Vibroacoustic stimulation for fetal assessment in labour in the presence of a nonreassuring fetal heart rate trace (Review)

East CE, Smyth RMD, Leader LR, Henshall NE, Colditz PB, Lau R, Tan KH

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[Intervention Review]

Vibroacoustic stimulation for fetal assessment in labour in the presence of a nonreassuring fetal heart rate trace

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Editorial group: Cochrane Pregnancy and Childbirth Group.
Publication status and date: New search for studies and content updated (no change to conclusions), published in Issue 1, 2013.
Review content assessed as up-to-date: 7 September 2012.

Citation: East CE, Smyth RMD, Leader LR, Henshall NE, Colditz PB, Lau R, Tan KH. Vibroacoustic stimulation for fetal assessment in labour in the presence of a nonreassuring fetal heart rate trace. *Cochrane Database of Systematic Reviews* 2013, Issue 1. Art. No.: CD004664. DOI: 10.1002/14651858.CD004664.pub3.

ABSTRACT

Background

Fetal vibroacoustic stimulation (VAS) is a simple, non-invasive technique where a device is placed on the maternal abdomen over the region of the fetal head and sound is emitted at a predetermined level for several seconds. It is hypothesised that the resultant startle reflex in the fetus and subsequent fetal heart rate (FHR) acceleration or transient tachycardia following VAS provide reassurance of fetal well-being. This technique has been proposed as a tool to assess fetal well-being in the presence of a nonreassuring cardiotocographic (CTG) trace during the first and second stages of labour.

Objectives

To evaluate the clinical effectiveness and safety of VAS in the assessment of fetal well-being during labour, compared with mock or no stimulation for women with a singleton pregnancy exhibiting a nonreassuring FHR pattern.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (6 September 2012) and reference lists of all retrieved articles. We sought unpublished trials and abstracts submitted to major international congresses and contacted expert informants.

Selection criteria

All published and unpublished randomised trials that compared maternal and fetal/neonatal/infant outcomes when VAS was used to evaluate fetal status in the presence of a nonreassuring CTG trace during labour, compared with mock or no stimulation.

Data collection and analysis

Two review authors independently sought to assess 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, to consult a third person. Where there was uncertainty about a particular study, we attempted to contact study authors for additional information. However, these attempts were unsuccessful.

Main results

The search strategies yielded six studies for consideration of inclusion. However, none of these studies fulfilled the requirements for inclusion in this review.

Authors' conclusions

There are currently no randomised controlled trials that address the safety and efficacy of VAS used to assess fetal well-being in labour in the presence of a nonreassuring CTG trace. Although VAS has been proposed as a simple, non-invasive tool for assessment of fetal well-being, there is insufficient evidence from randomised trials on which to base recommendations for use of VAS in the evaluation of fetal well-being in labour in the presence of a nonreassuring CTG trace.

PLAIN LANGUAGE SUMMARY

Vibroacoustic stimulation for fetal assessment in labour in the presence of a nonreassuring fetal heart rate trace

Vibratory and sound stimulation may help to tell how well a baby is during labour when the heart beat is showing possible concerns.

A baby's heart rate is checked during labour to try to identify babies who are having difficulties. However, changes in the baby's heart-rate patterns may not always mean the baby really is having difficulties. When the heart-rate pattern is not reassuring, extra tests may help to indicate which babies need help. Sound and vibratory stimulation (fetal vibroacoustic stimulation) is one such test. For healthy babies it produces a positive response, and absence of this could be a sign that the baby is having difficulty. The review authors found no randomised trials that considered vibroacoustic stimulation for this use. More research would be helpful.

BACKGROUND

Description of the condition

Approximately 18% of cardiotocograph (CTG) tracings during labour will be nonreassuring (East 2006) based on the heart rate, variability and deceleration patterns (NICE 2007; RANZCOG 2007). Other tests may be considered to evaluate fetal well-being and potentially reduce unnecessary operative interventions, including fetal scalp blood sampling for pH with acidosis defined as a pH less than 7.20 (Ingemarsson 1989), or lactate estimation with intervention indicated when values exceed 4.8 mmol/L (East 2010; Kruger 1999), the use of fetal pulse oximetry (nonreassuring values less than 30%, (East 2007; East 2008), fetal scalp stimulation (Rathore 2011), or electrocardiographic waveform analysis (Amer-Wahlin 2002; Neilson 2012). These tests are not without limitations, however. For example, fetal scalp blood sampling is an invasive procedure that requires dilation of the cervix, rupture of the membranes, and access to the fetal presenting part. An inadequate blood sample may be obtained due to inaccessibility of the presenting part or an inexperienced operator (Westgren 1998). A fetal oximetry sensor may only be applied following rupture of the amniotic membranes and at minimum 2 cm cervical dilatation (East 2008). A simple, non-invasive test that does not encounter these limitations would therefore be ideal. Vibroacoustic stimulation (VAS) may be one such test and has been proposed as a tool in the assessment of fetal well-being in the presence of a nonreassuring CTG during the first and second stages of labour (Lin 2001).

Description of the intervention

Fetal VAS is a non-invasive technique that is inexpensive and requires minimal operator expertise. A device such as an artificial larynx or a commercially available acoustic stimulator is placed on the maternal abdomen, over the region of the fetal head (Smith 1990). Sound is emitted at a predetermined level for several seconds.

How the intervention might work

The stimulus is expected to induce a startle reflex in the fetus, with subsequent fetal movement and fetal heart rate (FHR) acceleration (Spencer 1991). This may align with the neurological response of prominent pupillary dilatation following use of VAS (Cajal 2011).

There may be differing responses to VAS depending on the duration, intensity and the device used to produce the stimulus (Pietrantoni 1991; Polzin 1988); gestational age (Gagnon 1987; Hoh 2009); maternal administration of magnesium sulphate which is associated with decreased FHR variability and reactivity, resulting in a greater incidence of nonreactivity to VAS (Sherer 1994); or steroid use, which has also been found to induce a transient, but profound suppression of fetal limb movements, affecting fetal response to VAS (Rotmensch 1999).There is no standard protocol defining its optimal use. The VAS technique used varied widely from sound frequencies ranging from 20 to 9000 Hz, sound pressure levels from 82 to 120 dB, duration of stimulus from one to 10 seconds, and number of stimuli from one to seven (Richards 1990).

It is hypothesised that a FHR acceleration or transient tachycardia recorded following VAS provides reassurance of fetal well-being, obviating the need for further intervention (Perez-Delboy 2002).

Antenatal fetal vibroacoustic stimulation

A Cochrane systematic review of VAS during the antenatal period (Tan 2001) reported that VAS reduced the incidence of nonreassuring CTG and shortened testing time. Only one trial included a comparison of palpable fetal movement following VAS or a mock test and whether fetal movements following the test were accompanied by reactivity of the FHR (Marden 1997). They reported a significant increase in fetal movements following VAS and no difference in the number of non-reactive CTGs. The recording of fetal movement and use of mock testing may therefore be important considerations in future research. The review authors highlighted a number of areas where the randomised controlled trials did not evaluate important issues such as safety and perinatal outcome following VAS. They concluded that there was insufficient evidence from randomised controlled trials to recommend the routine antenatal use of VAS in the assessment of fetal well-being (Tan 2001).

Testing prenatal habituation to a vibroacoustic stimulus may play a role in evaluating the performance of the fetal central nervous system and therefore may be predictive of subsequent development after birth (Gonzalez-Gonzalez 2009; Leader 1984). This possibility is supported further in so far as deficits in central nervous system volume and function restrict the response to VAS in the anencephalic fetus (Park 2010). The use of VAS in conjunction with an abnormal biophysical profile or in high-risk pregnancies may provide reassurance of fetal well-being (Annunziata 2012; Papdopoulos 2007; Sood 2007).

Some researchers have raised safety concerns of the stress induced by VAS, such as passage of urine (Zimmer 1993), FHR deceleration (Ingemarsson 1989), or potential cochlear damage from increased intrauterine sound levels (Tan 2001). The risk of hearing impairment has been considered from a number of angles, including its implausibility given the decibel level changes in utero from the stimulus (Arulkumaran 1991; Arulkumaran 1992; Smith 1990); long-term follow-up of infants exposed to VAS antenatally, with no evidence of auditory nerve and brain stem evoked responses at two days of age (Ohel 1987); or of hearing impairment or neurological damage at 18 months and three years (Ratcliffe 2000) or four years of age (Nyman 1992). A further study examined 28 fetuses of hearing-impaired women, those who had previously had a baby with hearing impairment and three fetuses with congenital rubella. A negative response to VAS correctly predicted the three fetuses who were later identified as being hearing impaired, while those fetuses with a normal response to VAS had normal hearing when tested both after birth and at three years of age (Johansson 1992).

Intrapartum fetal vibroacoustic stimulation

Studies of VAS during labour, preceded by either no FHR monitoring or normal FHR patterns, have noted FHR accelerations following VAS, compared to either mock or no stimulus (Anyaegbunam 1994; Marden 1997). One study suggested that the combination of VAS and assessment of the amniotic fluid index during the latent phase of labour was a good predictor of the fetus's ability to withstand labour (Phelan 1989). Others have addressed some safety concerns. For example, Zimmer 1996 reported that, in women with single, term pregnancies, in early labour at cervical dilatation less than 4 cm, having intact membranes and a reassuring CTG, there was no difference in the rate of meconium-stained liquor when the membranes subsequently ruptured within an hour of either a real or mock stimulus. Murphy 1993 allocated women undergoing elective caesarean section to fetal VAS or no stimulus prior to uterine incision, and reported no difference in maternal venous, umbilical arterial or venous catecholamine or renin levels for the two groups.

A systematic review of observational studies where VAS was followed by fetal scalp pH estimation reported likelihood ratios and 95% confidence intervals (CI) for a positive test result, i.e. where no FHR acceleration following stimulus predicted the presence of fetal acidaemia, of 5.06 (CI 2.69 to 9.50) and a negative test result, i.e. where FHR acceleration predicted no acidaemia, of 0.32 (CI 0.19 to 0.55) (Skupski 2002a; Skupski 2002b). Having determined this degree of diagnostic accuracy, the authors suggested VAS was an appropriate test to evaluate fetal well-being in the presence of a nonreassuring CTG, with a recommendation that fetal scalp pH be estimated when the stimulus failed to elicit acceleration of the FHR (Skupski 2002a; Skupski 2002b). That systematic review was designed to examine the diagnostic accuracy of VAS, rather than to examine results from unpublished studies or randomised controlled trials for correlation between VAS and maternal/fetal outcomes, including mode of birth (including operative birth for fetal concerns), other forms of assessment of fetal well-being (including oxygen saturation or scalp pH/lactate val-

ues) or to evaluate the potential safety concerns. It therefore does not provide sufficient evidence on which to base practice.
Further studies not included in the Skupski 2002a and Skupski 2002b reviews have evaluated fetal scalp pH following VAS, with most reporting a scalp pH greater than 7.20 following a positive FHR response to VAS and scalp pH less than 7.20 when there had been a negative result following VAS (Edersheim 1987; Lin 2001; Polzin 1988; Smith 1986). There were some false negatives, where a positive result to VAS was followed by a pH greater than 7.20 (Ingemarsson 1989; Irion 1996; Lin 2001). The duration and intensity of the stimulus are likely to have contributed to these findings. Studies that did not observe false negative results used a three-second stimulus (Edersheim 1987; Smith 1986) whereas those with false negatives used a five-second stimulus (Ingemarsson 1989; Irion 1996). Different intensity of sound from different models of artificial larynx may also contribute to the occurrence of false negatives: Polzin 1988 and Lin 2001, who both reported false negatives, used different vibroacoustic stimulators to those used in the other studies cited. This possibility is supported by studies that examined the FHR response to scalp stimulation during fetal scalp blood sampling. Many fetuses exhibit an acceleration of their heart rate following such an intense stimulus, although the pH may be less than 7.20 (Ingemarsson 1989).

Why it is important to do this review

Fetal VAS is a simple, non-invasive technique that has the potential to provide reassurance of fetal well-being. Because of its simplicity and non-invasiveness, VAS has been proposed as a tool to assess fetal well-being in the presence of a nonreassuring CTG during the first and second stages of labour. Such an inexpensive test may be particularly useful in primary care when more sophisticated devices and/or interventions are not readily available (Hofmeyr 1997; Hofmeyr 1998). Since VAS is used and is perceived as convenient, quick, and effective, it is important that scientific research supports the use of VAS as a safe test of fetal well-being. This review will assess the clinical effectiveness and safety of VAS used to assess fetal well-being in labour in the presence of a nonreassuring CTG.

OBJECTIVES

To evaluate the effectiveness and safety of intrapartum fetal vibroacoustic stimulation (VAS) in the assessment of fetal well-being, compared with mock or no stimulation for women with a singleton pregnancy exhibiting a nonreassuring cardiotocographic (CTG) trace, considering the following hypotheses.

(i) Compared with mock or no stimulation, VAS may reduce the number of tests performed to confirm the presence or absence of fetal acidaemia.

(ii) Compared with mock or no stimulation, VAS may reduce the number of tests performed to evaluate fetal well-being without increasing the rate of fetal or neonatal acidaemia.

(iii) Compared with mock or no stimulation, VAS may reduce the number of operative deliveries (caesarean section, vacuum, forceps) performed for the indication of nonreassuring status.

(iv) Compared with mock or no stimulation, VAS may reduce the number of operative deliveries (caesarean section, vacuum, forceps) performed for the indication of nonreassuring status without increasing the rate of fetal or neonatal acidaemia.

(v) Compared with mock or no stimulation, VAS may reduce the overall number of operative deliveries (caesarean section, vacuum, forceps).

A secondary objective of the review is to determine whether the effectiveness and safety of intrapartum vibroacoustic stimulation is influenced by the following:

(i) stage of labour;

(ii) gestation: 26 to 31 weeks six days, or 32 to 36 weeks six days, or at least 37 weeks;

(iii) duration of stimulus: less than five seconds or at least five seconds;

(iv) maternal administration of magnesium sulphate or steroids.

METHODS

Criteria for considering studies for this review

Types of studies

All published and unpublished individually- or cluster-randomised trials that compared maternal and fetal/neonatal/infant outcomes when VAS was used to evaluate fetal status in the presence of a nonreassuring CTG, compared with mock or no stimulation. Mock stimulation is achieved by placing the vibroacoustic device against the maternal abdomen in the same manner as for a stimulus, but without activating the stimulus. It is important to distinguish mock from no stimulation to facilitate 'blinding' of the women to treatment allocation, which may in turn influence their report of fetal movement. Cross-over study designs are unlikely to be relevant for this intervention and were therefore unlikely to be identified. We planned not to include results only available in published abstracts.

Types of participants

Women with a live singleton pregnancy exhibiting a nonreassuring CTG trace in labour.

Types of interventions

Fetal VAS versus mock or no stimulation.

Types of outcome measures

Primary outcomes

1. Caesarean section
2. Operative vaginal birth (forceps or vacuum)
3. Neonatal hypoxic ischaemic encephalopathy
4. Neonatal seizures
5. Long-term infant disability

Secondary outcomes

Fetal/neonatal/infant outcomes

1. Fetal heart rate acceleration (increase of 15 beats per minute from baseline, sustained for minimum 15 seconds) within 60 seconds of the VAS (or mock stimulus)
2. Fetal heart rate deceleration (early, late, variable) within 60 seconds of the VAS (or mock stimulus)
3. Number of fetuses having additional tests performed to confirm presence or absence of acidaemia (fetal scalp sampling (e.g. pH, lactate), fetal oxygen saturation monitoring, fetal electrocardiogram waveform analysis)
4. Number of additional tests performed per fetus to confirm presence or absence of acidaemia (fetal scalp sampling (e.g. pH, lactate), fetal oxygen saturation monitoring, fetal electrocardiogram waveform analysis)
5. Fetal scalp pH less than 7.20
6. Fetal scalp lactate more than 4.8 mmol/L
7. Fetal oxygen saturation values less than 30%
8. Fetal movement the mother perceives
9. Apgar scores less than seven at five minutes
10. Umbilical arterial pH less than 7.10
11. Umbilical arterial base excess less than -12
12. Admission to neonatal intensive care unit
13. Meconium liquor
14. Length of hospital stay
15. Hearing impairment
16. Death
17. Death or hypoxic ischaemic encephalopathy
18. Death or neonatal seizures
19. Death or long-term infant disability

Maternal outcomes

1. Mode of birth: spontaneous vaginal, caesarean section, forceps, vacuum extraction
2. Caesarean section for nonreassuring fetal status
3. Operative vaginal birth (forceps or vacuum) for nonreassuring fetal status
4. Maternal satisfaction with fetal monitoring in labour
5. Maternal anxiety
6. Length of hospital stay

Search methods for identification of studies

Electronic searches

We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (6 September 2012).

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

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

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

Trials identified through the searching activities described above are each assigned to a review topic (or topics). The Trials Search Co-ordinator searches the register for each review using the topic list rather than keywords. Other searches performed by the review team for the previous version of the review are described in Appendix 1.

We did not apply any language restrictions.

Searching other resources

We also performed a manual search of the references of all retrieved articles. We sought unpublished trials and abstracts submitted to major international congresses and contacted expert informants.

We did not apply any language restrictions.

Data collection and analysis

For methods used in the previous published version, see Appendix 1.

Selection of studies

Two review authors (C East (CE) and N Henshall (NH)) 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.

Data extraction and management

We designed a form to extract data. For potentially eligible studies, two review authors (CE and NH) planned to extract the data using the agreed form. We planned to resolve any discrepancies through discussion with a third review author (LR Leader). There were no differences of opinion requiring resolution. We planned to enter data into Review Manager software (RevMan 2011) and check for accuracy.

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

Assessment of risk of bias in included studies

Two review authors (CE, NH) planned to independently assess the risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We planned to resolve any disagreement by discussion.

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

We planned to describe 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 planned to assess 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 planned to describe for each included study the method used to conceal the allocation sequence and determine whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

We planned to 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 planned to describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We would have 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 planned to assess blinding separately for different outcomes or classes of outcomes.

We planned to assess 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 planned to describe for each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received. We planned to assess blinding separately for different outcomes or classes of outcomes.

We planned to assess 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 planned to describe for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We would have stated whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information was reported, or could be supplied by the trial authors, we planned to re-include missing data in the analyses which we undertook. We planned to assess 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.

(5) Selective reporting bias

We planned to describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found.

We planned to assess 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 sources of bias

We planned to describe for each included study any important concerns we have about other possible sources of bias.

We planned to assess 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 planned to make 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 2011). With reference to (1) to (6) above, we planned to assess the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We planned to explore the impact of the level of bias through undertaking sensitivity analyses - *see* Sensitivity analysis.

Measures of treatment effect

Dichotomous data

For dichotomous data, we planned to present results as summary risk ratio with 95% confidence intervals.

Continuous data

If we identify studies in the future that report continuous data, we will use the mean difference if outcomes are measured in the same way between trials. We will use the standardised mean difference to combine trials that measure the same outcome, but use different methods.

Unit of analysis issues

Cluster-randomised trials

If we had identified cluster-randomised trials, we planned to include them in the analyses along with individually-randomised trials. If such trials are identified in the future, we will adjust their sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions* 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.

Cross-over trials

As a cross-over trial design would be inappropriate in this clinical setting, we planned to exclude such trials.

Dealing with missing data

For included studies, we planned to note 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 planned to carry out analyses, as far as possible, on an intention-to-treat basis, i.e. we would have attempted to include all participants randomised to each group in the analyses, and analysed all participants in the group to which they were allocated, regardless of whether or not they received the allocated intervention. The denominator for each outcome in each trial would have been the number randomised minus any participants whose outcomes were known to be missing.

Assessment of heterogeneity

We planned to assess statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We would have regarded heterogeneity as substantial if the I^2 was greater than 30% and either the T^2 was greater than zero, or there was a low P value (less than 0.10) in the Chi^2 test for heterogeneity.

Assessment of reporting biases

If we had included 10 or more studies in the meta-analysis, we planned to investigate reporting biases (such as publication bias) using funnel plots. If we identify additional trials in the future, we will assess funnel plot asymmetry visually, and use formal tests for funnel plot asymmetry. For continuous outcomes, we will use the test proposed by Egger 1997, and for dichotomous outcomes, we will use the test proposed by Harbord 2006. If we detect asymmetry in either of these tests or by a visual assessment, we will perform exploratory analyses to investigate it.

Data synthesis

We planned to carry out statistical analysis using the Review Manager software (RevMan 2011). We planned to use 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 were examining the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differed between trials, or if substantial statistical heterogeneity was detected, we planned to use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. We would have treated the random-effects summary as the average range of possible treatment effects and we would have discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful, we would not have combined trials.
If in future updates we use random-effects analyses, we will present the results as the average treatment effect with its 95% confidence interval, and the estimates of T^2 and I^2.

Subgroup analysis and investigation of heterogeneity

If we had identified substantial heterogeneity, we planned to investigate it using subgroup analyses and sensitivity analyses. We would have considered whether an overall summary was meaningful, and if it was, used random-effects analysis to produce it.
We planned to carry out the following subgroup analyses.

1. Stage of labour
2. Gestation: 26 to 31 weeks six days, 32 to 36 weeks six days, at least 37 weeks
3. Duration of stimulus: less than five seconds or at least five seconds
4. Maternal administration of magnesium sulphate or steroids

We planned to assess subgroup differences by interaction tests available within RevMan (RevMan 2011). In future updates, if we identify trials, we will report the results of subgroup analyses quoting the $\chi 2$ statistic and P value, and the interaction test I^2 value.

Sensitivity analysis

We planned to carry out sensitivity analysis of the primary outcomes to explore the effect of trial quality, including studies assessed as having adequate controls in place for the prevention of potential bias.

RESULTS

Description of studies

See: Characteristics of excluded studies.

Results of the search

The search strategies yielded six studies for consideration of inclusion. However, none of these studies met the basic inclusion criteria of nonreassuring fetal heart rate (FHR) traces recorded during labour.

Included studies

No studies were included.

Excluded studies

Three studies (Anyaegbunam 1994; Marden 1997; Zimmer 1996) addressed a number of the other outcomes of interest, but not for pre-recorded nonreassuring fetal status. The study by Marden 1997 appeared to include a mix of labouring and non-labouring women presenting to the labour ward, who had the CTG trace applied *following* the stimulus: the trial had been assumed to relate to non-labour vibroacoustic stimulation (VAS) when considered for the systematic review of antenatal VAS by Tan 2001, and we were unsuccessful in our attempts to contact the authors for clarification of this issue.
For more details on reasons for exclusion, *see* Characteristics of excluded studies.

Risk of bias in included studies

No studies met the eligibility criteria for inclusion in this review.

Effects of interventions

No studies met the eligibility criteria for inclusion in this review.

DISCUSSION

Summary of main results

The search strategy yielded six studies for consideration in the review. None of these studies met the inclusion criteria.

The need for simple, non-invasive evaluation of fetal well-being once a nonreassuring cardiotocographic trace (CTG) has been recorded in labour is important in attempts to reserve intervention, such as operative birth, for those fetuses truly warranting it. Current methods, including fetal scalp blood sampling, fetal electrocardiograph and fetal pulse oximetry, while offering additional and important information, are invasive, cumbersome, sometimes of uncertain benefit and not always available or widely utilised (Amer-Wahlin 2002; East 2008; East 2010; Ingemarsson 1989; Westgren 1998). The diagnostic accuracy of vibroacoustic stimulation (VAS) in labour has previously been evaluated (Edersheim 1987; Ingemarsson 1989; Irion 1996; Lin 2001; Polzin 1988; Skupski 2002a; Skupski 2002b). Following from this evaluation, randomised controlled trials could address its safety and efficacy in the assessment of fetal well-being when the fetus has demonstrated a nonreassuring heart-rate pattern during labour.

AUTHORS' CONCLUSIONS

Implications for practice

There are currently no randomised controlled trials that address the safety and efficacy of fetal vibroacoustic stimulation (VAS) following demonstration of a nonreassuring cardiotocograph (CTG) during labour. Although VAS is a simple, non-invasive test of fetal well-being, there is insufficient evidence from randomised trials to show whether VAS is effective in the evaluation of fetal well-being during labour.

Implications for research

Well conducted randomised controlled trials addressing the safety and effectiveness of VAS during labour are required before intrapartum VAS can be considered to have been adequately evaluated. Outcomes of interest could include those listed in this review. The primary outcome may be long-term neurodevelopmental disability: however, at least in the term fetus population, it is an adverse outcome of such low prevalence that any change would be difficult to power without a prohibitively large sample size. An outcome of clinical relevance may be as simple as the number of additional tests performed to assess fetal well-being following identification of a nonreassuring CTG, through to operative delivery rates.

ACKNOWLEDGEMENTS

Our thanks are extended to Philippa Middleton for her valuable assistance in preparing this review.

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

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Anyaegbunam 1994	Women at least 37 weeks' gestation with cephalic presentation of a singleton fetus, no heavy meconium, full cervical dilatation and a reassuring CTG were entered into a prospective randomised observational trial. The study group (n = 316) had an artificial larynx activated for 5 seconds above the maternal symphysis. Controls (n = 316) did not have the instrument activated. An investigator blinded to group allocation assessed the fetal heart rate tracing in the 5 minutes following the stimulus for (i) acceleration, (ii) acceleration followed by deceleration and (iii) no response. There were no differences in umbilical arterial pH or Apgar score at 5 minutes. There were more fetal heart rate accelerations and accelerations followed by decelerations in the study group than the control group (77.2% versus 12.5%, P < 0.05). Within the 3 groups of fetal heart rate response following the stimulus in the study group, there were no significant differences in fetal growth restriction, umbilical arterial pH or Apgar score less than 7 at 5 minutes. There were more cases of nuchal cord in the subgroup of cases with fetal heart rate acceleration followed by deceleration, than in the other 2 fetal heart rate response groups This study was excluded as women were only randomised if they had a reassuring fetal heart rate pattern and it was not an intervention study
Marden 1997	Women admitted to the labour ward with a singleton pregnancy, at 31 weeks' gestation or greater and with intact membranes were randomly assigned acoustic or sham stimulation, FOLLOWED by a CTG. There was no reference to CTG prior to study entry A subgroup analysis of women having less than 3 contractions per 10 minutes was conducted, implying that not all women were in established labour. By inference, however, some outcomes could be determined for those in established labour, including: 102 of 112 in the test group with a fetal heart rate acceleration following the stimulus, compared to 96 of 104 in the sham group; nil with a fetal heart rate deceleration following either the stimulus or sham test; and 2 of 112 women reporting fetal movement following the stimulus, compared to 3 of 104 following the sham test Attempts to contact the authors were unsuccessful.
Murphy 1993	Women undergoing elective caesarean section were randomly assigned to VAS (n = 25) or no stimulus (n = 23) prior to uterine incision. There was no statistical difference between maternal venous, umbilical arterial or umbilical venous catecholamine or renin levels for the 2 groups The study was excluded as it did not relate to nonreassuring CTG in labour
Phelan 1989	Women in the latent phase of labour (n = 400) were screened in 4 groups for subsequent development of fetal compromise using (i) control, (ii) FAS, (iii) AFI, or (iv) FAS and AFI. Entry criteria did not include a nonreassuring fetal heart rate tracing. The combined use of FAS and AFI gave the highest sensitivity and highest negative predictive value of subsequent fetal compromise in labour. Data were only available in conference abstract form and were inadequate for analysis. MEDLINE searches based on subject and each author failed to reveal a published report of a randomised controlled trial
Richards 1988	Low-risk labouring women (n = 40) were assigned by odd or even hospital number to either a 5 second VAS or sham stimulus. The fetal heart rate response was interpreted later by an investigator blinded to group allocation. There was no difference in 'abnormal baseline [fetal heart rate] pattern' in the hour preceding and following the stimulus for the 2 groups, or of 'distress at birth' (caesarean for distress, Apgar scores at 1 and 5 minutes, or umbilical arterial pH < 7.20). Insufficient data were provided to allow analysis of these findings.

(*Continued*)

	We were unable to contact the authors
Zimmer 1996	Women at term (n = 202) with a single pregnancy in vertex presentation, in early labour at cervical dilatation < 4 cm, with intact membranes and a reactive fetal heart rate tracing were assigned, according to their identification numbers, to receive a 3 second fetal stimulus from an electrolarynx or sham stimulus. If the membranes had not spontaneously ruptured within an hour of the stimulus, they were artificially ruptured and the amniotic fluid checked for the presence or absence of meconium. Twenty-four of the 101 stimulated and 24 of the 101 sham tested had meconium present in the liquor The trial was excluded from this analysis as the fetal heart rate tracing was reassuring at study entry

AFI: amniotic fluid index
CTG: cardiotocographic trace
FAS: fetal acoustic stimulation
VAS: vibroacoustic stimulation

DATA AND ANALYSES

This review has no analyses.

APPENDICES

Appendix 1. Methods from previously published version

Methods

Criteria for considering studies for this review

Types of studies

All published and unpublished randomised trials that compare maternal and fetal/neonatal/infant outcomes when vibroacoustic stimulation is used to evaluate fetal status in the presence of a non-reassuring cardiotocographic, compared with mock or no stimulation. Mock stimulation would be achieved by placing the vibroacoustic device against the maternal abdomen in the same manner as for a stimulus, but without activating the stimulus. It is important to distinguish mock from no stimulation to facilitate 'blinding' of the women to treatment allocation, which may in turn influence their report of fetal movement.

Types of participants

Women with a live singleton pregnancy exhibiting a non-reassuring cardiotocographic trace in labour.

Types of interventions

Fetal vibroacoustic stimulation versus mock or no stimulation.

Types of outcome measures

Primary outcomes

(1) caesarean section;
(2) operative vaginal birth (forceps or vacuum);
(3) neonatal hypoxic ischaemic encephalopathy;
(4) neonatal seizures;
(5) long-term infant disability.

Secondary outcomes

Fetal/neonatal/infant outcomes

(6) fetal heart rate acceleration (increase of 15 beats per minute from baseline, sustained for minimum 15 seconds) within 60 seconds of the vibroacoustic stimulation (VAS) (or mock stimulus);
(7) fetal heart rate deceleration (early, late, variable) within 60 seconds of the VAS (or mock stimulus);

(8) number of fetuses having additional tests performed to confirm presence or absence of acidaemia (fetal scalp sampling (e.g. pH, lactate), fetal oxygen saturation monitoring, fetal electrocardiogram waveform analysis);
(9) number of additional tests performed per fetus to confirm presence or absence of acidaemia (fetal scalp sampling (e.g. pH, lactate), fetal oxygen saturation monitoring, fetal electrocardiogram waveform analysis)
(10) fetal scalp pH less than 7.20;
(11) fetal scalp lactate more than 4.8 mmol/l;
(12) fetal oxygen saturation values less than 30%;
(13) fetal movement the mother perceives;
(14) Apgar scores less than seven at five minutes;
(15) umbilical arterial pH less than 7.10;
(16) umbilical arterial base excess less than -12;
(17) admission to neonatal intensive care unit;
(18) meconium liquor;
(19) length of hospital stay;
(20) hearing impairment;
(21) death;
(22) death or hypoxic ischaemic encephalopathy;
(23) death or neonatal seizures;
(24) death or long-term infant disability.

Maternal outcomes

(25) mode of birth: spontaneous vaginal, caesarean section, forceps, vacuum extraction;
(26) caesarean section for non-reassuring fetal status;
(27) operative vaginal birth (forceps or vacuum) for non-reassuring fetal status;
(28) maternal satisfaction with fetal monitoring in labour;
(29) maternal anxiety;
(30) length of hospital stay.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Pregnancy and Childbirth Group Trials Register by contacting the Trials Search Co-ordinator (30 September 2004).
The Cochrane Pregnancy and Childbirth Group's Trials Register is maintained by the Trials Search Co-coordinator and contains trials identified from:

1. quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
2. monthly searches of MEDLINE;
3. handsearches of 30 journals and the proceedings of major conferences;
4. weekly current awareness search of a further 37 journals.

Details of the search strategies for CENTRAL and MEDLINE (1966 to present), the list of hand searched journals and conference proceedings, and the list of journals reviewed via the current awareness service can be found in the 'Search strategies for identification of studies' section within the editorial information about the Cochrane Pregnancy and Childbirth Group
We also searched the Cochrane Central Register of Controlled Trials (*The Cochrane Library*, Issue 1, 2004), MEDLINE (January 1966 to May 2004), and EMBASE (January 1966 to May 2004) using the following:
(randomised controlled trial* OR randomized controlled trial* OR controlled clinical trial OR clinical trial OR single blind OR double blind OR placebo* OR random* OR comparative study OR prospective stud*) AND (vibroacoustic OR stimul* OR acoustic) AND (fetal OR fetus OR foetal OR foetus) AND (labour OR labor OR intrapartum).

Searching other resources

We also performed a manual search of the references of all retrieved articles. We sought unpublished trials and abstracts submitted to major international congresses and contacted expert informants.
We did not apply any language restrictions.

Data collection and analysis

We used the standard methods of The Cochrane Collaboration as described in the Cochrane Reviewers' Handbook (Alderson 2004). Two review authors (CE East and N Henshall) assessed the trials under consideration for appropriateness of inclusion and methodological quality. Any differences of opinion would have been resolved by discussion with a third review author (LR Leader): there were no differences of opinion requiring resolution. We did not undertake blinding of trial authorship and results.

Assessment of trial quality

Four major sources of potential bias and methods or avoidance of these biases were to be considered when assessing trial quality: (1) selection bias - allocation concealment; (2) performance bias - blinding of intervention; (3) attrition bias - completeness of follow up; (4) detection bias - blinding of outcome assessment. The quality assessment was based on a systematic assessment of the opportunity for each of these biases to arise.
A quality rating for allocation concealment was to be assigned to each trial, using the criteria outlined in the Cochrane Reviewers' Handbook (Alderson 2004): (A) adequate; (B) unclear; (C) inadequate; or (D) not used. We planned to assign a quality rating of (A) yes; (B) cannot tell; or (C) no, to the other quality components (blinding of intervention, completeness of follow up and blinding of outcome assessment).
Trials from the review with a 'B', 'C' or 'D' rating for allocation concealment would have been excluded. We made an *a priori* decision to also exclude trials where outcome data were unavailable for more than 20% of participants.

Data management and analysis

We developed data extraction forms that included information regarding study location, methods, participant characteristics at baseline, details of the intervention and control group management and outcome. Two independent review authors would have extracted the data and disagreements would have been resolved by discussion. We would have sought missing data from investigators of individual trials as necessary in order to perform analyses on an intention-to-treat basis. We planned to undertake double data entry.
We planned to report mean differences (and 95% confidence intervals) for continuous variables. For categorical outcomes, we intended to report the relative risk and risk difference (and 95% confidence intervals). For the meta-analysis, where possible, we planned to report weighted mean differences (and 95% confidence intervals) for continuous variables, and the relative risk and risk difference (and 95% confidence intervals) for categorical outcomes. We intended to calculate the number needed to treat where appropriate.
We did not assess heterogeneity since there were no studies to include in the meta-analysis.
We planned to undertake a priori subgroup analyses, as data permitted, as follows:
(i) stage of labour;
(ii) gestation: 26 to 31 weeks six days, 32 to 36 weeks six days, at least 37 weeks;
(iii) duration of stimulus: less than five seconds or at least five seconds;
(iv) maternal administration of magnesium sulphate or steroids.

WHAT'S NEW

Last assessed as up-to-date: 7 September 2012.

Date	Event	Description
7 September 2012	New search has been performed	Review updated with searches, converted to 2012 review format and updated literature review. Additional author added
7 September 2012	New citation required but conclusions have not changed	Studies assessed and excluded. No studies fulfil the requirements for inclusion in this review

HISTORY

Protocol first published: Issue 1, 2004

Review first published: Issue 2, 2005

Date	Event	Description
10 November 2008	Amended	Contact details updated.
18 February 2008	Amended	Converted to new review format.
31 January 2005	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

Christine East compiled the review with considerable input from Naomi Henshall, Rebecca Smyth and Leo Leader. Rosalind Lau contributed to the updated literature review in the 2012 update. Christine East, Naomi Henshall, Leo Leader and Rebecca Smyth examined trials for suitability of inclusion/exclusion. All review authors had input into the original protocol and read/advised on/approved the final draft of the review.

DECLARATIONS OF INTEREST

None known.

SOURCES OF SUPPORT

Internal sources

• Perinatal Research Centre, The University of Queensland, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia.

External sources

• Cochrane Perinatal Team, Brisbane, Centre for Clinical Studies - Women's and Children's Health, Mater Hospital, South Brisbane, Queensland, Australia.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Two aspects from the original protocol were adjusted for the 2012 review update.

1. Rosalind Lau assisted in updating the background and discussion and was added to the authorship.

2. We removed the duplication of searches of the Cochrane Central Register of Controlled Trials (CENTRAL), MEDLINE and EMBASE conducted by both the authors and the Trials Search Co-ordinator of the Cochrane Pregnancy and Childbirth Group's Trials Register.

INDEX TERMS

Medical Subject Headings (MeSH)

Acoustic Stimulation [*methods]; Fetal Monitoring [*methods]; Heart Rate, Fetal [physiology]; Reflex, Startle [physiology]

MeSH check words

Humans