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Local cooling for relieving pain from perineal trauma sustained during childbirth (Review)

East CE, Dorward EDF, Whale RE, Liu J

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Local cooling for relieving pain from perineal trauma sustained during childbirth.
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[Intervention Review]

Local cooling for relieving pain from perineal trauma sustained during childbirth

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ABSTRACT

Background

Perineal trauma is common during childbirth and may be painful. Contemporary maternity practice includes offering women numerous forms of pain relief, including the local application of cooling treatments. This Cochrane Review is an update of a review last updated in 2012.

Objectives

To evaluate the effectiveness of localised cooling treatments compared with no treatment, placebo, or other cooling treatments applied to the perineum for pain relief following perineal trauma sustained during childbirth.

Search methods

We searched Cochrane Pregnancy and Childbirth's Trials Register, [ClinicalTrials.gov](https://www.clinicaltrials.gov), the WHO International Clinical Trials Registry Platform (ICTRP) (7 October 2019) and reference lists of retrieved studies.

Selection criteria

Published and unpublished randomised and quasi-randomised trials (RCTs) that compared a localised cooling treatment applied to the perineum with no treatment, placebo, or another cooling treatment applied to relieve pain related to perineal trauma sustained during childbirth.

Data collection and analysis

Two review authors independently assessed study eligibility, extracted data and assessed the risk of bias of included studies. Data were double checked for accuracy. The certainty of the evidence was assessed using the GRADE approach.

Main results

We included 10 RCTs that enrolled 1233 women randomised to the use of one cooling treatment (ice, cold gel pad, cooling plus compression, cooling plus compression plus (being) horizontal) compared with another cooling treatment, no treatment, or placebo (water pack, compression). The included trials were at low or uncertain risk of bias overall, with the exception that the inability to blind participants and personnel to group allocation meant that we rated all trials at unclear or high risk for this domain.

We undertook a number of comparisons to evaluate the different treatments.

Cooling treatment (ice pack or cold gel pad) versus no treatment

Local cooling for relieving pain from perineal trauma sustained during childbirth (Review)

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There was limited very low-certainty evidence that cooling treatment may reduce women's self-reported perineal pain within four to six hours (mean difference (MD) -4.46, 95% confidence interval (CI) -5.07 to -3.85 on a 10-point scale; 1 study, 100 participants) or between 24 and 48 hours of giving birth (risk ratio (RR) 0.73, 95% CI 0.57 to 0.94; 1 study, 316 participants). The evidence is very uncertain about the various measures of wound healing, for example, wound edges gaping when inspected five days after giving birth (RR 2.56, 95% CI 0.58 to 11.33; 1 study, 315 participants). Women generally rated their satisfaction with perineal care similarly following cooling or no treatment. The potential exception was that there may be a trivially lower mean difference of -0.1 on a five-point scale of psychospiritual comfort with cooling treatment, that is unlikely to be of clinical importance.

Cooling treatment (cold gel pad) + compression versus placebo (gel pad + compression)

There was limited low-certainty evidence that there may be a trivial MD of -0.43 in pain on a 10-point scale at 24 to 48 hours after giving birth (95% CI -0.73 to -0.13; 1 study, 250 participants) when a cooling treatment plus compression from a well-secured perineal pad was compared with the placebo. Levels of perineal oedema may be similar for the two groups (low-certainty evidence) and perineal bruising was not observed. There was low-certainty evidence that women may rate their satisfaction as being slightly higher with perineal care in the cold gel pad and compression group (MD 0.88, 95% CI 0.38 to 1.38; 1 trial, 250 participants).

Cooling treatment (ice pack) versus placebo (water pack)

One study reported that no women reported pain after using an ice pack or a water pack when asked within 24 hours of giving birth. There was low-certainty evidence that oedema may be similar for the two groups when assessed at four to six hours (RR 0.96, 95% CI 0.50 to 1.86; 1 study, 63 participants) or within 24 hours of giving birth (RR 0.36, 95% CI 0.08 to 1.59). No women were observed to have perineal bruising at these times. The trialists reported that no women in either group experienced any adverse effects on wound healing. There was very low-certainty evidence that women may rate their views and experiences with the treatments similarly (for example, satisfied with treatment: RR 0.91, 95% CI 0.77 to 1.08; 63 participants).

Cooling treatment (ice pack) versus cooling treatment (cold gel pad)

The evidence is very uncertain about the effects of using ice packs or cold gel pads on women's self-rated perineal pain, on perineal bruising, or on perineal oedema at four to six hours or within 24 hours of giving birth. Perineal oedema may persist 24 to 48 hours after giving birth in women using the ice packs (RR 1.69, 95% CI 1.03 to 2.7; 2 trials, 264 participants; very low-certainty). The risk of gaping wound edges five days after giving birth may be decreased in women who had used ice packs (RR 0.22, 95% CI 0.05 to 1.01; 215 participants; very low-certainty). However, this did not appear to persist to day 10 (RR 3.06, 95% CI 0.63 to 14.81; 214 participants). Women may rate their opinion of treatment less favourably following the use of ice packs five days after giving birth (RR 0.33, 95% CI 0.17 to 0.68; 1 study, 49 participants) and when assessed on day 10 (RR 0.82, 95% CI 0.73 to 0.92; 1 study, 208 participants), both very low-certainty.

Authors' conclusions

There is limited very low-certainty evidence that may support the use of cooling treatments, in the form of ice packs or cold gel pads, for the relief of perineal pain in the first two days following childbirth. It is likely that concurrent use of several treatments is required to adequately address this issue, including prescription and non-prescription analgesia. Studies included in this review involved the use of cooling treatments for 10 to 20 minutes, and although no adverse effects were noted, these findings came from studies of relatively small numbers of women, or were not reported at all. The continued lack of high-certainty evidence of the benefits of cooling treatments should be viewed with caution, and further well-designed trials should be conducted.

PLAIN LANGUAGE SUMMARY

Local cooling for relieving pain from perineal trauma sustained during childbirth

We looked for evidence from randomised controlled trials on how effective localised cooling treatments are for reducing pain from damage to the area between the vagina and the anus, that is, 'perineal trauma', when giving birth.

What is the issue?

Perineal tears are common during childbirth. In addition, sometimes the person attending the birth cuts the perineum to give extra room for the baby to be born (an episiotomy).

These tears and cuts often cause pain and the mother may have difficulty walking or sitting comfortably, or to feed and care for her baby,

Why is this important?

The pain from perineal tears or cuts can decrease women's ability to move around and causes discomfort when passing urine or faeces. This can affect her emotional well-being. Persisting perineal pain can have longer-term effects, such as pain during sex and problems with bowel movements and urination. Women are encouraged to use different ways to relieve the pain, including the use of cooling treatments such as ice packs or cold gel pads. It is important to know if cooling works and whether it can slow healing of the cut or tear.

This is an update of a review that was first published in 2007 and updated in 2012.

What evidence did we find?

We updated the search for evidence in October 2019. We have now found 10 randomised controlled trials to include. Nine of these studies had information from 998 women that we could use in the review.

Ice packs or cold gel pads were placed on the perineum for 10 to 20 minutes at a time in the first two days following childbirth. They were compared to no treatment (5 studies, 612 women) or placebo treatment of a gel pad (1 study) or a water bag (1 study), both at room temperature. Ice packs were compared with cold gel pads in three studies (338 women).

The trials were largely of very low quality due to concerns about how valid the findings were, with small numbers of women for each comparison, wide variations in treatment effects, and women knowing which treatment (or if no treatment) they had used. Few trials looked at the same comparisons or trials used different assessment tools or outcomes. Most of the findings come from single studies.

Women's self-rated perineal pain following the use of the cold pad within six hours of giving birth may be less than for women who had no treatment (1 study, 100 women). There were no clear differences in self-reported pain within 24 hours or up to 48 hours after giving birth (1 study, 316 women) or in perineal healing.

A cold gel pad with compression in comparison to a placebo may result in a very small reduction in pain 24 to 48 hours after giving birth (1 study, 250 women). Perineal wound healing may not be adversely affected by cooling. None of the women with an ice pack or a water pack at room temperature reported pain in the first 24 hours after giving birth (1 study, 63 women). No adverse effects on wound healing were reported.

Comparing ice packs with cold gel pads, there may be no difference in self-rated perineal pain at any of the measurement times (3 studies, 338 women). One trial reported that fewer women using ice packs had gaping wound edges at day five but not at day 10 (215 women). In single studies, women rated their opinion of treatment less favourably with ice packs than with cold gel pads five days after giving birth (49 women) and when assessed on day 10 (208 women).

What does this mean?

There is only a small amount of low or very low-quality evidence from small trials suggesting that cooling treatments may help relieve perineal pain after having a baby. Further research is needed to see if cooling affects how well the tears or cuts heal. Ice is readily available in high-income countries but this may not be the case in low-middle income countries. Gel pads that need to be placed in a freezer for cooling may also not be readily available in low-middle income areas.

SUMMARY OF FINDINGS

Summary of findings 1. Cooling treatment (ice pack or cold gel pad) compared to no treatment for relieving pain from perineal trauma sustained during childbirth

Cooling treatment (ice pack or cold gel pad) compared to no treatment for relieving pain from perineal trauma sustained during childbirth

Patient or population: Women with perineal trauma (tear or episiotomy, or both) sustained during childbirth

Setting: Brazil, Iran, Turkey, United Kingdom

Intervention: cooling treatment (ice pack or cold gel pad)

Comparison: no treatment

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with no treatment	Risk with cooling treatment (ice pack or cold gel pad)				
Perineal pain within 4 - 6 hours of giving birth	The mean perineal pain within 4 - 6 hours of giving birth was 6.42	MD 4.46 lower (5.07 lower to 3.85 lower)	-	100 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b,c}	Scale of 0 (no pain) to 10 (worst possible pain)
Perineal pain within 24 hours of giving birth - Moderate + severe pain	Study population		RR 1.03 (0.82 to 1.29)	316 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d}	-
	515 per 1000	530 per 1000 (422 to 664)				
Perineal pain within 24 hours of giving birth	The mean perineal pain within 24 hours of giving birth was 4.05	MD 0.41 lower (1.78 lower to 0.95 higher)	-	166 (3 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,e,f,g}	Scale of 0 (no pain) to 10 (worst possible pain)
Perineal pain between 24 - 48 after giving birth - Moderate + severe pain	Study population		RR 0.73 (0.57 to 0.94)	316 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d}	-
	535 per 1000	390 per 1000 (305 to 503)				
Perineal pain 24 - 48 hours after giving birth	The mean perineal pain between 24 - 48 hours after giving birth was 4.36	MD 0.53 lower (1.45 lower to 0.39 higher)	-	71 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,f,g}	Scale of 0 (no pain) to 10 (worst possible pain)
Perineal oedema within 24 hours of giving birth	Study population		RR 1.00 (0.87 to 1.16)	316 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d,g}	-
	723 per 1000	723 per 1000				

	(629 to 838)					
Perineal bruising within 24 hours of giving birth	Study population		RR 0.98 (0.81 to 1.19)	316 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d,g}	-
	604 per 1000	592 per 1000 (489 to 719)				
Perineal bruising 24 - 48 hours after giving birth	Study population		RR 1.13 (0.97 to 1.32)	316 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d,g}	-
	673 per 1000	761 per 1000 (653 to 889)				
Perineal redness, oedema, bruising, discharge, wound gaping 24 - 48 hours of giving birth	The mean perineal redness, oedema, bruising, discharge, wound gaping between 24-48 hours of giving birth was 2.89	MD 1.19 lower (2.07 lower to 0.31 lower)	-	71 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,e,h,i}	The REEDA scale provides a rating of Redness, Edema, Ecchymosis (bruising), Discharge & Approximation (of skin edges): range 0 to 15, with higher scores representing increased tissue trauma
Adverse effects on perineal wound healing: Day 5 - Wound not healing	Study population		RR 1.24 (0.34 to 4.58)	315 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d}	-
	30 per 1000	37 per 1000 (10 to 137)				
Adverse effects on perineal wound healing: Day 5 - Wound edges gaping	Study population		RR 2.56 (0.58 to 11.33)	315 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d}	-
	20 per 1000	51 per 1000 (12 to 227)				
Maternal views and experiences of treatment - Satisfaction with overall perineal care (good + very good + excellent) Day 10	Study population		RR 1.07 (0.97 to 1.18)	308 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d}	-
	840 per 1000	899 per 1000 (815 to 991)				
Maternal views and experiences of treatment - Psychospiritual comfort within 6 hours of giving birth	The mean maternal views and experiences of treatment - Psychospiritual comfort within 6 hours of giving birth was 1.97	MD 0.1 lower (0.2 lower to 0.0)	-	100 (1 RCT)	⊕⊕⊕⊕ LOW ^{a,j}	Scale of 1 (low comfort) to 5 (high comfort)

Maternal views and experiences of treatment - Sociocultural comfort	The mean maternal views and experiences of treatment - Sociocultural comfort was 2.94	MD 0.01 higher (0.09 lower to 0.11 higher)	-	100 (1 RCT)	⊕⊕⊕⊕ LOW ^{a,j}	Scale of 1 (low comfort) to 5 (high comfort)
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***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; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** Risk ratio

GRADE Working Group grades of evidence

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

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

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

^aDowngraded one level for unblinding of outcome assessors.

^bDowngraded one level due to uncertainty about selection bias.

^cDowngraded one level for imprecision: unequal variance intervention vs no intervention.

^dDowngraded two levels for very serious limitations due to incomplete outcome data.

^eDowngraded one level for risk of selection bias.

^fDowngraded one level for risk of selective reporting.

^gDowngraded one level due to imprecision: confidence intervals crossing line of no effect.

^hDowngraded one level for possible unblinding of outcome assessors.

ⁱDowngraded one level for imprecision (wide confidence intervals).

^jDowngraded one level for imprecision: trivial difference (less than one point on a 5-point scale).

Summary of findings 2. Cooling treatment (cold gel pad)+compression compared to placebo (gel pad+compression) for relieving pain from perineal trauma sustained during childbirth

Cooling treatment (cold gel pad)+compression compared to placebo (gel pad+compression) for relieving pain from perineal trauma sustained during childbirth

Patient or population: Women with perineal trauma (tear or episiotomy, or both) sustained during childbirth

Setting: Thailand

Intervention: cooling treatment (cold gel pad)+compression

Comparison: placebo (gel pad+compression)

Outcomes	Anticipated absolute effects* (95% CI)	Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
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	Risk with placebo (gel pad +compression)	Risk with cooling treatment (cold gel pad)+compression				
Perineal pain within 4 - 6 hours of giving birth	The mean perineal pain within 4 - 6 hours of giving birth was 3.15	MD 0.32 lower (0.78 lower to 0.14 higher)	-	250 (1 RCT)	⊕⊕⊕⊕ LOW ^{a,b}	A scale of zero (no pain) to 10 (worst possible pain)
Perineal pain within 24 - 48 hours after giving birth	The mean perineal pain within 24 - 48 hours after giving birth was 2.48	MD 0.43 lower (0.73 lower to 0.13 lower)	-	250 (1 RCT)	⊕⊕⊕⊕ LOW ^c	A scale of zero (no pain) to 10 (worst possible pain)
Perineal oedema 24 - 48 hours after giving birth	The mean perineal oedema 24 - 48 hours after giving birth was 0.176	MD 0.15 lower (0.28 lower to 0.03 lower)	-	250 (1 RCT)	⊕⊕⊕⊕ LOW ^{a,d}	Scale zero: none - 3: > 2 cm
Perineal bruising 24 - 48 hours after giving birth			-	250 (1 RCT)	-	No women were observed to have perineal bruising
Adverse effects			-	(0 studies)	-	No trials reported on adverse effects
Satisfaction with perineal care	The mean satisfaction with perineal care was 6.87	MD 0.88 higher (0.38 higher to 1.38 higher)	-	250 (1 RCT)	⊕⊕⊕⊕ LOW ^{a,c}	Scale of zero (not satisfied) to 10 (most satisfied)

***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; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** Risk ratio

GRADE Working Group grades of evidence

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

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

^aDowngraded one level for unblinding of outcome assessors.

^bDowngraded one level due to imprecision: wide confidence intervals crossing the line of no effect.

^cDowngraded one level for imprecision: trivial difference on a 10-point scale.

^dDowngraded one level for imprecision: trivial difference on a 3-point scale.

Summary of findings 3. Cooling treatment (ice pack) compared to placebo (water pack) for relieving pain from perineal trauma sustained during childbirth

Cooling treatment (ice pack) compared to placebo (water pack) for relieving pain from perineal trauma sustained during childbirth

Patient or population: Women with perineal trauma (tear or episiotomy, or both) sustained during childbirth

Setting: Brazil

Intervention: cooling treatment (ice pack)

Comparison: placebo (water pack)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	N° of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with placebo (water pack)	Risk with cooling treatment (ice pack)				
Perineal pain within 24 hours after giving birth	Study population		-	63 (1 RCT)	-	No participants reported perineal pain within this time frame
	see comment	see comment				
Perineal oedema within 4 - 6 hours after giving birth	Study population		RR 0.96 (0.50 to 1.86)	63 (1 RCT)	⊕⊕⊕⊕ LOW ^{a,b}	-
	371 per 1000	357 per 1000 (186 to 691)				
Perineal oedema within 24 hours after giving birth	Study population		RR 0.36 (0.08 to 1.59)	63 (1 RCT)	⊕⊕⊕⊕ LOW ^{a,b}	-
	200 per 1000	72 per 1000 (16 to 318)				
Adverse effects on perineal healing	Study population		-	63 (1 RCT)	-	No adverse events were reported by participants or observed by outcome assessors
	see comment	see comment				
Maternal views and experiences with treatment - Satisfied with treatment	Study population		RR 0.91 (0.77 to 1.08)	63 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{b,c,d}	-
	943 per 1000	858 per 1000 (726 to 1000)				
	Study population		RR 0.88 (0.75 to 1.04)	63 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{b,c,d}	-

Maternal views and experiences with treatment - Would repeat treatment in future childbirth	971 per 1000	855 per 1000 (729 to 1000)				
Maternal views and experiences with treatment - Would recommend treatment	Study population		RR 0.89 (0.77 to 1.03)	63 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{b,c,d}	-
	1000 per 1000	890 per 1000 (770 to 1000)				

***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; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** Risk ratio

GRADE Working Group grades of evidence

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

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

^aDowngraded one level for imprecision: wide confidence intervals crossing the line of no effect.

^bDowngraded one level for small sample size.

^cDowngraded one level due to unblinding of outcome assessor.

^dDowngraded one level for imprecision: confidence intervals crossing the line of no effect.

Summary of findings 4. Cooling treatment (ice pack) compared to cooling treatment (cold gel pad) for relieving pain from perineal trauma sustained during childbirth

Cooling treatment (ice pack) compared to cooling treatment (cold gel pad) for relieving pain from perineal trauma sustained during childbirth

Patient or population: Women with perineal trauma (tear or episiotomy, or both) sustained during childbirth

Setting: Iran, United Kingdom

Intervention: cooling treatment (ice pack)

Comparison: cooling treatment (cold gel pad)

Outcomes	Anticipated absolute effects* (95% CI)		Relative effect (95% CI)	Nº of participants (studies)	Certainty of the evidence (GRADE)	Comments
	Risk with cooling treatment (cold gel pad)	Risk with cooling treatment (ice pack)

Perineal pain within 4 - 6 hours of giving birth - Moderate + severe pain	Study population		RR 0.57 (0.26 to 1.24)	49 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b,c,d}	-
	481 per 1000	274 per 1000 (125 to 597)				
Perineal pain within 24 hours of giving birth - Moderate + severe pain	Study population		RR 0.98 (0.78 to 1.22)	264 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b,e}	-
	541 per 1000	530 per 1000 (422 to 660)				
Perineal pain within 24 hours of giving birth	The mean perineal pain within 24 hours of giving birth was 3.84	MD 0.58 higher (0.44 lower to 1.6 higher)	-	74 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d,f,g}	Scale of 0 (no pain) to 10 (worst possible pain)
Perineal pain 24 - 48 hours after giving birth - Moderate + severe pain	Study population		RR 1.21 (0.89 to 1.65)	263 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b,c}	-
	343 per 1000	415 per 1000 (306 to 566)				
Perineal pain 24 - 48 hours of giving birth	The mean perineal pain between 24-48 hours of giving birth was 2.97	MD 0.86 higher (0.1 lower to 1.82 higher)	-	74 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,c,d,f}	Scale of 0 (no pain) to 10 (worst possible pain)
Perineal oedema within 4 - 6 hours of giving birth	Study population		RR 1.39 (0.93 to 2.09)	49 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b,c,d}	-
	556 per 1000	772 per 1000 (517 to 1000)				
Perineal oedema within 24 hours of giving birth	Study population		RR 0.97 (0.84 to 1.13)	264 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b,e}	-
	733 per 1000	711 per 1000 (616 to 829)				
Perineal oedema 24 - 48 hours after giving birth	Study population		RR 1.69 (1.03 to 2.77)	264 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{a,b,h}	-
	393 per 1000	663 per 1000 (404 to 1000)				
Perineal bruising within 4 - 6 hours of giving birth	Study population		RR 1.23 (0.51 to 2.97)	49 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b,d,h}	-
	259 per 1000	319 per 1000 (132 to 770)

Perineal bruising within 24 hours of giving birth	Study population		RR 0.95 (0.79 to 1.14)	264 (2 RCTs)	⊕⊕⊕⊕ VERY LOW ^{1 2 5}	-
	644 per 1000	612 per 1000 (509 to 735)				
Perineal redness, oedema, bruising, discharge, wound gaping within 24 hours of giving birth	The mean perineal redness, oedema, bruising, discharge, wound gaping within 24 hours of giving birth was 2.3	MD 0.13 lower (0.85 lower to 0.59 higher)	-	74 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,d,e}	The REEDA scale assesses 5 aspects of wound healing: redness, (o)edema, ecchymosis (bruising), discharge and (wound edge) approximation on a scale of 0 (best) to 3 (worst) for each component for a maximum score of 15
Adverse effects on perineal wound healing: Day 5 - Wound not healing	Study population		RR 1.01 (0.26 to 3.93)	215 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b,c}	-
	37 per 1000	37 per 1000 (10 to 146)				
Adverse effects on perineal wound healing: Day 5 - Wound edges gaping	Study population		RR 0.22 (0.05 to 1.01)	215 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b,h}	-
	83 per 1000	18 per 1000 (4 to 84)				
Maternal views and experiences with treatment - Opinion on treatment effects (good + very good + excellent) Day 5	Study population		RR 0.33 (0.17 to 0.68)	49 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b,d}	-
	815 per 1000	269 per 1000 (139 to 554)				
Maternal views and experiences with treatment - Satisfaction with overall perineal care (good + very good + excellent) Day 10	Study population		RR 0.82 (0.73 to 0.92)	208 (1 RCT)	⊕⊕⊕⊕ VERY LOW ^{a,b}	-
	934 per 1000	766 per 1000 (682 to 859)				

*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; **MD:** mean difference; **RCT:** randomised controlled trial; **RR:** Risk ratio

GRADE Working Group grades of evidence

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

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

^aDowngraded one level for unblinding of outcome assessors.

^bDowngraded two levels for very serious limitations due to incomplete outcome data.

^cDowngraded one level due to imprecision: wide confidence intervals crossing the line of no effect.

^dDowngraded one level for small sample size.

^eDowngraded one level due for imprecision: confidence intervals crossing line of no effect.

^fDowngraded one level for risk of selective reporting.

^gDowngraded one level for imprecision: trivial difference on a 10-point scale.

^hDowngraded one level for imprecision (wide confidence intervals).

BACKGROUND

Description of the condition

Perineal trauma: effects and prevention

Perineal trauma, whether by episiotomy (cutting of the perineum to enlarge the vaginal orifice during the end of the second stage of birthing) or from naturally-occurring tears, is common during childbirth. In Australia in 2018, 55% of women sustained tears and 23% had an episiotomy (AIHW 2020). In the United Kingdom, 22% of women having a vaginal birth undergo episiotomy and 3.5% sustain third- or fourth-degree tears (NMPA 2019), while average pooled estimated episiotomy rates in low-middle income countries are 46% (95% confidence interval 35% to 55%), ranging from 10% in Cameroon to 98% in Pakistan (Aguilar 2019). The combination of spontaneous tears and episiotomy therefore encompasses a large proportion of women who sustain perineal trauma with a vaginal birth (Abedzadeh-Kalahroudi 2019). Further sources of trauma include vaginal lacerations and trauma to the external genitalia (labia, clitoris, periurethra) (Wen 2018).

In the hours, days and months following childbirth, this trauma may be painful (East 2011; Francisco 2011; Manresa 2019) and can be increased in women with deeper trauma (> 2 cm) (Lawrence 2017). This pain can result in decreased mobility and increased discomfort with passing urine or faeces (Subki 2019), may negatively impact on the woman's ability to care for her new baby (East 2011) and affect emotional well-being (Shoorab 2019). Perineal pain that persists beyond the immediate postpartum period may warrant further evaluation and may have longer-term effects, such as sexual and pelvic dysfunction (Doğan 2017; Manresa 2019). A number of risk factors for severe perineal trauma have been identified, with some debate remaining. These generally include primiparity, ethnicity, with women from Southern Asia and Africa being at greater risk than others, instrumental birth, and prolonged length of second stage (for example, over two hours) (Davies-Tuck 2015; Gibson-Helm 2015).

A number of techniques may be applied for the prevention or minimisation of perineal trauma (Aasheim 2017), which may subsequently reduce the perineal pain associated with childbirth. Possible preventive or minimisation measures include perineal massage during pregnancy, application of warm packs to the perineum during second stage, mediolateral versus midline episiotomy, and birthing attendants' hands on the perineum during the birth of the baby's head, to name a few (Aasheim 2017). Selective use of episiotomy, for example, in situations where severe perineal trauma would otherwise occur, or for fetal indications, results in less severe perineal trauma (Jiang 2017). It remains unclear whether or not women's self-reported perineal pain is influenced by the routine or selected use of episiotomy (Jiang 2017).

Analgesia for perineal trauma

When perineal trauma does occur, regardless of the underlying contributing factors or interventions, pain, where present, requires attention. Contemporary maternity practice includes offering the woman numerous forms of pain relief, often used in combination. Several Cochrane Reviews have considered the evidence of the effectiveness of treatments used in recent decades. These include: methods and materials used for suturing perineal tears or episiotomies (Kettle 2010; Kettle 2012); topically-applied

anaesthetics (for example, lignocaine) and a topical preparation of pramoxine/hydrocortisone (Hedayati 2005); orally or rectally administered non-steroidal anti-inflammatory drugs (NSAIDs) (Hedayati 2003; Wuytack 2016); ultrasound (Hay-Smith 1998); and other oral medications such as aspirin (Molakatalla 2017) or paracetamol/acetaminophen (Chou 2013). While these treatments demonstrate varying levels of success in relieving pain from perineal trauma, they may also involve a degree of cost to the consumer, the health service, or both. Paracetamol and NSAIDs are considered safe in breastfeeding (Bisson 2019), while potentially harmful side effects of these and other medications also need to be considered. Women's satisfaction is also an important consideration of any treatment used for reducing perineal pain, although this is poorly studied (Molakatalla 2017; Wuytack 2016).

A safe, effective, low-cost alternative, available in primary healthcare settings as well as in hospitals, and that is acceptable to childbearing women, would be attractive. The use of cryotherapy (cooling treatment) in the form of ice packs or cold gel pads, may be one such alternative.

Description of the intervention

Cooling therapy for pain relief

Cooling to reduce inflammation and provide short-term relief of pain from localised tissue trauma has been used for over four decades (Ernst 1994; McMasters 1977), particularly for the treatment of delayed-onset muscle soreness (DOMS), sports trauma and following surgery (Adie 2010; Martimbianco 2014; Nogueira 2019; Oakley 2013; Torres 2012; Van den Bekerom 2012). Such cryotherapy may be in the form of local application of crushed ice or frozen gel, through to whole-body cryotherapy (WBC) or cold-water immersion (CWI) (Bleakley 2010). A common approach, attributed to Mirkin 1978, is to incorporate cooling within a 'bundle' of care, typically referred to as "RICE", involving Rest, local application of Ice, along with Compression and Elevation of the region.

Cooling treatments for perineal pain relief following childbirth have traditionally been applied intermittently in a number of ways, including: (i) solid or crushed ice applied directly to the perineum or between layers of a pad (Grant 1989; Leventhal 2010); (ii) a cold gel pack applied to the perineum (Leventhal 2010; Steen 1999); or (iii) bathing in iced water (Grant 1989).

How the intervention might work

The potential effects of cooling on wound healing

Bonica's theory (Bonica 1990) explains the physiology of local tissue injury and the potential effect of cold therapy. The accumulation of fluid (swelling/oedema) in an inflamed, injured area occurs due to increased permeability of the dilated peripheral blood vessels. When cold is applied, the skin blood supply is reduced. In turn, reduced tissue swelling and bleeding may also reduce bruising and localised pain. The effectiveness of this theory is supported by a systematic review showing that cryotherapy substantially reduces oedema following acute trauma (Collins 2008).

Pain signalling, inflammation and vascular changes are influenced by several biochemical mediators. These include serotonin, histamine and kinins. Serotonin dilates capillaries, increases

vascular permeability and contracts non-vascular smooth muscle. Actions of histamine include increased capillary permeability, arteriolar dilation and contraction of non-vascular smooth muscle, while kinins increase vascular permeability and vasodilation. Any mechanism that reduces these vascular responses will also reduce the effect of the mediator(s) (Dray 1995). Reducing soft tissue temperature by 10 to 15 degrees Celsius decreases local cell metabolism, reduces the oxygen requirement of the tissue and causes constriction of the peripheral blood vessels (Mac Auley 2001). Heat-activated receptors are thought to play a significant role in inflammation-related pain (Kettle 2012; Reid 2005). White 2013 concluded that metabolic rate and blood flow is reliably affected by tissue cooling. The use of a cooling treatment for between five and 15 minutes lowers the skin temperature and reduces swelling, thus providing analgesia (Bleakley 2012; Kuo 2013; Leventhal 2010; Machado 2016; Malanga 2015; White 2013).

White 2013 also states that although metabolic rate and blood flow seem to be reliably affected by cold, further studies are needed to investigate a dose-dependence.

Can cooling delay wound healing or pose safety concerns?

Concern about the safety and potential harm of ice has long been considered. This debate has arisen again, triggered in part by Mirkin 2015 using his online blog to debunk his original design of the clinical tool of RICE, published in his seminal textbook (Mirkin 1978). Dubois 2020 recently created a new approach for the management of soft tissue injury which suggests avoiding the use of ice therapy and anti-inflammatory medication due to the disruption in the inflammatory process and the potential negative effect on soft tissue repair. Inflammation and muscle regeneration are closely interconnected through complex interactions which in acute conditions are beneficial to muscle healing (Dushesne 2017). The theory may or may not translate to actual harms. An experimental randomised controlled trial showed that although cryotherapy effectively reduced inflammation mechanisms it did not negatively alter regeneration markers or collagen deposition (Ramos 2016), while in humans, icing was found to disrupt inflammation and some aspects of revascularisation in acutely-injured skeletal muscle but showed no substantial negative effect on muscle growth (Singh 2017). There appears to be no reported 'harm' from cooling to muscle function, but it was shown that it does not accelerate muscle recovery following exercise-induced muscle damage (Engelhard 2019).

Other potential risks of ice therapies include nerve palsies and ice burns. Beyond the desired localised/short-term numbing effect, true nerve palsies are more likely to occur at bony joints where there are exposed nerve areas (knee/elbow) or after prolonged, extreme temperature cooling as seen with WBC and CWI (Lubkowska 2012; Swenson 1996). Dosage recommendations for local ice therapy were originally described, limiting exposure to 10-minute sessions intermittently, to avoid skin damage (Mac Auley 2001). This along with other application care relevant to the injured area will further eliminate the risk of ice burns.

Why it is important to do this review

Cooling to relieve pain following childbirth-related perineal trauma, although lacking in supporting evidence, has been and continues to be commonly used in clinical practice for over 30 years (NICE 2006; Queensland Clinical Guidelines 2018; Sleep 1988). The

ongoing conflicting evidence on the efficacy of cooling treatments is complicated further by the emerging debate on potential harm such therapies may cause when used to treat sports injuries or surgical wounds, and needs to be considered for the perineal region as related to childbirth. The acceptability to women of any cooling therapy needs to be evaluated. This systematic review will provide childbearing women and their caregivers with updated evidence to inform clinical practice. This Cochrane Review is a further update of a review first published in 2007 and updated in 2012.

OBJECTIVES

To evaluate the effectiveness of localised cooling treatments compared with no treatment, placebo, or other cooling treatments applied to the perineum for pain relief following perineal trauma sustained during childbirth.

METHODS

Criteria for considering studies for this review

Types of studies

All published and unpublished randomised and quasi-randomised trials that compared localised cooling treatment(s) applied to the perineum with no treatment, placebo treatment, or another cooling treatment applied to the perineum to relieve pain related to perineal trauma sustained during childbirth. We excluded cross-over studies. We were able to confirm that all of the reports that were available in abstract form were also linked with later-published full trial reports. If we identify any other abstracts in future updates, we will include them if they contain sufficient information to assess study eligibility and risk of bias, and if the authors confirm in writing that they reported final results that would not change in subsequent publications.

Types of participants

Women with perineal trauma (tear or episiotomy, or both) sustained during childbirth.

Types of interventions

Application of localised cooling treatment to the perineum, versus no treatment, placebo treatment or another form of cooling treatment.

Types of outcome measures

We are aware of two publications: (i) a generic protocol for the systematic review of drugs used to relieve perineal pain in the early postpartum period (Chou 2009); and (ii) the WHO postnatal care guideline summary (personal communication, L Jones 11 December 2019), that have highlighted the outcomes to be considered when consolidating guidance for safe and effective interventions during the postnatal care of mothers and babies. We have revised the outcomes in this update to align with those in these two publications where possible (see [Differences between protocol and review](#)).

Primary outcomes

(1) Perineal pain, as measured by the trial authors, for example, using a visual analogue scale, at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 48 hours of giving birth.

Secondary outcomes

(2) Perineal pain, as measured by the trial authors, for example, using a visual analogue scale, associated with activities of daily living (for example, sitting, walking, urinating, caring for baby) at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 48 hours of giving birth.

(3) Perineal oedema, as measured by the study authors, at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 48 hours of giving birth.

(4) Perineal bruising, as measured by the study authors, at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 48 hours of giving birth.

(5) Additional analgesia for relief of perineal pain:

- within 24 hours of giving birth;
- between 24 and 48 hours of giving birth.

(6) Adverse effects on perineal healing, such as infection or wound breakdown, as measured by the study authors.

(7) Maternal exhaustion, as measured by the study authors, at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 48 hours of giving birth.

(8) Maternal views and experiences with treatment, using a validated instrument or as otherwise measured by the study authors.

(9) Women providing any breast milk to the baby 24 to 48 hours after giving birth (via the breast or as expressed breast milk).

(10) Cost of treatment.

Search methods for identification of studies

The following methods section is based on a standard template used by Cochrane Pregnancy and Childbirth.

Electronic searches

For this update, we searched Cochrane Pregnancy and Childbirth's Trials Register by contacting their Information Specialist (7 October 2019).

The Register is a database containing over 25,000 reports of controlled trials in the field of pregnancy and childbirth. It represents over 30 years of searching. For full current 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](#).

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

- monthly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
- weekly searches of MEDLINE (Ovid);
- weekly searches of Embase (Ovid);
- monthly searches of CINAHL (EBSCO);
- handsearches of 30 journals and the proceedings of major conferences;
- 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 that has been fully accounted for in the relevant review sections [Included studies](#); [Excluded studies](#); [Studies awaiting classification](#);

In addition, we searched ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP) for unpublished, planned and ongoing trial reports (7 October 2019), using the search methods detailed in [Appendix 1](#).

Searching other resources

We sought ongoing and unpublished trials by contacting experts in the field.

We searched the reference lists of retrieved studies.

We did not apply any language restrictions.

Data collection and analysis

For methods used in the previous version of this review, see [East 2012](#).

For this update, we used the following methods for assessing the reports that we identified as a result of the updated search.

The following methods section is based on a standard template used by Cochrane Pregnancy and Childbirth.

Selection of studies

Original review and 2012 update: two review authors (Christine East (CE), Naomi Henshall (NH), or Karen Wallace (KW)) independently assessed for inclusion all the potential studies we

identified as a result of the search strategy. We planned to resolve any disagreement through discussion or, if required, we would consult a third person (NH, KW, Lisa Begg or Paul Marchant).

2020 update: CE, Jiajia (Jessie) Liu (JL) and Emma Dorward (ED) assessed the previously-included studies for the updated criteria and the newly-identified studies for inclusion. We planned to resolve any disagreement through discussion or, if required, we would consult a third person (Rhiannon Whale (RW)).

Data extraction and management

We designed a form to extract data. For eligible studies, at least two review authors (2007 and 2012: CE, NH, KW, LB, PM, or JL; 2020: CE, JL, ED) extracted the data using the agreed form. We planned to resolve discrepancies through discussion or, if required, we would consult a third person from within the authorship. We double-checked a sub-sample of these data against the Review Manager 5 software (RevMan 2014).

When information on 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 (2007 and 2012: CE, NH, KW, LB, PM, or JL; 2020: CE, JL, ED) independently assessed risks of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020a). We planned to resolve any disagreement by discussion or by involving a third assessor from within the authorship.

(1) Random sequence generation (checking for possible selection bias)

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

We assessed the method as:

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

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

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

We assess the methods as:

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

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

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding 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. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include missing data in the analyses which we undertook.

We assessed methods as:

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

We planned to consider excluding studies with over 20% missing data unless there were good reasons to include them, based on other assessments of their 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 prespecified outcomes and all expected outcomes of interest to the review had been reported);

- high risk of bias (where not all the study's prespecified outcomes had been reported; one or more reported primary outcomes were not prespecified; outcomes of interest were reported incompletely and so could not be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear risk of bias.

(6) Other bias (checking for bias due to problems not covered by (1) to (5) above)

We described for each included study any important concerns we had about other possible sources of bias.

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 were at high risk of bias, according to the criteria given in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020a). 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

Dichotomous data

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

Continuous data

For continuous data, we used the mean difference if outcomes were measured in the same way between trials. We planned to use the standardised mean difference to combine trials that measure the same outcome, but used different scales.

We analysed data on all participants with available data in the group to which they were allocated, regardless of whether or not they received the allocated intervention. If in the original reports participants were not analysed in the group to which they were randomised, and there was sufficient information in the trial report, we planned to attempt to restore them to the group to which they had been randomised.

The trials reported assessments of pain, oedema and bruising at different time periods and by different criteria, necessitating the use of judgement by the review authors when selecting which assessment would most closely represent our stated outcome measures. We selected the assessment closest to the upper end of the timeframe specified in our outcomes. Where pain was reported as "any" or by degrees, we selected a total of the ratings, for example, moderate, severe and unbearable.

Unit of analysis issues

Cluster-randomised trials

We planned to include cluster-randomised trials in the analyses along with individually-randomised trials. If we identify suitable trials in future updates, we will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020b) 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 sensitivity analysis to investigate the effects of the randomisation unit.

Other unit-of-analysis issues

For this updated review, we adopted the approach recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2020b) to overcome a unit-of-analysis error for studies that could contribute multiple, correlated comparisons. Where data were reported in three groups (intervention one, intervention two, no treatment) we combined data for the intervention groups (cold gel pads and ice packs) where this was possible with the available data (Steen 2000; Steen 2002) for the comparison with no treatment. The continuous data reported by Navvabi 2009 did not allow for this: given that in previous versions of this review, we had not identified evidence of differences in outcomes when comparing one or other of these treatments (East 2012), we elected to report only the cold gel pad data and compared this with no treatment.

Dealing with missing data

For included studies, we noted levels of attrition. We planned to explore 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, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were to be 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 τ^2 , I^2 and χ^2 statistics. We regarded heterogeneity as substantial if I^2 was greater than 30% and either τ^2 was greater than zero, or there was a low P value (less than 0.10) in the χ^2 test for heterogeneity.

Assessment of reporting biases

If there are 10 or more studies in a future meta-analysis, we will investigate reporting biases (such as publication bias) using funnel plots. We will assess funnel plot asymmetry visually. If asymmetry is suggested by a visual assessment, we will perform exploratory analyses to investigate it. Such analyses may include inflated measures of effect related to poor methodological quality or small sample size ([Higgins 2020a](#)).

Data synthesis

We carried out statistical analysis using the Review Manager 5 software ([RevMan 2014](#)). We used a fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials examined the same intervention, and we judged the trials' populations and methods to be sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if we detected substantial statistical heterogeneity, we used a random-effects meta-analysis to produce an overall summary, if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we did not combine trials.

Where we used random-effects analyses, we present the results as the average treatment effect with 95% confidence intervals, and the estimates of τ^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

If we identified substantial heterogeneity, we investigated it using subgroup analyses and sensitivity analyses. We considered whether an overall summary was meaningful, and if it was, we used random-effects analysis to produce it. We considered whether there was clinical heterogeneity and if so, how this aligned with the PICO characteristics.

For fixed-effect inverse variance meta-analyses, we planned to assess differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we assessed differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicate a statistically significant difference in treatment effect between the subgroups.

We carried out the following subgroup analyses on the primary outcome for the one trial for which these data were available ([Steen 2002](#)):

- parity (primiparity, multiparity);
- mode of birth (spontaneous vaginal birth, assisted vaginal birth (forceps, vacuum))

Sensitivity analysis

We carried out sensitivity analysis to explore the potential effect of risks of bias for the very few outcomes that had more than one study contributing data, as had been undertaken in earlier versions of this review. In line with contemporary methodology, we will only undertake sensitivity analyses for primary outcomes if trials that report these are included in a future update and require such analysis.

Summary of findings and assessment of the certainty of the evidence

For this update we assessed the certainty of the evidence using the GRADE approach, as outlined in the [GRADE handbook](#), in order to assess the certainty of the body of evidence relating to the following outcomes for the main comparisons of:

- Cooling treatment (ice pack or cold gel pad) versus no treatment;
- Cooling treatment (cold gel pad) + compression versus placebo (gel pad + compression);
- Cooling treatment (ice pack) versus placebo (water pack);
- Cooling treatment (ice pack) versus cooling treatment (cold gel pad).

for the following outcomes:

- Perineal pain within four to six hours of giving birth;
- Perineal pain within 24 hours of giving birth;
- Perineal pain between 24 to 48 hours after giving birth;
- Perineal oedema within 24 hours of giving birth;
- Perineal bruising within 24 hours of giving birth;
- Adverse effects on perineal healing;
- Maternal views and experiences with treatment.

We did not generate 'Summary of findings' tables for the subgroups, given that only one trial contributed to these.

We used the [GRADEpro](#) Guideline Development Tool to import data from Review Manager 5 ([RevMan 2014](#)) in order to create 'Summary of findings' tables. We produced a summary of the intervention effect and a measure of certainty for each of the above outcomes, using the GRADE approach. The GRADE approach uses five considerations (study limitations, consistency of effect, imprecision, indirectness and publication bias) to assess the certainty of the body of evidence for each outcome. The evidence can be downgraded from 'high certainty' 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.

RESULTS

Description of studies

Results of the search

See: [Figure 1](#).

Figure 1. ReStudy flow diagram.

Figure 1. (Continued)

The searches for this update yielded 63 records. After screening out 41 records, there were 22 new reports. We also reassessed the 22 trial reports from the previous version of the review to meet eligibility for the fewer objectives in this update; recognition that a previously-included study enrolled women without perineal trauma; and that a study previously excluded on the grounds of quality concerns was eligible for inclusion.

We included 10 trials (21 reports) and excluded 15 trials (18 reports). There are two trials awaiting classification (four reports), as the authors have not been able to provide detail to allow for analysis of only those women with perineal trauma (see [Characteristics of studies awaiting classification](#)). The one ongoing study in the previous version of the review was a personal communication about the trial that is now awaiting classification. We did not identify any new ongoing studies.

Included studies

We included 10 studies ([Barclay 1983](#); [Beleza 2017](#); [East 2007](#); [Francisco 2018](#); [Morais 2016](#); [Navvabi 2009](#); [Senol 2017](#); [Steen 2000](#); [Steen 2002](#); [Yusamran 2007](#)) that enrolled 1233 women randomised to the use of one cooling treatment (ice, cold gel pad, cooling plus compression, cooling plus compression plus (being) horizontal) compared with another cooling treatment, with no treatment, or with placebo (water pack, compression). The report by [Barclay 1983](#) did not present any outcome data in a format that could be included in the review, while others had substantial rates of attrition (see below), giving a total of 998 women contributing data to the primary outcome of perineal pain and to various of the secondary outcomes. Few trials used the same comparisons, assessment tools or outcomes. We therefore conducted five comparisons, each with between one and three trials contributing data to the continuous or dichotomous outcomes (see below). We used descriptive categories within the analyses to provide adequate detail for the reader. See [Characteristics of included studies](#).

Design

The included studies were all randomised controlled trials.

Sample sizes

One study was a pilot to test feasibility for a larger planned trial and enrolled 16 women ([East 2007](#)). The remaining studies enrolled between 20 and 50 per treatment group ([Barclay 1983](#); [Beleza 2017](#); [Francisco 2018](#); [Morais 2016](#); [Navvabi 2009](#); [Senol 2017](#); [Steen 2000](#)),

while two studies enrolled 125 or 150 women to each group ([Steen 2002](#); [Yusamran 2007](#) respectively). Of note, two studies ([Steen 2000](#); [Steen 2002](#)) suffered considerable attrition with non-return of completed paperwork by the clinicians (see [Incomplete outcome data \(attrition bias\)](#)).

Setting

Studies were conducted in the birthing centres, or birthing suites or postnatal wards of hospitals, and continued to community care in Australia ([Barclay 1983](#); [East 2007](#)), Brazil ([Beleza 2017](#); [Francisco 2018](#); [Morais 2016](#)), Iran ([Navvabi 2009](#)), Thailand ([Yusamran 2007](#)), Turkey ([Senol 2017](#)) and the United Kingdom ([Steen 2000](#); [Steen 2002](#)).

Participants

Healthy primiparous or multiparous women of childbearing age with a singleton pregnancy and cephalic presentation who gave birth vaginally around term gestation were invited to participate. Some studies only included women with a normal vaginal birth ([Morais 2016](#); [Navvabi 2009](#)), enrolled women who had an instrumental birth ([Steen 2000](#)), included both normal and assisted (vacuum or forceps) vaginal births ([Beleza 2017](#); [East 2007](#); [Steen 2002](#)) or did not specify mode of vaginal birth ([Barclay 1983](#); [Senol 2017](#); [Yusamran 2007](#)). For some studies, a minimum level of perineal trauma (second degree tear, [Steen 2002](#)) or an episiotomy were criteria for study entry ([Barclay 1983](#); [Beleza 2017](#); [Navvabi 2009](#); [Steen 2000](#); [Steen 2002](#); [Yusamran 2007](#)), while for three studies, lesser levels of perineal trauma or even an intact perineum could qualify a woman for study entry: given that our prespecified inclusion criteria did not allow for an intact perineum, we contacted study authors to obtain data for women with some trauma; relevant data were made available by [East 2007](#), [Francisco 2018](#) and [Morais 2016](#).

The authors of [Senol 2017](#) confirmed the numbers of primiparous and multiparous women in each group and had reported data by parity: although the published report indicated that all the primiparous women had an episiotomy, detail later provided from the authors indicated that one primipara in each group had an intact perineum. We elected to retain the data in this review rather than remove them and suffer the delays in obtaining data for only the 98 women, given the potentially unlikely impact that only omitting outcomes from 2% of participants would have on the findings. Data for the 79% of multiparous women who had perineal

trauma (tear or episiotomy) were not available separately from the full sample for inclusion in this version of the review.

No studies enrolled women with severe perineal trauma, i.e. third- or fourth-degree laceration, as this requires more specialised treatment.

Interventions and comparisons

Cooling treatments

Ice packs were commonly used. These could be in the form of a plastic bag or a latex medical glove filled with crushed ice or filled with water then frozen, or commercially-available packs that would be soaked in water and frozen (Beleza 2017; East 2007; Francisco 2018; Morais 2016; Navvabi 2009; Steen 2000; Steen 2002). Cold gel pads that could be placed in a freezer came in a variety of forms, from those designed specifically for the studies (Steen 2000; Steen 2002), which were commercialised and incorporated into the trial by Navvabi 2009 or the use of a commercially-available heat/cold pack (Senol 2017; Yusamran 2007). In one study cooling was provided in the form of a "cold sitz bath" whereby ice and salt were added to a bowl of water (Barclay 1983). The addition of compression (East 2007; Sheikhhan 2011) and lying horizontally for a short time (East 2007) meant that the cooling treatment was part of a bundle of care, akin to the RICE principles. An overview of the cooling treatments is provided in Table 1. Four trials compared outcomes when one cooling therapy was compared with another therapy or regimen. For example, Navvabi 2009; Steen 2000 and Steen 2002 compared the use of ice packs and cold gel pads; East 2007 compared regular application of ice packs along with compression and being horizontal, compared with ad hoc ice pack usage.

Control/no treatment or placebo groups

Control or no-treatment groups involved 'routine' care, described by some as involving regular hygiene, use of a sanitary pad or analgesia or both on request (Barclay 1983; Beleza 2017; Senol 2017; Steen 2002). Placebo care was included in the form of a latex glove filled with water at 20 °C to 25 °C (Morais 2016) or a gel pad and compression (Yusamran 2007). Cooling treatments were therefore compared with no treatment or with the placebo.

Outcomes

Primary outcome

All included studies reported women's self-rated perineal pain at one or more of the prespecified times of between four and six hours after giving birth, within the first 24 hours of giving birth or between 24 to 48 hours after giving birth. A scale of zero (no pain) to 10 (worst possible pain) was used by Beleza 2017; Francisco 2018; Navvabi 2009; Senol 2017 and Yusamran 2007, or 1 (no pain) to 5 (severe pain, Barclay 1983). The remaining trialists reported data as none, mild, moderate, or severe (East 2007; Morais 2016 (converted from a numeric scale: 0 to 5 none/mild or 6 to 10 moderate/severe); Steen 2000; Steen 2002). Results of pain ratings in Barclay 1983 were only available in graphical form; as the authors were unable to be provide numeric data, this study did not contribute data for this outcome.

Secondary outcomes

No studies reported on all the prespecified secondary outcomes. Perineal pain that interfered with activities of daily living was

reported for some or all of sitting, walking, urinating and caring for the baby by East 2007; Senol 2017 and Steen 2002; perineal oedema and bruising were reported by Navvabi 2009; Senol 2017; Steen 2002 and Yusamran 2007. The use of additional analgesia was evaluated by East 2007; Morais 2016 and Steen 2002; while Morais 2016 and Steen 2002 reported on women providing any breast milk to their babies. Few trials reported on adverse effects of cooling, no treatment or placebo on perineal healing (Morais 2016; Senol 2017). Maternal exhaustion was reported in the form of maternal energy level in one study (East 2007) and women's views of their experience with perineal care was provided by Morais 2016; Senol 2017; Steen 2002 and Yusamran 2007. No studies conducted an economic analysis.

Timeframes

The studies were conducted across more than three decades, from the 1980s (implied for Barclay 1983), 1993 to 1994 and 1998 to 1999 for Steen 2000; Steen 2002 respectively, from 2005 to 2006 (Navvabi 2009; Yusamran 2007), 2007 to 2008 (Beleza 2017), 2008 to 2009 (East 2007) and between 2012 and 2013 (Francisco 2018; Morais 2016; Senol 2017).

Sources of funding

Funding sources were detailed in six reports (Beleza 2017; Francisco 2018; Morais 2016; Navvabi 2009; Steen 2000; Steen 2002). Lack of funding meant that the full study proposed by East 2007 did not proceed.

Declarations of interest

A potential interest was implied in the report by Steen 2000 for the gel pads co-designed by the authors and colleagues. This was formally declared in the subsequent study by Mary Steen who holds a patent for these gel pads (Steen 2002), although it was not declared in a study co-authored by the patent holder (Mary Steen) when it was used in the study by Navvabi 2009. The lead author of this review (CE) used the original Cochrane protocol and review to design a trial, which was subsequently registered and piloted (East 2007): two independent review authors abstracted the relevant information and included it in this review. A statement that there were no declarations of interest was provided by Beleza 2017; Francisco 2018 and Senol 2017, while declarations of interest were not included in the reports by Barclay 1983, Morais 2016 or Yusamran 2007.

Excluded studies

We excluded 15 studies. A number of studies identified in searches were not randomised, despite the relevant keywords being in the titles or abstracts (De Souza Bosco Paiva 2016; Dube 2013; Lu 2015; Pinkerton 1961) or were cross-over studies (LaFoy 1989; Nam 1991; Ramler 1986).

In the earlier versions of this review, we included comparisons between cooling treatments and other treatments, such as warmth, Hammamelis water (witch hazel), pramoxine or pulsed electromagnetic therapy. For the 2020 update, we followed the contemporary methods of minimising the number of comparisons and did not prioritise comparisons between cooling with other non-cooling treatments. We therefore excluded in this update the following studies that were included in the previous versions of the review for these comparisons: Gallie 2003; Hill 1989; Moore 1989; Sheikhhan 2011; Thangaraju 2006). We excluded a further three

studies identified in the updated search strategy that compared cooling treatment with another form of treatment (Amani 2015; Kaur 2012; NCT02024256 (See table of [Characteristics of excluded studies](#)).

Risk of bias in included studies

The included trials were at low or uncertain risk of bias overall, with the exception that the inability to blind participants and personnel

to group allocation meant that we considered all trials to be at unclear or high risk for this domain. Other areas at high risk of bias included two studies in which allocation concealment was unclear, while three studies had substantial attrition bias (detailed below). Blinding of outcome assessors was generally a source of unclear risk of bias (see below). See ([Figure 2](#) and [Figure 3](#)).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. 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)	Incomplete outcome data (attrition bias): All outcomes	Selective reporting (reporting bias)	Other bias	Blinding of participants and personnel (performance bias): All outcomes	Blinding of outcome assessment (detection bias): All outcomes
Barclay 1983	⊖	⊖	⊖	?	⊖	⊖	?
Beleza 2017	+	⊖	⊖	⊖	+	⊖	⊖
East 2007	+	+	+	+	?	?	?
Francisco 2018	+	+	?	?	+	?	?
Morais 2016	+	+	?	?	+	?	?
Navvabi 2009	+	?	⊖	⊖	?	?	?
Senol 2017	?	?	?	?	?	?	?
Steen 2000	+	+	⊖	?	?	?	?
Steen 2002	+	+	⊖	?	?	?	?
Yusamran 2007	+	+	+	?	?	?	?

Allocation

Random sequence generation was low risk of bias for all except two trials. [Barclay 1983](#) did not provide any detail on how it was determined that women were admitted to the ward area in which the particular treatment group was used (judged to be high risk of bias). A web-based random number table-generating website was used by [Senol 2017](#) and although the authors confirmed that a researcher undertook this, it remained unclear if the researcher had other responsibilities in the trial and could therefore have introduced some bias.

Blinding

Blinding of participants and clinicians was not feasible in the study designs and the risk of performance bias was generally judged as being unclear. [Barclay 1983](#) was subject to multiple risks of bias and unblinding of both participants and personnel was likely to have contributed to these concerns. For the remaining studies, it is unclear whether outcomes reported by the participants were at risk of detection bias: one author noted the potential for participants to wish to please the researcher and thus influence the outcomes ([Beleza 2017](#)). Two trials reported blinding of outcome assessors for assessment of perineal oedema/healing ([Morais 2016](#); [Steen 2000](#)): these were judged as low risk of detection bias when considering GRADE and unclear for women's perceptions of pain. For the remaining trials detection bias was judged as being at unclear risk of bias, particularly for objective outcomes such as perineal oedema, adverse events, rates of breastfeeding, use of additional analgesia and costs.

Incomplete outcome data

The proportions of incomplete outcome data ranged from 0% ([Barclay 1983](#); [Beleza 2017](#); [Francisco 2018](#); [Morais 2016](#); [Senol 2017](#); [Yusamran 2007](#)), 6% to 9% ([East 2007](#); [Navvabi 2009](#)), or higher in the two trials that required return of questionnaires once women had been seen at home daily to day 10 post-birth ([Steen 2000](#): 37.2% attrition; [Steen 2002](#): 29.8% attrition). The attrition rates were dissimilar for the ice pack (42%) and gel pad groups (32.5%) in [Steen 2000](#), while for [Steen 2002](#) there were similar rates across the ice pack (29.3%), gel pad (28.7%) and no-treatment groups (32.7%). We considered the potential effect of including the reported data, given our original a priori plan to consider excluding trials with more than 20% loss to follow-up in the earlier versions of the review. The losses to follow-up were related to challenges in obtaining the data forms from the community midwives. We considered that this would potentially contribute less bias than if the losses related to non-return by participants rather than their clinicians. We therefore included these studies in the (meta-) analyses.

Selective reporting

We judged the pilot trial by [East 2007](#) to be at low risk of reporting bias, given its prospective registration and that the raw data were available to the review authors. For studies with neither registration nor published protocols that were conducted some decades ago, we considered the risk of bias to be unclear, as this would not have been a reporting requirement when seeking journal publication at that time ([Barclay 1983](#); [Steen 2000](#); [Steen 2002](#); [Yusamran 2007](#)). Although studies conducted in the 2010s would often be required to be registered as a condition of publication, we determined that [Senol 2017](#) was at unclear risk of bias, given that enrolment

numbers and outcomes appeared to be consistent between the thesis and journal publication. We judged two reports to be at high risk of reporting bias, as they were registered five years after recruiting for their studies ([Beleza 2017](#); [Navvabi 2009](#)). Two studies registered with the Brazilian Trial Registry, for one, the authors provided a download of the information, but this is not accessible publicly ([Morais 2016](#)), while for the other the authors confirmed the registration, although it is not available online ([Francisco 2018](#)). We therefore judged these as being at unclear risk of reporting bias.

Other potential sources of bias

For [Barclay 1983](#), women had heard about the use of iced sitz baths and requested their use, as well as being influenced by some of the midwives to select this as an option. Findings were reported in the treatment groups in which they ultimately ended up, rather than the prospective expectation that there would be even numbers of women in each group. This may have introduced unknown biases in addition to those noted above.

Effects of interventions

See: [Summary of findings 1](#) Cooling treatment (ice pack or cold gel pad) compared to no treatment for relieving pain from perineal trauma sustained during childbirth; [Summary of findings 2](#) Cooling treatment (cold gel pad)+compression compared to placebo (gel pad+compression) for relieving pain from perineal trauma sustained during childbirth; [Summary of findings 3](#) Cooling treatment (ice pack) compared to placebo (water pack) for relieving pain from perineal trauma sustained during childbirth; [Summary of findings 4](#) Cooling treatment (ice pack) compared to cooling treatment (cold gel pad) for relieving pain from perineal trauma sustained during childbirth

Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment

Five studies ([Beleza 2017](#); [Francisco 2018](#); [Navvabi 2009](#); [Senol 2017](#); [Steen 2002](#)) enrolled 725 women and provided outcome data for 582 participants to compare cooling treatments as either an ice pack or a cold gel pad versus no treatment. Overall certainty of the evidence was very low, limited by the women, personnel and outcome assessors being unblinded to treatment allocation. Other concerns included unclear selection bias ([Beleza 2017](#); [Senol 2017](#)) and high attrition ([Steen 2000](#); [Steen 2002](#)). Additionally, small sample sizes for some outcomes, confidence intervals (CIs) that included the null and wide CIs contributed to concerns about the imprecision of the findings.

See: [Summary of findings 1](#).

Primary outcome

Perineal pain

Five trial reports provided data on women's self-rated moderate and severe perineal pain ([Steen 2002](#), n = 316) or using a scale of 0 (no pain) to 10 (worst possible pain) ([Beleza 2017](#) n = 50; [Francisco 2018](#) n = 45; [Navvabi 2009](#) n = 71; and [Senol 2017](#) n = 100). Women's self-rated perineal pain immediately following removal of the cold pad and within six hours of giving birth may be lower than for women who have no treatment ([Senol 2017](#): mean difference (MD) -4.46, 95% CI -5.07 to -3.85; 100 women; [Analysis 1.1](#)). We are left with uncertainty about the effect of cooling treatments compared with no treatment on women's self-reported moderate or severe

perineal pain within 24 hours of giving birth (1 study, 316 women; [Analysis 1.2](#)) or on a rating from zero to 10 (MD -0.41, 95% CI -1.78 to 0.95; 3 studies, 166 women; [Analysis 1.3](#)). Reported pain may be lower between 24 and 48 hours after giving birth for women when they use cooling, compared with no treatment (risk ratio (RR) 0.73, 95% CI 0.57 to 0.94; 1 study, 316 women; [Analysis 1.4](#)). [Beleza 2017](#) and [Navvabi 2009](#) reported that there may be no between-group differences for women's self-rated perineal pain (scale 0 no pain to 10 worst pain) within 24 hours of giving birth (MD -0.34, 95% CI -2.60 to 1.92, $I^2 = 57\%$; random effects; 2 studies, 121 women; [Analysis 1.3](#)) or within 24 and 48 hours of giving birth (MD -0.53, 95% CI -1.45 to 0.39; 1 study, 71 women, [Analysis 1.5](#)).

Secondary outcomes

Perineal pain associated with activities of daily living

One study ([Steen 2002](#)) reported on 312 women's self-assessed moderate and severe perineal pain associated with sitting ([Analysis 1.6](#); [Analysis 1.7](#)), walking ([Analysis 1.8](#); [Analysis 1.9](#)) and feeding baby ([Analysis 1.10](#); [Analysis 1.11](#)) within 24 hours and between 24 and 48 hours of giving birth, with no apparent between-group differences. [Senol 2017](#) noted that women had less pain associated with sitting, walking or breastfeeding in women following application of the cold gel pad, compared with no treatment (" $p < 0.001$ "), but no data were available to explore this further.

Perineal oedema, bruising and wound healing

Perineal oedema was reported as a distinct outcome by [Steen 2002](#) ($n = 316$), which may have favoured cooling treatments compared with no treatment between 24 and 48 hours of giving birth (RR 0.82, 95% CI 0.69 to 0.98; [Analysis 1.13](#)), although not within 24 hours of giving birth ([Analysis 1.12](#)).

Bruising of the perineum was reported as a distinct outcome for 316 women by [Steen 2002](#), with no between-group differences when measured within 24 hours, or between 24 and 48 hours of giving birth ([Analysis 1.14](#); [Analysis 1.15](#)).

[Navvabi 2009](#) reported a composite scale of perineal status, using the REEDA scale of zero (healthiest) to 15 (worst): this includes an assessment of redness, (o)edema, ecchymosis (bruising), discharge and approximation (wound gaping). They did not find any difference in this scale for women receiving cooling or no treatments within 24 hours of giving birth ([Analysis 1.16](#)), although those using ice packs were estimated to have a lower score than those with no treatment ([Analysis 1.17](#)). This scale was also used by [Senol 2017](#); however, we were unable to distinguish primiparous women (had episiotomy) from multiparous women (had episiotomy, tear or intact perineum), and could not include these data in the review. Although the trialists treated this variable as continuous data, this assumption cannot be guaranteed and we advise caution in interpreting the results.

Additional analgesia for relief of perineal pain

Women in both groups in [Steen 2002](#) used non-prescription and prescription analgesia similarly within 24 hours and between 24 and 48 hours after giving birth ([Analysis 1.18](#); [Analysis 1.19](#)).

Adverse effects of treatment on perineal healing

No women in either group reported adverse effects of an ice pack or no treatment within four to six hours after giving birth (100 women;

[Senol 2017](#)). A number of outcomes were assessed for 315 women by [Steen 2002](#). However, we are uncertain of whether there are differences in the reported outcomes: perineal wound healing: day 5 ([Analysis 1.20](#)) - wound not healing (RR 1.24, 95% CI 0.34 to 4.58), wound edges gaping (RR 2.56, 95% CI 0.58 to 11.33), any sign of infection (RR 0.47, 95% CI 0.12 to 1.82); day 10 ([Analysis 1.21](#)) - wound not healing (RR 0.70, 95% CI 0.20 to 2.42), wound edges gaping (RR 0.62, 95% CI 0.22 to 1.74), any sign of infection (RR 2.33, 95% CI 0.52 to 10.42), need for wound resuture (RR 2.34, 95% CI 0.11 to 48.25), noting that there were few events for these outcomes and where GRADE assessments were conducted ([Summary of findings 1](#)) they were of very low certainty.

Maternal exhaustion

No studies reported on maternal exhaustion.

Maternal views and experiences with treatment

[Steen 2002](#) asked women about their satisfaction with perineal care 10 days after giving birth. There may be no difference in women's ratings of their care as good, very good or excellent for the two groups (308 women; [Analysis 1.22](#)). The Postnatal Comfort Questionnaire, using a scale of 1 (low comfort) to 5 (high comfort) and administered by [Senol 2017](#), included two subgroups of relevance to maternal views and experiences. Women may have a trivially higher level of psychospiritual comfort when using the cooling treatment (cold gel pad) compared with no treatment (MD -0.10, 95% CI -0.20 to 0.00) and there may be no between-group difference in their sociocultural comfort ratings (MD 0.01, 95% CI -0.09 to 0.11; 1 study, 100 women; [Analysis 1.23](#)). [Beleza 2017](#) sought opinions from the 24 women who received cryotherapy: 96% responded that the ice bag was comfortable, 96% agreed that they would use this again, while all women reported that they were satisfied or very satisfied with the treatment.

Women providing any breast milk to the baby 24 to 48 hours after giving birth

Data from one study ([Steen 2002](#)) reported no difference in the proportion of women providing their babies with breast milk compared with no treatment (RR 0.89, 95% CI 0.73 to 1.07; 315 women; [Analysis 1.24](#)).

Cost of treatment

No studies evaluated the costs of treatments.

Subgroup analyses

The authors of one study ([Steen 2002](#)) made data available that allowed us to conduct the prespecified subgroup analyses for comparisons of the effectiveness of cooling treatment (ice packs, cold gel pads) and no treatment on the primary outcome, perineal pain.

Parity

There appeared to be some difference in effect between the subgroups for perineal pain by parity within 24 hours of giving birth but not between 24 and 48 hours of giving birth ([Analysis 1.25](#); [Analysis 1.26](#)).

Mode of birth

There did not appear to be any difference in effect between the subgroups for perineal pain by mode of vaginal birth when

measured within 24 hours or between 24 and 48 hours of giving birth ([Analysis 1.27](#); [Analysis 1.28](#)).

Comparison 2: Cooling treatment (cold gel pad) + compression versus placebo (gel pad + compression)

[Yusamran 2007](#) enrolled 250 women in a study comparing cooling using a cold gel pad plus compression from a well-fitting sanitary pad secured in place with a belt, compared with a placebo gel pad, also with the well-fitting pad to provide compression. Data were reported on all women enrolled. The overall evidence was of low certainty, with trivial effect sizes for some outcomes, wide CIs that included the null effect for other outcomes and the uncertainty of the potential bias introduced with unblinding.

See: [Summary of findings 2](#).

Primary outcome

Perineal pain

The one study suggested that there may be no difference in women's self-reported perineal pain on a scale of zero (no pain) to 10 (worst possible pain), assessed within four to six hours of giving birth (MD -0.32, 95% CI -0.78 to 0.14; 250 women; [Analysis 2.1](#)). Women may experience very slightly less perineal pain in the cooling therapy group than did those in the placebo group, when assessed between 24 and 48 hours following birth (MD -0.43, 95% CI -0.73 to -0.13; 250 women; [Analysis 2.2](#)).

Secondary outcomes

Perineal pain associated with activities of daily living

No studies evaluated this outcome.

Perineal oedema

There was less oedema (scale zero: none - 3; > 2 cm) in the cooling-therapy group compared with the placebo group when observed within 24 to 48 hours after giving birth (MD -0.15, 95% CI -0.28 to -0.03; 250 women; [Analysis 2.3](#)). Although the trialists treated this variable as continuous data, this assumption cannot be guaranteed and we advise caution in interpreting the results.

Perineal bruising

None of the women in either treatment group were observed to have perineal bruising when assessed within 24 to 48 hours of giving birth (250 women).

Additional analgesia for relief of perineal pain

No studies evaluated this outcome.

Adverse effects on perineal healing

No women in either group were noted to have poor wound approximation when assessed 24 to 48 hours after giving birth (250 women).

Maternal exhaustion

No studies reported on maternal exhaustion.

Maternal views and experiences with treatment

Women were slightly more satisfied with their perineal care after receiving cooling treatment compared with compression on a scale of zero (not satisfied) to 10 (most satisfied) ([Analysis 2.4](#)).

Women providing any breast milk to the baby 24 to 48 hours after giving birth

No studies provided detail of infant feeding.

Cost of treatment

No studies evaluated the costs of treatments.

Comparison 3: Cooling treatment (ice pack) versus placebo (water pack)

[Morais 2016](#) enrolled 63 women who had experienced perineal trauma, and provided outcome data for these 63 participants to compare cooling treatment in the form of an ice pack with a placebo of a water pack. Data were provided directly by the study authors, as the published data also included women with an intact perineum (total n = 80).

We judged the certainty of the evidence as being very low, given that participants and personnel were unblinded and the small sample size. Confidence intervals that included the null and wide CIs contributed to concerns about the imprecision of the findings.

See: [Summary of findings 3](#)

Primary outcome

Perineal pain

The study authors advised that no women reported pain within four to six hours, or within 24 hours of giving birth ([Morais 2016](#)).

Secondary outcomes

Perineal pain associated with activities of daily living

No studies addressed this outcome.

Perineal oedema

There may be no difference in perineal oedema between women in the cooling versus placebo group, when assessed within four to six hours of giving birth (RR 0.96, 95% CI 0.50 to 1.86; 63 women; [Analysis 3.1](#)) or within 24 hours of giving birth (RR 0.36, 95% CI 0.08 to 1.59; 63 women; [Analysis 3.2](#)).

Perineal bruising

No studies evaluated this outcome.

Additional analgesia for relief of perineal pain

There may be no between-group difference in the proportion of women using additional analgesia within 24 hours of giving birth (RR 0.63, 95% CI 0.35 to 1.11; 63 women; [Analysis 3.3](#)).

Adverse effects on perineal healing

No women were reported to have experienced adverse effects on wound healing (63 women).

Maternal exhaustion

None of the women reported that they were exhausted when assessed within four to six hours or within 24 hours of giving birth.

Maternal views and experiences with treatment

There may be no difference in the women's ratings of three aspects of their experiences with treatment ([Analysis 3.4](#)) as: (i) being satisfied with treatment (RR 0.91, 95% CI 0.77 to 1.08); (ii) would

repeat the treatment in future childbirth (RR 0.88, 95% CI 0.75 to 1.04); and (iii) would recommend treatment (RR 0.89, 95% CI 0.77 to 1.03).

Women providing any breast milk to the baby 24 to 48 hours after giving birth

All participants provided some breast milk to their babies within 24 to 48 hours of giving birth ([Analysis 3.5](#)).

Cost of treatment

No studies evaluated the costs of the ice pack or water bag.

Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad)

Three trials ([Navvabi 2009](#); [Steen 2000](#); [Steen 2002](#)) enrolled 459 women in their studies comparing one cooling treatment (ice pack) with an alternative cooling treatment (cold gel pad), and reported outcomes for 338 of these participants.

We judged the overall certainty of evidence to be very low, noting that all participants, personnel and outcome assessors were unblinded, there were high attrition rates in the studies by [Steen 2000](#) (37%) and [Steen 2002](#) (29%), and selection bias was unclear for [Navvabi 2009](#). Additionally, the small sample sizes for most outcomes and wide CIs contributed to concerns about the imprecision of the findings.

See: [Summary of findings 4](#).

Primary outcome

Perineal pain

Three trial reports provided data on women's self-rated perineal pain as moderate and severe ([Steen 2000](#), $n = 49$; [Steen 2002](#), $n = 215$) or using a scale of 0 (no pain) to 10 (worst possible pain, [Navvabi 2009 \$n = 74\$ \). There may be no differences between the groups in women's self-reported moderate or severe perineal pain within four and six hours of giving birth \(RR 0.57, 95% CI 0.26 to 1.24; 1 study, 49 women; \[Analysis 4.1\]\(#\)\). The evidence was too uncertain to suggest whether one cooling treatment was better than the other for relieving perineal pain within 24 hours of giving birth \(RR 0.98, 95% CI 0.78 to 1.22; 2 studies, 264 women; \[Analysis 4.2\]\(#\); MD 0.58, 95% CI -0.44 to 1.60; 1 study, 74 women; \[Analysis 4.3\]\(#\)\) or between 24 and 48 hours after giving birth \(RR 1.21 95% CI 0.89 to 1.65; 2 studies, 264 women; \[Analysis 4.4\]\(#\); MD 0.86, 95% CI -0.10 to 1.82; 1 study, \$n = 74\$; \[Analysis 4.5\]\(#\)\).](#)

Secondary outcomes

Perineal pain associated with activities of daily living (sitting, walking, feeding baby)

One study ([Steen 2002](#)) reported on 215 women's self-assessed perineal pain associated with sitting ([Analysis 4.6](#); [Analysis 4.7](#)), walking ([Analysis 4.8](#); [Analysis 4.9](#)) and feeding baby ([Analysis 4.10](#); [Analysis 4.11](#)) within 24 hours and between 24 and 48 hours of giving birth, with no apparent between-group differences.

Perineal oedema, bruising and wound healing

Perineal oedema was reported as a distinct outcome by [Steen 2000](#) and [Steen 2002](#), but we are uncertain of whether there are differences between women using ice packs or cold gel pads within four to six hours of giving birth (RR 1.39, 95% CI 0.93 to 2.09; 1 study,

49 women; [Analysis 4.12](#)), or within 24 hours of giving birth (RR 0.97, 95% CI 0.84 to 1.13; 2 studies, 264 women; [Analysis 4.13](#)). Women using ice packs may be more likely to have oedema between 24 and 48 hours after giving birth, compared with those using cold gel pads (RR 1.69, 95% CI 1.03 to 2.77; 2 studies, 264 women; [Analysis 4.14](#)).

Bruising of the perineum was reported as a distinct outcome by [Steen 2002](#), with no difference when using cooling treatments compared with no treatment within four to six hours of giving birth (RR 1.23, 95% CI 0.51 to 2.97; 1 study, 49 women; [Analysis 4.15](#)), within 24 hours (RR 0.95, 95% CI 0.79 to 1.14; 2 studies, 264 women; [Analysis 4.16](#)), or between 24 and 48 hours of giving birth (RR 1.07, 95% CI 0.92 to 1.25; 2 studies, 264 women; [Analysis 4.17](#)).

[Navvabi 2009](#) reported a composite scale of perineal status, using the REEDA scale of zero (healthiest) to 15 (worst): this includes an assessment of redness, (o)edema, ecchymosis (bruising), discharge and approximation (wound gaping). They reported that there may be no overall difference in this scale for women using ice packs or cold gel pads, either within 24 hours of giving birth (MD -0.13, 95% CI -0.85 to 0.59; 1 study, 74 women; [Analysis 4.18](#)) or between 24 and 48 hours after giving birth (MD 0.20, 95% CI -0.33 to 0.73; 1 study, 74 women; [Analysis 4.19](#)).

Additional analgesia for relief of perineal pain

Women in both groups in [Steen 2002](#) (215 women) used non-prescription and prescription analgesia similarly with 24 hours and between 24 and 48 hours after giving birth ([Analysis 4.20](#); [Analysis 4.21](#)).

Adverse effects of treatment on perineal healing

The report by [Navvabi 2009](#) included wound edge approximation as part of the REEDA scale: this component could not be analysed separately from the overall scale, but there were no apparent between-group differences, as noted above for "perineal oedema, bruising and wound healing".

Although wound healing was not reported in the time frame specified for this review, [Steen 2002](#) assessed healing on days five and 10 by inspecting the approximation of the skin edges. More women using ice packs possibly had wound edges gaping at day five than those who had used the gel pads (RR 0.22, 95% CI 0.05 to 1.01; 1 study, 215 women; [Analysis 4.22](#)). However, this did not appear to persist to day 10 (RR 3.06, 95% CI 0.63 to 14.81; 1 study, 214 women; [Analysis 4.23](#)). Other assessments of wound healing did not provide any certainty of evidence for between-group differences in terms of the wound not healing, any sign of wound infection, and by day 10 the need for wound resuture ([Analysis 4.22](#); [Analysis 4.23](#)), noting the wide CIs for these outcomes that had few events.

Maternal exhaustion

No studies reported on maternal exhaustion.

Maternal views and experiences with treatment

Maternal views were evaluated in slightly different formats and for different time frames in the two trials that reported this outcome, and we consider them separately ([Analysis 4.24](#)). Women may be less likely to rate their opinion of treatment effects favourably following the use of ice packs compared with cold gel pads five days after giving birth (RR 0.33, 95% CI 0.17 to 0.68; 1 study, 49 women), and may be less favourable in their ratings of ice packs than of cold

gel pads when assessed on day 10 following birth (RR 0.82, 95% CI 0.73 to 0.92; 1 study, 208 women; low certainty).

Women providing any breast milk to the baby 24 to 48 hours after giving birth

The one study (Steen 2002) reported similar proportions of women providing breast milk to their babies when using either the ice packs or cold gel pads (RR 1.05, 95% CI 0.84 to 1.33; 1 study, 212 women; Analysis 4.25).

Cost of treatment

No studies evaluated the costs of treatments.

Subgroup analyses

The authors of one study (Steen 2002) made data available that allowed us to conduct the prespecified subgroup analyses for comparisons of the effectiveness of the cooling treatment (ice packs, cold gel pads) on the primary outcome, perineal pain.

Parity

There appeared to be no difference in effect between the subgroups for perineal pain by parity within 24 hours of giving birth or between 24 and 48 hours of giving birth (Analysis 4.26; Analysis 4.27).

Mode of birth

There did not appear to be any difference in effect between the subgroups for perineal pain by mode of vaginal birth when measured within 24 hours or between 24 and 48 hours of giving birth (Analysis 4.28; Analysis 4.29).

Comparison 5: Cooling treatment (ice pack, compressing, being horizontal) versus cooling treatment (ad hoc application of ice packs)

East 2007 proposed a trial comparing the use of a structured regimen involving regular (approximately six times daily) application of an ice pack with compression and lying horizontally (I.C.H.), compared to the ad hoc application of ice packs. A pilot study on 20 women was conducted to assess the feasibility of the study processes. The study author provided unpublished data on the 16 women who had some degree of perineal trauma. Lack of funding meant that the full trial did not proceed. The wide CIs for each outcome reflect the small sample size.

The limitations of the study included unblinding of participants, personnel and outcome assessors, along with the very small numbers enrolled in the pilot feasibility study. We did not prepare a 'Summary of findings' table as there were so few participants in this single pilot study for this comparison.

Primary outcome

Perineal pain

There was no apparent difference in women's self-reported perineal pain from the I.C.H. regimen compared with the ad hoc application of ice packs within 24 hours (RR 3.33, 95% CI 0.49 to 22.90; 8 women; Analysis 5.1) or between 24 and 48 hours of giving birth (RR 1.00, 95% CI 0.20 to 4.95; 12 women; Analysis 5.2).

Secondary outcomes

Perineal pain associated with activities of daily living

There were no apparent between-group difference in women's self-reported moderate and severe pain for sitting, walking, urinating or caring for the baby within 24 hours of giving birth or 24 to 48 hours after giving birth (Analysis 5.3; Analysis 5.4; Analysis 5.5; Analysis 5.6; Analysis 5.7; Analysis 5.8; Analysis 5.9; Analysis 5.10).

Perineal oedema

The pilot study did not evaluate this outcome.

Perineal bruising

The pilot study did not evaluate this outcome.

Additional analgesia for relief of perineal pain

There were no apparent between-group differences in the proportion of women using additional analgesia within 24 hours of giving birth (RR 0.68, 95% CI 0.31 to 1.51; 8 women; Analysis 5.11) or between 24 and 48 hours of giving birth (RR 0.80, 95% CI 0.41 to 1.56; 12 women; Analysis 5.12).

Adverse effects on perineal healing

No studies evaluated this outcome.

Maternal exhaustion

The participants did not report differences in their energy levels, measured on a scale of 1 (much less than normal) to 5 (much more than normal) within 24 hours of giving birth (MD 0.70, 95% CI -0.11 to 1.51; 8 women; Analysis 5.13) or between 24 and 48 hours after giving birth (MD 0.00, 95% CI -0.92 to 0.92; 12 women; Analysis 5.14).

Maternal views and experiences with treatment

Women in each treatment group rated their experiences with treatment as being effective or extremely effective similarly, both within 24 hours of giving birth (RR 0.41, 95% CI 0.11 to 1.48; 8 women; Analysis 5.15) and within 24 and 48 hours after giving birth (RR 1.18, 95% CI 0.76 to 1.83; 12 women; Analysis 5.16).

Women providing any breast milk to the baby 24 to 48 hours after giving birth

There was no between-group difference in the proportion of women providing some breast milk to their babies between 24 and 48 hours after giving birth (RR 0.69, 95% CI 0.31 to 1.57; 7 women; Analysis 5.17).

Cost of treatment

The pilot study did not evaluate the cost of treatments.

DISCUSSION

Summary of main results

Ten trials considered the potential for cooling treatments to improve maternal perineal pain and other outcomes: nine of these trials contributed data from 998 women for this updated review. Across the studies primiparous and multiparous women experiencing normal vaginal births and assisted vaginal deliveries were included. No women with severe perineal trauma (3rd/4th degree tears) were included.

We considered the primary outcome of women's self-reported perineal pain ratings at four to six hours, within 24 hours, and 24 to 48 hours after giving birth.

The included studies provided some reports of the secondary outcomes of perineal pain interfering with activities of daily living, perineal oedema and bruising, additional analgesic use, adverse effects including perineal wound healing, maternal exhaustion, women's views/experiences with treatments (or no treatment) and breast milk provision to babies.

Few trials used similar comparisons, assessment tools and outcome measures, making it inherently difficult to draw conclusions. For the purpose of this review update we extracted five comparisons from the trials. These included cooling compared to either no treatment or a placebo treatment, or comparisons between different cooling modalities. It is important to note that gaining true participant/outcome assessor blinding of participants for this clinical intervention is difficult if not impossible, with such limitations being acknowledged by the trial authors. Blinding of outcome assessors was also problematic, with the women themselves reporting the primary outcome of pain and their experiences with treatments (or no treatment).

Primary outcome: perineal pain

There was very low-certainty evidence from relatively small studies to evaluate the effectiveness of cooling treatments on women's self-reported perineal pain.

When comparing perineal pain following the use of cooling treatments versus no treatment, there was very low-certainty evidence to suggest that cooling was more favourable at four to six hours after having the baby, or at 24 to 48 hours after giving birth.

When cooling was compared with a placebo option, one study that compared the use of a cold gel pad + compression with an unchilled gel pad + compression found a trivial difference of 0.43 points on a 10-point scale that favoured the cold gel pad + compression group within 24 and 48 hours of giving birth. Another placebo option was the use of a bag of water at room temperature, as the comparator to a bag of ice: the authors advised that no women experienced perineal pain in either group, thus providing no opportunity to evaluate this outcome further.

Looking at different methods of cooling, it remains uncertain if there was any evidence of an effect that favoured one form of cryotherapy over another on women's self-reported perineal pain within 24 hours or 24 to 48 hours after giving birth.

Secondary outcomes

The evidence available is of very low certainty for most outcomes and so we are unable to determine the impact of different interventions on women's recovery from childbirth-related perineal trauma. Women did not report different levels of perineal pain when they engaged in activities such as sitting, walking, urinating or caring for the baby, or exhaustion for any of the comparisons, for those trials that reported on this outcome. Nor did women appear to use additional analgesia differently following perineal cooling treatments, no treatments or placebos.

There was probably a reduction in perineal oedema following the use of cooling treatments compared with no treatment or a placebo

within 24 to 48 hours after giving birth, and it is possible that this improved with the use of ice packs compared with cold gel pads (very low-certainty evidence). Although not widely reported, there was very low-certainty evidence of no difference in perineal bruising when applying or not applying cooling therapies. This was the case both for bruising used as a distinct outcome (Steen 2002) and as part of a composite scale on perineal status using the REEDA scale (Navvabi 2009).

Data on adverse effects on perineal wound healing were available for the comparisons between cooling and no treatment, cooling and placebo (unchilled gel pad), and ice pack compared with cold gel pad. Only one study provided very low-quality certainty of evidence that there was probably less wound gaping five days after giving birth following the use of ice packs, compared with cold gel pads, with very wide 95% confidence intervals that suggest a very large potential effect (as little as 5% likelihood in the ice-pack group) through to 1% more likelihood in the cold gel pad group: this trend did not appear to persist to day 10. Furthermore, none of the other wound-healing indicators showed a difference between groups, influenced by the low numbers of those with adverse events and wide confidence intervals around the measures of effect. Two studies assessed wound gaping as a component of the REEDA scale. Extraction of this individual component of data for analysis could not be done, but the evidence from these studies did not suggest an overall difference in between-group measures at 24 to 48 hours after giving birth.

Women generally rated their satisfaction and experiences with perineal care very favourably, regardless of the use of cooling, no treatment or placebo. When two cooling methods, ice packs and cold gel pads, were compared, however, there was limited very low-certainty evidence that women preferred the cold gel pads over the ice packs: this finding needs to be interpreted cautiously, given that one of the investigators was the developer and patent-holder of the gel pads used, as well as acknowledging the small sample sizes, lack of blinding and wide confidence intervals around the measures of effect. We considered the very low-certainty evidence of a mean difference of -0.43 on a 10-point scale when assessed between 24 and 48 hours after giving birth to be a trivial finding, favouring the use of a cooling treatment plus compression over some compression.

The ability of women to supply breast milk to their babies appeared not to be affected by any modalities of treatment.

No studies reported an economic analysis of the treatments.

What is the future for cryotherapy overall?

Safe dosage recommendations of cooling (Mac Auley 2001) appear to have been applied in the methodology of the trials in this review.

Literature investigating the effects of cryotherapy/cooling in sporting or post-surgical environments describes a dose dependency (Bleakley 2006; Kuo 2013; Machado 2016). The same could be presumed for perineal trauma post-childbirth, which highlights the need to look at a dose-response relationship to tissue temperature and other outcome measures. In more recent studies (Beleza 2017; Morais 2016; Senol 2017; Yusamran 2007) we are beginning to see this taken into account, but assessment of this is beyond the scope of this current review. It appears there is now a pressing need for this dose-dependency data to examine the

cooling threshold or optimal window beyond which effectiveness can be seen while still reducing the risk of adverse effects.

Overall completeness and applicability of evidence

The studies enrolled relatively small numbers of women and may not represent all models of postnatal perineal care globally. The use of the combined principles of rest, ice, compression and elevation have not been well explored. Neither has there been adequate reporting of adverse effects from cooling treatments, that are not only important in this setting, but remain an area of concern with the use of cooling in the treatment of other injuries (Dubois 2020; Dushesne 2017; Singh 2017).

We await data from trialists that would allow inclusion of their findings for participants with perineal trauma and not for those with an intact perineum (Leventhal 2011; Oliveira 2012). Informal review of the published data for all women in these trials suggests that their ultimate inclusion would not change the overall findings of the review.

While ice is readily available in high-income countries, this may or may not be the case in low-middle income countries. Gel pads for cooling are suitable for use, cleaning and re-use by only one woman, cost money to acquire and require access to a freezer: they are therefore available to many in high-income countries and possibly less so in low-middle income areas. The developer and patent-holder has examined the effectiveness of cold gel pads in three trials (Steen 2000; Steen 2002; Navvabi 2009). Another commercially-available cold gel pad was adapted for use in the trial undertaken by Yusamran 2007. There is limited certainty of the evidence for the safety and effectiveness of cold gel pads for the relief of perineal pain following childbirth.

Quality of the evidence

Included studies were generally at unclear to high risk of bias. Most of the outcomes assessed using GRADE had a rating of very low-certainty evidence, with downgrading attributed to the high risk of bias associated with the inability to blind outcome assessments, with the participants providing data for many of the outcomes. One study had a very low sample size, being only a pilot study ($n = 16$; East 2007) and most of the remaining studies enrolled fewer than 100 women. Downgrading for imprecision was undertaken when there was high attrition and/or the confidence intervals included the null effect or were judged to be wide. Two trials were retrospectively registered (Beleza 2017; Navvabi 2009) and details of the registrations for Francisco 2018 and Morais 2016 are not publicly accessible online. There were very few outcomes examined by two or more trialists for each comparison, meaning that heterogeneity was limited and inconsistency of findings could not be judged.

Potential biases in the review process

The comprehensive search strategy was accompanied by rigorous screening, appraisal and data extraction methodology. Two other review authors performed data extraction and conducted the 'Risk of bias' assessments for the one study that was led by one of the review authors (East 2007). We contacted study authors to clarify uncertainties where at all possible. We therefore consider the risk of other biases in the review process to be low.

Agreements and disagreements with other studies or reviews

We are not aware of any other published systematic reviews or non-randomised studies that have examined the potential for cooling treatments to relieve perineal pain following childbirth.

AUTHORS' CONCLUSIONS

Implications for practice

There is limited very low-certainty evidence to support the use of cooling treatments, in the form of ice packs or cold gel pads, for the relief of perineal pain in the first two days following childbirth. It is likely that concurrent use of several treatments is required to adequately address this issue, including prescription and non-prescription analgesia (East 2011). Studies included in this review involved the use of cooling treatments for 10 to 20 minutes, and although no adverse effects were noted, these findings came from studies of relatively small numbers of women, or adverse events were not reported at all. The use of cooling therapies for the management of postnatal perineal pain is common practice and positively accepted by women, midwives, doctors and therapists alike. The continued lack of high-certainty evidence of the benefits of cooling treatments should be viewed with caution, and further well-designed trials should be conducted before we consider changing current clinical practices.

Implications for research

The effectiveness of cooling treatments for relief of perineal pain may be better assessed in larger studies that report the treatment regimens and examine the findings according to parity, mode of birth and degree of perineal trauma. Outcome assessors should be blinded to group allocation for evaluation of oedema, bruising and adverse effects on wound healing. Studies that use cold gel pads would ideally be conducted by investigators who have no commercial interest in these devices and/or ensuring that personnel caring for the women and the women themselves are not aware of any such commercial arrangements when providing their ratings for the various outcomes. Future studies may further consider the effects of removing the cooling treatment after a set period of time, replacing the cooling device at regular intervals and considering potential adverse effects of prolonged cooling, along with examining the effects of incorporating rest, compression and 'elevation' (lying down, rather than sitting or standing).

Given the limited evidence to support the use of cooling treatments and the general lack of effective alternatives compared with cooling identified in this review, future studies may ethically consider the use of a no-topical treatment group, to compare the potential effectiveness of agents that provide a greater degree of cooling that can be sustained for longer than current methods.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Barclay 1983

Study characteristics

Methods	Randomised controlled trial
Participants	Study setting: Woden Valley Hospital, Canberra, Australia Women admitted to the postnatal ward who had an episiotomy
Interventions	Of relevance to this review, the cooling intervention was an <i>iced sitz bath</i> : 30 g salt added to 1 - 2 litres of cold tap water, to which the contents of a jug of ice were added by the woman, to help her control how quickly the temperature lowered. Women sat in the dish for 10 minutes, 3 - 4 times daily (n = 40). The comparison group was <i>hygiene only</i> ("no treatment"): women were instructed in basic hygiene, including showering 3 times a day and drying the perineum carefully (n = 20). Of note, the investigators also considered the following interventions that were in common use at the time. The numbers of women in these groups are not counted in the overall numbers for this review: <i>warm sitz bath</i> (n = 30); <i>ray lamp</i> (n = 21) or <i>witch hazel solution</i> (n = 30)
Outcomes	Subjective perception of pain (scale of 1 = none to 5 = severe); objective assessment of healing, infection and analgesia usage
Notes	Additional data (numbers for the graphs) and clarification of group assignment were sought by email in July 2006. The lead author responded and explained about the contamination of the groups but was unable to provide further data Dates of study: not stated Proposed number of participants: 120 Funding sources: none stated

Local cooling for relieving pain from perineal trauma sustained during childbirth (Review)

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Barclay 1983 (Continued)

Declarations of interest: none stated

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	"A four-bed room was set aside for each method. Every woman with an episiotomy admitted to that room joined that particular method" (p16)
Allocation concealment (selection bias)	High risk	Unblinded. Women could request alternative treatments to those assigned.
Incomplete outcome data (attrition bias) All outcomes	High risk	The intention was to have 30 women in each group, but 10 women from the no-treatment group received iced sitz baths. The data were analysed by treatment received, rather than by intention to treat
Selective reporting (reporting bias)	Unclear risk	No protocol published
Other bias	High risk	Women had heard about the effectiveness or otherwise of treatments and requested them, hence 40 women were analysed for the iced sitz baths group, an additional 10 women than "allocated" to that group, who had been assigned to the hygiene-only (usual treatment) group. Midwives also had a preference for the iced sitz baths, which contaminated the study groups. Findings were reported according to treatment used (i.e. "per protocol"), rather than treatment assigned
Blinding of participants and personnel (performance bias) All outcomes	High risk	Women and midwives were not blinded to the treatment. Evidence of this resulting in bias was seen with women requesting to have the cold sitz baths
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women rated their own pain. Staff made the remaining judgements of wound healing/infection. No mention is made of blinding a researcher to abstract the data from the woman's record

Beleza 2017

Study characteristics

Methods	Randomised controlled trial
Participants	Study setting: Reference Centre of Women's Health of Ribeirao Preto, Sao Paulo, Brazil Primiparous women over 18 years of age with a low-risk pregnancy who are literate, have no cognitive defects within 6 - 24 hours of having a vaginal birth with episiotomy and where anti-inflammatory medication, if taken, has worn off by the time of assessment.
Interventions	Intervention: single perineal application of a bag of 150 g crushed ice for 20 minutes (n = 24) Control: "routine maternity care", being anti-inflammatory analgesia on request (n = 26)
Outcomes	Self-reported pain using a numerical rating scale (0 (least) to 10 (worst)): (i) pre-randomisation; (ii) 20 minutes after the 1st evaluation; and (iii) 1 hour after the 2nd evaluation Intervention group only - women's satisfaction with the cryotherapy

Beleza 2017 (Continued)

Notes

Authors clarified queries about:

(i) access to analgesia post-randomisation in each group: no women used analgesia during the treatment period (email 22 Dec 2019); and

(ii) timing of the treatment and evaluations, given that recruitment could occur up to 24 hours after giving birth: authors advised (email 7 Jan 2020) that the mean (SD) time for recruitment was 15.92 hours (6.28) for the control group and 16.17 (6.37) hours for the intervention group

Dates of study: July 2007 to January 2008

Funding sources: Ribeirao Preto School of Nursing of the University of Sao Paulo, Brazil

Declarations of interest: "Nothing to declare"

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Used computer-generated randomisation list from www.randomization.com
Allocation concealment (selection bias)	High risk	The sole researcher accessed the randomisation group and acknowledged that they could have known the allocation prior to randomising the participant
Incomplete outcome data (attrition bias) All outcomes	High risk	The consort flowchart suggests that outcome data were available for all participants, but the trial was registered 5 years after the study was undertaken, although prior to publication of the findings
Selective reporting (reporting bias)	High risk	The trial was registered 5 years after the study was undertaken and prior to publication of the findings
Other bias	Low risk	None noted
Blinding of participants and personnel (performance bias) All outcomes	High risk	Not possible to blind the researcher or the participants. The researcher noted that this "... may have caused some bias related to the tendency of participants to please the physiotherapist"
Blinding of outcome assessment (detection bias) All outcomes	High risk	The same researcher who undertook the group allocation and treatment also asked the women to rate their pain. The researcher noted that this "... may have caused some bias related to the tendency of participants to please the physiotherapist"

East 2007

Study characteristics

Methods	Randomised controlled trial
Participants	Study setting: Royal Women's Hospital, Melbourne, Australia Women having a vaginal birth who are willing and able to give informed consent and sustained perineal trauma (episiotomy/tear) or labial tears during childbirth

East 2007 (Continued)

Interventions	<p>Intervention: ice pack, compression, being horizontal (I.C.H): an ice pack to the perineum for 20 minutes every 2 - 3 hours for 2 - 3 days, wear well-fitting pads and underwear and lie down for 20 minutes (n = 7 in the pilot study)</p> <p>Control: ad-hoc application of ice packs to the perineum (n = 9 in the pilot study)</p>
Outcomes	Self-reported perineal pain, perineal pain associated with activities of daily living, perineal bruising, perineal oedema, self-reported energy level: rating 1 "much less than normal" to 5 "much more than normal", additional analgesic, impact of perineal pain on attending to baby, side effects of treatment within 24 hours; between 24 and 48 hours
Notes	<p>This is a trial registration document. The trial registration was initially registered on 30 October 2007 and was updated on 19 January 2016. A pilot study was undertaken to consider the feasibility of the protocol (n = 20 including intact perineum; n = 16 with perineal trauma and used in this review). The full study did not proceed due to lack of funding</p> <p>Additional information provided by author:</p> <ul style="list-style-type: none"> • The term of intervention: Rest, Ice, Compression and Elevation (R.I.C.E.) was updated to Ice, Compression and Horizontal (I.C.H) in 2016 (verbal communication 17 January 2020). • A validated VAS scale was used to measure perineal pain (email 20 January 2020). • The method of minimising similar horizontal rest or sitting compression in both control and intervention group: the default care in the postnatal ward involved women being up and about as much as possible. The intervention group were encouraged to rest horizontally. This was checked by asking the women in both groups the same questions about lying down (compared to sitting up). They also asked about their perception of the analgesic effectiveness, well-fitting pads and underwear, with a 'not applicable' option that the women could check (email 20 January 2020) • The author managed the first 3 of 6 total opportunities for surveying in the pilot phase (email 20 January 2020) • The author did not have an opportunity to measure perineal oedema and bruising in the pilot phase (email 20 January 2020) • The definition of "analgesic treatments" in the questionnaire includes: ice, pressure, oral, rectal, injection analgesia. One participant reported side effects of analgesic treatments, commented on constipation from the paracetamol (email 20 January 2020) <p>Dates of study: October 2008 to February 2009</p> <p>Funding sources: funding not secured, therefore trial recruitment did not continue beyond the pilot study</p> <p>Declarations of interest: the lead author of this systematic review (CE) was the lead on this pilot RCT. This trial registry was reviewed by E Dorward and J Liu</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Quote "A researcher not otherwise involved in the study will generate the sequence using block randomisation (1:1 control: intervention), stratified for number of children born (vaginally), mode of birth and degree of perineal trauma"
Allocation concealment (selection bias)	Low risk	Following informed consent and within the first 2 hours after giving birth, women are randomly allocated to 1 of the 2 treatment groups using consecutively numbered sealed, opaque envelopes
Incomplete outcome data (attrition bias) All outcomes	Low risk	The target sample size is 880 but actual recruitment is 20 (16 with perineal trauma). The full recruitment did not proceed due to funding issues

East 2007 (Continued)

		The author did not have an opportunity to measure bruising or oedema in the pilot phase
Selective reporting (reporting bias)	Low risk	The author reported on all the data collected
Other bias	Unclear risk	None noted
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Women and clinicians were unblinded to treatment allocation, due to the nature of the treatment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Participants self-reported perineal pain. It was designed that a researcher assessing perineal oedema and bruising was blinded to group allocation, but data on perineal bruising or oedema were not collected

Francisco 2018

Study characteristics

Methods	Randomised controlled trial
Participants	<p>Study setting: Midwife-led, alongside, no-profit birth centre, Sao Paulo City, Brazil.</p> <p>Inclusion criteria: women aged 18 years or older, no previous birth and within 6 - 24 hours of a normal vaginal birth following full-term, singleton pregnancy with cephalic presentation. Perineal pain score ≥ 3 on numeric rating scale (0 - 10) and having no analgesia for 3 hours prior to randomisation</p> <p>Exclusion criteria: 3rd or 4th degree perineal trauma, perineal haematoma, perineal oedema</p> <p>Post-randomisation exclusion: analgesia within 2 hours of randomisation.</p>
Interventions	<p>Intervention group: ice pack: water-filled plastic bag frozen and wrapped in thin cotton gauze. Applied to perineum with participant lying down. (n = 35)</p> <p>Control group: no treatment. (n = 35)</p> <p>Women in the control group could use an ice pack after the evaluation time frame</p>
Outcomes	Perineal pain, perineal temperature
Notes	<p>Email correspondence 23 December 2019 and 8 January 2020 requesting data on women without intact perineum (tears and episiotomy only). On 10 January 2020, authors advised data will be provided as soon as possible. No data received by 29 January 2020</p> <p>3 Mar 2020, additional data provided by author for perineal pain before, immediately after and 2 hours post-ice pack application for participants with perineal trauma only</p> <p>8 July 2020, authors confirmed that women were not able to use oral analgesia (routine treatment) in either the intervention or control groups during the follow-up period. Both groups of women were able to access oral analgesia after the follow-up period</p> <p>8 July 2020, authors confirmed trial was registered at start of recruitment and that website detail currently unavailable (therefore noted to be "personal communication" rather than a referenced publication); confirmed that no protocol was published</p> <p>Dates of study: December 2012 to February 2013</p>

Francisco 2018 (Continued)

Funding sources: Sao Paulo Research Foundation, National Council for Scientific and Technological Development

Declarations of interest: "The authors declare no conflicts of interest to [disclose]" p.e340

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	The study used computer-generated random sampling
Allocation concealment (selection bias)	Low risk	Sequentially-numbered, sealed and opaque envelopes prepared by a professional not involved in the research
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	In the original research paper, the outcome group data were reported for 69 out of 70 participants. Additional information received 3 March 2020 provide data for the 45 participants reported to have perineal trauma. However, the trial registration is not available online and no protocol was published
Selective reporting (reporting bias)	Unclear risk	The trial registration details are not publicly available online at 8 July 2020 and authors confirm no protocol published
Other bias	Low risk	None noted
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were unblinded, due to the nature of the treatment.
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women assessed their pain and as such were unblinded to treatment. The person who assessed perineal temperature was blinded to the kind of intervention that has been delivered to the women. To ensure this, she was not allowed to enter the maternity ward until the end of ice pack application and the participants were instructed not to comment about the group to which they were assigned

Morais 2016

Study characteristics

Methods	Randomised controlled trial
Participants	<p>Study setting: low-risk maternity ward at Instituto de Medicina Integral Professor Fernando Figueira (IMIP), Recife, Pernambuco, Brazil</p> <p>Inclusion criteria: singleton pregnancy, cephalic presentation, normal vaginal birth between 37 - 42 weeks' gestation</p> <p>Exclusion criteria: received intrapartum analgesia, episiotomy, assisted vaginal birth, uterine curettage, active perineal haemorrhage, previous perineal injury before giving birth</p>
Interventions	Intervention: cryotherapy group: latex glove filled with crushed ice, wrapped in wet surgical dressing, applied for 20 minutes with ice added as necessary to maintain the temperature of the perineal body at 10 °C to 15 °C, with 60 minutes between applications. First application at 2 hours after giving birth and repeated 6 times, with perineal temperature measured at zero, 10 and 20 minutes

Morais 2016 (Continued)

Total number randomised: 40 including intact perineum (28 with perineal trauma - data used for this review)

Placebo group: latex medical glove filled with water at 20 °C to 25 °C, wrapped in wet surgical dressing, applied for 20 minutes with 60 minutes between applications. First application at 2 hours after giving birth and repeated 6 times, with perineal temperature measured at zero, 10 and 20 minutes

Total number randomised: 40 including intact perineum (35 with perineal trauma - data used for this review)

Outcomes	Primary outcome: perineal pain, measured using the "Combined scale for assessing pain", which combines the use of a numeric scale of zero (no pain) to 10 (extreme pain) and a faces scale: results between 0 and 5 were analysed as none/mild while values between 6 and 10 were coded as moderate/severe. Other outcomes included perineal oedema, use of additional analgesia and adverse effects of cryotherapy. Not all data could be obtained for women with perineal trauma only. The authors provided additional unpublished data for maternal views of treatments and provision of breast milk for feeding baby
Notes	<p>Additional information sought and provided by authors for:</p> <ul style="list-style-type: none"> women with perineal trauma only (published data included women with an intact perineum) - authors provided dichotomous data where able: data for continuous outcomes were not accessible (11 January 2020 and 28 January 2020); access of researcher to randomised allocation sequence (28 January 2020); access to published trial registration (28 January 2020) - now listed as "personal communication" as copy provided but is not publicly available to view online <p>Dates of study: May to October 2012</p> <p>Source of funding: Fundação de Amparo à Ciência e Tecnologia do Estado de Pernambuco (FACEPE)</p> <p>Declarations of interest: not noted</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Notes from main publication and as clarified by the authors 28 January 2020: Random Allocation Software, version 1.0 used to generate list of random numbers by a collaborator who was not involved in data collection. Sealed numbered envelopes then created
Allocation concealment (selection bias)	Low risk	Authors clarified (28 January 2020) envelope only opened after participant consent signed
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	Data available for all those enrolled, but it is unclear whether or not the trial was registered prior to undertaking the study
Selective reporting (reporting bias)	Unclear risk	The trial registration was referenced in the main RCT publication, but although the website is visible, the registration detail is not available publicly. The authors provided a copy of the registration download by email and advise that it was registered prior to seeking ethical approval for the study
Other bias	Low risk	No other bias noted
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Not possible to blind the participants fully or the researcher applying the treatment, although for both, the glove was wrapped in wet surgical dressings to "... disguise the treatments being provided" p 327 (quote)

Morais 2016 (Continued)

Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women (unblinded) rated their pain. The researcher who obtained the outcome data was blinded to group allocation. The same researcher was retained for the duration of the study
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Navvabi 2009
Study characteristics

Methods	Randomised controlled trial
Participants	<p>Study setting: Mashhad, Iran</p> <p>121 participants</p> <p>Inclusion criteria: Iranian nationality; primiparous; age 16 - 35 years; lives with a partner; ability to read and write (Farsi) at level of 5th primary; term, singleton fetus 37 to 42 weeks; birthweight 2500 - 4000 g; normal delivery; mediolateral episiotomy; have an address and phone number.</p> <p>Exclusion criteria: medical or obstetric complications; smoker; alcohol or cigarette consumption; use of perineal stretching or massage during pregnancy or labour; use of lubricant during delivery; second stage longer than 120 minutes; retained placenta; postpartum haemorrhage; haematoma; stillbirth; fetal anomaly; admission to neonatal intensive care unit</p> <p>All participants birthed in lithotomy, had an episiotomy, repaired with chromic catgut. All received oral analgesia within 4 hours of the episiotomy repair and self-administered further doses of oral analgesia</p>
Interventions	<p>Randomisation within 4 hours of episiotomy repair</p> <p>Ice pack group (n = 40): the report implies that this was a one-off application. No details provided about duration of application. Ice packs measured 12 x 5 cm, filled with water</p> <p>Gel pad group (n = 41): the report implies that this was a one-off application. No details provided about duration of application. Gel pads contained propylene glycol (antifreeze), measured 23 x 5 x 1.5 cm (Femepad, Florri-Femé Pharmaceuticals Ltd, UK)</p> <p>No treatment group (n = 40).</p>
Outcomes	<p>Self-reported perineal pain on a numeric rating scale (NRS), 0 (no pain) to 10 (worst pain)</p> <p>Use of analgesia on day 10</p> <p>Women's satisfaction with oral analgesia and with local treatment (e.g. ice pack or gel pad) on day 10 (NRS)</p> <p>Wound healing: REEDA scale of redness, oedema, ecchymosis (i.e. bruising), discharge and approximation of skin edges. Categories are assigned a total score of 0 to 15, with higher scores representing increased tissue trauma</p> <p>The influence of pain on activities such as sitting, urination and holding the baby were rated on a scale of 0 to 10</p>
Notes	<p>Study data were provided to us by the author in 2007. At that time, we elected to await inclusion in the review until the publication was available. The findings were published in 2009 and 2011 and were included in the 2012 update of this Cochrane Review. Where data were unavailable from the publication and previously-provided data aligned with the published data, data missing from the 2009 publication were incorporated (to correct the typesetting error in Table 1 of the publication and to obtain the SD of women's satisfaction with perineal care)</p> <p>Dates of study: October 2005 to February 2006</p>

Navvabi 2009 (Continued)

Funding sources: Mashhad University of Medical Science

Declarations of interest: none stated. However, one of the study authors (M Steen-Greaves) holds the patent for the cold gel pad used

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random-number table
Allocation concealment (selection bias)	Unclear risk	Not stated
Incomplete outcome data (attrition bias) All outcomes	High risk	Flow chart of eligible and enrolled women was provided. Data were reported for 110 of the 121 women randomised. However, the trial was registered 5 years after completing recruitment
Selective reporting (reporting bias)	High risk	The trial was registered 5 years after recruitment was completed
Other bias	Unclear risk	None identified. It remains unknown if having one of the authors being the developer and patent-owner for the gel pads contributed bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were unblinded, due to the nature of the treatment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women (unblinded) self-assessed their pain and satisfaction. Outcome assessors (for the REEDA scale) were blinded, but it was noted that it may have been possible for the assessors to see the ice pack or gel pad in the woman's hospital room. One of the trial authors holds a patent on the gel pad: it is unclear if women may have known this and unconsciously influenced their outcome ratings

Senol 2017

Study characteristics

Methods	Randomised controlled trial
Participants	<p>Study setting: Mersin Obstetrics and Gynecology Hospital, Turkey</p> <p>Women aged ≥ 18 years, having 1st, 2nd or 3rd baby, singleton pregnancy, cephalic presentation, gave birth vaginally more than 1 hour previously, at term gestation, baby healthy, not receiving oral analgesia within 4 hours of giving birth</p> <p>Data included in this review only include the 100 primiparous women (all reported to have had an episiotomy in the published article (subsequently revealed to be 49 of the 50 women in each group)). Data for the 78 multiparous women with a tear or episiotomy 78 (of the 100 enrolled) were not available for analysis separately and were not included in this review</p>
Interventions	Intervention group (50 primiparous, 50 multiparous): cold gel pad wrapped in sterile pad. Applied for 20 minutes within 2 hours of giving birth and again 4 hours after the initial application

Senol 2017 (Continued)

Control group (50 primiparous, 50 multiparous): hygienic absorbent maternity pad

Outcomes	<p>Prior to and immediately following each of the applications</p> <ul style="list-style-type: none"> • Perineal pain (VAS), analysed on the scale of zero to 10 (most painful) • Perineal pain with activities of daily living • Perineal temperature • Perineal REEDA (redness, edema, ecchymosis, discharge, approximation of skin edges) • Postpartum Comfort Questionnaire (PCQ): for each component, score of 1 reflects low comfort and 5 indicates high comfort <ul style="list-style-type: none"> ◦ Physical comfort ◦ Psychospiritual comfort: feelings (for example, self-concept, self-respect, self-awareness, sexuality) ◦ Sociocultural comfort: counselling, information, care provided consistent with traditions and religious belief <p>Cold gel pad group: side effects only</p>
Notes	<p>Email sent 6 January 2020 requesting clarification of perineal status at enrolment</p> <p>Responses received 30 January 2020. Some relevant detail provided on outcomes, but no data for multiparous women with perineal trauma only.</p> <p>Further email 31 January requesting details of personnel preparing the random sequence generation and sealed randomisation envelopes, and whether the latter were opaque or sequentially-numbered. Response 7 February advised that the researchers prepared the random-numbers table and the envelopes. They noted that individuals did not know which group they would be allocated to in advance</p> <p>Numbers reported in this review only relate to the 100 primiparous. If the separate data for multiparous women with perineal trauma become available, this detail will be considered in a future update of this review</p> <p>Dates of study: 2013</p> <p>Funding sources: none declared, although this could be available information in the Turkish thesis</p> <p>Declaration of interest: "The authors declared no potential conflicts of interest with respect to research, authorship, and/or publication of this article" p 281</p>

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Random-number table generated from randomizer.org . The authors clarified that this was prepared by the researchers
Allocation concealment (selection bias)	Unclear risk	Group allocation by sealed envelopes: pink for primiparous women (n = 100) and blue for multiparous women (n = 100). Authors advised that the researchers prepared the envelopes and numbered them and that the individuals participating in the study did not know which group they would be in before opening the envelope
Incomplete outcome data (attrition bias) All outcomes	Unclear risk	No evidence to suggest incomplete data. Authors confirmed no published trial registration or protocol; this would normally have been expected for CONSORT reporting standards for a trial published at this time. Detail in the thesis aligns with the numbers in the publication
Selective reporting (reporting bias)	Unclear risk	Authors confirmed no published trial registration or protocol; this would normally have been expected for CONSORT reporting standards for a trial pub-

Senol 2017 (Continued)

		lished at this time. Detail in the thesis aligns with the outcomes in the publication
Other bias	Unclear risk	No evidence of other bias. This cannot be fully assessed as there was no published protocol or trial registration
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were unblinded, due to the nature of the treatment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Women and clinicians reporting outcomes were unblinded, due to the nature of the treatment

Steen 2000

Study characteristics

Methods	Randomised controlled trial
Participants	<p>120 participants Study setting: St James University Hospital, Leeds, UK</p> <p>Inclusion criteria: women, 20 - 35 years, English-speaking, primigravid, term fetus, cephalic presentation, instrumental delivery, episiotomy sutured with Vicryl</p> <p>Exclusion criteria: any medical disorder, retained placenta, multiple pregnancy</p>
Interventions	<p>Cooling treatment 1: ice packs (n = 38). Normal saline sachets frozen prior to use, covered with sterile gauze prior to use</p> <p>Cooling treatment 2: cold gel pads (n = 40). Developed by a midwife and an obstetrician specifically for the trial. High thermal capacity cellulose-based gel plus propylene glycol anti-freeze within a heat-welded soft plastic sachet. Measured 5 x 23 x 1.5 cm. Frozen prior to use. Reusable by the individual. Covered in sterile gauze before use</p> <p>Women chose (i) the initial time of application, within 4 hours of suturing; and (ii) how many times treatment was reapplied for up to 48 hours after suturing</p> <p>Unpublished information from the authors noted that gel pad groups took 20 minutes to warm to perineal temperature, compared with ice packs, which melted more quickly</p> <p>Of note, a 3rd group used pramoxine/hydrocortisone topical aerosol foam (Epifoam) (n = 42), a steroidal anti-inflammatory. Foam placed on sterile gauze and applied directly to perineum. These numbers are not counted in the review</p>
Outcomes	<p>Perineal oedema and bruising assessed within 4 hours of suturing and at 24 and 48 hours. Wherever possible, the same midwife made the assessments for each woman. Perineal healing assessed at 5 and 10 days after giving birth. Pain self-assessed using 10-point visual analogue scale within first 4 hours, then at 24 and 48 hours, with assistance from the midwife assessors, then at 5 days by community midwives.</p> <p>At day 5, the community midwives asked the women to complete a 5-point rating of their opinions of the benefits of treatments</p>
Notes	12 experienced, hospital-based midwives underwent training in the use of a visual assessment tool for oedema and bruising, with significant inter-rater reliability

Steen 2000 (Continued)

Perineal pain assessed by 10-point visual analogue scale, analysed as continuous numerical data.
Women rated benefits of treatment on a 5-point ordinal rating scale

Dates of study: September 1993 to March 1994

Funding sources: Elizabeth Clark Charitable Trust

Declarations of interest: although not written specifically as declarations of interests, the report clearly states that 2 of the authors "developed and manufactured 100 maternity gel pads for the trial" (p. 50), when they were unable to have these produced by a medical company

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Randomisation by a specially-commissioned software programme for the delivery suite computer (implies appropriate random sequence generation)
Allocation concealment (selection bias)	Low risk	Randomisation by a specially-commissioned software programme for the delivery suite computer
Incomplete outcome data (attrition bias) All outcomes	High risk	<p>Data sheets containing all details and outcomes for each woman were initiated in hospital and sent to community midwives for follow-up of the 78 women in their homes; if the data sheet was not returned, all details for that participant were unavailable for analysis. With further post-randomisation refusals by participants and exclusions (on advice received at the time of analysis), the overall attrition was 29/78 (37.2%):</p> <p>Ice pack group: 16/38 (42%); 10 data sheets not returned, 2 refusals, 4 exclusions</p> <p>Gel pad group: 13/40 (32.5%); 9 data sheets not returned, 4 exclusions</p> <p>Information was sought and provided about the length of time that ice packs or gel pads were in place</p>
Selective reporting (reporting bias)	Unclear risk	<p>The publication noted that wound healing was assessed, but no detail was provided on this outcome</p> <p>This cannot be fully assessed as there was no published protocol or trial registration</p>
Other bias	Unclear risk	This cannot be fully assessed as there was no published protocol or trial registration. Potential but unknown impact of author developing the gel pad
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were unblinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	<p>Women self-evaluated pain and it is unclear whether the novelty of the gel pad, or potential knowledge that the lead investigator designed it, could have influenced this, given that the report also notes that midwives were asked by non-participants if they could use the gel pad</p> <p>Evaluation of perineal oedema and bruising was made by trained midwife assessors, with 'every attempt' made to blind them to treatment allocation</p>

Steen 2002

Study characteristics

Methods	Randomised controlled trial Intention-to-treat analysis.
Participants	450 participants Study setting: St James University Hospital, Leeds, UK Inclusion criteria: women aged 16 - 45 years, English-speaking, cephalic presentation, term, singleton fetus, normal or instrumental birth, episiotomy or second degree perineal tear sutured with Vicryl Rapide
Interventions	Ice pack group (n = 150): normal saline sachets frozen, covered with sterile gauze prior to use Cold gel pad group (n = 150): maternity gel pads developed for the trial by a midwife and an obstetrician. Made from high thermal capacity cellulose-based gel plus propylene glycol anti-freeze, within a heat welded soft plastic sachet. Frozen prior to use and reusable by the individual Covered with sterile gauze prior to use No-treatment group (n = 150): no application of ice packs or gel pads All groups bathed and used additional analgesia as required
Outcomes	Self-assessed pain, midwives' assessments of bruising, oedema, wound healing; maternal satisfaction
Notes	Additional information was sought and provided by the authors about blinding of assessors, whether the initial assessment was undertaken prior to treatment allocation and rates of wound healing. Raw data were sought and provided in 2007: permission was sought and confirmed 7 February 2020 for continued/further analysis of these data. This allowed calculation of event rates for perineal pain for the subgroup analyses, pain that interfered with breastfeeding, breastfeeding, perineal wound-healing outcomes, frequency of cooling treatment usage Dates of study: August 1998 to June 1999 Funding sources: Executive Northern and Yorkshire Regional fellowship and a Smith and Nephew Nursing Foundation fellowship Declarations of interest: M Steen has a patent for the gel pad device. At the time of reporting the study, no royalties had been received from this patent

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Computer-generated, block size 15.
Allocation concealment (selection bias)	Low risk	Randomisation by a specially commissioned software programme for the delivery-suite computer during data entry of delivery details
Incomplete outcome data (attrition bias) All outcomes	High risk	Data sheets containing all details and outcomes for each woman were initiated in hospital and sent to community midwives for follow-up of the 450 women in their homes; if the data sheet was not returned, all details for that participant were unavailable for analysis. With further post-randomisation withdrawals, the overall attrition was 136/450 (30.2%): Ice pack group: 44/150 (29.3%); 43 data sheets not returned and 1 withdrawal Gel pad group: 43/150 (28.7%); 42 data sheets not returned and 1 withdrawal

Steen 2002 (Continued)

No treatment group: 49/150 (32.7%); 49 data sheets not returned

Selective reporting (reporting bias)	Unclear risk	This cannot be assessed as there was no published protocol or trial registration
Other bias	Unclear risk	None identified. This cannot be fully assessed as there was no published protocol or trial registration. M Steen has a patent for the gel pad device. At the time of reporting the study, no royalties had been received from this patent and it remains unknown if this contributed any bias
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants and personnel were unblinded. The lead investigator holds a patent on the gel pad: it is unclear if women may have known this and unconsciously influenced their outcome ratings of perineal pain and satisfaction with perineal treatment
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	No details were provided of blinding of outcome assessors (wound healing)

Yusamran 2007
Study characteristics

Methods	Randomised controlled trial
Participants	<p>250 participants</p> <p>Study setting: Siriraj Hospital, Bangkok, Thailand</p> <p>Inclusion criteria: 1st delivery, over 37 weeks' gestation, normal labour, mediolateral episiotomy (2nd degree), sutured with subcuticular catgut, received 10 - 20 mL 1% lignocaine</p> <p>Exclusion criteria: antepartum, intrapartum or postpartum complications, including: temperature 38 °C, serious perineal trauma (as judged by the obstetrician), vaginal infection before delivery, antepartum or intrapartum antibiotics, instrumental delivery, 2nd stage > 60 minutes, problems with cold treatment (e.g. poor circulation), physical condition that could impact on perineal recovery (e.g. malnutrition, anaemia, diabetes), postpartum haemorrhage, manual removal of placenta, known sensitivity to lignocaine</p>
Interventions	<p>Intervention group: compression with cold gel pad (n = 125) - placed in freezer</p> <p>Control group: compression with gel pad (n = 125)</p> <p>Gel pads were modified from existing 11 x 25 cm to 11 x 9 cm (edge sealed by hot air banding equipment) and inserted in a cotton pack that was then suspended from a belt, to provide compression</p>
Outcomes	<p>Self-reported pain on visual analogue scale, analysed on the scale of zero to 10 (most painful), at 15, 30, 45, 60 minutes (before and after application), prior to leaving delivery suite and 48 hours after delivery</p> <p>REEDA scale (redness, edema, ecchymosis, discharge, approximation) with results provided for each category and the total score</p> <p>Satisfaction with compression on visual analogue scale 0 - 10 (10 most satisfied)</p>
Notes	<p>We contacted the authors to clarify the results of pain at 2 days, given an apparent typographical error in the published report. Data included in the review are the corrected data, provided by the authors 16 June 2011</p> <p>Dates of study: August 2005 to April 2006.</p>

Yusamran 2007 (Continued)

Funding sources: not noted

Declarations of interest: not noted

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Random-number table prepared by an off-site research associate
Allocation concealment (selection bias)	Low risk	Sealed opaque envelopes
Incomplete outcome data (attrition bias) All outcomes	Low risk	Outcomes were presented for 249 - 250 of the 250 reported to be enrolled
Selective reporting (reporting bias)	Unclear risk	This cannot be assessed as there was no published protocol or trial registration
Other bias	Unclear risk	None identified. This cannot be fully assessed as there was no published protocol or trial registration
Blinding of participants and personnel (performance bias) All outcomes	Unclear risk	Participants were unblinded. It is unclear whether or not personnel were blinded
Blinding of outcome assessment (detection bias) All outcomes	Unclear risk	Unclear

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Amani 2015	Compared cooling treatment with topical olive oil (not placebo, no treatment or another cooling treatment)
De Souza Bosco Paiva 2016	Not a randomised trial
Dube 2013	Not a randomised trial; had noted "quasi experimental approach" in abstract
Gallie 2003	Compared cooling treatment with pulse electromagnetic energy (not placebo, no treatment or another cooling treatment)
Hill 1989	Compared cooling treatment with warm perineal pack or warm sitz bath (not placebo, no treatment or another cooling treatment)
Kaur 2012	Trial registration for a study comparing cooling treatment with warm black tea bags (not placebo, no treatment or another cooling treatment)
LaFoy 1989	Cross-over trial. This was included in the original 2007 review: the 2012 update changed to exclude cross-over trials

Study	Reason for exclusion
Lu 2015	Not randomised. Women chose the group they wished to participate in. Had "quasi-randomised controlled trial" in title
Moore 1989	Compared cooling treatment with Epifoam or Hammamelis water (not placebo, no treatment or another cooling treatment)
Nam 1991	Cross-over trial. The 2012 update changed to exclude cross-over trials
NCT02024256	Compared pads soaked in cold water (potentially a cooling treatment) with pads soaked in magnesium sulfate solution (not placebo, no treatment or another cooling treatment)
Pinkerton 1961	This letter to the Editor described the use of an ice-pack and is not a randomised controlled trial
Ramler 1986	Cross-over trial. The update of this review in 2012 now excludes cross-over trials
Sheikhan 2011	Compared cooling treatment with warm sitz bath + povidone iodine (not placebo, no treatment or another cooling treatment)
Thangaraju 2006	Compared cooling treatment with regular oral analgesia (not placebo, no treatment [e.g. routinely available analgesia by request, rather than prescribed regularly] or another cooling treatment)

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

Leventhal 2011

Methods	Randomised controlled trial
Participants	<p>117 participants</p> <p>Inclusion criteria: maternal age 18 years or older, full-term, nulliparous, live, singleton fetus, cephalic presentation, perineal pain score of over 3 on a numeric scale, within 2 to 48 hours of giving birth, no analgesia in the 2 hours prior to randomisation</p> <p>Exclusion criteria: pain score of 1 or 2; 2 or more births; maternal age less than 17 years</p>
Interventions	<p>Ice pack group (n = 38): plastic sack 8 x 16 cm, filled with 250 mL water, then frozen and wrapped in fine cotton cloth</p> <p>Placebo group (n = 38): plastic sack 8 x 16 cm, filled with 250 mL water, wrapped in fine cotton cloth</p> <p>No treatment group (n = 38). No ice or water pack applied</p>
Outcomes	<p>Perineal pain by numeric rating scale (NRS), 0 = no pain, to 10, worst pain:</p> <p>(1) prior to intervention; (2) 20 minutes after intervention; (3) 40 minutes after intervention; (4) 60 minutes after intervention</p> <p>Perineal temperature recorded every 5 minutes during the application of the ice pack or water pack</p>
Notes	<p>Authors contacted 9 January 2020 seeking data only from women with some degree of perineal trauma (publication includes intact perineum). Response 16 January 2020 from corresponding author that she does not have access to the data since retiring. No other authors' contact details yet identified</p> <p>Study location: Amparo Maternal, Brazil</p>

Leventhal 2011 (Continued)

Additional information extracted from trial registration details (including inclusion and exclusion criteria)

Dates of study: January and February 2008

Funding sources: Research Support Foundation of the Sao Paulo state (FAPESP), Brazil

Declarations of interest: "The authors have no conflicts of interest to disclose" p.146

Oliveira 2012

Methods	Randomised controlled trial comparing 2 time frames for ice pack application. Additional third group allocated to ice treatment in a separate randomised controlled trial, with the same inclusion/exclusion criteria, ice applied for a different time frame (Leventhal 2011)
Participants	<p>Women aged 18 and over, having had a normal birth of their first baby, singleton pregnancy, cephalic presentation</p> <p>Scoring 3 or more on a numeric scale (0, no pain to 10, worst imaginable pain) at recruitment</p> <p>No analgesia past 6 hours prior to recruitment</p> <p>No clinical obstetric concerns, e.g. haematomas, perineal oedema, haemorrhoids</p> <p>No comprehension or communication challenges</p> <p>Baby healthy</p>
Interventions	Ice pack applied to the perineum for 10 (n = 38) or 15 (n = 39) in the new study or for 20 minutes (n = 38) in a previous study (Leventhal 2011)
Outcomes	<p>30% decrease in perineal pain on the numerical scale, from immediately prior to immediately after the cryotherapy treatment</p> <p>Reduction in perineal temperature, expected to be 10 ° to 15 °C at 10 - 15 minutes following ice pack application</p>
Notes	Author contacted 9 January 2020 to establish perineal status for participants. Response received 15 January 2020 stating that she no longer has access to the data since retiring. No other authors' contact details yet determined

DATA AND ANALYSES

Comparison 1. Cooling treatment (ice pack or cold gel pad) versus no treatment

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.1 Perineal pain within 4-6 hours of giving birth	1	100	Mean Difference (IV, Fixed, 95% CI)	-4.46 [-5.07, -3.85]
1.2 Perineal pain within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.2.1 Moderate + severe pain	1	316	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.82, 1.29]
1.3 Perineal pain within 24 hours of giving birth	3	166	Mean Difference (IV, Random, 95% CI)	-0.41 [-1.78, 0.95]
1.4 Perineal pain between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.4.1 Moderate + severe pain	1	316	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.57, 0.94]
1.5 Perineal pain between 24 -48 hours after giving birth	1	71	Mean Difference (IV, Random, 95% CI)	-0.53 [-1.45, 0.39]
1.6 Pain associated with activities of daily living (sitting) within 24 hours of giving birth	1	312	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.98, 1.09]
1.7 Pain associated with activities of daily living (sitting) between 24 - 48 hours of giving birth	1	312	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.95, 1.05]
1.8 Pain associated with activities of daily living (walking) within 24 hours of giving birth	1	312	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.94, 1.08]
1.9 Pain associated with activities of daily living (walking) between 24 - 48 hours of giving birth	1	312	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.93, 1.09]
1.10 Pain associated with activities of daily living (feeding baby) within 24 hours of giving birth	1	311	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.84, 1.55]
1.11 Pain associated with activities of daily living (feeding baby) between 24 - 48 hours of giving birth	1	311	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.63, 1.21]
1.12 Perineal oedema within 24 hours of giving birth	1	316	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.87, 1.16]
1.13 Perineal oedema between 24 - 48 hours after giving birth	1	316	Risk Ratio (M-H, Fixed, 95% CI)	0.82 [0.69, 0.98]
1.14 Perineal bruising within 24 hours of giving birth	1	316	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.81, 1.19]
1.15 Perineal bruising between 24 - 48 hours after giving birth	1	316	Risk Ratio (M-H, Fixed, 95% CI)	1.13 [0.97, 1.32]
1.16 Perineal redness, oedema, bruising, discharge, wound gaping within 24 hours of giving birth	1	71	Mean Difference (IV, Fixed, 95% CI)	-0.38 [-1.14, 0.38]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.17 Perineal redness, oedema, bruising, discharge, wound gaping between 24 - 48 hours of giving birth	1	71	Mean Difference (IV, Fixed, 95% CI)	-1.19 [-2.07, -0.31]
1.18 Additional analgesia for relief of perineal pain: within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.18.1 Non-prescription analgesia	1	316	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.60, 1.24]
1.18.2 Prescription analgesia	1	316	Risk Ratio (M-H, Fixed, 95% CI)	1.25 [0.82, 1.89]
1.19 Additional analgesia for relief of perineal pain between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.19.1 Non-prescription analgesia	1	316	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.58, 1.27]
1.19.2 Prescription analgesia	1	316	Risk Ratio (M-H, Fixed, 95% CI)	1.34 [0.87, 2.08]
1.20 Adverse effects on perineal wound healing: Day 5	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.20.1 Wound not healing	1	315	Risk Ratio (M-H, Fixed, 95% CI)	1.24 [0.34, 4.58]
1.20.2 Wound edges gaping	1	315	Risk Ratio (M-H, Fixed, 95% CI)	2.56 [0.58, 11.33]
1.20.3 Any sign of infection	1	315	Risk Ratio (M-H, Fixed, 95% CI)	0.47 [0.12, 1.82]
1.21 Adverse effects on perineal wound healing: Day 10	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.21.1 Wound not healing	1	315	Risk Ratio (M-H, Fixed, 95% CI)	0.70 [0.20, 2.42]
1.21.2 Wound edges gaping	1	315	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.22, 1.74]
1.21.3 Any sign of infection	1	315	Risk Ratio (M-H, Fixed, 95% CI)	2.33 [0.52, 10.42]
1.21.4 Wound resutured	1	315	Risk Ratio (M-H, Fixed, 95% CI)	2.34 [0.11, 48.25]
1.22 Maternal views and experiences of treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.22.1 Satisfaction with overall perineal care (good + very good + excellent) Day 10	1	308	Risk Ratio (M-H, Fixed, 95% CI)	1.07 [0.97, 1.18]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1.23 Maternal views and experiences of treatment	1		Mean Difference (IV, Fixed, 95% CI)	Subtotals only
1.23.1 Psychospiritual comfort within six hours of giving birth	1	100	Mean Difference (IV, Fixed, 95% CI)	-0.10 [-0.20, 0.00]
1.23.2 Sociocultural comfort	1	100	Mean Difference (IV, Fixed, 95% CI)	0.01 [-0.09, 0.11]
1.24 Women providing any breastmilk to baby 24 - 48 hours after giving birth	1	315	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.73, 1.07]
1.25 Subgroup: Parity and perineal pain within 24 hours of giving birth	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.25.1 Moderate + severe pain: primiparous women	1	201	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.76, 1.21]
1.25.2 Moderate + severe pain: multiparous women	1	115	Risk Ratio (M-H, Random, 95% CI)	1.26 [0.74, 2.16]
1.26 Subgroup: Parity and perineal pain between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.26.1 Moderate + severe pain: primiparous women	1	201	Risk Ratio (M-H, Fixed, 95% CI)	0.65 [0.50, 0.84]
1.26.2 Moderate + severe pain: multiparous women	1	115	Risk Ratio (M-H, Fixed, 95% CI)	1.03 [0.59, 1.80]
1.27 Subgroup: Mode of birth and perineal pain within 24 hours of giving birth	1		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.27.1 Moderate + severe perineal pain: spontaneous vaginal birth	1	231	Risk Ratio (M-H, Random, 95% CI)	1.18 [0.87, 1.60]
1.27.2 Moderate + severe pain: assisted vaginal birth	1	85	Risk Ratio (M-H, Random, 95% CI)	0.75 [0.56, 1.00]
1.28 Subgroup: Mode of birth and perineal pain between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.28.1 Moderate + severe pain: spontaneous vaginal birth	1	231	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.52, 1.02]
1.28.2 Moderate + severe pain: assisted vaginal birth	1	85	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.50, 0.93]

Analysis 1.1. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 1: Perineal pain within 4-6 hours of giving birth

Analysis 1.2. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 2: Perineal pain within 24 hours of giving birth

Analysis 1.3. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 3: Perineal pain within 24 hours of giving birth

Analysis 1.4. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 4: Perineal pain between 24 - 48 hours after giving birth

Analysis 1.5. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 5: Perineal pain between 24 -48 hours after giving birth

Analysis 1.6. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 6: Pain associated with activities of daily living (sitting) within 24 hours of giving birth

Analysis 1.7. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 7: Pain associated with activities of daily living (sitting) between 24 - 48 hours of giving birth

Analysis 1.8. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 8: Pain associated with activities of daily living (walking) within 24 hours of giving birth

Analysis 1.9. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 9: Pain associated with activities of daily living (walking) between 24 - 48 hours of giving birth

Analysis 1.10. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 10: Pain associated with activities of daily living (feeding baby) within 24 hours of giving birth

Analysis 1.11. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 11: Pain associated with activities of daily living (feeding baby) between 24 - 48 hours of giving birth

Analysis 1.12. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 12: Perineal oedema within 24 hours of giving birth

Analysis 1.13. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 13: Perineal oedema between 24 - 48 hours after giving birth

Analysis 1.14. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 14: Perineal bruising within 24 hours of giving birth

Analysis 1.15. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 15: Perineal bruising between 24 - 48 hours after giving birth

Analysis 1.16. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 16: Perineal redness, oedema, bruising, discharge, wound gaping within 24 hours of giving birth

Analysis 1.17. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 17: Perineal redness, oedema, bruising, discharge, wound gaping between 24 - 48 hours of giving birth

Analysis 1.18. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 18: Additional analgesia for relief of perineal pain: within 24 hours of giving birth

Analysis 1.19. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 19: Additional analgesia for relief of perineal pain between 24 - 48 hours after giving birth

Analysis 1.20. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 20: Adverse effects on perineal wound healing: Day 5

Analysis 1.21. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 21: Adverse effects on perineal wound healing: Day 10

Analysis 1.22. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 22: Maternal views and experiences of treatment

Analysis 1.23. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 23: Maternal views and experiences of treatment

Analysis 1.24. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 24: Women providing any breastmilk to baby 24 - 48 hours after giving birth

Analysis 1.25. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 25: Subgroup: Parity and perineal pain within 24 hours of giving birth

Analysis 1.26. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 26: Subgroup: Parity and perineal pain between 24 - 48 hours after giving birth

Analysis 1.27. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 27: Subgroup: Mode of birth and perineal pain within 24 hours of giving birth

Analysis 1.28. Comparison 1: Cooling treatment (ice pack or cold gel pad) versus no treatment, Outcome 28: Subgroup: Mode of birth and perineal pain between 24 - 48 hours after giving birth

Comparison 2. Cooling treatment (cold gel pad)+compression versus placebo (gel pad+compression)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
2.1 Perineal pain within 4 - 6 hours of giving birth	1	250	Mean Difference (IV, Fixed, 95% CI)	-0.32 [-0.78, 0.14]
2.2 Perineal pain within 24 - 48 hours after giving birth	1	250	Mean Difference (IV, Fixed, 95% CI)	-0.43 [-0.73, -0.13]
2.3 Perineal oedema between 24 - 48 hours after giving birth	1	250	Mean Difference (IV, Fixed, 95% CI)	-0.15 [-0.28, -0.03]
2.4 Satisfaction with perineal care	1	250	Mean Difference (IV, Fixed, 95% CI)	0.88 [0.38, 1.38]

Analysis 2.1. Comparison 2: Cooling treatment (cold gel pad)+compression versus placebo (gel pad+compression), Outcome 1: Perineal pain within 4 - 6 hours of giving birth

Analysis 2.2. Comparison 2: Cooling treatment (cold gel pad)+compression versus placebo (gel pad+compression), Outcome 2: Perineal pain within 24 - 48 hours after giving birth

Analysis 2.3. Comparison 2: Cooling treatment (cold gel pad)+compression versus placebo (gel pad+compression), Outcome 3: Perineal oedema between 24 - 48 hours after giving birth

Analysis 2.4. Comparison 2: Cooling treatment (cold gel pad)+compression versus placebo (gel pad+compression), Outcome 4: Satisfaction with perineal care

Comparison 3. Cooling treatment (ice pack) versus placebo (water pack)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.1 Perineal oedema within 4 - 6 hours after giving birth	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.50, 1.86]
3.2 Perineal oedema within 24 hours after giving birth	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.36 [0.08, 1.59]
3.3 Additional analgesia for relief of perineal pain within 24 hours of giving birth	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.62 [0.35, 1.11]
3.4 Maternal views and experiences with treatment	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.4.1 Satisfied with treatment	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.91 [0.77, 1.08]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
3.4.2 Would repeat treatment in future childbirth	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.88 [0.75, 1.04]
3.4.3 Would recommend treatment	1	63	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.77, 1.03]
3.5 Women providing any breastmilk to baby 48 hours after giving birth	1	63	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.94, 1.06]

Analysis 3.1. Comparison 3: Cooling treatment (ice pack) versus placebo (water pack), Outcome 1: Perineal oedema within 4 - 6 hours after giving birth

Analysis 3.2. Comparison 3: Cooling treatment (ice pack) versus placebo (water pack), Outcome 2: Perineal oedema within 24 hours after giving birth

Analysis 3.3. Comparison 3: Cooling treatment (ice pack) versus placebo (water pack), Outcome 3: Additional analgesia for relief of perineal pain within 24 hours of giving birth

Analysis 3.4. Comparison 3: Cooling treatment (ice pack) versus placebo (water pack), Outcome 4: Maternal views and experiences with treatment

Analysis 3.5. Comparison 3: Cooling treatment (ice pack) versus placebo (water pack), Outcome 5: Women providing any breastmilk to baby 48 hours after giving birth

Comparison 4. Cooling treatment (ice pack) versus cooling treatment (cold gel pad)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.1 Perineal pain within 4 - 6 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1.1 Moderate + severe pain	1	49	Risk Ratio (M-H, Fixed, 95% CI)	0.57 [0.26, 1.24]
4.2 Perineal pain within 24 hours of giving birth	2		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.2.1 Moderate + severe pain	2	264	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.78, 1.22]
4.3 Perineal pain within 24 hours of giving birth	1	74	Mean Difference (IV, Fixed, 95% CI)	0.58 [-0.44, 1.60]
4.4 Perineal pain between 24 - 48 hours after giving birth	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.4.1 Moderate + severe pain	2	263	Risk Ratio (M-H, Random, 95% CI)	1.21 [0.89, 1.65]
4.5 Perineal pain between 24 - 48 hours of giving birth	1	74	Mean Difference (IV, Fixed, 95% CI)	0.86 [-0.10, 1.82]
4.6 Pain associated with activities of daily living (sitting) within 24 hours of giving birth	1	212	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.94, 1.03]
4.7 Pain associated with activities of daily living (sitting) between 24 - 48 hours after giving birth	1	212	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.92, 1.03]
4.8 Pain associated with activities of daily living (walking) within 24 hours of giving birth	1	212	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.89, 1.04]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.9 Pain associated with activities of daily living (walking) between 24 - 48 hours after giving birth	1	212	Risk Ratio (M-H, Fixed, 95% CI)	0.94 [0.85, 1.03]
4.10 Pain associated with activities of daily living (feeding baby) within 24 hours of giving birth	1	212	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.68, 1.28]
4.11 Pain associated with activities of daily living (feeding baby) between 24 - 48 hours after giving birth	1	211	Risk Ratio (M-H, Fixed, 95% CI)	1.09 [0.73, 1.63]
4.12 Perineal oedema within 4 - 6 hours of giving birth	1	49	Risk Ratio (M-H, Fixed, 95% CI)	1.39 [0.93, 2.09]
4.13 Perineal oedema within 24 hours of giving birth	2	264	Risk Ratio (M-H, Fixed, 95% CI)	0.97 [0.84, 1.13]
4.14 Perineal oedema between 24 - 48 hours after giving birth	2	264	Risk Ratio (M-H, Random, 95% CI)	1.69 [1.03, 2.77]
4.15 Perineal bruising within 4 - 6 hours of giving birth	1	49	Risk Ratio (M-H, Fixed, 95% CI)	1.23 [0.51, 2.97]
4.16 Perineal bruising within 24 hours of giving birth	2	264	Risk Ratio (M-H, Fixed, 95% CI)	0.95 [0.79, 1.14]
4.17 Perineal bruising between 24 - 48 hours after giving birth	2	264	Risk Ratio (M-H, Random, 95% CI)	1.07 [0.92, 1.25]
4.18 Perineal redness, oedema, bruising, discharge, wound gaping within 24 hours of giving birth	1	74	Mean Difference (IV, Fixed, 95% CI)	-0.13 [-0.85, 0.59]
4.19 Perineal redness, oedema, bruising, discharge, wound gaping between 24 - 48 hours after giving birth	1	74	Mean Difference (IV, Fixed, 95% CI)	0.20 [-0.33, 0.73]
4.20 Additional analgesia for relief of perineal pain: within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.20.1 Non-prescription analgesia	1	215	Risk Ratio (M-H, Fixed, 95% CI)	0.98 [0.63, 1.51]
4.20.2 Prescription analgesia	1	215	Risk Ratio (M-H, Fixed, 95% CI)	0.86 [0.56, 1.31]
4.21 Additional analgesia for relief of perineal pain: 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.21.1 Non-prescription analgesia	1	215	Risk Ratio (M-H, Fixed, 95% CI)	1.14 [0.70, 1.84]
4.21.2 Prescription analgesia	1	215	Risk Ratio (M-H, Fixed, 95% CI)	0.67 [0.43, 1.05]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.22 Adverse effects on perineal wound healing: Day 5	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.22.1 Wound not healing	1	215	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.26, 3.93]
4.22.2 Wound edges gaping	1	215	Risk Ratio (M-H, Fixed, 95% CI)	0.22 [0.05, 1.01]
4.22.3 Any sign of infection	1	215	Risk Ratio (M-H, Fixed, 95% CI)	9.08 [0.50, 166.67]
4.23 Adverse effects on perineal wound healing: Day 10	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.23.1 Wound not healing	1	215	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.09, 2.70]
4.23.2 Wound edges gaping	1	214	Risk Ratio (M-H, Fixed, 95% CI)	3.06 [0.63, 14.81]
4.23.3 Any sign of infection	1	205	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.45, 5.31]
4.23.4 Wound resutured	1	215	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.06, 15.93]
4.24 Maternal views and experiences with treatment	2		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
4.24.1 Opinion on treatment effects (good + very good + excellent) Day 5	1	49	Risk Ratio (M-H, Random, 95% CI)	0.33 [0.17, 0.68]
4.24.2 Satisfaction with overall perineal care (good + very good + excellent) Day 10	1	208	Risk Ratio (M-H, Random, 95% CI)	0.82 [0.73, 0.92]
4.25 Women providing any breastmilk to the baby 48 hours after giving birth	1	212	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.84, 1.33]
4.26 Subgroup: Parity and perineal pain within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.26.1 Moderate + severe pain: primiparous women	1	137	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.68, 1.18]
4.26.2 Moderate + severe pain: multiparous women	1	78	Risk Ratio (M-H, Fixed, 95% CI)	1.19 [0.69, 2.05]
4.27 Subgroup: Parity and perineal pain between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.27.1 Moderate + severe pain: primiparous women	1	137	Risk Ratio (M-H, Fixed, 95% CI)	1.06 [0.72, 1.57]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.27.2 Moderate + severe pain: multiparous women	1	78	Risk Ratio (M-H, Fixed, 95% CI)	1.54 [0.78, 3.02]
4.28 Subgroup: Mode of birth and perineal pain within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.28.1 Moderate + severe pain: spontaneous vaginal birth	1	154	Risk Ratio (M-H, Fixed, 95% CI)	0.93 [0.68, 1.26]
4.28.2 Moderate + severe pain: assisted vaginal birth	1	61	Risk Ratio (M-H, Fixed, 95% CI)	1.01 [0.66, 1.53]
4.29 Subgroup: Mode of birth and perineal pain between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.29.1 Moderate + severe pain: spontaneous vaginal birth	1	154	Risk Ratio (M-H, Fixed, 95% CI)	1.32 [0.83, 2.09]
4.29.2 Moderate + severe pain: assisted vaginal birth	1	61	Risk Ratio (M-H, Fixed, 95% CI)	1.05 [0.66, 1.67]

Analysis 4.1. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 1: Perineal pain within 4 - 6 hours of giving birth

Analysis 4.2. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 2: Perineal pain within 24 hours of giving birth

Analysis 4.3. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 3: Perineal pain within 24 hours of giving birth

Analysis 4.4. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 4: Perineal pain between 24 - 48 hours after giving birth

Analysis 4.5. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 5: Perineal pain between 24 - 48 hours of giving birth

Analysis 4.6. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 6: Pain associated with activities of daily living (sitting) within 24 hours of giving birth

Analysis 4.7. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 7: Pain associated with activities of daily living (sitting) between 24 - 48 hours after giving birth

Analysis 4.8. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 8: Pain associated with activities of daily living (walking) within 24 hours of giving birth

Analysis 4.9. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 9: Pain associated with activities of daily living (walking) between 24 - 48 hours after giving birth

Analysis 4.10. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 10: Pain associated with activities of daily living (feeding baby) within 24 hours of giving birth

Analysis 4.11. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 11: Pain associated with activities of daily living (feeding baby) between 24 - 48 hours after giving birth

Analysis 4.12. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 12: Perineal oedema within 4 - 6 hours of giving birth

Analysis 4.13. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 13: Perineal oedema within 24 hours of giving birth

Analysis 4.14. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 14: Perineal oedema between 24 - 48 hours after giving birth

Analysis 4.15. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 15: Perineal bruising within 4 - 6 hours of giving birth

Analysis 4.16. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 16: Perineal bruising within 24 hours of giving birth

Analysis 4.17. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 17: Perineal bruising between 24 - 48 hours after giving birth

Analysis 4.18. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 18: Perineal redness, oedema, bruising, discharge, wound gaping within 24 hours of giving birth

Analysis 4.19. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 19: Perineal redness, oedema, bruising, discharge, wound gaping between 24 - 48 hours after giving birth

Analysis 4.20. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 20: Additional analgesia for relief of perineal pain: within 24 hours of giving birth

Analysis 4.21. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 21: Additional analgesia for relief of perineal pain: 24 - 48 hours after giving birth

Analysis 4.22. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 22: Adverse effects on perineal wound healing: Day 5

Analysis 4.23. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 23: Adverse effects on perineal wound healing: Day 10

0.01 0.1 1 10 100
Favours ice pack Favours gel pad

Analysis 4.24. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 24: Maternal views and experiences with treatment

Analysis 4.25. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 25: Women providing any breastmilk to the baby 48 hours after giving birth

Analysis 4.26. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 26: Subgroup: Parity and perineal pain within 24 hours of giving birth

Analysis 4.27. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 27: Subgroup: Parity and perineal pain between 24 - 48 hours after giving birth

Analysis 4.28. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 28: Subgroup: Mode of birth and perineal pain within 24 hours of giving birth

Analysis 4.29. Comparison 4: Cooling treatment (ice pack) versus cooling treatment (cold gel pad), Outcome 29: Subgroup: Mode of birth and perineal pain between 24 - 48 hours after giving birth

Comparison 5. Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1 Perineal pain within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.1.1 Moderate + severe pain	1	8	Risk Ratio (M-H, Fixed, 95% CI)	3.33 [0.49, 22.90]
5.2 Perineal pain between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.2.1 Moderate + severe pain	1	12	Risk Ratio (M-H, Fixed, 95% CI)	1.00 [0.20, 4.95]
5.3 Perineal pain associated with activities of daily living (sitting) within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.3.1 Moderate + severe pain	1	8	Risk Ratio (M-H, Fixed, 95% CI)	10.50 [0.72, 153.07]
5.4 Perineal pain associated with activities of daily living (sitting) between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.4.1 Moderate + severe pain	1	12	Risk Ratio (M-H, Fixed, 95% CI)	0.33 [0.05, 2.37]
5.5 Perineal pain associated with activities of daily living (walking) within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.5.1 Moderate + severe pain	1	8	Risk Ratio (M-H, Fixed, 95% CI)	3.33 [0.49, 22.90]
5.6 Perineal pain associated with activities of daily living (walking) between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.6.1 Moderate + severe pain	1	12	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.14, 1.77]
5.7 Perineal pain associated with activities of daily living (urinating) within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.7.1 Moderate + severe pain	1	8	Risk Ratio (M-H, Fixed, 95% CI)	4.50 [0.24, 85.12]
5.8 Perineal pain associated with activities of daily living (urinating) between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.8.1 Moderate + severe pain	1	12	Risk Ratio (M-H, Fixed, 95% CI)	3.00 [0.15, 61.74]
5.9 Perineal pain associated with activities of daily living (caring for baby) within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5.9.1 Moderate + severe pain	1	8	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.03, 9.46]
5.10 Perineal pain associated with activities of daily living (caring for baby) between 24 - 48 hours after giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.10.1 Moderate + severe pain	1	12	Risk Ratio (M-H, Fixed, 95% CI)	0.50 [0.06, 4.15]
5.11 Additional analgesia for relief of perineal pain: within 24 hours of giving birth	1	8	Risk Ratio (M-H, Fixed, 95% CI)	0.68 [0.31, 1.51]
5.12 Additional analgesia for relief of perineal pain: between 24 - 48 hours after giving birth	1	12	Risk Ratio (M-H, Fixed, 95% CI)	0.80 [0.41, 1.56]
5.13 Self-reported energy level: within 24 hours of giving birth	1	8	Mean Difference (IV, Fixed, 95% CI)	0.70 [-0.11, 1.51]
5.14 Self-reported energy level: between 24 - 48 hours of giving birth	1	12	Mean Difference (IV, Fixed, 95% CI)	0.00 [-0.92, 0.92]
5.15 Maternal views of effectiveness of ice packs: within 24 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.15.1 Quite effective + extremely effective	1	8	Risk Ratio (M-H, Fixed, 95% CI)	0.41 [0.11, 1.48]
5.16 Maternal views of effectiveness of ice packs: between 24 - 48 hours of giving birth	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.16.1 Quite effective + extremely effective	1	12	Risk Ratio (M-H, Fixed, 95% CI)	1.18 [0.76, 1.83]
5.17 Women providing any breastmilk to the baby between 24 - 48 hours after giving birth	1	7	Risk Ratio (M-H, Fixed, 95% CI)	0.69 [0.31, 1.57]

Analysis 5.1. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 1: Perineal pain within 24 hours of giving birth

Analysis 5.2. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 2: Perineal pain between 24 - 48 hours after giving birth

Analysis 5.3. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 3: Perineal pain associated with activities of daily living (sitting) within 24 hours of giving birth

Analysis 5.4. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 4: Perineal pain associated with activities of daily living (sitting) between 24 - 48 hours after giving birth

Analysis 5.5. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 5: Perineal pain associated with activities of daily living (walking) within 24 hours of giving birth

Analysis 5.6. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 6: Perineal pain associated with activities of daily living (walking) between 24 - 48 hours after giving birth

Analysis 5.7. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 7: Perineal pain associated with activities of daily living (urinating) within 24 hours of giving birth

Analysis 5.8. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 8: Perineal pain associated with activities of daily living (urinating) between 24 - 48 hours after giving birth

Analysis 5.9. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 9: Perineal pain associated with activities of daily living (caring for baby) within 24 hours of giving birth

Analysis 5.10. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 10: Perineal pain associated with activities of daily living (caring for baby) between 24 - 48 hours after giving birth

Analysis 5.11. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 11: Additional analgesia for relief of perineal pain: within 24 hours of giving birth

Analysis 5.12. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 12: Additional analgesia for relief of perineal pain: between 24 - 48 hours after giving birth

Analysis 5.13. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 13: Self-reported energy level: within 24 hours of giving birth

Analysis 5.14. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 14: Self-reported energy level: between 24 - 48 hours of giving birth

Analysis 5.15. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 15: Maternal views of effectiveness of ice packs: within 24 hours of giving birth

Analysis 5.16. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 16: Maternal views of effectiveness of ice packs: between 24 - 48 hours of giving birth

Analysis 5.17. Comparison 5: Cooling treatment (I.C.H. (ice, compression, (being) horizontal)) versus cooling treatment (ad hoc ice pack usage), Outcome 17: Women providing any breastmilk to the baby between 24 - 48 hours after giving birth

ADDITIONAL TABLES

Table 1. Summary of cooling methods and results

Study	Form of cooling	Additional technique	1st application post-birth	Length of application	Frequency	Perineal temperature	Assessment of perineal pain	Adverse effects on perineal healing
Iced sitz bath								
Barclay 1983	30 g salt added to 1 - 2 litres cold tap water (~ 7 °C) + ice	immersion	Day 1	10 minutes	3 - 4 a day	not assessed	post-treatment - days 1 - 5	not assessed
Ice packs								
Beleza 2017	15 cm bag filled with 150 g crushed ice	wrapped in thin cotton tissue	within 24 hours; average of 15 hours	20 minutes	single application	pre-application: 34.5 °C post-application - 10 minutes: 20.5 °C - 20 minutes: 23.4 °C - 1 hour: 33.8 °C	pre-application post-application -20 minutes -60 minutes	not reported
East 2007	commercial product (Medichill, USA) soaked in water then frozen	within perineal pad	birth suite	20 minutes	2 - 3 hourly for 2 - 3 days	not assessed	post-application - within 24 hours - 24 - 48 hours	no women had adverse effects
Francisco 2018	plastic pack filled with 250 mL water and placed in freezer – removed in the form of ice	wrapped in thin cotton gauze applied to the perineum – par-	meant of 12.7 hours after birthing; rooming-in unit, birth centre	10 minutes	single application	pre-application of ice (intact and perineal trauma): mean 33.8 °C post-application	pre-application - immediately after intervention - 2 hours later	adverse effects not recorded

Table 1. Summary of cooling methods and results (Continued)

		participant lying down				- immediately after: mean 15.6 °C - 2 hours later: mean 34.1 °C		
Morais 2016	latex glove, crushed ice	wrapped in sterile wet gauze	2 hours	20 minutes	6 applications at 6-hourly intervals	reduction by 10-15 °C at 10 - 20 minutes of application	pre-application post application - immediately - 24 hours	no women had adverse effects
Navvabi 2009	"ice pack"	no detail	within 4 hours after episiotomy repair	no detail	single application	not assessed	post-application - 4 hours - days 1 - 2 - day 5 - day 10	wound approximation is part of REEDA scale – not able to access separate result but no between-group differences in overall scale with other groups.
Steen 2000	saline sachets frozen, for 2 hours	in sterile gauze cover	within 4 hours after suturing	Unpublished information from the authors noted that gel pad groups took 20 minutes to warm to perineal temperature, compared with ice packs, which melted more quickly.	as per women's preferences for 48 hours (mean number of applications 10.4, SD 4.3)	-	post-application - 0 - 4 hours - day 1 - day 2	wound healing and closure of wound edges assessed days 5 and 10: findings not reported
Steen 2002	saline sachets frozen, for 2 hours	in sterile gauze cover	within 4 hours after suturing	not described	as per women's preferences for 4 days.	not assessed	pre-application post-application - days 1-5	wound healing and closure of wound edges assessed days 5, 10 and 14: low prevalence and wide confidence intervals

Table 1. Summary of cooling methods and results *(Continued)*

					Day/Median/Range			
						- day 10		
					1 5 0 - 8	- day 14		
					2 26 0 - 8			
					3 4 0 - 10			
					4 2 0 - 14			
Gel pads								
Navvabi 2009	gel pad (Femepad, Florri-Femé Pharmaceuticals Ltd, UK) with “antifreeze” gel	freeze for 2 hours prior to app	within 4 hours of episiotomy repair	not assessed	Initial application then as per women’s preferences for 10 days	not assessed	post-application - 4 hours - days 1-2 - day 5 - day 10	wound approximation is part of REEDA scale – not able to access separate result, however, no evidence of between-group differences in overall scale.
Senol 2017	ThermoGEL, freezer 1 hour: -10 °C once in form of ice	wrapped sterile “pad”	2 hours post-birth	20 minutes	at 2 hours and 6 hours	post-1st application 24.4 (SD 0.72) °C post-2nd application 25.5 (SD 0.61) °C	2 hours after each application	no women had adverse effects
Steen 2000	gel pad, propylene glycol (anti-freeze), frozen for 2 hours	sterile gauze covers	within 4 hours after suturing	Unpublished information from the authors noted that gel pad groups took 20 minutes to warm to perineal temperature, compared with ice packs, which	as per women’s preferences for 48 hours (mean 84, SD 5.0 applications)	not assessed	post-application - 0 - 4 hours - day 1 - day 2	wound healing and closure of wound edges assessed days 5 and 10: findings not reported

Table 1. Summary of cooling methods and results (Continued)

				melted more quickly				
Steen 2002	gel pad, propylene glycol (anti-freeze), frozen for 2 hours	sterile gauze covers	within 4 hours after suturing	not described	as per women's preferences for 4 days.	not assessed	pre-application post-application - days 1 - 5 - day 10 - day 14	wound healing and closure of wound edges assessed days 5, 10 and 14: low prevalence and wide confidence intervals
					Day/Median/Range			
					1 20 0 - 12			
					2 36 0 - 14			
					3 5 0 - 13			
					4 2 0 - 14			
Yusamran 2007	adapted commercially-available gel pack (3M Thailand Ltd) to suit perineum (11 x 9 cm), placed in 4 °C fridge-freezer	designed cotton pack to insert gel pad and support sanitary pad – attached loops to suspend it	-	15 minutes to maintain pad temperate of 4 - 12.8 °C 2 hours	replaced every 15 minutes for 2 hours	not assessed	pre- and post each application in the 2 hours, then at 48 hours	wound approximation included in the overall REEDA score

°C – degrees Celsius; cm – centimetres; hr – hour(s); REEDA score – redness, (o)edema, ecchymosis, discharge, (wound edge) approximation; SD – standard deviation

APPENDICES

Appendix 1. Search methods for ICTRP and ClinicalTrials.gov

ICTRP

cooling AND episiotomy

cooling AND perineum

ice AND episiotomy

ice AND perineum

cryotherapy AND episiotomy

cryotherapy AND perineum

ClinicalTrials.gov

Advanced search

Interventional Studies | Episiotomy | cryotherapy

episiotomy | Interventional Studies | cooling

perineum | Interventional Studies | cooling

perineum | Interventional Studies | ice

episiotomy | Interventional Studies | ice

Appendix 2. Methods used in the previous version of this review and changed for the 2020 update

Objective

To evaluate the effectiveness and side effects of localised cooling treatments compared with:

- (i) no treatment;
- (ii) other cooling treatments; and
- (iii) non-cooling treatments applied to the perineum following perineal trauma sustained during childbirth.

To meet this objective, we examined the effect of these treatments on pain, bruising and oedema and considered how each of these affected activities such as daily living, breastfeeding and attending to baby. We also considered other factors, including depression and women's views of and experience with treatments for perineal pain relief.

Outcomes

Primary outcomes

(1) Perineal pain, as measured by the trial authors, at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 72 hours of giving birth;
- between three and 14 days after giving birth;
- three months after giving birth.

(2) Perineal pain, as measured by the trial authors, associated with activities of daily living (for example, sitting, walking, urinating, caring for baby) at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 72 hours of giving birth;
- between three and 14 days after giving birth;
- three months after giving birth.

(3) Painful sexual intercourse at three months postpartum.

(4) Additional analgesia for relief of perineal pain:

- need for and timing of additional analgesia in hospital;

- need for and type of additional analgesia after discharge from hospital.

(5) Perineal oedema, as measured by the study authors, at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 72 hours of giving birth;
- between three and 14 days after giving birth.

(6) Perineal bruising, as measured by the study authors, at the following time periods (or as close to the time period as possible):

- within four to six hours of giving birth;
- within 24 hours of giving birth;
- between 24 and 72 hours of giving birth;
- between three and 14 days after giving birth.

(7) Adverse effects on perineal healing, as measured by the study authors.

(8) Side effects severe enough to discontinue treatment.

(9) Cost of treatment.

(10) Women breastfeeding at:

- discharge from postpartum care;
- six weeks postpartum.

(11) Adverse effects on mother-baby interactions, as measured by the study authors.

(12) Maternal views and experiences with treatment, as measured by the study authors.

(13) Maternal length of postnatal stay.

(14) Effects on maternal quality of life, as measured by the study authors.

(15) Women with postnatal depression.

(16) Maternal exhaustion, as measured by the study authors, at the following time periods (or as close to the time period as possible):

- within 24 hours of giving birth;
- between 24 and 72 hours of giving birth;
- between three and 14 days after giving birth;
- three months after giving birth.

WHAT'S NEW

Date	Event	Description
7 October 2019	New search has been performed	Search updated: 24 trial reports assessed for eligibility. Four new trials (nine reports) added to included studies. Six studies previously included are now excluded and one previously excluded is now included. We have updated the objectives and outcomes to reflect current methodologies: fewer outcomes were reviewed in fewer comparisons. The update includes 10 trials, excludes 15 trials and has two trials awaiting classification.
7 October 2019	New citation required but conclusions have not changed	The conclusions remained unchanged in this update, compared with previous versions of the review.

HISTORY

Protocol first published: Issue 1, 2007

Review first published: Issue 4, 2007

Date	Event	Description
8 August 2012	Amended	<p>We have corrected the following errors.</p> <p>Error in misreporting Leventhal 2011a as having 23% missing data now removed from text.</p> <p>Error in stating that measured temperature may have been from the ice pack, when the review authors had not understood that this recording was taken after the ice pack was removed (Leventhal 2011a).</p> <p>Note that skin temperature measured by Leventhal 2011a was considerably less than normal temperature and can be challenged by other literature. As this discussion is beyond the scope of this review, we have removed the comment.</p>
1 February 2012	New search has been performed	<p>Search updated. Six new studies identified. Five have been included (Leventhal 2011a; Nawabi 2009a; Sheikhan 2011a; Thangaraju 2006a; Yasumran 2007a). One trial is ongoing (Sao Paulo 2011).</p> <p>This updated review is now comprised of 10 included studies (involving 1825 women). The conclusions have not changed.</p>
1 February 2012	New citation required but conclusions have not changed	Updated.
5 October 2011	Amended	Search and review updated
10 November 2008	Amended	Contact details updated.
18 February 2008	Amended	Converted to new review format.
11 July 2007	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Protocol and Review 2007 ; updated review 2012 ([East 2012](#)): Christine East compiled the protocol, reviewed trials, abstracted data and wrote the review and its updates. Lisa Begg, Naomi Henshall and Karen Wallace performed data abstraction. Paul Marchant provided statistical advice, particularly on the issue of dealing with studies that had three comparison groups and provision of additional data for one study ([Steen 2002](#)). All co-authors previewed and contributed to the content of the review and its update.

Updated Review 2020: Christine East continued to author, with the remaining original authors declining or not otherwise being available to continue. Three new authors joined the review team. JiaJia (Jessie) Liu, Emma Dorward and Rhianonn Whale joined the authorship and assessed trials for inclusion, abstracted data and contributed to the data interpretation and general text. All co-authors previewed and contributed to the content of the review and its update.

DECLARATIONS OF INTEREST

Protocol and Review 2007; updated Review 2012 ([East 2012](#))

Christine E East: received AUD 25,000 grant from the Queensland Nursing Council to support the 2007 protocol and review. Christine E East conducted an unpublished pilot study comparing the use of cold gel pads with ice packs in 2009. The study was not pursued due to lack of funding resources. It had not been considered for inclusion in the early versions of this review.

Lisa Begg: no interests to declare.

Paul R Marchant: collaborated in randomised controlled trials comparing the effectiveness of two cooling treatments for the relief of perineal pain following childbirth. These reports were included in the review ([Steen 2000](#); [Steen 2002](#)) but were reviewed by other authors.

Karen Wallace: no interests to declare.

Updated review 2020

Christine E East: conducted an unpublished pilot study comparing the use of cold gel pads with ice packs in 2009. The study was not pursued due to lack of funding resources. It had been overlooked in previous versions of the review, given the pilot status.

Jiajia Liu: no interests to declare.

Emma Dorward: no interests to declare.

Rhiannon Whale: no interests to declare.

SOURCES OF SUPPORT

Internal sources

- Queensland Health Nursing Research Grant, Australia

For the initial protocol and review, 2007

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The protocol and original review had included cross-over studies. We excluded such studies in the previous update of this review ([East 2012](#)) and retained this approach in the current update, for the reasons noted in the [Methods](#) section.

We made a number of changes for the 2020 update to align with the evolution of the systematic review methodology over time:

Objectives: We edited these to compare: (i) one form of cooling with no treatment; (ii) cooling with placebo; or (iii) two different cooling treatments: we did not conduct the comparisons that were in the previous version of the review between a cooling treatment and other forms of treatment. This was to streamline the review process to better align with the topic. The previous objectives are provided in [Appendix 2](#).

Types of studies: in previous versions of this review (e.g. [East 2012](#)), we excluded studies available only in abstract form. For this 2020 update, we were able to confirm that all of the reports that were available in abstract form were also linked with later-published full trial reports. If we identify any other abstracts in future updates, we will include them if they contain sufficient information to assess study eligibility and risk of bias and if the authors confirm in writing that they reported final results that would not change in subsequent publications. Additionally, we had previously excluded the study by [Barclay 1983](#), due to concerns about quality. We have now included this study as it met the inclusion criteria, although it did not contribute data to the meta-analysis.

The change in objectives (and therefore in the comparisons with a cooling treatment) meant that we excluded comparisons between cooling treatments and some alternate form of treatment in the original and previous versions of the review ([East 2012](#)) in this 2020 update. This included the following treatments: pulsed electromagnetic therapy ([Gallie 2003](#)), warmth ([Hill 1989](#); [Sheikhan 2011](#)), regular administration of paracetamol ([Thangaraju 2006](#)), hammamelis water ([Moore 1989](#)) and Pramoxine/Hydrocortisone foam ([Steen 2000](#); [Moore 1989](#)).

Outcomes: there has been a trend towards examining fewer outcomes in Cochrane Reviews over recent years. We proposed in our earlier update ([East 2012](#)) that we would reconsider using the outcomes listed in the generic protocol for reporting trials of pharmacological analgesia for the relief of perineal pain by [Chou 2009](#). We therefore reduced the number of outcomes and the multiple time frames for which they could be considered from the previous versions of this review (see [Appendix 2](#)).

NOTES

Nil

INDEX TERMS

Medical Subject Headings (MeSH)

Combined Modality Therapy [methods]; Episiotomy [adverse effects]; Hypothermia, Induced [adverse effects] [*methods]; Pain Management [adverse effects] [*methods]; Parturition; Perineum [*injuries]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy