pain < 10 days (self-reported pain up to 2 days): 55% in sutured group and 50% in non-sutured group 2. Pain up to 3 months (self-reported pain): 13% in sutured group and 8% in non-sutured group 3. Pain up to 6 months (self-reported pain): 0% in sutured group and 0% in non-sutured group 4. Use of analgesia: 18% sutured vs 8% non-sutured at 2-3 days and 11% sutured vs 0% non-sutured at 8 weeks 5. Wound healing (midwife evaluation) < 10 days: <i>vagina</i> n = 70; 92% sutured group vs 78% non-sutured ; <i>perineum</i> n = 43; 89% sutured group vs 87% non-sutured. 6. Wound healing (midwife evaluation) up to 3 months: <i>vagina</i> not SD; <i>perineum</i> not SD. 7. Suturing had no SD on the length of breastfeeding, but had a negative influence on breastfeeding according to 16% in sutured group vs 0% in non-sutured group (P = 0.03) 8. At 6 months 90% of sutured and 89% of non-sutured women had intercourse at least once, but 18% of sutured women thought sexual activity painful versus 8% of non-sutured women

SD: standard deviation

vs: versus

APPENDICES

Appendix I. Search strategies for CENTRAL and MEDLINE

CENTRAL

- #1 MeSH descriptor Parturition explode all trees
- #2 MeSH descriptor Delivery, Obstetric explode all trees
- #3 vagina* near deliver*
- #4 birth or childbirth
- #5 MeSH descriptor Perineum explode all trees
- #6 perine*
- #7 MeSH descriptor Vulva explode all trees with qualifier: IN
- #8 MeSH descriptor Vagina explode all trees with qualifier: IN
- #9 suture* or repair* or non-suture* or non-repair* or surgical* or stitch* or unrepair* or unsuture*
- #10 (#1 OR #2 OR #3 OR #4)
- #11 (#5 OR #6 OR #7 OR #8)
- #12 (#9 AND #10 AND #11)

MEDLINE via OVID (1966 to current)

- 1 exp Parturition/
2 Delivery, Obstetric/
3 (vagina\$ adj2 deliver*).mp.
4 (birth or childbirth).mp.
5 Perineum/
6 perine\$.ti,ab.
7 Vulva/in
8 Vagina/in
9 randomized controlled trial.pt.
10 controlled clinical trial.pt.
11 randomized.ab.
12 placebo.ab.
13 drug therapy.fs.
14 randomly.ab.
15 trial.ab.
16 groups.ab.
17 or/9-16
18 (animals not (humans and animals)).sh.
19 1 or 2 or 3 or 4
20 5 or 6 or 7 or 8
21 17 and 19 and 20
22 (suture\$ or repair\$ or non-suture\$ or non-repair\$ or surgical\$ or stitch\$ or unrepair\$ or unsuture\$).mp.
23 21 and 22
24 23 not 18

HISTORY

Protocol first published: Issue 6, 2010

Review first published: Issue 8, 2011

CONTRIBUTIONS OF AUTHORS

Suzan Elharmeel (SE) registered the title and is guarantor for the review. SE, Yasmin Chaudhary, Stephanie Tan, Elly Scheermeyer and Mieke van Driel (MvD) developed the protocol with input from Ashraf Hanafy (AH). AH provided a clinical perspective and MvD provided methodological guidance and supervision.

DECLARATIONS OF INTEREST

The authors have no known conflicts of interest.

SOURCES OF SUPPORT

Internal sources

- PHCRED, Australia.

The medical students (Y Chaudhary and S Tan) received an encouragement award upon completion of the review from the Primary Health Care Research Evaluation and Development Program (PHCRED) at Bond University.

External sources

- No external support received, Australia.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

We have reported on additional outcomes, including use of analgesics and initiation of breast feeding as these were considered meaningful outcomes to women.

NOTES

None.

INDEX TERMS

Medical Subject Headings (MeSH)

*Watchful Waiting; Lacerations [*surgery]; Obstetric Labor Complications [*surgery]; Perineum [*injuries]; Randomized Controlled Trials as Topic; Rupture, Spontaneous [etiology; surgery]; Soft Tissue Injuries [surgery]

MeSH check words

Adult; Female; Humans; Pregnancy