Sterile water injection for labour pain: a systematic review and meta-analysis of randomised controlled trials

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CRD summary
The authors concluded that further research is needed to confirm the review's findings that sterile water reduced the rate of caesarean section. The authors' conclusions are likely to be reliable, but in light of the small size of included trials and the lack of blinding of some trials, their recommendation for further research is warranted.

Authors' objectives
To assess the impact of sterile water injection compared to placebo or alternative therapies on caesarean section rates and pain in women with low back pain during labour.

Searching
The Cochrane library, EMBASE, MEDLINE and CINAHL were searched from inception to 2009 for articles in any language. Search terms were reported.

Study selection
Randomised controlled trials (RCTs) that compared intracutaneous or subcutaneous injections of sterile water with placebo or other non-pharmacological methods of pain relief, in women with low back pain in the active stage of labour, were eligible for inclusion. The primary outcome of interest was rate of caesarean section. Other outcomes eligible for inclusion were: pain at 10 to 30 minutes, 45 to 60 minutes and 90 to 120 minutes post-intervention; use of regional analgesia/anaesthesia; and participants' subjective assessment of the intervention.

Included trials were of intracutaneous (four injections of 0.1ml) or subcutaneous injections (one or four to eight injections of 0.5ml) of sterile water. Comparison conditions were transcutaneous electric nerve stimulation (TENS), acupuncture, usual care or isotonic saline injections. Pain was assessed using visual analogue or Likert-type scales.

Three reviewers independently selected the studies for review.

Assessment of study quality
The methodological quality of the studies was assessed using a modified Jadad Scale. The authors did not report what items the scale contained or the maximum score. Trials were deemed to be high quality if they had a quality score of ten or more.

Three reviewers independently assessed the methodological quality of the included trials.

Data extraction
For dichotomous data, the number of events in each group was extracted and used to calculate relative risks (RR) with 95% confidence intervals (CIs) for each trial. For continuous data, means and standard deviations (SDs) were extracted and used to calculate mean differences for each trial. Where standard deviations were not reported, they were estimated as 0.25 of the range. Where medians and interquartile range (IQR) were reported, the median was used for the mean and standard deviation was estimated as 1.35 of the interquartile range. Where one trial had both a subcutaneous and an intracutaneous intervention group, only data from the intracutaneous group was used. Where one trial had two control groups, the data were combined for both groups.

Three reviewers independently extracted the data using a pre-prepared data extraction form. Disagreements were resolved by re-reviewing the articles and reaching consensus.
Methods of synthesis
Pooled relative risks, with 95% confidence intervals, were calculated for dichotomous data. Weighted mean differences (WMDs), with 95% confidence intervals, were calculated for continuous data. Statistical heterogeneity was assessed using the $I^2$ statistic. Where $I^2$ was greater than 50%, a random-effect model was used. Otherwise, the Mantel-Haenszel fixed-effect model was used.

Results of the review
Eight RCTs were included in the review (n=828 women). One RCT scored 13 points on the validity assessment; two RCTS scored 12, four RCTs scored 10, and one RCT scored 8 points. The authors reported that some of the trials were not blinded.

Caesarean rates: Sterile water injection significantly reduced the risk of having a caesarean section (RR 0.51, 95% CI 0.30 to 0.87; eight RCTs, n=828 women) compared with placebo or alternative therapy. There was no evidence of significant statistical heterogeneity ($I^2$=0%).

Pain: Sterile water injection significantly reduced pain (measured on Visual Analogue Scale) at: 10 to 30 minutes (WMD -26.04mm, 95% CI -34.14 to -17.94; four RCTs, n=289); 45 to 60 minutes (WMD -36.27mm, 95% CI -50.80 to -21.74; five RCTs, n=542 women); and at 90 to 120 minutes (WMD -27.74mm, 95% CI -39.03 to -16.45; five RCTs, n=488 women) compared with placebo or alternative therapies. There was evidence of significant statistical heterogeneity at all time points (65% at 10 to 30 minutes, 94% at 45 to 60 minutes and 86% at 90 to 120 minutes).

There were no significant differences between groups on use of regional analgesia or anaesthesia or subjective rating of the intervention.

Authors’ conclusions
Further research is needed to confirm the review’s findings that sterile water injection reduced the rate of caesarean section.

CRD commentary
The review addressed a clear question with well-defined inclusion criteria. Several databases were searched for articles in any language, minimising the risk of language bias. There did not appear to have been a search for unpublished data and publication bias was not assessed, so publication bias could not be ruled out. Appropriate steps were taken in the review process to minimise the risk of reviewer error and bias. However, there was limited information about the scale used for quality assessment and the methodological quality of included trials. Some trials were not blinded, possibly affecting the reliability of the results. The decision to combine trials in a meta-analysis was appropriate. Statistical heterogeneity was assessed, but sources of significant heterogeneity were not investigated. The authors’ conclusions are likely to be reliable, but in light of the small size of included trials and the lack of blinding of some trials, their recommendation for further research is warranted.

Implications of the review for practice and research
Practice: The authors did not state any implications for practice.

Research: The authors stated that a large, double-blinded, placebo-controlled trial is needed investigating the impact of sterile water injection on caesarean section rates, use of regional analgesia, rates of spontaneous versus assisted deliveries and pain relief.

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Bibliographic details
Record Status
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.