Fetal pulse oximetry for fetal assessment in labour (Review)

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[Intervention Review]

Fetal pulse oximetry for fetal assessment in labour

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ABSTRACT

Background

Pulse oximetry could contribute to the evaluation of fetal well-being during labour.

Objectives

To compare the effectiveness and safety of fetal pulse oximetry with conventional surveillance techniques.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (May 2010), MEDLINE (1994 to May 2010), EMBASE (1994 to May 2010), Current Contents (1994 to May 2010) and contacted experts in the field.

Selection criteria

All published and unpublished randomised controlled trials that compared maternal and fetal outcomes when fetal pulse oximetry was used in labour, with or without concurrent use of conventional fetal surveillance, compared with using cardiotocography (CTG) alone.

Data collection and analysis

At least two independent authors performed data extraction. We performed analyses on an intention-to-treat basis. We sought additional information from the investigators of three of the reported trials.

Main results

We included six published trials comparing fetal pulse oximetry and CTG with CTG alone (or when fetal pulse oximetry values were blinded). The published trials, with some unpublished data, reported on a total of 7654 pregnancies. Differing entry criteria necessitated separate analyses, rather than meta-analysis of all trials.

Systematic review of four trials from 34 weeks not requiring fetal blood sampling prior to study entry showed no significant differences in the overall caesarean section rate between those monitored with fetal oximetry and those not monitored with fetal pulse oximetry or for whom the fetal pulse oximetry results were masked (risk ratio (RR) 0.99, 95% confidence intervals (CI) 0.86 to 1.13, n = 4008). Neonatal seizures and neonatal encephalopathy were rare. No studies reported details of assessment of long-term disability.

There was a statistically significant decrease in caesarean section for nonreassuring fetal status in the fetal pulse oximetry plus CTG group compared to the CTG group, gestation from 34 weeks (RR 0.65, 95% CI 0.46 to 0.90). There was no statistically significant difference in caesarean section for dystocia when fetal pulse oximetry was added to CTG monitoring, compared with CTG monitoring alone, although the incidence rates varied between the trials.

Authors' conclusions

The data provide limited support for the use of fetal pulse oximetry when used in the presence of a nonreassuring CTG, to reduce caesarean section for nonreassuring fetal status. The addition of fetal pulse oximetry does not reduce overall caesarean section rates. A better method to evaluate fetal well-being in labour is required.

PLAIN LANGUAGE SUMMARY

Fetal pulse oximetry for fetal assessment in labour

Using fetal pulse oximetry to assess the baby's well-being during labour does not change overall caesarean section rates.

During labour, the well-being of the baby can be assessed intermittently using a Pinard stethoscope or hand held monitor, or continuously using cardiotocography (CTG, sometimes called electronic fetal monitoring, EFM) or assessing the baby's condition with an electrocardiogram (ECG). There are also additional tests that can be used if the baby is thought to be getting short of oxygen, like testing the baby's blood in a sample taken from the baby's head or bottom. A new method, fetal pulse oximetry, measures how much oxygen the baby's blood is carrying. It uses a probe that sits inside the vagina during labour. The probe is said not to inhibit the woman's mobility during labour. This review looked at fetal pulse oximetry and only found trials that used it in conjunction with a CTG and compared the combined use with CTG alone. The review identified six trials involving 7654 women. Fetal pulse oximetry plus CTG showed no difference in caesarean section rates overall, nor any difference in the mother's or newborn's health, compared with CTG alone. If there was concern about the baby's well-being before the fetal pulse oximetry probe was placed, the use of fetal pulse oximetry reduced caesarean sections performed for the baby's well-being. In one of the trials, the company making the fetal pulse oximetry machines provided some funding. Further trials may be helpful.

BACKGROUND

Cardiotocography (CTG) was introduced in the 1960s with the aim of improving neonatal outcomes by improving intrapartum fetal surveillance. Fetal heart rate patterns may be classified as reassuring, nonreassuring or abnormal, based on the rate, variability and decelerations, and to some extent comparing these to the timing of uterine contractions. There are several published guidelines for the interpretation of these patterns (for example, RANZCOG 2002; RCOG 2001). Reassuring patterns require no specific action. Nonreassuring patterns occur in about 15% of labours monitored by CTG (Umstad 1993) and may prompt clinical actions ranging from simple manoeuvres, such as a change of maternal position, through to expedited birth of the baby (vacuum, forceps, caesarean section). Abnormal patterns usually prompt expedited birth with the aim of preventing or minimising hypoxia in the fetus. The positive predictive value of CTG for adverse outcome is low and the negative predictive value high (Umstad 1993), although this is improving with computerised interpretation of CTGs (Strachan 2001). Thus, while a normal CTG usually indicates reassuring fetal status, a nonreassuring or abnormal CTG does not necessarily equate with 'fetal distress'. These features, combined with marked inter-observer variation in CTG interpretation by midwives (Devane 2005) and doctors (Palomaki 2006), result in variable but inappropriately high operative delivery rates for nonreassuring fetal status in many hospitals. Electronic fetal monitoring rapidly gained widespread acceptance for monitoring the fetal heart rate during labour, but it was not until the 1970s that randomised controlled trials were conducted to assess the benefits of this technology. A Cochrane systematic review found that the use of electronic monitoring increased the odds of having a caesarean section, compared to intermittent auscultation of the fetal heart (Alfirevic 2006). Despite these shortcomings, cardiotocography remains a widely used means of assessing fetal well-being during labour. One conclusion of the systematic review of CTG monitoring was to consider how to best convey the uncertainty of the benefits of such monitoring to enable women to

make an informed choice, while not compromising labour normality (Alfirevic 2006). The Royal College of Obstetricians and Gynaecologists (RCOG 2001) suggested that, as for all aspects of care, the woman herself should be involved in decision-making for choice of fetal monitoring, with adequate access to evidence-based information; and recommended that electronic monitoring be offered where there is an increased risk of perinatal death, neonatal encephalopathy or cerebral palsy, and during labours induced or augmented by oxytocin.

Once a nonreassuring fetal heart rate pattern has been identified, a number of additional assessments of fetal well-being may be considered. These do not replace the CTG, but are usually used as complementary to it, either intermittently or continuously. One example is fetal scalp blood sampling for pH or lactate analysis. A low pH (for example, less than 7.20) or a high lactate (for example greater than 4.8 mmol/L) may be considered abnormal (Kruger 1999). The addition of fetal scalp blood sampling to standard electronic monitoring reduces the odds for caesarean section, although the odds are not significantly different compared to intermittent auscultation of the fetal heart (Alfirevic 2006). A Cochrane systematic review of the addition of fetal electrocardiogram monitoring reported no difference in overall caesarean section rate when compared to electronic monitoring only (Neilson 2006).

Fetal pulse oximetry is a new technology aimed at improving the accuracy of the evaluation of fetal well-being during labour (Colditz 1999; East 2007). It is generally reserved for use when a nonreassuring CTG has been recorded, to assist in identifying those fetuses that may benefit from further intervention (East 2002; East 2008) and as an adjunct to, rather than replacement of, the CTG monitor. This method has two potential advantages over conventional fetal heart rate monitoring: (i) it directly measures the proportion of haemoglobin that is carrying oxygen: thus, oxygenation, the primary variable underlying the tissue damaging effects of hypoxia/ischaemia is being monitored; and (ii) it relies on an established, safe, noninvasive, widely-used technology found in every modern intensive care unit and operating theatre. A variety of fetal pulse oximetry sensors has been studied. These are placed during a vaginal examination to attach to the top of the fetal head by suction (Arikan 2000) or clip (Knitza 2004), lie against the fetal temple or cheek (Mallinckrodt 2000; Nellcor 2004), or to lie along the fetal back (OB Scientific 2002). The sensor remains in situ and fetal pulse oximetry values are recorded for approximately 81% of the monitoring time (East 1997). Results of animal and human research suggest that when using sensors calibrated for the fetal environment, fetal oximetry values greater than or equal to 30% are considered reassuring, even when the CTG is nonreassuring, while values less than 30% warrant consideration of interventions, ranging from maternal position change, through to urgent birth via caesarean section (Kuhnert 1998; Nijland 1995; Seelbach-Gobel 1999). One manufacturer recommends this technology for singleton pregnancies only (Nellcor 2004). Consideration for monitoring multiple pregnancies by monitoring the first fetus during labour, then the second or subsequent fetuses following birth of the preceding fetus may be possible. Women have rated their experience with fetal oximetry during observational studies. One survey included questions about the woman's perceived level of comfort during sensor placement, mobility with the sensor in place and ongoing comfort with the sensor in place: these factors were all rated favourably by the women (East 1996). Arikan 1998 reported that the majority of women did not consider that a fetal oximetry sensor restricted their movement during labour.

The value of any fetal monitoring system during labour, including the CTG or any additional surveillance, is usually expressed by its ability to predict which fetuses are hypoxic or acidotic. Measures of this may include umbilical cord blood gases (including base excess values less than or equal to 12 mmol/L and pH values less than 7.00 (Sehdev 1997), or less than 7.10 (Arikan 2000) or lactate values; or clinical outcomes including Apgar scores (an assessment of neonatal condition shortly after birth, usually at one and five minutes: Apgar scores of less than seven at five minutes or later are nonspecific but may be associated with hypoxia (MacLennan 1999; Sehdev 1997)); or abnormal neurological status of the baby, possibly caused by lack of oxygen or blood supply (hypoxic-ischaemic encephalopathy), or both. Other outcomes of interest may include fetal/maternal infections, for example of the membranes (chorioamnionitis), or the uterine lining (endometritis). Interventions resulting from such tests are also important. For example, it is important to note not only overall modes of birth following different forms of monitoring, but also specific interventions, such as operative birth (vacuum, forceps and caesarean section) for the indication of nonreassuring fetal status, since nonreassuring fetal status is what the monitoring is intended to discern. In the longer term, such interventions may also impact on future pregnancies. For example, the likelihood of a successful vaginal birth after caesarean (VBAC) in a subsequent pregnancy is improved for women whose previous caesarean was performed for the indication of nonreassuring fetal status, compared with those where the previous caesarean was performed for dystocia (Grinstead 2004; Shipp 2000). Successful VBAC in a subsequent pregnancy will also have economic benefits, with vaginal births costing the health system considerably less than caesarean sections (Henderson 2001; Petrou 2002).

This review was undertaken to evaluate the clinical effectiveness and safety of fetal pulse oximetry to assess fetal well-being in labour.

OBJECTIVES

To compare the effectiveness and safety of fetal intrapartum pulse oximetry with conventional fetal surveillance techniques, using the results of randomised controlled trials.

METHODS

Criteria for considering studies for this review

Types of studies

All published and unpublished randomised and quasi-randomised trials with reported data that compared maternal and fetal/neonatal/infant outcomes when fetal pulse oximetry was used in labour, with or without concurrent use of conventional fetal surveillance, compared with the use of conventional fetal surveillance techniques alone.

Types of participants

Women in labour with a live baby where fetal monitoring is clinically indicated.

Types of interventions

Use of fetal pulse oximetry compared with not using fetal pulse oximetry, with or without concurrent use of conventional fetal monitoring (fetal heart rate monitoring by intermittent auscultation, intermittent/continuous cardiotocography, or fetal blood sampling for blood gas analysis).

Types of outcome measures

Primary outcomes

(1) Caesarean section
(2) Hypoxic-ischaemic encephalopathy
(3) Neonatal seizures
(4) Long-term neurodevelopmental outcome

Secondary outcomes

Maternal

(5) Caesarean section for nonreassuring fetal status
(6) Caesarean section for dystocia (added since the protocol and original review were first published)
(7) Overall operative delivery (caesarean section, forceps, vacuum extraction) for all indications
(8) Overall operative delivery (caesarean section, forceps, vacuum extraction) for nonreassuring fetal status
(9) Use of intrapartum antibiotics
(10) Overall antibiotic use
(11) Intrapartum haemorrhage
(12) Postpartum haemorrhage
(13) Chorioamnionitis
(14) Endometritis (added since the protocol was first published)
(15) Uterine rupture
(16) Length of hospital stay
(17) Satisfaction with labour
(18) Satisfaction with fetal monitoring in labour
(19) Death

Fetal/neonatal

(20) Skin trauma
(21) Apgar scores less than four at five minutes
(22) Apgar scores less than seven at five minutes
(23) Umbilical arterial pH less than 7.10
(24) Umbilical arterial base excess less than -12
(25) Admission to neonatal intensive care unit
(26) Length of hospital stay
(27) Death
(28) Death, hypoxic-ischaemic encephalopathy, or both
(29) Death, seizures, or both
(30) Death, long-term neurodevelopmental problem, or both

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 (May 2010).

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.

In addition, we searched MEDLINE (1994 to May 2010), EMBASE (1994 to May 2010) and Current Contents (1994 to May 2010): searches were conducted from 1994 onwards as pulse oximetry technology calibrated for the fetal environment has only been available since 1994. *See:* Appendix 2 for search strategy used.

Searching other resources

We also sought ongoing and unpublished trials by contacting experts in the field.
We did not apply any language restrictions.

Data collection and analysis

For the methods used when assessing the trials identified in the previous version of this review, *see* Appendix 1.
For this update we used the following methods when assessing the reports identified by the updated search (Caliskan 2009; an economic analysis of East 2006; a conference abstract by Prieto 2008; and an abstract and published sub-study by Rouse, from the Bloom 2006 trial).

Selection of studies

Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We planned to resolve any disagreement through discussion or, if required, we planned to consult a third person.

Data extraction and management

We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We planned to resolve discrepancies through discussion or, if required, we planned to consult a third person. We entered data into Review Manager software (RevMan 2008) and checked for accuracy.
When information regarding any of the above were unclear, we planned to attempt contact with authors of the original reports to provide further details.

Assessment of risk of bias in included studies

Two review authors independently assessed risk of bias for each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2009). We planned to resolve any disagreement by discussion or by involving a third assessor.

(1) Sequence generation (checking for possible selection bias)

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

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

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

We described 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 assessed the methods as:

- adequate (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- inadequate (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth);
- unclear.

(3) Blinding (checking for possible performance bias)

We described for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding could not have affected the results. We assessed blinding separately for different outcomes or classes of outcomes.
We assessed the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

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

- adequate;
- inadequate;
- unclear.

(5) Selective reporting bias

We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- adequate (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review had been reported);
- inadequate (where not all the study's pre-specified outcomes had been reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so cannot be used; study failed to include results of a key outcome that would have been expected to have been reported);
- unclear.

(6) Other sources of bias

Weplanned to describe for each included study any important concerns about other possible sources of bias.

We assessed whether each study was free of other problems that could put it at risk of bias:

- yes;
- no;
- unclear.

(7) Overall risk of bias

We made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2009). With reference to (1) to (6) above, we assessed 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 presented results as summary risk ratio with 95% confidence intervals.

Continuous data

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

Unit of analysis issues

Cluster-randomised trials

We planned to include cluster-randomised trials in the analyses along with individually randomised trials. We planned to adjust their sample sizes or standard errors using the methods described in the *Handbook* Higgins 2009 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 had used ICCs from other sources, we would have reported this and conducted sensitivity analyses to investigate the effect of variation in the ICC. If we had identified both cluster-randomised trials and individually-randomised trials, we planned to synthesise the relevant information. We would have considered it reasonable to combine the results from both if there was little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit was considered to be unlikely.

We also planned to acknowledge heterogeneity in the randomisation unit and perform a sensitivity analysis to investigate the effects of the randomisation unit.

Crossover trials

We planned to exclude crossover trials in this review, as they are not an appropriate study design for assessment of the effects of fetal monitoring during labour.

Dealing with missing data

For included studies, we noted levels of attrition. We planned to explore the impact of including studies with high levels of missing data in the overall assessment of treatment effect by using sensitivity analysis.

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

Assessment of heterogeneity

We assessed statistical heterogeneity in each meta-analysis using the T^2, I^2 and Chi^2 statistics. We regarded heterogeneity as substantial if T^2 was greater than zero and either I^2 was greater than

30% or there was a low P-value (less than 0.10) in the Chi² test for heterogeneity.

Assessment of reporting biases

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

Data synthesis

We carried out statistical analysis using the Review Manager software (RevMan 2008). We used fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials examined the same intervention, and the trials' populations and methods were judged sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity was detected, we used random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. The random-effects summary was treated as the average range of possible treatment effects and we discussed the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful we did not combine trials (see Subgroup analysis and investigation of heterogeneity) .

If we used random-effects analyses, we presented 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 identified substantial heterogeneity, we investigated it using subgroup analyses and sensitivity analyses.

We planned to carry out the following subgroup analyses.

Fetal pulse oximetry compared with:

1. fetal heart rate monitoring by:
   - intermittent auscultation;
   - intermittent cardiotocography;
   - continuous cardiotocography;
   - continuous cardiotocography and fetal scalp stimulation;
   - continuous cardiotocography and fetal electrocardiogram (ECG) analysis (ST segment);
   - continuous cardiotocography and fetal ECG analysis (PR interval); and

2. fetal blood sampling for blood gas analysis.

Several trials indicated that fetal blood sampling was performed (East 2006; Garite 2000; Kuhnert 2004). However, data were only available to allow for one of these to be included in a subgroup analysis (East 2006). None of the remaining subgroup analyses were conducted, as we were unable to identify trials that addressed these questions.

We planned to use the following primary outcomes in subgroup analysis.

1 Caesarean section
2 Hypoxic-ischaemic encephalopathy
3 Neonatal seizures
4 Long-term neurodevelopmental outcome

For fixed-effect inverse variance meta-analyses we planned to assess differences between subgroups by interaction tests (we did not meta-analyse the subgroups). For random-effects and fixed-effect meta-analyses using methods other than inverse variance, we assessed differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals indicated a statistically significant difference in treatment effect between the subgroups.

The differences in entry criteria for the reported studies made combined statistical analysis problematic. We addressed this by considering the following analyses:

(A) nonreassuring fetal heart rate prior to study entry:

(i) gestation from 34 weeks (or from 36 weeks where this was the earliest gestation enrolled), fetal blood sampling not required prior to study entry;

(ii) gestation from 36 weeks, fetal blood sampling prior to study entry;

(iii) gestation from 28 weeks, fetal blood sampling not required prior to study entry; and

(B) gestation from 36 weeks, nonreassuring fetal status not required prior to study entry.

One study (Bloom 2006) enrolled women regardless of nonreassuring fetal status prior to study entry, i.e. "(A)" above. We included the results for all women in relevant analyses, and for the group of women within the study where nonreassuring fetal status was reported prior to study entry (i.e. "(B)" above). Therefore in several analyses (Analysis 1.1, Analysis 1.3, Analysis 2.5, Analysis 2.6), the same data were reported differently, meaning that it was not appropriate to provide an overall total estimate of effect.

Sensitivity analysis

Inclusion of the study results from Garite 2000 contributed to heterogeneity for some outcomes (for e.g. Caesarean section overall, Analysis 1.1. and Caesarean section for dystocia,Analysis 2.6). We considered that the overall summary remained useful and used random-effects to produce it.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies; Characteristics of studies awaiting classification.
See Characteristics of included studies table.
The search identified six published randomised controlled trials (Bloom 2006; Caliskan 2009; East 2006; Garite 2000; Klauser 2005; Kuhnert 2004), one study published as a conference abstract only (see Studies awaiting classification, Prieto 2008) and two observational studies (Andres 2004; Golaszewski 1993). The trial by Garite 2000 had also been published in a number of forms and sub analyses addressing issues that were not considered in this review. Similarly, the trials by East 2006 and Bloom 2006 had several related publications, some of which were considered in this review and were added with this update.

Trials with nonreassuring fetal status required prior to study entry

The trial published by Garite 2000 was conducted in the United States of America (USA) and compared caesarean section rates for nonreassuring fetal status when conventional fetal monitoring (CTG) was used, versus when fetal pulse oximetry was used in addition to CTG, with reported data on 1010 cases. An unpublished report included some pilot data for a total of 1189 cases.
Kuhnert 2004 reported a trial from Germany which compared operative delivery and fetal scalp blood sampling for nonreassuring fetal status in two groups: those with CTG monitoring and those with fetal pulse oximetry added to the CTG, for a total of 146 cases. Fetal blood sampling was required prior to study entry. Whilst not stated in the report, it is appropriate to consider that if the scalp pH was nonreassuring, intervention would have been undertaken to correct this or to deliver the baby prior to enrolment in the study. It can therefore be considered that this represents, at least in part, a different study population to that of the other studies.
A single-centre trial from the USA, reported by Klauser 2005, included 327 women with gestation from 28 weeks onward. This study compared caesarean delivery for nonreassuring fetal status in women with and without fetal pulse oximetry added to CTG monitoring (Klauser 2005). Interpretation of fetal heart rate monitoring is different in premature babies, compared with term babies. The report did not allow the reader to distinguish outcomes by gestational age. It may therefore be appropriate to consider that this represents a heterogenous population. This would make subsequent combination with other trials inappropriate. We were unable to contact the authors to consider analysis by gestation.
An Australian multicentre trial compared operative delivery for nonreassuring fetal status in those with and without fetal pulse oximetry added to CTG monitoring (East 2006) on 600 pregnancies.
The trial reported by Bloom 2006 included 2168 women with a nonreassuring CTG at the time of study entry, of the 5341 enrolled in the study overall (*see* below).
Caliskan 2009 reported a single-centre trial from Turkey, which enrolled 230 women undergoing induction of labour with misoprostol. Women were randomised to either CTG monitoring, or CTG plus intermittent fetal pulse oximetry.
A conference abstract by Prieto 2008 reported limited findings from a pilot randomised study comparing the use of fetal pulse oximetry with fetal electrocardiography, in the presence of a nonreassuring fetal heart rate trace during labour. We have been unable to identify a full report of this study or to contact the study authors. Given that the likelihood of results being different in a conference abstract and the final study report, we have elected to await full publication rather than include the limited results in this review. This study therefore remains as a study awaiting classification.

Trials with nonreassuring fetal status not required prior to study entry

Bloom 2006 reported a multicentre trial conducted in the USA (n = 5341), which enrolled nulliparous women with CTG monitoring in labour. All participants had a fetal pulse oximetry sensor placed and were then randomly allocated to the 'open' arm with fetal pulse oximetry values displayed or the 'masked' arm with fetal pulse oximetry values stored to computer disk and not displayed to the woman or clinician. These results were analysed separately from the other studies, as the study population, labouring women with a CTG, could not be considered in the same manner as those with a nonreassuring CTG. The report included limited outcomes for a separate analysis of those with a nonreassuring CTG prior to study entry.
The study reported by Caliskan 2009 enrolled women from 34 weeks gestation undergoing induction of labour by oral misoprostol. All participants had misoprostol administered and were then randomised to either intermittent fetal pulse oximetry+electronic fetal monitoring, or electronic fetal monitoring only.
We found no unpublished studies.

Risk of bias in included studies

The published studies were unblinded (in terms of group allocation) randomised controlled trials, with complete follow up. The 'masked' group in the study by Bloom 2006 meant that the labouring woman and clinicians were blinded to fetal oximetry values. Outcome assessment of all trials was unblinded with the exception of (i) a post hoc analysis of partograms in the trial by Garite 2000, constructed to demonstrate progress in labour for all cases of dystocia (defined) and failed induction of labour (defined), for which the review author was blinded to group allocation; and (ii) review of women's records in the study reported by Bloom 2006,

when the initial data indicated the presence of a placental abruption, prolonged fetal heart rate deceleration at the time of sensor insertion and serious neonatal outcomes, including death or five-minute Apgar score less than four.

Women in labour at greater than or equal to 28 (Klauser 2005), 34 (Caliskan 2009), or 36 weeks' gestation (East 2006; Garite 2000; Klauser 2005) who gave informed consent and whose fetuses displayed nonreassuring heart rate traces, were randomised to conventional cardiotocography monitoring, or to the addition of fetal pulse oximetry. Management of fetal heart rate patterns and fetal pulse oximetry followed an algorithm. In contrast to the other reported trials, the study by Bloom 2006 did not require nonreassuring fetal status prior to study entry. The 'masked' group of this trial is treated in this review as 'cardiotocography-only' for the purposes of meta-analysis, since the fetal pulse oximetry values did not influence clinical decisions. The primary outcome for each trial was caesarean section or overall operative birth for nonreassuring fetal status. *See* 'Characteristics of included studies' for further details. Methods of randomisation and allocation concealment were not reported in some studies (Klauser 2005; Kuhnert 2004). The reports of the trials by Kuhnert 2004 and by Klauser 2005 were less detailed overall than for the other trials. All trials were included in the meta-analysis to allow a comprehensive representation of the findings. The use of a summary measure of effect for all trials was not used, however, as the appropriateness of combining studies with differing quality, entry criteria and significant heterogeneity if separate analyses were not used, remained uncertain.

Effects of interventions

We included six trials involving 7724 participants in this review. (One report from an updated search in October 2009 remains in Studies awaiting classification, as it is only available in abstract form and with limited details.)

Primary outcomes

Meta-analysis of five of the six trials resulted in no significant differences in the overall caesarean section rate between those monitored with fetal oximetry and those not monitored with fetal pulse oximetry or for whom the fetal pulse oximetry results were masked (risk ratio (RR) 0.99, 95% confidence intervals (CI) 0.86 to 1.13). A smaller study for which fetal blood sampling was required prior to study entry (n = 146) reported a significant decrease in caesarean section in the fetal oximetry group, compared with the control group (Kuhnert 2004). Neonatal seizures were rare, with only one case in the control group of the trial by Garite 2000 and one clinical case in the intervention group of the trial by East 2006. Hypoxic ischaemic encephalopathy was reported in only one case, in the masked group of the study by Bloom 2006. No studies reported details of assessment of long-term disability.

Secondary outcomes: maternal

There was a statistically significant decrease in caesarean section for nonreassuring fetal status in the fetal pulse oximetry plus CTG group compared to the CTG group in two of the four analyses: (i) gestation from 34weeks with fetal blood sampling not required prior to study entry (RR 0.65, 95% CI 0.46 to 0.90); and (ii) when fetal blood sampling was required prior to study entry (RR 0.03, 95% CI 0.00 to 0.44). There was a statistically significant decrease in operative delivery (caesarean section, forceps or vacuum birth) for nonreassuring fetal status when fetal pulse oximetry was added to CTG monitoring, in all three studies that reported this outcome (n = 1756).

There was no statistically significant difference in caesarean section for dystocia when fetal pulse oximetry (fetal pulse oximetry) was added to CTG monitoring, compared with CTG monitoring alone.

The addition of fetal pulse oximetry to CTG monitoring resulted in no differences for overall operative delivery rates (with the exception of the smaller study reported by Kuhnert 2004), endometritis, intrapartum haemorrhage, postpartum haemorrhage, chorioamnionitis, endometritis, uterine rupture, length of hospital stay, satisfaction with labour or satisfaction with fetal monitoring in labour, compared to CTG only. No maternal deaths occurred. The study by Kuhnert 2004 reported less antibiotic use in the fetal pulse oximetry group, compared with the CTG group.

Women reported similar levels of satisfaction with their labour and fetal monitoring when fetal pulse oximetry was added to CTG monitoring, compared to CTG monitoring alone (East 2006).

Secondary outcomes: fetal/neonatal

No statistically significant differences were noted for Apgar scores less than four at five minutes or less than seven at five minutes, umbilical arterial pH less than 7.10, umbilical arterial base excess less than -12, admission to the neonatal intensive care unit, length of hospital stay, death or skin trauma. Transient skin markings attributable to the fetal oximetry sensor were noted in 11 of 638 babies (2%) Garite 2000; in 30 of 305 babies (10%) East 2006; and for 152 of 2629 babies (6%) in the open group and 155 of 2712 babies (6%) in the masked group Bloom 2006.

Subgroup analyses

Data were available from one trial (East 2006) to allow the planned subgroup analyses of fetal scalp blood sampling post randomisation. There were no significant differences in the primary outcome of caesarean section and no seizures were reported for any of the babies in this subgroup. Data were not available to allow the remaining subgroup analyses to be conducted.

DISCUSSION

When systematically reviewed, five of the six published trials (with some unpublished data available), comparing fetal intrapartum pulse oximetry with CTG or masked fetal pulse oximetry, reported no difference in the overall caesarean section rate between the fetal pulse oximetry group and the CTG group. One smaller study did note a significant difference in favour of the fetal pulse oximetry plus CTG group.

Meta-analysis of the four studies with nonreassuring fetal status from 34 weeks' gestation prior to randomisation demonstrated a reduction in caesarean section for nonreassuring fetal status, with no differences in neonatal outcomes. That is, a decision not to perform a caesarean section for nonreassuring fetal status in the fetal pulse oximetry group did not result in worse outcomes for those babies (but a larger sample would be required to demonstrate a difference in such low-prevalence outcomes). There were no between-group differences in caesarean section for nonreassuring fetal status when all participants in the largest study were considered, when analysed without consideration of fetal status at study entry.

These findings from more than 7000 participants in high-quality studies provide substantial evidence to suggest that knowledge of fetal pulse oximetry values does not influence overall caesarean section rate. However, several issues warrant consideration: (1) does the indication for caesarean section matter if the overall incidence of caesarean section is the same? (2) Does the presence of a fetal oximetry sensor contribute to dystocia?

The decision pathway leading to performing a caesarean section may be important. The additional information that fetal pulse oximetry can provide, when a nonreassuring fetal heart rate trace has been identified, may translate to avoidance of a caesarean section for nonreassuring fetal status, with its associated stress levels for the mother and resource implications for the health service providers. An 'inevitable' caesarean section may still be performed for other indications, when the woman has had more time to consider her options. Staffing levels can also be adjusted over a number of hours, rather than the immediate and potentially costly provision of staff for an emergency operation. One trial reported that the addition of fetal pulse oximetry to CTG monitoring was cost effective in reducing operative delivery for nonreassuring fetal status (East 2006).

When the findings of the first trials of fetal pulse oximetry became available, there was debate about why the incidence of caesarean section for dystocia more than doubled from 9% in the CTG-only group to 19% when fetal pulse oximetry was added. The investigators explored several possible causes for the increase in dystocia in the fetal pulse oximetry group, including potential mislabelling of dystocia and the presence of the oximetry sensor slowing the labour (Garite 2000). The authors concluded that mislabelling of the indication for caesarean section had not occurred and the presence of the sensor did not result in a longer labour. They suggested that the nonreassuring CTG may indicate an underlying risk for dystocia (Garite 2000). To test this hypothesis, Porreco 2004 conducted a multicentre, prospective, observational cohort study of fetal pulse oximetry in nulliparous labouring women, with a standardised labour management protocol and a specific focus on the management of dystocia (defined). The investigators concluded that the presence of persistent, progressive and moderate to severely nonreassuring CTGs may predict the need for delivery by caesarean section for dystocia, despite adequate fetal oxygenation (Porreco 2004). No other trials in this systematic review demonstrated a difference in caesarean section for dystocia. However, the incidence of dystocia in each trial varied: from 11% in the fetal pulse oximetry group and 14% in the CTG-only group (East 2006) to 19% for all women in both the open and masked groups, where all participants had a fetal oximetry sensor placed (Bloom 2006), which was similar to that of the fetal pulse oximetry group of the Garite 2000.The incidence of dystocia was much lower in the study reported by Caliskan 2009 (2.6% in the fetal oximetry group and 3.4% in the CTG-only group). These researchers considered that the intermittent use of the fetal oximetry probe may have avoided an over representation of dystocia in the oximetry group. It remains possible that the presence of a fetal oximetry sensor alongside the fetal head contributes to dystocia.

Women's reports of satisfaction with their labour and with fetal monitoring were similar when fetal pulse oximetry was added to CTG monitoring, compared to CTG monitoring alone. This is an important consideration, given that the use of technology may impact on women's perceived control over their labour experience (Wagner 2001). Although an ideal study would compare women's satisfaction with fetal pulse oximetry and without any technology, such a study is not feasible. It can be considered, however, that once continuous CTG monitoring is in use during labour, the addition of fetal pulse oximetry technology does not adversely affect women's perceptions of their labour experience or of fetal monitoring overall.

Both the clinicians and the women in labour were unblinded to the use of a fetal oximeter and display of fetal oximetry values in the intervention groups of the trials (Bloom 2006; Caliskan 2009; East 2006; Garite 2000; Klauser 2005; Kuhnert 2004). Is blinding feasible? Given that clinicians were to act on the results of the intervention, that is, the fetal pulse oximetry readings, it would not be possible to blind at that stage. Bloom 2006 placed a fetal oximetry sensor with values stored to computer, thus blinding the fetal pulse oximetry values to the labouring woman and her clinicians. A design feature of future studies could be blinded outcome assessment: that is, present the data in two groups, not revealing actual group allocation.

Safety of fetal pulse oximetry has been partially addressed by the published trials: fetal/neonatal and maternal outcomes were not different in the two groups of monitoring, although power was low for some low prevalence outcomes. Long-term neurodevelop-

mental outcome has not been measured.

AUTHORS' CONCLUSIONS

Implications for practice

Is fetal pulse oximetry ready for use in clinical practice? European clinicians published guidelines for fetal pulse oximetry use (Kuhnert 1998; Saling 1996) that were consistent with the management of fetal pulse oximetry in Garite 2000 and prior to its results being known. Only one small randomised controlled trial of fetal pulse oximetry has since been reported from Europe to test these guidelines (Kuhnert 2004). That trial did report a significant decrease in both overall caesarean section rate and caesarean section for nonreassuring fetal status when fetal pulse oximetry was added to cardiotocography (CTG) monitoring, compared with CTG only (Kuhnert 2004). Current data suggest that knowledge of fetal pulse oximetry does not affect overall caesarean section rates.

The American College of Obstetrics and Gynecology (ACOG) reviewed the results of the trial reported by Garite 2000 and recommended further trials before the introduction of fetal pulse oximetry into clinical practice (ACOG 2001). Their recommendation was based mainly on the increase in dystocia reported with the use of fetal pulse oximetry and the potential to increase fetal monitoring costs without improving clinical outcomes (ACOG 2001). One trial reported that the addition of fetal pulse oximetry to cardiotocography was cost effective in reducing operative delivery for nonreassuring fetal status (East 2006).

The use of CTG has some parallels. Current clinical practice recommendations are that the clinician and the individual woman should consider the appropriateness of CTG to enable an informed choice for each case (Alfirevic 2006; RCOG 2001). Given the high quality of evidence from several of the reported fetal pulse oximetry trials and the reduction in caesarean section for nonreassuring fetal status (but not for overall caesarean section rates) in those for which a nonreassuring CTG was required prior to study entry, it may be prudent when developing recommendations to encourage the individual woman and her clinicians to make the decision to use or not use fetal pulse oximetry. Unlike CTG, however, the randomised controlled trials of fetal pulse oximetry have been conducted prior to widespread clinical acceptance and medico-legal expectation of fetal pulse oximetry usage where there is concern about fetal well-being.

Commercial availability of the fetal pulse oximetry system used in the studies was discontinued during 2006. Other systems that have not yet been subject to trials remain available commercially.

The data provide limited support for the use of fetal pulse oximetry when used in the presence of a nonreassuring CTG, to reduce caesarean section for nonreassuring fetal status. This finding is similar to other tests available to evaluate fetal well-being in labour (fetal scalp blood sampling for pH estimation (Alfirevic 2006) and fetal electrocardiogram (Neilson 2006)), which also do not reduce caesarean sections. A better method to evaluate fetal well-being in labour is required.

Implications for research

Further trials could address: entry criteria related to the severity of nonreassuring CTG patterns; action levels for fetal pulse oximetry values, such as a decline by 10% or 20%, rather than an absolute cut-off value; and the endpoint of long-term neurodevelopmental outcomes. The ideal study to address the issue of dystocia when a fetal pulse oximetry sensor is placed alongside the fetal head would compare caesarean section for dystocia in three groups: those with fetal oximetry displayed, those with fetal pulse oximetry masked and those without fetal pulse oximetry. Further studies using fetal oximetry sensors attached to the fetal scalp, rather than placed alongside the fetal head, could also be considered.

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

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

Bloom 2006

Methods	RCT.
Participants	Nulliparous women from 36 weeks' gestation with a singleton pregnancy and cephalic presentation, in early labour (2-5 cm cervical dilatation) with ruptured amniotic membranes who gave informed consent
Interventions	'Open' group: FPO sensor placed and FPO values displayed. 'Masked' group: FPO sensor placed and FPO values not displayed (FPO values recorded on computer) Both groups: standard fetal heart rate monitoring; labour management at the clinician's discretion
Outcomes	Primary: caesarean section (any indication). Secondary: caesarean section for nonreassuring fetal status or dystocia; "fetal vulnerability index" (stillbirth, neonatal death, 5-min Apgar score less than 3, umbilical pH less than or equal to 7, seizures, admission to neonatal intensive care unit for greater than or equal to 24 hours); other neonatal morbidity
Notes	Fetal oximetry system used: Nellcor OxiFirst.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Allocation concealment?	Unclear risk	Unclear.
Blinding? All outcomes	High risk	Blinding of intervention = women and clinicians blinded to FPO values in the 'masked' group: however, not actually blinded to intervention (C); completeness of follow up = A; blinding of outcome assessment = B, however, if certain outcomes were identified, blinded chart review authors then confirmed the outcomes
Incomplete outcome data addressed? All outcomes	Low risk	No evidence of incomplete outcome data.
Free of selective reporting?	Low risk	No evidence of selective reporting. Report aligns with limited details of protocol published when RCT in progress
Free of other bias?	Low risk	No evidence of other bias.

Caliskan 2009

Methods	RCT, single centre (Turkey).
Participants	Women from 34 weeks' gestation undergoing induction of labour with oral misoprostol Inclusion: singleton live pregnancy with vertex presentation and maternal and/or fetal indications for induction of labour; gestational age from 34 weeks; Bishop score less than or equal to 5; absence of spontaneous uterine contractions; estimated fetal body weight less than 4250 g; reactive non-stress test Exclusion: fetal demise; gestational age less than 34 weeks; known hypersensitivity to prostaglandin; previous caesarean section or other uterine surgery; contraindication to vaginal delivery
Interventions	Group 1: electronic fetal monitoring by CTG only. If the CTG was reassuring, labour continued unless otherwise indicated. If the CTG was nonreassuring (defined), simple measures, including lateral positioning, were instigated, with escalation to operative delivery if simple measures were not effective Group 2: CTG plus $FSpO_2$ monitoring - intermittently for 15 minutes every 2 hours. If reassuring it was removed. If nonreassuring, remained in situ. If the CTG was reassuring and $FSpO_2$ values were greater than or equal to 30%, labour continued unless otherwise indicated. If the CTG was nonreassuring (defined) and $FSpO_2$ values were less than 30% for 3 minutes, simple measures, including lateral positioning, were instigated. If FSpO2 values remained < 30% for 10 minutes, then operative delivery was performed
Outcomes	Primary outcome: caesarean delivery rates. Secondary outcomes: induction to delivery interval, caesarean section for nonreassuring CTG, neonatal outcomes, including umbilical arterial pH < 7.16, admission to neonatal intensive care
Notes	Fetal oximetry system used: Nellcor OxiFirst. 37 weeks used as 'restriction point' to randomly allocate preterm and term fetuses to the 2 groups. This is interpreted as stratification by term/preterm, however, no further details provided of outcomes within these groups Data were not available to allow subgroup analysis in this review by term/preterm. Similar numbers of term (total n = 195)/preterm (total n = 35) were randomised to the control and intervention groups, with the larger proportion being term in each group. There were similar neonatal outcomes (including birthweight and admission to neonatal intensive care unit), both between the groups and compared with other studies enrolling over 36 weeks. We have therefore included these participants in the analyses of later gestations, renaming the analyses that include participants from this study as "... gestation from 34 weeks ..." Attempts at establishing contact details to clarify this were unsuccessful

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Reported to be "Directed by a physician".
Allocation concealment?	Low risk	Sequentially numbered opaque envelopes.

Caliskan 2009 (*Continued*)

Blinding? All outcomes	High risk	It would not have been feasible to blind the clinician or participant, given that $FSpO_2$ values were used for clinical judgement. It is not stated whether or not outcome assessment was blinded
Incomplete outcome data addressed? All outcomes	Low risk	No evidence of incomplete outcome data.
Free of selective reporting?	Low risk	No evidence of selective reporting, however, protocol not published
Free of other bias?	Low risk	No evidence of other bias.

East 2006

Methods	Multicentre RCT. Survey of women's perceptions: identical surveys to participants in each group within a few days of giving birth and 3 months later. Women were asked to rate their experience in 3 domains: labour (maximum score 12), fetal monitoring (maximum score 16) and participation in research (maximum score 12). Cost-effectiveness analysis the RCT. Costs included diagnosis-related group costs, FBS, medications, use of oxygen or intravenous fluid, or both, FPO. Effect was the primary outcome of the RCT (operative delivery for nonreassuring fetal status)
Participants	601 women in labour. 1 exclusion, leaving 600 analysed. Inclusion criteria: nonreassuring CTG (defined), $\geq$ 36 weeks' gestation, early or active labour, ruptured amniotic membranes or eligible for artificial rupture of membranes Exclusion criteria: multiple gestations, non vertex presentation, placenta praevia, abruptio placentae, uterine anomaly, antepartum haemorrhage, fetal anomaly, known significant viral infections (e.g. HIV), any other contraindications to invasive monitoring such as thrombocytopenia
Interventions	Control group: fetal heart rate monitoring (CTG) (doppler/fetal scalp electrode) Intervention group: CTG plus fetal pulse oximetry. Protocol for action with reassuring ($\geq$ 30%) and nonreassuring fetal oximetry values (< 30% for 10 minutes, or not recording)
Outcomes	Primary outcome: operative delivery (caesarean section, vacuum, forceps) for nonreassuring fetal status Maternal outcomes including: caesarean section and assisted vaginal delivery for nonreassuring fetal status; caesarean and assisted vaginal delivery section for dystocia/failure to progress; caesarean or assisted vaginal birth for combined indication of nonreassuring fetal status and dystocia; caesarean section; assisted vaginal birth; spontaneous vaginal birth; labour interventions and fetal evaluations (e.g. scalp pH); endometritis; postpartum haemorrhage; length of stay Women's perceptions: satisfaction measured in 3 domains: labour, fetal monitoring and participation in research Neonatal outcomes including: Apgar scores; umbilical cord blood gases; resuscitation; admission to neonatal intensive care unit; length of hospital stay

East 2006 (*Continued*)

	Economic analysis: cost-effectiveness of FPO to prevent operative delivery for nonreassuring fetal status
Notes	Sample size calculation: yes, based on reduction in caesarean section rate for nonreassuring fetal status. Fetal oximetry system used: Nellcor OxiFirst. Women's perceptions: results from the first survey are used in this report

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Developed by research associate not involved in recruitment.
Allocation concealment?	Low risk	Adequate, through use of password protected computer randomisation system
Blinding? All outcomes	High risk	Not feasible to blind participants or clinicians. Outcome analysis unblinded except for interim analysis where data presented to data monitoring committee in 2 unlabelled groups by study associate
Incomplete outcome data addressed? All outcomes	Low risk	All participants accounted for.
Free of selective reporting?	Low risk	No evidence of selective reporting.
Free of other bias?	High risk	Authors declared commercial funding in all publications.

Garite 2000

Methods	Random allocation: telephone randomisation.
Participants	1189 women in labour. This consisted of 1010 in the published trial and 179 in a pilot of the trial conducted using the same protocol, where unpublished data were accessible Inclusion criteria: nonreassuring CTG, ≥ 36 weeks' gestation, active labour, single fetus, cephalic presentation, cervical dilatation of at least 2 cm and at station -2 or below, ruptured amniotic membranes (or have amniotomy) Exclusion criteria: planned caesarean section, placenta praevia, need for immediate delivery, active genital herpes or known HIV infection, participation in other studies
Interventions	Control group: fetal heart rate monitoring (CTG) (doppler/fetal scalp electrode) Study group: CTG plus fetal pulse oximetry. Protocol for action with reassuring and nonreassuring fetal oximetry values

Garite 2000 (*Continued*)

Outcomes	Caesarean section for nonreassuring status; caesarean section for all indications; caesarean section for fetal intolerance to labour with dystocia, mixed indication; caesarean dystocia, single indication; spontaneous vaginal delivery; assisted vaginal delivery for nonreassuring fetal status or for all other indications; fetal heart rate patterns; labour interventions and fetal evaluations (e.g. scalp pH) Neonatal outcomes including: Apgar scores; umbilical cord blood gases; resuscitation; admission to neonatal intensive care unit; length of hospital stay Maternal outcomes including: endometritis; length of stay; bleeding; uterine rupture; intrapartum fever
Notes	Some additional unpublished data from a pilot of the trial, using the same protocol, were available. Further data were requested but were unable to be accessed. Sample size calculation: yes, based on reduction in caesarean section rate for nonreassuring fetal status. Fetal oximetry system used: Nellcor OxiFirst.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Low risk	Computer randomisation.
Allocation concealment?	Low risk	Adequate, with computer randomisation.
Blinding? All outcomes	High risk	Participants, clinicians and researchers unblinded. Some blinded outcome analysis, e.g. retrospective examination of partograms to determine diagnosis of dystocia
Incomplete outcome data addressed? All outcomes	High risk	All participant data accounted for.
Free of selective reporting?	Low risk	No evidence of selective reporting. Available data for this review included a report to the Food and Drug Administration, which included comprehensive and otherwise unpublished results that were consistent with published findings
Free of other bias?	High risk	Commercially funded study, acknowledged by report authors.

Klauser 2005

Methods	Single-centre RCT.
Participants	360 women in labour. Control group: 1 post randomisation exclusion as no consent. Intervention group: 30 post randomisation exclusions where FPO sensor not placed and 2 additional exclusions due to randomisation issues Inclusion criteria: nonreassuring CTG, ≧ 28 weeks' gestation, single fetus, cephalic presentation, cervical dilatation of at least 2 cm and at station -5 or below, ruptured amniotic membranes (spontaneous or artificial) Exclusion criteria: planned caesarean section, contraindication to vaginal delivery (including genital herpes, transverse lie), unexplained vaginal bleeding, placenta praevia, ominous CTG requiring immediate delivery, known HIV infection, hepatitis B or C, unable to give consent due to intrapartum parenteral analgesia
Interventions	Control group: fetal heart rate monitoring (CTG) (Doppler/fetal scalp electrode) Study group: CTG plus fetal pulse oximetry (Nellcor OxiFirst). Protocol for action with reassuring fetal oximetry (≧ 30%) and nonreassuring values (< 30% for 3 minutes)
Outcomes	Primary outcome: caesarean section for nonreassuring fetal status Maternal outcomes: caesarean section for all indications; caesarean section for dystocia; amnioinfusion and length of labour Neonatal outcomes including: Apgar scores; umbilical cord blood gases; resuscitation; admission to neonatal intensive care unit
Notes	Further data were requested, awaiting reply. Sample size calculation: yes, based on reduction in caesarean section rate for nonreassuring fetal status. Fetal oximetry system used: Nellcor OxiFirst.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	Method of randomisation not stated.
Allocation concealment?	Unclear risk	Unclear. No mention in the report, although two participants were excluded on the basis of "randomization issues"
Blinding? All outcomes	High risk	The report did not comment on blinding, but it is implicit that the clinician and participant were unblinded, given that FSpO2 values were used for clinical judgement
Incomplete outcome data addressed? All outcomes	Low risk	Accounted for in diagram.
Free of selective reporting?	Low risk	No evidence of selective reporting.
Free of other bias?	Low risk	No evidence of other bias.

Kuhnert 2004

Methods	Single-centre, RCT.
Participants	146 women in labour. Inclusion criteria: CTG with International Federation of Gynecology and Obstetrics (FIGO) score ≤ 8, gestational age ≥ 36 weeks, active labour, single fetus, cephalic presentation, cervical dilatation of at least 2 cm and at station -2 or below, ruptured amniotic membranes (or have amniotomy). All cases had FBS prior to randomisation Exclusion criteria: planned caesarean section, placenta praevia, need for immediate delivery, active genital herpes or known HIV infection
Interventions	Control group: fetal heart rate monitoring (CTG) and FBS. Protocol for action with reassuring, suspicious and pathologic CTG and FBS pH values Intervention group: CTG plus FBS plus FPO. Protocol for action with reassuring (≥ 30%) and nonreassuring FPO values (< 30% for ≥ 10 mins or repeatedly ('summation effect'), and for reassuring and nonreassuring CTG and FBS pH
Outcomes	Caesarean section or vacuum extraction for pathologic CTG; caesarean section or vacuum extraction for all indications; caesarean section or vacuum for arrest of labour; caesarean section for pelvic malformation or amnioinfection; vacuum extraction for maternal exhaustion; spontaneous vaginal delivery; fetal heart rate patterns; FBS (including pH) Neonatal outcomes including: umbilical cord blood gases; resuscitation; admission to neonatal intensive care unit Maternal outcomes: 'adverse maternal events'.
Notes	Some additional unpublished data were provided by the authors (use of antibiotics, haemorrhage, chorioamnionitis, endometritis, uterine rupture, length of hospital stay, satisfaction with labour and fetal monitoring, death, neonatal skin trauma, Apgar score, umbilical arterial base excess, admission to neonatal intensive care, hypoxic-ischaemic encephalopathy, seizures, long-term disability). No details of the assessment of long-term disability were provided (e.g. age of the infant, assessments made) Sample size calculation: no. Fetal oximetry system used: Nellcor OxiFirst.

Risk of bias

Bias	**Authors' judgement**	**Support for judgement**
Adequate sequence generation?	Unclear risk	Random allocation: method not stated and not provided on request
Allocation concealment?	Unclear risk	Unclear. No details provided in the report.
Blinding? All outcomes	Unclear risk	It would not have been feasible to blind the clinician or participant, given that FSpO2 values were used for clinical judgement. The report states "data acquisition was done anonymously for both group". It is unclear whether this related to de-identifying the data (likely) or that the data were collected without knowledge of group allocation

Kuhnert 2004 (*Continued*)

Incomplete outcome data addressed? All outcomes	Unclear risk	No supporting evidence of inclusion of all participants.
Free of selective reporting?	Unclear risk	Results differ widely from other published studies. It is unclear whether there was any selective reporting
Free of other bias?	Unclear risk	The limited details in the report (see above) make it difficult to exclude the possibility of other bias

CTG: cardiotocography
FBS: fetal blood sampling (scalp)
FPO: fetal pulse oximetry
$FSpO_2$: fetal oxygen saturation value
HIV: human immunodeficiency virus
min: minute
RCT: randomised controlled trial

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

Study	Reason for exclusion
Andres 2004	This study was conducted in Spain. It compared caesarean section rates for pathological or nonreassuring CTG when FPO was added to CTG monitoring or when FPO was not used. The groups were not randomised
Golaszewski 1993	This was an observational study of fetal pulse oximetry, where participants were randomised to be monitored with 1 of 2 oximeters

CTG: cardiotocography
FPO: fetal pulse oximetry

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

Prieto 2008

Methods	Randomised pilot study, comparing use of fetal ECG and fetal pulse oximetry
Participants	Singleton pregnancy with nonreassuring fetal status in active stage of labour Conference abstract does not give numbers of participants.
Interventions	Fetal ECG group: STAN21 system in use. Fetal pulse oximetry: intermittent recordings of FPO if values reassuring, continuous FPO recording if values non-

Prieto 2008 (*Continued*)

	reassuring
Outcomes	Caesarean section (overall and for indications of nonreassuring fetal status / dystocia); Umbilical blood pH; Apgar scores
Notes	Conference abstract only. No publication available on PubMed search of 25 May 2010 and no author contact details identified

ECG: electrocardiogram
FPO: fetal pulse oximetry

DATA AND ANALYSES

Comparison 1. Primary outcomes: FPO + CTG versus CTG only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
1.1 Gestation from 34 weeks, FBS not required prior to study entry	4	4008	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.86, 1.13]
1.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.44 [0.24, 0.81]
1.3 Gestation from 28 weeks, FBS not required prior to study entry	1	327	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.76, 1.14]
1.4 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.87, 1.04]
2 Hypoxic-ischaemic encephalopathy	3	6087	Risk Ratio (M-H, Random, 95% CI)	0.34 [0.01, 8.44]
2.1 Gestation from 36 weeks, FBS not required prior to study entry	1	600	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
2.3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.34 [0.01, 8.44]
3 Neonatal seizures	4	7276	Risk Ratio (M-H, Random, 95% CI)	0.69 [0.21, 2.32]
3.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.10, 8.79]
3.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
3.3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.62 [0.15, 2.59]

Comparison 2. Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
5 Caesarean section for nonreassuring fetal status	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
5.1 Gestation from 34 weeks, FBS not required prior to study entry	4	4008	Risk Ratio (M-H, Random, 95% CI)	0.65 [0.46, 0.90]
5.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.03 [0.00, 0.44]
5.3 Gestation from 28 weeks, FBS not required prior to study entry	1	327	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.64, 1.24]
5.4 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.91 [0.75, 1.09]
6 Caesarean section for dystocia	6		Risk Ratio (M-H, Random, 95% CI)	Subtotals only
6.1 Gestation from 34 weeks, FBS not required prior to study entry	4	4008	Risk Ratio (M-H, Random, 95% CI)	1.38 [0.91, 2.09]
6.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	1.4 [0.47, 4.21]
6.3 Gestation from 28 weeks, FBS not required prior to study entry	1	327	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.66, 1.46]
6.4 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.87, 1.08]
7 Operative delivery (caesarean section, forceps, vacuum extraction) for all indications	5	7327	Risk Ratio (M-H, Random, 95% CI)	0.92 [0.81, 1.06]
7.1 Gestation from 34 weeks, FBS not required prior to study entry	3	1840	Risk Ratio (M-H, Random, 95% CI)	1.03 [0.92, 1.15]
7.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.51 [0.36, 0.73]
7.3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.96 [0.90, 1.03]
8 Operative delivery (caesarean section, forceps, vacuum) for nonreassuring fetal status	3	1756	Risk Ratio (M-H, Random, 95% CI)	0.51 [0.27, 0.96]
8.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1610	Risk Ratio (M-H, Random, 95% CI)	0.74 [0.62, 0.89]
8.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.05 [0.01, 0.22]
9 Use of intrapartum antibiotics	2	746	Risk Ratio (M-H, Random, 95% CI)	0.78 [0.38, 1.61]

9.1 Gestation from 36 weeks, FBS not required prior to study entry	1	600	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.87, 1.35]
9.2 Gestation from 36 weeks, FBS required prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.52 [0.30, 0.88]
10 Overall antibiotic use	1	146	Risk Ratio (M-H, Random, 95% CI)	0.52 [0.30, 0.88]
10.1 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.52 [0.30, 0.88]
11 Intrapartum haemorrhage	3	1756	Risk Ratio (M-H, Random, 95% CI)	1.40 [0.52, 3.81]
11.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1610	Risk Ratio (M-H, Random, 95% CI)	1.48 [0.51, 4.31]
11.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	1.0 [0.06, 15.69]
12 Postpartum haemorrhage	3	1935	Risk Ratio (M-H, Random, 95% CI)	1.52 [0.53, 4.39]
12.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	1.52 [0.53, 4.39]
12.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
13 Chorioamnionitis	2	5487	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.85, 1.16]
13.1 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.11, 3.87]
13.2 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	1.00 [0.86, 1.17]
14 Endometritis	4	7276	Risk Ratio (M-H, Random, 95% CI)	0.99 [0.79, 1.26]
14.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	1.29 [0.43, 3.88]
14.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
14.3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.98 [0.76, 1.26]
15 Uterine rupture	3	1935	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.12, 6.13]
15.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	0.87 [0.12, 6.13]
15.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
16 Length of hospital stay (days)	2	746	Mean Difference (IV, Random, 95% CI)	-0.05 [-0.32, 0.22]
16.1 Gestation from 36 weeks, FBS not required prior to study entry	1	600	Mean Difference (IV, Random, 95% CI)	-0.06 [-0.36, 0.24]
16.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Mean Difference (IV, Random, 95% CI)	0.0 [-0.65, 0.65]
17 Satisfaction with labour	1	448	Mean Difference (IV, Random, 95% CI)	0.20 [-0.16, 0.56]

17.1 Gestation from 36 weeks, FBS not required prior to study entry	1	448	Mean Difference (IV, Random, 95% CI)	0.20 [-0.16, 0.56]
18 Satisfaction with fetal monitoring in labour	1	448	Mean Difference (IV, Random, 95% CI)	0.40 [-0.05, 0.85]
18.1 Gestation from 36 weeks, FBS not required prior to study entry	1	448	Mean Difference (IV, Random, 95% CI)	0.40 [-0.05, 0.85]
19 Death	3	1935	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
19.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
19.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Comparison 3. Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
20 Skin trauma	2	746	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.16, 3.21]
20.1 Gestation from 36 weeks, FBS not required prior to study entry	1	600	Risk Ratio (M-H, Random, 95% CI)	0.73 [0.16, 3.21]
20.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
21 Apgar score less than 4 at 5 minutes	4	7276	Risk Ratio (M-H, Random, 95% CI)	2.14 [0.60, 7.63]
21.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	2.60 [0.11, 63.70]
21.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
21.3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	2.06 [0.52, 8.24]
22 Apgar score less than 7 at 5 minutes	5	2492	Risk Ratio (M-H, Random, 95% CI)	0.70 [0.41, 1.18]
22.1 Gestation from 34 weeks, FBS not required prior to study entry	3	2019	Risk Ratio (M-H, Random, 95% CI)	0.67 [0.38, 1.18]
22.2 Gestation from 36 weeks, FBS required prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	3.00 [0.12, 72.45]
22.3 Gestation from 28 weeks, FBS not required prior to study entry	1	327	Risk Ratio (M-H, Random, 95% CI)	0.71 [0.17, 2.91]
23 Umbilical arterial pH less than 7.10	4	2174	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.45, 1.30]

23.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1701	Risk Ratio (M-H, Random, 95% CI)	1.01 [0.66, 1.53]
23.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.17 [0.02, 1.35]
23.3 Gestation from 28 weeks, FBS not required prior to study entry	1	327	Risk Ratio (M-H, Random, 95% CI)	0.45 [0.17, 1.24]
24 Umbilical arterial base excess less than -12	3	1816	Risk Ratio (M-H, Random, 95% CI)	1.04 [0.59, 1.86]
24.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1670	Risk Ratio (M-H, Random, 95% CI)	1.05 [0.57, 1.92]
24.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	1.0 [0.14, 6.91]
25 Admission to neonatal intensive care unit	6	7833	Risk Ratio (M-H, Random, 95% CI)	0.97 [0.83, 1.14]
25.1 Gestation from 34 weeks, FBS not required prior to study entry	3	2019	Risk Ratio (M-H, Random, 95% CI)	1.09 [0.85, 1.40]
25.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	1.0 [0.30, 3.31]
25.3 Gestation from 28 weeks, FBS not required prior to study entry	1	327	Risk Ratio (M-H, Random, 95% CI)	0.94 [0.55, 1.63]
25.4 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.88 [0.70, 1.11]
26 Length of hospital stay (days)	2	746	Mean Difference (IV, Random, 95% CI)	0.0 [-0.23, 0.23]
26.1 Gestation from 36 weeks, FBS not required prior to study entry	1	600	Mean Difference (IV, Random, 95% CI)	0.0 [-0.33, 0.33]
26.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Mean Difference (IV, Random, 95% CI)	0.0 [-0.32, 0.32]
27 Death	4	7276	Risk Ratio (M-H, Random, 95% CI)	0.77 [0.19, 3.13]
27.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.20, 4.44]
27.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
27.3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.34 [0.01, 8.44]
28 Death, hypoxic-ischaemic encephalopathy, or both	4	7276	Risk Ratio (M-H, Random, 95% CI)	0.68 [0.17, 2.73]
28.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.20, 4.44]
28.2 Gestation from 36 weeks, FBS required prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

28.3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry	1	5341	Risk Ratio (M-H, Random, 95% CI)	0.21 [0.01, 4.30]
29 Death, seizures, or both	3	1935	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.22, 3.55]
29.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	0.89 [0.22, 3.55]
29.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]
30 Death, long-term neurodevelopmental problem, or both	3	1935	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.20, 4.44]
30.1 Gestation from 36 weeks, FBS not required prior to study entry	2	1789	Risk Ratio (M-H, Random, 95% CI)	0.93 [0.20, 4.44]
30.2 Gestation from 36 weeks, FBS prior to study entry	1	146	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Comparison 4. Subgroup: fetal blood sampling: primary outcomes

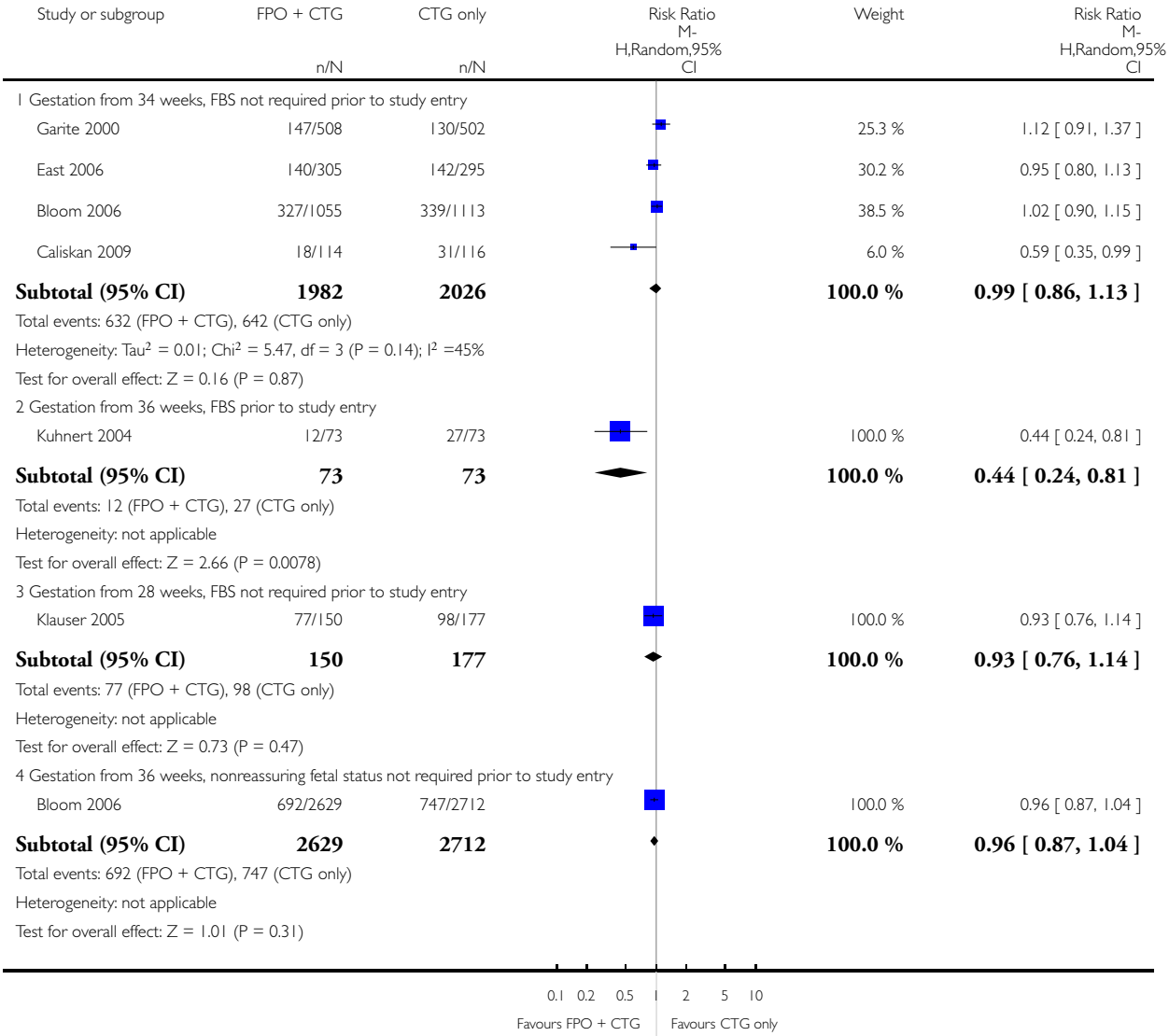
Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Caesarean section	1	198	Risk Ratio (M-H, Random, 95% CI)	1.23 [0.94, 1.60]
2 Neonatal seizures	1	198	Risk Ratio (M-H, Random, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Primary outcomes: FPO + CTG versus CTG only, Outcome 1 Caesarean section.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 1 Primary outcomes: FPO + CTG versus CTG only

Outcome: 1 Caesarean section



Analysis 1.2. Comparison 1 Primary outcomes: FPO + CTG versus CTG only, Outcome 2 Hypoxic-ischaemic encephalopathy.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 1 Primary outcomes: FPO + CTG versus CTG only

Outcome: 2 Hypoxic-ischaemic encephalopathy

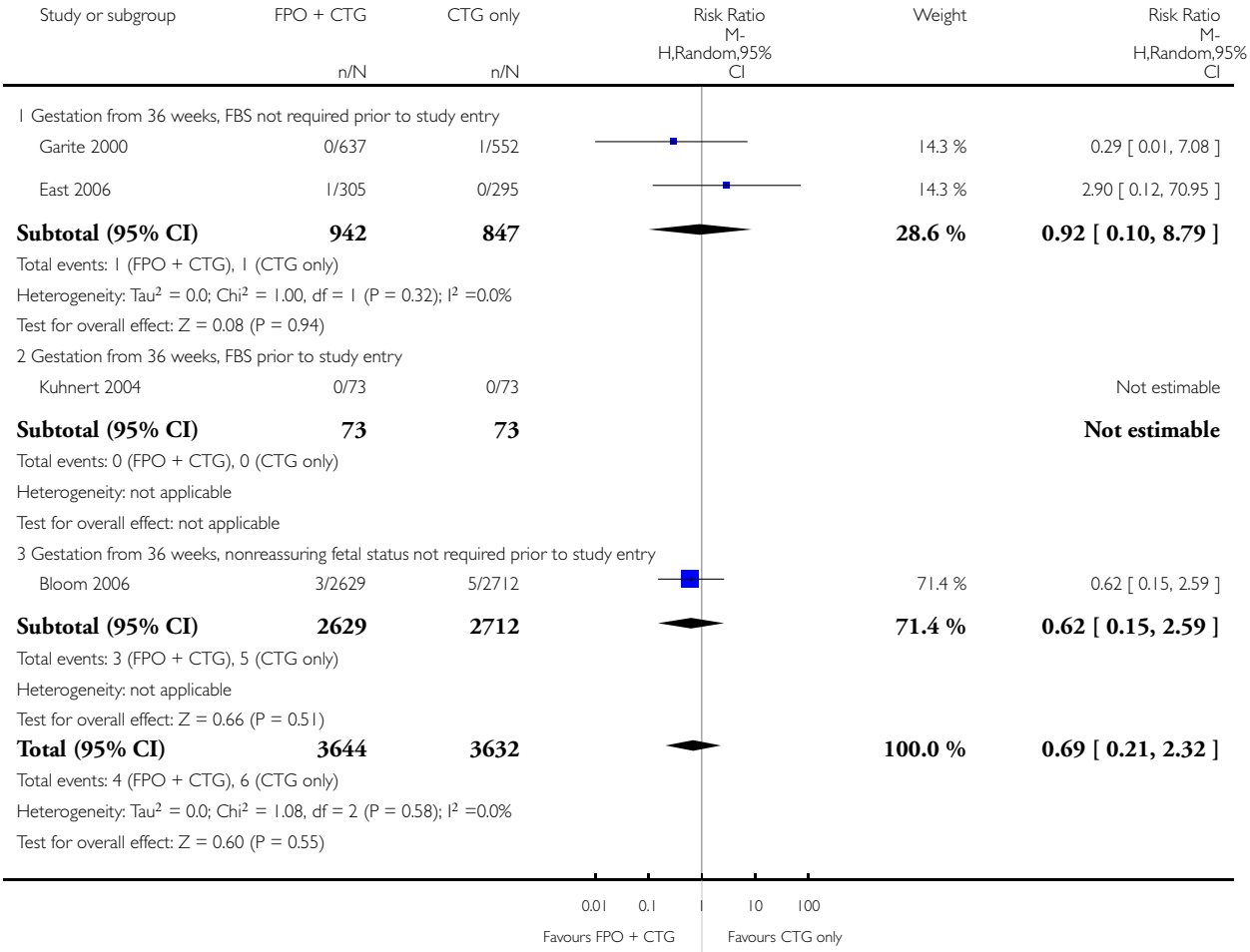
Study or subgroup	FPO + CTG n/N	CTG only n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry					
East 2006	0/305	0/295			Not estimable
Subtotal (95% CI)	**305**	**295**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
2 Gestation from 36 weeks, FBS prior to study entry					
Kuhnert 2004	0/73	0/73			Not estimable
Subtotal (95% CI)	**73**	**73**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry					
Bloom 2006	0/2629	1/2712		100.0 %	0.34 [0.01, 8.44]
Subtotal (95% CI)	**2629**	**2712**		**100.0 %**	**0.34 [0.01, 8.44]**
Total events: 0 (FPO + CTG), 1 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.65 (P = 0.51)					
Total (95% CI)	**3007**	**3080**		**100.0 %**	**0.34 [0.01, 8.44]**
Total events: 0 (FPO + CTG), 1 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.65 (P = 0.51)					

Analysis 1.3. Comparison 1 Primary outcomes: FPO + CTG versus CTG only, Outcome 3 Neonatal seizures.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 1 Primary outcomes: FPO + CTG versus CTG only

Outcome: 3 Neonatal seizures

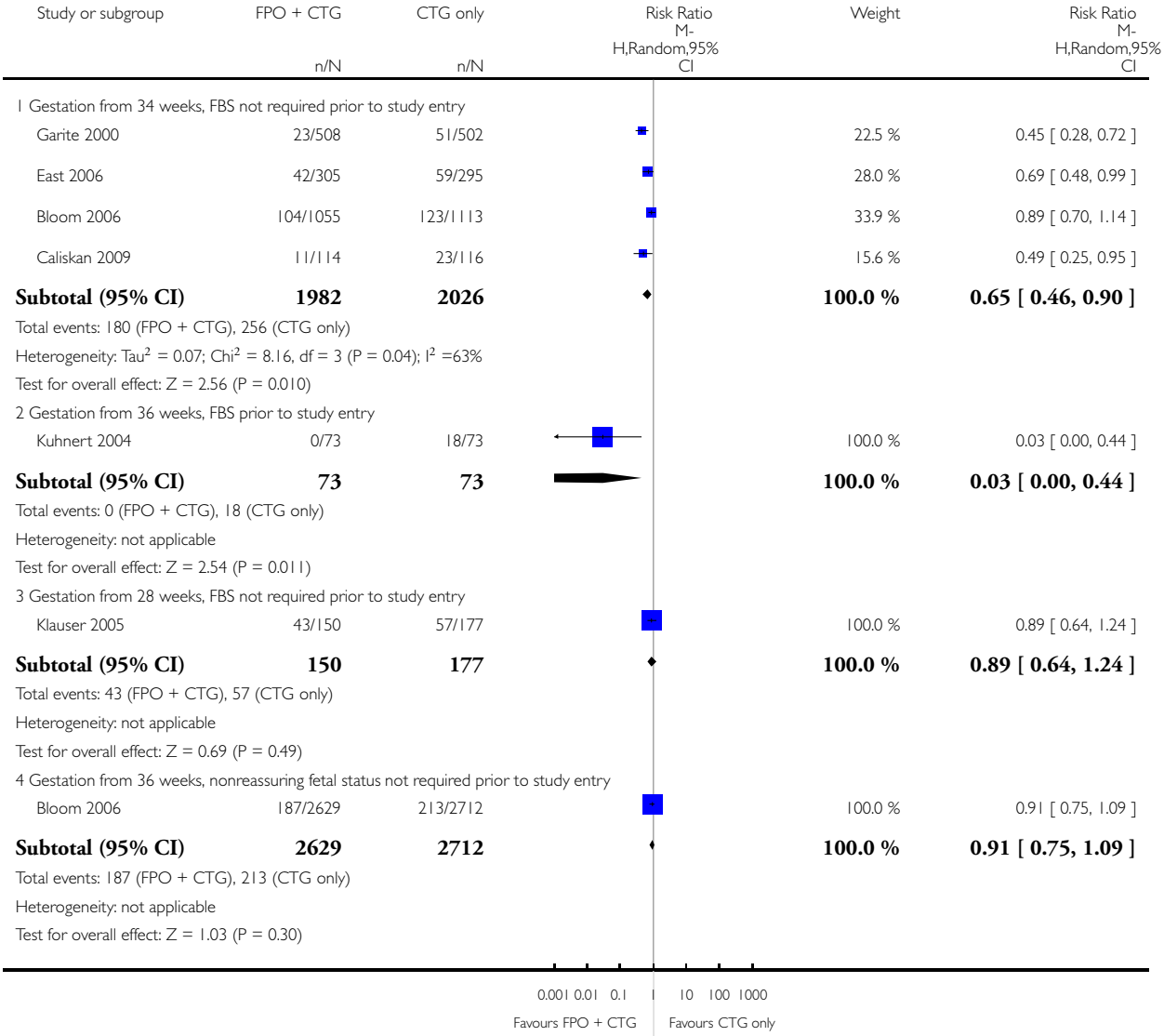


Analysis 2.5. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 5 Caesarean section for nonreassuring fetal status.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 5 Caesarean section for nonreassuring fetal status

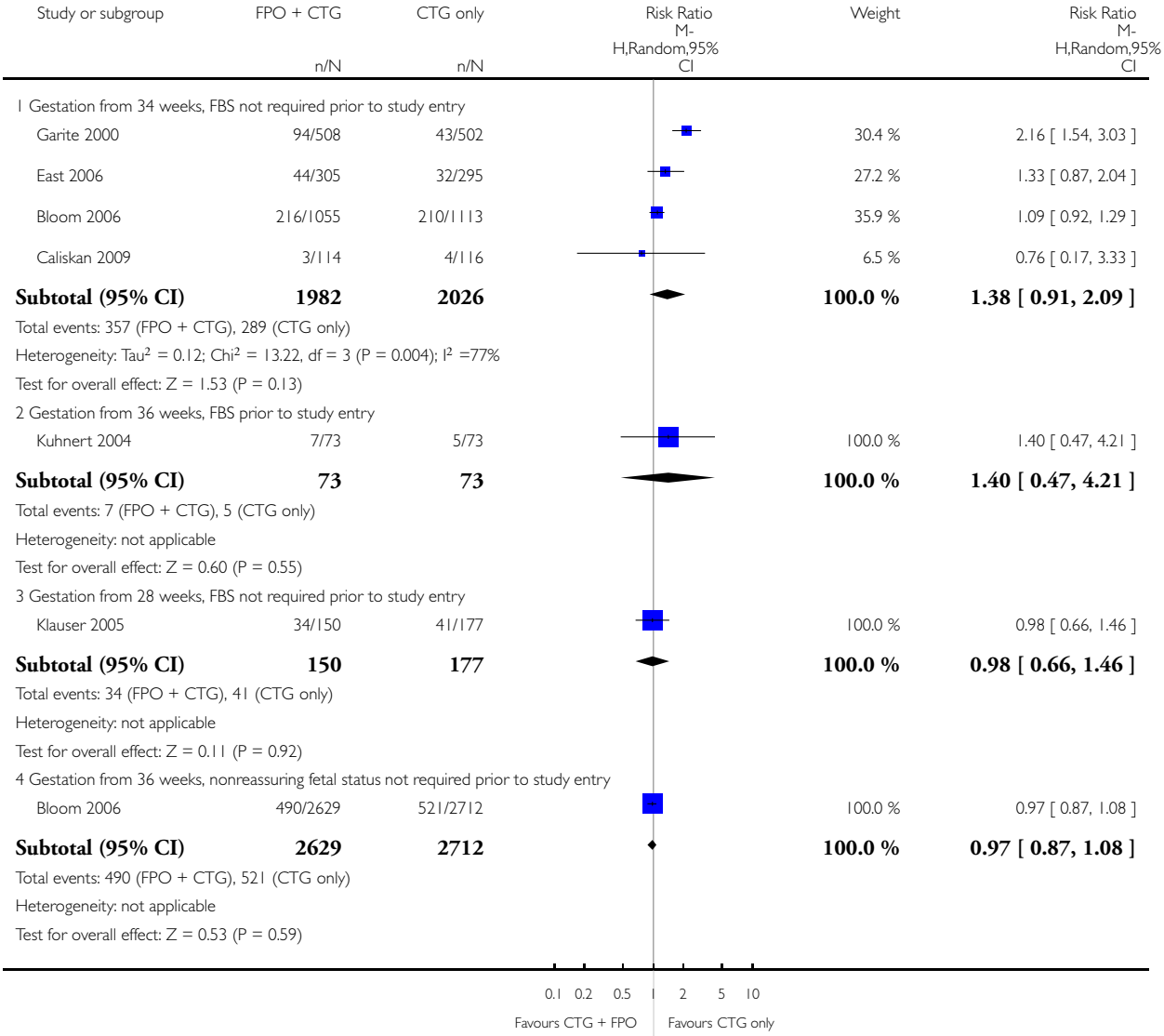


Analysis 2.6. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 6 Caesarean section for dystocia.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 6 Caesarean section for dystocia



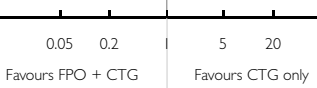
Analysis 2.7. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 7 Operative delivery (caesarean section, forceps, vacuum extraction) for all indications.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 7 Operative delivery (caesarean section, forceps, vacuum extraction) for all indications

Study or subgroup	FPO + CTG n/N	CTG only n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Gestation from 34 weeks, FBS not required prior to study entry					
Garite 2000	267/508	247/502		25.6 %	1.07 [0.95, 1.21]
East 2006	224/305	209/295		27.4 %	1.04 [0.94, 1.15]
Caliskan 2009	23/114	34/116		6.9 %	0.69 [0.43, 1.09]
Subtotal (95% CI)	**927**	**913**		**59.9 %**	**1.03 [0.92, 1.15]**
Total events: 514 (FPO + CTG), 490 (CTG only)					
Heterogeneity: $Tau^2 = 0.00$; $Chi^2 = 3.30$, df = 2 (P = 0.19); $I^2 = 39\%$					
Test for overall effect: Z = 0.45 (P = 0.65)					
2 Gestation from 36 weeks, FBS prior to study entry					
Kuhnert 2004	25/73	49/73		10.2 %	0.51 [0.36, 0.73]
Subtotal (95% CI)	**73**	**73**		**10.2 %**	**0.51 [0.36, 0.73]**
Total events: 25 (FPO + CTG), 49 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 3.70 (P = 0.00021)					
3 Gestation from 36 weeks, nonreassuring fetal status not required prior to study entry					
Bloom 2006	1072/2629	1147/2712		29.9 %	0.96 [0.90, 1.03]
Subtotal (95% CI)	**2629**	**2712**		**29.9 %**	**0.96 [0.90, 1.03]**
Total events: 1072 (FPO + CTG), 1147 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.12 (P = 0.26)					
Total (95% CI)	**3629**	**3698**		**100.0 %**	**0.92 [0.81, 1.06]**
Total events: 1611 (FPO + CTG), 1686 (CTG only)					
Heterogeneity: $Tau^2 = 0.02$; $Chi^2 = 18.80$, df = 4 (P = 0.00086); $I^2 = 79\%$					
Test for overall effect: Z = 1.12 (P = 0.26)					

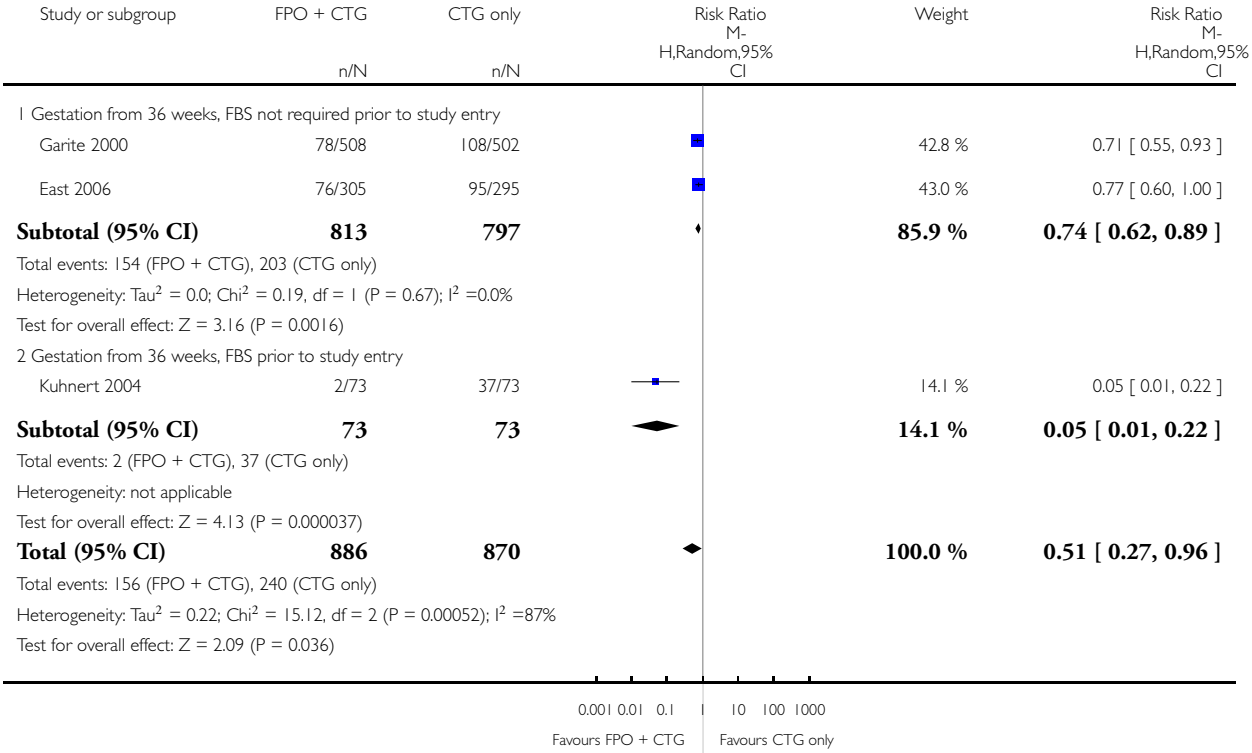


Analysis 2.8. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 8 Operative delivery (caesarean section, forceps, vacuum) for nonreassuring fetal status.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 8 Operative delivery (caesarean section, forceps, vacuum) for nonreassuring fetal status

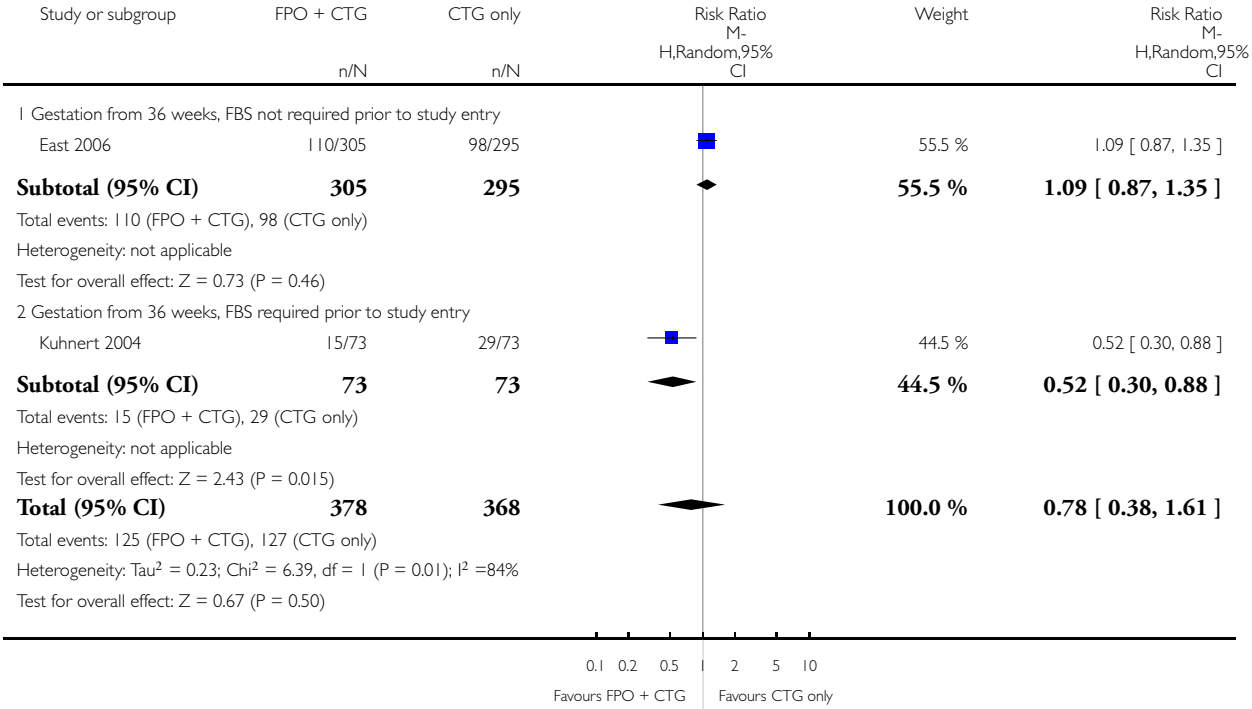


Analysis 2.9. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 9 Use of intrapartum antibiotics.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 9 Use of intrapartum antibiotics

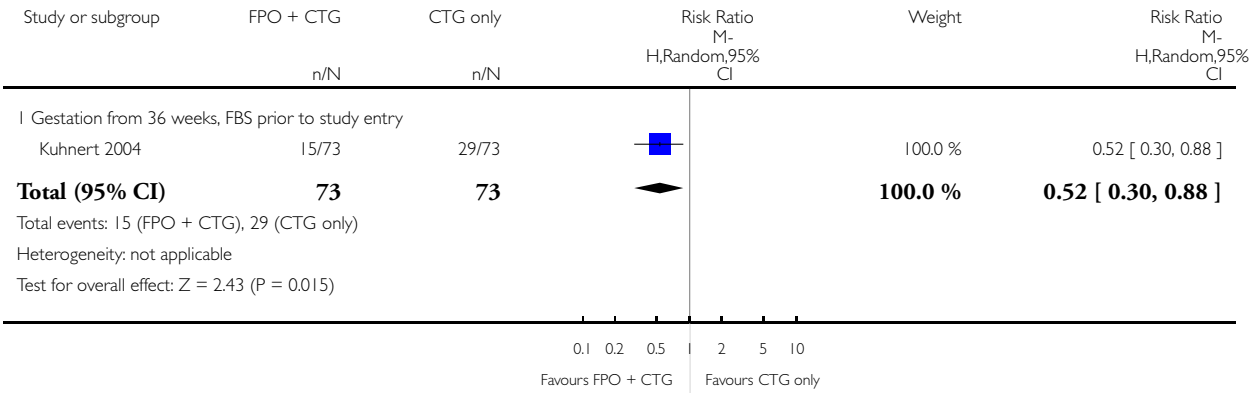


Analysis 2.10. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 10 Overall antibiotic use.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 10 Overall antibiotic use

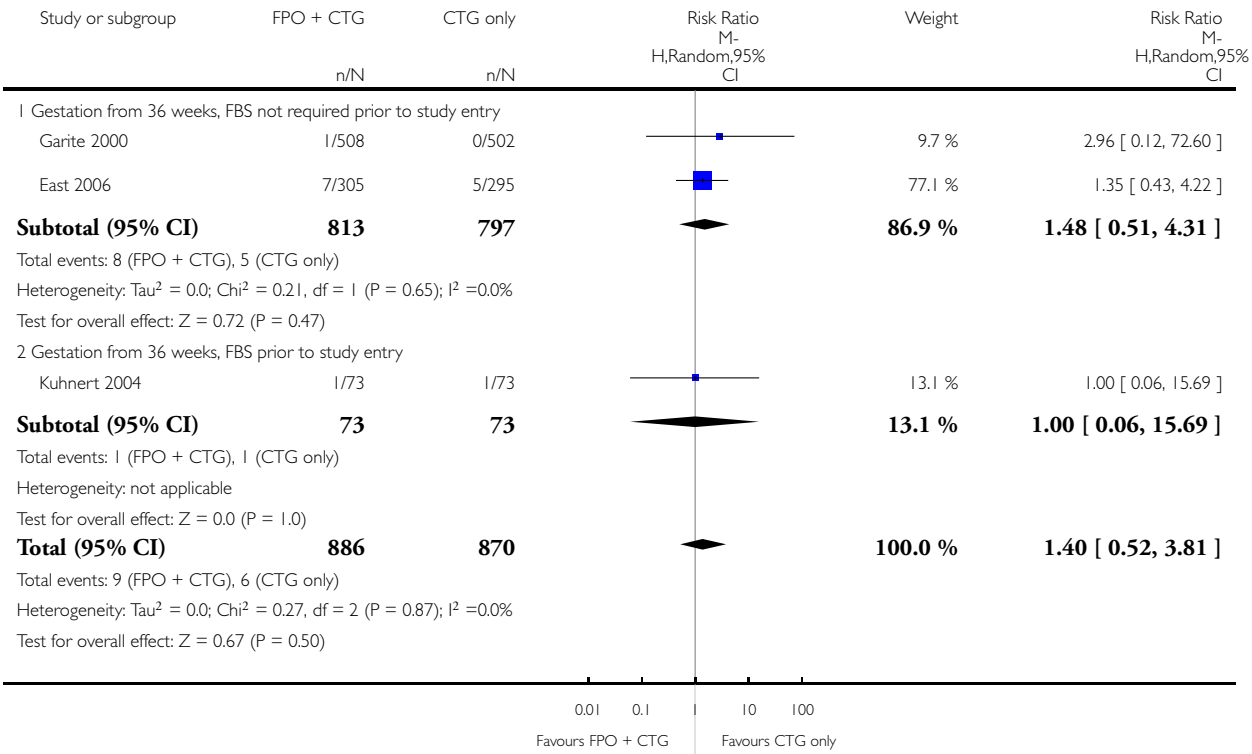


Analysis 2.11. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 11 Intrapartum haemorrhage.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 11 Intrapartum haemorrhage

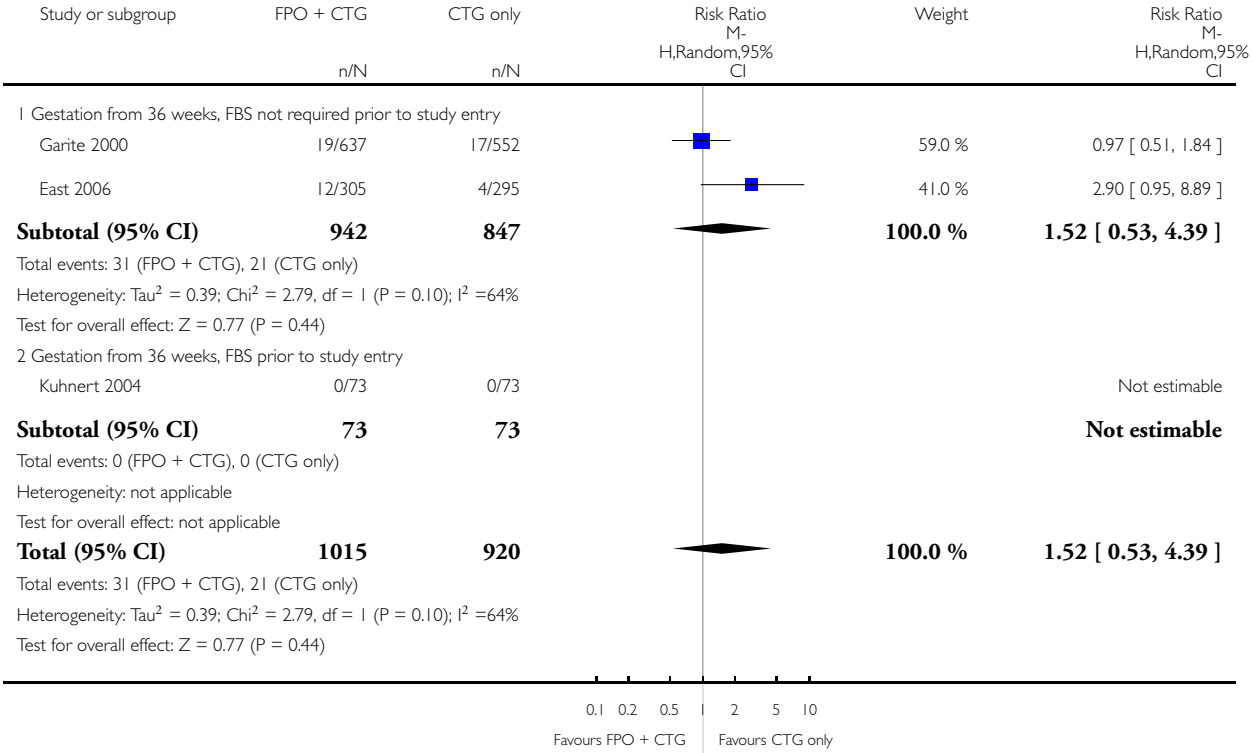


Analysis 2.12. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 12 Postpartum haemorrhage.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 12 Postpartum haemorrhage

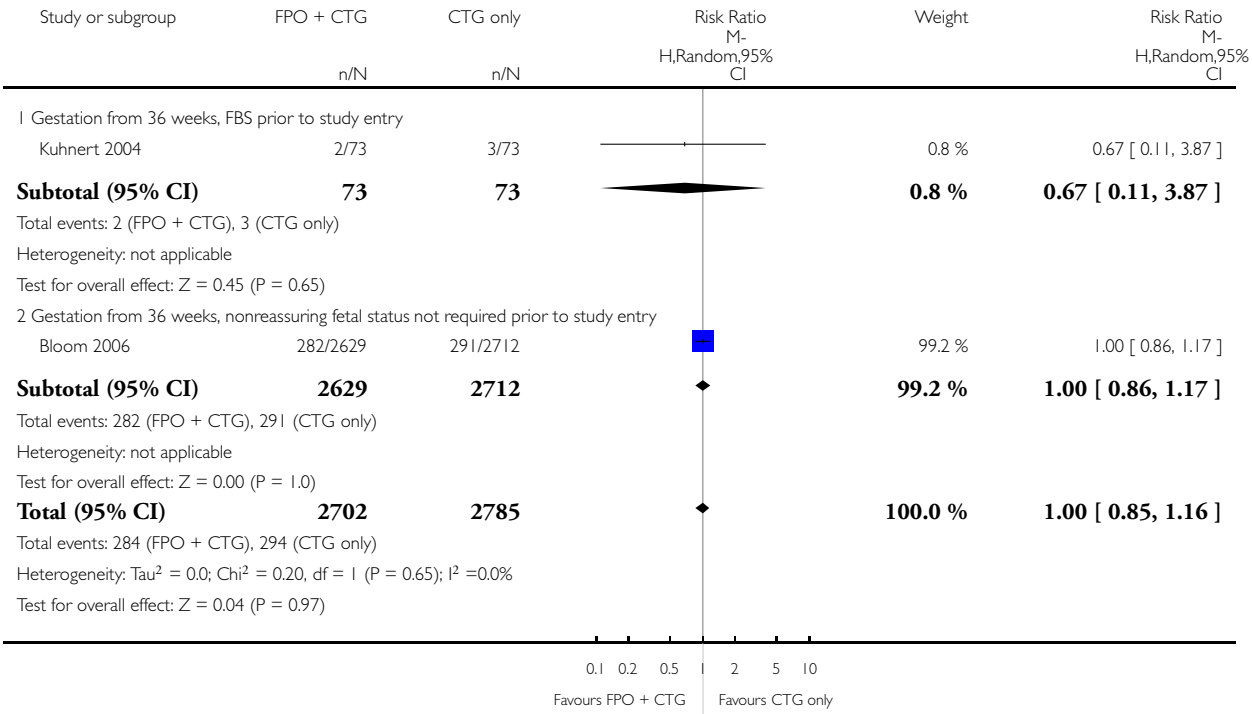


Analysis 2.13. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 13 Chorioamnionitis.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 13 Chorioamnionitis

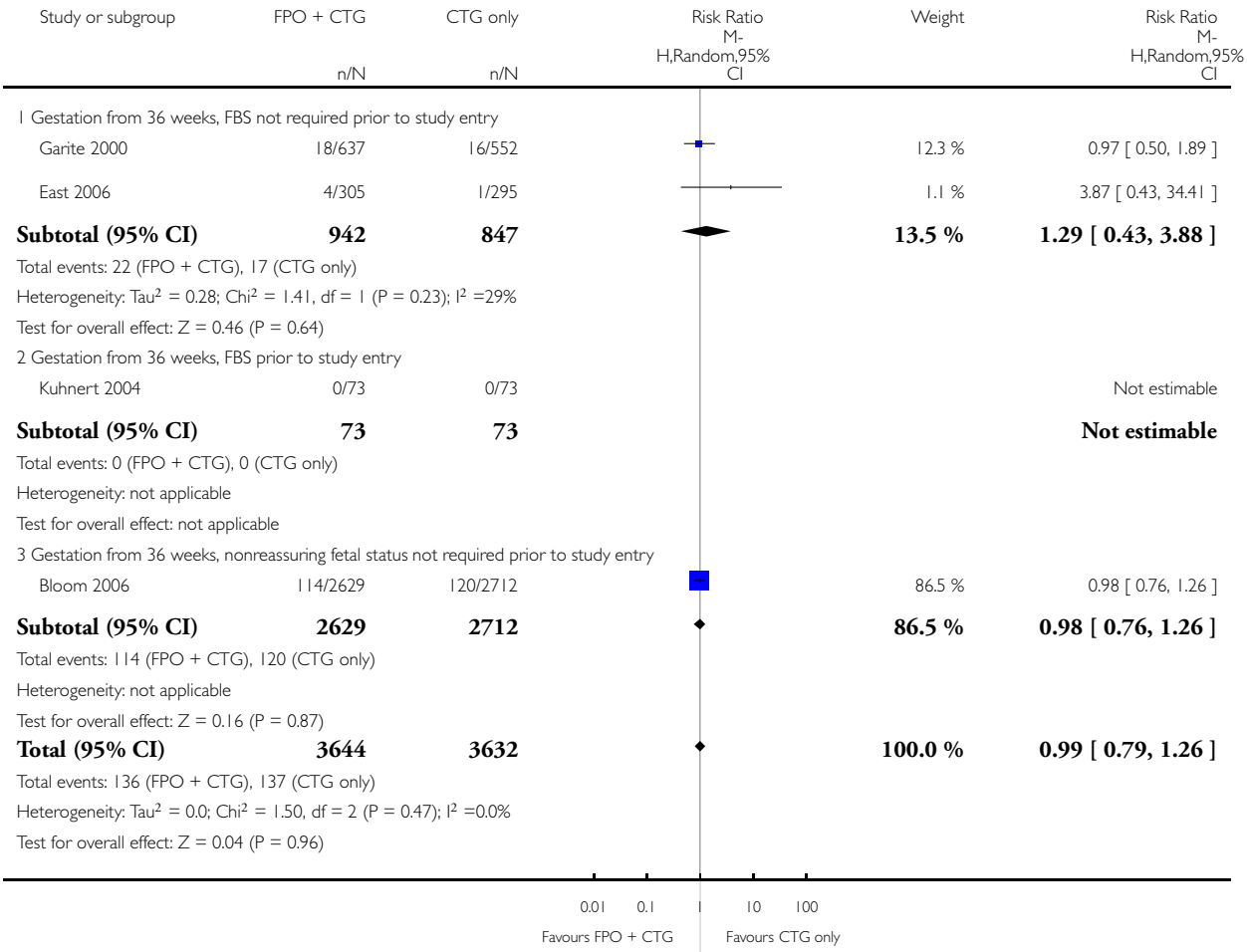


Analysis 2.14. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 14 Endometritis.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 14 Endometritis



Analysis 2.15. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 15 Uterine rupture.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 15 Uterine rupture

Study or subgroup	FPO + CTG n/N	CTG only n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry					
Garite 2000	2/637	2/552		100.0 %	0.87 [0.12, 6.13]
East 2006	0/305	0/295			Not estimable
Subtotal (95% CI)	**942**	**847**		**100.0 %**	**0.87 [0.12, 6.13]**
Total events: 2 (FPO + CTG), 2 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.14 (P = 0.89)					
2 Gestation from 36 weeks, FBS prior to study entry					
Kuhnert 2004	0/73	0/73			Not estimable
Subtotal (95% CI)	**73**	**73**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1015**	**920**		**100.0 %**	**0.87 [0.12, 6.13]**
Total events: 2 (FPO + CTG), 2 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.14 (P = 0.89)					

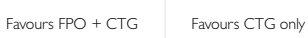
Analysis 2.16. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 16 Length of hospital stay (days).

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 16 Length of hospital stay (days)

Study or subgroup	FPO + CTG N	Mean(SD)	CTG only N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry							
East 2006	305	4.4 (1.86)	295	4.46 (1.85)		82.7 %	-0.06 [-0.36, 0.24]
Subtotal (95% CI)	**305**		**295**			**82.7 %**	**-0.06 [-0.36, 0.24]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.40 (P = 0.69)							
2 Gestation from 36 weeks, FBS prior to study entry							
Kuhnert 2004	73	4 (2)	73	4 (2)		17.3 %	0.0 [-0.65, 0.65]
Subtotal (95% CI)	**73**		**73**			**17.3 %**	**0.0 [-0.65, 0.65]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.0 (P = 1.0)							
Total (95% CI)	**378**		**368**			**100.0 %**	**-0.05 [-0.32, 0.22]**
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.03, df = 1 (P = 0.87); I^2 =0.0%							
Test for overall effect: Z = 0.36 (P = 0.72)							

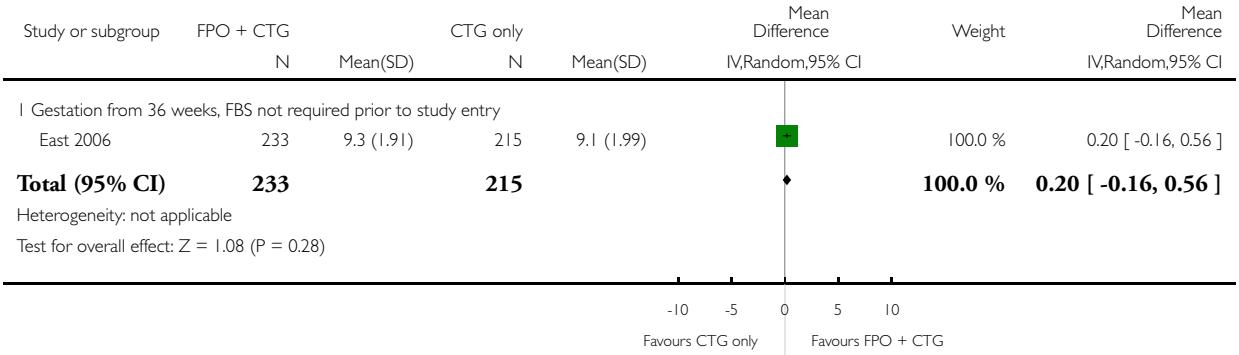


Analysis 2.17. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 17 Satisfaction with labour.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 17 Satisfaction with labour

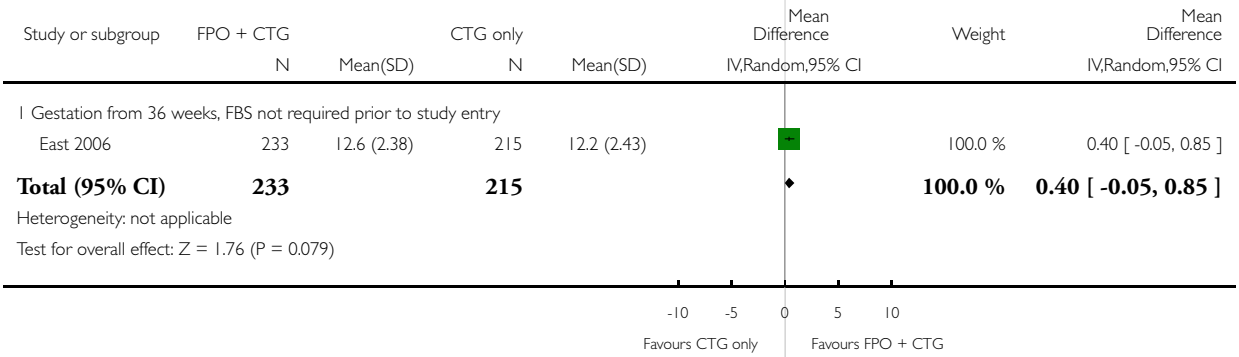


Analysis 2.18. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 18 Satisfaction with fetal monitoring in labour.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 18 Satisfaction with fetal monitoring in labour



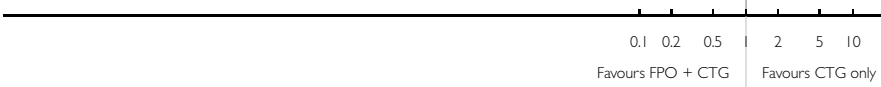
Analysis 2.19. Comparison 2 Secondary outcomes: maternal: FPO + CTG versus CTG only, Outcome 19 Death.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 2 Secondary outcomes: maternal: FPO + CTG versus CTG only

Outcome: 19 Death

Study or subgroup	FPO + CTG n/N	CTG only n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry					
Garite 2000	0/637	0/552			Not estimable
East 2006	0/305	0/295			Not estimable
Subtotal (95% CI)	**942**	**847**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
2 Gestation from 36 weeks, FBS prior to study entry					
Kuhnert 2004	0/73	0/73			Not estimable
Subtotal (95% CI)	**73**	**73**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1015**	**920**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					



Analysis 3.20. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 20 Skin trauma.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 20 Skin trauma

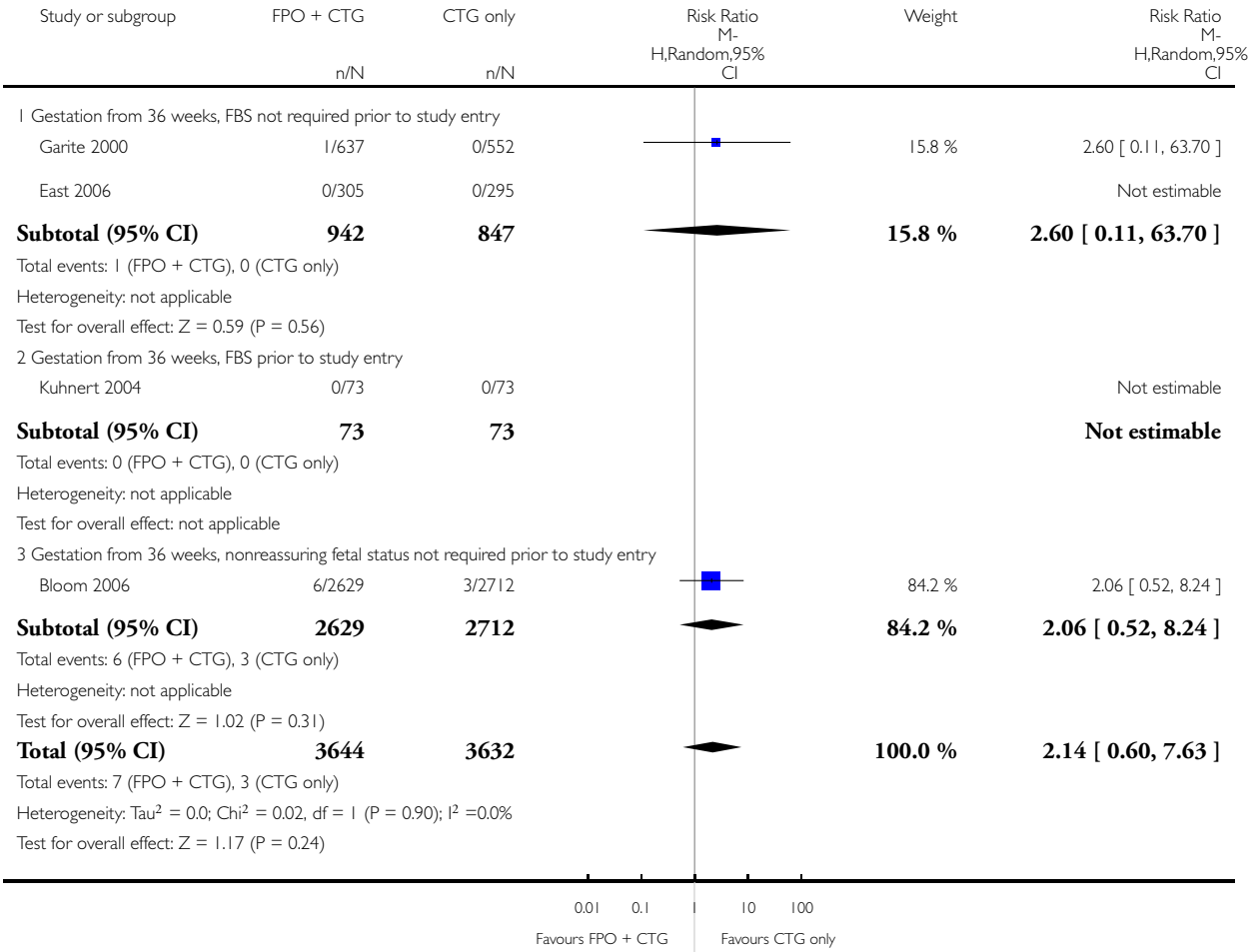
Study or subgroup	FPO + CTG n/N	CTG only n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry					
East 2006	3/305	4/295		100.0 %	0.73 [0.16, 3.21]
Subtotal (95% CI)	**305**	**295**		**100.0 %**	**0.73 [0.16, 3.21]**
Total events: 3 (FPO + CTG), 4 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.42 (P = 0.67)					
2 Gestation from 36 weeks, FBS prior to study entry					
Kuhnert 2004	0/73	0/73			Not estimable
Subtotal (95% CI)	**73**	**73**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**378**	**368**		**100.0 %**	**0.73 [0.16, 3.21]**
Total events: 3 (FPO + CTG), 4 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 0.42 (P = 0.67)					

Analysis 3.21. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 21 Apgar score less than 4 at 5 minutes.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 21 Apgar score less than 4 at 5 minutes

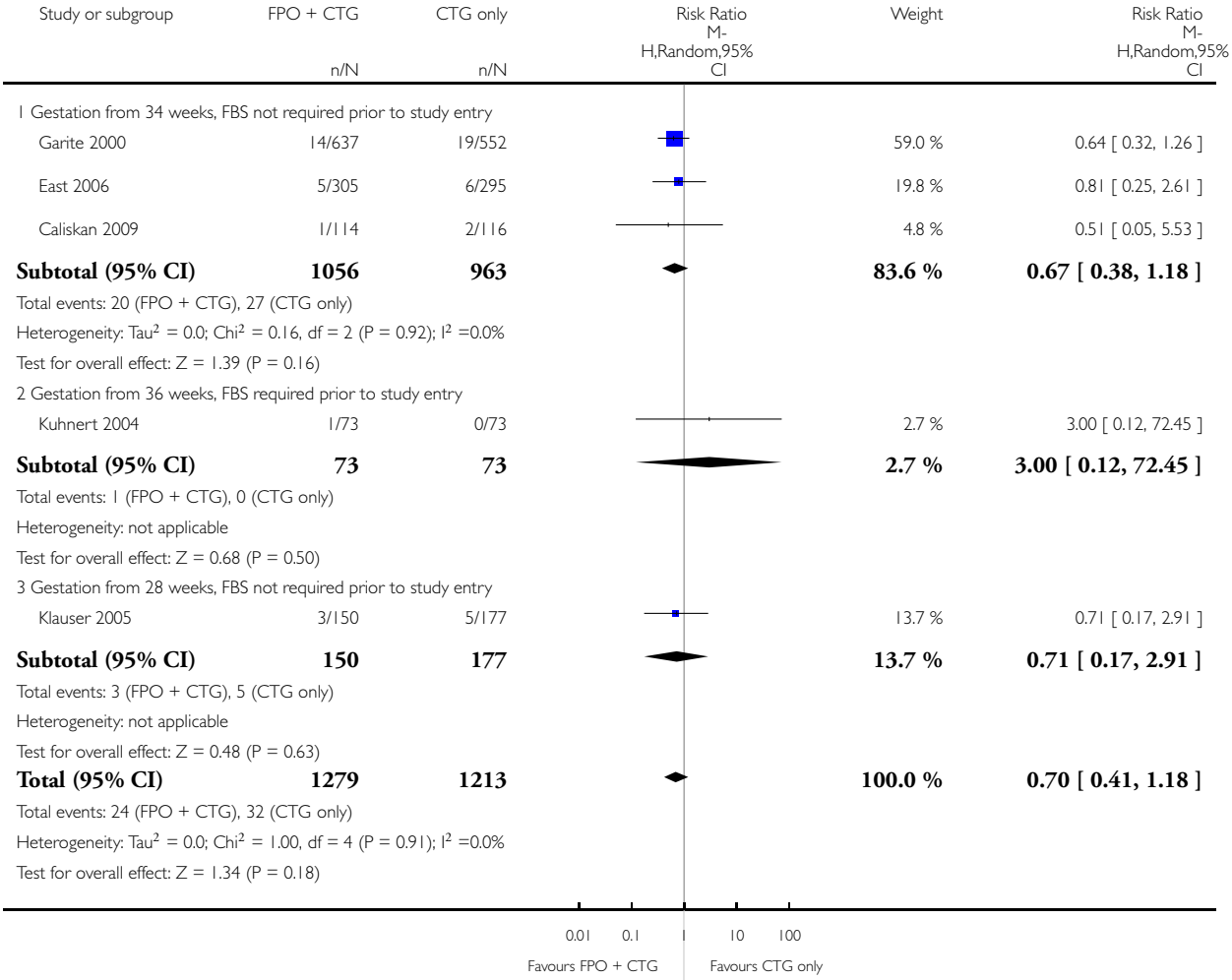


Analysis 3.22. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 22 Apgar score less than 7 at 5 minutes.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 22 Apgar score less than 7 at 5 minutes



Analysis 3.23. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 23 Umbilical arterial pH less than 7.10.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 23 Umbilical arterial pH less than 7.10

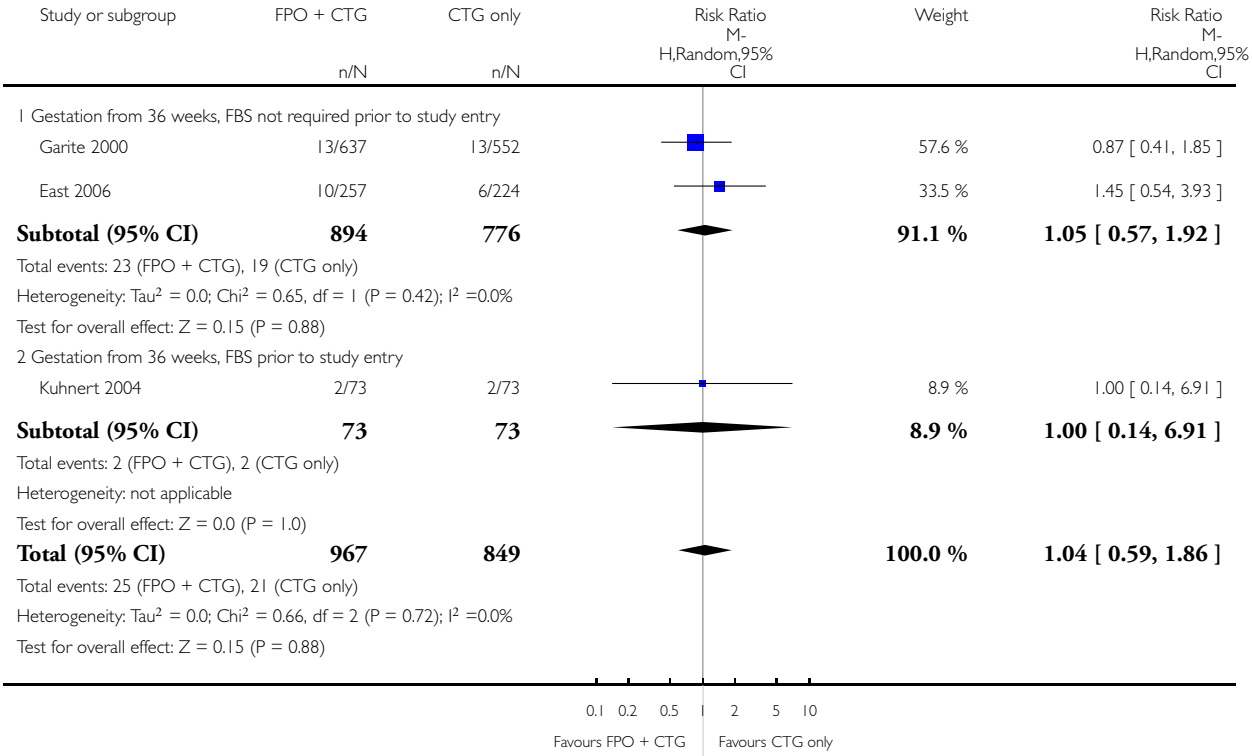
Study or subgroup	FPO + CTG n/N	CTG only n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry					
Garite 2000	32/637	27/552		44.9 %	1.03 [0.62, 1.69]
East 2006	13/272	12/240		29.1 %	0.96 [0.44, 2.05]
Subtotal (95% CI)	**909**	**792**		**74.0 %**	**1.01 [0.66, 1.53]**
Total events: 45 (FPO + CTG), 39 (CTG only)					
Heterogeneity: $Tau^2 = 0.0$; $Chi^2 = 0.02$, df = 1 (P = 0.88); $I^2 = 0.0\%$					
Test for overall effect: Z = 0.02 (P = 0.98)					
2 Gestation from 36 weeks, FBS prior to study entry					
Kuhnert 2004	1/73	6/73		5.9 %	0.17 [0.02, 1.35]
Subtotal (95% CI)	**73**	**73**		**5.9 %**	**0.17 [0.02, 1.35]**
Total events: 1 (FPO + CTG), 6 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.68 (P = 0.093)					
3 Gestation from 28 weeks, FBS not required prior to study entry					
Klauser 2005	5/150	13/177		20.1 %	0.45 [0.17, 1.24]
Subtotal (95% CI)	**150**	**177**		**20.1 %**	**0.45 [0.17, 1.24]**
Total events: 5 (FPO + CTG), 13 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: Z = 1.54 (P = 0.12)					
Total (95% CI)	**1132**	**1042**		**100.0 %**	**0.77 [0.45, 1.30]**
Total events: 51 (FPO + CTG), 58 (CTG only)					
Heterogeneity: $Tau^2 = 0.10$; $Chi^2 = 4.51$, df = 3 (P = 0.21); $I^2 = 33\%$					
Test for overall effect: Z = 0.98 (P = 0.33)					

Analysis 3.24. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 24 Umbilical arterial base excess less than -12.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 24 Umbilical arterial base excess less than -12

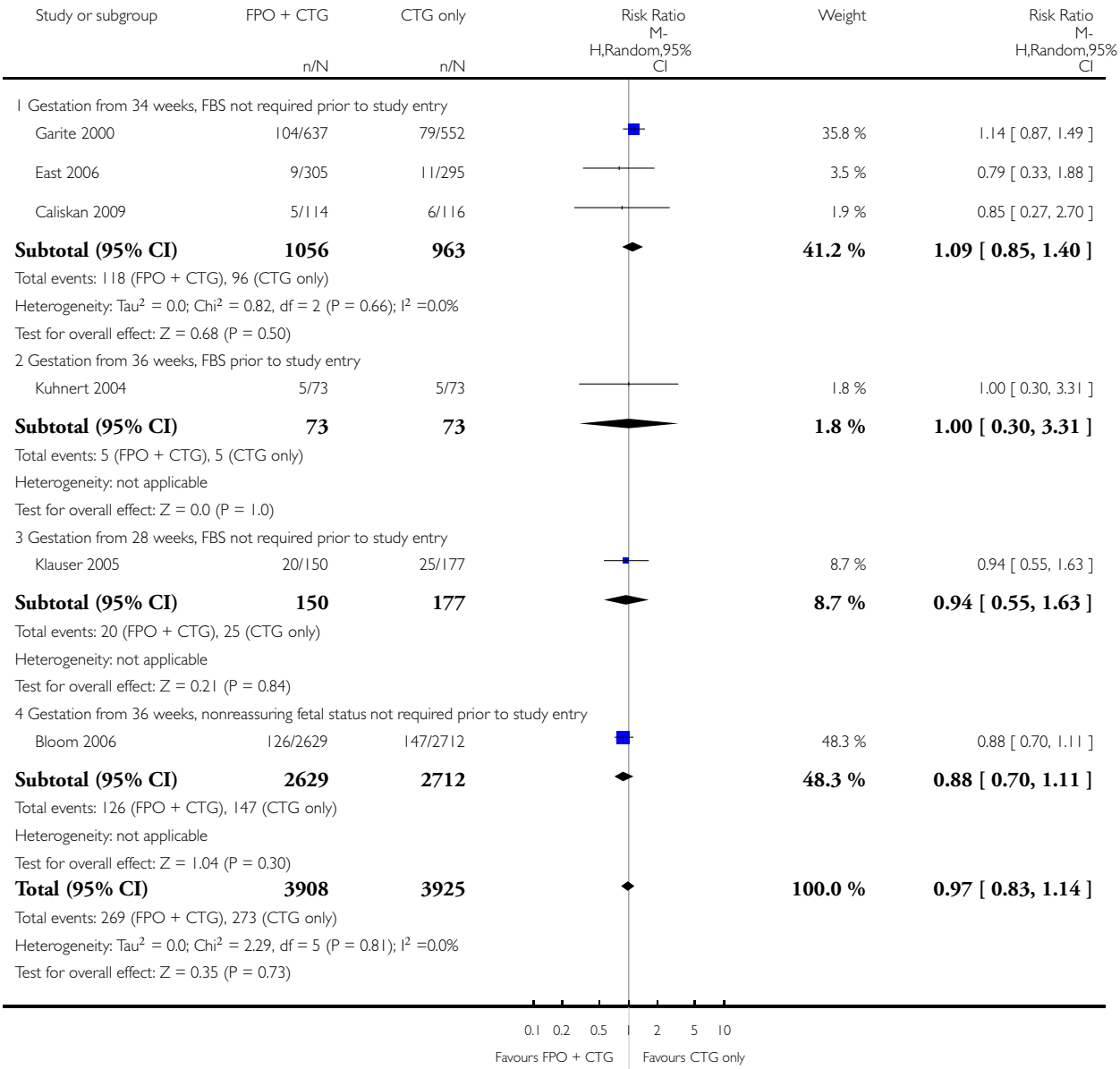


Analysis 3.25. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 25 Admission to neonatal intensive care unit.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 25 Admission to neonatal intensive care unit



Analysis 3.26. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 26 Length of hospital stay (days).

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 26 Length of hospital stay (days)

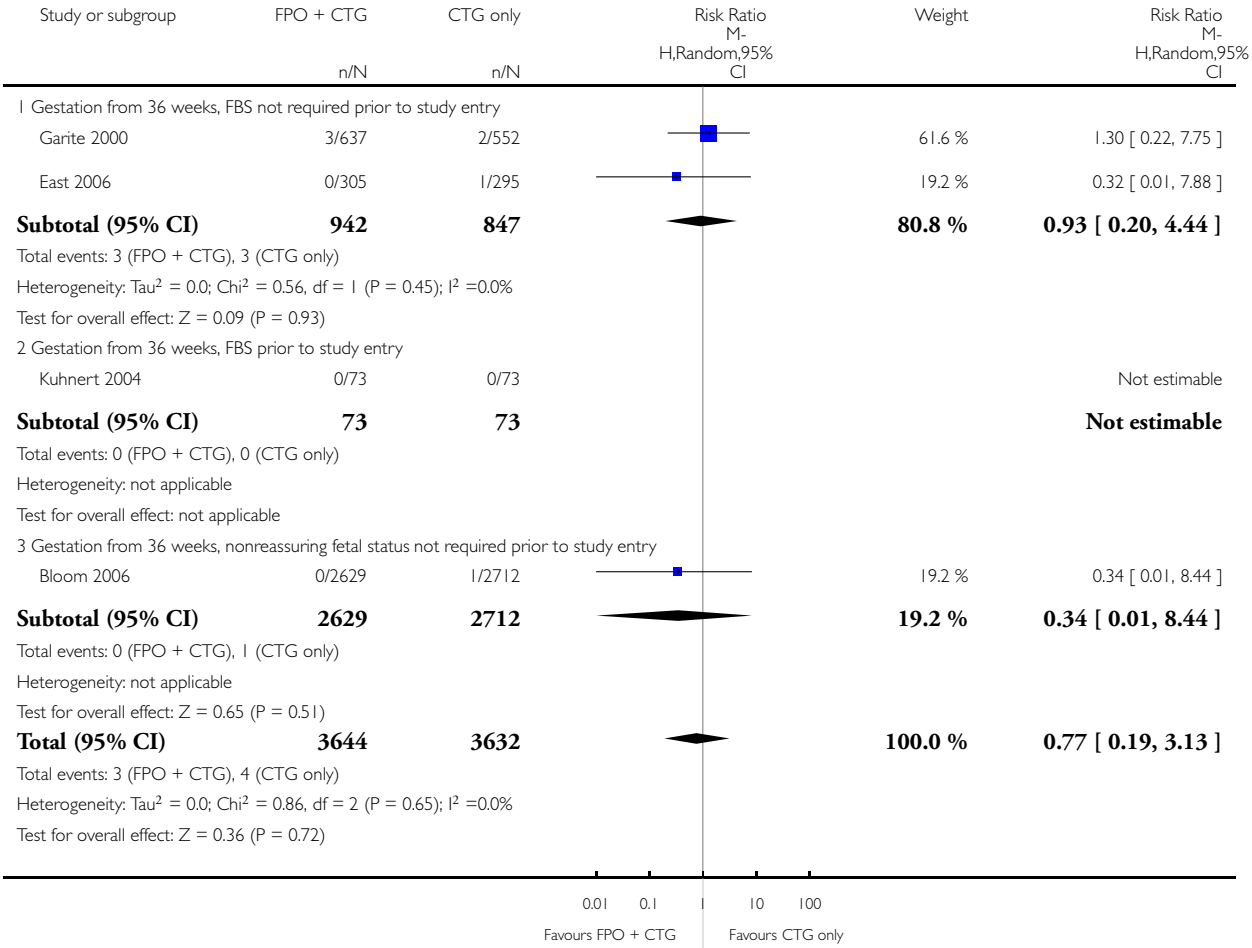
Study or subgroup	FPO + CTG N	Mean(SD)	CTG only N	Mean(SD)	Mean Difference IV,Random,95% CI	Weight	Mean Difference IV,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry							
East 2006	305	3.74 (2.35)	295	3.74 (1.74)		49.1 %	0.0 [-0.33, 0.33]
Subtotal (95% CI)	**305**		**295**			**49.1 %**	**0.0 [-0.33, 0.33]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.0 (P = 1.0)							
2 Gestation from 36 weeks, FBS prior to study entry							
Kuhnert 2004	73	2 (1)	73	2 (1)		50.9 %	0.0 [-0.32, 0.32]
Subtotal (95% CI)	**73**		**73**			**50.9 %**	**0.0 [-0.32, 0.32]**
Heterogeneity: not applicable							
Test for overall effect: Z = 0.0 (P = 1.0)							
Total (95% CI)	**378**		**368**			**100.0 %**	**0.0 [-0.23, 0.23]**
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.0, df = 1 (P = 1.00); I^2 =0.0%							
Test for overall effect: Z = 0.0 (P = 1.0)							

Analysis 3.27. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 27 Death.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 27 Death

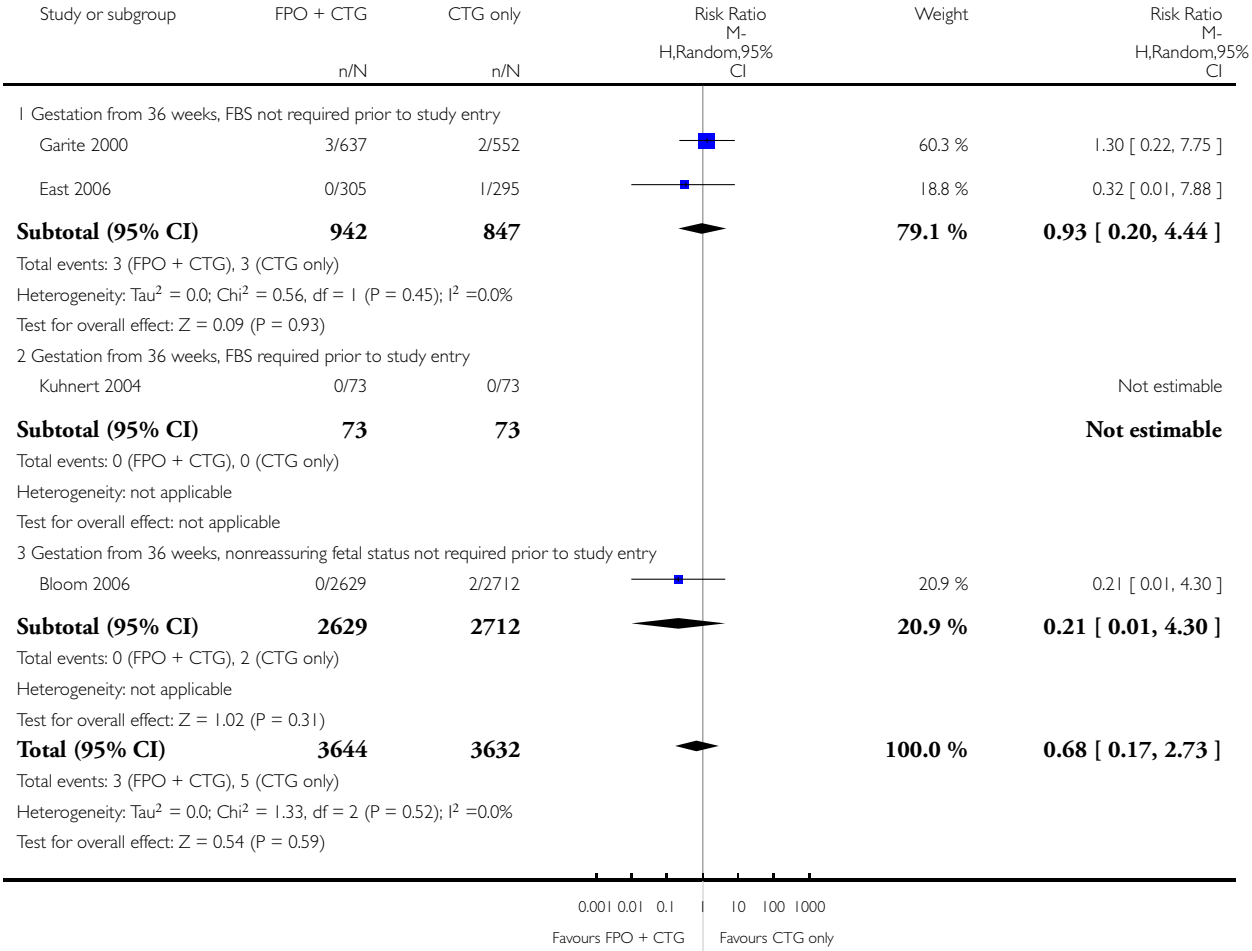


Analysis 3.28. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 28 Death, hypoxic-ischaemic encephalopathy, or both.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 28 Death, hypoxic-ischaemic encephalopathy, or both

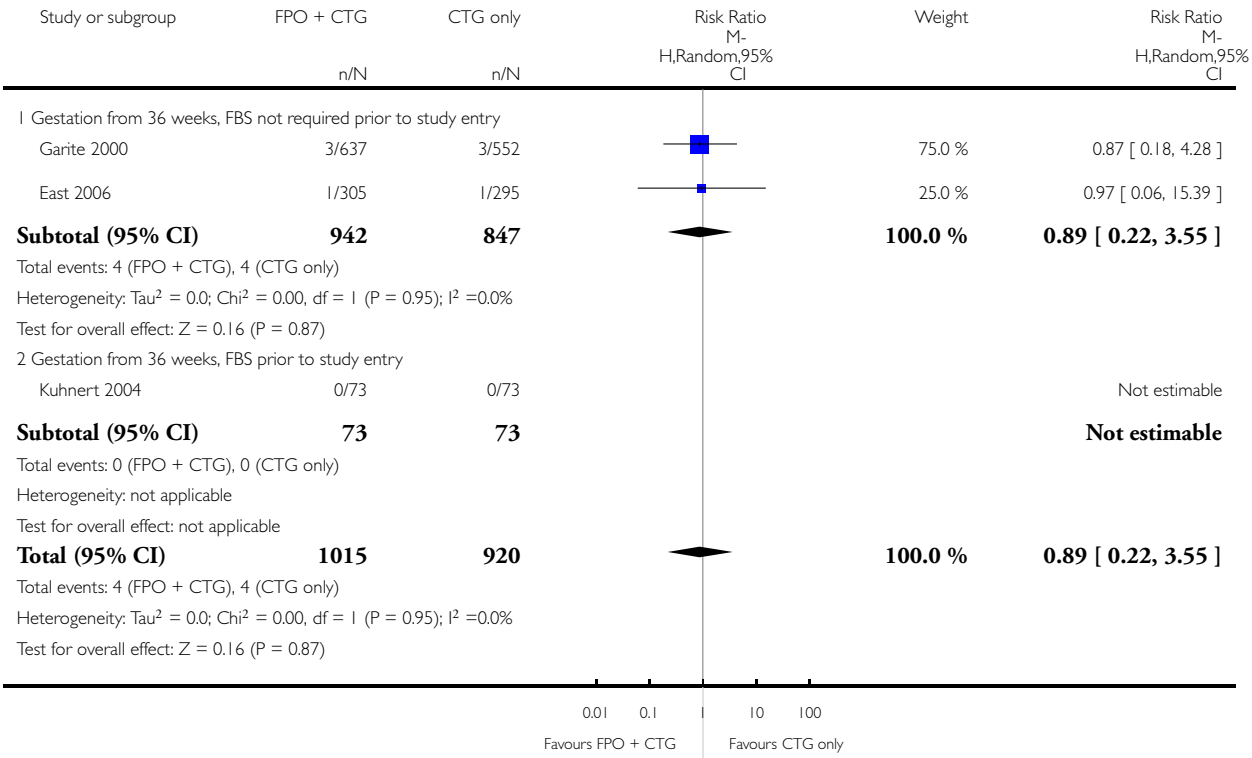


Analysis 3.29. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 29 Death, seizures, or both.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 29 Death, seizures, or both



Analysis 3.30. Comparison 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only, Outcome 30 Death, long-term neurodevelopmental problem, or both.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 3 Secondary outcomes: fetal/neonatal: FPO + CTG versus CTG only

Outcome: 30 Death, long-term neurodevelopmental problem, or both

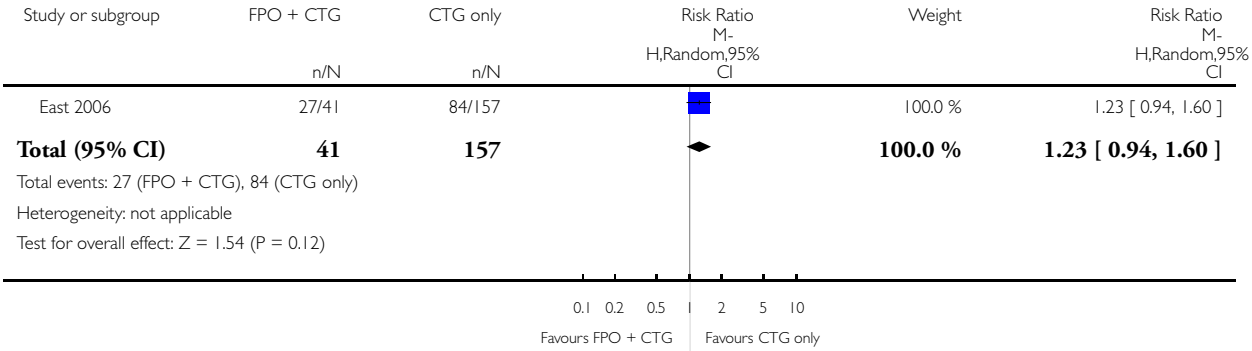
Study or subgroup	FPO + CTG n/N	CTG only n/N	Risk Ratio M-H,Random,95% CI	Weight	Risk Ratio M-H,Random,95% CI
1 Gestation from 36 weeks, FBS not required prior to study entry					
Garite 2000	3/637	2/552		76.2 %	1.30 [0.22, 7.75]
East 2006	0/305	1/295		23.8 %	0.32 [0.01, 7.88]
Subtotal (95% CI)	**942**	**847**		**100.0 %**	**0.93 [0.20, 4.44]**
Total events: 3 (FPO + CTG), 3 (CTG only)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.56, df = 1 (P = 0.45); I^2 =0.0%					
Test for overall effect: Z = 0.09 (P = 0.93)					
2 Gestation from 36 weeks, FBS prior to study entry					
Kuhnert 2004	0/73	0/73			Not estimable
Subtotal (95% CI)	**73**	**73**			**Not estimable**
Total events: 0 (FPO + CTG), 0 (CTG only)					
Heterogeneity: not applicable					
Test for overall effect: not applicable					
Total (95% CI)	**1015**	**920**		**100.0 %**	**0.93 [0.20, 4.44]**
Total events: 3 (FPO + CTG), 3 (CTG only)					
Heterogeneity: Tau^2 = 0.0; Chi^2 = 0.56, df = 1 (P = 0.45); I^2 =0.0%					
Test for overall effect: Z = 0.09 (P = 0.93)					

Analysis 4.1. Comparison 4 Subgroup: fetal blood sampling: primary outcomes, Outcome 1 Caesarean section.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 4 Subgroup: fetal blood sampling: primary outcomes

Outcome: 1 Caesarean section

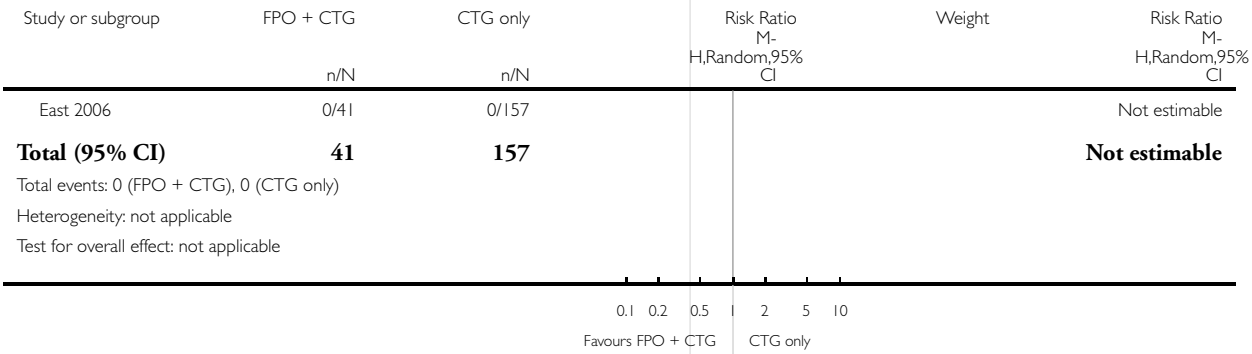


Analysis 4.2. Comparison 4 Subgroup: fetal blood sampling: primary outcomes, Outcome 2 Neonatal seizures.

Review: Fetal pulse oximetry for fetal assessment in labour

Comparison: 4 Subgroup: fetal blood sampling: primary outcomes

Outcome: 2 Neonatal seizures



APPENDICES

Appendix 1. Methods used to assess trials included in previous versions of this review

The following methods were used to assess Bloom 2006; East 2006; Garite 2000; Klauser 2005; Kuhnert 2004.
We used the standard methods of the Cochrane Collaboration as described in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2005). At least two authors (Chris East (CE), Fung Yee Chan (FYC), Lisa Begg (LB), Paul Colditz (PC)) assessed trials under consideration for appropriateness of inclusion and methodological quality without consideration of their results. LB assessed, in particular, the quality and findings of the trials for which the remaining authors were co-investigators (East 2006). There were no differences of opinion requiring resolution by an alternative author. Blinding of trial authorship was not undertaken.

Assessment of trial quality

We considered four major sources of potential bias and methods or avoidance of these biases 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.
We assigned a quality rating for allocation concealment, using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions (Higgins 2005): (A) adequate; (B) unclear; (C) inadequate; or (D) not used. A quality rating of (A) = yes; (B) = cannot tell; or (C) = no, was assigned to the other quality components (blinding of intervention, completeness of follow up and blinding of outcome assessment).
We made an a priori decision to exclude trials where outcome data were unavailable for more than 20% of participants.

Data management

We sought additional information from the authors of three trials (*see* 'Characteristics of included studies' table).
At least two independent authors (CE, FYC, LB, PC) performed data extraction and any disagreements were to have been resolved by discussion with an alternative author. There were no disagreements. Analyses were performed on an intention-to-treat basis.
We reported mean differences (and 95% confidence intervals) for continuous variables with reported data. For categorical outcomes, the relative risks (and 95% confidence intervals) were reported.

Data analysis

The differences in entry criteria for the reported studies made combined statistical analysis problematic. We addressed this by considering the following analyses:
(A) nonreassuring fetal heart rate prior to study entry:
(i) gestation from 36 weeks, fetal blood sampling (fetal blood sampling) not required prior to study entry;
(ii) gestation from 36 weeks, fetal blood sampling prior to study entry;
(iii) gestation from 28 weeks, fetal blood sampling not required prior to study entry; and
(B) gestation from 36 weeks, nonreassuring fetal status not required prior to study entry.
Sensitivity analyses were conducted to evaluate the effect of trial quality: separate analysis of different types of studies within each outcome allowed inclusion of all identified studies, regardless of trial quality. Heterogeneity was addressed by the use of separate analyses of different types of studies within each analysis and random-effects modelling.
We planned subgroup analyses, to be conducted separately for singleton and multiple pregnancies as data permitted, for the primary outcomes as follows.
Fetal pulse oximetry compared with:
(i) fetal heart rate monitoring by:

- intermittent auscultation;
- intermittent cardiotocography;
- continuous cardiotocography;
- continuous cardiotocography and fetal scalp stimulation;
- continuous cardiotocography and fetal electrocardiogram (ECG) analysis (ST segment);
- continuous cardiotocography and fetal ECG analysis (PR interval); and

(ii) fetal blood sampling for blood gas analysis.
Several trials indicated that fetal blood sampling was performed (East 2006; Garite 2000; Kuhnert 2004). However, data were only available to allow for one of these to be included in a subgroup analysis (East 2006). None of the remaining subgroup analyses were conducted, as we were unable to identify trials that addressed these questions.

Appendix 2. Search strategies

Authors searched MEDLINE (1994 to May 2010), EMBASE (1994 to May 2010) and Current Contents (1994 to May 2010): searches were conducted from 1994 onwards as pulse oximetry technology calibrated for the fetal environment has only been available since 1994. Searches were conducted using search terms: (labour OR labor OR intrapartum) AND (oximetry OR pulse oximetry OR oxygen saturation) AND (clinical trial phase 1 OR clinical trial phase II OR clinical trial phase III OR controlled clinical trial OR randomized controlled trial OR randomised controlled trial) AND (fetal distress OR fetal heart OR fetal monitoring OR nonreassuring OR non-reassuring).

F E E D B A C K

Thornton, July 2006

Summary

The abstract states 'Use of fetal pulse oximetry with CTG decreased operative delivery (caesarean section, forceps, vacuum) for nonreassuring fetal status (RR 0.71, 95% CI 0.55 to 0.93) compared with CTG alone.'
The results text also states 'There was a statistically significant decrease in operative delivery (caesarean section, forceps or vacuum birth) for nonreassuring fetal status (RR 0.71, 95% CI 0.55 to 0.93).
But the results tables show a Relative Risk (Fixed) 95% CI 1.07 [0.95, 1.21]. Am I missing something, or has there been a mistake?
(Summary of comment from Jim Thornton, July 2006)

Reply

The data in the text are correct. The data quoted from the results table refer to the outcome 'operative delivery (caesarean section, forceps or vacuum birth)', which is for all indications; the data quoted in the text are for 'operative delivery (caesarean section, forceps or vacuum birth) for nonreassuring fetal status' and are correct.
To help clarify this, the outcome in the review now includes the wording 'for all indications'.
(Summary of response from Christine East, November 2006)

Contributors

Feedback: Jim Thornton
Reply: Christine East

WHAT'S NEW

Last assessed as up-to-date: 18 May 2010.

Date	Event	Description
11 September 2012	Amended	Contact details updated.

HISTORY

Protocol first published: Issue 1, 2003

Review first published: Issue 4, 2004

Date	Event	Description
31 May 2010	New search has been performed	One new trial added to the review. This did not change the conclusions of the review. Prof FY Chan removed from authorship (deceased 2007) although previous input gratefully recognised
1 October 2009	Amended	Search updated. Five reports added to Studies awaiting classification (Caliskan 2009a; East 2006b; Prieto 2008; Rouse 2008; Rouse 2009).
10 November 2008	Amended	Contact details updated.
18 February 2008	Amended	Converted to new review format.
17 January 2007	New citation required and conclusions have changed	Search updated in November 2006. We identified and included four new trials (Bloom 2006; East 2006; Klauser 2005; Kuhnert 2004). The original version of this review concluded that the addition of fetal pulse oximetry to cardiotocography decreased the caesarean section and operative delivery rates for nonreassuring fetal status, with no difference in overall caesarean section rates. The addition of the four new trials confirmed these conclusions when nonreassuring fetal status was identified prior to study entry. When nonreassuring fetal status was not present prior to study entry, knowledge of fetal pulse oximetry values made no difference to caesarean section rates for nonreassuring fetal status or for all indications

CONTRIBUTIONS OF AUTHORS

C East compiled the protocol and original review with input from all co-authors. L Begg joined the authorship in 2006 for the 2007 update. FY Chan died in 2007 and has not been replaced on the authorship in the 2010 update.

C East, FY Chan (to 2007), P Colditz and/or L Begg reviewed the articles for consideration of inclusion/exclusion and abstracted data for the review. In particular, L Begg, who was not a co-investigator on the trial by the other three authors, reviewed that trial for quality and suitability for inclusion in this review.

DECLARATIONS OF INTEREST

Three authors (C East, FY Chan, P Colditz) were chief investigators in the Australian multicentre randomised controlled trial of fetal intrapartum pulse oximetry (East 2006). That trial was supported in part by a research grant and equipment loan from Nellcor Inc, manufacturers of a fetal pulse oximetry system. An additional co-author who was not an investigator in that trial, L Begg, joined the review team to evaluate that trial for incorporation in the 2007 update of the review.

SOURCES OF SUPPORT

Internal sources

- Perinatal Research Centre, The University of Queensland, Royal Brisbane and Women's Hospital, Herston, Queensland, Australia.
- Department of Obstetrics and Gynaecology, University of Melbourne, Australia.

External sources

- No sources of support supplied

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

This update (May 2010) incorporates the current standard methods used by the Pregnancy and Childbirth Group, which have been modified since the original protocol was published (East 2003). See Appendix 1 for the methods used in earlier versions of this review, which aligned with those published in the protocol.

INDEX TERMS

Medical Subject Headings (MeSH)

Cardiotocography; Cesarean Section; Delivery, Obstetric [statistics & numerical data]; Fetal Monitoring [*methods]; Oximetry [adverse effects; *methods]

MeSH check words

Female; Humans; Pregnancy