

Appendix 2 Table of included studies - report 250E

Table 1. Main characteristics of systematic reviews with low or moderate risk of bias (high or moderate study quality).

Titel First author Year Reference Country	Objectives Outcomes	Number of included studies (participants) Study design of included studies	Main results and the estimated level of evidence according to the systematic review
Suturing of perineal trauma and sphincter ruptures			
Dudley et al. 2013 [20] United Kingdom	To evaluate the therapeutic effectiveness of secondary suturing of dehisced perineal wounds compared to non-suturing (healing by secondary intention, expectancy). Outcomes considered Wound healing within 4 weeks PP. Resumed intercourse within 2 months or 6 months PP Dyspareunia at 2 or 6 months PP	2 studies from Denmark (52 women with a dehisced and/or infected episiotomy wound). However, only one study was included in each analysis and the number of participants varied from 17 to 35 women. RCTs were included	There is currently insufficient evidence available to either support or refute secondary suturing for the management of broken down perineal wounds following childbirth. There is an urgent need for a robust randomised controlled trial to evaluate fully the comparative effects of both treatment options. The level of evidence was not determined.
Elharmeel et al. 2011 [19] Australia	To assess the evidence for surgical (any perineal repair technique) versus non-surgical management of first- and second-degree perineal tears sustained during childbirth. Outcomes considered Pain (day 1 day to 6 months PP) Discomfort (2 days to 6 months PP) Use of analgesia Wound healing (2 days to 6 months PP) Dyspareunia	2 studies (154 women) (conducted in Sweden and in the UK) RCTs were included	The two studies could not be analysed together. 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. The surgery techniques used in the two studies were either “one layer of interrupted stiches in the labia, the vagina and the perineum and subcuticular technique in the perineum using polyglycolic acid” or “continuous sutures to the posterior vaginal wall, intermittent sutures to the muscle layer, continuous subcutaneous sutures to the perineal skin using polyglycolic acid”.

			<p>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.</p> <p>The level of evidence was not determined.</p>
<p>Fernando et al. 2013 [21] United Kingdom</p>	<p>To compare the effectiveness of overlap repair versus end-to-end repair following obstetric anal sphincter injuries (OASIS) in reducing subsequent anal incontinence, perineal pain, dyspareunia and improving quality of life.</p> <p>Outcomes considered Faecal urgency Flatus incontinence Faecal incontinence Alteration in faecal incontinence Deterioration of anal incontinence symptoms Perineal pain Need for perineal injection Perineal pain/dyspareunia Dyspareunia Quality of life Anal incontinence score Anal incontinence score >10</p> <p>Depending on outcome analysed, the follow-up time varied from 6 weeks to 36 months PP.</p>	<p>In total 6 studies (588 women) were included.</p> <p>However, depending on outcome analysed, the number of studies and participants varied from 1 to 3 studies and 41 to 256 women, respectively.</p> <p>RCTs were included</p>	<p>The available data shows that at one-year follow-up, immediate primary overlap repair of the external anal sphincter compared with immediate primary end-to-end repair appears to be associated with lower risks of developing faecal urgency and anal incontinence symptoms. At the end of 36 months follow-up there appears to be no difference in flatus or faecal incontinence between the two techniques.</p> <p>More research evidence is needed in order to confirm or refute these findings.</p> <p>The level of evidence was not determined.</p>
<p>Kettle et al 2010 [17] United Kingdom</p>	<p>To assess the effects of different suture materials on short- and long-term morbidity following perineal repair.</p> <p>Materials compared Fast absorbing versus standard synthetic sutures. Absorbable monofilament sutures versus standard polyglycolic sutures.</p> <p>Outcomes considered Short term pain Long term pain Use of analgesic</p>	<p>Only parts of the review relevant for this systematic map are included, which included 6 studies and 3488 women in total. However, the number of studies and participants varied from 1 to 4 studies and 727 to 1968 women, respectively, depending on comparison and outcome analysed.</p> <p>RCTs and quasi-randomised trials were included, of which they also accepted studies that were only reported as abstracts.</p>	<p>There was no difference between groups sutured with standard versus rapidly absorbing sutures in the number of women experiencing perineal pain at up to 14 days after delivery.</p> <p>There was no evidence of any significant differences between groups sutured with standard versus rapidly absorbing sutures for long-term pain (at three months after delivery) or for dyspareunia at three months.</p> <p>One trial examining monofilament versus standard polyglycolic sutures found no</p>

	<p>Wound gaping Re-suturing of wound Suture material removed Wound problems Dyspareunia Maternal satisfaction</p> <p>The follow-up time varied from 3 days to 12 months post-partum (PP), depending on comparison and outcome analysed.</p>		<p>differences for the investigated outcome pain.</p> <p>For other materials there was insufficient evidence to draw conclusions.</p> <p>The level of evidence was not determined.</p>
<p>Kettle et al. 2012 [18] United Kingdom</p>	<p>To assess the effects of continuous versus interrupted absorbable sutures for repair of episiotomy or second-degree perineal tears following childbirth.</p> <p>Outcomes considered Short term pain Long term pain Use of analgesic Wound gaping Re-suturing of wound Removal of suture material Wound problems Dyspareunia Failure to resume pain-free intercourse</p> <p>Depending on outcome analysed, the follow-up time varied from 2 days to 3 months PP.</p>	<p>In total 16 studies and 8184 women.</p> <p>However, depending on outcome and comparison analysed, the number of studies and participants varied from 2 to 9 studies and 2487 to 4231 women, respectively.</p> <p>RCTs and quasi-randomised studies were included, of which they also accepted studies that were only reported as abstracts.</p> <p>The studies were conducted in the UK, Denmark, Italy, Brazil, Switzerland, Nigeria, Spain, Turkey and Pakistan.</p>	<p>Meta-analysis showed that continuous suture techniques compared with interrupted sutures for perineal closure (all layers or perineal skin only) are associated with less pain for up to 10 days postpartum. There was an overall reduction in analgesia use associated with the continuous subcutaneous technique versus interrupted stitches for repair of perineal skin. There was also a reduction in suture removal in the continuous suturing groups versus interrupted, but no significant differences were seen in the need for re-suturing of wounds or long-term pain.</p> <p>Future trials relating to perineal trauma need to address outcomes that are important to women, including sexual problems and pelvic floor muscle dysfunction in the immediate and long-term period following childbirth.</p> <p>The level of evidence was not determined.</p>
Analgesia for perineal pain			
<p>Chou et al 2013 [24] Switzerland, Argentina and United Kingdom</p>	<p>To determine the efficacy of a single administration of paracetamol (acetaminophen) systemic drugs used in the relief of acute postpartum perineal pain.</p> <p>Postpartum period was defined as the first four weeks after giving birth.</p> <p>Comparisons considered</p>	<p>10 studies describing two dosages of paracetamol. Of these, five studies (526 women) assessed 500 mg to 650 mg and six studies (841 women) assessed 1000 mg of paracetamol.</p> <p>However, depending on comparison and outcome analysed, the number of studies and participants varied from 3 to 6 studies and 317 to 815 women, respectively.</p>	<p>More women experienced pain relief, and fewer had additional pain relief, with paracetamol compared with placebo, although potential adverse effects were not assessed and generally the quality of the studies was unclear.</p> <p>Due to ethical considerations, it is unlikely that future studies, of good methodological quality, will be conducted to determine the efficacy of paracetamol compared with</p>

	<p>Paracetamol, single administration of 500–650 or 1000 mg versus placebo, 4 hours after intake of drug</p> <p>Outcomes considered Adequate pain relief as reported by the women Additional pain relief</p> <p>The follow-up time was 4 hours after intake of drug</p>	<p>The included studies were conducted in Canada, France, USA and Venezuela.</p> <p>RCTs were included</p>	<p>placebo. Additional studies which compare paracetamol to other pain relievers may address the gaps in evidence concerning maternal and neonatal adverse effects.</p> <p>The level of evidence was not determined</p>
<p>Hedayati et al 2005 [22] Australia</p>	<p>To assess the effects of topically applied anaesthetics for relief of perineal pain following childbirth whilst in hospital and following discharge.</p> <p>Comparisons considered</p> <p>Topical agents (lignocaine or lidocaine or 1% hydrocortisone acetate+ 1% pramoxine hydrochloride) versus placebo.</p> <p>Topical agents (lignocaine or 1% hydrocortisone acetate + 1% pramoxine hydrochloride) versus placebo.</p> <p>Topical agents (1% hydrocortisone acetate+ 1% pramoxine hydrochloride) versus placebo.</p> <p>Topical agents (lignocaine or lidocaine) versus placebo.</p> <p>Topical agent (lignocaine) versus suppositories (indomethacin).</p> <p>Outcomes considered Pain Additional analgesia for perineal pain Women not satisfied with treatment.</p> <p>Depending on outcome and comparison analysed, the follow-up time varied from 1 to 3 days PP.</p>	<p>8 studies (976 women) conducted in Ireland, the UK, USA and Turkey.</p> <p>However, depending on comparison and outcome analysed, the number of included studies and participants varied from 1 to 3 studies and 58 to 287 women, respectively.</p> <p>RCTs were included</p>	<p>Evidence for the effectiveness of topically applied local anaesthetics for treating perineal pain is not compelling.</p> <p>There has been no evaluation for the long-term effects of topically applied local anaesthetics</p> <p>The level of evidence was not determined.</p>
<p>Hedayati et al 2003 [23]</p>	<p>To assess the effectiveness of analgesic rectal suppositories for pain from perineal trauma following childbirth.</p>	<p>3 studies (249 women).</p> <p>However, depending on which outcome that was analysed, the number of studies and</p>	<p>Treatment with Non-Steroidal Anti-inflammatory Drugs (NSAID) rectal suppositories is associated with less pain, up to 24 hours after birth, and less additional analgesia use is required.</p>

Australia	<p>Comparison considered Rectal suppository (NSAID) versus placebo.</p> <p>Outcomes considered Any pain experienced Mild pain experienced Moderate pain experienced Severe pain experienced Use of additional analgesia for perineal pain.</p> <p>Depending on which outcome and comparison that was analysed, the follow-up time varied from ≤ 24 h to 72 h PP.</p>	<p>participants varied from 1 to 2 studies and 89 to 150 women, respectively.</p> <p>One study was conducted in Saudi Arabia and two studies were conducted in the UK.</p> <p>RCTs were included.</p>	<p>More research is required regarding long-term effects and maternal satisfaction with the treatment.</p> <p>The level of evidence was not determined.</p>
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H= hour; PP= post partum; RCT= randomised controlled trial