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[Intervention Review]

Prophylactic intravenous preloading for regional analgesia in labour

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ABSTRACT

Background

Reduced uterine blood flow from maternal hypotension may contribute to fetal heart rate changes which are common following regional analgesia (epidural or spinal or combined spinal-epidural (CSE)) during labour. Intravenous fluid preloading may help to reduce maternal hypotension but using lower doses of local anaesthetic, and opioid only blocks, may reduce the need for preloading.

Objectives

To assess the effects of prophylactic intravenous fluid preloading before regional analgesia during labour on maternal and fetal well-being.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (19 February 2004). We updated this search on 30 June 2010 and added the results to the awaiting classification section of the review.

Selection criteria

Randomised and quasi-randomised trials comparing prophylactic intravenous preloading before regional analgesia during labour with a control group (dummy or no preloading).

Data collection and analysis

Two reviewers independently applied eligibility criteria, assessed trial quality and extracted data.

Main results

Six studies are included (473 participants). In one epidural trial using high-dose local anaesthetic, preloading with intravenous fluids was shown to counteract the hypotension which frequently follows traditional epidural analgesia (relative risk (RR) 0.07, 95% confidence interval (CI) 0.01 to 0.53; 102 women). This trial was also associated with a reduction in fetal heart rate abnormalities (RR 0.36, 95% CI 0.16 to 0.83; 102 women); no differences were detected in other perinatal and maternal outcomes for this trial and another high-dose epidural trial. In the two epidural low-dose anaesthetic trials, no significant difference in maternal hypotension was found (RR 0.73, 95% CI 0.36 to 1.48; 260 women), although they were underpowered to detect less than a very large effect. No significant differences were seen between groups in these trials for fetal heart rate abnormalities (RR 0.64, 95% CI 0.39 to 1.05; 233 women).

In the two CSE trials, no differences were reported between preloading and no preloading groups. In the spinal/opioid trial, the RR for hypotension was 0.89, 95% CI 0.43 to 1.83 (40 women) and 0.70, 95% CI 0.36 to 1.37 for fetal heart rate abnormalities (32 women). In the opioid only study (30 women), there were no instances of hypotension or fetal heart rate abnormalities in either group.

Authors' conclusions

Preloading prior to traditional high-dose local anaesthetic blocks may have some beneficial fetal and maternal effects in healthy women. Low-dose epidural and CSE analgesia techniques may reduce the need for preloading. The studies reviewed were too small to show whether preloading is beneficial for women having regional analgesia during labour using the lower-dose local anaesthetics or opioids. Further investigation of low-dose epidural or CSE (including opioid only) blocks, and the risks and benefits of intravenous preloading for women with pregnancy complications, is required.

[Note: The five citations in the awaiting classification section of the review may alter the conclusions of the review once assessed.]

PLAIN LANGUAGE SUMMARY

Prophylactic intravenous preloading for regional analgesia in labour

The effect of giving intravenous fluid to prevent low blood pressure, following regional analgesia for women in labour, is unclear.

Regional (epidural, spinal or combined spinal-epidural) analgesia is a common form of pain relief used during labour. Some women have hypotension (low blood pressure) following regional analgesia which can affect both mother and baby. Intravenous fluids before epidural analgesia with high-dose local anaesthetics reduces hypotension. This benefit is not seen when the more recent low-dose local anaesthetics are used, probably due to a lower risk of hypotension with these drugs. There was not enough evidence to show whether preloading is beneficial for women having regional analgesia during labour using the lower-dose agents, or for women with pregnancy complications.

BACKGROUND

Regional analgesia is commonly used for pain relief during labour. A fine catheter may be inserted into the space outside the membrane surrounding the cerebro-spinal fluid ('epidural'), or a needle inserted into the cerebro-spinal fluid ('spinal'), or both may be combined ('combined spinal-epidural'). Local anaesthetic (such as bupivacaine) and/or opioid drugs (such as fentanyl) are injected to block pain sensation. Side-effects include a loss of muscle power and blockade of the sympathetic nervous system causing dilatation of blood vessels (vasodilatation). This may in turn cause a fall in blood pressure. Intravenous fluid preloading (volume expansion by infusing fluid intravenously) prior to regional analgesia during labour ([Ramanathan 1983](#)) is widely practised. The rationale is to prevent the occurrence of hypotension ([Grant 1989](#)) which is thought to result at least in part from relative hypovolaemia due to vasodilation following sympathetic blockade. Fetal heart rate changes are commonly observed following regional analgesia during labour, although the clinical significance of these changes is not entirely clear. They are thought to be at least in part caused by reduced uterine blood flow due to maternal hypotension, though fetal bradycardia (slowing of the fetal heart rate) following induction of epidural analgesia without overt systemic hypotension has been described ([Stavrou 1989](#)). Newer techniques using low concentrations of local anaesthetic solution may reduce the need for preloading ([Kinsella 2000](#)). Intrathecal opioid injection has little effect on sympathetic activity and would therefore not be expected to cause hypotension ([Mandell 1996](#)), though hypotension has been found in practice ([D'Angelo 1994](#)).

Rapid fluid infusion may potentially cause side-effects such as fluid overload and, in susceptible women, pulmonary oedema. Three deaths due to pre-eclampsia or eclampsia have been associated with iatrogenic fluid overload in a report on maternal death ([UK Dept Health 1998](#)).

OBJECTIVES

To assess, from the best available evidence, the effects on maternal and fetal well-being of intravenous fluid preloading before regional analgesia in labour.

METHODS

Criteria for considering studies for this review

Types of studies

Clinical trials comparing the effects of prophylactic intravenous fluid preloading for regional analgesia during labour on clinically meaningful outcomes, with a control group (dummy or no preloading); random or quasi-random allocation to the treatment and control group; violations of allocated management and exclusions after allocation not sufficient to materially affect outcomes.

Types of participants

Women undergoing regional analgesia during labour.

Types of interventions

Prophylactic intravenous fluid preloading before regional analgesic administration, compared with dummy or no prophylactic preloading.

Types of outcome measures

Maternal outcomes including blood pressure; fetal heart rate changes; perinatal outcomes.

Outcome measures were included if: clinically meaningful; reasonable measures taken to minimise observer bias; missing data insufficient to materially influence conclusions; data available for analysis according to original allocation, irrespective of protocol violations; data available in a format suitable for analysis.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register by contacting the Trials Search Co-ordinator (19 February 2004). We updated this search on 30 June 2010 and added the results to [Studies awaiting classification](#).

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

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

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

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

We did not apply any language restrictions.

Data collection and analysis

We considered all studies identified by the search strategy outlined above for inclusion. We evaluated trials included for appropriateness and methodological quality without consideration of their results. Two reviewers independently assessed the trials for inclusion. We resolved any differences of opinion by discussion. We recorded and reported reasons for excluding trials.

We assigned quality scores for allocation concealment to each trial, using the criteria described in Section six of the Cochrane Reviewers' Handbook ([Clarke 2003](#)):

A = adequate; B = unclear; C = clearly inadequate.

We recorded completeness of follow up.

We also assessed studies for blinding but, due to the nature of the interventions, we planned to include studies that were not blinded.

Two reviewers independently extracted the data. Whenever necessary, we sought unpublished data from investigators. We performed statistical analyses using the Review Manager software (RevMan 2004). We processed included trial data as described in the Cochrane Reviewers' Handbook (Clarke 2003).

We compared categorical data using relative risks and 95% confidence intervals using a fixed effect model. We tested statistical heterogeneity between trials using the I^2 statistic, regarding I^2 greater than 50% as statistically significant heterogeneity.

Subsequent to the original protocol being written, low-dose local anaesthetic and opioid only analgesia became common practice. We therefore amended the original protocol to include a subgroup analysis of epidural high-dose local anaesthetic, epidural low-dose local anaesthetic, combined spinal-epidural or opioid only (epidural or intrathecal) analgesia. Because the effects of intravenous preloading could differ between low- and high-dose, we have not combined the data from the subgroups in this review.

RESULTS

Description of studies

Six trials have been included in this version of the review and one trial is awaiting assessment, pending extra data from the authors. Four trials were excluded.

(Three reports from an updated search in September 2009 have been added to [Studies awaiting classification](#).)

Participants

In Cheek 1996, participants were 34 healthy women in spontaneous term labour. In Collins 1978, participants were 104 women who received epidural analgesia in labour. Women were excluded if they suffered from systemic disease or were more than 20% outside predicted norms for height and weight, or if fetal heart rate was abnormal before the induction of epidural analgesia. Kinsella 2000 recruited 100 healthy labouring women with a singleton cephalic fetus and cervical dilatation of not more than 8 cm who had requested epidural analgesia. Women with hypertension, body mass greater than 100 kg, or fetal distress were excluded. Kubli 2003 included 168 women between the ages of 16 and 44 years who requested epidural analgesia. Women with body weight greater than 110 kg, multiple pregnancies, breech presentation, cervical dilatation greater than 9 cm, hypertensive disorders of pregnancy or existing abnormal cardiotocograph traces, and those receiving oxytocin were excluded. Macaulay 2000 included 40 women with singleton pregnancies. Shannon 1998 studied 30 healthy labouring women at term with a healthy singleton gestation. None of the women had any pregnancy-induced complications or pre-existing medical disease.

Interventions

Type, quantity and timing of fluid preload

In Cheek 1996, women were randomised to one of three groups; 500 ml of normal saline infused over 10 minutes, 1000 ml of normal saline; or no fluid load. All women received maintenance intravenous fluids of 5% glucose 125 ml per hour in 1/2 normal saline from admission to the labour ward to just before the start of the study (mean 550 ml). In Collins 1978, women in the preload

group, were infused (over 10 to 15 minutes) with one litre of Hartmann's solution starting immediately before the injection of local anaesthetic; and women in the no preload group did not receive any additional fluids before the epidural anaesthetic. In the preload group in Kinsella 2000, women were infused rapidly with one litre of Hartmann's solution before the epidural; and in the no preload group, the infusion was run at the slowest possible speed. In the preload group in Kubli 2003, women were given 7 ml/kg Hartmann's solution intravenously after epidural insertion but before drug administration; and no fluid was given in the no preload group. In Macaulay 2000, women in the preload group received 500 ml of intravenous lactated Ringer's solution and the no preload group received maintenance fluids only. In Shannon 1998, women in the preload group received 500 ml of lactated Ringer's solution intravenously over 10 minutes prior to commencing the procedure. The women in the no preload group did not receive any fluid, but the start of their procedure was delayed for 10 minutes.

Type of analgesia

Epidural analgesia was used in four studies, and combined spinal-epidural (CSE) analgesia was used in two studies.

Epidural

In Cheek 1996, 12 ml 0.25% bupivacaine without adrenaline was used (high-dose). In Collins 1978, 10 ml of plain 0.375% bupivacaine was used (high-dose). In Kinsella 2000, 15 ml of bupivacaine containing 50 µg (low-dose) was used (0.1% bupivacaine if cervical dilatation was less than 5 cm, otherwise 0.2% was used). In Kubli 2003, both the preload and no preload groups received a 15 ml epidural loading dose of 0.1% bupivacaine (low dose) containing 2 µg/ml fentanyl over two minutes.

CSE

In Macaulay 2000, women were given 2.5 mg intrathecal bupivacaine and 1.2 µg sufentanil. In Shannon 1998, women were injected with 25 µg fentanyl (opioid only) through a 24-gauge, 120 mm Sprotte spinal needle which was inserted through the epidural needle.

Woman's position

In Cheek 1996, after insertion of the extradural, continuous uterine displacement with a right hip wedge was maintained throughout the study. In Collins 1978, women were supine with a pillow under the right buttock when lumbar epidural analgesia was induced; they were then turned to their left side for the duration of labour. In Kinsella 2000, women's blood pressure was taken while in the left lateral position. In Kubli 2003, women were in the sitting or lateral position, with a change to left lateral if not already in that position if they became hypotensive. Position of the women was not stated in Macaulay 2000. In Shannon 1998, women were in the sitting position to locate the epidural space, and all haemodynamic measurements were made with the woman in the supine position, with a wedge placed under the right hip (left uterine displacement).

Outcomes

Hypotension

Since there is no commonly accepted definition for hypotension (Emmett 2004), we used each study author's definition of the hypotension measure that required intervention. This was defined as a fall in systolic blood pressure of over 20 mm Hg in Collins

1978; a fall greater than 20% in systolic blood pressure from baseline in [Macaulay 2000](#); and a fall greater than 20% in mean arterial pressure from baseline (within 30 minutes of the epidural) in [Kinsella 2000](#); [Kubli 2003](#) and [Shannon 1998](#). Maternal blood pressure (rather than hypotension) was recorded in [Cheek 1996](#).

Fetal heart rate abnormality

[Cheek 1996](#), [Macaulay 2000](#) and [Shannon 1998](#) did not provide definitions for fetal heart rate abnormalities. In [Collins 1978](#), fetal heart rate abnormalities were classified according to Beard's system. In [Kinsella 2000](#), fetal heart traces were classified as normal, suspicious or abnormal (according to Steer and Danielian's scheme). Fetal heart rate abnormality was defined as a 10% difference in the number of deteriorations in the fetal cardiotocograph in [Kubli 2003](#).

Also, see the table of 'Characteristics of included studies'.

Risk of bias in included studies

Allocation concealment

In [Collins 1978](#), allocation of the participants was quasi-random (coded C), as case note numbers were used. [Cheek 1996](#) described allocation as random and prospective; in [Kinsella 2000](#), allocation was "determined on the basis of a computer-generated list"; [Macaulay 2000](#) stated that women were "randomly allocated"; [Shannon 1998](#) also made assignments according to a computer-generated random number table; and so these four studies were coded B (unclear) for allocation concealment. [Kubli 2003](#) used sealed envelopes and so this study was also coded B.

Use of a placebo

No trial reported the use of a dummy infusion.

Blinding

Investigators (who measured blood pressure) were not blinded in [Kinsella 2000](#); however, the outcome assessor for fetal heart rate measurements was blinded, as were the two obstetrician outcome assessors in [Kubli 2003](#). In [Macaulay 2000](#), the obstetrician assessing the fetal heart rate tracings was blinded. Blinding of outcome assessors or of women was not stated in [Cheek 1996](#); [Collins 1978](#); or [Shannon 1998](#). There is no record of attempts to avoid outcome assessment bias by the use of random-zero or automatic sphygmomanometers (but Shannon used automated blood pressure).

Losses to follow up

In [Cheek 1996](#), two women were excluded from the no preload group and one woman was excluded from each of the two preload groups because of rapid progression of labour. In [Collins 1978](#), two women (both from the preload group) were excluded from analysis; no reasons were stated. In [Kinsella 2000](#), one woman from each group was excluded; one had a placental abruption and caesarean section, and the other gave birth vaginally. One woman in the preload group and two in the no preload group were excluded after study completion, as they were found to have had abnormal baseline fetal heart rate patterns before the epidural. Fetal heart rate readings were only available for 81 women.

In [Kubli 2003](#), two women from the preload group and one from the no preload group were found to be in the second stage of labour before the study could be completed, and so these three women

were excluded from further analysis. In [Macaulay 2000](#), there were no losses to follow up for the outcome of hypotension, but only 32 out of 40 babies had fetal heart traces available. There were no losses to follow up in [Shannon 1998](#).

Intention to treat

In [Cheek 1996](#), 34 women were randomised and analysis was performed on 30 (11 in the no preload group, eight in the 500 ml preload group and 11 in the 1000 ml preload group). In [Collins 1978](#), 104 women were randomised and analysis was performed on 102 (49 in the preload group and 53 in the no preload group). In [Kinsella 2000](#), 100 women were randomised and analysis was performed on 95 (49 in the preload group and 46 in the no preload group). In [Kubli 2003](#), two women in the no preload group were treated with intravenous fluid and one woman in the preload group was given additional fluid. Results for these 165 women were analysed by intention to treat. In [Macaulay 2000](#), fetal heart abnormality was not analysed on an intention to treat basis.

The possibility of various sources of bias was therefore not effectively excluded in these trials. The small numbers studied in all trials has resulted in wide confidence intervals, and the review is underpowered to detect differences in uncommon outcomes.

Effects of interventions

Seven eligible studies were identified for inclusion. We are awaiting additional data from [Hawthorne 2001](#) and so this trial is currently awaiting assessment until we can incorporate the additional data. Therefore, six trials (with a total of 473 participants) were included in this version of the review. Four trials used epidural anaesthesia ([Cheek 1996](#); [Collins 1978](#); [Kinsella 2000](#); [Kubli 2003](#)) and two trials used combined spinal-epidural anaesthesia (CSE) ([Macaulay 2000](#); [Shannon 1998](#)).

Hypotension

High-dose local anaesthetic

In the study using high-dose local anaesthetic as an epidural ([Collins 1978](#)), preloading with intravenous fluids was shown to counteract the hypotension which frequently follows epidural analgesia (relative risk (RR) 0.07, 95% confidence interval (CI) 0.01 to 0.53; 102 women).

In [Cheek 1996](#) (high-dose anaesthetic), outcomes were not presented in a format which could be used in this review; however, no differences in blood pressure changes between the three groups (total of 30 women) were noted.

Low-dose local anaesthetic

In [Kinsella 2000](#) and [Kubli 2003](#), where low-dose local anaesthetic was used as an epidural, no significant difference in maternal hypotension was found (RR 0.73, 95% CI 0.36 to 1.48; 260 women), although the studies were underpowered to detect less than a very large effect.

In [Macaulay 2000](#) where CSE (spinal local anaesthetic and opioid) was used, the relative risk of hypotension was 0.89, 95% CI 0.43 to 1.83; 40 women.

Spinal opioid only

In [Shannon 1998](#) where spinal opioids only were used as a CSE, there were no cases of maternal hypotension in either group (total of 30 women).

Fetal heart rate (FHR) abnormalities

In the traditional high dose local anaesthetic epidural trials, there was a significant reduction in the risk of fetal heart rate abnormalities in [Collins 1978](#) (RR 0.36, 95% CI 0.16 to 0.83; 102 women) but not in [Shannon 1998](#) where no cases of fetal rate abnormality were reported in either group. In the two low-dose epidural trials ([Kinsella 2000](#); [Kubli 2003](#)), there was a trend to reduced FHR abnormalities which did not reach significance between groups (RR 0.64, 95% CI 0.39 to 1.05; 233 women). In the two CSE trials, [Cheek 1996](#) reported no cases of fetal heart rate abnormality while [Macaulay 2000](#) showed no significant differences between intervention and control groups (RR 0.70, 95% CI 0.36 to 1.37; 32 women).

Delivery mode

No differences in mode of delivery between the two preload groups and the no preload group were seen in [Cheek 1996](#) (assisted vaginal delivery: RR 0.96, 95% CI 0.28 to 3.28); or caesarean section: RR 0.87, 95% CI 0.17 to 4.42); total of 30 women. [Macaulay 2000](#) reported that the outcome of labour was similar in both groups (but did not provide figures). In [Shannon 1998](#), no emergency caesarean sections for fetal distress were reported.

Other outcomes

[Collins 1978](#) was too small to show any potential differences between preload and no preload groups for Apgar scores, with a RR of 0.54, 95% CI 0.05 to 5.78 (102 women) for Apgar scores less than seven at one minute.

In [Cheek 1996](#), uterine activity after infusion in the 1000 ml preload group was significantly reduced. No significant changes were seen in the 500 ml and no preload groups, nor in any of the groups after epidural block.

DISCUSSION

Although there are methodological shortcomings in the trials reviewed, the effects of fluid preloading, on reducing maternal hypotension and fetal heart rate abnormalities when high-dose local anaesthetics are used as part of a regional technique, appear clear-cut, with a 26% reduction in hypotension (from 28% of women with hypotension without preloading reduced to 2% with preloading in [Collins 1978](#)). While it is unlikely that such large differences are entirely due to bias or chance, [Plaat 2001](#) notes that the supine position used in the Collins high-dose epidural study ([Collins 1978](#)) may have influenced the incidence of hypotension.

The use of high-dose local anaesthetic is no longer usual practice, but unfortunately the data on the use of low-dose local anaesthetics or opioids during epidural or combined spinal-epidural are insufficient for meaningful analysis. No statistically significant differences between preloading and no preloading were seen for hypotension and fetal heart rate abnormalities but the wide confidence intervals do not refute (or confirm) a difference. If there is indeed an effect from preloading before low-dose local anaesthetics, it would probably not be as pronounced as when high-dose local anaesthetics are used. [Popham 2001](#) notes that the need to prevent maternal hypotension no longer applies for the majority of women who receive low-dose local anaesthetic as part of their regional analgesia, although the situation for fetal heart rate abnormalities is not as clear. The two low-dose epidural trials ([Kinsella 2000](#); [Kubli 2003](#)) which found a statistically nonsignificant trend to less fetal heart rate abnormalities with preloading, are likely to be underpowered.

No studies reported maternal outcomes such as lightheadedness, fainting, nausea and vomiting. These symptoms may reflect an otherwise undetected fall in blood pressure and should be recorded in future studies of preloading.

The possibility of uncommon adverse effects of the fluid preload cannot be excluded on the basis of these studies.

AUTHORS' CONCLUSIONS

Implications for practice

Although intravenous preloading before traditional high-dose epidural anaesthesia shows value in reducing hypotension and fetal heart rate abnormalities, benefits have not been demonstrated when the more common low-dose epidural anaesthetics have been used. Low-dose epidural and combined spinal-epidural (CSE) anaesthetics may reduce the need for preloading. However, the small evidence base does not allow a difference between preloading and no preloading to be ruled out or confirmed, when low-dose epidural or CSE anaesthetics are used.

Implications for research

The use of preloading for low-dose epidural and CSE (including opioid only) blocks in labour, relative risks and benefits of preloading prior to epidural anaesthesia in the presence of pregnancy complications such as pre-eclampsia and cardiac disease, the optimal type and volume of fluid, maternal outcomes such as lightheadedness, fainting, nausea and vomiting, potential side-effects, and women's views require further investigation.

[Note: The five citations in the awaiting classification section of the review may alter the conclusions of the review once assessed.]

ACKNOWLEDGEMENTS

None.

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* Indicates the major publication for the study

CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Cheek 1996

Methods	Allocated "randomly and prospectively". Blinding: not stated. Losses to follow up: 4/34 (12%) - one woman each excluded from the saline infusion groups and two from the no fluid load group, because of rapid labour progression.
Participants	34 healthy women in spontaneous labour. Primiparae and multiparae.
Interventions	Normal saline 500 ml IV over 10 minutes versus 1000 ml over 10 minutes (n = 19 for both fluid groups) versus no fluid load (n = 11). Epidural block with 12 ml 0.25% bupivacaine.
Outcomes	Fetal heart rate; maternal blood pressure; internal measurement of uterine activity.
Notes	
Risk of bias	
Bias	Authors' judgement Support for judgement

Prophylactic intravenous preloading for regional analgesia in labour (Review)

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Cheek 1996 (Continued)

Allocation concealment?	Unclear risk	B - Unclear
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Collins 1978

Methods	"Random" allocation on the basis of case-note numbers. Blinding: not stated. Losses to follow up: 2/102 (2%) - no reasons given.
Participants	104 women. Inclusion criteria: women undergoing epidural analgesia during labour. Exclusion criteria: systemic disease; more than 20% outside the predicted norms for height and weight; abnormal fetal heart rate.
Interventions	Intravenous Hartmann's solution 1000 ml immediately before injection of the epidural local anaesthetic (n = 49), compared with no preloading (n = 53).
Outcomes	Maternal blood pressure; fetal heart rate abnormality; perinatal outcome.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	High risk	C - Inadequate

Kinsella 2000

Methods	Allocation was "determined on the basis of a computer-generated list". Blinding: not done for assessment of hypotension, but the outcome assessor for FHR was blinded. Losses to follow up: 5/100 (5%) - one in each group excluded before being studied because of rapid delivery; one in the study and two in the control excluded after the study because found to have had abnormal baseline fetal heart rate patterns.
Participants	100 women. Inclusion criteria: healthy labouring women; single cephalic fetus; cervix 8 cm or less; requesting epidural analgesia. Exclusion criteria: hypertension, body mass > 100 kg, fetal distress.
Interventions	Hartmann's solution 1000 ml rapidly intravenously before the test dose (n = 49), versus infusion at the slowest possible speed (n = 46). Epidural analgesia achieved with 0.1% or 0.2% bupivacaine 15 ml with fentanyl 50 micrograms.
Outcomes	Hypotension (decrease > 20% from the lowest systolic baseline pressure within 30 minutes); fetal heart rate change (normal/suspicious/abnormal).
Notes	Power analysis by study authors indicated that 1530 women would be needed to determine if preloading reduces hypotension; and 200 women would have been needed to show a difference in FHR between groups.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Prophylactic intravenous preloading for regional analgesia in labour (Review)

Kubli 2003

Methods	Computer random number generation. Allocation concealment: sealed envelopes. Blinding: not stated except for FHR where two obstetrician outcome assessors were blinded. Losses to follow up: 3/168 (2%) - 2 in the preload group and 1 in the no preload group, as they were found to be in the second stage of labour before the study could be completed. Intention to treat: Two women in the no preload group were treated with IV fluid and one woman in the preload group was given additional fluid. Results for these 165 women were analysed by intention to treat.
Participants	168 women between the ages of 16 and 44 who requested an epidural anaesthesia. Exclusions: Women with body weight > 110 kg, multiple pregnancies, breech presentation, cervical dilatation > 9 cm, pregnancy hypertensive disorders or existing abnormal CTG traces, and those receiving oxytocin.
Interventions	Preload group (n = 83): Hartmann's solution 7 ml per kg IV epidural insertion but before drug administration; No preload group (n = 82): no fluid was given.
Outcomes	Hypotension (> 20% fall in mean arterial pressure from baseline); fetal heart rate deteriorations (from pre to postepidural CTGs).
Notes	Note that the group given preload is referred to as the control group; and the no preload group was referred to the intervention group in the primary paper.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

Macaulay 2000

Methods	"Randomly allocated". Blinding: not stated except for FHR where an obstetrician outcome assessor was blinded. Losses to follow up: 8/40. FHR traces were not available. Intention to treat: This was possible for the outcome of hypotension since there were no losses to follow up, but for FHR an intention to treat analysis was not possible.
Participants	40 women with singleton pregnancies.
Interventions	Preload (n = 20): 500 ml intravenous lactated Ringer's solution. No preload group (n = 20): maintenance fluids only.
Outcomes	Hypotension (> 20% fall in systolic blood pressure); fetal heart rate abnormality.
Notes	

Risk of bias

Bias	Authors' judgement	Support for judgement
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Macaulay 2000 (Continued)

Allocation concealment?	Unclear risk	B - Unclear
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Shannon 1998

Methods	Assignment using a computer-generated random number table. Blinding: not stated. Losses to follow up: none.
Participants	30 healthy women at term; healthy singleton pregnancy. Exclusion criteria: pregnancy-induced complications; pre-existing medical disease.
Interventions	Lactated Ringers' solution 500 ml IV over 10 minutes prior to the procedure ('fluid' group, n = 15); versus no fluid bolus ('no fluid' group, n = 15).
Outcomes	Automated systolic and diastolic blood pressure; hypotension (> 20% fall in systolic blood pressure from antenatal level); cardiac index using impedance cardiograph; intensity of pain; electronic fetal heart rate monitoring; visual analogue scale for pain; emergency CS for fetal distress (none).
Notes	Data collection discontinued if epidural bupivacaine needed.

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment?	Unclear risk	B - Unclear

CS: caesarean section
CTG: cardiotocograph
FHR: fetal heart rate
IV: intravenous

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Eledjam 1989	Excluded because no usable data in the abstract publication.
Evans 1986	Excluded because no control group not receiving preloading. Preloading with predominantly saline based fluid (Hartmann's solution) compared with dextrose saline. Minor biochemical differences noted in the woman but not the fetus.
Murray 1989	Excluded because did not meet inclusion criteria (preloading not compared with no preloading). Sixty mothers were randomly allocated to receive either two litres of crystalloid or one litre of colloid solution (hydroxyethyl starch) in order to preload the circulation prior to elective caesarean section under epidural anaesthesia. There were no differences in the incidence of hypotension, degree of haemodilution, umbilical cord blood gas tensions or umbilical blood osmolalities between the two groups.
Zamora 1996	Excluded because there was no non-treatment group. Ringer's lactate 1000 ml (n = 46) was compared with 500 ml (n = 46), before induction of epidural analgesia with lidocaine 2%. There were no differences between the groups in systolic blood pressure or pulse. 2/46 in each group developed maternal hypotension.

DATA AND ANALYSES

Comparison 1. Prophylactic intravenous preloading before epidural anaesthesia in labour

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Maternal hypotension	5		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
1.1 Epidural, high-dose anaesthetic	1	102	Risk Ratio (M-H, Fixed, 95% CI)	0.07 [0.01, 0.53]
1.2 Epidural, low-dose anaesthetic	2	260	Risk Ratio (M-H, Fixed, 95% CI)	0.73 [0.36, 1.48]
1.3 CSE, spinal local anaesthetic and spinal opioid	1	40	Risk Ratio (M-H, Fixed, 95% CI)	0.89 [0.43, 1.83]
1.4 CSE, spinal opioid only	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Maternal resuscitation	0		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
2.1 Epidural, high-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.3 CSE, spinal local anaesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Fetal heart rate abnormality	6		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
3.1 Epidural, high-dose anaesthetic	2	132	Risk Ratio (M-H, Fixed, 95% CI)	0.36 [0.16, 0.83]
3.2 Epidural, low-dose anaesthetic	2	233	Risk Ratio (M-H, Fixed, 95% CI)	0.64 [0.39, 1.05]
3.3 CSE, spinal local anaesthetic and spinal opioid	1	32	Risk Ratio (M-H, Fixed, 95% CI)	0.7 [0.36, 1.37]
3.4 CSE, spinal opioid only	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Assisted vaginal delivery	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
4.1 Epidural, high-dose anaesthetic	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.96 [0.28, 3.28]
4.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.3 CSE, spinal local anaesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Caesarean section	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
5.1 Epidural, high-dose anaesthetic	1	30	Risk Ratio (M-H, Fixed, 95% CI)	0.87 [0.17, 4.42]
5.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.3 CSE, spinal local anaesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 1 minute Apgar score < 7	1		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
6.1 Epidural, high-dose anaesthetic	1	102	Risk Ratio (M-H, Fixed, 95% CI)	0.54 [0.05, 5.78]
6.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.3 CSE, spinal local anaesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 5 minute Apgar score < 7	0		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
7.1 Epidural, high-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.3 CSE, spinal local anaesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Umbilical artery pH < 7.2	0		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
8.1 Epidural, high-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8.3 CSE, spinal local anaesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
8.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Neonatal encephalopathy	0		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
9.1 Epidural, high-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.3 CSE, spinal local anesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Serious neonatal morbidity or death	0		Risk Ratio (M-H, Fixed, 95% CI)	Subtotals only
10.1 Epidural, high-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.2 Epidural, low-dose anaesthetic	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.3 CSE, spinal local anaesthetic and spinal opioid	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10.4 CSE, spinal opioid only	0	0	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Prophylactic intravenous preloading before epidural anaesthesia in labour, Outcome 1 Maternal hypotension.

Analysis 1.3. Comparison 1 Prophylactic intravenous preloading before epidural anaesthesia in labour, Outcome 3 Fetal heart rate abnormality.

Analysis 1.4. Comparison 1 Prophylactic intravenous preloading before epidural anaesthesia in labour, Outcome 4 Assisted vaginal delivery.

Analysis 1.5. Comparison 1 Prophylactic intravenous preloading before epidural anaesthesia in labour, Outcome 5 Caesarean section.

Analysis 1.6. Comparison 1 Prophylactic intravenous preloading before epidural anaesthesia in labour, Outcome 6 1 minute Apgar score < 7.

WHAT'S NEW

Date	Event	Description
4 October 2010	Amended	Contact details edited.

HISTORY

Protocol first published: Issue 2, 1996

Review first published: Issue 2, 1996

Date	Event	Description
30 June 2010	Amended	Search updated. Three reports added to Studies awaiting classification (Makris 2008; Roofthoof 2007; Wells-Brooks 2001).
20 September 2008	Amended	Converted to new review format.
28 June 2004	New search has been performed	Search updated February 2004: Two new trials included (Kubli 2003 and Macaulay 2000); one other trial awaiting assessment (Hawthorne 2001) because we are waiting for additional data. (This study was previously excluded.) The conclusions remain largely unchanged.
28 June 2004	New citation required but conclusions have not changed	Subsequent to the original protocol being written, low-dose local anaesthetic and opioid only analgesia became common practice. We have therefore amended the original protocol to include a subgroup analysis of epidural high-dose local anaesthetic, epidural low-dose local anaesthetic, combined spinal-epidural or opioid only (epidural or intrathecal) analgesia.

CONTRIBUTIONS OF AUTHORS

Justus Hofmeyr prepared and maintained the previous version of the review. Allan Cyna and Philippa Middleton prepared the 2004 update of the review and Justus Hofmeyr commented on the draft.

DECLARATIONS OF INTEREST

None known.

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- South African Medical Research Council, South Africa.
- Australian Department of Health and Ageing, Australia.

INDEX TERMS

Medical Subject Headings (MeSH)

*Anesthesia, Epidural [methods]; *Anesthesia, Obstetrical [methods]; *Fluid Therapy [methods]; *Heart Rate, Fetal; Hypotension [*prevention & control]; Pregnancy Complications, Cardiovascular [*prevention & control]; Randomized Controlled Trials as Topic

MeSH check words

Female; Humans; Pregnancy